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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION,
1 Health Plaza
East Hanover, NJ 07936-1016,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services,
200 Independence Ave., SW
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244;

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,
200 Independence Ave., SW
Washington, DC 20201;

CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

Civil Action No. 23-14221

COMPLAINT

INTRODUCTION

1. This case challenges an unprecedented and unconstitutional attempt to compel the nation's drug manufacturers to sell their products at prices dramatically below their market value. Under the newly-established "Drug Price Negotiation Program" (the "Program"), enacted in the Inflation Reduction Act ("IRA"), manufacturers are forced to enter into a sham "negotiation" process, where they are obligated to accept a "maximum fair price" for their most popular drugs that is far below the prevailing market price—or else pay a draconian "tax" amounting to tens of billions of dollars. That remarkable forced-sale regime is unique in United States history, and far exceeds Congress's lawful authority. It constitutes, simultaneously: (1) an unconstitutional taking of private property, (2) an excessive fine that is wildly disproportionate to the punished conduct, and (3) an effort to compel misleading speech in violation of the First Amendment. Each of these constitutional defects alone would be enough to deem the Program unlawful. Taken together, they reflect a flagrant disregard of the constitutional limits on Congress's power. This Court's intervention is urgently needed.

2. The advances of modern medicine rest on the innovative efforts of pharmaceutical manufacturers to find and develop new treatments for disease. These manufacturers, including Plaintiff Novartis Pharmaceuticals Corporation and its affiliates (together, "Novartis"), spend massive sums every year on the research and

development processes that are necessary to discover and refine the miracle drugs that save lives and improve the quality of life for patients the world over. Every effort to develop a new drug is a shot in the dark: Most drugs in the research and development pipeline go nowhere; and even many of the drugs that proceed through a manufacturer's internal research and development phases will ultimately fail to win regulatory approval from pharmaceutical regulators in the United States and abroad. The few drugs that gain approval and make it to market are thus the ones that fund future research and development on the next set of drugs that will save and improve people's lives, including the research and development costs incurred for drug candidates that ultimately are unsuccessful.

3. This cycle of innovation only works if manufacturers can assume that they will receive the appropriate and prevailing market price for the handful of products that actually succeed. In other words, manufacturers must be able to trust that they will receive a predictable, market-based return for their drug advancements.

4. In keeping with that principle, the federal government—one of the world's largest health-insurance providers and the world's leading indirect purchaser of pharmaceutical drugs through its administration of Medicare—has always paid prevailing market rates for the pharmaceutical drugs it obtains through Medicare. That approach not only reflects the United States' enduring commitment to free-market principles; it reflects a deep concern that, if the government used its coercive

power to force sales at below-market rates, the result would be to fundamentally imperil the research, development, and supply of essential, life-saving drugs.

5. In the recently enacted IRA, however, Congress upended this longstanding framework. Through the IRA's new Drug Price Negotiation Program, Congress instructed the Centers for Medicare and Medicaid Services ("CMS") to pay no more than a fraction of the market value for particular manufacturers' most popular and widely used drugs, which CMS then wrongly deems the "maximum fair price." While the IRA attempts to wrap Congress's scheme in the mantle of "market" pricing and "negotiation," these terms are empty: CMS is directed to drive prices as low as it can, and to set whatever price *CMS* (in its unfettered discretion) determines is "fair." That price is then imposed on the manufacturer without any process for appeal to a neutral third party. And if a manufacturer does not like the price that CMS sets for a particular drug, it cannot just walk away—instead it must pay an "excise tax" that escalates quickly to *nineteen times* the revenues derived from that drug. For Novartis, that tax would amount to approximately $44.65 billion—a figure almost as large as all of Novartis's gross worldwide net sales, and undoubtedly the largest single corporate tax bill paid in United States history. No company could ever realistically pay such a penalty, as Congress itself has acknowledged. *See* Congressional Budget Office, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con.

Res. 14, at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf (predicting that this "tax" would raise exactly zero dollars). The only possibility is for the manufacturer to sell its products at whatever price the government deems "fair"—which could be a $1 or a penny, if the government demands.

6. Worse still, the scheme compels manufacturers to enter into a sham "negotiation" and assent to the description of the government-imposed rate as a "maximum fair price." In other words, Congress deliberately sought to disguise its forced-sale regime as the product of marketplace dynamics by compelling manufacturers to describe the program in ways that are patently false. In reality, Congress's program for dictating the price of pharmaceutical drugs bears no resemblance to marketplace "negotiation," nor are companies "agreeing" to participate in it of their own volition; it is a mandate that manufacturers sell their drugs to the government at a price of the government's choosing, or else pay a fine that would bankrupt the company.

