

February 12, 2026

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

Dear Secretary Kennedy:

We write you today to request that the Trump Administration authorize generic competitors for semaglutide and tirzepatide, two glucagon-like-peptide-1 (GLP-1) receptor agonists used for weight management, the treatment of type 2 diabetes, and the treatment of other conditions. Semaglutide is sold by Novo Nordisk under the brand names Ozempic, Wegovy, and Rybelsus. Tirzepatide is sold by Eli Lilly under the brand names Mounjaro and Zepbound. The companies' outrageous pricing 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 and tirzepatide, including how federal health programs cover these drugs for their different uses; Novo Nordisk's and Eli Lilly's price gouging on the drugs 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 and Tirzepatide

Ozempic, Wegovy, and Rybelsus are effectively the same drug, semaglutide, approved for 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, to reduce the risk of death, heart attack, or stroke in patients with type 2 diabetes and known heart disease, and to reduce the risk of worsening kidney disease, kidney failure, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease.¹ The FDA approved Wegovy, in addition to diet and exercise, for chronic weight management in patients with obesity and overweight with at least one weight-related comorbid condition, to reduce the risk of death, heart attack, or stroke in adults with established cardiovascular disease and either obesity or overweight, and for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with

¹ *OZEMPIC (semaglutide) injection, for subcutaneous use*, U.S. FOOD & DRUG ADMIN. (Oct 14, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209637s035,209637s037lbl.pdf.

moderate to advanced liver fibrosis.² Recently, the FDA approved an oral form of Wegovy for the same weight management and cardiovascular risk reduction indications in adults as the injectable form.³ The FDA previously approved Rybelsus, another oral form of semaglutide, to help control blood sugar levels in people with type 2 diabetes in addition to diet and exercise and to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes who are at high risk for these events.⁴

Similarly, Mounjaro and Zepbound are effectively the same drug, tirzepatide, approved for different uses. The FDA approved Mounjaro to help control blood sugar levels in patients with type 2 diabetes as an adjunct to diet and exercise.⁵ The FDA approved Zepbound, in addition to diet and exercise, for chronic weight management in adults with obesity or overweight with at least one weight-related comorbid condition and to treat moderate to severe obstructive sleep apnea in adults with obesity.⁶

In the United States, the Centers for Disease Control and Prevention estimates that about 38 million Americans have diabetes (about one in every 10 people), and between 90-95% have type 2 diabetes.⁷ Additionally, nearly 100 million American adults have prediabetes.⁸ 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.⁹

According to the National Institute of Diabetes and Digestive and Kidney Diseases, nearly one in

² *WEGOVY (semaglutide) injection, for subcutaneous use*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215256s023lbl.pdf.

³ *WEGOVY (semaglutide) injection, for subcutaneous use, WEGOVY (semaglutide) tablets, for oral use*, U.S. FOOD & DRUG ADMIN. (Dec. 22, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218316Orig1s000lbl.pdf.

⁴ *RYBELSUS (semaglutide) tablets, for oral use*, U.S. FOOD & DRUG ADMIN. (Oct. 17, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213051s024,s028s029lbl.pdf.

⁵ *MOUNJARO (tirzepatide) Injection, for subcutaneous use*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215866s039lbl.pdf.

⁶ *ZEPBOUND (tirzepatide) Injection, for subcutaneous use*, U.S. FOOD & DRUG ADMIN. (Sept. 25, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217806s031lbl.pdf.

⁷ *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 (last visited Dec. 30, 2025).

⁸ *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 (last visited Dec. 30, 2025).

⁹ *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 (last visited Jan. 13, 2026).

three adults are overweight (31%) and two in five adults have obesity (42%) in the United States.¹⁰ 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.¹¹ 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.¹²

Currently, Medicare is prohibited from covering drugs used for weight loss, but it can cover these drugs for other medical indications, such as diabetes, reducing the risk of adverse cardiovascular events, and sleep apnea.¹³ Bicameral, bipartisan legislation has been proposed to 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.¹⁴ 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.¹⁵ Medicaid is required to cover these drugs for other medically accepted indications, like diabetes, mitigating the risk of adverse cardiovascular events, and sleep apnea.¹⁶ In December 2025, the Centers for Medicare and Medicaid Services (CMS) announced a voluntary model (the Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth, or, “BALANCE” model) to negotiate pricing and expanded coverage terms for GLP-1 drugs with manufacturers for use in participating Medicaid programs and Medicare Part D plans.¹⁷ Direct federal purchasers also provide these drugs. The Department of Veterans Affairs covers Ozempic, Rybelsus, Mounjaro, Wegovy, and Zepbound pursuant to certain restrictions, the Federal Bureau of Prisons covers Ozempic, Rybelsus, and Wegovy also pursuant to certain restrictions, and TRICARE (which supplies military service members) covers

¹⁰ *Overweight & Obesity Statistics*, NAT’L INST. DIABETES & DIGESTIVE & KIDNEY DISEASES, <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity> (last visited Dec. 30, 2025).

¹¹ *Health Risks of Overweight & Obesity*, NAT’L INST. DIABETES & DIGESTIVE & KIDNEY DISEASES, <https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks> (last visited Jan. 13, 2026).

¹² *Id.*

¹³ 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/>; 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>.

¹⁴ Treat and Reduce Obesity Act of 2025, S.1973, 119th Cong (2025); H.R.4231, 119th Cong (2025), <https://www.congress.gov/bill/119th-congress/house-bill/4231>.

¹⁵ Elizabeth Williams, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Jan. 16, 2026), <https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/>.

¹⁶ *Id.*

¹⁷ Press Release, Ctrs. Medicare & Medicaid Services, CMS Launches Voluntary Model to Expand Access to Life-Changing Medicines, Promote Healthier Living (Dec. 23, 2025), <https://www.cms.gov/newsroom/press-releases/cms-launches-voluntary-model-expand-access-life-changing-medicines-promote-healthier-living>.

Ozempic, Rybelsus, and Mounjaro if certain criteria are met and covers Wegovy and Zepbound in certain plans if certain criteria are met.¹⁸

With respect to these drugs, it is important to acknowledge limitations in the use of Body Mass Index (BMI) 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.¹⁹ But the skyrocketing use of these medications threatens to impose unprecedented financial consequences on federal health programs and patients due to the pricing abuses of the originator companies, Novo Nordisk and Eli Lilly.

Novo Nordisk's and Eli Lilly's Exorbitant Pricing of Semaglutide and Tirzepatide and Its Extreme Financial Consequences

Novo Nordisk charges Americans up to 16 times as much for its semaglutide products as in peer countries.²⁰ Whereas Ozempic costs \$155 in Canada and \$59 in Germany, the list price of Ozempic and Rybelsus is an astounding \$997 for a month's supply in the United States.²¹ Similarly, the list price of Wegovy is just \$140 in Germany and \$92 in the United Kingdom, but Novo Nordisk charges Americans \$1,349 per month for the medication.²² Eli Lilly charges \$1,112 for a month's supply of Mounjaro and \$1,086 for Zepbound in the United States.²³ In the United Kingdom, a

¹⁸ U.S. Dept. of Veterans Aff., *SEAGLUTIDE INJ,SOLN*, VAFORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040140-SEAGLUTIDE-INJ-SOLN> (last visited Jan. 5, 2026); U.S. Dept. of Veterans Aff., *SEAGLUTIDE INJ,SOLN*, VAFORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040576-SEAGLUTIDE-INJ-SOLN> (last visited Jan. 5, 2026); U.S. Dept. of Veterans Aff., *TIRZEPATIDE INJ,SOLN*, VAFORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4041426-TIRZEPATIDE-INJ-SOLN> (last visited Jan. 5, 2026); Fed. Bureau of Prisons, *National Formulary*, HEALTH SERVS. MGMT., https://www.bop.gov/resources/health_care_mngmt.jsp (last visited Jan. 5, 2026); FED. BUREAU OF PRISONS HEALTH SERVS., NATIONAL FORMULARY PART I 13 (Winter 2023), https://www.bop.gov/resources/pdfs/2023_winter_formulary_part_1.pdf; *Does TRICARE cover Wegovy, Ozempic, and Mounjaro?*, TRICARE, https://tricare.mil/FAQs/Pharmacy/PharmProg_Wegovy (last visited Jan. 5, 2026).

