

May 29, 2024

RFI NO. 270-20240419GLP
NC Department of State Treasurer
State Health Plan Division
Attn: Kimberly Alston, Contracting Agent
3200 Atlantic Avenue, Raleigh, NC 27604

Dear Kimberly Alston,

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

We write this submission in response to the Request for Information (RFI) by the North Carolina State Health Plan for Teachers and State Employees ("Plan") on the feasibility of providing benefit coverage to Plan members to use GLP1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss in a manner that is financially sustainable. Specifically, we present a solution for addressing how to:

- (A) Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss.

We recommend that the Plan request that the U.S. Department of Health and Human Services (HHS):

1. Pursue voluntary licenses from branded manufacturers to produce generics for the Plan's beneficiaries and other similarly situated patients across the United States, in exchange for a reasonable royalty to the patent holder and
2. Invoke 28 U.S.C. § 1498, which provides for government use of patented products, including pharmaceuticals, and authorize manufacturers to produce generics of the weight loss medications. These generics, in turn, can be supplied to the beneficiaries of the Plan and similar entities in other states.

Through licensing, other manufacturers can make the same weight loss drugs for cheaper. Consequently, the prices of the drugs would drop due to generic competition, which would mean

lower out-of-pocket costs and premiums for the Plan’s beneficiaries and enrollees of other state health plans, as well as dramatic savings to the Plan and the entire healthcare system. If voluntary licensing is successful in the short term, or manufacturers offer price concessions sufficient to support coverage, then invoking § 1498 need not be pursued.

Background

The Plan announced that it was revoking coverage of drugs for weight loss uses effective April 1, 2024.¹ 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.² These costs result from the plan paying a net of \$800 per month for each subscriber for weight loss medications.³

Novo Nordisk sells semaglutide under the brand name, Wegovy, which is currently the most prescribed GLP-1 medication for weight loss. The company charges Americans almost fifteen times more for GLP-1 drugs than their peers in other high income nations.⁴ Whereas Wegovy costs just \$186 in Denmark (where Novo Nordisk is headquartered), \$140 in Germany, and \$92 in the United Kingdom, the list price of Wegovy is an astounding \$1,349 for a month’s supply in the United States.⁵ Considering net prices (prices after rebates and discounts), Novo Nordisk charges Americans over eight times more than the price of the drug in the United Kingdom.⁶

The price of these GLP-1 medications and similar drugs is of national concern, as the associated costs of covering these medications for weight loss uses would impose virtually unheard financial consequences on patients and insurers. This justifies the Plan’s potential request for assistance from HHS. A recent report from the Senate Committee on Health, Education, Labor, and Pensions found that the annual cost to the healthcare system for covering just one GLP-1 drug, Wegovy, for half of the eligible population (\$411 billion) would exceed the expenditure on all retail

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

² *Id.*

³ North Carolina Department of State Treasurer, *Treasurer Folwell Calls on Novo Nordisk to Lower the Unfair Cost of Weight Loss Drugs*, PRESS RELEASES (Oct. 24, 2023), <https://www.nctreasurer.com/news/press-releases/2023/10/24/treasurer-folwell-calls-novo-nordisk-lower-unfair-cost-weight-loss-drugs>.

⁴ Letter from U.S. Senator Bernard Sanders, Chair of the United States Senate Committee 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>.

⁵ *Id.*

⁶ MAJORITY STAFF OF THE SENATE HELP COMMITTEE, *BREAKING POINT: HOW WEIGHT LOSS DRUGS COULD BANKRUPT AMERICAN HEALTH CARE 2* (May 15, 2024).

prescription drugs in 2022 (\$406 billion).⁷ 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.⁸

Beyond the unprecedented costs to the American healthcare system, these drugs' widespread use combined with their excessive prices pose significant financial challenges to wide swathes of American patients. According to a Kaiser Family Foundation Poll, one in eight adults have used these new weight loss drugs, with over half saying that it was difficult to afford their costs.⁹ This was true for both patients with and without health insurance.¹⁰

For additional context as to the almost unheard financial consequences of covering these drugs, a recent study published in the *Journal of the American Medical Association* shows that these drugs could be sustainably priced at less than \$5 a month, and potentially as low as 89 cents, or around 0.07 percent of the current U.S. list price of Wegovy based on its cost of manufacture.¹¹