7. This forced-sale regime deprives manufacturers of a market price for the few drugs that actually make it to market. This, in turn, harms pharmaceutical innovation and reduces the public's access to lifesaving drugs. The Congressional Budget Office's ("CBO") own estimate finds that the Program will prevent the development of numerous lifesaving drugs over the coming decades, *see* Estimated

Budgetary Effects of Public Law 117-169, at 15, although even that projection grossly underestimates the true extent of the future impact to innovation. Indeed, in a direct response to the IRA's price controls, numerous drug manufacturers have already announced cuts to their drug development pipelines. *See, e.g.*, Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because of Medicare Price Negotiations*, Barron's (May 19, 2023), https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7; Steve Usdin, *AstraZeneca May Defer U.S. Cancer Drug Launches in Response to IRA*, Biocentury (Nov. 10, 2022), https://www.biocentury.com/article/645834/astrazeneca-may-defer-u-s-cancer-drug-launches-in-response-to-ira; Deena Beasley, *Focus: Drug Companies Favor Biotech Meds Over Pills, Citing New U.S. Law*, Reuters (Jan. 13, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/drug-companies-favor-biotech-meds-over-pills-citing-new-us-law-2023-01-13/.

8. The Program is thus unconstitutional in three distinct ways. First, it effects a physical taking of private property for public use without just compensation, in violation of the Fifth Amendment. Pharmaceutical manufacturers are forced to surrender their private property, which will be physically taken for the federal government's public use, to Medicare beneficiaries at below-market prices. In a genuine price-control program—in which the government sets prices that

manufacturers may charge for certain goods or services—the seller maintains the freedom not to sell. Here, by contrast, Congress has established a regime that effects a requisition rather than a price control—it *compels* below-market sales by requiring that the seller provide access to its drug to Medicare beneficiaries at prices the government dictates. And these compelled sales do not provide manufacturers like Novartis with the just compensation the Fifth Amendment requires. To the contrary, under the Program, CMS is expressly *forbidden* from paying the market value of patented drugs like Novartis's ENTRESTO®. Instead, manufacturers like Novartis will be deprived of at least a quarter of the market value of their private property upon the seizure of that property by the government—and almost certainly far more. These forced transfers of property at far below-market rates violate the Fifth Amendment.

9. Second, the Program imposes massive penalties on any pharmaceutical manufacturer that refuses to go along with CMS's imposition of its claimed "maximum fair price" for a particular drug; those penalties take the form of an "excise tax" running up to *nineteen times* the manufacturer's nationwide revenues from the sale of the drug. This purported "tax" is so plainly punitive that the government itself does not anticipate deriving *any* revenue from it—because no manufacturer would or could ever pay it. The "excise tax" is really a civil fine for refusal to participate in the government's scheme; and that fine is so wildly

disproportionate that it falls afoul of the Eighth Amendment's Excessive Fines Clause.

10. Third, the Program forces pharmaceutical manufacturers to espouse views with which they fundamentally disagree as a condition of doing business with the United States government. Under the Program, Congress not only empowered CMS to set its preferred "maximum fair price" for each and every drug subject to the Program; it also forced CMS's counterparties (the manufacturers) to say that they agree that this is a negotiation; that the price set by CMS is "fair"; and that it is actually the "maximum fair price," and thus that the market-based prices that the manufacturer is currently charging are unfair—all of which are propositions with which Novartis vehemently disagrees. But the government cannot compel participants in a government program to profess specific views that they do not hold as a condition of participation in the program. *See Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 220 (2013) (requiring federal program participants to "pledge allegiance to the Government's policy" violates the First Amendment).

11. This ill-conceived and unconstitutional scheme will harm pharmaceutical innovation, and reduce the public's access to lifesaving drugs. And the government cannot then be allowed to conscript Novartis to deliver a political message with which Novartis disagrees, and which wrongfully shifts accountability

to manufacturers for those harmful consequences, including any resulting scarcity of innovative drugs. Because the Program far exceeds Congress's lawful authority, it must be struck down.

PARTIES

12. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey. Novartis Pharmaceuticals Corporation and its affiliates (together, "Novartis") invest billions of dollars every year to bring innovative medicines to market in order to enhance health outcomes for patients.

13. Novartis manufactures, sells, and is the New Drug Application holder for ENTRESTO®. ENTRESTO® is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

14. Defendant United States Department of Health and Human Services ("HHS") is an executive department of the United States Government headquartered in Washington, D.C. HHS is responsible for administering the Medicare program and the relevant statutory provisions challenged here.

