

September 23, 2024

Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

Dear Secretary Becerra:

We write to strongly urge you to use your existing legal authority under 28 U.S.C. § 1498 to lower prices for the diabetes and weight management medicine semaglutide, sold under the brand names of Ozempic and Wegovy. Licensing competition on Ozempic and Wegovy would help lower costs for patients and save taxpayers billions of dollars.

Ozempic and Wegovy are effectively the same drug, semaglutide, approved for two different uses. The Food and Drug Administration (FDA) approved Ozempic to help control blood sugar levels in people with type 2 diabetes in addition to diet and exercise and to reduce the risk of death, heart attack, or stroke in patients with type 2 diabetes and known heart disease.<sup>1</sup> The FDA approved Wegovy for chronic weight management in patients with obesity and excess weight.<sup>2</sup> More recently, the FDA approved Wegovy for the additional use of reducing the risk of death, stroke, or heart attack in these patients.<sup>3</sup>

One-in-ten Americans has diabetes and an additional 100 million American adults have prediabetes.<sup>4</sup> Already, semaglutide is used by hundreds of thousands of patients who receive health care through programs like Medicare and Medicaid, costing beneficiaries and taxpayers billions of dollars annually. For Ozempic alone, these two health programs spent more than \$5 billion in 2022, and these costs have been growing rapidly with time.<sup>5</sup>

Wegovy threatens to impose even more astronomical costs to patients and health programs. Wegovy is currently approved for chronic weight management in patients with obesity and excess weight and reducing the risk of cardiovascular death, stroke and heart attack in these patients. While Medicare is currently limited from covering drugs solely for weight loss, if rules changed to lift this prohibition, as many policymakers have proposed, the costs would be enormous. At current

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<sup>1</sup> *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss*, U.S. Food & Drug Admin., <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss> (last visited May 30, 2024).

<sup>2</sup> *Id.*

<sup>3</sup> Press Release, Food & Drug Admin., 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>.

<sup>4</sup> *National Diabetes Statistics Report*, U.S. Centers for Disease Control and Prevention, <https://www.cdc.gov/diabetes/php/data-research/index.html> (last visited Sept. 13, 2024).

<sup>5</sup> *Public Citizen Petitions HHS to License Generic Competition on Ozempic and Wegovy*, Public Citizen, August 5, 2024, <https://www.citizen.org/article/public-citizen-petitions-hhs-to-license-generic-competition-on-ozempic-and-wegovy/>

net prices, covering Wegovy for even half of the eligible patients with Medicare and Medicaid would cost more than \$160 billion in a single year, nearly the amount that Medicare and Medicaid spent on all outpatient prescription drugs in 2022 (\$175.1 billion).<sup>6,7</sup>

Why are the costs and estimated spending on Ozempic and Wegovy so extreme? Novo Nordisk charges patients in the United States up to 15 times more for these drugs than their peers in Canada, Japan, or Europe.<sup>8</sup> Whereas Ozempic costs \$155 in Canada and \$59 in Germany, the list price of Ozempic is an astounding \$969 for a month's supply in the United States.<sup>9</sup> Similarly, the list price of Wegovy is just \$140 in Germany and \$92 in the United Kingdom, but Novo Nordisk charges Americans \$1,349 a month for the medication.<sup>10</sup>

Novo Nordisk's exorbitant pricing of semaglutide for American patients is not justified by production costs. A recent study published in the *Journal of the American Medical Association* showed Ozempic could be sustainably priced at less than \$5 a month, and potentially as low as 89 cents, or around 0.09 percent of the current U.S. list price based on its cost of manufacture.<sup>11</sup> Similarly, Wegovy could be sustainably priced for as little as \$13 a month, which is approximately 1 percent of the current list price.<sup>12</sup>

Novo Nordisk's pricing is also not justified by research and development (R&D) expenses. Novo Nordisk has made 340 billion Danish Kroner in revenue from Ozempic and Wegovy since their launch, which roughly equates to nearly \$50 billion.<sup>13</sup> These revenues are an order of magnitude higher than even the most generous estimates of research and development costs for drugs that

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<sup>6</sup> *Breaking Point: How Weight Loss Drugs Could Bankrupt American Health Care*, U.S. Senate Health, Education, Labor, and Pensions Committee Majority Staff, May 15, 2024, <https://www.sanders.senate.gov/wp-content/uploads/Wegovy-report-FINAL.pdf>

<sup>7</sup> National Health Expenditure Retail Prescription Drug Expenditures 2022, Centers for Medicare and Medicaid Services. <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet> (last accessed Sept. 13, 2024).

<sup>8</sup> Letter from U.S. Senator Bernard Sanders, Chair of the United States S. Comm. on Health, Education, Labor, and Pensions to Lars Fruergaard Jørgensen, Chief Executive Officer of Novo Nordisk, Inc. (Apr. 24, 2024), <https://www.sanders.senate.gov/wp-content/uploads/Letter-from-Sen.-Bernard-Sanders-to-Novo-Nordisk.pdf>.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 *JAMA Network Open* e243474 (2024), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2816824>.

