

August 5, 2024

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Dear Secretary Becerra:

We write you today to request that the Biden-Harris Administration authorize generic competitors for semaglutide, sold by Novo Nordisk under the brand names Ozempic and Wegovy. Novo Nordisk's outrageous pricing of semaglutide threatens to break the coffers of federal health programs. Pursuant to 28 U.S.C. § 1498, the Administration should authorize use of any and all patents necessary to allow manufacturers to produce generic alternatives to these treatments on behalf of the United States government, which can be used to supply Medicare, Medicaid, and other federal health programs. This will facilitate competition and make the treatments more affordable and accessible for patients.

This request will address the health background for semaglutide, including how federal health programs cover it for its different uses; Novo Nordisk's price gouging on the drug and its extreme financial consequences to public programs and patients in the United States; the authority granted to the U.S. government under 28 U.S.C. § 1498 to address these monopoly abuses; and how the government would exercise this authority to help expand access to these drugs.

### **Background on Semaglutide**

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>

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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->

In the United States, the Centers for Disease Control and Prevention estimates about 38 million Americans have diabetes (about one in every 10 people), and between 90-95% have type 2 diabetes.<sup>4</sup> Additionally, nearly 100 million American adults have prediabetes.<sup>5</sup> Diabetes is associated with a number of health complications, including increased risk of heart disease and stroke; blindness and other eye problems, like glaucoma and cataracts; chronic kidney disease, which if left untreated can lead to kidney failure; nerve damage often affecting legs and feet, but also a person's digestion, blood vessels, and heart; depression; gum disease; and amputations when necessary to stop the spread of infections.<sup>6</sup>

According to the National Institute of Diabetes and Digestive and Kidney Diseases, nearly one in 3 adults are overweight (31%) and two in 5 adults have obesity (42%) in the United States.<sup>7</sup> The institute states that obesity and having excess weight are correlated with a number of health issues, often linked to damage from excess fat tissue and fat concentration in certain areas like the waist.<sup>8</sup> These include type 2 diabetes, high blood pressure, heart disease, stroke, metabolic syndrome, fatty liver disease, certain cancers, breathing issues like sleep apnea and asthma, osteoarthritis, gallbladder and pancreatic diseases, chronic kidney diseases, pregnancy complications, fertility challenges, and some mental health issues.<sup>9</sup>

Currently, Medicare is prohibited from covering drugs used for weight loss, but it can cover these drugs for other medical indications, including diabetes and reducing the risk of adverse cardiovascular events mentioned above.<sup>10</sup> Bicameral, bipartisan legislation has been proposed to

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[events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or.](#)

<sup>4</sup> *About Type 2 Diabetes*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html?CDC\\_AAref\\_Val=https://www.cdc.gov/diabetes/basics/type2.html](https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/basics/type2.html) (last visited May 30, 2024).

<sup>5</sup> *National Diabetes Statistics Report*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/diabetes/php/data-research/?CDC\\_AAref\\_Val=https://www.cdc.gov/diabetes/data/statistics-report/index.html](https://www.cdc.gov/diabetes/php/data-research/?CDC_AAref_Val=https://www.cdc.gov/diabetes/data/statistics-report/index.html) (last visited May 30, 2024).

<sup>6</sup> *Put the Brakes on Diabetes Complications*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/diabetes/prevention-type-2/stop-diabetes-complications.html?CDC\\_AAref\\_Val=https://www.cdc.gov/diabetes/library/features/prevent-complications.html](https://www.cdc.gov/diabetes/prevention-type-2/stop-diabetes-complications.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/library/features/prevent-complications.html) (last visited May 30, 2024).

<sup>7</sup> *Overweight & Obesity Statistics*, NAT'L INST. DIABETES & DIGESTIVE & KIDNEY DISEASES, <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity> (last visited May. 30, 2024).

<sup>8</sup> *Id.*

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

<sup>10</sup> Juliette Cubanski & Tricia Neuman, *Medicare Spending on Ozempic and Other GLP-1s Is Skyrocketing*, KFF: POL'Y WATCH (Mar. 22, 2024), <https://www.kff.org/policy-watch/medicare-spending-on-ozempic-and->

end the Medicare coverage exclusion for drugs used for the treatment of obesity or for weight loss management for individuals with excess weight and who have one or more related comorbidities.<sup>11</sup> Medicaid is required to cover almost all of the FDA-approved drugs of a participating manufacturer in the Medicaid Drug Rebate Program, but weight loss medications are part of a small class of drugs that can be excluded, so states vary in their coverage of these treatments solely for weight loss purposes.<sup>12</sup> Medicaid is required to cover these drugs for other medically accepted indications, like diabetes and mitigating the risk of adverse cardiovascular events in the above patient group.<sup>13</sup> Direct federal purchasers like the Department of Veteran Affairs and the Federal Bureau of Prisons cover Ozempic pursuant to certain restrictions as well, whereas TRICARE (which supplies active duty service members) covers Wegovy and Ozempic if certain criteria are met.<sup>14</sup>

With respect to these drugs, it is important to acknowledge limitations in the use of Body Mass Index as a metric undergirding determinations of obesity and overweight (such as misclassification of risk based on race), the stigma patients have often faced in experiencing concern over issues of weight in healthcare settings, and issues associated with the use of these drugs for weight management and diabetes,<sup>15</sup> but the skyrocketing use of these medications

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[other-glp-1s-is-skyrocketing/](#); Memorandum from Ctrs. Medicare & Medicaid Services, Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications (Mar. 20, 2024), <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-march-18-22>.

