

April 24, 2024

Lars Fruergaard Jørgensen
Novo Nordisk A/S
Novo Allé, 2880 Bagsvaerd
Denmark

Dear Mr. Jørgensen:

I am writing to inform you that the Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) is undertaking an investigation into the outrageously high prices that Novo Nordisk charges for Ozempic and Wegovy in the United States. The scientists at Novo Nordisk deserve great credit for developing these drugs that have the potential to be a game changer for millions of Americans struggling with type 2 diabetes and obesity. As important as these drugs are, they will not do any good for the millions of patients who cannot afford them. Further, if the prices for these products are not substantially reduced they also have the potential to bankrupt Medicare, Medicaid, and our entire health care system. The United States Congress and the federal government cannot allow that to happen.

Today, Novo Nordisk is charging patients in the United States up to fifteen times more for Ozempic and Wegovy than it charges patients in Canada, Europe, or Japan. For example, your company charges \$969 in the United States for one month of Ozempic but just \$155 in Canada and just \$59 in Germany.¹ Further, Novo Nordisk charges Americans \$1,349 for one month of Wegovy but just \$140 in Germany and just \$92 in the United Kingdom.²

Meanwhile, researchers at Yale University estimate that both of these drugs can be profitably manufactured for less than \$5 a month.³

Moreover, your company is also charging patients two different prices for the exact same drug. While Novo Nordisk asked the U.S. Food and Drug Administration (FDA) to approve Ozempic for type 2 diabetes and Wegovy for chronic weight management for people with obesity, they are the same drug: semaglutide.⁴ Semaglutide for diabetes is marketed as Ozempic, while

¹ Navlin Int'l Pharm. Pricing Database, <https://www.navlin.com/> (last visited Apr. 23, 2024).

² Navlin Int'l Pharm. Pricing Database, <https://www.navlin.com/> (last visited Apr. 23, 2024).

³ Melissa J. Barber et al., *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7(3):e243474 JAMA NETWORK OPEN (2024), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2816824>.

⁴ There are also trivial differences in dosage strengths and delivery devices. Novo Nordisk sells 0.25 mg, 0.5 mg and 1 mg of semaglutide as both Ozempic and Wegovy. The company sells 2 mg of semaglutide only as Ozempic, and 1.7 and 2.4 mg of semaglutide only as Wegovy. Ozempic is sold in multi-dose pens. Wegovy is sold in single-dose pens. See *FDA Label: Ozempic* (Revised: 09/2023),

semaglutide for weight management is marketed as Wegovy. Novo Nordisk charges Americans with obesity nearly \$400 more every month than those with type 2 diabetes for the same product provided in similar doses.

The result of these astronomically high prices is that Ozempic and Wegovy are out of reach for millions of Americans who need them. Unfortunately, Novo Nordisk's pricing has turned drugs that could improve people's lives into luxury goods, all while your company made over \$12 billion in profits last year—up 76 percent from 2021.⁵

Ozempic was first approved in 2017 by the FDA to lower blood sugar levels for adults with type 2 diabetes as well as to reduce the risks of stroke, heart attack, or death in patients with type 2 diabetes.⁶ The FDA approved Wegovy in 2021 for chronic weight management for people with obesity.⁷ Just last month, this product was also approved to reduce the risk of death, heart attack, and stroke in adults who are overweight or obese and have heart disease.⁸

The good news is that these prescription drugs could lead to significant and sustained improvements in the quality of life for people all across the United States. Approximately 35 million Americans have type 2 diabetes, which is associated with increased risk of heart disease, stroke, amputations, blindness, and kidney failure later in life.⁹ In addition, more than 40 percent of adults and 20 percent of children in America have obesity and face increased risk of heart disease, stroke, and some types of cancer, as well as increased risks of experiencing depression, anxiety, and other mental health conditions.¹⁰

Consider the potential impact of Wegovy. People who lose 5 to 10 percent of their body weight often see improvements in blood pressure and cholesterol levels, decreased risks of developing diabetes, and other health benefits.¹¹ Wegovy could make losing weight easier, which could result in significant and sustained quality of life improvements for millions of Americans. In trials before Wegovy's approval, Novo Nordisk found that patients on Wegovy “lost an average

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf; *FDA Label: Wegovy* (Revised: 03/2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s011lbl.pdf.