¹⁹ 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-201603302500>; *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 Jan 12, 2026); Public Citizen, *Semaglutide (WEGOVY) for Weight Loss: Substantial Risks, Including Weight Regain*, WORST PILLS, BEST PILLS NEWSLETTER (Aug. 2023).

²⁰ *See*, Letter from Sen. 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> (after updating to compare with current U.S. list prices); *Find out the cost for Ozempic*, NOVO NORDISK, <https://www.novocare.com/diabetes/products/ozempic/explaining-list-price.html> (last visited Jan. 4, 2026).

²¹ *Id.*

²² *Id.*

²³ *How much should I expect to pay for Mounjaro® (tirzepatide)?*, ELI LILLY, <https://pricinginfo.lilly.com/mounjaro> (last visited Jan. 6, 2026); *How much should I expect to pay for Zepbound® (tirzepatide)?*, ELI LILLY,

one-month supply of the lowest dose of tirzepatide for weight management is around \$179 and the highest dose is \$444.²⁴ In Canada, lower doses of Mounjaro and Zepbound are about \$219 and higher doses are \$394.²⁵ In Japan, Zepbound is \$78 at the lowest dose and \$287 at the highest dose.²⁶ Even using volatile estimates of net prices (prices after rebates) Ozempic is five times as expensive in the United States as in Germany.²⁷ Wegovy is more than six times as expensive here than in the United Kingdom.²⁸ Similarly, Zepbound is as much as three times as expensive in the U.S. as in Canada and as much as 8.5 times as expensive in the U.S. as in Japan.²⁹

Further, these drastic 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.³⁰

The Trump Administration rightfully recognizes that Novo Nordisk's and Eli Lilly's prices are far too high. The Medicare Drug Price Negotiation Program negotiated a 71% discount off the list price for Ozempic, Wegovy, and Rybelsus.³¹ Additionally, the Administration announced

<https://pricinginfo.lilly.com/zepbound> (last visited Jan. 6, 2026).

²⁴ *Tirzepatide for managing overweight and obesity*, NAT'L INST. FOR HEALTH AND CARE EXCELLENCE (Dec. 23, 2024),

<https://www.nice.org.uk/guidance/ta1026/resources/tirzepatide-for-managing-overweight-and-obesity-pdf-2973528337587397> (converted from GBP based on U.S. Department of Treasury-reported exchange rate as of Dec. 25, 2025).

²⁵ See, Chris Hannay, *Eli Lilly & Co. cuts price of popular diabetes and weight-loss drugs in Canada*, THE GLOBE & MAIL (Dec. 17, 2025), <https://www.theglobeandmail.com/business/article-eli-lilly-co-cuts-price-of-popular-diabetes-and-weight-loss-drugs-in/> (converted from CAD based on U.S. Department of Treasury-reported exchange rate as of Dec. 25, 2025).

²⁶ Ministry of Health, Labor, & Welfare, *Information on the Drug Price List and Generic Drugs (effective February 1, 2026)*, <https://www.mhlw.go.jp/topics/2025/04/tp20250401-01.html> (converted from JPY based on U.S. Department of Treasury-reported exchange rate as of Dec. 25, 2025).

²⁷ *Find out the cost for Ozempic*, NOVO NORDISK, <https://www.novocare.com/diabetes/products/ozempic/explaining-list-price.html> (last visited Jan. 4, 2026); MEDICARE COVERAGE OF ANTI-OBESITY MEDICATIONS, U.S. DEP'T HEALTH & HUMAN SERVS. (Nov. 26, 2024), <https://aspe.hhs.gov/sites/default/files/documents/127bd5b3347b34be31ac5c6b5ed30e6a/medicare-coverage-anti-obesity-meds.pdf> (basis for Ozempic net price estimate).

²⁸ *Price your Wegovy*, NOVO NORDISK, <https://www.novocare.com/patient/medicines/wegovy.html> (last visited Jan. 18, 2026); SEMAGLUTIDE AND TIRZEPATIDE FOR OBESITY: EFFECTIVENESS AND VALUE, ICER (Sept. 9, 2025), https://icer.org/wp-content/uploads/2025/09/ICER_Obesity_Draft-Report_For-Publication_090925.pdf (showing Q1 2025 Wegovy net price estimate).

²⁹ *How much should I expect to pay for Zepbound® (tirzepatide)?*, ELI LILLY, <https://pricinginfo.lilly.com/zepbound> (last visited Jan. 6, 2026); SEMAGLUTIDE AND TIRZEPATIDE FOR OBESITY: EFFECTIVENESS AND VALUE, ICER (Sept. 9, 2025), https://icer.org/wp-content/uploads/2025/09/ICER_Obesity_Draft-Report_For-Publication_090925.pdf (showing Q1 2025 Zepbound net price estimate).

³⁰ 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/277371265a705c356c968977e87446ac/international-price-comparisons.pdf>.

³¹ Ctrs. Medicare & Medicaid Servs., Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027 (Nov. 2025), <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay->

voluntary agreements with both companies “to dramatically reduce the prices Americans pay” for Ozempic, Wegovy, Mounjaro, and Zepbound.³²

However, even at the lowered prices achieved through the Medicare negotiation program, Novo Nordisk’s semaglutide products will remain among the most costly drugs for Medicare. Based on 2024 spending data, estimated spending at the negotiated prices would be higher than *gross spending* for all but nine drugs in Medicare Part D.³³ Similarly, while the proposed coverage expansion and price reductions announced with the voluntary agreements could improve access for some, their scope and impact remain somewhat limited. The announced Medicare and Medicaid price of \$245 per month for Ozempic, Wegovy, Mounjaro, and Zepbound could still cost taxpayers billions of dollars and could impact premiums.³⁴ A subset of Medicare beneficiaries who meet the specific coverage criteria under the associated CMS BALANCE model would pay a \$50 per month co-pay for the drugs.³⁵ This is an improvement compared to current cost-sharing in Medicare of around \$100 to \$200 for Ozempic and Mounjaro but may still be prohibitively expensive for some, particularly considering research showing that higher out-of-pocket costs are associated with lower medication adherence.³⁶ Even relatively low charges can have an impact, for example, patients with an out-of-pocket cost over \$20 per dispensing are at a greater risk of poor adherence than those with no out-of-pocket cost, according to one study.³⁷

For those purchasing without insurance, Novo Nordisk and Eli Lilly agreed to make their GLP-1

[2027.pdf](#).

³² The White House, Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients (Nov. 6, 2025), <https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/>.

³³ Anna Anderson-Cook & Richard G. Frank, Estimated savings from year two of the IRA Prescription Drug Negotiation Program, BROOKINGS (Dec. 5, 2025), <https://www.brookings.edu/articles/estimated-savings-from-year-two-of-the-ira-prescription-drug-negotiation-program/>; Ctrs. Medicare & Medicaid Servs., *Medicare Quarterly Part D Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-quarterly-part-d-spending-by-drug> (last visited Jan. 14, 2026).