<sup>11</sup> Treat and Reduce Obesity Act of 2023, S.2407, 118th Cong. (2023); H.R.4818, 108<sup>th</sup> Cong. (2023) <https://www.congress.gov/bill/118th-congress/senate-bill/2407>.

<sup>12</sup> Elizabeth Williams, Alice Burns, & Robin Rudwitz, *Medicaid Utilization and Spending on New Drugs Used for Weight Loss*, KFF: POL'Y WATCH (Sept. 8, 2023), <https://www.kff.org/policy-watch/medicaid-coverage-of-and-spending-on-new-drugs-used-for-weight-loss/>.

<sup>13</sup> *Id.*; Ahmed Aboulenein & Patrick Wingrove, *Wegovy to be covered by US Medicare for heart disease patients*, REUTERS (Mar. 22, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/wegovy-be-covered-by-us-medicare-heart-disease-patients-2024-03-21/>.

<sup>14</sup> U.S. Dept. of Veterans Aff., *SEMAGLUTIDE INJ,SOLN*, VA FORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040140-SEMAGLUTIDE-INJ-SOLN> (last visited Apr. 25, 2024); Fed. Bureau of Prisons, *National Formulary*, HEALTH SERVS. MGMT., [https://www.bop.gov/resources/health\\_care\\_mngmt.jsp](https://www.bop.gov/resources/health_care_mngmt.jsp) (last visited May 31, 2024); FED. BUREAU OF PRISONS HEALTH SERVS., NATIONAL FORMULARY PART I 21 (2022); *Does TRICARE cover Wegovy and Ozempic?*, TRICARE, [https://tricare.mil/FAQs/Pharmacy/PharmProg\\_Wegovy#:~:text=TRICARE%20only%20covers%20Wegovy%20for,covers%20Ozempic%20to%20treat%20diabetes](https://tricare.mil/FAQs/Pharmacy/PharmProg_Wegovy#:~:text=TRICARE%20only%20covers%20Wegovy%20for,covers%20Ozempic%20to%20treat%20diabetes) (last visited May 31, 2024).

<sup>15</sup> Robert H. Shmerling, *How useful is the body mass index (BMI)?*, HARVARD HEALTH PUB. (May 5, 2023), <https://www.health.harvard.edu/blog/how-useful-is-the-body-mass-index-bmi-201603309339>; *Talking with Your Patients about Weight*, NAT'L INST. DIABETES & DIGESTIVE & KIDNEY DISEASES, <https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/weight-management/talking-with-your-patients-about-weight> (last visited May 31, 2024); Public Citizen, *Semaglutide (WEGOVY) for Weight Loss: Substantial Risks, Including Weight Regain*, WORST PILLS, BEST PILLS NEWSLETTER (Aug. 2023).

threatens to impose unprecedented financial consequences on federal health programs and patients due to the pricing abuses of the originator company, Novo Nordisk.

### **Novo Nordisk's Exorbitant Pricing of Semaglutide and Its Extreme Financial Consequences**

Novo Nordisk charges Americans up to 15 times more for these drugs than their peers in Canada, Japan, or Europe.<sup>16</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>17</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>18</sup> Even using volatile estimates of net prices (prices after rebates) for these drugs shows that Ozempic is nearly five times more expensive in the United States than in Germany. Similarly, Wegovy is more than 7.5 times more expensive here than in the United Kingdom.<sup>19</sup> Further, these drastic price differences between net prices in the U.S. and prices abroad likely significantly understate the true price gap, because prices abroad do not reflect discounts and rebates from manufacturers in those countries. Factoring in those reductions would yield a higher magnitude of difference compared to net prices in the United States.<sup>20</sup>

The pharmaceutical industry often asserts that exorbitantly high drug prices for Americans are necessary to recuperate sunk research and development costs. But the prices and associated revenues of Ozempic and Wegovy cannot reasonably be said to reflect the research and development expenditures of Novo Nordisk. According to publicly available filings with the Securities Exchange Commission, Novo Nordisk has made 262.31 billion Danish Kroner in revenue from Ozempic and Wegovy since their launch, which roughly equates to over **\$38 billion**.<sup>21</sup> These revenues are an order of magnitude higher than even the most generous estimates of research and development costs for drugs that take into account failed candidates

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<sup>16</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>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Gina Kolata, *Ozempic and Wegovy Don't Cost What You Think They Do*, N.Y. TIMES (Oct. 22, 2023), <https://www.nytimes.com/2023/10/22/health/ozempic-wegovy-price-cost.html>; BENEDIC N. IPPOLITO & JOSEPH F. LEVY, AM. ENTERPRISE INST., ESTIMATING THE COST OF NEW TREATMENTS FOR DIABETES AND OBESITY (Sept. 2023).

