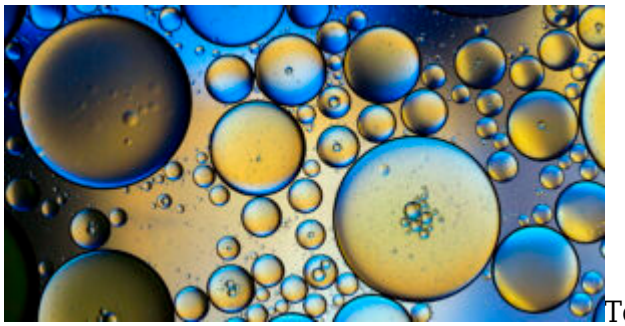
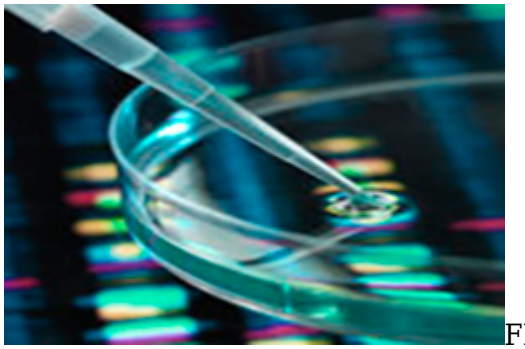
Life Sciences and Medtech Policy Update: Key Things to Know Q4 2025

 To help companies and investors stay ahead of the rapidly evolving regulatory landscape across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team provides timely insights into key developments. Each quarter, we publish a tracker spotlighting the most impactful regulatory updates—essential intelligence for industry leaders navigating change. You can read about the Q4 2025 updates **here**.

Move Fast: FDA is Accepting Submissions for the Pilot Program Class for FDA Commissioner's National Priority Voucher Program

 FDA is now accepting submissions to the Commissioner's National Priority Voucher (CNPV) pilot program, and with only five vouchers to be awarded as part of the initial year of the program, the competition is anticipated to be fierce. It has been a little over a month since the FDA **announced** the CNPV pilot program, and the FDA has now provided additional information to help interested companies through the process and criteria for applying for these vouchers.

On June 17, 2025, the FDA announced that through the CNPV program, selected sponsors will receive non-transferable vouchers that can be redeemed for expedited review of their drug or biologic product candidates. The FDA touts the CNPV program as a "novel" priority program that "shortens [the agency's] review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission." The vouchers awarded through the program can be applied to drug or biologic product candidates in any area of medicine and will focus on companies

that are aligned with the following national priorities:

1. Addressing a health crisis in the US,
2. Delivering more innovative cures for the American people,
3. Increasing affordability,
4. Addressing unmet public health needs, and
5. Increasing domestic drug manufacturing as a national security issue.

In an update posted July 22, 2025, the FDA provided **examples** of each of the national priorities that could make a company or its drug candidate eligible for a CNPV voucher. Of notable interest to the rare disease community, FDA's example for addressing a large unmet medical need specifically includes condition(s) that available therapies do not adequately diagnose or treat, "including drugs to treat or prevent rare diseases."

Here are four things to know about the CNPV program, based on the information the FDA has provided thus far:

- **Participation Process**: Interested and eligible companies should submit a statement of interest to FDA through the **CNPV Program Submission** page. Interested companies can submit a maximum of one statement of interest each, although the FDA has indicated that vouchers can be granted for review of a specific drug or as an undesignated voucher, allowing a company to use the voucher for review of an application for a drug "at the company's discretion subject to consistency with the program's objectives." The FDA will select companies based on the submitted statement of interest for "possible acceptance" into the pilot program. These statements are short—just 350 words or fewer—and should discuss one national priority the drug development program addresses and any specific issue(s) for which the company may be seeking enhanced communications with FDA to facilitate program development. If the program addresses more than one national priority, companies should identify the primary national priority in their statement of interest.
- **Submission and Review Process**: The CNPV program submissions will be evaluated by a senior, multi-disciplinary committee of experts, led by FDA's Office of Chief Medical and Scientific Officer, and the committee will pre-review the submitted statements of interest and convene for a 1-day "tumor board style" meeting. The Commissioner's **YouTube announcement** for the program explains that such meetings allows experts "to consider hard questions in light of all the latest clinical evidence," and the CNPV committee plans to utilize a similar approach. Companies must be prepared to respond promptly to any FDA inquiries about their submission. FDA is accepting statements of interest on a rolling basis, and although there is not a specific deadline for submissions, we recommend that interested companies act with urgency in order to get considered for the initial pilot program class.
- **CNPV Voucher Benefits**: As **highlighted** by FDA, a CNPV voucher entitles the company holding it to enhanced communications and rolling review to allow for a shortened review time. The FDA plans to provide a limited number of vouchers to companies aligned with US national priorities. A non-transferable voucher issued by the FDA could either be directed at a specific product or awarded to a company as an "undesignated voucher" that the company could use for a new drug at its discretion and consistent with the CNPV program's objectives. The FDA has published a frequently asked questions document, "**FAQs: Commissioner's National Priority Voucher Program**," and notes that this page will be updated regularly as questions arise.
- **Alignment with President Trump's Executive Order**: Among the national priorities that the CNPV program seeks to advance is the goal to increase affordability of drugs and biologics, and that goal is a direct focus of President Trump's May 12, 2025, **Executive**

