press release

Novo Nordisk protects US patients with legal wins against compounders, including ruling that permanently prohibits compounding pharmacy from selling illegitimate, knockoff Wegovy® or Ozempic®

- **Federal court ruling leaves in place FDA's decision resolving the shortage of Wegovy® and Ozempic®, which are fully available nationwide, and ends the grace period for pharmacies to make or sell compounded "versions" of these medicines**
- **Separate federal court ruling permanently bars MediOak Pharmacy LLC from marketing or selling illegitimate "semaglutide" drugs**
- **Legal wins build on 111 lawsuits filed by Novo Nordisk across 32 states against entities unlawfully marketing and selling compounded "semaglutide" drugs, helping safeguard Americans from knockoffs made with unsafe or illicit foreign API**
- **Novo Nordisk is dedicated to dialogue with companies to support patient access to authentic, FDA-approved Wegovy® under the care of a licensed healthcare professional**

PLAINSBORO, N.J., April 25, 2025 – Yesterday, a Texas federal court ruled in favor of Novo Nordisk and FDA, denying a compounding trade association's motion to freeze the FDA's decision to end the shortage of semaglutide injectable medicines. The court's ruling left in place FDA's prior determination that all doses of Wegovy® and Ozempic® are fully available nationwide and that Novo Nordisk's supply of these FDA-approved medicines is meeting or exceeding current and projected nationwide patient demand. With the FDA's resolution of the shortage of Ozempic® and Wegovy®, as left in place by this court ruling, it is illegal under US compounding laws to make or sell knockoff "semaglutide drugs," with rare exceptions.

In light of the court's decision today, FDA may immediately take action against 503A pharmacies compounding knockoff versions of Novo Nordisk's FDA-approved semaglutide medicines. The ruling also means the grace period for 503B outsourcing facilities to compound semaglutide injectable drugs will expire on May 22, 2025, and FDA may take enforcement action against these entities after that date.

This latest win on behalf of patients follows another key decision by the District Court for the Southern District of Texas, where a federal judge entered a final judgment and permanent injunction in favor of Novo Nordisk, against a 503A pharmacy, MediOak Pharmacy LLC,

permanently prohibiting them from marketing or selling compounded “semaglutide” knockoff drugs.

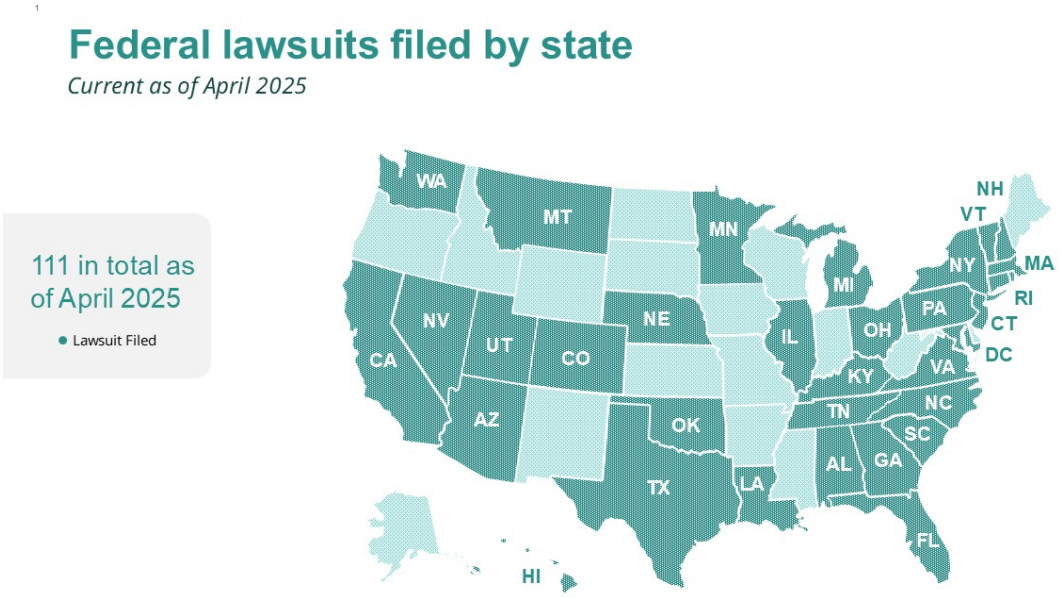
“We are pleased the court has rejected the compounders’ attempts to undermine FDA’s data-based decision that the shortage of Wegovy® and Ozempic® is resolved,” said Steve Benz, Corporate Vice President, US Legal and General Counsel, Novo Nordisk. “FDA’s determination was based on a thorough review of Novo Nordisk’s stable and growing supply of these important FDA-approved medicines. With the end of the shortage of Wegovy® and Ozempic®, no patient should have to be exposed to unsafe, inauthentic ‘semaglutide’ drugs. Patient safety remains a top priority for Novo Nordisk and the extensive nationwide legal actions we have taken to protect Americans from the health risks posed by illegitimate 'semaglutide' drugs are working. We will continue driving these actions forward and escalate our efforts as necessary, while closely engaging with regulators and law enforcement.”