<sup>12</sup> Melissa Barber, Joseph S. Ross, & Reshma Ramachandran, *To get a fair deal on Wegovy, buying Novo Nordisk might not be Medicare's worst option*, *Stat News* (July 29, 2024), <https://www.statnews.com/2024/07/23/wegovy-medicare-medicaid-costs-why-not-buy-manufacturer-novo-nordisk/>.

<sup>13</sup> Financial results, events, and calendar, Novo Nordisk, [Financial results and events overview - Novo Nordisk](#) (last visited Sept. 23, 2024) (reporting Q1 & Q2 sales data for FY 2024); Novo Nordisk, FY 2023 Form 20-F, at 6 (2024); Novo Nordisk, FY 2022 Form 20-F, at 6 (2023); Novo Nordisk, FY 2021 Form 20-F, at 6 (2022); Novo Nordisk, FY 2020 Form 20-F, at 6 (2021); Novo Nordisk, FY 2019 Form 20-F, at 7 (2020); Novo Nordisk, FY 2018 Form 20-F, at 7 (2019); Novo Nordisk, FY 2023 Form 20-F (2024), Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 57.

take into account failed candidates and a reasonable return on investment.<sup>14</sup> Further, in 2023, Novo Nordisk spent nearly twice as much (\$8.95 billion) on activities enriching its shareholders, like stock buybacks and dividends, as it did on research and development (\$4.71 billion).<sup>15</sup> This is not an aberration for the company. Since 2018, when Novo Nordisk launched Ozempic, the company has spent over \$38 billion on share repurchases and shareholder dividends—more than double its spending on R&D across its entire portfolio (~\$18 billion).<sup>16</sup>

Through § 1498, the U.S. government has the authority to make or purchase a patented invention without the permission of the patent holder in exchange for reasonable compensation.<sup>17,18</sup> By authorizing generic competition, the Biden-Harris Administration can secure historic savings to public programs. Several firms have sought to produce generic equivalents to Ozempic and Wegovy and have submitted Abbreviated New Drug Applications (ANDAs) to the FDA to obtain approval for generics.<sup>19</sup> Under § 1498, the Biden-Harris Administration could contract with, enter into rebate agreements with, and issue statements authorizing production and supply by firms seeking to make generic equivalents of these drugs for provision to beneficiaries of Medicare, Medicaid, and direct federal purchasers.

Data released by the FDA demonstrates that robust generic competition routinely brings down prices by an order of magnitude or more, compared to the pre-competition, monopoly price.<sup>20</sup> In the context of the extraordinary costs projected for these drugs, even with limited uptake, savings from generic semaglutide could amount to more than ten billion dollars in a single year.<sup>21</sup>

Americans should not have to pay the highest prices in the world for Ozempic and Wegovy, only to enrich Novo Nordisk's shareholders and executives. Through licensing competition, Medicare, Medicaid, patients and the public stand to save many billions of dollars. Please authorize generic competitors to Ozempic and Wegovy without delay.

Sincerely,

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<sup>14</sup> Cong. Budget Off., Research and Development in the Pharmaceutical Industry (Apr. 2021), <https://www.cbo.gov/publication/57126#:~:text=Only%20about%2012%20percent%20of,than%20%24%20billion%20per%20drug>.

<sup>15</sup> Novo Nordisk, Form 20-F (2024), Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 50-52.

<sup>16</sup> Novo Nordisk, Form 20-F (2024), Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 51-52; Novo Nordisk, Form 20-F (2021), Ex. 15.1: Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2020, at 47-48.

<sup>17</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 Yale J. L. & Tech. 275, 279-80 (2017).

<sup>18</sup> For further details on exercising § 1498 to authorize generic competitors for Ozempic and Wegovy, see Public Citizen's August petition to Secretary Becerra to license generic competition. <https://www.citizen.org/article/public-citizen-petitions-hhs-to-license-generic-competition-on-ozempic-and-wegovy/>

<sup>19</sup> Novo Nordisk, Form 20-F (2024), at 7.

<sup>20</sup> Generic Competition & Drug Prices, Food & Drug Admin, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (last visited May 31, 2024).

<sup>21</sup> *Estimate of Savings from Generic Competitors to Ozempic and Wegovy*, Public Citizen, Sept. 17 2024, <https://www.citizen.org/article/estimate-of-savings-from-generic-competitors-to-ozempic-and-wegovy/>

ACA Consumer Advocacy  
American Federation of State, County and Municipal Employees (AFSCME)  
Beta Cell Action  
CASA, Inc.  
Center for Medicare Advocacy  
Center for Popular Democracy Action  
Consilium Scientific  
Consumer Action  
Doctors for America  
Health Care Voices  
Health GAP (Global Access Project)  
Healthcare is a Human Right WA  
Just Care USA  
Labor Campaign for Single Payer  
National Committee to Preserve Social Security and Medicare  
NETWORK Lobby for Catholic Social Justice  
New Jersey Citizen Action  
Oregonizers  
People's Action  
Public Citizen  
Social Security Works  
Unity Fellowship of Christ Church-NYC  
Universities Allied for Essential Medicines  
VOCAL-NY