Order on drug pricing, signaling the Administration's goal of "equalizing" prices among the United States and other developed countries throughout the world. Among other directives, the Executive Order directs FDA to contemplate approaches that may involve pricing (for example, examining whether case-by-case importation of products would be appropriate if manufacturers do not lower their prices or whether there may be some sort of action with respect to the product's approval). *See **Goodwin Alert** on the Most Favored Nation Drug Pricing Executive Order*. Companies are paying attention. In just the last couple weeks, two large drug makers have announced direct-to-consumer programs to offer a low-cost option to patients.

If a company is selected as one of the five pilot participants in the initial year of the CNPV program, the FDA states that the "voucher process must be commenced within two years" after receipt of the CNPV, although we note that the current information provided by the Agency does not expressly state whether an NDA or BLA must be submitted within two years. Since the voucher can be applied to a product "at any stage of development," we anticipate that this two-year timeframe may be an area where FDA will provide more clarity as it selects sponsors for the program.

We encourage interested stakeholders to reach out to a member of the Goodwin **Life Sciences Regulatory and Compliance** team for further questions or assistance with submitting a statement of interest for the CNPV program.

FDA's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters

On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be

limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

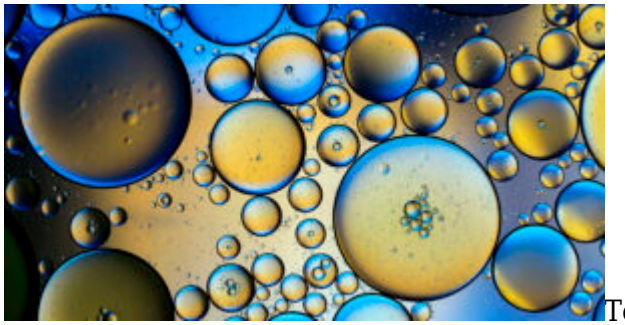
- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1) centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts, competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.

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

 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices,

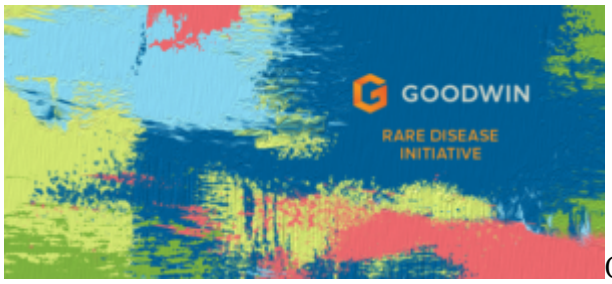
diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q3 2025 updates **here**.

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**.

Charting a Conditional Approval Pathway for Rare Disease Drugs – A Top Priority for a Revamped FDA?