<sup>20</sup> ANDREW W. MULCAHY, DANIEL SCHWAM & SUSAN L. LOVEJOY, RAND, INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: ESTIMATES USING 2022 DATA 20 (2024), <https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf>.

<sup>21</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.

and a reasonable return on investment.<sup>22</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>23</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>24</sup> Novo Nordisk's extraordinary pricing and revenues for semaglutide cannot be justified by R&D spending, and they are neither reasonable nor fair.

The prices charged by Novo Nordisk on these drugs are even more egregious considering a recent study published in the Journal of the American Medical Association that 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>25</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>26</sup>

Novo Nordisk's pricing of these drugs in the United States has imposed widespread cost barriers to patients and colossal financial burdens on public programs. According to a KFF Poll, one in 8 adults have used these new weight loss drugs, with over half saying that it was difficult to afford their costs.<sup>27</sup> This was true for both patients with and without health insurance.<sup>28</sup>

Medicare Part D's gross spending on Ozempic in 2022 (the latest year for which data is available) was \$4.628 billion for approximately 780,000 beneficiaries, which is approximately

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<sup>22</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%242%20billion%20per%20drug>.

<sup>23</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>24</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>25</sup> Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 JAMA NETWORK OPEN e243474 (2024).

<sup>26</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>27</sup> Alex Montero, Grace Sparks, Marley Presiado, & Liz Hamel, *KFF Health Tracking Poll May 2024: The Public's Use and Views of GLP-1 Drugs*, KFF POLLING (May 10, 2024), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs/>.

<sup>28</sup> *Id.*

\$6,000 per enrollee.<sup>29</sup> It was the sixth highest-spend drug for Medicare Part D that year.<sup>30</sup> Medicaid spent \$944 million on Ozempic and \$40.26 million on Wegovy in 2022.<sup>31</sup> Ozempic was the thirteenth highest-spend drug for the program that year.<sup>32</sup>

The costs imposed on taxpayer-funded health programs by Novo Nordisk's price gouging on semaglutide are growing rapidly. Between 2020 and 2021, Medicare's spending on Ozempic increased by more than a billion dollars, and between 2021 and 2022, spending increased by an astonishing \$2 billion.<sup>33</sup> A recent report from the Senate Committee on Health, Education, Labor, and Pensions found that the annual cost to the healthcare system for covering Wegovy for half of the eligible population (\$411 billion) would exceed the expenditure on all retail prescription drugs in 2022 (\$406 billion).<sup>34</sup> Notably, these estimates used the net price of the weight loss drug. The report further illustrated that covering Wegovy could cost one trillion dollars by 2031 and potentially almost two trillion dollars depending on uptake of the drug.<sup>35</sup>

Current federal program prior authorization criteria and access restrictions partially limit the explosive costs of these drugs. For example, the Department of Veterans Affairs' criteria for patients to use Ozempic to manage diabetes require that they have failed two or more oral medications, or insulin and one other medication (one of the medications should have been metformin, a widely prescribed diabetes drug).<sup>36</sup> TRICARE requires prior authorization for Ozempic, where the patient has tried and failed to achieve blood sugar control on metformin, and either (1) experienced impaired kidney function that prevents metformin use, or (2) a history of lactic acid build up in the patient's blood while on metformin.<sup>37</sup> TRICARE also

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<sup>29</sup> Ctrs. Medicare & Medicaid Servs., *Medicare Part D Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug> (last visited Apr. 26, 2024).

<sup>30</sup> *Id.*

<sup>31</sup> Ctrs. Medicare & Medicaid Servs., *Medicaid Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicaid-spending-by-drug> (last visited Apr. 26, 2024).

<sup>32</sup> *Id.*

<sup>33</sup> Juliette Cubanski & Tricia Neuman, *Medicare Spending on Ozempic and Other GLP-1s Is Skyrocketing*, KFF: POL'Y WATCH (Mar. 22, 2024), <https://www.kff.org/policy-watch/medicare-spending-on-ozempic-and-other-glp-1s-is-skyrocketing/>.

<sup>34</sup> MAJORITY STAFF OF THE SENATE HELP COMMITTEE, *BREAKING POINT: HOW WEIGHT LOSS DRUGS COULD BANKRUPT AMERICAN HEALTH CARE 6-7* (May 15, 2024).

<sup>35</sup> *Id.*

<sup>36</sup> U.S. Dept. of Veterans Aff., *SEMAGLUTIDE INJ,SOLN*, VA FORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040140-SEMAGLUTIDE-INJ-SOLN> (last visited Apr. 25, 2024).

