This is one of the more disingenuous bits of propaganda we've seen in a while. As ever with PSM, this "report" makes no distinction between compounded drugs prepared by a legitimate state-licensed pharmacy and illicit or counterfeit substances. Moreover, while it insinuates that illicit substances are being used in drugs compounded by legitimate pharmacies, the data reported do not indicate, much less prove, that assertion.

New Report Reveals Illegal Ingredients for Knockoff Weight Loss Drugs Flooding into U.S. from Foreign Sources, Endangering Patient Safety

Originally posted on: businesswire A BERKSHIRE HATHAWAY COMPANY

The Original Report was Published on Feb 20, 2025

Annotations by Alliance for Pharmacy Compounding CEO Scott Brunner

The Partnership for Safe Medicines and an FDA law enforcement expert conducted the first-of-its-kind analysis. FDA regulators must enforce restrictions on unsafe drug imports to protect Americans.

WASHINGTON, D.C. (Feb. 20, 2025) – The Partnership for Safe Medicines today released a new report that found suspicious, unauthorized, and illegal ingredients for popular diabetes and obesity injectables (commonly known as weight loss drugs) are flooding into the U.S. from foreign sources despite U.S. laws forbidding them from coming through the border. The U.S. Food and Drug Administration (FDA) has warned against drug compounders' use of unauthorized bulk drug ingredients, semaglutide and tirzepatide, which are being imported into the U.S. from several countries, including China.

This is misleading. FDA has not warned against "unauthorized ... semaglutide and tirzepatide, which are being imported into the US from several countries.". FDA warned in 2023 against the use of semaglutide salts in compounded drugs. It has made no statement about "drug compounders' use of unauthorized" tirzepatide. Nor has it issued a warning about GLP1 API "imported to the US from several countries" except to say that API used compounding must come from FDA-registered manufacturers.

"Use of compounded versions of GLP-1 medications has surged, with telehealth companies and compounding pharmacies aggressively marketing them to consumers," said Shabbir Safdar, executive director of the Partnership for Safe Medicines. "Consumers remain largely unaware that, unlike prescription medicines, these knockoffs are not FDA-approved and they're not generics.[1] Our report reveals these knockoff GLP-1s may contain active ingredients from unregulated, overseas manufacturers that are not be suitable for human use."[2]

[1] Unlike prescription medicines? Compounded GLP1s ARE prescription medicines.

[2] Does the report reveal that? Where is the evidence of that? The PSM news release wants us to believe that because a counterfeiter said the product description was "Rx API for Compounding", the substance must therefore actually have been used in a compounded product prepared by a legitimate compounding pharmacy. There's zero proof of that presented. This seems to be more a strained effort to disparage compounding than an assertion based on any evidence.

NOTATED REVIEW

Originally posted on: businesswire

PSM partnered with former director of the FDA's Office of Criminal Investigations and federal prosecutor George Karavetsos to analyze the FDA's publicly available import dashboard against the agency's database for registered drug manufacturers between September 2023 and January 2025 to better understand the scope and scale of the risk. Drug importers are required by law to register their facilities with the FDA to ensure the safety of the U.S. drug supply.

The report uncovered several concerning facts:

- The FDA and U.S. Customs and Border Patrol (CBP) records show 239 shipments of semaglutide and tirzepatide arrived from foreign manufacturers that failed to register their facility, an essential legal requirement to ensure the safety of the U.S. drug supply.
- The FDA stopped just 44 of these shipments, allowing 195 illegal shipments into the U.S. market, where they were likely used in knockoff products sold to unsuspecting Americans.

Once again, where is evidence of this? It's certainly not a "finding" of the report. And to be clear, it's certainly no indication that a state-licensed pharmacy used the unauthorized substance in compounded drugs.

- 60 shipments of unregistered semaglutide and tirzepatide originated from China or Hong Kong; 42 originated from India.
- Many of these shipments were identified as ingredients for use in drug compounding.

Indeed, but that's merely how the counterfeiter labeled them. The report presents no evidence the substance were actually used compounded drugs prepared in legitimate state-licensed pharmacies.

