Weekly Checkup

Inside the Compounding Boom

JOHN WALKER | JANUARY 31, 2025

On Tuesday, online telehealth prescription company Hims & Hers announced it had purchased a 30-second ad spot during Super Bowl LIX to air its new "Sick of the System" commercial. This builds on a May 2024 release where the company announced it would begin selling compounded (comp) GLP-1 weight-loss injections for $199 per month – roughly a fifth of the out-of-pocket cost of other brand-name options. If you're wondering how a company can sell comp weight loss drugs online – without Food and Drug Administration (FDA) approval – for a fraction of the cost of its brand-name competitors to any uninsured consumer, it's because of that one word: "compounded." **Let's discuss the compounding pharmacies that manufacture these comp alternatives to understand how telehealth prescription companies can sell inexpensive, non-FDA approved drugs over the internet.**

A compounding pharmacy is defined as "any pharmacy that provides medications that are not commercially available and prepares them onsite." In practice, compounding pharmacies effectively manufacture customized medications for patients based on their specific needs. They are governed by Section 503 of the Food, Drug, and Cosmetic Act, which allows certain approved pharmacies to qualify for a status that entitles them to produce essential copies of brand-name drugs known as compounded drugs – so called because these pharmacies alter, mix, or compound previously approved medications – in the case of shortage and in some cases to personalize the drug for particular patient needs. **While these compounded drugs – made by compounding pharmacies – are governed by FDA regulations and intended to follow good manufacturing practices, they are not evaluated by the FDA for safety, efficacy, or quality, nor is there a guarantee that the FDA will regularly inspect these facilities to ensure they remain compliant.** This is not exactly a small problem, either: Of the roughly 56,000 community or retail pharmacies located in the United States, approximately 7,500, or about 13 percent, qualify as compounding pharmacies.

To put it simply, **we have two entirely different regulatory regimes governing the production and sale of prescription drugs: one that is highly regulated and relatively expensive but safe, and another that is largely unregulated and relatively cheap but a complete mystery box in terms of safety.** While this dual market may have resulted from an entirely understandable regulatory caveat to help get drugs to patients who need them, it seems reasonable to question how it was this offshoot market was able to take out high-priced spots for the most-watched television event in the country to advertise underregulated and inexpensive weight-loss drugs that Americans can purchase on the internet without a prescription.

Are these drugs unsafe? Because the FDA does not officially evaluate comp drugs for safety, efficacy, or quality, and often these drugs are prescribed and administered with little if any doctor oversight, the FDA has raised concerns about the practices of some compounders. Notably, last month, the FDA put out a press release alerting consumers that many compounders were replacing the semaglutide on which these GLP-1s are based with less costly, untested, and unproven salt derivatives. As explained in the release, "The agency does not have information on whether these salts have the same chemical and pharmacologic properties as the active ingredient in the approved drug, and we are not aware of any lawful basis for their use in compounding." **The FDA also warned consumers about the risk of dosing errors when using these comp drugs with little to no doctor oversight, noting that it had "received multiple reports of adverse events, some requiring hospitalization,"** and adding that the dosing errors "resulted from patients measuring and self-administering incorrect doses of the drug."

This shadow prescription drug market isn't the result of some groundbreaking innovation or the solution to some market inefficiency. It arose purely from a regulatory carveout originally intended to address drug shortages for patients with special needs. Certainly, this stopgap measure was never intended to become a household name.