³⁴ The White House, Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients (Nov. 6, 2025), <https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/>; Nyah Phengsithy, *Ozempic, Wegovy Medicare Prices Muddled by Trump’s Dueling Deals*, BLOOMBERG L. (Nov. 26, 2025), <https://news.bloomberglaw.com/health-law-and-business/ozempic-wegovy-medicare-prices-muddled-by-trumps-dueling-deals>.

³⁵ Press Release, Ctrs. Medicare & Medicaid Services, CMS Launches Voluntary Model to Expand Access to Life-Changing Medicines, Promote Healthier Living (Dec. 23, 2025), <https://www.cms.gov/newsroom/press-releases/cms-launches-voluntary-model-expand-access-life-changing-medicines-promote-healthier-living>; The White House, Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients (Nov. 6, 2025), <https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/>.

³⁶ Elaine Chen, *Is the White House’s deal with pharma on GLP-1 drugs a game changer?*, STAT NEWS (Nov. 10, 2025) <https://www.statnews.com/2025/11/10/what-to-expect-trump-glp-1-deals-eli-lilly-novo-nordisk/>.

³⁷ Andrew J Karter et al, *Effect of Out-of-Pocket Cost on Medication Initiation, Adherence, and Persistence among Patients with Type 2 Diabetes: The Diabetes Study of Northern California (DISTANCE)*, HEALTH SERV. RES. (2018), <https://pmc.ncbi.nlm.nih.gov/articles/PMC5867086/>.

drugs available to cash-paying patients through direct-to-consumer purchasing platforms at an average price of about \$350 per month.³⁸ That is a decrease from previously available cash-pay prices of about \$500 per month, depending on the drug and dose.³⁹ But it is still so high as to raise concerns about affordability and sustainable access for those who cannot afford to pay thousands of dollars each year for one medication. Patient access through direct-to-consumer platforms could also be impacted by manufacturer compliance with the federal anti-kickback statute, which prohibits manufacturers from knowingly and willfully soliciting or receiving any remuneration in return for referring an individual to any item or service reimbursable by a federal health care program.⁴⁰ Lawmakers recently raised concerns that existing platforms may not meet all necessary criteria stipulated in a U.S. Department of Health and Human Services (HHS) Office of Inspector General bulletin as necessary to minimize the risk that a manufacturer would violate the anti-kickback law.⁴¹ Additionally, as the voluntary agreement prices to be made available to Medicare and Medicaid do not appear to extend to the commercial market, beneficiaries with these plans will face coverage restrictions, increased spending on premiums, or both.

The pharmaceutical industry often asserts that exorbitantly high drug prices for Americans are necessary to recoup sunk research and development costs. But the prices and associated revenues of Eli Lilly's tirzepatide products and Novo Nordisk's semaglutide products cannot reasonably be said to reflect the companies' research and development expenditures. According to publicly available company financial reports, Eli Lilly has made \$58.79 billion in revenue from Mounjaro and Zepbound since their launch.⁴² Novo Nordisk has made \$94.33 billion in revenue from Ozempic, Wegovy, and Rybelsus since their launch.⁴³ These revenues are an order of magnitude

³⁸ The White House, Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients (Nov. 6, 2025), <https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/>.

³⁹ The lower prices announced with the voluntary agreements apply only to lower doses. For example, Novo Nordisk and Eli Lilly will make their oral GLP-1s for weight management available at a direct-to-consumer price of around \$150 per month for the starting dose. According to the FDA label for oral Wegovy, the initial dose is given for one month before increasing to a higher maintenance dosage, indicating that patients will likely pay for higher-priced dosage forms for the large majority of their time taking these medications. *WEGOVY (semaglutide) injection, for subcutaneous use, WEGOVY (semaglutide) tablets, for oral use*, U.S. FOOD & DRUG ADMIN. (Dec. 22, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218316Orig1s000lbl.pdf; Stacie B. Dusetzina & Rachel E. Sachs, *Insurance Coverage and Pricing of Weight-Loss Drugs in the United States*, 394 *NEW ENG. J. MED.* PERSPECTIVE 105-107 (2025).

⁴⁰ 42 U.S.C. § 1320a-7b(b).

⁴¹ Letter from Sens. Richard J. Durbin, Peter Welch, & Elizabeth Warren to T. March Bell, Inspector General, U.S. Dep't of Health & Human Servs. OIG, (Jan. 29, 2026), https://www.durbin.senate.gov/imo/media/doc/durbin_hhs_oig_letter_on_trumprx.pdf.

⁴² Q4 2025 Financial Workbook, ELI LILLY (Feb. 4, 2026), <https://investor.lilly.com/webcasts-and-presentations>; Eli Lilly, Form 10-K, at 67 (Feb. 19, 2025).

⁴³ Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2025, at 90 (Feb. 4, 2026); Novo Nordisk, Form 20-F, at 109 (Jan. 31, 2024); Novo Nordisk, Form 20-F, at 6 (Jan. 31, 2024); Novo Nordisk, Form 20-F, at 6 (Feb. 1, 2023); Novo Nordisk, Form 20-F, at 6 (Feb. 2, 2022); Novo Nordisk, Form 20-F, at 6 (Feb. 3, 2021); Novo Nordisk, Form 20-F, at 7 (Feb. 5, 2020); Novo Nordisk, Form 20-F, at 7 (2019); Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 57 (Jan. 31, 2024).

higher than even the most generous estimates of research and development costs for drugs that take into account failed candidates and a reasonable return on investment.⁴⁴ Further, in 2025, Novo Nordisk spent more (\$8.19 billion) enriching its shareholders through stock buybacks and dividends than it did on research and development (\$8.02 billion).⁴⁵ This is not an aberration for the company. Since 2018, when Novo Nordisk launched Ozempic, the company has spent over \$56.3 billion on share repurchases and shareholder dividends—1.7 times as much as it spent on R&D *across its entire portfolio* (\$32.76 billion).⁴⁶ Eli Lilly has spent \$23.67 billion on share buybacks and dividends over the four years since Mounjaro launched, nearly \$3 billion more than it spent on these activities over the preceding four years.⁴⁷ Novo Nordisk’s and Eli Lilly’s extraordinary pricing and revenues for semaglutide and tirzepatide 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 2024 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.⁴⁸ Similarly, Wegovy could be sustainably priced for as little as \$13 a month, which is approximately one percent of the current list price.⁴⁹ The same 2024 study found that oral semaglutide could be priced at \$72.50 a month, and potentially as low as \$39 a month, which is less than four percent of the Wegovy pill and Rybelsus list prices.

Novo Nordisk’s and Eli Lilly’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, nearly one in five (18%) adults have used GLP-1 drugs (an increase of 6 percentage points from 18 months ago), with over half saying that it was difficult to afford their

⁴⁴ CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (Apr. 2021), <https://www.cbo.gov/publication/57126>.

⁴⁵ Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2025, at 83-84 (Feb. 4, 2026).

⁴⁶ Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2025, at 83-84 (Feb. 4, 2026); Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2024, at 102-103 (Feb. 5, 2025); Novo Nordisk, Form 20-F, Ex. 15.1: The Registrant's Annual Report for the fiscal year ended December 31, 2023, at 51-52 (Jan. 31, 2024); Novo Nordisk, Form 20-F, Ex. 15.1: Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2020, at 47-48 (Feb. 3, 2021).

