InsideHealthPolicy
An Inside Washington news service

APC: FDA's GLP-1 Compounding Concerns Based On Shaky Data

By Jessica Karins / March 21, 2025 at 6:06 PM

The Alliance for Pharmacy Compounding (APC) is "protest(ing) in the strongest terms" FDA's assertion it has received hundreds of reports of adverse events linked to compounding of GLP-1 weight loss and diabetes drugs, alleging the agency is casing doubt on the integrity and quality of compounding pharmacies based on unverified reports from consumers. The compounding group's protest comes as FDA prepares to enforce its limitations on compounding following the end of GLP-1 shortages.

FDA's recent update on its webpage cites the FDA Adverse Event Reporting System (FAERS), saying it has received, as of Feb. 28, more than 455 reports of adverse events with compounded semaglutide and more than 320 reports of adverse events with compounded tirzepatide. It also says adverse events may be underreported because state-licensed pharmacies that are not outsourcing facilities are not required to submit reports to FAERS.

"The agency has identified some areas of concern for compounded GLP-1 drugs. FDA is working with its state regulatory partners and will continue to communicate with compounders regarding these concerns," FDA's statement says.

APA's letter objects to the use of FAERS data, saying the information is unverified and alleges the agency's statement is "both inflammatory and misrepresentative." The group says FDA fails to acknowledge in its statement the unreliability of FAERS reports or to differentiate between illicit, sometimes fraudulent substances acquired from unlicensed online pharmacies and compounded drugs prepared by legitimate state-licensed pharmacies.

"Given this context, it is deeply concerning that the FDA has chosen to highlight FAERS reports in a manner that suggests definitive risks associated with compounded GLP-1s without providing appropriate context about those reported adverse events," APC wrote. "Nor does the agency apply the same scrutiny to FDA-approved versions of these medications. The selective application of concern disproportionately burdens compounding pharmacies and misleads the public -- many of whom rely on compounded therapies to live normal lives."

The letter also says FDA has repeatedly used "inflammatory language" about compounded GLP-1s without acknowledging the role they're played in providing patients with access to the drugs in their prolonged period of shortage. "The FDA's statements on this issue have not only undermined pharmacy compounding but also have risked driving patients toward unregulated sources of medication out of fear and misinformation," APC wrote.

The organization asks for a meeting with FDA to discuss its concerns and advocate for the agency to adopt a different approach to communications about GLP-1s.

On its website, FDA says it has received multiple reports of adverse events that may be related to dosing errors with compounded semaglutide products, some requiring hospitalization. The errors stem either from providers miscalculating doses of the drugs or patients self-administering the medications.

"Additionally, the agency has received adverse event reports that may be related to patients prescribed compounded semaglutide or tirzepatide products in doses beyond what is in the FDA-approved drug label," FDA wrote. "This could mean using more product in a single dose, taking doses more frequently or increasing the amount more quickly (titration schedule). Some of the adverse events are serious and some patients reported seeking medical attention for their symptoms, including nausea, vomiting, diarrhea, abdominal pain and constipation."

The agency said it has additional concerns about counterfeit Ozempic, illegal online sales of GLP-1s, and versions purportedly being sold for research purposes that are actually intended for human consumption.

FDA commissioner nominee Marty Makary was formerly the chief medical officer at Sesame, a telehealth company that offers compounded GLP-1 medications along with other services. Sen. Elizabeth Warren (D-MA) has said Makary should recuse himself from decisions involving GLP-1 compounding. Makary is expected to be confirmed as soon as next week.

Wednesday (March 19) was the deadline for outsourcing compounders to stop making compounded versions of Eli Lilly's tirzepatide GLP-1 drugs after a district court ruled FDA didn't act improperly in removing them from the list of drugs in shortage, though the Outsourcing Facilities Association has appealed that decision.

State-licensed pharmacies must stop making compounded versions of Novo Nordisk's semaglutide drugs by April 22 or when a district court rules on a pending injunction about FDA's decision on those drugs, whichever is first. -- *Jessica Karins* (jkarins@iwpnews.com)

147506

RELATED NEWS

- **OFA Appeals Court Decision Backing FDA's End Of GLP-1 Shortage**
- **Court Mum On Why It Said FDA Can Keep Tirzepatide Off Shortage List**
- **Outsourcing Facilities Sue FDA Over End Of Semaglutide Shortage**
- **FDA Declares Semaglutide Shortage Over, Compounders Aim To Adjust**
- **Trump Comments On GLP-1 Prices Add To Drug Policy Uncertainty**