15. Defendant Xavier Becerra is the Secretary of HHS. Secretary Becerra (or "Secretary") oversees the Medicare program and is responsible for administering the relevant statutory provisions challenged here. He is sued in his official capacity only.

16. Defendant Centers for Medicare and Medicaid Services ("CMS") is an administrative agency within HHS that is headquartered in Baltimore County, Maryland, and which administers the Medicare program, including the Program, with respect to which it has issued implementation guidance.

17. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Administrator Brooks-LaSure administers the Program on behalf of the Secretary. She is sued in her official capacity only.

JURISDICTION AND VENUE

18. The Court has jurisdiction under 28 U.S.C. § 1331 (civil action arising under the laws of the United States) and 28 U.S.C. § 1346 (claims against the federal government). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 703-06. Equitable relief is also authorized under this Court's inherent powers.

19. Sovereign immunity poses no bar to this action for declaratory and injunctive relief. *Id.* § 702.

20. There is a live controversy between the parties. Novartis's drug ENTRESTO® was selected by CMS on August 29, 2023 and is now subject to the Program. Other Novartis drugs will follow in subsequent years.

21. Venue is proper in this district under 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities, and Novartis's corporate headquarters is located within this District.

FACTUAL ALLEGATIONS

A. Market-Based Pricing For Pharmaceutical Drugs Is Critical To Making Pharmaceutical Innovation Possible

22. Novartis is one of the world's leading pharmaceutical companies. It deploys cutting-edge research to address some of society's most challenging healthcare problems. Novartis's mission is to develop new, high-value medicines that transform the treatment of diseases across many therapeutic areas with high unmet patient needs. Its medicines treat major diseases from cancer to heart disease to rare genetic disorders, and are distributed in approximately 140 countries around the world. Among Novartis's lifechanging drugs is ENTRESTO®, a medicine for heart failure that helps improve the heart's ability to pump blood to the body. ENTRESTO® contains two active ingredients that work in different—and innovative—ways. The first, valsartan, has been used for years to treat heart failure. But the second, sacubitril, works unlike any existing heart failure treatment to relax blood vessels and decrease sodium and fluid in the body. Sacubitril cannot be found

in any other medication. The combination of these two ingredients represents a significant innovation and advance in the treatment of heart failure.

23. ENTRESTO® is now included as a treatment option for the majority of patients with heart failure. In 2022, ENTRESTO® registered global net sales of $4.6 billion, up 37% from the prior year. ENTRESTO® provides a 20% relative risk reduction of cardiovascular death compared to patients receiving other heart failure medications. ENTRESTO® has helped 1.7 million United States heart failure patients, including approximately 400,000 Medicare beneficiaries.

24. Developing a lifesaving drug such as ENTRESTO® entails enormous investments in time and expenses—on average, it takes nearly $3 billion, and ten to fifteen years, to develop just one new medicine. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016). Accordingly, Novartis makes significant investments to support its research and development focus. In 2022 alone, Novartis invested $10 billion in research and development, an increase from $9.5 billion in the prior year. Approximately 21,000 Novartis employees work in research and development—around one fifth of its total workforce. Over 5,000 of these research and development employees are located in the United States.

25. Given the nature of pharmaceutical research and the complexity of the regulatory process, the development of new drugs such as ENTRESTO® requires

Novartis to invest great sums and time with no guarantee of a return on that investment. Most drugs never even secure FDA approval. *See* Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004) (approximately one in 5,000 compounds that start preclinical testing will receive FDA approval); *see also Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1303 (11th Cir. 2021) ("The process of submitting [a drug application] is both onerous and lengthy, and it involves significant risk and expense." (citations omitted)).

26. And even where Novartis does secure approval, few drugs provide an economic return significant enough to allow for continued innovation. *See* John A. Vernon & Joseph H. Golec, Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence 7 (2008) (of approved treatments, only approximately one-third earn enough to cover their development costs).

27. The federal government acts as one of the world's largest health insurers and as the largest indirect purchaser of pharmaceutical drugs in its capacity as the administrator of Medicare, which provides healthcare for senior citizens in the United States. The federal government thus plays a pivotal role in the market for pharmaceutical drugs.

28. The Medicare program includes two parts of significance here. The first, Medicare Part B, insures Medicare beneficiaries with respect to a wide variety

of outpatient healthcare services, including coverage for drugs administered by physicians. *See* 42 U.S.C. § 1395k(a)(1); *id.* § 1395x(s)(2)(A). Under Medicare Part B, manufacturers sell medications to physicians, and the government reimburses the physicians for the costs of acquiring and administering the drug.

