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United States Senate
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COMMITTEES
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June 5, 2025

The Honorable Pam Bondi
Attorney General
United States Department of Justice
Washington, D.C. 20530

The Honorable Kristi Noem
Secretary
Department of Homeland Security
Washington, DC 20528

The Honorable Martin A. Makary. M.D.
Commissioner
United States Food and Drug Administration
Silver Spring, MD 20993

Dear Attorney General Bondi, Secretary Noem, and Commissioner Makary:

I write to express serious concerns over the growing public health threat posed by counterfeit and illegally imported GLP-1 receptor agonist medications, including semaglutide and tirzepatide, as well as unregulated active pharmaceutical ingredients (APIs) entering the U.S. market through illegitimate channels.

Food and Drug Administration (FDA)-approved GLP-1 therapies such as Ozempic, Wegovy, Mounjaro, and Zepbound have revolutionized the treatment of obesity and Type 2 diabetes for millions of Americans. Unfortunately, the success of and demand for these therapies have also attracted the attention of criminal enterprises seeking to exploit vulnerable patients. Counterfeiters have introduced falsified products into the U.S. market, including counterfeit Ozempic pens bearing fraudulent lot and serial numbers, non-sterile needles, and misleading labeling. These products have even infiltrated legitimate distribution channels, putting patients at risk of receiving contaminated, ineffective, or unsafe medications.

In addition to these finished counterfeits, a recent report from the Partnership for Safe Medicines details a disturbing pattern of illegal importation of unverified semaglutide and tirzepatide APIs from unregistered foreign suppliers, particularly from China. Between 2023 and 2025, 239 shipments of these unapproved APIs were identified, with more than 80% allowed to enter the United States. Shockingly, many shipments were misrepresented as originating from entities such as hotels, fitness centers, and public schools, which raises significant concerns about the legitimacy of these supply chains. It is my understanding that some domestic compounders may have used these APIs during a period when the drugs were in shortage. However, federal regulations require that ingredients be sourced only from FDA-registered manufacturers to ensure compliance with quality and safety standards. With drug shortage resolved, compounding of GLP-1s is now considered unlawful, unless a prescriber determines that a commercially available product cannot meet the specific needs of an individual patient.

The consequences of these actions are already evident. According to the FDA's own Adverse Event Reporting System (FAERS), as of March 2025, there have been at least 925 reported adverse events associated with compounded semaglutide and tirzepatide, including 18 deaths. This represents a more than fourfold increase over all adverse events reported for compounded drugs in fiscal year 2022. Due to gaps in adverse event reporting requirements for state-licensed pharmacies, these figures likely underrepresent the true scale of patient harm. This growing threat erodes patient trust in the safety and reliability of medications available in the United States. Patients deserve confidence that the treatments they depend on meet the highest standards of quality and regulatory oversight.

To that end, I encourage the FDA to expand public and provider education about the dangers of counterfeit and illegally imported GLP-1 products, while also prioritizing enforcement efforts to hold accountable those responsible for introducing these unsafe products into the supply chain. Strengthened collaboration between the FDA, U.S. Customs and Border Protection, and the Department of Justice is essential to prevent these illicit products from reaching patients in the first place. Equally important is providing clear guidance to health care providers and pharmacies to ensure that all medications are sourced exclusively from FDA-registered manufacturers. Finally, the FDA can help restore public confidence by improving transparency around its enforcement actions and ensuring these efforts are clearly communicated to the public.

I appreciate the FDA's ongoing commitment to protecting the health and safety of the American public. I stand ready to support these efforts and welcome any opportunity to collaborate on safeguarding the U.S. pharmaceutical supply chain from these emerging threats. Thank you for your attention to this critical issue.

Sincerely,

Thom Tillis
United States Senator