⁴⁷ Based on full-year financials except for 2025 which runs through Q3 (full year data on dividends and share repurchases were not yet available at the time of writing). Eli Lilly Form 10-Q, at 10 (Oct. 30, 2025); Eli Lilly Form 10-K, at 62 (Feb. 19, 2025); Eli Lilly Form 10-K, at 59 (Feb. 23, 2022); Eli Lilly Form 10-K, at 61 (Feb. 17, 2021).

⁴⁸ Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 JAMA NETWORK OPEN e243474 (2024).

⁴⁹ 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/>.

costs.⁵⁰ This was true for both patients with and without health insurance.⁵¹

Medicare Part D's gross spending on Ozempic in 2024 (the latest year for which data is available) was \$12.97 billion for approximately 1,952,704 beneficiaries, which is approximately \$6,642 per enrollee.⁵² It was the second highest-spend drug for Medicare Part D that year.⁵³ Gross spending on Rybelsus in 2024 was \$1.89 billion for 310,000 beneficiaries, which is approximately \$6,097 per enrollee.⁵⁴ Gross spending on Wegovy in 2024 was \$301.29 million for 52,962 beneficiaries (\$5,688 per enrollee).⁵⁵ Medicare Part D's gross spending on Mounjaro in 2024 was nearly \$6.34 billion (the fourth highest-spend drug that year) while spending on Zepbound was \$387,343.⁵⁶ In 2024, Medicaid gross spending was \$3.3 billion for Ozempic, \$1.2 billion for Wegovy, \$304.3 million for Rybelsus, \$955.7 million for Mounjaro, and \$273.8 million for Zepbound.⁵⁷

The costs imposed on taxpayer-funded health programs by Novo Nordisk's and Eli Lilly's price gouging on semaglutide and tirzepatide are growing rapidly. Between 2020 and 2023, Medicare's gross spending on semaglutide products doubled or nearly doubled each year, amounting to a \$1.5 billion increase in 2021, a \$2.5 billion increase in 2022, and a \$5.2 billion increase in 2023, compared to each of the preceding years.⁵⁸ In 2024, spending increased by \$4.3 billion compared to 2023, reaching an astonishing total of \$15.16 billion.⁵⁹ Between 2022 and 2023, Medicare's spending on tirzepatide products increased by \$2.2 billion.⁶⁰ Between 2023 and 2024, Medicare's spending on tirzepatide products increased by nearly \$4 billion, reaching a total gross spend of

⁵⁰ Alex Montero, Audrey Kearney, Mardet Mulugeta, Ashley Kirzinger, and Liz Hamel, *KFF Health Tracking Poll: Prescription Drug Costs, Views on Trump Administration Actions, and GLP-1 Use*, KFF POLLING (Nov. 14, 2025), <https://www.kff.org/public-opinion/kff-health-tracking-poll-prescription-drug-costs-views-on-trump-administration-actions-and-glp-1-use/>.

⁵¹ *Id.*

⁵² The 2024 spending data is preliminary based on quarterly data, meaning it is subject to change before CMS releases finalized 2024 annual spending data.; Ctrs. Medicare & Medicaid Servs., *Medicare Quarterly Part D Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-quarterly-part-d-spending-by-drug> (last visited Jan. 14, 2026).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Elizabeth Williams, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Jan. 16, 2026), <https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/>.

⁵⁸ 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 Jan. 5, 2026); Ctrs. Medicare & Medicaid Servs., *Medicare Quarterly Part D Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-quarterly-part-d-spending-by-drug> (last visited Jan. 14, 2026).

⁵⁹ *Id.*

⁶⁰ 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 Jan. 6, 2026).

over \$6.3 billion.⁶¹ Between 2020 and 2023, Medicaid’s spending on semaglutide products has similarly increased, doubling or more than doubling each year before reaching \$4.8 billion in 2024.⁶² In 2024, Medicaid’s spending on tirzepatide products reached over \$1.2 billion—nearly three times as much as it had been the previous year.⁶³ A 2024 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).⁶⁴ Notably, these estimates used the net price of the weight loss drug.⁶⁵ 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.⁶⁶

Without lower prices to help limit the explosive costs of these drugs, federal programs instead employ prior authorization criteria and access restrictions to limit the number of beneficiaries for whom the drugs are covered. For example, the Department of Veterans Affairs’ criteria for patients to use Ozempic to manage diabetes require, in addition to a diagnosis of type 2 diabetes, that 1) they are not a good candidate for empagliflozin and have established cardiovascular disease and/or chronic kidney disease or 2) their blood sugar goals are not met with empagliflozin and metformin.⁶⁷ For Mounjaro, in addition to a diagnosis of type 2 diabetes, patients must have been unable to achieve blood sugar control with at least 1mg of semaglutide plus two or more glucose lowering drugs for at least 6 months, among several other criteria.⁶⁸ For Wegovy and Zepbound, the VA requires patients to participate in a comprehensive lifestyle intervention and

⁶¹ 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 Jan. 6, 2026); Ctrs. Medicare & Medicaid Servs., *Medicare Quarterly Part D Spending by Drug*, DATA.CMS.GOV, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-quarterly-part-d-spending-by-drug> (last visited Jan. 14, 2026).

⁶² Elizabeth Williams, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Jan. 16, 2026), <https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/>.

⁶³ *Id.*

⁶⁴ MAJORITY STAFF OF THE SENATE HELP COMMITTEE, *BREAKING POINT: HOW WEIGHT LOSS DRUGS COULD BANKRUPT AMERICAN HEALTH CARE 6-7* (May 15, 2024).

⁶⁵ *Id.*; *See also*, MAJORITY STAFF OF THE SENATE HELP COMMITTEE, *NOVO NORDISK’S UNTENABLE DRUG PRICING STRATEGY IN AMERICA: GREED, GREED, GREED 3* (Sept. 24, 2024), <https://www.sanders.senate.gov/wp-content/uploads/9.23.2024-Novo-Nordisk-Untenable-Strategy-final.pdf>. Wegovy’s net price was estimated to be \$809 per month (a 40% rebate from the list price) based on publicly reported figures in 2024. The majority staff noted that the rebate “aggregate figure likely overestimates the discounts available to most commercial plans,” and that “[p]harmaceutical companies often combine rebates with other kinds of government-mandated discounts (e.g., 340B pricing, Medicaid rebates) to present a misleading figure of the net price.”

⁶⁶ *Id.*

⁶⁷ U.S. Dept. of Veterans Aff., *SEMAGLUTIDE INJ,SOLN*, VA FORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040140-SEMAGLUTIDE-INJ-SOLN> (last visited Jan. 8, 2026).