29. The other relevant part of the Medicare program, Medicare Part D, permits patients to choose from a variety of private insurance plans providing coverage for self-administered drugs (such as orally ingested pills and self-administered injections). These plans are offered by private insurers under contracts with the government. To determine which private insurers receive government contracts, the government assesses and awards contracts based on bids that estimate the costs the private plans anticipate incurring to provide their drug coverage. *See* Ryan Knox, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 Yale J. Health Pol'y L. & Ethics 191, 205 (2020).

30. Until Congress's passage of the IRA, both parts of the Medicare program relied on market-based pricing. Medicare Part B reimbursement was based on a drug's average sales price, which ensured that reimbursement tracked market prices. *See* 42 U.S.C. § 1395w-3a. And when Congress enacted Medicare Part D, it expressly prohibited HHS from "[i]nterfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of

Part D drugs in order to ensure that market forces drove pricing. *Id.* § 1395w-111(i). Historically, plan sponsors "can and do negotiate prices with prescription drug manufacturers," and have market incentives to secure lower pharmaceutical prices. Knox, at 206-07.

31. To date, the United States' market-based approach to determining the federal government's pharmaceutical reimbursements has helped enable Americans to reap the full rewards of Novartis's and other manufacturers' pharmaceutical innovation. For example, patients in the United States had access to 89% of new active substances that entered the market between 2011 and 2018, while patients in certain other developed countries had, on average, access to fewer than 50% of new active substances during the same period. *See* Doug Badger, *Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access* 15 (2019), https://galen.org/assets/Badger-Report-March-2019.pdf.

B. The Inflation Reduction Act Upends Market-Based Pricing And Threatens Innovation

32. The IRA's new "Drug Price Negotiation Program" topples the prior market-driven approach that has long encouraged innovation and ensured that Americans have access to new drug therapies. But rather than acknowledge that it directly sets prices and compels sales, the Program cloaks its price controls in a process of sham "negotiations" with manufacturers that take place in the shadow of

devastating penalties if manufacturers do not comply. Not only does the statute compel manufacturers such as Novartis to agree to the government's price, it also forces them to endorse those prices as the "maximum fair prices" for their drugs.

33. The Program functions in the following way. First, through authority HHS has delegated to it, *see* 88 Fed. Reg. 1390 (Jan. 10, 2023), CMS selects the drugs that are subject to the Program. Starting in 2023, CMS must rank single-source (*i.e.*, "brand") "negotiation-eligible drugs" based on total Medicare expenditures over the prior twelve-month period. 42 U.S.C. § 1320f-1(b)(1)(A). Congress directed that the drugs involving the greatest Medicare expenditures be ranked highest. *Id.* § 1320f-1(b)(1)(B).

34. Once the negotiation-eligible drugs have been ranked, CMS must select several of the highest-ranked drugs for negotiation. That selection mechanism ensures that a manufacturer's most valuable and widely used drugs are targeted. These are precisely the products that manufacturers like Novartis depend on to fuel ongoing investments in the research and development of new medicines.

35. Starting in 2023, ten Part D drugs will be selected, with maximum fair prices going into effect in 2026. *Id.* § 1320f-1(a)(1). That number will increase in subsequent years, with fifteen additional Part D drugs subject to the maximum fair price in 2027, fifteen additional Part D and B drugs in 2028, and twenty additional Part D and B drugs in 2029 and each year after that one. *Id.* §§ 1320f-1(a)(1)-(4),

1320f-1(b)(1)(A). These selections are cumulative: once a drug has been selected, it remains subject to the Program unless the agency determines a generic has been approved and the generic's manufacturer is "engaging in bona fide marketing" under a "totality-of-the-circumstances" inquiry. *Id.* § 1320f-1(c)(1); Revised Guidance, Implementation of Sections 1191–1198 of the Soc. Sec. Act for Initial Price Applicability Year 2026 164-66 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("Revised Guidance").

36. On August 29, 2023, CMS released its list of drugs that were selected for 2023. Novartis's ENTRESTO® was included on the list and is accordingly subject to the negotiation process.

37. Once a drug is chosen for inclusion on the list, the manufacturer has just 30 days to enter into an initial "agreement" with CMS. 42 U.S.C. §§ 1320f(d)(2)(A), 1320f-2(a). That agreement binds the manufacturer to participation in the Program's "negotiation" process and compels it to "agree" that the price CMS eventually chooses—whatever that price is—is the "maximum fair price" for the drug. *Id.*

38. Manufacturers have no say over the contents of their initial agreements with CMS. Instead, CMS unilaterally dictates the contents of these agreements, and manufacturers are forced to sign these initial agreements without modification.

