

Expanding Access to Semaglutide through 28 U.S.C. § 1498

On August 5, 2024, Public Citizen submitted a [petition](#) to Xavier Becerra, Secretary of the U.S. Department of Health and Human Services (HHS), requesting that the Biden administration use statutory authority under 28 U.S.C. § 1498 to authorize generic competitors for semaglutide, sold by Novo Nordisk under the brand names Ozempic and Wegovy.

Surging demand for GLP-1 drugs, including semaglutide, has propelled Novo Nordisk to become [Europe's most valuable company](#) and [one of the most valuable pharmaceutical companies in the world](#). At the same time, the company's outrageous pricing of semaglutide threatens to break the coffers of federal health programs. In response, payers have turned to federal solutions to Novo Nordisk's price gouging. North Carolina, after unsuccessful efforts to negotiate lower prices for its State Health Plan with GLP-1 manufacturers, recently sent a [letter](#) requesting that HHS initiate efforts with branded manufacturers to voluntarily license their weight loss drugs in order to supply federal, state, and local government payers.¹

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

Unsustainable costs for patients and taxpayers

Novo Nordisk's exorbitant pricing in the U.S. has imposed widespread cost barriers on patients and financial burden on public programs.

According to a KFF poll, **1 in 8 adults have used GLP-1s**. Of these, **over half found it difficult to afford the cost**. Both those with and without insurance found it difficult to afford.²

Even those with insurance may end up paying higher premiums, if their provider can cover them at all.

- State health programs have noted the financial consequences of extending coverage for GLP-1s for weight management at their current price. Officials in states like North Carolina and West Virginia have raised alarm over how these drugs could cost state health plans covering public employees over \$150 million a year, which could increase the cost of premiums in some cases up to 200%.³

Considering the increasing interest in these drugs for weight management, and proposed legislation to end the exclusion of weight loss drugs from Medicare coverage,⁴ budgetary pressures imposed by these drugs are likely to increase drastically.

- 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.⁵
- 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).⁶
- Without substantial price reductions, Wegovy could cost the U.S. health care system \$1 trillion by 2031, potentially approaching \$2 trillion with greater uptake.⁷

To avert the ruinous financial consequences of Novo Nordisk's pricing abuses, the Biden administration should use its authority under 28 U.S.C. § 1498 to allow generic production of semaglutide, resulting in lower costs for federal health programs and their beneficiaries.

Using 28 U.S.C. § 1498 to expand access to semaglutide

Under [28 U.S.C. § 1498](#), the federal government can allow use of 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.

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.⁸ 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.⁹ This authority can be used to allow generic competition, a proven method to realize lower prescription drug prices.¹⁰

The law has been used for more than a century across technologies, including for the procurement of low-cost generic versions of patented drugs.¹¹ Invoking the law to help expand affordable access to semaglutide would be relatively simple. Federal entities including the Veteran's Health Administration and the Centers for Medicare and Medicaid Services (CMS) can procure generics under § 1498 by incorporating the government's authorization into contracts with generic manufacturers and issuing statements assuming infringement liability. In doing so, the U.S. can secure billions in savings for public programs and help safeguard affordable access to semaglutide.

Disparity between U.S. and international pricing

Novo Nordisk charges Americans \$969 per month for Ozempic and \$1,349 per month for Wegovy.¹² The company **charges the U.S. up to 15 times more** for these drugs than in places like Canada, Europe, and the United Kingdom.¹³ Even using estimates of net prices (prices after rebates, which may be passed through to pharmacy benefit managers), these drugs remain priced far higher in the U.S. than in other countries.¹⁴

The cost of Novo Nordisk's monopoly is underscored by recent research showing that generic Ozempic could be profitably priced at **less than \$5 per month**,¹⁵ while generic Wegovy could be priced as low as **\$13 per month**.¹⁶

Novo Nordisk's excessive profit seeking

The pharmaceutical industry often argues that exorbitantly high drug prices are necessary to recoup investment into the research and development (R&D) of medicines. Novo Nordisk has similarly pointed to the cost of developing its GLP-1 drugs in response to questions over pricing.¹⁷ However, the prices and associated revenues of Ozempic and Wegovy show that Novo Nordisk has recouped its R&D investment many times over.

- Novo Nordisk has amassed **over \$38 billion in revenue** from Ozempic and Wegovy since their launch¹⁸—far beyond even the most generous estimates of R&D costs.
- Meanwhile, since Ozempic's launch in 2018, Novo Nordisk has spent **\$38 billion enriching its shareholders** through stock buybacks and dividends—**over twice as much as it spent on R&D across its entire portfolio in the same period**.¹⁹

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- ¹ *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>
- ² 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/>
- ³ *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>; Oliver Whang, *In States That Won't Pay for Obesity Drugs, They May as Well Have Never Been Created*, N.Y. TIMES (June 25, 2024), <https://www.nytimes.com/2024/06/25/health/obesity-ozempic-wegovy-west-virginia.html>
- ⁴ Treat and Reduce Obesity Act of 2023, S.2407, 118th Cong. (2023); H.R.4818, 108th Cong. (2023) <https://www.congress.gov/bill/118th-congress/senate-bill/2407>
- ⁵ 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/>
- ⁶ MAJORITY STAFF OF THE SENATE HELP COMMITTEE, BREAKING POINT: HOW WEIGHT LOSS DRUGS COULD BANKRUPT AMERICAN HEALTH CARE 6-7 (May 15, 2024).
- ⁷ *Id.*
- ⁸ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 279-80 (2017).
- ⁹ *Id.* at 302, 330-31.
- ¹⁰ 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).
- ¹¹ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. (2017).
- ¹² 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>
- ¹³ MAJORITY STAFF OF THE SENATE HELP COMMITTEE, BREAKING POINT: HOW WEIGHT LOSS DRUGS COULD BANKRUPT AMERICAN HEALTH CARE (May 15, 2024) (Ozempic can be purchased for \$155 in Canada, \$122 in Italy, \$71 in France, and \$59 in Germany. Wegovy can be purchased for \$186 in Denmark, \$137 in Germany and \$92 in the United Kingdom.).
- ¹⁴ 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). (Ozempic is nearly five times more expensive in the U.S. than in Germany and Wegovy is more than 7.5 times more expensive in the U.S. than in the United Kingdom.).
- ¹⁵ Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 JAMA NETWORK OPEN e243474 (2024).
- ¹⁶ 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/>
- ¹⁷ Naomi Kresge, *Novo Blames US Health System After Sanders' Wegovy Criticism*, BLOOMBERG (May 28, 2024), <https://www.bloomberg.com/news/articles/2024-05-28/novo-blames-us-health-system-after-sanders-wegovy-criticism>
- ¹⁸ 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.
- ¹⁹ 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.