⁶⁸ U.S. Dept. of Veterans Aff., *TIRZEPATIDE INJ,SOLN*, VA FORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4041426-TIRZEPATIDE-INJ-SOLN> (last visited Jan. 8, 2026).

to have a BMI of greater than or equal to 30 with at least one weight-related comorbidity.⁶⁹ TRICARE requires prior authorization for Ozempic, Mounjaro, and Rybelsus in which, in addition to having a diagnosis of type 2 diabetes, the patient has first tried and failed to achieve blood sugar control on metformin unless they cannot use metformin for some reason.⁷⁰ TRICARE also requires a clinician to fill out a medical necessity form for active duty beneficiaries for Ozempic and Mounjaro, explaining why the patient cannot use an alternative diabetes management drug, Trulicity.⁷¹ For TRICARE plans that cover Wegovy and Zepbound, patients are required to have engaged in documented behavioral modification for six months and to continue to do so while on the treatment, tried three months of alternative medications (unless contraindicated) without achieving a 5% reduction in baseline weight, and either 1) have a BMI of over 27 with an additional comorbidity or 2) have a BMI greater than 30.⁷² For Zepbound's sleep apnea indication, TRICARE prior authorization requires that the patient has documented moderate to severe sleep apnea, a BMI greater than or equal to 30, and has engaged in documented behavioral modification for six months and will continue to do so while on the treatment.⁷³ For Wegovy, the Federal Bureau of Prisons requires that patients have either a BMI of greater than or equal to 30 or a BMI of greater than or equal to 27 with at least one weight-related comorbidity and requires verified lifestyle interventions with documentation about diet and exercise, among other requirements.⁷⁴

⁶⁹ U.S. Dept. of Veterans Aff., *SEMAGLUTIDE INJ,SOLN*, VAFORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4040576-SEMAGLUTIDE-INJ-SOLN> (last visited Jan. 8, 2026); U.S. Dept. of Veterans Aff., *TIRZEPATIDE INJ,SOLN*, VAFORMULARY ADVISOR, <https://www.va.gov/formularyadvisor/drugs/4041426-TIRZEPATIDE-INJ-SOLN> (last visited Jan. 8, 2026).

⁷⁰ TRICARE PRIOR AUTHORIZATION REQUEST FORM FOR OZEMPIC, MOUNJARO, https://www.express-scripts.com/interaction/member-proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7BA0A84492-0000-CD1B-A68E-B1E40C5D1CA%7D (last visited Jan. 8, 2026); TRICARE PRIOR AUTHORIZATION REQUEST FORM FOR SEMAGLUTIDE ORAL TABLET (RYBELSUS), https://www.express-scripts.com/interaction/member-proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7B309ADD8A-0000-CF1B-BAE1-1536F5987E28%7D (last visited Jan. 8, 2026).

⁷¹ *Does TRICARE cover Wegovy, Ozempic, and Mounjaro?*, TRICARE, https://tricare.mil/FAQs/Pharmacy/PharmProg_Wegovy (last visited Jan. 8, 2026); TRICARE PHARMACY PROGRAM MEDICAL NECESSITY FORM FOR SEMAGLUTIDE (OZEMPIC), https://www.express-scripts.com/interaction/member-proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7B30B7E49A-0000-C012-8DAF-AD2D2850E79F%7D (last visited Jan. 8, 2026); TRICARE PHARMACY PROGRAM MEDICAL NECESSITY FORM FOR TIRZEPATIDE (MOUNJARO), https://www.express-scripts.com/interaction/member-proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7B2061C099-0000-CB1B-9BAA-2B15A5F3A205%7D (last visited Jan. 8, 2026).

⁷² TRICARE PRIOR AUTHORIZATION REQUEST FORM FOR SEMAGLUTIDE INJECTION/TABLETS (WEGOVY), TIRZEPATIDE INJECTION (ZEPBOUND PEN INJECTOR), https://www.express-scripts.com/interaction/member-proxinator/1/member/v1/drugpricing/prelogin/fst/drug/forms/content?repository=EIS_P8_DC%3AesiCPS&documentId=%7B1018949B-0000-C115-9DAF-3120C8A8A1D9%7D (last visited Jan. 8, 2026).

⁷³ *Id.*

⁷⁴ FED. BUREAU OF PRISONS HEALTH SERVS., NATIONAL FORMULARY PART I 13 (Winter 2023), https://www.bop.gov/resources/pdfs/2023_winter_formulary_part_1.pdf.

Novo Nordisk's and Eli Lilly's exorbitant pricing of these drugs is having catastrophic effects on state health program budgets. In 2024, 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.⁷⁵ 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 following six years.⁷⁶ These costs result from the plan paying \$800 per month for each subscriber for weight loss medications.⁷⁷ North Carolina State Treasurer at the time 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."⁷⁸ Recognizing the need for a federal solution, Treasurer Folwell requested that HHS initiate efforts with branded manufacturers to voluntarily license their weight loss drugs in order to supply federal, state, and local government payers.⁷⁹

Connecticut has also called for a federal solution to rein in the overwhelming costs caused by high demand and drug company profiteering on GLP-1s.⁸⁰ In 2025, the state passed a law directing the Department of Social Services to petition HHS to authorize generic forms of GLP-1s pursuant to 28 U.S.C. § 1498.⁸¹ The state's Medicaid program spent \$85 million on GLP-1s over the previous year, which amounted to 35% of the program's pharmaceutical budget that year.⁸²

Like Connecticut, many state Medicaid programs are struggling with the costs of these medicines. Currently, only 13 states cover GLP-1 drugs for weight loss.⁸³ Several states have recently rescinded coverage. California rescinded coverage as spending on the drugs had surged 1,400

⁷⁵ *Statement Regarding GLP-1 Coverage*, N.C. STATE HEALTH PLAN FOR TEACHERS & STATE EMPLOYEES (Mar. 7, 2024), available at: <https://web.archive.org/web/20240501111144/https://www.shpnc.org/blog/2024/03/07/statement-regarding-glp-1-coverage>.

⁷⁶ *Id.*

⁷⁷ 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>.

⁷⁸ *Id.*

⁷⁹ 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), <https://www.shpnc.gov/documents/folwell-request-usdhhs-glp1/download?attachment>.

⁸⁰ Press release, Connecticut Senate Democrats, Senator Lesser Welcomes Pilot to Expand Coverage of Weight Loss Drugs (Aug. 1, 2025), <https://www.senatedems.ct.gov/senator-lesser-welcomes-pilot-to-expand-coverage-of-weight-loss-drugs>.

⁸¹ H.B. 7192, 2025 Gen. Assemb., Reg. Sess. (Conn. 2025), https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB07192&which_year=2025.

⁸² Katy Golvala, *People call GLP-1s life-changing. CT says it can't afford them.*, THE CONNECTICUT MIRROR (Mar. 23, 2025), <https://ctmirror.org/2025/03/23/ct-glp-1-weight-loss-drug-coverage/>.

⁸³ Elizabeth Williams, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Jan. 16, 2026), <https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/>.

percent, to about \$809 million, since the program began covering the drugs in 2023.⁸⁴ New Hampshire, South Carolina, and Pennsylvania also ended coverage for the drugs in 2026.⁸⁵ Other states have introduced coverage restrictions to help contain ballooning costs. Virginia’s Medicaid program narrowed the eligible patient population to only those with severe obesity (BMI over 40) or moderate obesity (BMI over 37) with one weight-related condition.⁸⁶ Michigan restricted coverage to Medicaid patients with severe obesity.⁸⁷ If these drugs were affordably priced, programs would not need expansive access restrictions to manage the costs. “If we had the same questions about long-term benefit, but it costs \$5 for treatment, I don’t think states would be hesitating to cover it,” noted Pete Croughan, deputy secretary of Louisiana’s Department of Health.⁸⁸

Unfortunately, CMS’ newly announced BALANCE model for GLP-1 drugs may not offer relief for these programs because the proposed prices appear similar to current Medicaid net prices.⁸⁹ Faced with the ongoing cost burden of these medications at current prices, many Medicaid programs and Medicare plans may choose not to participate in the BALANCE model, thereby limiting the number of patients who could benefit from the expanded coverage. Moreover, even among beneficiaries covered by plans that choose to participate, coverage is not guaranteed. CMS’ proposed coverage expansion will reportedly apply certain restrictions that limit the number of patients covered to fewer than would be eligible to use the drugs for weight management based on FDA guidelines.⁹⁰ For example, not all patients considered to have obesity would be eligible under the proposed plan. To be eligible, patients who have mild obesity (those with a BMI of 30–34.9) will reportedly need to have an additional condition, such as uncontrolled hypertension.⁹¹

Generic competition would result in substantial savings, which could help plans ease coverage restrictions and expand access to the drugs for all patients who could benefit from them. For

⁸⁴ Kelly Hooper, *Doctors call Ozempic a miracle drug. Medicaid officials aren’t so sure.*, POLITICO (Dec. 2, 2025), <https://www.politico.com/news/2025/12/02/weight-loss-medicaid-drugs-ozempic-wegovy-zepbound-00663581>.

