

**NABP Responses to E&C QFRs from June 11 Hearing
Due Aug 12, 2025**

The Honorable Erin Houchin

Mr. Bolin, in your testimony you discussed how Pulse by the National Association of Boards of Pharmacy enabled the identification of counterfeit GLP-1 medications that had made their way into our supply chain. Can Pulse trace the origin of illicit active pharmaceutical ingredients (APIs), particularly those from China, when verifying or tracing products?

The DSCSA enables tracing and verification of finished dosage forms of products, but not the active pharmaceutical ingredients (APIs) that are used to manufacture the products. Pulse by NABP is a directory of legitimate trading partners (manufacturers, distributors, and pharmacies) in the supply chain, as well as the pharmaceutical products that move through the supply chain. Utilizing Pulse, regulators and trading partners can scan the 2D bar code of a finished, saleable unit of product and ask questions of trading partners about the product.

Accordingly, Pulse can scan products that are in finished dosage forms and have been affixed with a GS1 Data Matrix. Due to the limitations of the DSCSA, Pulse would not trace the origin of APIs – legitimate, illicit or otherwise, but, it would enable trading partners and/or regulators to ask that question about the legitimacy of the product and the prior ownership of that product.

a. If not, what enhancements to Pulse or the Drug Supply Chain Security Act would be needed to better identify and block China-sourced counterfeit APIs?

As discussed above, the DSCSA does not require serialization or tracking of APIs – for manufacturing of FDA-approved products, or for compounding, but Pulse can help regulators ask questions about the legitimacy of a product and the prior ownership of that product.

A recent report by the Partnership for Safe Medicines, conveys that there is visibility into APIs coming into the US, but FDA and Customs and Border Patrol (CBP) resources and enforcement authority may be lacking. Based on publicly available data for April - May 2025, the [PSM report](#) details that 74.5% of shipments of API manufactured in facilities **not known to FDA** were being allowed into the country.

FDA's [Report on the State of Pharmaceutical Quality](#) released last week (August 8, 2025) reveals a concerning trend related to illicit APIs used in compounded products: "During the past five years, 72% of actions (e.g., warning letters, import alerts, and regulatory meetings) taken against API manufacturers were for sites that only supply compounding pharmacies, even though these sites represent just 18% of API manufacturers in the Site Catalog."

FDA ensures that drug manufacturers utilize API from legitimate FDA-registered sources via the requirement that manufacturers follow current good manufacturing practices (CGMPs) and associated inspections, recall authority, and oversight. However, as cited in the recent FDA report, section 503A compounding pharmacies are not subject to CGMP requirements and might not test their API prior to use. To assist regulators in knowing the source of API used by both finished product manufacturers and compounding pharmacies, it could be required that the original FDA-registered API manufacturer be listed on the certificate of analysis (COA).

There may also be an opportunity for more information sharing between FDA Office of Criminal Investigation and state boards of pharmacy and state Attorney General Offices. Our understanding is that FDA OCI has details on *where* API shipments are being sent, which would help inform state investigative and enforcement activities.

Congress should maintain oversight of FDA, CBP, and other agencies and ensure they have the resources and enforcement authority needed.

Additionally, not particular to DSCSA, there are several policy approaches that can help identify and block counterfeit API from China and other countries, and NABP supports the FDA's [FY2026 legislative proposals](#) to require labeling to include original manufacturer and supply chain information and require the destruction of imported products that pose a significant public health risk. Senators Grassley and Hassan and Reps. Moore and Schneider also recently introduced legislation to detect and halt counterfeit and pirated imports (S. 2677 and H.R. 4930). A major source of illegitimate product in the U.S., including with China-sourced counterfeit APIs, is social media. Thus, NABP supports the Protecting Patients from Deceptive Drugs Act (S.652), enhancing the FDA's enforcement capabilities against social media platforms.

The Honorable Robin Kelly

Following my question during the House Committee on Energy and Commerce Subcommittee on Health Hearing on counterfeit and compounded glucogen-like peptide-1 receptor (GLP-1) products, as well as your comments on the potential dangers of these products in your opening statement, I wanted to submit additional questions on the Food and Drug Administration's (FDA) role and responsibilities:

a. How have recent workforce cuts impacted the FDA's ability to inspect foreign drug manufacturers and their facilities?

FDA's ability to conduct its business to ensure that drugs in the U.S. supply chain are safe and effective is critical. This includes FDA's ability to inspect foreign drug manufacturers and their facilities, inspect imported shipments of finished dosage forms and active pharmaceutical ingredients (APIs), and inspect domestic manufacturing and 503B facilities.

For the inspection of domestic 503A compounding pharmacies, FDA relies on partnership with state boards of pharmacy, who hold the primary enforcement authority over state-licensed 503A compounding pharmacies.

NABP has not yet experienced the impacts of FDA workforce cuts in its ability to conduct inspections, but a further reduction in inspection ability would be concerning. FDA has historically been understaffed for this critical function, and we would encourage more robust resources for foreign inspections. However, we are encouraged by FDA's recent announcement to utilize limited resources better by [expanding unannounced inspections at foreign manufacturing facilities](#).

b. How is the FDA coordinating with other federal agencies to enforce the May 22, 2025, compounding prohibition for GLP-1 drugs? Specifically, how is the FDA coordinating with the Federal Trade Commission (FTC) to regulate online advertising of these products?

FDA has [declared that GLP-1s are no longer in shortage](#), so the authority to compound due to shortage should no longer be available. Now, GLP-1s may only be compounded based on a documented patient-specific clinical need. While the shortage was in effect, it unlocked a new market for “compounding” in med spas and wellness clinics.

This is one of the most troubling patient safety threats that NABP's member boards are seeing—the rapid proliferation of un-regulated or under-regulated compounding outside of licensed pharmacies, including in med spas. Many of these entities are engaged in aggressive local marketing campaigns using social media that mislead patients.

The regulation of med spas is fragmented, with most states lacking a comprehensive statutory or regulatory framework tailored to med spas. All states regulate the individual practitioners providing the professional services at the med spas – nurses are overseen by professional nurse licensure boards, doctors by boards of medicine, etc.

Only four states currently require specific licensure or registration of a med spa facility depending on types of services provided – Mississippi, Ohio, Tennessee, and Utah. Given the concerns raised, additional states are considering action and Colorado, Nevada, Rhode Island, and Texas have recently passed legislation or enacted regulations touching on med spas regulation. Overall, most states still lack the authority to regulate med spas, let alone conduct robust inspections.

NABP and our member boards of pharmacy are actively working to address these gaps by collaborating with boards of medicine and nursing, gathering inspection data from states that have authority over med spas and preparing legislative proposals to help address existing gaps in state law and regulation.

Given the risk of illegal online drug sales, NABP supports the FTC's efforts to address deceptive marketing practices of medications sold on the internet. However, regulatory

authority to take action against the social media companies that allow illegitimate actors to market illegitimate products is limited. To help close this loophole, Senators Durbin and Marshall introduced the Protecting Patients from Deceptive Drugs Online Act (S.652). The legislation would hold influencers and providers—including telehealth providers—accountable for making false or misleading claims, such as omitting side effects, presenting inaccurate information, or failing to disclose key facts.

NABP is not privy to particular information and cannot comment on whether FDA and FTC are coordinating on these issues. Provide