39. Unlike in a real negotiation, manufacturers cannot simply refuse CMS's unilaterally drafted contract terms. If a manufacturer refuses to sign the initial agreement by the statutory deadline, the Program imposes a swiftly increasing penalty based on all United States sales of the listed drug (not merely Medicare sales), which the Program terms an "excise tax." 26 U.S.C. § 5000D(b).

40. The penalty is designed to force a manufacturer to enter into the agreement even if it would not have done so voluntarily. The penalty is based on a formula for an "applicable percentage," which begins at 65% of the drug's total price and increases by 10% for each quarter the manufacturer is out of compliance until it reaches 95% of the total price. *Id.* § 5000D(d). Under the statutory formula, the penalty is "an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold." *Id.* § 5000D(a). Applying that statutory formula, for a drug sold for $100 and subject to the 65% applicable percentage, the penalty would be $186 (or 186% of the "pre-tax" price) per sale. Once that percentage goes up to 95%, the penalty would be $1,900 per sale—1,900% of the drug's daily revenue. *See* Cong. Rsch. Serv., Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) 4 tbl. 2, R47202 (2022) ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance.").

41. In order to escape the Program and its gargantuan penalties, a manufacturer would need to exit Medicare and Medicaid entirely—not merely for the selected drug, but for *all* of its drugs. *See* 26 U.S.C. § 5000D(c) (purporting to "suspend[]" the Program's penalty for days when "none of the drugs of the manufacturer" is covered by Medicare or Medicaid). However, at least for the first year of the Program, it is legally impossible for a manufacturer to do so: The Medicare statute delays a manufacturer's ability to exit from Part D of Medicare for between 11 and 23 months after the manufacturer terminates its agreements with CMS. *See* 42 U.S.C. § 1395w–114a(b)(4)(B)(ii); *see also infra* at 43 ¶ 90.

42. Once a manufacturer has been given a Hobson's choice between entering into an initial "negotiation" agreement or incurring ruinous monetary penalties, and has chosen the only real path available to it ("negotiation"), the manufacturer then has little say in the "negotiation" process that follows. Manufacturers are forced to provide all "information that [CMS] requires to carry out the negotiation." *Id.* § 1320f-2(a)(4)(B). If a manufacturer fails to provide a piece of information that CMS deems required, it is subject to a civil monetary penalty of $1,000,000 for each day that it is in violation, whether or not it knowingly failed to provide such information. *Id.* § 1320f-6(c).

43. Following submission of that information, a coercive process unfolds, at the end of which CMS has the unfettered discretion, unchecked by any processes

of administrative or judicial review, to set a "maximum fair price." *Id.* § 1320f-7. CMS unilaterally announces the price it has selected as the "maximum fair price," along with a "concise justification." *Id.* § 1320f-3(b)(2)(B). The Program provides no floor below which CMS may not set the price—with the limited exception of a small, time-limited floor for certain small biotech manufacturers not relevant here. *Id.* §§ 1320f-3(c), 1320f-3(b)(2)(F)(ii). Further, there appears to be no mechanism by which manufacturers can request the information that manufacturers believe is relevant be considered by CMS or included in that explanation. Revised Guidance at 69 ("CMS does not intend to share the explanations of the [maximum fair price] with manufacturers before releasing the explanations to the public."). Every manufacturer is forced to accept CMS's price or face devastating penalties.

44. The law does not limit how low a price CMS can demand, nor does it provide a clear standard for the agency to use in setting prices. But it does impose a ceiling on how *high* a price CMS can set. Under the Program, CMS is directed to use as the ceiling price the lowest number produced by two specified statutory methods. 42 U.S.C. § 1320f-3(c)(1)(A); *see id.* § 1320f-3(b)(2)(F). These methods are expressly designed to yield prices that are well below market value. One method directs CMS to calculate the ceiling by discounting the drug's non-federal average manufacturer price ("non-FAMP")—that is, the actual market price paid by buyers other than the federal government. *Id.* § 1320f-3(c)(1)(C). Under this method, the

price *ceiling* for pharmaceutical drugs purchased by Medicare would run from only 75% of the average non-FAMP for certain drugs to only 40% for certain other drugs. *Id.*

45. The other method uses as the ceiling the average Part D net price from the most recent year for which data is available (so, for the first year of the Program, the 2022 price). *Id.* § 1320f-3(c)(2)(A); Revised Guidance at 138-39. This number does not take into account the inevitable inflation that will occur during the four years before sales under that price begin. And it is not adjusted to reflect the fact that the Part D net price generally reflects a significant discount from the market price in order to facilitate greater access to medicines for Part D beneficiaries. Of course, CMS is free to go below whichever ceiling applies—there is no floor. And doing so would be consistent with CMS's statutory directive to "achieve the lowest" possible price for each selected drug. 42 U.S.C. § 1320f-3(b)(1) (CMS must use a "methodology and process . . . that aims to achieve the lowest maximum fair price for each selected drug.").