⁸⁵ *Id.*; Elizabeth Williams, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Jan. 16, 2026), <https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/>.

⁸⁶ Kelly Hooper, *Doctors call Ozempic a miracle drug. Medicaid officials aren’t so sure.*, POLITICO (Dec. 2, 2025), <https://www.politico.com/news/2025/12/02/weight-loss-medicaid-drugs-ozempic-wegovy-zepbound-00663581>.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* (“In Michigan, where Medicaid covers the obesity medications, the new price [\$245 per month] “doesn’t look too different” than what the state currently pays with a rebate, said Medicaid Director Meghan Groen.”); Stacie B. Dusetzina & Rachel E. Sachs, *Insurance Coverage and Pricing of Weight-Loss Drugs in the United States*, 394 NEW ENG. J. MED. PERSPECTIVE 105-107 (2025).

⁹⁰ Rebecca Robbins, Margot Sanger-Katz, & Dani Blum, *Obesity Drugs May Drop to as Little as \$149 a Month*, N.Y. TIMES (Nov. 6, 2025), <https://www.nytimes.com/2025/11/06/health/obesity-drug-prices-trump.html> (“Starting around the middle of next year, Medicare and Medicaid’s costs for the injectable drugs will drop to \$245 a month. That coverage will be for people who meet certain medical criteria, like having moderate or severe obesity. People can also have mild obesity accompanied by kidney disease, heart failure or uncontrolled hypertension. Or they can have a body mass index of 27 alongside prediabetes or established cardiovascular disease.”).

⁹¹ *Id.*

Medicare alone, estimated savings from generic competition to Ozempic, Mounjaro, Rybelsus, and Wegovy as currently covered under Medicare Part D over the first two years of competition would be \$8.07 billion.⁹² Notably, generic competition would deliver more substantial savings than the currently proposed plan to lower prices through the CMS demonstration model. If the \$245 price associated with Novo Nordisk's and Eli Lilly's voluntary agreements with the Administration were made available across all plans, the resulting savings would be \$3.26 billion less than savings from generic entry.⁹³ In addition to currently covered indications, the Trump Administration has proposed expanding coverage for GLP-1s for weight loss in Medicare through a voluntary CMS model. In a scenario in which the proposal to adjust coverage and pricing through the model were taken up across all Medicare Part D plans and included coverage for all patients for whom the drugs are indicated by the FDA, generic competition to Wegovy and Zepbound for just 25% of patients eligible solely for overweight and obesity would result in an estimated \$8.09 billion in savings compared to the same uptake at the voluntary agreement price and \$16.1 billion in savings at 50% uptake.⁹⁴

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

⁹² Based on estimates of net spending for Ozempic, Wegovy, Rybelsus, and Mounjaro using 2024 Medicare Part D spending data. Net spending estimated based on estimated rebates for endocrine metabolic agents published by GAO (for Ozempic, Wegovy, Rybelsus, we went a step further to estimate spending at the Medicare-negotiated "maximum fair price"). Estimate assumes that generic options cost \$100 per month and that there is 66.1% uptake of generics and 82.7% uptake of generics in the first and second year of generic competition, respectively. This calculation reflects spending based on medically-accepted indications in Medicare Part D in 2024. Zepbound is excluded as the only accepted indication (sleep apnea) had been approved for less than a month of the reporting period. The GAO data used to estimate net prices are from 2021 as this was the most recent data available. Differences between the estimated net price here and the actual net price paid by Medicare will impact this analysis. Benjamin N. Rome, ChangWon C. Lee, Joshua J. Gagne, & Aaron S. Kesselheim, *Factors Associated With Generic Drug Uptake in the United States, 2012 to 2017*, 24 VALUE HEALTH 804 (2021) (showing that experts have found that in the first year of generic competition for a drug, there is 66.1% uptake of generics; in the second year, uptake of generics increases to 82.7%).

⁹³ This assumes all plans provide coverage for these drugs at the voluntary agreement price. In the likely scenario that fewer than 100% of plans opt in to the proposed coverage and pricing demonstration, savings would be significantly less. For example, if half of projected spending were at the voluntary agreement price and the other half left unchanged, savings would be halved, resulting in about \$5.6 billion less in savings compared to savings that could be generated in a scenario of increasing generic uptake. The GAO data used to estimate net prices are from 2021 as this was the most recent data available. Differences between the estimated net price here and the actual net price paid by Medicare will impact this analysis.

⁹⁴ Based on estimates of net spending for Wegovy and Zepbound if 25% and 50% of Medicare beneficiaries eligible for anti-obesity medications solely for overweight and obesity (about 12.5 million total beneficiaries, according to the Congressional Budget Office) used these drugs for weight management. Estimate assumes that generic options cost \$100 per month, there is 66.1% uptake of generics and 82.7% uptake of generics in the first and second year of generic competition, respectively, and baseline spending for comparison is \$245 per month.; CONG. BUDGET OFF., HOW WOULD AUTHORIZING MEDICARE TO COVER ANTI-OBESITY MEDICATIONS AFFECT THE FEDERAL BUDGET? (Oct. 2024), <https://www.cbo.gov/system/files/2024-10/60441-medicare-coverage-obesity.pdf>.

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.⁹⁵

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.⁹⁶ 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.⁹⁷

In modern cases, reasonable compensation under § 1498 has consistently been determined to be a reasonable royalty payment and not "lost profits."⁹⁸ 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."⁹⁹ Experts suggest that reasonable royalty rates in § 1498 cases rarely exceed 10% of the third-party manufacturers' sales.¹⁰⁰ Previously, some courts have also ruled that reasonable compensation should reflect development costs plus a reasonable return on investment.¹⁰¹

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.¹⁰² The federal government even repeatedly used the law in the 1960s to

⁹⁵ 28 U.S.C. § 1498.

⁹⁶ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 279-80 (2017).

⁹⁷ *Id.* at 302, 330-31.

⁹⁸ *Id.* at 311.

⁹⁹ *Id.* at 313.

¹⁰⁰ 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*, 43 YALE J. L. & TECH. 1, 45 n. 194 (2020).

¹⁰¹ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 314-315 (2017).

¹⁰² *Id.* at 302.

buy low-cost generic versions of patented drugs.¹⁰³ 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.¹⁰⁴ 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.¹⁰⁵ 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.¹⁰⁶ 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-Moderna COVID-19 vaccine.¹⁰⁷

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.¹⁰⁸

Invoking 28 U.S.C. § 1498 to Contain the Unprecedented Costs from Novo Nordisk's Semaglutide Products and Eli Lilly's Tirzepatide Products

The Trump Administration can secure historic savings to public programs by using § 1498 to authorize generic competitors for semaglutide and tirzepatide, as researchers at Yale University and Harvard Medical School have articulated.¹⁰⁹ There are no special administrative or legal

¹⁰³ *Id.* at 302-306.

¹⁰⁴ *Id.* at 303.

¹⁰⁵ 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>.

¹⁰⁶ 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>.

¹⁰⁷ 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>.

¹⁰⁸ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 279-80, 302, (2017).

