

Feedback



The Potential Risks Associated with Compounded Semaglutide: What Medical Professionals Should Know

August 25, 2022

Semaglutide is the main API in the weight management medication Wegovy[®]. Semaglutide is a GLP1 receptor agonist that was originally developed to treat diabetes by lowering blood glucose levels by stimulating the release of insulin. It later received FDA approval as a **weight loss medication** for obese patients in June 2021. The sheer popularity of this drug has led to supply shortages that are expected to be resolved in the second half of 2022.¹ In addition to supply concerns, GLP1 drugs are also quite expensive. These two issues have caused prescribers to seek alternatives to semaglutide, such as compounding it with other drugs. However, compounding is often intended to be performed on an as-needed basis and specific to each patient, such as when the patient is allergic to an ingredient in a commercially-available drug.

Issues with Compounding Semaglutide

Semaglutide is a polypeptide and was originally classified as a *biologic*, which cannot be compounded under sections 503A and 503B of the Federal Food, Drug, and Cosmetic (FD&C) Act.² However, under the FDA's newly revised definition, semaglutide is no longer classified as a biologic because it contains fewer than 40 amino acids.³ Thus, it is now governed by the regulations that restrict the compounding of commercially available drugs (Section 503A of the FD&C Act), which state that a pharmacy must only make a compounded medication on-demand and must not stockpile it. Regulations restrict compounding pharmacies from making replications of patented therapeutics.

In defiance of these regulations, some compounding pharmacies have compounded semaglutide with other medications, such as L-carnitine.⁴ There are a variety of concerns with compounding semaglutide, including a potentially lower bioavailability due to the destruction of the absorption enhancer used in the formulation. Furthermore, many suppliers are selling the sodium salt of semaglutide. The FDA often considers different salts of APIs to be pharmaceutical alternatives, not necessarily therapeutic equivalents. Currently, only semaglutide—not its sodium salt—is listed in the FDA's *Orange Book*, with no therapeutic equivalents listed. Therefore, there is no FDA-backed guarantee that the sodium salt is as effective as the non-salt form. To be clear, compounded medications are not FDA approved and often, active pharmaceutical ingredients (APIs) are not FDA approved. FDA approves commercially manufactured finished products containing APIs that are in turn used in compounds (or not used when they are not reputedly available to pharmacies).

More alarmingly, it is unclear where the semaglutide is being sourced from, as to our knowledge and at the time of publication, the only FDA-approved source of the drug, Novo Nordisk, is currently facing a shortage. According to their website,¹ they "[do] not sell Wegovy[®] (or its active ingredient, semaglutide) for the purposes of compounding with other products." Thus, it is unclear where the semaglutide is being obtained from, but it is certainly not being obtained from an FDA-approved manufacturer.

Why does this matter? The FDA assesses the safety and effectiveness of drugs produced by regulated manufacturers but not those compounded by pharmacies. Thus, there is no way to guarantee the potency of the medications, as even the FDA-approved versions have a 10% variance. Because of these slightly looser regulations, some compounding pharmacies have continued to use compounded semaglutide in their medications. However, the FDA has previously taken action against companies that defy its guidance. Earlier this year, the FDA issued warning letters to several companies for selling hydroquinone and even issued an import alert to help stop this product from illegally entering the USA.⁵ One of the **warning letters** went directly to the dermatologist prescribing a hydroquinone-containing medication. It is likely only a matter of time before similar actions are taken against companies illegally sourcing semaglutide and (potentially) the doctors and clinicians who prescribe it.

