Alliance for Pharmacy Compounding

Compounding the Joy of Living®

APC CEO SCOTT BRUNNER IN RESPONSE TO ELI LILLY OPEN LETTER

March 7, 2024

Lilly and other drug manufacturers have developed GLP-1 medications at great expense, and they have been received with great fanfare because of their effectiveness. Unfortunately, they are not able to meet current demand for those drugs.

Compounding pharmacies are authorized by federal law and follow FDA rules in preparing copies of an FDA-approved drug when that drug is listed as "currently in shortage" on FDA's Drug Shortage list – as both tirzepatide and semaglutide currently are. FDA guidance is plainly worded on this matter.

In its letter, Lilly rather cleverly conflates legitimate compounded medications prepared by a compounding pharmacy with illicit counterfeit substances obtained without a prescription. Surely the drugmaker knows this is misleading.

Legitimate compounded drugs are prescribed by a physician or other prescriber for a specific patient when an FDA-approved drug is not appropriate for or available to that patient. They are prepared and dispensed by state-licensed compounding pharmacies using documented pure active pharmaceutical ingredients that come from FDA-registered facilities.

Lilly rightly notes that compounded drugs are not FDA-approved. But that fact does not mean compounded drugs are unsafe – any more than it means that FDA-approved drugs are always safe.

Lilly states that it *"has discovered products claiming to be compounded tirzepatide medicines that contain bacteria, high impurity levels, different chemical structures, and different colors than Mounjaro or Zepbound. In at least one instance, the product was nothing more than sugar alcohol."*

Lilly should not be allowed to freely make headline-grabbing claims without answering a few questions and providing evidence of those claims.

First, are we sure this is a compounded drug? Was it prepared by a state-licensed pharmacy? If not, it's not a compounded drug at all. It's not even pharmacy.

But let's say was prepared by a legitimate pharmacy. Next question is, was it legally acquired? How exactly does a corporation get its hands on a drug that can only be dispensed to a specific patient pursuant to a prescription from a physician or other provider?

But let's say some good-hearted patient to whom the drug was legally dispensed brought it to Lilly. More questions:

- How old was the substance at the time Lilly acquired and had it tested?
- Who did the testing?
- Had it been properly refrigerated?

Answers to these questions matter in determining the legitimacy of Lilly's claims. Lilly's claims make for great headlines, but they may be misleading. In this case, the drug behemoth should answer a few questions and show its work.

"Lilly will continue to pursue legal remedies against those who falsely claim their products are Mounjaro, Zepbound, or FDA-approved tirzepatide, including certain medical spas, wellness centers, and compounding pharmacies."

Mounjaro and Zepbound are trademarks, owned by Lilly. It is never legal to refer to a compounded drug by a brand name. Compounded drugs are referred to by the name of the active pharmaceutical ingredient. Nor is it accurate to refer to compounded drugs as "generic." Compounded drugs are not the same as generic drugs. Moreover, compounded drugs are not FDA-approved because they are prescribed for an individual patient, but the API in those drugs **is** FDA regulated.

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The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

Learn more at compounding.com and a4pc.org.