

Market for knockoff GLP-1 products is still like the Wild West

BY LISA JARVIS

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Telehealth company Hims & Hers unleashed a wild few days in the obesity drug market last week when it introduced a cheap, compounded version of Novo Nordisk's new Wegovy pill.

It was an audacious attempt for a piece of the lucrative GLP-1 market that came to a swift and disastrous end — the company pulled its product just two days after its launch after U.S. regulators vowed to take “decisive” action against its knockoff drug and others like it. On Monday, Novo said it was suing Hims over its copycat drugs.

Although the Wegovy pill hoopla might have subsided, the Wild West of GLP-1 drugs persists. As the Food and Drug Administration now increases efforts to rein it in, it's worth asking why it took so long — and whether it's too little, too late.

As a reminder, the door was opened for these copycat drugs when companies could not keep up with demand. Regulatory authorities allow for so-called “compounded” versions of medicines that are in shortage — and Wegovy and Zepbound were in shortage after their approvals for weight loss in 2021 and 2023, respectively. A gray market took off, with telehealth companies, online pharmacies and wellness spas offering knockoff versions of the products.

Companies finally got their manufacturing acts together, and the shortage has been officially over for more than a year for Zepbound and nearly a year for Wegovy. The FDA gave telehealth firms and online pharmacies a grace period to shut down sales, yet the gray market for compounded weight-loss drugs has stuck around.

The No. 1 rule with compounded GLP-1s in the U.S. is “Let the buyer beware.” These are not generic versions of Wegovy or Zepbound — a subtle, but critical distinction. A generic drug is regulated by the FDA, which has deemed it to be equivalent to the original product. A compounded drug isn't subject to that same oversight, meaning there's no guarantee it's as effective or safe as the original product.

A compounded version of the Wegovy pill seems especially fraught. Semaglutide, the active ingredient in Wegovy, is a peptide, a type of molecule that historically has been difficult to turn into a pill.

So when Hims & Hers said it would sell its own cheap version of the Wegovy pill, it raised red flags.

Beyond Novo's patent infringement claims, there was a more practical one for consumers: Could their product possibly work as well as the Novo one?

The question might be moot now that Hims & Hers has pulled its product, yet that one product is only the start of the problem in the GLP-1 market. For starters, a vast universe of compounded injectable drugs, which can be mixed with other ingredients that claim without evidence to offer some added benefit, are still widely available.

And it's easy to find a wide range of unapproved and unproven formulations of GLP-1 knockoffs. Those include lozenges, “microdose” pills and under-the-tongue drops.

Consumers can't be blamed for their confusion over, or interest in, these copycat GLP-1s. Some companies had been describing their compounded drugs as "generics," and too many experts casually use that erroneous term. And when the public is bombarded with ads for cheap, easily accessible alternatives to FDA-approved drugs, it's no wonder some people are eager to buy them.

The FDA has been warning consumers for years that these products might not work and could be unsafe. Commissioner Marty Makary escalated those efforts last Friday, saying that in addition to cracking down on Hims & Hers and other compounders, the agency would take "steps to combat misleading direct-to-consumer advertising and marketing" by companies claiming to sell "generic" or equivalent products.

More enforcement is welcome, but given the size of the gray market, it's hard to imagine it will be easy to shut it all down. The best solution would be for the branded drugs to become more accessible to everyone. Sure, competition is finally starting to bring down their prices, yet insurance coverage remains spotty at best.

So long as they remain out of reach for the many millions of people who are eligible for them, there will be demand for whatever is cheapest — even if it's not in consumers' own best interest.

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