## Congress of the United States Washington, DC 20515

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 protect the public's health and safety to ensure reasonable prices on semaglutide, a prescription drug sold under the brand names of Ozempic and Wegovy and commonly used to treat diabetes and obesity. By utilizing your competitive licensing authority to permit generic competitors to Wegovy and Ozempic, you can stabilize supplies at a time of enormous demand and lower outrageous prices that have severely limited access to these life-changing drugs.

Approximately 38 million, or one in ten, Americans has diabetes, and an additional 100 million American adults have prediabetes.<sup>1</sup> Nearly one-third of adults are overweight and 42% are obese.<sup>2</sup> Diabetes and obesity are associated with heart disease, stroke, kidney disease, and more. Yet, the federal government has failed to restrain Big Pharma price gouging to ensure patients can afford the newest treatments.

With a sticker price of up to \$1,400 per month, patients can rarely afford Wegovy or Ozempic out-of-pocket and few insurance plans offer complete coverage due to the prohibitive cost. One study has found that covering these drugs for just 10% of Medicare beneficiaries with obesity would cost taxpayers \$27 billion a year.<sup>3</sup> Coverage for all Americans would cost nearly \$1 trillion.<sup>4</sup> A recent report from the Congressional Budget Office (CBO) estimated that the cost to cover these drugs would outweigh any savings from reduced utilization of associated health services and treatments.<sup>5</sup>

Due to budget-busting prices, only 16 states offer state employee or Medicaid coverage for these drugs.<sup>6</sup> About 34% of employer plans offer coverage and only about 1% of Affordable Care Act (ACA) Marketplace plans do the same.<sup>7</sup> Put another way, 99% of consumers with Marketplace

<sup>6</sup> <u>https://www.urban.org/sites/default/files/2022-02/obesity-across-america.pdf;</u>

<sup>7</sup> <u>https://blog.ifebp.org/employer-coverage-of-glp-1-drugs-on-the-rise/;</u>

https://www.healthsystemtracker.org/brief/insurer-strategies-to-control-costs-associated-with-weight-

<sup>&</sup>lt;sup>1</sup> <u>https://www.cdc.gov/diabetes/php/data-research/index.html</u>

<sup>&</sup>lt;sup>2</sup> https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity

<sup>&</sup>lt;sup>3</sup> <u>https://www.nejm.org/doi/full/10.1056/NEJMp2300516</u>

<sup>&</sup>lt;sup>4</sup> <u>https://www.sanders.senate.gov/wp-content/uploads/Wegovy-report-FINAL.pdf</u>

<sup>&</sup>lt;sup>5</sup> https://www.cbo.gov/system/files/2024-03/60116-Duchovny.pdf

https://www.kff.org/report-section/50-state-medicaid-budget-survey-fy-2023-20;

plans have no access to these drugs, while 66% of workers with private employer plans and 68% of state employees and Medicaid recipients are denied access. The few insurers that offer coverage for Ozempic and Wegovy often include several restrictions to limit the financial impact. For example, the Department of Veterans Affairs requires patients with diabetes to try and fail with two or more medications before the VA will cover Ozempic.

We do not condemn the states and insurers that have limited access to these drugs under such difficult circumstances. It would be irresponsible to offer unlimited coverage when prices are also unlimited. The North Carolina State Health Plan ended coverage after spending \$100 million in a single year on these drugs—spending that would have required insurance premiums to double to offset the cost.<sup>8</sup> If half of all Americans with obesity could access these drugs, it would cost an estimated \$411 billion a year, more than all existing prescription drug spending in the U.S.<sup>9</sup>

We do not need to waste taxpayer dollars, bankrupt health systems, or deny patients access to effective treatments. We can save consumers' health and be fiscally responsible by stopping Big Pharma monopoly abuse. These drugs cost Americans up to 15 times more than patients in peer countries like Canada, Japan, Germany, the UK, and Denmark.<sup>10</sup> There is no reason for Americans to pay the world's highest prices, substantially more than other wealthy Nations, for the exact same medicines.

Manufacturers will frequently cite the cost of innovation and the need to recoup research and development costs as the reason for charging sky-high prices. Yet, time and again, this is debunked. In the case of Ozempic and Wegovy, the manufacturer has earned over \$38 billion in revenue from these two drugs and Goldman Sachs Research predicts revenue will reach \$100 billion within this decade.<sup>11</sup> Meanwhile, last year, the manufacturer spent nearly twice as much on enriching its shareholders with stock buybacks and dividends (\$8.95 billion) than on research and development (\$4.71 billion).<sup>12</sup>

The exorbitant prices paid by Americans are financing corporate greed, not innovation. While we recognize the important role of the private sector in research and development and support the ability to make a reasonable profit, industry interests should not outweigh meeting health and safety needs for all consumers and providing accountability to taxpayers. When manufacturers

loss-drugs/

<sup>&</sup>lt;sup>8</sup> <u>https://www.nbcnews.com/health/health-news/one-state-trying-make-weight-loss-drugs-cheaper-rena148997</u>

<sup>&</sup>lt;sup>9</sup> <u>https://www.sanders.senate.gov/wp-content/uploads/Wegovy-report-FINAL.pdf</u>

<sup>&</sup>lt;sup>10</sup> <u>https://www.sanders.senate.gov/wp-content/uploads/Wegovy-report-FINAL.pdf</u>

<sup>&</sup>lt;sup>11</sup> Novo Nordisk, Form 20-F, at 6 (2024); Novo Nordisk, Form 20-F, at 6 (2023); Novo Nordisk, Form 20-F, at 6 (2022); Novo Nordisk, Form 20-F, at 6 (2021); Novo Nordisk, Form 20-F, at 7 (2020); Novo Nordisk, Form 20-F, at 7 (2019); Novo Nordisk, Form 20-F (2024), Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 57.

https://www.bloomberg.com/news/articles/2023-09-22/obesity-drug-market-set-to-hit-100-billion-by-2035-bmo-says

<sup>&</sup>lt;sup>12</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.

use their monopoly power to extract unfair and unjustified prices at the expense of consumers, the federal government must restrain such abuse.

Under Section 1498, the Administration has the clear authority to license generic competition on any patented invention "used or manufactured by or for the United States." Rightly, patentholders are entitled to reasonable compensation set by the U.S. Court of Federal Claims. This law ensures Americans may access important goods while protecting the rights of inventors and providing fair compensation. For over a century, this authority has been used across technologies, ranging from fraud detection banking software and electronic passports to methods of removing hazardous waste.<sup>13</sup> Section 1498 has also been used to authorize generic, lower cost drugs, and just the threat of this authority, has incentivized brand-name manufacturers to voluntarily cut prices.<sup>14</sup>

You have the opportunity and responsibility to dramatically improve health care access and achieve substantial taxpayer savings by using Section 1498 to authorize generic competitors to Ozempic and Wegovy. We strongly urge you to use your clear statutory authority and stand ready to assist in your efforts to deliver long overdue relief to American taxpayers and consumers.

Sincerely,

Lloyd Doggett Member of Congress

United States Senator

Sheila Cherfilus-McCormick Member of Congress

Elizabeth Warren United States Senator

Eleanor Holmes Norton Member of Congress

Ro Khanna Member of Congress

<sup>&</sup>lt;sup>13</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, A Prescription for Excessive Drug Pricing, 18 YALE J. L. & TECH. 275, 314-315 (2017).

<sup>&</sup>lt;sup>14</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, A Prescription for Excessive Drug Pricing, 18 YALE J. L. & TECH. 275, 314-315 (2017).

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