⁵ Novo Nordisk, *Annual Report 2023* at 9 (2024), <https://www.novonordisk.com/investors/annual-report.html>.

⁶ Press Release, Novo Nordisk, Ozempic® (semaglutide) approved in the US (Dec. 5, 2017), <https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=712>; Kyle Blankenship, *Novo's Ozempic scores major win with heart-helping FDA approval. Is Rybelsus next?*, FIERCE PHARMA (Jan. 17, 2020), <https://www.fiercepharma.com/pharma/novo-s-ozempic-scores-major-win-heart-helping-fda-approval-rybelsus-next>.

⁷ Press Release, U.S. Food and Drug Administration (FDA), FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014 (June 4, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>.

⁸ Press Release, FDA, FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight (Mar. 8, 2024), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or-overweight>.

⁹ Div. of Population Health, Nat'l Ctr. For Chronic Disease Prevention and Health Promotion, *Type 2 Diabetes*, CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC) (Apr. 18, 2023), <https://www.cdc.gov/diabetes/basics/type2.html>.

¹⁰ *Health Effects of Overweight & Obesity Facts*, CDC (Sept. 24, 2022), <https://www.cdc.gov/healthyweight/effects/index.html>.

¹¹ Donna H. Ryan & Sarah Ryan Yockey, *Weight Loss and Improvement in Comorbidity: Differences at 5%, 10%, 15%, and Over*, 6(2) CURR. OBES. REP. 187 (June 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497590>.

of 12.4% of their initial body weight.”¹² In later trials, Novo Nordisk also found that Wegovy reduced the risk of heart attacks, strokes, and cardiovascular deaths.¹³ In a country where 1.6 million people suffer heart attacks or strokes each year and where heart disease is the leading cause of death, the reduced risk of those life-altering events could lead to increased longevity and higher quality of life for tens of thousands of patients every year.¹⁴

Unfortunately, your company has chosen to maximize its profits by making these products exorbitantly expensive in the United States.

The prices for these drugs are so high in the United States that everyone—regardless of whether they use the products or not—will likely be forced to bear the burden of Novo Nordisk’s profit maximizing strategy through higher insurance premiums and taxes.

Even after insurance companies and pharmacy benefit managers negotiate lower “net” prices, covering Ozempic and Wegovy in the United States will cause massive spikes in insurance premiums. In fact, a major private health insurance company has told me that they would have to double the premiums for every single subscriber if they chose to cover Wegovy and Ozempic for all eligible patients. Public health insurance plans are facing similar problems. Earlier this year, the North Carolina State Health Plan, the health plan for state employees and teachers, stopped covering Wegovy and other GLP-1 drugs for employees who were using them for weight loss after Novo Nordisk refused to lower prices.¹⁵ In 2023, weight loss glucagon-like peptide-1 (GLP-1) drugs accounted for 10 percent of all prescription drug spending for the plan.¹⁶ The North Carolina State Health Plan Board of Trustees estimated that continuing coverage would require them to double the premiums for every single subscriber, regardless of whether they were taking the medication.¹⁷

The unjustifiably high prices of Ozempic and Wegovy are already straining the budgets of Medicare and Medicaid and severely limiting access for patients who need these drugs.

Last year, researchers at Vanderbilt University’s Department of Health Policy and the University of Chicago’s Department of Medicine estimated in the *New England Journal of Medicine* that it would cost Medicare over \$150 billion a year to cover Wegovy and other similar weight loss drugs.¹⁸ To put this in perspective, the cost of all retail prescription drugs covered by Medicare in 2022 was less than \$130 billion.¹⁹

¹² Press Release, FDA, *supra* note 7.

¹³ Press Release, FDA, *supra* note 8.

¹⁴ *Heart Disease Facts*, CDC, <https://www.cdc.gov/heartdisease/facts.htm#> (last accessed April 22, 2024); *Stroke Facts*, CDC, <https://www.cdc.gov/stroke/facts.htm#> (last accessed Apr. 22, 2024).