Potential Legal Issues with Compounding Semaglutide

In addition to safety issues, there are legal concerns associated with the compounding of semaglutide. Novo Nordisk owns the patents for this medication and can likely prosecute to protect their intellectual property. Thus, there is potential legal liability on the part of both the compounding pharmacies and the physicians who prescribe this medication, especially if the compounded medication harms the patient.⁶

There is precedent for a pharmaceutical company pursuing legal action after compounding pharmacies essentially manufactured copies of commercially available drugs, such as Firvanq.⁷ In this case, Azurity Pharmaceuticals filed a lawsuit against the compounding company, Edge Pharma, which issued a voluntary recall of all its drug products⁸ in 2022.⁹ Although it is typically the compounding pharmacy that is held liable in such circumstances, the physician or prescriber may also be partially liable and open themselves up to litigation, depending on the nature of their relationship with the compounding pharmacy.¹⁰

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Ordering semaglutide from a non-FDA-approved source puts your patient's health at risk and could potentially open the door for litigation, as previous court cases have shown. Although compounding represents a useful method for prescribers to tailor medications to an individual patient's needs, there is currently no FDA-approved source for semaglutide. Therefore, as we wait for semaglutide to become available once again, physicians should consider prescribing alternative **weight management** treatments that are manufactured in an FDA-approved 503A pharmacy.

As a 503A pharmacy specializing in sterile and non-sterile compounding, VLS Pharmacy and New Drug Loft will support you and your patients by creating safe, individualized, and effective pharmaceutical therapies. For men and women at any age, feeling healthy, confident, and comfortable is of the utmost importance. Your patients' needs will change with each life stage. As such, they require an adaptive and personalized treatment plan. By working with a trusted compounding pharmacy like VLS Pharmacy and New Drug Loft, you are expanding the possibilities for successful and sustainable care.

Reach out to our team to learn about best practices and to partner with our experts on custom compounded medications for your patients.

All medications from VLS Pharmacy and New Drug Loft are prepared in a lab that follows safety and quality standards per our status as a 503A pharmacy.

References

- Product Supply Information | Wegovy™ (semaglutide) Injection 2.4 mg. Accessed August 21, 2022. <https://www.novomedlink.com/obesity/products/treatments/wegovy/resources/product-supply-information.html>
- Compounding and the FDA: Questions and Answers | FDA. Accessed August 21, 2022. <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>
- Federal Register: Definition of the Term "Biological Product." Accessed August 21, 2022. <https://www.federalregister.gov/documents/2020/02/21/2020-03505/definition-of-the-term-biological-product>
- Semaglutide and Weight Loss. Accessed August 21, 2022. <https://compoundingrxusa.com/blog/semaglutide-weight-loss-drug/>
- FDA works to protect consumers from potentially harmful OTC skin lightening products | FDA. Accessed August 23, 2022. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-works-protect-consumers-potentially-harmful-otc-skin-lightening-products>
- Pharmacist pleads guilty to adulterating drug linked to eye injuries | Reuters. Accessed August 21, 2022. <https://www.reuters.com/legal/government/pharmacist-pleads-guilty-adulterating-drug-linked-eye-injuries-2021-10-13/>
- Azurity lawsuit over compounding pharmacy's rival drug revived -court | Reuters. Accessed August 21, 2022. <https://www.reuters.com/legal/government/azurity-lawsuit-over-compounding-pharmacies-rival-drug-revived-court-2022-08-15/>
- Edge Pharma, LLC Issues Voluntary Nationwide Recall of All Drug Products Due to Lack of Sterility Assurance | FDA. Accessed August 21, 2022. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edge-pharma-llc-issues-voluntary-nationwide-recall-all-drug-products-due-lack-sterility-assurance>
- A Vermont Drug Company's Failure to Maintain Standards Led to Recalls — and Its Demise | Health Care | Seven Days | Vermont's Independent Voice. Accessed August 21, 2022. <https://www.sevendaysvt.com/vermont/a-vermont-drug-companys-failure-to-maintain-standards-led-to-recalls-and-its-demise/Content?oid=35853429>
- Physicians denied in tainted drugs lawsuits — amednews.com. Accessed August 23, 2022. <https://amednews.com/article/20130211/profession/130219977/2/>
- FDA Drug Shortages. Accessed August 21, 2022. [https://www.accessdata.fda.gov/SCRIPTS/DRUGSHORTAGES/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide \(WEGOVY®\) Injection&st=c](https://www.accessdata.fda.gov/SCRIPTS/DRUGSHORTAGES/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide (WEGOVY®) Injection&st=c)

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