JIM BANKS
INDIANA

United States Senate
WASHINGTON, DC 20510

March 25, 2025

Sara Brenner, M.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Brenner:

I write to share my deep concern about the use of foreign-made active pharmaceutical ingredients (APIs) in compounded glucagon-like peptide 1 (GLP-1) agonist medications (injectable weight-loss drugs) used by millions of American patients. Booming online gray and black markets are flooding the country with knock-off and counterfeit GLP-1s contaminated with foreign-made APIs, and few Americans purchasing these drugs are aware of the risks they pose. I request detailed information about how the Food and Drug Administration (FDA) will prevent unlawful APIs from entering the country and potentially harming Americans.

As of December 31, 2024, the FDA's Adverse Event Reporting System database lists more than 900 cases of adverse health events associated with compounded "semaglutide" and "tirzepatide," of which 17 involved deaths.[1] These adverse events represent more than *quadruple* the number of adverse events recorded for *all* compounded drugs in FY 2022.

Even after the FDA declared the end of the tirzepatide medication shortage on October 2, 2024 and the end of the semaglutide medication shortage on February 21, 2025, and the judge's March 5, 2025 denial of an injunction in Outsourcing Facilities Association v. FDA—which upheld the FDA's declaration and confirmed that compounding pharmacies must cease making such knock-off drugs—these drugs remain readily available. Many patients using such knock-off medications are unaware they are inauthentic, lack FDA approval, and may be adulterated or non-sterile. This marketplace has become deceptive, and many patients are unaware of the risks they are taking.

I share the state attorneys general's alarm about the proliferation of injectable weight-loss drugs compounded using tainted APIs imported from China, India, and other countries.[2]

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[1] FDA Adverse Events Reporting System Public Dashboard (last updated Dec. 31, 2024), available at: https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis.
[2] National Association of Attorneys General Letter to Acting Commissioner Sara Brenner, Feb. 19, 2025.

These drugs come in formulations that the FDA has never approved, have inconsistent doses, misrepresent injectable insulin as semaglutide, contain contaminants, or are in reality completely different drugs. Unscrupulous compounders and merchants selling these drugs must be shut down.

Under federal law, compounders can only use APIs that are accompanied by a valid certificate of analysis (COA) and manufactured at a facility registered with the FDA. However, there is no evidence that the FDA is assessing at the border (or anywhere else) whether imported APIs come from duly registered sources, whether these shipments have COAs, whether the COAs are valid, or whether the COAs demonstrate acceptable quality testing. The FDA has issued very few warning letters to compounders for breaking these rules, and the agency rarely seems to be checking the validity of COAs during inspections of compounding facilities.

As a result of lax oversight, the FDA is allowing in mass amounts of APIs that were manufactured at unregistered foreign plants and should not be allowed entry into the U.S. This is particularly a problem in China, where companies that export APIs are not even required to hold drug manufacturing licenses or meet safety requirements that apply to medicines sold within China.

I encourage the FDA to fully enforce the Federal Food, Drug, and Cosmetic Act and close the loopholes that unscrupulous compounders, telehealth providers, and merchants continue to exploit. I also urge the FDA to increase inspections and work more closely with Customs and Border Protection to intercept illicit bulk drug ingredients and shut down unregistered compounders.

I respectfully ask that you provide answers to the following questions by no later than April 25, 2025:

1) With the end of the compounders' authorization to produce such drugs, how will the FDA, particularly the Office of Criminal Investigations, enforce the law?

2) How will the FDA educate patients and the general public about authentic vs knock-off vs counterfeit weight-loss drugs?

3) How will the FDA work more closely with Customs and Border Protection to intercept illicit bulk drug ingredients and shut down compounders using these ingredients?

4) How does the FDA monitor 503B compounding facilities and enforce violations of law and regulation? What steps can be taken to monitor them more stringently?

5) How will the FDA enforce the Federal Food, Drug, and Cosmetic Act's truthful advertising requirements including the accurate disclosure of side effects, contraindications, and effectiveness with respect to telehealth providers and compounders?

6) How many *domestic* companies supplying APIs for GLP-1 compounding in the U.S. have duly registered as manufacturers with the FDA and reported their APIs? How many of them have been inspected in the last year?

7) How many *foreign* companies supplying APIs for GLP-1 compounding in the U.S. have duly registered as manufacturers with the FDA and reported their APIs? How many of them have been inspected in the last year?

8) How many Chinese companies supplying APIs for GLP-1 compounding in the U.S. have licenses to sell them in China?

9) How does the FDA assess how imported APIs will be used, how frequently does the FDA collect and analyze samples at the border, and what are FDA's processes to inspect COAs at the border?

10) How many companies that have violated such laws and regulations has the FDA added to Red Lists/import alerts?

Thank you for your attention to this important matter.

Sincerely,

Jim Banks
U.S. Senator for Indiana