46. The Program's provision for a manufacturer counteroffer does little to salvage the process. First, as noted above, regardless of what the manufacturer submits, CMS will still—at Congress's mandate—force the manufacturer to sell the government its product at a steep discount far below the fair market price. Next, unlike in a real negotiation, manufacturers are constrained in what factors they can

rely on to support their counteroffer. *See id.* §§ 1320f-3(b)(2)(C)(ii), 1320f-3(e). Noticeably absent from the list is any factor involving the extensive research and development costs associated with drugs that do not pan out as treatments, or the cost of future research and development. *See id.* § 1320f-3(e). The list also expressly ignores the sizeable investments made by manufacturers to develop new treatments. Finally, and more fundamentally, the statute does not even require CMS to seriously consider the counteroffer—indeed, the only directive is to "respond in writing to such counteroffer." *Id.* §§ 1320f-3(b)(2)(C)(ii)(I), 1320f-3(b)(2)(D). And the statutory factors that CMS is directed to consider do not include the amount of the manufacturer's counteroffer. *See id.* § 1320f-3(e).

47. The Program then imposes a date by which manufacturers must agree that CMS's demand is the "maximum fair price" for their drugs. For drugs subject to price caps in 2026, that date is August 1, 2024. *Id.* §§ 1320f(d)(5), 1320f-3(b)(2)(E). While CMS claims that manufacturers are bound to respond to CMS's "final offer" by "either accepting or rejecting [it]," Revised Guidance at 158, manufacturers cannot in reality "reject" CMS's offer and walk away as in a normal negotiation. If a manufacturer does reject CMS's final "maximum fair price" demand, it is subjected to the previously discussed, enterprise-destroying excise "tax" that starts at over 180% and runs up to 1900% (nineteen times) of the total revenue derived from sales of that drug in the United States. 42 U.S.C. § 1320f-

2(a)(1); 26 U.S.C. § 5000D; *see* Tax Provisions in the Inflation Reduction Act of 2022, at 29.

48. For Novartis, that would likely equate to a penalty as high as $44.65 billion. The statute does not specify whether the penalty is calculated using gross or net sales. But either way, the "tax" would be catastrophic. In 2022, ENTRESTO®'s net sales in the United States totaled $2.35 billion, which means that the penalty for not reaching an agreement would quickly rise to an annual rate of $44.65 billion—almost as large as Novartis's entire annual gross revenue.

49. No rational manufacturer could ever pay that penalty instead of accepting CMS's final "maximum fair price." Congress was well aware of this reality; in fact, the CBO projected that this "tax" would raise exactly zero dollars, since no manufacturer would ever be able to pay it. *See* Estimated Budgetary Effects of Public Law 117-169, at 5. The result then, as intended, is unfettered discretion for CMS to set whatever price it wants and force manufacturers to supply drugs at that price. Indeed, even if CMS were to set a drug's "maximum fair price" at a penny, any rational manufacturer would still be forced to accept that price over the alternative of paying (at a minimum) almost *double* that drug's daily sales revenue to the government. No matter how low the price set by CMS, there is no real choice.

50. Once manufacturers have been forced into asserting "agreement" to the government-dictated price, they are denied administrative or judicial recourse.

Congress's framework expressly bars *any* administrative or judicial review of "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(3).

51. The manufacturer then must provide "access" to its drug at the specified "maximum fair price" to a wide array of individuals and entities: all eligible individuals dispensed drugs under Medicare Part B and D; all "pharmacies, mail order services, and other dispensers" with respect to their dispensing of drugs to Medicare beneficiaries; and all "hospitals, physicians, and other providers of services and suppliers" with respect to their dispensing or administration of drugs to Medicare beneficiaries. *Id.* §§ 1320f-2(a)(1)(A)-(B), 1320f(c)(2). If a manufacturer does not do so, it is subject to civil monetary penalties at the extraordinary rate of ten times the amount of the alleged overcharge. *Id.* §§ 1320f-2(a)(1), 1320f-6(a)-(b). And this forced requisition continues indefinitely—with the only escape being the approval and marketing of a generic or biosimilar version of the drug that CMS unilaterally and with no stated parameters deems to be sufficiently marketed, *id.* § 1320f-1(c)(1), or CMS's selection of the drug for "renegotiation," again on CMS's sole terms, *id.* § 1320f-3(f).