¹⁰⁹ 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

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.¹¹⁰ 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 contract.¹¹¹ Even a blanket authorization statement for firms to produce the generics under § 1498 would be sufficient.¹¹²

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 semaglutide and tirzepatide products 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 § 1498.¹¹³

For Medicaid, CMS would enter a rebate agreement with a manufacturer of generic versions of semaglutide and tirzepatide, which is a precondition of reimbursement of the medicines by Medicaid.¹¹⁴ The agency would include in the rebate agreement an express authorization and consent clause.¹¹⁵ Given the multiple entities and complexity involved in the 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 semaglutide and tirzepatide under § 1498, such that CMS assumes liability for infringement claims.¹¹⁶ 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.¹¹⁷

Finally, for Medicare, CMS would issue letters to the generic manufacturers invoking § 1498 and

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/>.

¹¹⁰ Christopher Morten & Charles Duan, *Who’s Afraid of Section 1498: A Case for Government Patent Use 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.”)).

¹¹¹ 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...”).

¹¹² 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*, 43 YALE J. L. & TECH. 1, 92 (2020)).

¹¹³ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 346-348 (2017).

¹¹⁴ *Id.* at 349.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

assuming infringement liability for the provision of generic versions of semaglutide and tirzepatide to its beneficiaries.¹¹⁸ 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.¹¹⁹ Like with Medicaid, CMS would publish public statements that third parties involved in procurement and distribution of medicines to Medicare enrollees, including wholesalers, pharmacy benefit managers, and pharmacies, are authorized to supply beneficiaries with generic semaglutide and tirzepatide under § 1498 and that CMS will assume liability for claims of infringement.¹²⁰

To date, several firms have sought to produce generic equivalents to Ozempic, Wegovy, and Rybelsus and have submitted Abbreviated New Drug Applications (ANDAs) to the FDA to obtain approval for generics.¹²¹ According to the FDA's database, nine ANDAs for Ozempic, one ANDA for Wegovy, and two ANDAs for Rybelsus have been filed.¹²² Generics companies will likely submit ANDAs for tirzepatide beginning in May 2026, as this coincides with the earliest date that a generic applicant for a drug containing a new chemical entity can file.¹²³ Under § 1498, the Trump 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 in the U.S. (including Mylan, Rio, Sun, Zydus, Apotex, & Dr. Reddy's for semaglutide),¹²⁴ for provision to beneficiaries of Medicare, Medicaid, and direct federal purchasers.

Notably, Apotex and Dr. Reddy's are among several generics manufacturers that are preparing to launch generic versions of semaglutide this year in Canada, as soon as Canada's regulatory authority approves the drugs.¹²⁵ Unlike in the U.S. where the main compound patent covering semaglutide has been extended by over five years beyond the standard 20-year term of protection,¹²⁶ patent and regulatory exclusivities on Ozempic and Wegovy in Canada had expired

¹¹⁸ *Id.* at 349-50.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ Novo Nordisk, Form 20-F (Feb. 5, 2025), at 7.

¹²² *Paragraph IV Certifications: January 5, 2026*, FOOD & DRUG ADMIN, <https://www.fda.gov/media/166048/download> (last visited Jan. 31, 2026).

¹²³ *See*, 21 C.F.R. § 314.108(b)(2).

¹²⁴ *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>; Complaint, *Novo Nordisk, Inc. v Apotex Inc.*, Case No. 1:24-cv-09729 (D.N.J. Oct 10, 2024).

¹²⁵ Health Canada, Generic submissions under review, <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/generic-submissions-under-review.html> (last visited Jan. 23, 2026) (other applicants include Sandoz Canada, Teva Canada, Taro Pharmaceuticals, and Aspen Pharmacare Canada); Abhijeet Singh, *Dr Reddy's expects to launch Semaglutide generic in Canada by May*, THE ECONOMIC TIMES (Jan. 22, 2026), <https://pharma.economictimes.indiatimes.com/amp/news/pharma-industry/dr-reddys-expects-to-launch-semaglutide-generic-in-canada-by-may/127139141>.

¹²⁶ I-MAK, THE HEAVY PRICE OF GLP-1 DRUGS (2025), <https://www.i-mak.org/wp-content/uploads/2025/04/The-Heavy-Price-of-GLP-1-Drugs.pdf>.

by early January 2026, paving the way for price-lowering generic competition.¹²⁷ Generics are expected to launch at prices as low as 100 Canadian dollars (equivalent to about \$73) per month.¹²⁸ Novo Nordisk is itself expected to launch cheaper versions of Ozempic and Wegovy (the same drugs under new names) priced to be competitive with generics.¹²⁹

Pursuant to the terms of § 1498, Novo Nordisk or Eli Lilly would not be able to obtain injunctive relief to prevent generics firms from supplying 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.¹³⁰ 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.¹³¹ 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.¹³² Manufacturers have indicated that they could introduce generic versions of Ozempic in the U.S. for less than \$100 per month.¹³³ Through licensing generic competition, the public stands to save billions of dollars.

Two additional issues may be considered and overcome to accelerate the benefits of using § 1498's authority to license generics of semaglutide and tirzepatide. First, when manufacturers try to obtain approvals for a generic via filing ANDAs, the generic manufacturer must certify that current patents listed with the brand name drug in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) are invalid, unenforceable, or not

¹²⁷ Chris Hannay, *Health Canada approval backlog expected to push back arrival of generic Ozempic*, THE GLOBE & MAIL (Nov. 20, 2025), <https://www.theglobeandmail.com/business/economy/article-health-canada-approval-backlog-expected-to-push-back-arrival-of/>; Derek Lowe, *Novo Nordisk's Canadian Mistake*, SCIENCE (June 10, 2025), <https://www.science.org/content/blog-post/novo-nordisk-s-canadian-mistake>; Kelly Grant & Chris Hannay, *Novo Nordisk prepares new cheaper version of Ozempic as generics face delays*, THE GLOBE & MAIL (Jan. 5, 2026), <https://www.theglobeandmail.com/canada/article-ozempic-cheaper-version-novo-nordisk-health-canada-generics/>.

¹²⁸ Amina Zafar, *Cheaper obesity medications could come to Canada this summer, as Health Canada reviews generics*, CBC (Jan. 6, 2026), <https://www.cbc.ca/news/health/ozempic-glp1-health-canada-generic-9.7034498>.

¹²⁹ Kelly Grant & Chris Hannay, *Novo Nordisk prepares new cheaper version of Ozempic as generics face delays*, THE GLOBE & MAIL (Jan. 5, 2026), <https://www.theglobeandmail.com/canada/article-ozempic-cheaper-version-novo-nordisk-health-canada-generics/>.

¹³⁰ 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).

¹³¹ Chintan Dave, Abraham Hartzema, & Aaron Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. CORRESPONDENCE 2597 (2017).

¹³² *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 Jan. 21, 2026).