<sup>37</sup> TRICARE PRIOR AUTHORIZATION REQUEST FORM FOR OZEMPIC, MOUNJARO, <https://www.express-scripts.com/frontendservice/proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?reposit>

requires a clinician to fill out a medical necessity form, explaining why the patient cannot use an alternative diabetes management drug, Trulicity.<sup>38</sup> The Federal Bureau of Prisons appears to be most restrictive, requiring a patient to have “type 2 diabetes and established atherosclerotic cardiovascular disease AND A1C goal not met on maximum tolerated therapeutic dose of metformin or documented contraindication to metformin” and seems to require documentation about diet and exercise and the prisoner’s purchases, among other restrictions.<sup>39</sup>

Novo Nordisk’s exorbitant pricing of these drugs is having catastrophic effects on state health program budgets. In March, the North Carolina State Health Plan, which provides health coverage to teachers and state employees, announced that it was revoking coverage of these drugs for weight loss uses (even as NC Medicaid intends to cover obesity management medications starting August 1, 2024).<sup>40</sup> Continuing to provide coverage for these drugs at current prices would have nearly doubled health insurance premiums for every member, with costs set to exceed \$170 million in 2024 and \$1 billion over the next six years.<sup>41</sup> These costs result from the plan paying \$800 per month for each subscriber for weight loss medications.<sup>42</sup> North Carolina State Treasurer Dale Folwell summarized the situation: “[W]e simply can’t afford these medications at the manufacturer’s current price point. ... It’s price gouging. We just want to pay the same price that Novo Nordisk charges its customers in their home region.”<sup>43</sup> Recognizing the need for a federal solution, Treasurer Folwell has requested that the U.S. Department of

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[tory=EIS\\_P8\\_DC%3AesiCPS&documentId=%7B106A968B-0000-C615-836F-78B669F5CC91%7D](#) (last visited May 31, 2024).

<sup>38</sup> *Does TRICARE cover Wegovy and Ozempic?*, TRICARE, [https://tricare.mil/FAQs/Pharmacy/PharmProg\\_Wegovy#:~:text=TRICARE%20only%20covers%20Wegovy%20for,covers%20Ozempic%20to%20treat%20diabetes](https://tricare.mil/FAQs/Pharmacy/PharmProg_Wegovy#:~:text=TRICARE%20only%20covers%20Wegovy%20for,covers%20Ozempic%20to%20treat%20diabetes) (last visited May 31, 2024); TRICARE PHARMACY PROGRAM MEDICAL NECESSITY FORM FOR OZEMPIC, [https://www.express-scripts.com/frontendservice/proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS\\_P8\\_DC%3AesiCPS&documentId=%7BE039488B-0000-C416-B359-355221517AE1%7D](https://www.express-scripts.com/frontendservice/proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7BE039488B-0000-C416-B359-355221517AE1%7D) (last visited May 31, 2024).

<sup>39</sup> Fed. Bureau of Prisons, *National Formulary*, HEALTH SERVS. MGMT., [https://www.bop.gov/resources/health\\_care\\_mngmt.jsp](https://www.bop.gov/resources/health_care_mngmt.jsp) (last visited May 31, 2024); FED. BUREAU OF PRISONS HEALTH SERVS., NATIONAL FORMULARY PART I 21 (2022).

<sup>40</sup> *Statement Regarding GLP-1 Coverage*, N.C. STATE HEALTH PLAN FOR TEACHERS & STATE EMPLOYEES (Mar. 7, 2024), <https://www.shpnc.org/blog/2024/03/07/statement-regarding-glp-1-coverage>; Press Release, N.C. Dep’t Health & Human Servs., NC Medicaid to Add Coverage for Obesity Management Medications (July 17, 2024), <https://medicaid.ncdhhs.gov/blog/2024/07/17/nc-medicaid-add-coverage-obesity-management-medications>.

<sup>41</sup> *Id.*

<sup>42</sup> Press Release, N.C. Dept. of State Treasurer, Treasurer Folwell Calls on Novo Nordisk to Lower the Unfair Cost of Weight Loss Drugs (Oct. 24, 2023), <https://www.nctreasurer.com/news/press-releases/2023/10/24/treasurer-folwell-calls-novo-nordisk-lower-unfair-cost-weight-loss-drugs>.

<sup>43</sup> *Id.*

Health and Human Services (HHS) initiate efforts with branded manufacturers to voluntarily license their weight loss drugs in order to supply federal, state, and local government payers.<sup>44</sup>

As HHS explores how to alleviate the extreme financial burden imposed on payers by Novo Nordisk's price gouging with respect to Ozempic and Wegovy, it should consider leveraging authority under 28 U.S.C. § 1498 to involuntarily license generic production and expand affordable supply.

### **Background on 28 U.S.C. § 1498**

Under 28 U.S.C. § 1498, the federal government can authorize competition on any patented invention:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.<sup>45</sup>

The law gives the U.S. government the authority to make or purchase a patented invention without the permission of the patent holder in exchange for reasonable compensation.<sup>46</sup> When the government exercises its authority under § 1498, the patent holder may not seek injunctive relief, nor can a government contractor or subcontractor be held liable for infringement by the patent holder.<sup>47</sup>

In modern cases, reasonable compensation under § 1498 has consistently been determined to be a reasonable royalty payment and not "lost profits."<sup>48</sup> What is deemed an appropriate royalty payment is determined by previous licenses, where they exist, or the use of a range of factors, such as the "willing buyer, willing seller" rule, and a set of considerations known as the "Georgia-Pacific factors."<sup>49</sup> Experts suggest that reasonable royalty rates in § 1498 cases rarely

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<sup>44</sup> Letter from Dale Folwell, Chair, Board of Trustees, N.C. State Health Plan, to Xavier Becerra, Secretary, U.S. Dep't Health & Human Servs. (July 29, 2024).

