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February 19, 2025

Sara Brenner, M.D., M.P.H.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: GLP-1 Drugs

Dear Acting Commissioner Brenner:

We, the undersigned state attorneys general, write to urge the Food and Drug Administration to take decisive action against bad actors unlawfully profiting off the high demand for FDA-approved weight loss and diabetes drugs.

Demand for the medications Mounjaro, Zepbound, Ozempic, and Wegovy (GLP-1 drugs) has skyrocketed, but supply shortages and high costs have created opportunities for wrongdoers to cash in and endanger consumers.[1] The FDA has the expertise and the resources to stop this conduct and better protect consumers.

Most alarmingly, we understand that counterfeit GLP-1 drugs have infiltrated the U.S. supply chain[2] from China, Turkey, India, and other foreign sources.[3] These counterfeits can contain contaminants, other unknown drugs, or dangerously high amounts

[1] National Association of Boards of Pharmacy, *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers are Taking Advantage of Patients*, p. 2 (2024).
[2] *See* https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain; https://investor.lilly.com/news-releases/news-release-details/open-letter-eli-lilly-and-company-regarding-certain-practices
[3] *See* https://www.nbcnews.com/health/health-news/ozempic-underworld-black-market-obesity-drugs-rcna174680.

of active ingredient(s).[4] Scammers have also repackaged injectable insulin and falsely sold it as Ozempic.[5] Injecting these fake medications can lead to serious side effects for consumers, sometimes necessitating hospitalization.[6] Most consumers are not equipped to determine if their medication is legitimate or fake. The FDA must work with federal partners like the Department of Homeland Security to intercept counterfeit GLP-1 drugs before they reach unsuspecting consumers.

Separately, we further understand that online retailers are illegally selling the active ingredients of GLP-1 drugs directly to consumers, without a prescription. These retailers claim that the active ingredients they sell are "for research purposes only" or "not for human consumption".[7] In reality, these companies advertise directly to consumers on social media, claiming that their products are an easier and more affordable way to obtain GLP-1 drugs.[8] Much like with counterfeit versions, these active ingredients come from unregulated, undisclosed sources in countries like China and India and pose risks of contamination and inclusion of foreign substances.[9]

Making this issue worse, when sellers supply only active ingredients, consumers are often forced to formulate the medication themselves, creating a host of other risks. Many consumers lack the supplies and knowledge to safely dissolve the active ingredient, draw it into a syringe, and inject it.[10] Patient error in self-dosing has contributed to the dramatic increase in reports of semaglutide overdoses in the U.S.[11] Consumers may also expose themselves to danger by improperly storing active ingredients or using non-sterile equipment.[12] The FDA must continue to send warning letters to these operations and follow up with enforcement action if companies continue to act unlawfully.

The FDA should also ramp up enforcement against any compounding pharmacies that may be illegally participating in this market. With certain GLP-1 active ingredients added to the FDA's drug shortage list, compounding pharmacies have been allowed to produce GLP-1 medications. Compounding pharmacies can provide an important conduit for Americans' access to certain drugs. Unfortunately, while many compounding pharmacies adhere admirably to the best practices of

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[4] https://www.nytimes.com/2024/07/12/well/ozempic-fake-counterfeit-drugs.html
[5] https://www.vanityfair.com/news/story/counterfeit-ozempic-global-growth-industry
[6] *Supra* note 4.
[7] *See* Jordyn Belcourt et al., *Bypassing Prescribers and Pharmacists: Online Purchasing of Semaglutide and Tirzepatide "For Research Purposes,"* Annals of Pharmacotherapy, p.1 (2024).
[8] *See* https://www.wsj.com/health/healthcare/ozempic-mounjaro-no-prescription-websites-726b3928
[9] https://www.nbcnews.com/health/health-news/ozempic-underworld-black-market-obesity-drugs-rcna174680
[10] *Supra* note 7.
[11] https://nabp.pharmacy/news/blog/regulatory_news/poison-control-report-increase-semaglutide-medications/
[12] *Supra* note 7 at 2-3.

their profession, some have cut corners in pursuit of a quick profit. These pharmacies can be exempt from certain regulatory provisions of the Federal Food, Drug, and Cosmetic Act, but they are not exempt from the provision deeming drugs produced under insanitary conditions as "adulterated".[13] The FDA has previously investigated "numerous serious adverse events" associated with contaminated drug products produced by compounding pharmacies.[14] In one tragic example, injectable drug products from a compounding pharmacy caused a fungal meningitis outbreak that led to sixty deaths and 750 cases of infection.[15] The manufacturer of Mounjaro and Zepbound has reportedly discovered compounded versions of the medications with high impurity levels or that were contaminated with bacteria.[16] With consumers looking to compounding pharmacies to meet the high demand, insanitary conditions at these facilities could lead to serious public health issues. The FDA must work in partnership with state pharmacy boards to ensure compounded GLP-1 drugs are produced in a safe, sanitary way.

While States play a role in protecting their own consumers, many organizations that sell unsafe, unregulated versions of GLP-1 operate outside the country. Concurrent federal action will provide the most robust protection against all the illegal and deceptive conduct. With its broad jurisdiction and resources, the FDA is uniquely positioned to lead the campaign against dangerous adulterations of GLP-1 medications in the U.S. drug supply. We urge the FDA to exercise its statutory authority through investigations, inspections, and enforcement actions to safeguard consumers.

Sincerely,

Jonathan Skrmetti
Tennessee Attorney General

Phil Weiser
Colorado Attorney General

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[13] Food and Drug Administration, Center for Drug Evaluation and Research, *Insanitary Conditions at Compounding Facilities: Guidance for Industry*, p. 1 (2020).
[14] *Id.* at 2.
[15] *Id.*
[16] https://investor.lilly.com/news-releases/news-release-details/open-letter-eli-lilly-and-company-regarding-certain-practices

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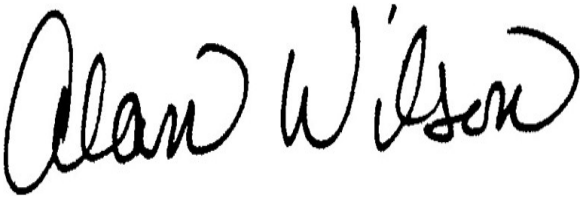

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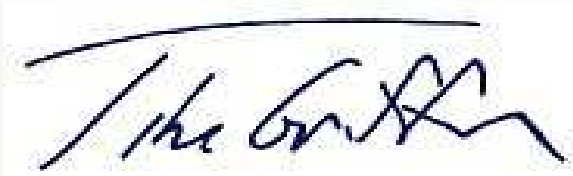

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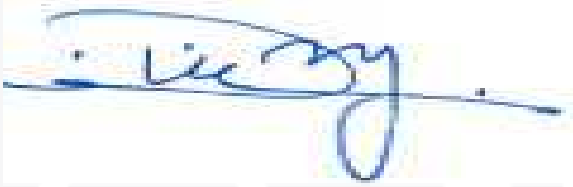

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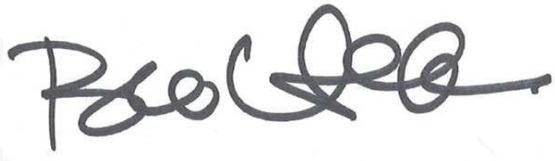

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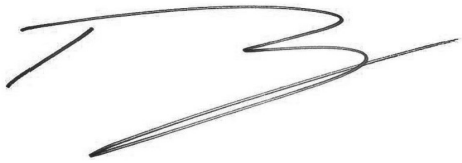

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