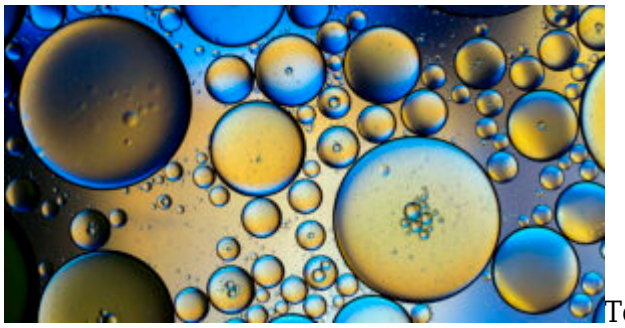
On April 18, U.S. Food and Drug Administration (FDA) Commissioner Marty Makary **announced plans** to roll-out a new approval pathway for rare disease drugs. Commissioner Makary's comments build on sentiments expressed across both the patient community and industry that rare disease drug development needs greater regulatory flexibility in

order to speed access to treatments for patients with no or limited options. This is an initiative that has also been **trumpeted by Janet Woodcock**, former Principal Deputy Commissioner and Acting Commissioner of the FDA, in her work since retiring from the FDA. Prior legislative proposals (including the "Promising Pathway Act" **proposed** in 2024) have attempted to create a time-limited conditional approval pathway in the rare disease space, and Commissioner Makary's remarks may signal a renewed push for action.

In last week's interview, Commissioner Makary emphasized the following potential eligibility factors in how he is thinking about a new "conditional" approval pathway: rare conditions affecting only a small number of people, where a randomized clinical trial has not been conducted and is not feasible, but where a "plausible mechanism" physiologically exists. Commissioner Makary also noted that post-approval monitoring of adverse events and other data may be an important tool to support more flexible regulatory decision making about drug approvals.

Whether *and when* the FDA or Congress will take further steps in outlining a conditional approval pathway, and what form that outline may take (e.g., Agency guidance, expansion of the current accelerated approval authorities, or new legislation), remains unclear at this time. This is an area rare disease researchers and developers should monitor for developments, including any opportunities to provide comments to the FDA on its potential plans.

A Look Ahead in Life Sciences: What We Are Tracking in the Second 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 Q2 2025 updates **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

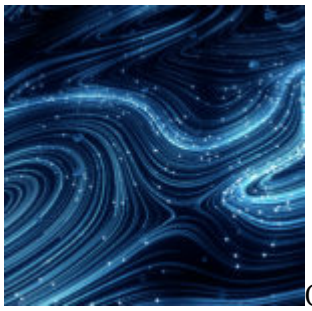
reduce the burdens of chronic disease.

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**.

How to (Finally) Get Your SIUU Out: FDA Issues Final Guidance on Communicating Off-Label Scientific Information

 On January 7, 2025, FDA announced the availability of a final guidance document titled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products." The **final guidance** supersedes the agency's revised draft guidance of the same title issued in October 2023 (see our analysis of the draft guidance **here**) and includes several key updates, including further describing scientific standards for appropriate source publications, providing additional examples of the separate dissemination of information on approved and unapproved uses in different scenarios, and expanding the section on firm-generated presentations with further context on what is permitted and what would be viewed as inappropriate when an SIUU communication includes a source publication and firm-generated content.

Several of these updates appear to be responsive to comments from industry stakeholders on the draft guidance. For example, the draft guidance stated that source publications for SIUU communications should describe "scientifically sound" studies and analyses that provide "clinically relevant" information. Multiple commenters requested that the "clinically relevant" and "scientifically sound" concepts be either removed or more clearly defined. The final guidance no longer contains the "clinically relevant" terminology, but provides some further recommendations on what constitutes a "scientifically sound" study or analysis, noting for example that certain early-phase studies *could* meet this standard.

Similar to the draft guidance, the final guidance document is written 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 and clinical reference resources). The final guidance includes a new question and answer focusing specifically on recommendations for firm-generated presentations.

The final guidance also provides an expanded list of examples of communication techniques that FDA regards as "encouraging" an unapproved use of a medical product. In addition to celebrity endorsements, premium offers, and gifts (which were noted in the draft guidance), the final guidance identifies emotional appeals unrelated to scientific content, promotional tag lines, and jingles, along with "calls to value" that "pre-judge the benefit(s) of the medical product for individual patients" (e.g., "Click here to start improving your patients' lives today"), as techniques that would take a firm-generated presentation *outside* the scope of the guidance's enforcement policy.

FDA has submitted the guidance to the Office of Management and Budget for review and clearance of certain information collection provisions contained in the guidance. As such, the final guidance is not for current implementation, but we expect to see a Federal Register notice about the final guidance's applicability once this administrative step is complete.

Please contact any of the authors or your Goodwin attorney if you have any questions about this final guidance.