<sup>45</sup> 28 U.S.C. § 1498.

<sup>46</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>47</sup> *Id.* at 302, 330-31.

<sup>48</sup> *Id.* at 311.

<sup>49</sup> *Id.* at 313.



exceed 10% of the third-party manufacturers' sales.<sup>50</sup> Previously, some courts have also ruled that reasonable compensation should reflect development costs plus a reasonable return on investment.<sup>51</sup>

The law has been used for more than a century across technologies, ranging from fraud detection banking software and electronic passports to methods of removing hazardous waste and genetically mutated mice.<sup>52</sup> The federal government, even, repeatedly used the law in the 1960s to buy low-cost generic versions of patented drugs.<sup>53</sup> More recently, the Bush Administration publicly considered using § 1498 to procure generic versions of antibiotics during the Anthrax Scare of 2001, which led the manufacturer to cut the price of the antibiotic in half.<sup>54</sup> In 2017, the Louisiana Secretary of Health began simply to explore whether she should request the federal government to use § 1498 on a hepatitis C cure. The drug corporation price gouged on the cure by setting its price initially at \$84,000 for a drug that cost \$150 to produce, reaping billions in the process.<sup>55</sup> Leveraging the prospect of licensing using § 1498, the Secretary negotiated major discounts. More Louisiana residents received the cure in the next 75 days than in the entire fiscal year before.<sup>56</sup> Finally, the federal government included 59 authorizations of non-voluntary use of third-party patents under § 1498 across an array of COVID-19 contracts during the pandemic, some of which benefited Moderna, enabling its production of the NIH-

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<sup>50</sup> Amy Kapczynski & Aaron Kesselheim, *Government Patent Use: A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFF. 791, 793 (2016); Christopher Morten & Charles Duan, *Who's Afraid of Section 1498: A Case for Government Patent Use in Pandemics and Other National Crises in Pandemics and Other National Crises*, 43 YALE J. L. & TECH. 1, 45 n. 194 (2020).

<sup>51</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>52</sup> *Id.* at 302.

<sup>53</sup> *Id.* at 302-306.

<sup>54</sup> *Id.* at 303.

<sup>55</sup> Allison Kodjak, *Hepatitis Drug Among the Most Costly for Medicaid*, NPR (Dec. 15, 2015), <https://www.npr.org/sections/health-shots/2015/12/15/459873815/hepatitis-drug-among-the-most-costly-for-medicaid>; Andrew Hill, Saye Khoo, Joe Fortunak, Bryony Simmons, & Nathan Ford, *Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries*, 58 CLIN. INFECTIOUS DISEASES 928 (2014); Press Release, Gilead, Gilead Sciences Announces Fourth Quarter and Full Year 2017 Financial Results (Feb. 6, 2018), <https://www.gilead.com/news-and-press/press-room/press-releases/2018/2/gilead-sciences-announces-fourth-quarter-and-full-year-2017-financial-results>.

<sup>56</sup> Rachael Thomas, *More La. Residents Able to Get Treatment Thanks to State's New Payment Model*, WAFB CHANNEL 9 (Dec. 5, 2019), <https://tinyurl.com/ror8bch>.

Moderna COVID-19 vaccine that generated tens of billions of dollars of revenues for the corporation.<sup>57</sup>

The brand-name pharmaceutical industry itself has recognized its reach and purpose: “Every patent granted by the U.S. government comes with an important caveat—the patentee may not inhibit the Government from having its suppliers work on its behalf to make or use an invention, subject to compensation in the Court of Federal Claims,” said Moderna in a brief seeking to dismiss a patent infringement lawsuit for its work performed for the government.<sup>58</sup>

In the pharmaceutical context, the government could either produce a patented medicine or contract with generic producers to manufacture the treatment under § 1498. In exchange, the government would provide the patent holder with compensation. If the patent holder does not believe it has been adequately compensated, it can sue the government over the level of compensation, but it may not prevent the government or a government contractor from producing the generic.<sup>59</sup>

### **Invoking 28 U.S.C. § 1498 to Contain Ozempic & Wegovy’s Unprecedented Costs**

The Biden-Harris Administration can secure historic savings to public programs by using § 1498 to authorize generic competitors to Ozempic and Wegovy, as researchers at Yale University and Harvard Medical School have articulated.<sup>60</sup> There are no special administrative or legal procedures necessary to invoke the authority: even a letter from the relevant agency to the infringer after the fact of infringement can confirm the government’s authorization and consent.<sup>61</sup> Authorization and consent under § 1498 can also be given simply through inclusion of the standard Federal Acquisition Regulation (FAR) clause granting such consent in a supply

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<sup>57</sup> JAMES LOVE, KNOWLEDGE ECOLOGY INTERNATIONAL, KEI REVIEW OF 62 COVID 19 CONTRACTS REVEALS 59 AUTHORIZATIONS FOR NON-VOLUNTARY USE OF THIRD PARTY PATENTS UNDER 28 USC 1498 (July 20, 2022), <https://www.keionline.org/37987>.