Others used even more troubling descriptions, such as "non-sterile liquids." Semaglutide and tirzepatide are injectable products that must be sterile.

No, semaglutide and tirzepatide are active pharmaceutical ingredients. While they might be compounded into an injection, they are not themselves "injectable products." Semaglutide is also the API in Rybelsus, Novo's oral drug. Rybelsus is a tablet, not an injection, in which semaglutide is the API.

The FDA has warned patients of serious and potentially life-threatening risks posed by compounders that use non-sterile ingredients to make knockoff weight loss injectables.

The FDA has warned of the risks associated with compounded drugs. It has not warned specifically about "the risks posed by compounders that use non-sterile ingredients to make knockoff weight loss injectables." This is spin, attributing to FDA something it didn't quite say.

"Under the law, the FDA is required to block shipments of pharmaceutical ingredients from unregistered manufacturing facilities at the border," Karavetsos said. "Yet this report shows dangerous, unchecked drug ingredients are entering the U.S. in large numbers bound for use in compounded and counterfeit products. —

There is ZERO evidence, based on the data presented, that the substances in question were actually "bound for use in compounded ... products."

—U.S. law enforcement and regulators must ensure Americans are not exposed to the dangers of illegal drug ingredients from foreign sources."

The report outlines several urgent actions to protect the health and safety of Americans:

- The FDA must refuse entry to any drugs that "appear" to be misbranded, adulterated, or otherwise unapproved.
- The FDA should add the rogue manufacturers identified in our analysis to the Import Alert system to flag their future shipments.
- The FDA and state boards of pharmacy should prioritize inspections of compounders that attempt to import GLP-1 API from unregistered facilities.

This demonstrates ignorance of the supply chain for API while also being misleading. Compounders generally do not order API directly from the manufacturer. They source API from FDA-registered resellers, and that API must come with a Certificate of Analysis demonstrating its identity, potency and purity. Moreover, where is ANY evidence – in the report or elsewhere – of state-licensed compounding pharmacies attempting "to import GLP-1 API from unregistered facilities"?

- The FDA must refuse shipments if their shipping information and labeling does not meet regulatory requirements.
- Compounders of GLP-1 medicines should disclose the FDA-registered manufacturer of their API to their customers as a minimal assurance of legitimacy.

Okay, sure. The fact is, any compounder would be happy to share that info if a patient asks. But very few patients ever ask. And what would they do with that info if they had it – rush to the FDA website to see if the manufacturer is legit? All while standing in line at the pharmacy counter? No. There ARE questions patients can ask the pharmacist if they want confidence that the API used in their compounded drug is indeed what the pharmacy says it is, and the answers can be helpful. But "who is the manufacturer?" is not one of them.

NOTATED REVIEW

"PSM respects and appreciates the FDA and CBP's obligation, without discretion, to protect Americans from unsafe, unchecked products coming into the country from foreign sources," Safdar said. "Despite their efforts, far too many suspicious shipments are making their way into the country. We call on the agencies to use the tools at their disposal to assure the American public that their weight loss drugs are safe. Similarly, we call on drug compounders, including medspas and telehealth companies, to operate with transparency, integrity, and responsibility to their customers."

This too, indicates some ignorance of compounding. Med spas and telehealth companies are not pharmacies. If by "drug compounders" the news release is referring to state licensed pharmacies, we would assert that with very few exceptions, those pharmacies DO "operate with transparency, integrity, and responsibility." Perhaps PSM should hold itself to the same standard?

Click here to view the full report.

Media inquiries: editors@safemedicines.org

###

About the Partnership for Safe Medicines

The Partnership for Safe Medicines is a public health group committed to ensuring the safety of prescription drugs and protecting consumers from counterfeit, substandard or otherwise unsafe medicines. Comprised of more than 45 non-profit organizations, PSM studies counterfeit drug crime, threats to American patients, and educates the public, policymakers, and health care professionals about threats to the safety of the U.S. drug supply.

What's missing here is "PSM is funded by drugmakers."