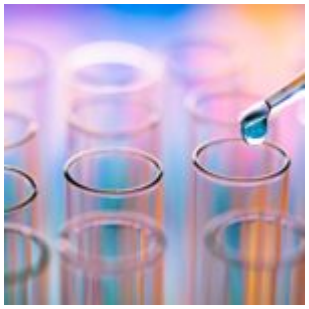
FDA Issues Final Rule on Regulation of Laboratory Developed Tests

 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**.

Significant 340B Drug Pricing Program Litigation May Impact 340B Scope

 Two recent federal court cases signal new significant developments with respect to the 340B Drug Pricing Program. Specifically: (1) new federal district court litigation challenging a recent HRSA Notice involving 340B Program “child site” registration and eligibility; and (2) a court decision in other litigation that implicates the scope of the 340B “eligible patient” definition. Details regarding these developments are in the client alert.

Read the client alert **here**.

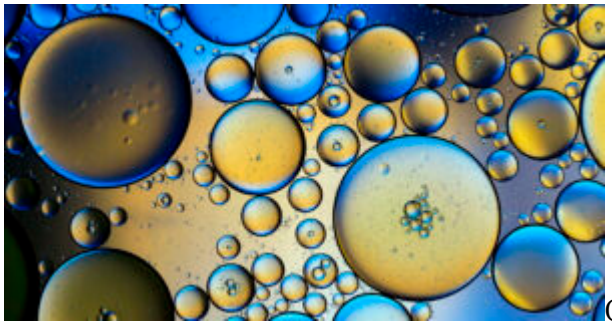
2023 State Drug Transparency Law Development Update

 In October 2021, we **reported** on an uptick in the passage of state drug price transparency legislation. As an update to that report, as of October 2023, approximately 22 states have now passed drug price transparency laws creating new requirements for drug manufacturers.

Each state has its own unique set of requirements, but reporting is often completed via an online portal administered by the state's implementing agency. Generally, these laws require manufacturers to report pricing and other information related to the cost, development, and sale of drugs to the state or state-affiliated entities. Some states will use this data to produce public reports about the cost of prescription drugs with the goal of creating pricing transparency for drug manufacturers as well as to educate the state legislature and public about the drug pricing process.

Read the full alert **here**.

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**.

Federal Court Strikes Down Copay Accumulator Programs

Summary:

On September 29, 2023, the U.S. District Court for the District of Columbia **vacated** a Trump-era rule from 2021 that allowed insurers to exclude drug manufacturer co-pay support coupons and assistance from a patient's annual cost-sharing caps. This practice, commonly referred to as a copay accumulator program, is typically used by insurance companies and pharmacy benefit managers to control drug spending, especially for high-cost specialty drugs, like those required by HIV patients.

Under typical prescription drug insurance programs, patients are obligated to pay a deductible and cost-sharing (i.e. a copay) throughout the plan year, up to an out-of-pocket spend cap. Once the patient hits that spend cap, the insurance company is responsible for the patient's prescription drug costs.

Under an accumulator program, on the other hand, an insurance company does not count a manufacturer's copay support (for example, a copay card that a patient presents at a pharmacy to cover the cost of the copay) towards a patient's annual deductible or out-of-pocket maximum. By excluding manufacturer copay support and coupons from patients' cost-sharing cap, this means that, even after a manufacturer's copay support is exhausted for the year, patients remain on the hook for all cost sharing obligations up to the insurance plan's out of pocket maximums. Many states have implemented laws to ban copay accumulator programs, asserting that such programs actually increase the financial burden on patients, especially with respect to specialty or more expensive

drugs. As of June 2023, 19 states have implemented copay accumulator program bans.

HIV and Hepatitis Policy Institute et al v. HHS was brought by patient advocacy groups including the HIV and Hepatitis Policy Institute and the Diabetes Patient Advocacy Coalition, among others, who challenged a May 2020 rule from HHS, the "Notice of Benefit and Payment Parameters for 2021" (85 Fed. Reg. 29164, 29230-35, 29261 (May 14, 2020)) (the "2021 NBPP") that permitted insurers to impose accumulator polices. Plaintiffs opposed the accumulator program, asserting that manufacturer copay support should count *towards* calculating patients' cost sharing obligations and should not be excluded from such calculations.

In ruling in favor of the plaintiffs on their motion for summary judgment, the U.S. District Court set aside the 2021 NBPP, largely supporting plaintiffs' challenges that the 2021 NBPP rule's language is internally contradictory, that it runs counter to the statutory definition of "cost sharing" found in the Affordable Care Act, and that it runs counter to the agencies' pre-existing regulatory definition of "cost sharing." HHS had previously defined "cost sharing" in a 2012 regulation as "any expenditure required by or on behalf of an enrollee with respect to essential health benefits," which by its terms includes "deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services." *See* 45 C.F.R. 155.20. In other words, the regulation treats cost sharing is an "expenditure" by or on behalf of a plan enrollee. According to plaintiffs, and as affirmed by the court, this includes manufacturer copay assistance support.

The court disagreed with the government's technical arguments regarding the language of the 2021 NBPP (i.e. that manufacturer copay support is actually a "reduction" in the amount the patient owes towards cost sharing or a reduction in the "actual economic impact" on the drug manufacturer and not an "expenditure"), concluding that the 2012 regulation was likely intended to define "cost sharing" as costs that are (1) required of an insurance plan enrollee and (2) paid by or on behalf of that enrollee – including manufacturer copay coupons and assistance.

It is unclear if the ruling will be appealed; however, as a result of the District Court's ruling, the government will use an earlier 2020 version of the rule which allowed insurers to exclude from cost-sharing caps only copay support coupons for branded drugs that have available generic equivalents; if there is no generic equivalent, under the 2020 version of the rule, manufacturer copay support must be counted toward cost sharing.

Conclusions: The U.S. District Court ruling is a significant development for drug manufacturers who offer copay support as a means of providing relief to patients with respect to cost-sharing requirements under their insurance coverage as opposed to offering significant rebates, discounts, or other contracting strategies. However, manufacturers of branded drugs with a generic equivalent will still need to consider how copay accumulator programs could affect access in those states that have not yet banned the practice. Notably, in the wake of this ruling, patient advocacy organizations have indicated that they will continue to advocate for a comprehensive state and federal level ban on copay accumulator programs (*e.g.* **Immune Deficiency Foundation**).

Goodwin will continue to monitor any further developments in this case and the impact of copay accumulator programs on the market.