52. The "negotiation" claimed by the Program, then, is not in reality a "negotiation" at all. Unlike in a genuine negotiation, manufacturers are compelled to participate in the process, compelled to provide any information (including proprietary and highly confidential information) that their counterparty demands for

it to use in that negotiation, compelled to base any counteroffer on a limited number of factors unilaterally designated by the counterparty, and ultimately compelled to accept whatever offer the counterparty settles on—or face intentionally ruinous penalties at every step. And, unlike a true negotiation, the seller has no right to walk away if it is unhappy with the price the buyer is willing to pay. That is not a negotiation in any sense of the word.

53. As noted, the compulsory nature of the "agreement" is confirmed by the government's own analysis. The CBO score for the IRA presumes that the excise tax itself will not generate *any* revenue. *See* Estimated Budgetary Effects of Public Law 117-169, at 5. And the Joint Committee on Taxation also concluded with regard to similar, predecessor legislation that the excise tax would have "no revenue effect." Joint Comm. on Taxation No. JCX42-21, Estimated Budget Effects of the Revenue Provisions of Title X–II - Committee on Ways and Means of H.R. 5376, Fiscal Years 2022-2031, at 8 (Comm. Print 2021), https://bit.ly/3plC4cd. This unequivocally shows that the "excise tax" targeting non-compliant manufacturers was never intended nor expected to raise any revenue, but instead to compel manufacturers to capitulate to the government's terms.

C. The Program Expropriates Novartis's Private Property Without Just Compensation In Violation Of The Fifth Amendment

54. The Program's compelled transfer of Novartis's drugs at a below-market price is a *per se*, physical taking of property because it deprives Novartis of its right to possess, use, and control the drugs it manufactures.

55. The Takings Clause prevents the government from taking "private property … for public use, without just compensation." U.S. Const. amend. V. Under the Takings Clause, the government may physically requisition private property for public benefit only if it pays the fair market value of that property.

56. Pharmaceutical drugs are "private property" protected by the Takings Clause. The drugs themselves are—until they are sold—the manufacturers' personal property, and are therefore protected from uncompensated takings. *See, e.g.*, *Horne v. Dep't of Agric.*, 576 U.S. 350, 358-59 (2015) ("[n]othing in [Anglo-American] history suggests that personal property was any less protected against physical appropriation than real property") (holding that raisins sold by farmers are property protected by the Takings Clause); *United States v. Gen. Motors Corp.*, 323 U.S. 373, 383-84 (1945) (recognizing that an owner's rights in personal property are "no less" than his rights in real property).

57. Novartis's patented pharmaceutical drugs, including ENTRESTO®, are also protected as a matter of intellectual property. A patent confers on the patentee "an exclusive property in the patented invention which cannot be

appropriated or used by the government itself, without just compensation." *Horne*, 576 U.S. at 359 (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)); *see also Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 & n.11 (1945) (collecting cases) ("That a patent is property, protected against appropriation both by individuals and government, has long been settled."); 35 U.S.C. § 261 (providing that "patents shall have the attributes of personal property").

58. The Program uses the threat of ruinous excise taxes to force Novartis and other targeted manufacturers to provide products such as ENTRESTO® to Medicare beneficiaries and those who buy drugs on their behalf at steeply discounted rates. 42 U.S.C. §§ 1320f(c)(2)(A), 1320f-2(a)(3); *see id.* § 1395w-114a(b)(1). Under the Program, Novartis *must* transfer its products to third parties at the dictated price; it cannot refuse to sell to them on those terms. *See id.* §§ 1320f(c)(2)(A), 1320f-2(a)(3); *see also id.* § 1395w-104(b)(3)(I).