<sup>58</sup> Motion to Dismiss, *Arbutus Biopharma Corp. v. Moderna, Inc.*, Case No.: 1:22-cv-00252-MSG (D. Del. 2020), <https://www.keionline.org/wp-content/uploads/Case-1-22-cv-00252-MSG-moderna-1948.pdf>.

<sup>59</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 279-80, 302, (2017).

<sup>60</sup> Catherine Hwang, Aaron Kesselheim, & Benjamin Rome, *Medicare Should Cover Weight Loss Drugs as Long as the Prices are Affordable*, 52 J. L. MED. & ETHICS 188, 189 (2024); 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 23, 2024), <https://www.statnews.com/2024/07/23/wegovy-medicare-medicaid-costs-why-not-buy-manufacturer-novo-nordisk/>.

<sup>61</sup> Christopher Morten & Charles Duan, *Who’s Afraid of Section 1498: A Case for Government Patent Use in Pandemics and Other National Crises in Pandemics and Other National Crises*, 43 YALE J. L. & TECH. 1, 52 (2020) (citing *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, 583 F.3d 1371, 1377 (Fed. Cir. 2009); *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 608 (M.D.N.C. 2006) (“§ 1498 does not require the authorization to take any specific form.”)).

contract.<sup>62</sup> Even a blanket authorization statement for firms to produce the generics under § 1498 would be sufficient.<sup>63</sup>

Using § 1498 to supply direct federal purchasers would be simple. The Veterans Health Administration, which regularly procures drugs for itself and other direct federal purchasing programs, could solicit bids for generic versions of Ozempic and Wegovy and include the FAR authorization and consent clause in its solicitation, manufacturing, and distribution agreements to cover all the relevant entities in the supply chain under § 1498.<sup>64</sup>

For Medicaid, the Centers for Medicare and Medicaid Services (CMS) would enter a rebate agreement with a manufacturer of generic versions of Ozempic and Wegovy, which is a precondition of reimbursement of the medicines by Medicaid.<sup>65</sup> The agency would include in the rebate agreement an express authorization and consent clause.<sup>66</sup> Given the multiple entities and complexity involved in provision of drugs through Medicaid, additionally, CMS would issue public statements that all third parties involved in procurement and distribution of medicines to Medicaid beneficiaries are authorized to supply these patients with generic Ozempic and Wegovy under § 1498, such that CMS assumes liability for infringement claims.<sup>67</sup> These parties would include state Medicaid agencies, managed care organizations, wholesalers, pharmacy benefit managers, and pharmacies, and statements could be published as Dear State Medicaid Director Letters and Informational Bulletins frequently issued by CMS.<sup>68</sup>

Finally, for Medicare, CMS would issue letters to the generic manufacturers invoking § 1498 and assuming infringement liability for the provision of generic equivalents to Ozempic and Wegovy to its beneficiaries.<sup>69</sup> Further, CMS would include in its contracts with Part D plans the express authorization and consent FAR clause for the supply of these generics to their enrollees and issue policy statements urging Part D plans to add these generics to their formularies.<sup>70</sup> Like with Medicaid, CMS would publish public statements that third parties involved in

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<sup>62</sup> Federal Acquisition Regulation (FAR) 52-227-1. (“The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent...”).

<sup>63</sup> Memorandum from Alfred B. Engelberg to Sen. Charles Schumer, Increasing Access to CIPRO: A Strategy for Rapid Creation of a Government Stockpile (Oct. 13, 2001) (attached as an Appendix to Christopher Morten & Charles Duan, *Who’s Afraid of Section 1498: A Case for Government Patent Use in Pandemics and Other National Crises in Pandemics and Other National Crises*, 43 YALE J. L. & TECH. 1, 92 (2020)).

<sup>64</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 346-348 (2017).

<sup>65</sup> *Id.* at 349.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 349-50.

<sup>70</sup> *Id.*

procurement and distribution of medicines to Medicare enrollees, including wholesalers, pharmacy benefit managers, and pharmacies, are authorized to supply beneficiaries with generic Ozempic and Wegovy under § 1498 and that CMS will assume liability for claims of infringement.<sup>71</sup>

To date, 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>72</sup> According to the FDA's database, nine ANDAs for Ozempic and one ANDA for Wegovy have been filed.<sup>73</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 (including Mylan, Rio, Sun, Zydus, & Dr. Reddy as of August 2022),<sup>74</sup> for provision to beneficiaries of Medicare, Medicaid, and direct federal purchasers.

Pursuant to the terms of § 1498, Novo Nordisk would not be able to obtain injunctive relief to prevent these firms from supplying these federal programs; its only remedy would be reasonable compensation as determined by a court. The savings introduced by generic competition would significantly outweigh any reasonable royalty rate that a court would set in these circumstances. A study in the *New England Journal of Medicine* found that, on average, drugs with three generic manufacturers are priced at 60% of the brand name level.<sup>75</sup> Drugs with five manufacturers are priced at less than half the brand price, and prices of drugs with 10 or more manufacturers are only about one-fifth of brand prices.<sup>76</sup> 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>77</sup> Through licensing generic competition, the public stands to save billions of dollars.

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<sup>71</sup> *Id.*

<sup>72</sup> Novo Nordisk, Form 20-F (2024), at 7.

