

press release

Novo Nordisk expands legal action to protect US patients from unsafe, non-FDA-approved compounded "semaglutide"

- New legal actions are directed at organizations involved in illegal activities, including violating laws prohibiting the corporate practice of medicine, interfering with doctors' decisions and steering patients toward unapproved knockoff drugs under the false quise of personalization
- Novo Nordisk has filed more than 130 lawsuits across 40 states, resulting in 44
 permanent injunctions to stop unsafe, illegal marketing and selling of knockoff Wegovy®
 and Ozempic®
- These filings come after FDA issued its latest warning to patients and healthcare professionals about the serious dangers of compounded GLP-1 drugs, as the medical community and consumer advocacy groups continue to call for urgent action to protect public health

Plainsboro, N.J., August 05, 2025 – Novo Nordisk today announced the filing of 14 new lawsuits to safeguard patients from unsafe and unapproved compounded drugs claiming to contain "semaglutide." The defendants named in these lawsuits employ tactics that deceive patients into believing compounded products have been reviewed and approved by FDA or have equivalent safety or effectiveness as Novo Nordisk's approved semaglutide medicines. The lawsuits allege that telehealth providers violate state corporate practice of medicine laws by improperly influencing doctors' decisions and steering patients toward knockoff compounded "semaglutide" under the false guise of personalized medicine. In reality, these are unapproved knockoffs that have not been approved as safe and effective and are often made with illicit foreign active pharmaceutical ingredients (API).

"Patients deserve safe, effective treatments from companies they can trust. No one should have to gamble with their health by using knockoff drugs made with ingredients that lack oversight and safety standards," said Dave Moore, Executive Vice President, US Operations of Novo Nordisk Inc. "Novo Nordisk is addressing this issue through education, advocacy, and legal action against businesses that mislead Americans and jeopardize their health with unsafe and unapproved knockoffs. We urge regulators to enforce laws designed to protect public health."

Taking action to protect patients

To date, Novo Nordisk has filed 132 complaints in federal courts across 40 states, targeting companies whose illegal marketing and business practices put patient safety at risk. Today's lawsuits build on Novo Nordisk's earlier litigation successes and expand the focus of its legal actions into two new areas:

• Pharmacies producing unapproved compounded "semaglutide" drugs under the fake guise of personalization in violation of state law.

 Telehealth companies where corporations, not doctors, improperly steer patient care to compounded "semaglutide" drugs using sham claims of personalization, violating California law.

Courts have already issued 44 permanent injunctions against defendants in similar cases, prohibiting them from a variety of unlawful conduct including unlawfully compounding "semaglutide" and falsely claiming that compounded "semaglutide" products are FDA-approved, safe, or equivalent to Novo Nordisk's authentic medicines like Wegovy® or Ozempic®. Courts have also taken steps to deter similar conduct, including ordering defendants to forfeit illegally obtained profits.

Federal lawsuits filed by state



The risks of compounded "semaglutide" made with illicit foreign API

FDA has issued multiple alerts, the latest on <u>July 29th</u>, warning patients and healthcare professionals about the dangers of these knockoff drugs, including reports of patients overdosing by mistakenly administering five to 20 times the intended dose and requiring hospitalization.

Independent data underscores the dangers posed by compounded "semaglutide" products:

- A recent <u>Brookings Institution</u> report highlights that many compounded "semaglutide" products rely on synthetic API imported from facilities in China that lack FDA oversight or quality controls. Alarmingly, 60% of Chinese manufacturers importing "semaglutide" for use in compounding or further manufacture are not even permitted to distribute that API in China for use in human drugs.
- According to FDA data, all "semaglutide" imported into the US designated for use in compounding since June 2023 originated from suppliers in China.

These findings confirm that the API in compounded "semaglutide" products often fail to meet basic safety standards, putting patients at serious risk.

Novo Nordisk has launched educational campaigns like "Check Before You Inject" and "Choose The Real Thing" to raise awareness about the risks of unapproved knockoffs. Novo Nordisk also created semaglutide.com, a resource for patients to learn about the dangers of compounded and counterfeit products, as well as how to access authentic, FDA-approved treatments.

With all doses of Wegovy[®] and Ozempic[®] available nationwide, the company continues to explore new channels to meet patients where they receive care, ensuring they can access safe, effective treatments under the supervision of licensed healthcare professionals.

The company is fighting on behalf of patients who deserve to know what they are injecting into their bodies. For more information about these 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 <u>semaglutide.com</u>.

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