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# The GLP-1 Saga Continues: FDA Ends the Tirzepatide Shortage: Frequently Asked Questions

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On December 19, 2024, FDA formally announced the end of the tirzepatide shortage in a Declaratory Order issued to Eli Lilly & Co. ("**Lilly**"). Lilly is tirzepatide's patentholder and the manufacturer of the two branded versions of tirzepatide, Mounjaro® (for diabetes) and Zepbound® (for weight loss and, announced on December 20, sleep apnea).

FDA's December 19 announcement ended a regulatory back and forth that I previously summarized here. In short, on October 2, 2024, FDA announced that Lilly had resolved the tirzepatide shortage, but five days later the Outsourcing Facilities Association ("**OFA**") sued FDA on the grounds that FDA's decision to end the tirzepatide shortage was unlawful because, inter alia, FDA failed to provide notice and seek comments from interested stakeholders. Just over a week later, FDA paused the end of the shortage and announced that it was reconsidering its position and promised to publish an updated final decision shortly. That final decision came on December 19, and today tirzepatide is no longer on FDA's list of shortage drugs.

FDA's resolution of the tirzepatide shortage dramatically changes how the law applies to companies making and distributing compounded copies. Please read below for some of the frequently asked questions ("**FAQs**") I have received since FDA issued its Declaratory Order:

1. Q. What is the state of the law for companies still making and selling compounded tirzepatide?

A. When tirzepatide was on FDA's list of shortage drugs, federal law allowed for the compounding of "copies" pursuant to 21 USC § 353a (for compound pharmacies) and 353b (for outsourcing facilities). However, those protections dissipated once tirzepatide was removed from the shortage list, so compounding pharmacies and outsourcing facilities can be held in violation of the law to the extent they still compound copies. FDA can deem compounded tirzepatide to be in violation of the adulteration and misbranding provisions of the FDCA, and Lilly can sue them under the Lanham Act for violating Lilly's tirzepatide patent.

2. Q. Can I sell the rest of my inventory of compounded tirzepatide?

A. In its Declaratory Statement, FDA explained that it will abstain from taking action against compound pharmacies so long as they discontinue making and distributing compounded tirzepatide before February 18, 2025. Outsourcing facilities have an extra 30 days, or until March 19, 2025. However, FDA exercising its "enforcement discretion" during this wind down period may not not prevent Lilly from initiating its own Lanham Act cases, so in practical terms the off-ramp from compounded tirzepatide might be shorter than what FDA has established for itself.

3. Q. I market compounded tirzepatide to patients, but I am not the compounder. Does this change in the status of tirzepatide impact me?

A. Yes. FDA's Declaratory Statement makes clear that, once the deadlines expire, it can take action against companies "compounding, distributing, ***or*** dispensing" compounded tirzepatide. For its part, Lilly would likely be able to bring Lanham Act cases against a similarly broad array of actors.

4. Q. What about patients?

A. The best interests of patients should not be disregarded in this

discussion. If, for instance, your company has been prescribing compounded tirzepatide to patients during the shortage period, those patients should be advised about the inevitable discontinuation as soon as possible to ensure a smooth transition. Unfortunately, many patients may choose to forego additional treatments due to the dramatic increase in cost associated with brand name versus compounded GLP-1 drugs.

5. Q. Are any GLP-1s still on FDA's shortage list?

A. Yes. As of the date of this post, semaglutide, dulaglutide, and liraglutide remain on FDA's shortage list – so compounding pharmacies and outsourcing facilities can still make and dispense compounded copies. Novo Nordisk and Lilly have told FDA that these GLP-1 drugs are "available", but FDA has yet to publicly verify this information. However, it can at any time. In its Declaratory Statement, FDA made clear that it can remove drugs from the shortage list without notice to stakeholders, so companies making compounded copies must be nimble and have backup plans.

6. Q. If I issue a three or six month prescription to a patient for compounded tirzepatide, will the patient still be able to get the prescription filled after the deadline?

A. Probably not. Even assuming a practitioner could prescribe tirzepatide for an extended time period, compounding pharmacies and outsourcing facilities are still restricted by the removal of tirzepatide from FDA's shortage list and would continue to face legal consequences for making and dispensing compounded copies.

7. Q. What if a patient needs compounded tirzepatide due to a unique medical need?

A. Traditional compounding involves the preparation of medications that are not commercially available, for instance for patients allergic to certain ingredients in approved, mass-produced drugs. Traditional compounding is

still commonplace today, see § 353a, and theoretically a patient could be allergic to an ingredient in Zepbound® and require compounded tirzepatide instead. However, if this occurred at an industrial scale, it could draw the ire of FDA or Lilly as an end-around to the rules prohibiting the compounding of "copies" of commercially available drugs.

Ultimately, whether the traditional compounding of tirzepatide could survive a challenge by FDA or Lilly would be fact dependent. The law prohibits compounding pharmacies from compounding "regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product." § 353(b)(1)(D). So, at the threshold, the pharmacy would need to establish that i) it does not compound tirzepatide regularly or in inordinate amounts, and ii) its compounded tirzepatide is not merely a copy of Zepbound® or Mounjaro®.

In a 2018 guidance, FDA explained that it would consider a compounded drug to be essentially a copy of a commercially available drug if it has (i) the same API, (ii) the same or similar dosage, and (iii) the same route of administration, ***unless*** "a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, ***a significant difference*** from the commercially available drug product." The guidance also explains that, if a change is made for an identified patient, the prescriber should document the determination on the prescription, and the notations should be specific. Of course, in a footnote to the guidance, FDA explained that it retains the authority to determine that the "significant difference" is merely a "pretext" for the compounding of copies of commercially available products, in which instance it could bring an enforcement action.

8. Q. How was FDA able to remove tirzepatide from the shortage list without notifying the public and requesting comments? Can this happen again to other shortage drugs?

A. In its Declaratory Order, FDA cited a list of reasons why it was able to

remove tirzepatide from its shortage list without providing the public with notice and the opportunity to submit comments. Among other reasons, FDA explained that the law did not require notice and comment, providing notice would require the publication of the manufacturer's trade secrets, and notice could lead to hoarding. Yes, this can happen again.

9. Q. Is there any chance that tirzepatide will return to the shortage list?

A. OFA has sued FDA based on FDA's removal of tirzepatide from the shortage list, and that case is ongoing. More recently, Lilly has asked for permission to intervene. Regardless of whether Lilly joins the fray, OFA has an uphill battle in court. The Trump administration may wish to look into the issue, but it is not on any list of initial priorities.

10. Q. My tirzepatide is labeled "for research use only." I should be in the clear, right?

A. No. For more insight on "research use only" GLP-1s, please see my prior article here.



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