Company statement

Novo Nordisk escalates legal actions to safeguard patients from potentially harmful compounded "semaglutide" drugs

- *Novo Nordisk filed 9 new legal proceedings against medical spas, weight loss clinics, pharmacies, and other companies for unlawful marketing and sales of compounded drugs claiming to contain semaglutide*
- *Testing of the compounded drugs from pharmacies revealed no semaglutide, up to 24% of impurities and/or unknown impurities*
- *One defendant is an online retailer selling "semaglutide" directly to patients without any prescription from a medical professional*
- *Compounded "semaglutide" drugs are neither FDA-approved nor sourced from and/or equivalent to Novo Nordisk's FDA-approved semaglutide medicines*

PLAINSBORO, N.J., May 30, 2024 – Novo Nordisk announced today, as part of its ongoing commitment to patient safety, it is filing 9 new lawsuits and seeking to add claims to two existing lawsuits against several medical spas, weight loss clinics, pharmacies, and other companies in Colorado, Florida, Illinois, Montana, Tennessee, and Texas. These actions aim to protect US patients and consumers from deceptive marketing by these entities as well as potentially harmful and improperly compounded drugs claiming to contain semaglutide.

As of March 31, 2024, the FDA Adverse Event Reporting System (FAERS) data includes 442 cases of adverse events associated with compounded drugs claiming to contain semaglutide. Of those cases, 319 were classified as "serious" adverse events, 99 reported hospitalization, and seven involved death.

With these new lawsuits, Novo Nordisk has filed 21 legal actions against entities that have engaged in deceptive, unfair, unlawful, and dangerous practices regarding the marketing and sales of alleged "semaglutide" products. The latest round of legal actions is based on alarming new evidence collected by Novo Nordisk on the practices and products being sold by these entities. Some of these include:

- Mounting evidence of high levels of known impurities and the presence of unknown impurities in injectable compounded products claiming to contain semaglutide, potentially exposing patients to significant health risks. In one instance, testing showed that a compounded product claiming to contain semaglutide consisted of more than 24% impurities, including unknown impurities

- False claims that the compounded drugs are FDA-approved

- False claims that these products are sourced from and/or are equivalent to Novo Nordisk's FDA-approved semaglutide medicines. In one instance, Novo Nordisk testing showed that an oral sublingual compounded product labeled as having 1 mg/mL of semaglutide actually contained no semaglutide whatsoever
    - Novo Nordisk does not directly or indirectly provide or sell bulk semaglutide to compounding pharmacies or any other entity for the purposes of compounding semaglutide products

- Potentially dangerous advertisements by retailers on "how to make your own" injectable semaglutide at home and sales of" semaglutide" products without any prescription from a medical professional

"Non-FDA approved compounded drugs claiming to contain semaglutide with high levels of known impurities and unknown impurities pose significant risks to patients and may lead to serious and life-threatening reactions," said Doug Langa, executive vice president, North America operations and president of Novo Nordisk. "We will continue to pursue legal action against those who provide potentially unsafe and ineffective compounded "semaglutide" products and knowingly deceive patients who are seeking treatment, thereby eroding public trust in the safety of FDA-approved medicines."

Among the prior 12 lawsuits brought forward by Novo Nordisk, courts thus far have already entered five final judgments, permanently barring the defendants in those matters from engaging in deceptive, misleading, and unlawful marketing practices related to the sales of compounded "semaglutide" drugs. The other lawsuits are still in active litigation.

Novo Nordisk's ongoing surveillance and testing of compounded semaglutide underscores the company's ongoing commitment to patient safety and concerns about the dangers of improperly compounded products. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide and does not sell semaglutide to any entities for use in compounding. Novo Nordisk does not directly or indirectly provide or sell bulk semaglutide to compounding pharmacies or any other entity for the purposes of compounding semaglutide products. Novo Nordisk is strongly committed to continuing to reinforce the responsible use of Novo Nordisk's semaglutide medicines – including on semaglutide.com – and to helping patients and providers understand the differences between our FDA-approved semaglutide medicines and unapproved compounded drugs claiming to contain semaglutide.

Websites selling counterfeit, tampered and unlawfully compounded drugs should be reported to the FDA. Suspected counterfeit products may be reported to FDA by calling the FDA's Office of Criminal Investigations (OCI) at 1-800-551-3989 or a local OCI field office. If an individual is experiencing any side effects that may be related to the use of a counterfeit, tampered or compounded product, that person should contact their health care provider, and is additionally encouraged to report the event to FDA's MedWatch Safety Information and Adverse Event Reporting Program (1-800-FDA-1088 or www.fda.gov/medwatch) as well as to Novo Nordisk's customer care number (1-800-727-6500).

About Ozempic®
Ozempic® (semaglutide) injection 0.5 mg, 1 mg or 2 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes and to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes with known heart disease.

About Rybelsus®
Rybelsus® (semaglutide) tablets 7 mg or 14 mg is an analog of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). Rybelsus® is the first and only GLP-1 receptor agonist (RA) in a pill. It is taken once daily and is approved for use in two therapeutic doses: 7 mg and 14 mg.

About Wegovy®
Wegovy® (semaglutide) injection 2.4 mg is FDA approved in combination with a reduced calorie diet and increased physical activity to reduce the risk of major cardiovascular events such as death, heart attack, and stroke in adults with known heart disease and either obesity or overweight; and to help adults and children aged ≥ 12 years with obesity, or some adults with overweight with weight-related medical problems, lose excess body weight and keep it off.

Further information

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