# GLP-1 AGONISTS, INTELLECTUAL PROPERTY, AND THE HIDDEN DANGERS OF COMPOUND DRUGS TO AMERICAN CONSUMERS


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## FDA-APPROVED GLP-1S: A LIFELINE FOR PATIENTS

Conditions like obesity and diabetes pose serious costs to American health expenditure, business, and overall living standards. Looking at diabetes alone, around 38.4 million Americans (or 11.4% of the population) suffer from the disease, 8.7 million of whom are not even aware they are affected. The estimated costs include both direct disadvantages, in terms of expenditure, and indirect costs, in terms of productivity and life-years lost; according to the National Center for Chronic Disease Prevention and Health Promotion, these costs total around $413 billion, equivalent to $1 in $4 of total health expenditure being spent on diabetes.

Data on obesity is even more dramatic. Care must be taken, as the threshold for those who count as obese versus overweight has changed over time and is subject to debate. While keeping such limitations in mind, the average adult obesity rate between March 2023 and March 2024 was 43.1%, with an average year-over-year increase of 0.6 percentage points from 2011 to 2019. At the same time, one can see that the toll of living with obesity can be extremely high. According to a 2020 report from the Milken Institute, which compiled the costs of obesity treatment, obesity-related conditions, work absenteeism, and the impact on work productivity, the downsides can be as significant as $1.4 trillion per year.

Some of the extra expenditure manifests in unforeseen ways. During the 1990s, the average weight of an American airline passenger increased by approximately 10 pounds. By 2000, U.S. airlines had to spend an additional $275 million on jet fuel to accommodate the increased weight of passengers. This extra spending corresponded to roughly 350 million extra gallons of fuel burned in 2000 solely due to the population's weight gain. A recent estimate suggested that if the average passenger were 10 pounds lighter, a major airline (such as United Airlines) could save on the order of $80 million in fuel costs per

year.

It is no exaggeration, then, to say that FDA-approved GLP-1 medicines have been transformative for patients with diabetes and obesity. Backed by rigorous clinical trials (including the STEP and SELECT trials with hundreds of thousands of participants), robust manufacturing standards, and FDA oversight, these drugs deliver proven results while safeguarding patient safety. Patients and providers alike can trust these medicines because they are tested, regulated, and transparently manufactured. New data from the Centers for Disease Control and Prevention's National Center for Health Statistics shows that adult obesity rates in the U.S. may finally be flatlining, with even a 0.2-percentage-point decrease from the 43.3-percent average in the year earlier (March 2022 to March 2023). Literal trillions of dollars and longer, healthier, more productive lives are waiting in terms of savings.

However, bad actors are threatening to undermine the health revolution with fraud and danger. Across the country, illicit, compounded versions of GLP-1 drugs are flooding the market, built on hard-to-trace, unregulated, and unsafe active pharmaceutical ingredients (APIs). What's worse, some telehealth companies are pushing these untested drugs to American consumers through misleading advertisements designed to boost sales through deception.

Such compound products are destructive to the healthcare sector. Future medical improvements and discoveries depend on innovators having a viable financial stake in the innovative process itself. That is guaranteed when strong property rights allow companies to recover the initial research and development (R&D) costs of developing GLP-1 drugs. Conversely, firms will have fewer reasons to commit to the risk of investing in a new product if they have to compete with others offering a diluted formula for a fraction of the general price.

Worse still, such compounded products pose a danger to consumers. These alternatives rely on inaccuracies and misreporting, are far less effective than the originals, lack testing, oversight, and accountability, and sometimes contain toxic (and non-human!) chemical doses.

Finally, in committing fraud, compound products risk sapping trust in the medical and pharmaceutical industries at a time when such trust is already at a low point. Doctors enjoy the trust of a thin majority of the population at 53%, representing a 14% drop in confidence in the medical profession compared to 2021, and the lowest recorded figure since the mid-1990s. Pharmacists enjoy

