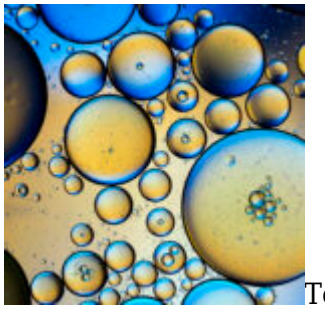
A Look Ahead in Life Sciences: What We Are Tracking in the First Quarter of 2025 and Beyond

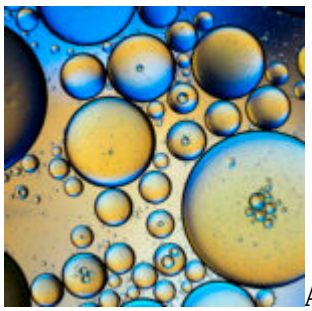
 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q1 2025 updates **here**.

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

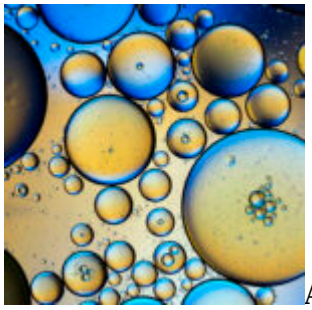
 On October 4, 2024, a US House version of the revised Promising Pathway Act (PPA) 2.0 was introduced, sponsored by Rep. Bruce Westerman (R-AR). The bill (**H.R.9938**) mirrors a US Senate version that was introduced in May 2024 (**S.4426**) that would authorize the US Food and Drug Administration (FDA) 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**.

A Look Ahead in Life Sciences: What We Are Tracking in the Fourth Quarter of 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q4 2024 updates **here**.

A Look Ahead in Life Sciences: What We Are Tracking in the Third Quarter of 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q3 2024 updates **here**.

Form FDA 483 Response Best Practices Announced by the FDA

In Draft Guidance published this week by the U.S. Food and Drug Administration (FDA), **Guidance for Industry – Processes and Practices Applicable to Bioresearch Monitoring Inspections**, the Agency provides some wisdom on best practices for responding to Form FDA 483s, albeit in the context of its Bioresearch Monitoring (BIMO) program inspections, but very much translatable to *any* Form FDA 483 response. FDA notes the following best practices:

> A response should demonstrate the establishment's acknowledgment and understanding of FDA's observations. It should also demonstrate the establishment's commitment to address the observations, including a commitment from senior leadership.
>
> Responses should be well-organized and structured to:
>
> - Address each observation separately
> - Note whether the establishment agree(s) or disagree(s), and why
> - Provide both corrective and preventive actions and timelines for completion
> - Provide both completed and planned actions and related timelines
> - Provide a method of verifying or monitoring the effectiveness of the actions
> - Submit documentation (e.g., training, Standard Operating Procedures (SOPs), corrective action plans, records, etc.)

Importantly, FDA also states that timely Form FDA 483 responses that include "appropriate corrective and preventive actions could impact FDA's determination of the need for subsequent Agency action." FDA encourages responses within 15 business days after the end of an inspection and, helpfully, notes that any responses received within that window "will be considered before further Agency action or decision." Interested stakeholders may submit comments **here** on FDA's Draft Guidance until August 5, 2024.

*Please contact **Julie Tibbets** or any member of our **Life Sciences Regulatory & Compliance practice** with questions on FDA's Draft Guidance or on responding to Form FDA 483s.*

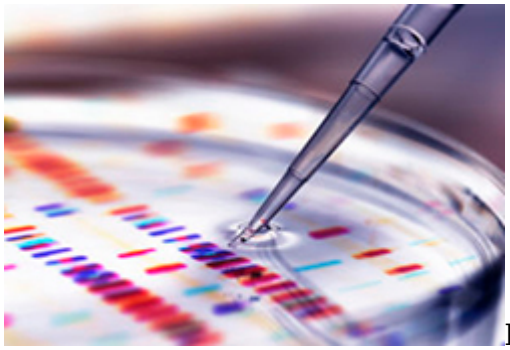
Lawsuit Filed Challenging FDA Final Rule Regulating Laboratory Developed Tests

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**.

2nd BCLT Advanced Life Sciences Institute



Rapid advancement in life sciences technologies has made keeping up with the legal implications more important than ever. Join the **Berkeley Center for Law and Technology** for the **2nd BCLT Advanced Life Sciences Institute**, where you will learn from the experts about cutting-edge issues impacting your life sciences practice.

The programming will share key insights and best practices related to the rapid rise of AI in the life sciences and new trends for licensing, deals, and life sciences funding models. Expert will review

key developments in the law (Section 112, obviousness-type double patenting), anti-counterfeiting and patient safety, and the ever-complex interplay of regulatory and IP exclusivities. Finally, don't miss in-depth discussions on future pandemic preparedness and use of trade secrets v. patents for portfolio protection!

The Advanced Life Sciences Institute will be launched virtually through **B-CLE** on May 21 and 22.

Registration is free and available to all, and CLE will be offered.

FDA Issues Final Rule on Regulation of Laboratory Developed Tests

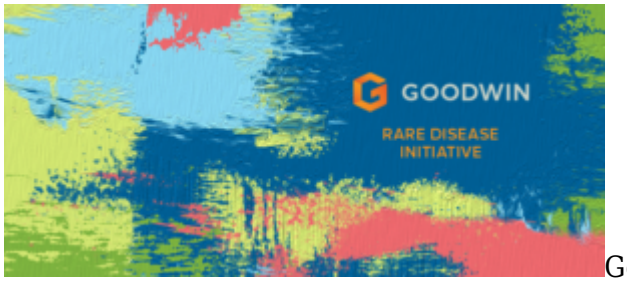
 On April 29, 2024, the U.S Food and Drug Administration (FDA) announced its **final rule** on Laboratory Developed Tests (LDTs). This final ruling amends the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs), including those manufactured by laboratories, are devices under 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**.

The European Parliament Adopts Position on the European Commission's Proposal for the First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years

 In April 2023, we published an **alert** in relation to two European Commission legislative proposals: new **Regulation 2023/0131** and new **Directive 2023/0132**, to replace the current EU regulatory framework for all medicines (including those for rare diseases and children). On April 10, 2024, the European Parliament adopted its position on the European Commission's legislative proposals with respect to (i) Regulation 2023/0131 that can be found **here** and (ii) Directive 2023/0132 that can be found **here**. For certain key areas covered in the proposed EU legislation, we have set out a brief summary of (i) the European Commission's original proposals and (ii) the European Parliament's proposed amendments. You can read more **here**.

Recap: Goodwin Rare Disease Symposium 2024



Goodwin's **Rare Disease Initiative** hosted its Annual Rare Disease Symposium in Boston on March 13, 2024. Participants were invited to join for an afternoon of engaging and inspirational conversations led by **Julie Tibbets**, **Matt Wetzel**, and **Danielle Lauzon**, in addition to networking with peers in the rare disease community. The program included speakers covering the patient, advocacy, policy, research, and CEO perspectives.

For more event highlights and key takeaways from our speakers, please visit the **Goodwin Rare Disease Symposium 2024** page.