The impact of these drugs' excessive costs on patient access and the colossal challenge of covering these weight loss drugs for the Plan's beneficiaries, and the United States as a whole, warrant requesting that HHS help secure generic manufacturers to make the same drugs and offer them at a fraction of current market costs to the Plan and its beneficiaries. This would enable the Plan to cover the GLP-1 drugs and similar medications for its beneficiaries in a sustainable manner. In securing additional manufacturers and creating a generic supply of these medications, HHS could also distribute these lower-cost alternatives to similarly situated state health insurance plans and their enrollees. In doing so, HHS would be able to obtain economies of scale to attract manufacturers willing to supply many patients across the nation in need of lower-cost alternatives.

Voluntary Licensing

HHS can first try to secure voluntary licenses from the branded manufacturers to enable the production of lower-cost generics by other manufacturers. For example, HHS could approach Novo Nordisk about issuing voluntary licenses for Wegovy. To date, there is at least one firm

⁷ *Id.* at 6-7.

⁸ *Id.*

⁹ 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/>.

¹⁰ *Id.*

¹¹ Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 JAMA NETWORK OPEN e243474 (2024).

seeking to produce a generic equivalent to Wegovy in the United States. According to the Food and Drug Administration's (FDA) database, a firm submitted an Abbreviated New Drug Application (ANDA) in October 2022 to obtain approval for a generic based on Novo Nordisk's initial New Drug Application (NDA) for Wegovy and its submitted data.¹² Novo Nordisk admits that demand is outstripping supply for its popular drug,¹³ and as such, HHS can propose that the company voluntarily license the production of the drug in order to supplement the manufacturing base. HHS can also help seek royalty terms that would reasonably compensate Novo Nordisk for licensing out its drug. This approach is more likely to be successful if HHS simultaneously considers leveraging its authority to involuntarily license generic production by invoking 28 U.S.C. § 1498 to permit expanded affordable supply. Alternatively, Novo Nordisk and other branded manufacturers may offer price concessions to the Plan and others when faced by these licensing proposals, which could enable the Plan to provide coverage for these weight loss drugs to its members.

Given the nationwide concerns raised by the cost of these weight loss drugs and their impact on patient access, HHS's assistance in securing other manufacturers is appropriate; however, that does not preclude the Plan and other state officials from entering simultaneous discussions with Novo Nordisk and other branded manufacturers to voluntarily license their weight loss drugs or provide price concessions in the context of potential federal exercise of § 1498 authority. As discussed in more detail below, Louisiana was successful in eliciting significant price concessions in providing coverage for a hepatitis C cure using a similar strategy.¹⁴

Section 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

¹² FOOD & DRUG ADMINISTRATION, PARAGRAPH IV CERTIFICATIONS (May 13, 2024), <https://www.fda.gov/media/166048/download>; NOVO NORDISK, FORM 20-F: ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DEC. 31, 2023 (Jan 31, 2024), at 7.

¹³ UPDATES ABOUT WEGOVY, <https://www.novonordisk-us.com/supply-update.html> (last visited May 22, 2024).

¹⁴ Sarah J. Tribble, *Louisiana Proposes Tapping A Federal Law To Slash Hepatitis C Drug Prices*, KFF HEALTH NEWS (May 4, 2017), <https://kffhealthnews.org/news/louisiana-proposes-tapping-a-federal-law-to-slash-hepatitis-c-drug-prices/>; 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>.

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.¹⁵

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.¹⁶ 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.¹⁷

In modern cases, reasonable compensation under § 1498 has consistently been determined to be a reasonable royalty payment and not "lost profits."¹⁸ 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."¹⁹ Experts suggest that reasonable royalty rates in § 1498 cases rarely exceed 10% of the third-party manufacturers' sales.²⁰ Previously, some courts have also ruled that reasonable compensation should reflect development costs plus a reasonable return on investment.²¹

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.²² The federal government, even, repeatedly used the law in the 1960s to buy low-cost generics of patented drugs.²³ More recently, the Bush Administration publicly

¹⁵ 28 U.S.C. § 1498.