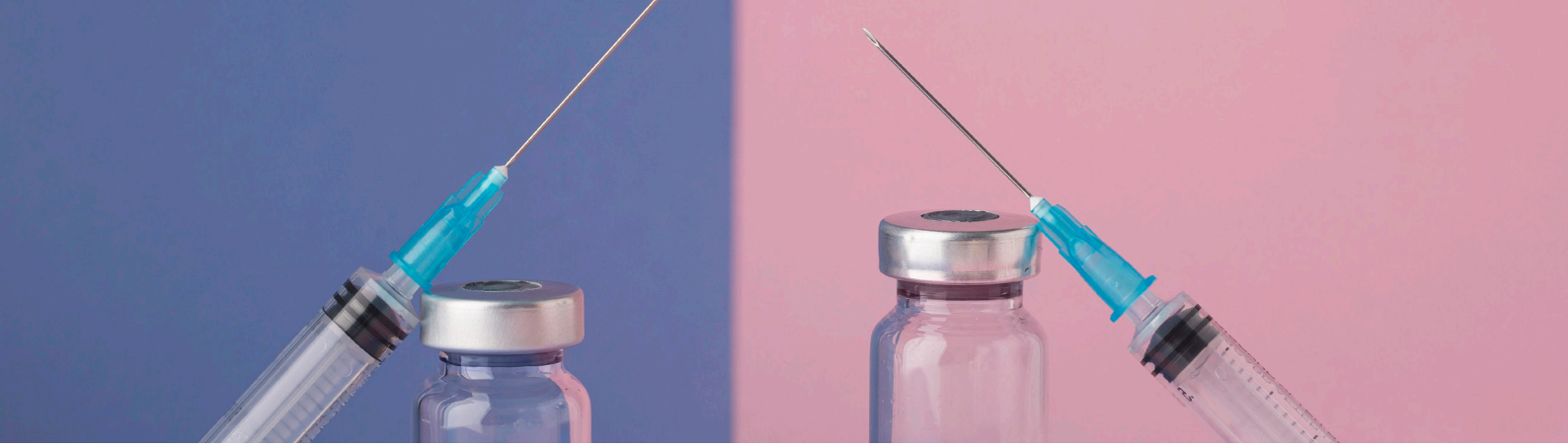
only a marginally more positive figure at 57%. More fraud involving products sold in compounded pharmacies will alienate an increasing number of consumers. When someone has a bad experience with a fake or contaminated version, they may begin to doubt all weight loss innovations. That fear can ripple through the health system, making insurers and doctors more hesitant to support treatments that are helping with the genuine public health emergency of obesity.

The remainder of this primer provides a brief background on how semaglutide compounding became legally accepted in the wake of GLP-1 shortages, compiles the overwhelming evidence for the risks associated with compounded drugs, and highlights how suppliers exploit regulatory inconsistencies and marketing tactics to deceive consumers. The primer concludes by outlining the actions policymakers must take to combat fraudulent schemes, defend patient safety, and protect innovation: **intercept high-risk shipments of illicit APIs at the border (often imported from China), and ensure that key ingredients intended for compounding come from FDA-registered manufacturers.**

## BACKGROUND

As the popularity of semaglutide for weight loss surged, the Food and Drug Administration added Wegovy to the shortage list in March 2022, followed by Ozempic in August 2022, based on internal determinations regarding manufacturers' capacity and ability to meet market demand. This decision provided the initial legal loophole for compounding pharmacies to start producing semaglutide themselves. According to the Federal Food, Drug, and Cosmetic Act, § 503A state-licensed compounding pharmacies and § 503B outsourcing facilities are allowed to prepare "essentially a copy" of FDA-approved drugs, particularly their active pharmaceutical ingredients, though only in the event of a shortage.

Unfortunately, this single exception created a burgeoning gray and black market that persisted long after the initial shortage conditions had been resolved. The FDA issued a decision memorandum, dated February 21, 2025, titled "Resolution of Semaglutide Injection Product Shortage and Supply Status" (Decision Memorandum), which determined that the semaglutide shortage was resolved by February 21, 2025. Thus, the original manufacturers would regain their exclusive right to manufacture GLP-1 agonists. **Conversely, 503A compound**



**pharmacies would no longer be allowed to mass-produce the goods from April 22, 2025, onwards, except in cases where consumers had allergies.**

**However, a return to the previous status quo would not happen. A cottage industry has emerged around compound semaglutide products, with millions of patients already utilizing them, primarily due to the lack of oversight of the facilities that supply compound pharmacies, lower prices compared to patent-protected variants, and the absence of guardrails on manufacturing and marketing.**

## THE THREAT OF COMPOUNDED DRUGS

Americans are injecting drugs with origins and safety that cannot be verified:

- **As of September 9, 2025, the FDA has received 1,424 reports of adverse events associated with compounded GLP-1 drugs, including reports of 329 hospitalizations and 23 deaths.** The FDA warns that it is "likely that adverse events from compounded versions of GLP-1 drugs are underreported," considering most compounding pharmacies are not required to report them.
- As a recent Brookings Report notes, FDA-approved and meticulously tested semaglutide manufacturing uses one of two methods: either recombinant RNA methods or a chemical synthesis process called solid-state peptide synthesis. Compounded manufacturers generally pursue the synthesis option, yet they have no external reference for quality, leaving them fully responsible for determining product specifications. That is especially worrying for a complex peptide like semaglutide that nefarious black-market actors can easily exploit. **It is easy and remains legal to produce a batch of compounding semaglutide salts that contain up to 15% impurities, which are not semaglutide (including toxic heavy metals and formaldehyde).**

