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COMMENTARY

A Checklist for Compounded Semaglutide or Tirzepatide

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Consider this: If you're taking your child to the beach, how do you protect them from drowning? You don't tell them, "Don't go into the ocean." You teach them how to swim; you give them floaties; and you accompany them in the water and go in only when a lifeguard is present. In other words, you give them all the tools to protect themselves because you know they will go into the ocean anyway.

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Patients are diving into the ocean. Patients with obesity, who know that a treatment for their disease exists but is inaccessible, are diving into the ocean. Unfortunately, they are diving in without floaties or a lifeguard, and well-meaning bystanders are simply telling them to not go.

Compounded peptides are an ocean of alternative therapies. Even though compounding pharmacists need specialized training, facilities and equipment need to be properly certified, and final dosage forms need extensive testing, pharmacies are not equal when it comes to sterile compounding. Regulatory agencies like the US Food and Drug Administration (FDA) have expressed caution around compounded semaglutide. Professional societies like the Obesity Medicine Association (OMA) advise against compounded peptides because they lack clinical trials that prove their safety and efficacy. Ask any individual doctor and you are likely to receive a range of opinions.

As an endocrinologist specializing in obesity, I practice evidence-based medicine as much as possible. However, I also recognize how today's dysfunctional medical system compels patients to dive into that ocean in search of an alternative solution.

Doctors can't be lifeguards, but we can at least empower patients who want to decide for themselves whether the risk of compounded peptides is worth it.

With the help of pharmacists, compounding pharmacists, researchers, and clinicians, here is a checklist for patients who seek compounded semaglutide or tirzepatide:

1. Check the state licensing board website to see if there have been any complaints or disciplinary actions made against the pharmacy facility. These government-maintained websites vary in searchability and user-friendliness, but you are specifically looking for whether the FDA ever issued a 483 form.

2. Ask for the pharmacy's state board inspection report. There should be at least one of these reports, issued at the pharmacy's founding, and there may be more depending on individual state regulations on frequencies of inspections.

3. Ask if the compounding pharmacy is accredited by the Pharmacy Compounding Accreditation Board (PCAB). Accreditation is an extra optional step that some compounding pharmacies take to be legitimized by a third party.

4. Ask if the pharmacy follows Current Good Manufacturing Practice (CGMP). CGMP is not required of 503a pharmacies, which are pharmacies that provide semaglutide or tirzepatide directly to patients, but following CGMP means an extra level of quality assurance. The bare minimum for anyone doing sterile compounding in the United States is to meet the standards found in the US Pharmacopeia, chapter <797>, Sterile Compounding.

5. Ask your compounding pharmacy where they source the medication's active pharmaceutical ingredient (API).

6. Find out if this supplier is registered with the FDA by searching here or here.

7. Confirm that semaglutide base, not semaglutide salt, is used in the compounding process.

8. Request a certificate of analysis (COA) of the active pharmaceutical ingredient, which should be semaglutide base. This shows you whether the medication has impurities or byproducts due to its manufacturing process.

9. Ask if they have third-party confirmation of potency, stability, and sterility testing of the final product.

In generating this guidance, I'm not endorsing compounded peptides, and in fact, recognize that there is nothing keeping small-time compounding pharmacies from skirting some of these quality measures, falsifying records, and flying under the radar. However, I hope this checklist serves as a starting point for education and risk mitigation. If a compounder is unwilling or unable to answer these questions, consider it a red flag and look elsewhere.

In an ideal world, the state regulators or the FDA would proactively supervise instead of reactively monitor; trusted compounding pharmacies would be systematically activated to ease medication shortages; and patients with obesity would have access to safe and efficacious treatments for their disease. Until then, we as providers can acknowledge the disappointments of our healthcare system while still developing realistic and individualized solutions that prioritize patient care and safety.

Disclosures: Dr Tchang is an advisor for Novo Nordisk, which manufactures Wegovy, and an advisor for Ro, a telehealth company that offers compounded semaglutide.

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