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**.

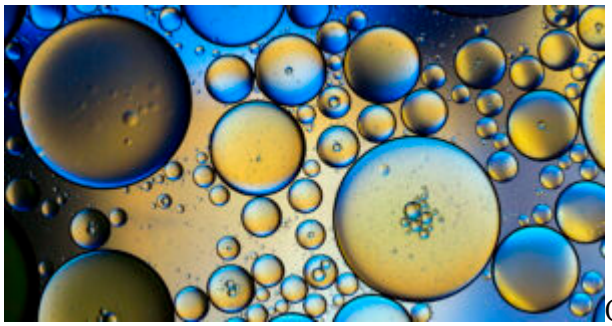
2023 State Drug Transparency Law Development Update

 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**.

How to Get Your SIUU Out: FDA Provides Long-Awaited Update for Industry on Communicating Off-Label Information

 On October 23, 2023, FDA announced the availability of a revised draft guidance titled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products." The draft guidance supersedes the agency's 2014 draft guidance, "Distributing Scientific and Medical Publications on Unapproved New Uses," and it provides more direction for industry on how information regarding unapproved uses of approved/cleared medical products can appropriately be shared with healthcare providers (HCPs).

The draft guidance coins a new acronym, SIUU, for scientific information on unapproved uses of an approved/cleared medical product, and provides recommendations for how to communicate SIUU in a "truthful, non-misleading, factual, and unbiased" manner. FDA explains that HCPs can prescribe

medical products for unapproved uses when they determine that an unapproved use is medically appropriate for a given patient, but it is critical that company communications about unapproved uses include all of the information necessary for HCPs to evaluate the strengths, weaknesses, validity, and utility of the information about the unapproved use to make these determinations.

The revised draft guidance is organized in a question and answer format and addresses: (1) what firms should consider when determining whether a source publication is appropriate to be the basis for an SIUU communication; (2) what information should be included as part of an SIUU communication; (3) how SIUU communications should be presented (e.g., the format and accompanying disclosures); and (4) recommendations for specific types of materials (including reprints, clinical reference resources, and firm-generated presentations of scientific information from an accompanying reprint).

For industry stakeholders looking to understand what is new and/or different about these recommendations relative to the 2014 draft guidance, we note that the agency continues to recommend providing disclosures about how the information in these communications compares with the FDA-approved labeling, and that such communications be non-promotional in nature. However, the revised draft guidance provides more insight into what studies or analyses are "scientifically sound" and provide "clinically relevant information," such that they could be the basis for SIUU communications. Scientifically sound studies or analyses should "meet generally accepted design and other methodological standards for the particular type of study or analysis performed, taking into account established scientific principles and existing scientific knowledge." Clinically relevant information is information that is pertinent to HCPs when making clinical practice decisions for an individual patient. FDA notes that while randomized, double-blind, controlled trials are the most likely to provide scientifically sound and clinically relevant information, other types of well-designed and well-conducted trials, or even analyses of real-world data, could also generate this type of information. In contrast, studies that lack detail to permit scientific evaluation, communications that "distort" studies, and data from early stages of development that are not borne out in later studies are examples of information that may not be appropriate as the basis of SIUU communications.

Another clear theme in the revised draft guidance is the need to separate SIUU communications from promotional communications. FDA explains that the use of "persuasive marketing techniques" (such as celebrity endorsers, premium offers, and gifts) suggests a firm may be trying to convince an HCP to prescribe or use a product for an unapproved use, not merely presenting scientific content to help an HCP make an informed clinical practice decision, and thus would fall outside the scope of the enforcement policy outlined in the revised draft guidance. FDA also recommends several ways to separate SIUU communications from promotional communications, including using "dedicated vehicles, channels, and venues" for SIUU communications that are separate from those used for promotional communications—such as distinct web pages that do not directly link to each other, sharing the types of information via separate email messages, and dividing booth space to separate the presentation of these types of information at medical and scientific meetings. In addition, FDA advises that if a media platform has features (such as character limits) that do not allow a company to provide the disclosures recommended for an SIUU communication, then that platform should not be used to disseminate SIUU, but could be used to direct HCPs to an SIUU communication (e.g., via a link to a website).

Companies may already be following many of the recommendations in the revised draft guidance, but the updates and clarifications throughout reflect FDA's continued emphasis on ways to appropriately share accurate, scientifically sound data with HCPs to inform clinical practice decisions. In line with the agency's 2018 guidances on **communicating information that is consistent with product labeling** and **communicating with payors, formulary committees**

and similar entities, this draft guidance acknowledges the evolving realities of medical product communications and provides guardrails for companies to assess whether and how to communicate product information that is not included in its FDA-required labeling, while at the same time reminding the industry that there are "multiple important government interests" served by statutory requirements for premarket review and the prohibition on introducing a misbranded product into interstate commerce.

Comments on the draft guidance are due December 24, 2023, and can be submitted to the docket available **here**. Please contact any of the authors or your Goodwin attorney if you have any questions about this revised draft guidance.

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.

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**.

A Look Ahead in Life Sciences: What We Are Tracking in Q4 2023 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so do 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 2023 updates **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.