- Compounded drugs often arrive labeled "not for human consumption" or "for research use only" and then are sold to consumers with generic instructions for dosages, **even though the initial quantity and quality might not have been intended for a human in the first place!**
- There are large volumes of unverified products coming from abroad with no medical control or federal oversight. The same Brookings report found that "**The median shipment size was 51g, which might seem small, but 1g is equivalent to 4,000 starting doses of semaglutide. The highest six shipments had reported volumes that ranged between 23kg and 50kg—all so high that they might appear as reporting mistakes, but FDA data suggest that each of the first large shipments was initially detained for each company at the border and subsequently released. These six shipments accounted for 221kg out of the 268kg reported metric volume during the March 2023 to September 2024 timeframe.**"

## INCONSISTENT REGULATION AND DECEPTIVE MARKETING

While legitimate pharmaceutical innovation is subject to rigorous regulation, compounders exploit loopholes with impunity:

- Deceptive online advertising often overlooks side effects and overstates efficacy. One JAMA study found that **nearly half of websites selling compounded GLP-1s made no mention of side effects, while 40% made efficacy claims not authorized in the FDA-approved medicines.**
- Compounded semaglutide products do not feature on the list of U.S Pharmacopeia monographs, which are the lists used to establish reasonable expectations around a drug's strength and purity. Moreover, there is no requirement to comply with a drug master file containing the initial intellectual property behind the semaglutide compound for drug applications. **As such, manufacturers can simply decide that checking their products for heavy metals or poisons is not necessary, even though a large part of the batch may contain such toxic substances.**
- State boards of pharmacy and the FDA have so far failed to enforce rules requiring API to come from FDA-registered manufacturers.
- Data from Redica Systems, a firm specializing in cataloging FDA facility inspections, reveals that **some facilities importing unregulated semaglutide have not undergone inspection since 2000. Of the 11 firms included in**

**the 2023-2024 timeframe, Brookings investigators found that three firms, responsible for 20% of the imported volume, have never been inspected, while another three, responsible for 44% of the imported volume, have been cited for violations. In turn, the other three companies had no good manufacturing practices observations noted during their most recent inspection. In fact, only two were definitively found to have had no violations.**

## POLICYMAKERS MUST COMBAT FRAUDULENT SCHEMES AND DEFEND PATIENT SAFETY.

The U.S. government already has tools to stop this and must act with urgency.

- **Bipartisan concerns** are rightly mounting over illicit online drug sales, with lawmakers and state officials warning that copycat GLP-1 products are proliferating despite FDA warnings. Sen. Marsha Blackburn (R-Tenn.) and Tennessee AG Jonathan Skrmetti have urged the FTC to investigate shady websites that falsely claim FDA approval and use manipulative marketing to target vulnerable patients. Other members of Congress are likewise pressing federal agencies to clamp down on fake semaglutide and tirzepatide entering the U.S. supply chain.
- **As many as 38 state Attorneys General** have already called on the FDA and federal partners, such as the Department of Homeland Security, to "intercept" copycat GLP-1s before they reach unsuspecting consumers.
- **FDA authority is clear**. Key ingredients intended for compounding must come from FDA-registered manufacturers. Anything else is illegal. However, shady suppliers who are not registered with the FDA continue to flood the US market with mislabeled APIs.
- The FDA can and should **intercept high-risk shipments of illicit API at the border**. Unfortunately, the FDA's new "Green List" doesn't require any examination, sampling, or testing of the API ultimately used in compounded drugs. Without forceful action, consumers will face the risks of a shadow market of deceptive online marketing and dangerous, fake products.
- The agency can **exercise wide-enforcement latitude to restrict facilities that do not provide concrete proof of good manufacturing practices** and that refuse to provide any documentation whatsoever from selling any semaglutide products.

- **The FDA must establish a reference standard for product specifications in the form of U.S Pharmacopeia monographs and drug master files to continue to safeguard IP and innovation.**
- **The FDA must establish rules requiring the compound to be identical to the reference list, ensuring consumer health and safety.**

# ABOUT THE AUTHORS

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Emil Panzaru is the Research Director at the Consumer Choice Center. He defended his PhD in Political Economy (Research) at King's College London in 2022. Before working at the Center, Emil was a Teaching Assistant at King's College London, teaching students contemporary issues at the intersection of philosophy, politics, and economics. He was also a Frederic Bastiat/Research Fellow at George Mason University's Mercatus Center. He has published and helped publish academic research on incentives, knowledge problems, and public policy.

## Fred Roeder

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Fred Roeder is a consumer advocate at heart. He has been working in the field of grassroots activism for over ten years. He is a Health Economist from Germany and has worked in healthcare reform in North America and Europe. One of his passions is to analyze how disruptive industries and technologies allow consumers more choice at a lower cost. He also loves researching how innovation makes our lives better.

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