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Beyond the Headlines: FDA Warning Letters to GLP-1 Compounders

As part of a larger crackdown on direct-to-consumer prescription drug advertising, the FDA published over 55 warning letters on September 16 to online sellers of compounded versions of the popular GLP-1 medications for type-2 diabetes and weight loss. The letters alleged that some of the words used in advertising the products gave rise to an "Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers over the Internet." The FDA demanded immediate action, suggesting the online marketers cease and desist from using the language cited in the FDA's warning letter from their online advertising.

This is the latest in ongoing disputes over compounding of GLP-1 products, and claims over the booming GLP-1 market with current estimated revenue over $50 billion.

Background

There were two GLP-1 products that were initially approved and marketed for treating type-2 diabetes but, because they also had successful weight loss results, the manufacturers each got FDA approval to sell the products under two separate indications, one indicated for type 2 diabetes and one for weight loss, each with its own brand name and National Drug Code (NDC) identification number. This strategy allowed insurers that didn't cover weight loss products to include the diabetes-indicated version on their drug formularies, while excluding the weight loss version.

Novo Nordisk received FDA approval for its semaglutide-based GLP-1 products, Ozempic for diabetes and Wegovy for weight loss, in December 2017 and June 2021, respectively. Eli Lilly received FDA approval for its tirzepatide-based GLP-1 products,

Mounjaro for diabetes and Zepbound for weight loss in May 2022 and November 2023, respectively. The list prices for these products approached or exceeded $1,000 for a one-month supply.

The FDA-approved, branded versions of GLP-1 products were so popular that the brand manufacturers were not able to keep up with demand, prompting the FDA to declare a shortage for each of the semaglutide and tirzepatide products over the course of 2022.

Generally, under the Federal Food, Drug, & Cosmetic Act (FDCA), only the manufacturer with an FDA-approved product is permitted to manufacture and sell that FDA-approved product; others are not allowed to manufacture their own versions except for particular clinical needs of a patient or by getting their version FDA-approved. And this makes sense – the FDA wants to incentivize products going through the rigorous approval process to ensure safety and efficacy.

But, when a product is in shortage, licensed pharmacies and FDA-registered compounding facilities are permitted to manufacture versions of the FDA-approved product that are "essentially a copy" of the FDA-approved product until the shortage is resolved. This also makes sense; the FDA wants to incentivize manufacturers to ensure they have manufacturing capacity to meet demand so patients don't suffer if they fall short.

In the case of these GLP-1 products, enterprising compounders saw an incredible opportunity to build the cash-paying weight-loss market for these products. They also understood that there were millions of consumers who would not pay $1,000 or even $500 per month for the product, but who would be interested if they could get to the right price point. They learned that the ingredient cost to manufacture a one-month supply of the products was so low (one study estimated less than $5 for semaglutide products) that they could manufacture and sell to cash-paying patients for $100 to $300 and still earn a significant profit.

At that price point, the market grew quickly. It took the brand manufacturers more than two years to build enough capacity for the FDA to declare the shortages over, which happened on December 19, 2024, for Eli Lilly's tirzepatide products, and February 21, 2025, for Novo Nordisk's semaglutide products. The FDA gave pharmacies and compounding facilities 60 and 90 days, respectively, from the end

of each shortage to wind down operations and for patients to switch to the FDA-approved brand products that were no longer in shortage. With those deadlines set, many pharmacies and compounding facilities did wind down their GLP-1 compounding operations.

But many also continued, most commonly by asserting the clinical need exception for a personalized version of the products, much to the frustration of the FDA and brand manufacturers. Eli Lilly and Novo Nordisk have each worked to reduce the price for cash-paying patients (both have cash programs for their weight loss products for around $500 per month) but have not come close to the pricing accessibility that compounders and vendors of compounded products have been offering. They have also sent cease-and-desist letters and have initiated litigation against some compounders with various allegations that are working their way through the courts. And now the FDA is taking its first large-scale public action related to the massive GLP-1compounding market since the shortages ended by sending this batch of warning letters.

Content of Warning Letters

Generally, any direct-to-consumer messaging about drugs, including by compounders, must include material facts, be balanced, and not be false or misleading. If a product has not been FDA-approved to treat a condition, it cannot be promoted as safe and effective for treating that condition. Since compounded products are not FDA-approved, advertisements for them, including on a company's website, should avoid claiming the products are safe or effective for treating any condition.

In reviewing the content of the claims in this batch of warning letters, most of the concerning language on online websites advertising these products that was flagged by the FDA is unsurprising, including:

- Named the brand product as a comparative reference or therapeutic equivalent
- Stated the compounded product was a "generic" of the brand product
- Included efficacy claims for the compounded product
- Used the words "FDA-approved" in the advertising copy

But some of the language that was flagged by the FDA was less direct, with the FDA's expressed concern being that the advertising may have given the impression of FDA approval. For example, in one letter the following was flagged as offending language, despite not naming the branded products: "Doctors frequently recommend Compounded Tirzepatide or Compounded Semaglutide, both of which are GLP-1 agonists with the same active ingredient as the brand name medications." In another letter, the only offending language was: "Clinically proven weight loss treatments." The FDA said this language "implies that [the seller's] products are the same as an FDA-approved product when they are not."

What's Next?

The FDA has expressed concern with direct-to-consumer marketing across the pharmaceutical industry and an intent to more aggressively enforce laws that "require fair balance between a product's risks and benefits; avoid exaggerating benefits; not create a misleading overall impression; properly disclose financial relationships; and include information regarding major side effects and contraindications."[1] But, with so little guidance from the FDA on what will be considered misleading in the context of compounded products, the enforcement outlook for advertising remains unclear.

Some of the advertisers who received letters have already removed the specific offending language; some have not. But many still have efficacy claims with respect to GLP-1 products more generally that were not named in their letters. In any case, anyone continuing to sell compounded GLP-1 products should review their websites in light of the FDA's enforcement position on advertising and the content that was flagged in the letters that we now have publicly available.

The $50 billion elephant in the room is whether there will be enforcement by the FDA against compounders alleging violations of the FDCA prohibition on compounding products that are "essentially a copy" of FDA-approved products now that the branded GLP-1 products are no longer in shortage. It's hard to imagine having to remove some words from their websites will change much in the practicing of compounding for these products. And, so far, while quality and safety inspections and enforcement typical among compounders are occurring with compounders of GLP-1 products, we have not seen evidence publicly that the FDA is taking action

specifically against the practice of compounding GLP-1 products that are no longer in shortage as products that are "essentially a copy" of the FDA-approved products.

This blog post was drafted by Beth Siemer and ***Kaleb Rasmussen****, an attorney and law clerk, respectively, in the St. Louis, Missouri office of Spencer Fane. For more information, visit www.spencerfane.com.*

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1 https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising#:~:text=Current%20law%20requires%20that%20advertisements,hold%20the%20pharmaceutica

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