¹⁶ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 279-280 (2017).

¹⁷ *Id.*

¹⁸ *Id.* at 311.

¹⁹ *Id.* at 313.

²⁰ 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).

²¹ Brennan et al., *supra* note 16, at 314.

²² *Id.* at 302-306.

²³ *Id.*

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.²⁴

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 medicine by setting its price initially at \$84,000 for a drug that cost \$150 to produce, reaping billions in the process.²⁵ At the time, covering the cure for residents on Medicaid and the uninsured would have cost the state \$764 million, which was impossible given its budgetary constraints.²⁶ Leveraging the prospect of licensing using § 1498, the Secretary negotiated major discounts. The Secretary wrote to the nation's top public health experts asking for their advice on whether she should ask HHS to invoke § 1498 to secure generic versions of the cure, and they concluded that the authority should be exercised.²⁷ Subsequently, the state was able to enter a voluntary agreement with the branded manufacturer to secure an unrestricted amount of the cure while capping the state's spending at an amount based on its authorized funding levels.²⁸ More Louisiana residents received the cure in the next 75 days than in the entire fiscal year before.²⁹ Although not identical to the circumstances faced by the Plan with respect to weight loss medications, Louisiana's demonstrated success in obtaining price concessions on the hepatitis C cure via potential exercise of § 1498 illustrates how the Plan could also leverage this authority.

Most recently, 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-Moderna COVID-19 vaccine that generated tens of billions of dollars of revenues for the corporation.³⁰

²⁴ *Id.* at 303.

²⁵ 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); Gilead, *Gilead Sciences Announces fourth Quarter and Full Year 2017 Financial Results*, PRESS RELEASES (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>; 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>.

²⁶ Tribble, *supra* note 14.

²⁷ *Id.*

²⁸ Thomas, *supra* note 14.

²⁹ *Id.*

³⁰ 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>.

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.³¹

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 contactor from producing the generic.³²

The savings introduced by generic competition will 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.³³ Drugs with five manufacturers are priced at less than half the brand price, and that prices of drugs with 10 or more manufacturers are only about one-fifth of brand prices.³⁴ 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.³⁵

Recommendation

In order to permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for the purpose of weight loss, we recommend that the Plan request HHS to pursue licensing of these medications to generic manufacturers. Given the colossal financial consequences of these medications that are impacting access for patients—not only for the Plan, but patients and healthcare systems across the United

³¹ Motion to Dismiss, *Arbutus Biopharma Corporation et al. v. Moderna, Inc. et al.*, Case No.: 1:22-cv-00252-MSG (D. Del. 2020), <https://news.bloomberglaw.com/health-law-and-business/modernas-vaccine-patent-defense-poses-shield-for-us-deal-makers>.

³² Brennan, *supra* note 16, at 343.

³³ Chintan Dave, Abraham Hartzema, & Aaron Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 N. ENG. J. MED. 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).

³⁴ Dave, Hartzema, & Kesselheim, *supra* note 33, at 2597.

³⁵ FDA, *Generic Competition and Drug Prices*, CENTER FOR DRUG EVALUATION & RESEARCH, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (last visited May 28, 2024).



States—we believe a complementary approach of pursuing voluntary licensing and invoking § 1498 for achieving generic competition is warranted.

We first encourage the Plan to write to HHS requesting it to engage in negotiations with the branded manufacturers in order to obtain voluntary licenses to enable generic production. Simultaneously, HHS should start the contracting process under 28 U.S.C. § 1498 with companies that can make generic versions of the weight loss drugs. Should a voluntary licensing approach yield a satisfactory outcome, it would not be necessary to pursue government patent use further. Moreover, pursuing these options in tandem can increase the likelihood that the branded manufacturers enter voluntary licensing agreements, as these manufacturers would seek to avoid licensing without their permission under § 1498. Moreover, branded manufacturers may be willing to offer price concessions to avoid voluntary or involuntary licensing entirely, which could allow the Plan to sustainably cover the weight loss medications. However, if licensing is achieved, the savings that would accrue from the resulting generic competition would allow the Plan to accomplish its goal of providing effective coverage for weight loss medications to its members.

Sincerely,
Public Citizen