Illicit foreign API in compounded “semaglutide”

The resolution of the semaglutide injection shortage and the court’s ruling also help protect patients against the proliferation of unsafe and unlawful drugs compounded using imports of synthetic “semaglutide” active pharmaceutical ingredients (APIs) that are manufactured overseas. A recently published Brookings Institute report titled *The Wild East of semaglutide* confirms that many US patients are being exposed to unsafe and illegal imports of synthetic semaglutide APIs from China. The report highlights numerous issues, including that manufacturers of chemically synthesized semaglutide API have no external reference standard for quality and instead determine specifications themselves. It also demonstrated that three Chinese firms are responsible for 20% of the reported quantity of semaglutide imported into the US between March 2023 and September 2024 and have never been inspected by FDA, as of September 2024. Additionally, another three Chinese firms, responsible for nearly 45% of reported imported volume during this 18-month period, were cited during their latest FDA inspection for current good manufacturing practice violations. As this report shows, the quality of API originating from China and used in compounded “semaglutide” in the US cannot be assured and puts patients at serious risk. Novo Nordisk does ***not*** directly or indirectly distribute the semaglutide API in its FDA-approved medicines to any entity for use in compounding.

Novo Nordisk federal lawsuits filed to date

To date, the company has filed 111 lawsuits in federal courts across 32 states against entities unlawfully marketing and selling compounded “semaglutide,” including drugs that pose significant risks to patient safety due to high levels of impurities (as high as 33%) or misbranded due to inaccurately labeled strengths.



Many of these courts have already issued injunctions permanently prohibiting these entities from the unlawful marketing and sales of compounded drugs:

- Earlier this year, a federal court in Delaware entered an $8.5 million default judgment in Novo Nordisk's favor against a business for willfully and falsely claiming that their compounded "semaglutide" drugs were equivalent to Ozempic® or used the same active ingredient as FDA-approved Ozempic®. Another federal court permanently prohibited a compounding pharmacy in Tennessee, Midtown Express, from marketing or selling knockoff "semaglutide" after Novo Nordisk sued it for selling a drug that contained no semaglutide at all.
- In another case, a federal court granted a default judgement against an online marketer sued by Novo Nordisk, ending its unlawful practice of selling compounded "semaglutide" directly to consumers without a prescription or instructions for use, misleadingly labeling it as for "Research Use Only."

Dozens of other courts have entered permanent injunctions against the entities sued by Novo Nordisk, permanently forbidding them from falsely claiming that knockoff "semaglutide" drugs: (1) are genuine Novo Nordisk medicines; (2) are approved by FDA, are authentic generic medicines, or are safe and effective; (3) achieve any therapeutic result or are safe or effective based on the clinical trial results for Novo Nordisk's approved medicines; and (4) contain semaglutide that has been approved by FDA, is supplied by Novo Nordisk, or is the same as that in Wegovy® and Ozempic®.

The court orders also direct businesses to correct misimpressions among patients that were caused by the defendants' deceptive practices. This includes posting prominent disclosures in marketing and advertising to make clear that the unapproved compounded drugs have not been reviewed or approved by the FDA, that the manufacturing processes used to make the drugs are not FDA-reviewed, and that actual FDA-approved semaglutide medicines are available.

Actions taken by third parties to warn the public

Novo Nordisk supports the actions that have already been taken by law enforcement to protect patients from illegal marketing and sales of compounded drugs. A bipartisan coalition of 38 state Attorneys General have called on the FDA to take swift action against compounding pharmacies that "cut corners in pursuit of a quick profit" and sell knockoff drugs that could lead to "serious public health issues." The Ohio Attorney General recently issued a press release about letters it sent to 14 entities warning them to stop deceiving patients into believing that compounded drugs are approved by the FDA or have been reviewed for safety, effectiveness, or quality and declaring that patients "deserve clear and accurate information about the medication they're putting in their bodies." Similarly, in December 2024, the Illinois Attorney General issued cease-and-desist letters to five Chicagoland med spas advertising name brand medications like Wegovy® and Ozempic® but "instead offering unapproved versions of these products that may put people's health at risk." In addition, over a dozen Attorneys General have issued statements discussing the dangers posed by knockoff "semaglutide," including North Carolina, South Carolina, and Tennessee.

The Federal Bureau of Investigation also recently warned the public about safety concerns related to fraudulent compounding practices associated with weight loss drugs, warning that "[s]ome healthcare providers are using compounded mixtures of unknown drugs that do not contain semaglutide, drugs with high levels of impurities, and unsafe or unapproved drugs."

Novo Nordisk is continuing to actively address this issue through education, advocacy, and legal action, fighting on behalf of patients who deserve to know what they are injecting into their body.

For more information about Novo Nordisk's efforts to protect patients and ensure access to safe, effective FDA-approved treatments, visit semaglutide.com

About Novo Nordisk

Novo Nordisk is a leading global healthcare company that's been making innovative medicines to help people with diabetes lead longer, healthier lives for more than 100 years. This heritage has given us experience and capabilities that also enable us to drive change to help people defeat other serious chronic diseases such as obesity, rare blood, and endocrine disorders. We remain steadfast in our conviction that the formula for lasting success is to stay focused, think long-term, and do business in a financially, socially, and environmentally responsible way. With

a US presence spanning 40 years, Novo Nordisk US is headquartered in New Jersey and employs over 10,000 people throughout the country across 12 manufacturing, R&D and corporate locations in eight states plus Washington DC. For more information, visit novonordisk-us.com, Facebook, Instagram, and X.

Novo Nordisk is committed to the responsible use of our semaglutide-containing medicines which represent distinct products with different indications, dosages, prescribing information, titration schedules, and delivery forms. These products are not interchangeable and should not be used outside of their approved indications. Learn more at semaglutide.com.

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