

Semaglutide Compounding: A Primer for Reporters

For the sake of clarity and accuracy, following are some things about #pharmacycompounding reporters should know when reporting on compounding, particularly related to semaglutide:

1. Pharmacies don't "sell" drugs. Pharmacies DISPENSE drugs pursuant to a prescription from a physician or other prescriber. Selling drugs is a different endeavor altogether.
2. Compounding pharmacists don't get to decide when a compounded drug – rather than an FDA-approved drug – is dispensed. The PRESCRIBER makes that decision when in their judgment the compounded drug is the better therapy for the patient.
3. Manufactured drugs are always first choice but don't come in strengths and dosage forms that are right for all. Physicians, NPs and PAs prescribe customized meds when, in their judgment, an FDA-approved drug is not the best course of therapy for the patient.
4. Compounded drugs are not "knock-offs" as referred to in some media stories. They are authorized by law and created from pure ingredients by pharmacies that adhere to rigorous compliance standards and are licensed and inspected by state boards of pharmacy and FDA.
5. A compounded drug is not a substitute for an FDA-approved drug; rather, the prescriber has intentionally prescribed a compounded drug in a specific dosage strength or form or combination of medications that they believe is right for their patient.
6. Federal law permits the compounding of copies of FDA-approved drugs when a drug is in shortage because it is essential for continuation of patient care – as, amid continuing post-COVID supply chain issues, many, including semaglutide, continue to be.
7. Do compounded drugs generally do for patients what they purport to do? According to patient reporting, yes they do, without question. Do we say they are "safe" and "effective"? No, because those words have LEGAL meanings associated with FDA approval.
8. In its recent statement on semaglutide, FDA says "Patients should not use a compounded drug if an approved drug is available." Exactly right. But the FDA-approved version of semaglutide hasn't been available for more than a year now. While in shortage, federal law allows compounding of it.
9. Like FDA, we're concerned about folks purchasing substances purporting to be semaglutide from unregulated, unlicensed online sources without a prescription. That's not compounding. Those aren't even pharmacies – and claims about those substances cannot be substantiated or trusted.
10. FDA's statement warns against taking a compounded medication made from an active pharmaceutical ingredient that is NOT the same active ingredient as found in Wegovy and Ozempic. Beyond that, the agency didn't say anything different about compounded medications than it ever has.



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11. True, compounded meds aren't FDA-approved. But because they are custom-made for each patient, how could they be? That doesn't mean unsafe, however. And FDA approval is no blanket guarantee of safety – as recent FDA-approved eyedrop recalls demonstrate.

About APC

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 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.