¹³³ Press release, Senator Bernie Sanders, Sanders Announces Generic Pharma Companies Willing to Sell Ozempic for Less than \$100 (Sept. 17, 2024), <https://www.sanders.senate.gov/press-releases/news-sanders-announces-generic-pharma-companies-willing-to-sell-ozempic-for-less-than-100/>.

infringed by the generic product (called a “paragraph IV certification”).¹³⁴ 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.¹³⁵ 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.¹³⁶ 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.¹³⁷

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.¹³⁸ Therefore, the automatic 30-month stay for approving these ANDA applications, extended by the 7.5-year provision, elapsed in May 2025. Mylan filed a second ANDA for the highest dose of Ozempic and Novo Nordisk amended its complaint accordingly in March 2023.¹³⁹ Accordingly, if a 30-month stay is triggered by Mylan’s second ANDA and subsequent receipt of notice by Novo Nordisk on February 10, 2023,¹⁴⁰ the FDA could approve Mylan’s ANDA for the highest dose as of August 2025. Mylan also filed an ANDA with paragraph IV certifications for Wegovy that Novo Nordisk received notice of in December 2022.¹⁴¹ A 30-month stay resulting from Novo Nordisk’s lawsuit in this case would have expired as of June 2025. Novo Nordisk also sued Apotex Inc after receiving an August 2024 notice of Apotex’s ANDA and paragraph IV certification regarding a generic version of Rybelsus.¹⁴² If a 30-month stay is triggered in this case, the stay would expire in February 2027. For tirzepatide, assuming the first ANDA applications are submitted in May 2026 (the earliest date that an ANDA with a paragraph IV certification can be submitted for the drug), and assuming Eli Lilly responds with an infringement suit, any corresponding stay would elapse in November 2029.

The Trump Administration does not have to wait to rein in Novo Nordisk’s and Eli Lilly’s abuses,

¹³⁴ *Paragraph IV Certifications: January 5, 2026*, FOOD & DRUG ADMIN, <https://www.fda.gov/media/166048/download> (last visited Jan. 11, 2026).

¹³⁵ *Id.*

¹³⁶ JOHN R. THOMAS, CONG. RES. SERV., *THE HATCH-WAXMAN ACT: A PRIMER* 7-8 (2016).

¹³⁷ 21 C.F.R. § 314.107(3)(i)(B).

¹³⁸ Novo Nordisk, Form 20-F (2024), at 7. Christopher Yasjejko, *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).

¹³⁹ 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.

¹⁴⁰ *Id.* at ¶ 39.

¹⁴¹ Complaint, *Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.*, 1:23-cv-00101, (D. Del. Jan 27, 2023).

¹⁴² Aruni Soni, *Novo Nordisk Sues Apotex to Block Generic Version of Rybelsus*, BLOOMBERG L. (Oct. 14, 2024), <https://news.bloomberglaw.com/ip-law/novo-nordisk-sues-apotex-to-block-generic-version-of-rybelsus>; Complaint, *Novo Nordisk, Inc. v. Apotex Inc.*, Case No. 1:24-cv-09729 (D.N.J. Oct 10, 2024).

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.¹⁴³ Engelberg explains, as have other experts, that manufacturers can state in their paragraph IV certification that the product of their application is intended only for use by the United States government.¹⁴⁴ 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.¹⁴⁵ Applying this same reasoning here, generic production of semaglutide and tirzepatide could commence immediately upon the dismissal of such lawsuits, so long as the barrier posed by exclusivities (discussed below) does not apply.

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.¹⁴⁶ Thus, generic manufacturers are typically barred from relying on such data for their abbreviated new drug applications for a specified period of time. For drugs containing a new chemical entity, exclusivity prevents generics firms from submitting applications for five years from the reference drug's approval, except that an application may be submitted after four years if it contains a certification of patent invalidity or noninfringement.¹⁴⁷ These exclusivities present another potential barrier to the generic production of semaglutide and tirzepatide. 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.¹⁴⁸

There is only one regulatory exclusivity that remains applicable to Ozempic; since a new indication to reduce the risk of worsening kidney disease and cardiovascular death in adults with type 2 diabetes and chronic kidney disease was granted in 2025, regulatory exclusivity for this use extends until January 1, 2028.¹⁴⁹ Thus, there are no regulatory exclusivities limiting approval

¹⁴³ 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*, 43 YALE J. L. & TECH. 1, 92 (2020)).

¹⁴⁴ *Id.* at 95; Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 343 (2017).

¹⁴⁵ *Id.*

¹⁴⁶ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 330 (2017).

¹⁴⁷ 21 U.S.C. § 355(c)(3)(E)(ii).

¹⁴⁸ 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).

¹⁴⁹ Food & Drug. Admin., Letter to Novo Nordisk Inc. (Jan. 28, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/209637Orig1s025ltr.pdf; Food & Drug. Admin., *Patent and Exclusivity for: N209637*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS,

of generics for any of the other approved uses or for any of the approved dosage forms of Ozempic (0.25, 0.5, 1, and 2 mg doses). Rybelsus has one regulatory exclusivity extending until October 17, 2028 for its cardiovascular-related indication.¹⁵⁰ For injectable 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).¹⁵¹ While the FDA could approve generic injectable Wegovy for weight management for adults in June 2024, the currently approved use covered under Medicare (to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight) is protected by exclusivity until March 2027.¹⁵² The most recently approved use (for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis with moderate to advanced liver fibrosis in adults) is protected by exclusivity until 2028.¹⁵³ There are no exclusivities currently listed for the oral form of Wegovy.¹⁵⁴

There is one regulatory exclusivity applicable to Mounjaro; since the drug was first approved in May 2022, new chemical entity exclusivity extends until May 2027.¹⁵⁵ In addition to the new chemical entity exclusivity, Zepbound is protected by three other exclusivities covering the drug's approval for weight management, updated labeling information, and the drug's use as a treatment for moderate to severe obstructive sleep apnea in adults with obesity until November 2026, October 2027, and December 2027, respectively.¹⁵⁶

One potential approach the Trump 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

https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=003&Appl_No=209637&Appl_type=N (last visited Dec. 30, 2025).

¹⁵⁰ Food & Drug Admin., *Patent and Exclusivity for: N213051*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=006&Appl_No=213051&Appl_type=N (last visited Jan. 10, 2026).

¹⁵¹ 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 (last visited Dec. 30, 2025).

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ Food & Drug Admin., *Patent and Exclusivity for: N218316*, 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=218316&Appl_type=N

¹⁵⁵ Food & Drug Admin., *Patent and Exclusivity for: N215866*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=007&Appl_No=215866&Appl_type=N (last visited Dec. 30, 2025).

¹⁵⁶ Food & Drug Admin., *Patent and Exclusivity for: N217806*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=217806&Appl_type=N (last visited Dec. 30, 2025).

applications.¹⁵⁷ 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.”¹⁵⁸ 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.”¹⁵⁹ An executive order buttressing the FDA’s discretion to approve generic equivalents from high-quality suppliers could also be beneficial.¹⁶⁰ 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 an abbreviated new drug application. Although this approach is less applicable to generic manufacturing of Ozempic and Rybelsus, given that the regulatory exclusivities have expired or expire soon, the Administration may consider this method for facilitating the generic production of Wegovy, Mounjaro, and Zepbound.

Therefore, we request that the Trump Administration begin taking all necessary and appropriate actions to procure generics of semaglutide and tirzepatide and supply them to beneficiaries of federal health programs to avert the ruinous financial consequences of Novo Nordisk’s and Eli Lilly’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,



Peter Maybarduk
Director, Access to Medicines Program
Public Citizen

cc:

The Honorable Mehmet Oz, Administrator for the Centers for Medicare & Medicaid Services
The Honorable Vince Haley, Director of the Domestic Policy Council
The Honorable Kevin Hassett, Director of the National Economic Council
Keith Bass, Assistant Secretary of Defense for Health Affairs
The Honorable Douglas A. Collins, Secretary of Veterans Affairs
Kevin E. Lunday, Commandant of the U.S. Coast Guard

¹⁵⁷ Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing*, 18 YALE J. L. & TECH. 275, 343-45 (2017).

¹⁵⁸ *Id.* at 344.

¹⁵⁹ *Id.* at 344-45.

¹⁶⁰ *Id.* at 345.