<sup>73</sup> *Paragraph IV Certifications: May 13, 2024*, FOOD & DRUG ADMIN, <https://www.fda.gov/media/166048/download> (last visited May 31, 2024).

<sup>74</sup> *In Re: Ozempic (Semaglutide) Patent Litigation*, Case MDL No. 3038 (Aug. 8, 2022), <https://www.jpml.uscourts.gov/sites/jpml/files/MDL-3038-Initial-Transfer-Order-7-22.pdf>.

<sup>75</sup> Chintan Dave, Abraham Hartzema, & Aaron Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 *NEW ENG. J. MED. CORRESPONDENCE* 2597 (2017); *see also* Sean R. Dickson & Tyler Kent, *Association of Generic Competition With Price Decreases in Physician-Administered Drugs and Estimated Price Decreases for Biosimilar Competition*, 4 *JAMA NETWORK OPEN* e2133451 (2021) (finding, similarly, that the price of physician-administered drugs in Medicare Part B fell 53% after 3 generic competitors were approved).

<sup>76</sup> Chintan Dave, Abraham Hartzema, & Aaron Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 *NEW ENG. J. MED. CORRESPONDENCE* 2597 (2017).

<sup>77</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).

Two additional intricacies must be considered and overcome in exercising § 1498's authority to license generics of Ozempic and Wegovy. First, when manufacturers try to obtain approvals for a generic via the abbreviated new drug application (ANDA), the generic manufacturer must certify that current patents listed with the brand name drug in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation (the Orange Book) are invalid, unenforceable, or not infringed by the generic product (called a "paragraph IV certification").<sup>78</sup> The generic manufacturer is required to notify the brand name company of its ANDA and paragraph IV certification about the patents the company listed in the Orange Book.<sup>79</sup> The brand name company then has 45 days to file a patent infringement suit from the date of the notice, which triggers a 30-month stay from the date of notice under which the FDA cannot approve the generic unless the relevant patents expire, or a judge rules them invalid or not infringed before that period elapses.<sup>80</sup> Moreover, the stay is extended until at least 7.5 years after a drug is first approved if a suit is brought during the new chemical entity exclusivity period.<sup>81</sup>

In March 2022, Novo Nordisk filed patent infringement lawsuits against Mylan, Rio, Sun, Zydus, Dr. Reddy, and Alvogen, with which it has already entered into a confidential settlement after receiving notice of the paragraph IV certification.<sup>82</sup> Therefore, the automatic 30-month stay for approving these ANDA applications, extended by the 7.5-year provision, will elapse in May 2025. Mylan filed a second ANDA for the highest dose of Ozempic, and Novo Nordisk amended its complaint accordingly in March 2023.<sup>83</sup> Accordingly, if a 30-month stay is triggered by Mylan's second ANDA and subsequent receipt of notice by Novo Nordisk on February 10, 2023,<sup>84</sup> the FDA could approve Mylan's ANDA for the highest dose as of August 2025.

The Biden-Harris Administration does not have to rein in Novo Nordisk's abuses, though. A memorandum from expert Alfred Engelberg to Senator Schumer in 2001, addressing the use of § 1498 for producing generic antibiotics against anthrax, lays out how the stay can be overcome.<sup>85</sup> The memo explains that manufacturers can state in their paragraph IV certification

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<sup>78</sup> *Paragraph IV Certifications: May 13, 2024*, FOOD & DRUG ADMIN, <https://www.fda.gov/media/166048/download> (last visited May 31, 2024).

<sup>79</sup> *Id.*

<sup>80</sup> JOHN R. THOMAS, CONG. RES. SERV., THE HATCH-WAXMAN ACT: A PRIMER 7-8 (2016).

<sup>81</sup> 21 C.F.R. § 314.107(3)(i)(B).

<sup>82</sup> Novo Nordisk, Form 20-F (2024), at 7. Christopher Yasiejko, *Novo Files Patent-Infringement Suits to Block Ozempic Copies*, BLOOMBERG L. (Mar. 7, 2022), <https://news.bloomberglaw.com/ip-law/novo-files-six-patent-infringement-suits-to-block-ozempic-copies>; Complaint, *Novo Nordisk, Inc. v. Mylan Pharm.*, Case No. 1:22-cv-23 (N.D. W. Va. Mar. 18, 2022).

<sup>83</sup> First Amended Complaint, *Novo Nordisk, Inc. v. Mylan Pharm.*, MDL Case. No. 22-MD-3038 (CFC) (Mar. 21, 2023), [https://insight.rpxcorp.com/litigation\\_documents/15156767](https://insight.rpxcorp.com/litigation_documents/15156767).

<sup>84</sup> *Id.* at ¶ 39.

<sup>85</sup> Memorandum from Alfred B. Engelberg to Sen. Charles Schumer, *Increasing Access to CIPRO: A Strategy for Rapid Creation of a Government Stockpile* (Oct. 13, 2001) (attached as an Appendix to Christopher Morten & Charles Duan, *Who's Afraid of Section 1498: A Case for Government Patent Use in*

that they will not infringe the patents because they are supplying the United States.<sup>86</sup> In light of the voluminous caselaw preventing federal courts from issuing any injunctive relief to stifle supply to the federal government under § 1498, Engelberg argues that a court would be required to dismiss an originator company's lawsuit.<sup>87</sup> Applying this same reasoning here, generic production of Ozempic and Wegovy could commence immediately upon the dismissal of such lawsuits.