¹⁵ North Carolina State Health Plan, Statement Regarding GLP-1 Coverage (Mar. 7, 2024), <https://www.shpnc.org/blog/2024/03/07/statement-regarding-glp-1-coverage>.

¹⁶ North Carolina State Health Plan, *GLP-1 Weight Loss Drugs, Revenues and Expenditures Fact Sheet* (Jan. 2024), <https://www.shpnc.org/media/3396/download?attachment>.

¹⁷ North Carolina State Health Plan, Statement, *supra* note 15.

¹⁸ Benjamin Y. Liu & Benjamin N. Rome, *State Coverage and Reimbursement of Antiobesity Medications in Medicaid*, 331(14) *JAMA* 1230 (Mar. 14, 2024), <https://jamanetwork.com/journals/jama/article-abstract/2816585>.

¹⁹ Centers for Medicare and Medicaid Services, National Health Expenditure Tables, available for download at <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical> (in “NHE Tables (ZIP)”).

Further, more than 35 state Medicaid programs do not cover Wegovy at all, and dozens of states have severely restricted Ozempic coverage because of the outrageously high prices of these drugs.²⁰

In my view, the American people should not have to pay up to \$1,349 a month for prescription drugs that cost less than \$5 to manufacture and can be purchased at a fraction of this price in other developed countries.

The Senate HELP Committee has jurisdiction over matters related to biomedical research and development.²¹ As Chairman of the Committee, I am asking Novo Nordisk to substantially reduce the price of Ozempic and Wegovy so that these important drugs can be available to Americans with type 2 diabetes and obesity.

Accordingly, I request answers to the following by May 8, 2024:

- 1) Will Novo Nordisk substantially reduce both the list price and the net price of both Ozempic and Wegovy?
- 2) For both Ozempic and Wegovy, please provide, in table format, the following information for each calendar year since each drug received FDA approval:
 - a. The costs of goods sold;
 - b. The volume sold;
 - c. The revenue generated, broken out by payer type; and
 - d. The prices paid by government payers, each of the 10 largest commercial health plans (defined by the number of covered lives), and the five largest pharmacy benefit managers that Novo Nordisk contracts with.
- 3) Please provide the following information for U.S. Patents 9,108,002 (Automatic injection device with a top release mechanism) 9,132,239 (Dial-down mechanism for windup-pen); and RE46363 (Dial-down mechanism for wind-up pen), which Novo Nordisk listed in the FDA Orange Book as claiming Ozempic:
 - a. An explanation of the value, including any clinical benefit, that the patented invention adds for patients; and
 - b. All memoranda, analyses, forecasts, and presentations related to the development, acquisition, or licensing of the patented invention, the incorporation of the patented invention into an injector product, or the listing of the patent in the Orange Book.
- 4) For both Ozempic and Wegovy, please provide all communications, including but not limited to emails and internal messages, and documents, including but not limited to memoranda, presentations, spreadsheets, reports, studies, analyses, and forecasts, since January 1, 2016 that relate to any of the following:
 - a. The price of the product in the United States;
 - b. The lifecycle management of the product or product line;

²⁰ Liu & Rome, *supra* note 18.

²¹ Standing Rules of the Senate XXV(m)(1).

- c. Any strategy to protect or extend the product or product line's exclusivity;
 - d. The potential or actual generic competition for the product;
 - e. Any agreement regarding an authorized generic for the product; and
 - f. Any agreement with another company concerning a potential or actual competitor product, including any agreement relating to the market entry, marketing, promotion, labeling, conditions of use, or approval pathway of the competitor product.
- 5) Please provide, in table form, the company's spending on research and development in each year directly related to Ozempic and Wegovy, broken out by product and calendar year, showing how much was spent on preclinical research, clinical testing by phase, acquisition or licensing of intellectual property, manufacturing process development, activities related to regulatory submissions, and all other spending.
- 6) Please explain why Novo Nordisk charges nearly \$400 per month more for Wegovy than Ozempic, given they are the same drug (semaglutide).

Thank you for your prompt attention to this investigation.

Sincerely,



Bernard Sanders

Chairman

United States Senate Committee on Health, Education, Labor, and Pensions