The second intricacy to be overcome is exclusivity barriers to FDA approval of products produced using a license under § 1498. Data and marketing exclusivity periods attach upon the approval of new medicines, and in certain other circumstances, in theory to reward companies for producing novel safety and efficacy data to the FDA.<sup>88</sup> Thus, other generic manufacturers are typically barred from relying on such data for their abbreviated new drug applications for a specified period of time, including five years from the reference drug's approval. These exclusivities present another potential barrier to the generic production of Ozempic and Wegovy. Notably, the United States has provided for flexibility in data exclusivity obligations in several free trade agreements, such that other countries can issue compulsory licenses pursuant to TRIPS flexibilities without fear of these data protections.<sup>89</sup>

In these circumstances, there is only one regulatory exclusivity that remains applicable to Ozempic: Since the highest maintenance dose of 2 mg was approved in 2022, regulatory exclusivity extends until March 28, 2025.<sup>90</sup> That is, there are no regulatory exclusivities limiting approval of generics for the lower dosage forms of Ozempic (the 0.25, 0.5, and 1 mg doses). For Wegovy, there is a regulatory exclusivity extending until July 2026 for the 1.7 mg dosage form (the fourth highest dose of the five dosage forms).<sup>91</sup> While the FDA could approve Wegovy for

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*Pandemics and Other National Crises in Pandemics and Other National Crises*, 43 YALE J. L. & TECH. 1, 92 (2020)).

<sup>86</sup> *Id.* at 95.

<sup>87</sup> *Id.*

<sup>88</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 330 (2017).

<sup>89</sup> Ellen F. M. 't Hoen, Pascale Boulet, & Brook K. Baker, *Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation*, 10 J. PHARM. POL'Y PRAC. 19 (2017).

<sup>90</sup> Food & Drug Admin., *Patent and Exclusivity for: N209637*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, [https://www.accessdata.fda.gov/scripts/cder/ob/patent\\_info.cfm?Product\\_No=003&Appl\\_No=209637&Appl\\_type=N](https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=003&Appl_No=209637&Appl_type=N).

<sup>91</sup> Food & Drug Admin., *Patent and Exclusivity for: N215256*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, [https://www.accessdata.fda.gov/scripts/cder/ob/patent\\_info.cfm?Product\\_No=004&Appl\\_No=215256&Appl\\_type=N](https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=004&Appl_No=215256&Appl_type=N) (last visited May 31, 2024).

weight loss for adults in June 2024, the currently approved use covered under Medicare is protected by exclusivity until March 2027.<sup>92</sup>

One potential approach the Biden-Harris Administration could use to overcome the issues posed by these exclusivities is that the generic manufacturer could submit a new drug application (NDA), rather than an abbreviated new drug application. As legal experts have articulated, the FDA has some flexibility in determining what studies are necessary for approval of new drug applications.<sup>93</sup> The FDA could determine that “appropriate studies would be of shorter duration and smaller size because the drugs’ side effects and efficacy are already well characterized, including in the published literature.”<sup>94</sup> The FDA could also accept data from “trials that demonstrate the generic drug is not inferior to an existing reference product rather than make a full showing of superiority over placebo or existing treatments.”<sup>95</sup> An Executive Order buttressing the FDA’s discretion to approve generic equivalents from high-quality suppliers could also be beneficial.<sup>96</sup> Further, an added benefit of submitting an NDA is that manufacturers may avoid the 30-month automatic stay against FDA approval that can be triggered by submission of abbreviated new drug applications. Although this approach is less applicable to generic manufacturing of Ozempic given that the regulatory exclusivities expire soon, the Administration may consider this method for facilitating the generic production of Wegovy.

Therefore, we request that the Biden-Harris Administration begin taking all necessary and appropriate actions to procure generics of Ozempic and Wegovy and supply them to beneficiaries of federal health programs to avert the ruinous financial consequences of Novo Nordisk’s pricing abuses to both patients and these programs. Pursuant to 28 U.S.C. § 1498, the Administration should authorize use of any and all patents necessary to allow for the production of these generics and delivery systems, on behalf of the United States government.

Sincerely,  
Public Citizen

cc:

The Honorable Chiquita Brooks-LaSure, Administrator for the Centers for Medicare & Medicaid Services

The Honorable Neera Tanden, Director of the Domestic Policy Council

The Honorable Lael Brainard, Director of the National Economic Council

Dr. Lester Martínez-López, Assistant Secretary of Defense for Health Affairs

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<sup>92</sup> *Id.*

<sup>93</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 343-45 (2017).

<sup>94</sup> *Id.* at 344.

<sup>95</sup> *Id.* at 344-45.

<sup>96</sup> *Id.* at 345.

The Honorable Denis Richard McDonough, Secretary of Veterans Affairs  
Admiral Linda L. Fagan, Commandant of the U.S. Coast Guard