59. That forced sale distinguishes the Program from a genuine rate-setting regime. When the government engages in true rate setting, the result is a regulatory cap on what the seller may charge *if* it chooses to sell its product. A challenge to that cap would properly be evaluated as a potential regulatory taking. But here, the statute goes much further. It does not merely set a price, allowing the seller to choose whether or not to sell. Instead, it compels the manufacturer to *provide access* to its

drug at that below-market price. In other words, it requisitions the manufacturer's property by *forcing it to sell.*

60. This compelled transfer is a *per se*, physical taking of property because it deprives Novartis of its "right 'to possess, use, and dispose of'" the drugs it manufactures. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (quoting *Gen. Motors Corp.*, 323 U.S. at 378); *Horne*, 576 U.S. at 364 (noting that "physical surrender … and transfer of title" differentiates a *per se* taking from a regulatory taking). Just as the statute in *Horne* effected a *per se* taking by requiring raisin farmers to turn over a portion of their crop to the government, reserving for the farmers only a contingent interest in resale proceeds, *see* 576 U.S. at 361-62, the Program's forced-sale regime does the same by compelling drug manufacturers to surrender their property to third parties for public use at below-market prices. Dressing up this expropriation as a "sale" does not change the fact that it is a *per se* taking of Novartis's property: For takings purposes, it does not matter how the government's seizure "comes garbed." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021).

61. Because the Program appropriates manufacturers' patented personal property for a public use, the government must pay "just compensation" equivalent to "the fair market value of the property at the time of the taking." *United States v. Reynolds*, 397 U.S. 14, 16 (1970) (citation omitted). But the Program actually

ensures that the government does *not* pay just compensation. By design, the Program compensates manufacturers at rates that are far below the actual "fair market value." The *ceiling*, which is the lowest number yielded by alternative calculations, itself results in a price well below fair market value. Under one calculation, CMS must extract at least a 25% discount (and almost certainly far steeper discounts) off of the average price paid by pharmaceutical drug buyers other than the federal government. *See* 42 U.S.C. § 1320f-3(c)(1)(C). In other words, CMS would force Novartis to turn over to the government a supply of ENTRESTO® at a minimum of 25% *less* than its current fair market value. That is, by definition, not just compensation. *See, e.g.*, *Horne*, 576 U.S. at 362-63 (answering "no" to the question "[w]hether the government may avoid the categorical duty to pay just compensation for a physical taking of property by reserving to the property owner a contingent interest in a portion of the value of the property, set at the government's discretion").

62. The same is true for the other "ceiling" arrived at by the alternative calculation. That method uses the average Part D net price from the latest year for which complete data is available—which, for the first year of the Program, is 2022—as the highest price CMS can offer. *See* 42 U.S.C. § 1320f-3(c)(2)(A); Revised Guidance at 138-39. But this number does not take into account inflation from the years between selection and implementation—which means Novartis would be

forced to sell ENTRESTO® in 2026 based on the unadjusted *2022* Part D net price. This alone guarantees that the price set by CMS will be below the fair market price. Nor is it adjusted to reflect the fact that the Part D net price generally reflects a significant discount from the market price already, in order to facilitate greater access to medicines for Part D beneficiaries. So this number necessarily does not reflect the fair market value of the drug itself, and thus cannot—as a matter of law—constitute just compensation either. And, of course, CMS is free to—and almost certainly will—go far below whichever ceiling applies given Congress's directive that CMS "achieve the lowest" possible price for each selected drug, 42 U.S.C. § 1320f-3(b)(1), with no floor and no prospect of judicial review, *id.* § 1320f-7.

D. The Program Imposes Unconstitutionally Excessive Fines

63. The Program is also invalid because the purported "excise tax" it mandates is in reality an excessive fine. In order to punish a manufacturer that fails to "agree" to the government's pricing scheme for a particular drug, the Program imposes an escalating "excise tax" beginning at 186% (1.86 times) and, after 271 days, reaching 1900% (19 times) of a drug's total national sales revenues. 26 U.S.C. § 5000D(b)(1)-(4). For ENTRESTO®, this would amount to a tax that begins at an annual rate of approximately $4.3 billion and that quickly reaches approximately $44.65 billion annually once the penalty has fully escalated. That punishment

violates the Constitution because it is grossly disproportionate to the "offenses" triggering the fine.

64. The Eighth Amendment bars the imposition of excessive fines. U.S. Const., amend. VIII. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). "Because 'sanctions frequently serve more than one purpose' … the Excessive Fines Clause applies to any statutory scheme that 'serv[es] *in part* to punish.'" *Tyler v. Hennepin Cnty.*, 143 S. Ct. 1369, 1381 (2023) (Gorsuch, J., concurring) (emphasis added) (quoting *Austin v. United States*, 509 U.S. 602, 610 (1993)); *see also Hudson v. United States*, 522 U.S. 93, 103 (1997).

65. In related contexts, courts have considered the size and purpose of a fine in determining whether it has a punitive character. *See Dep't of Revenue of Mon. v. Kurth Ranch*, 511 U.S. 767, 780 (1994) (holding, in the context of deciding whether imposition of a tax violated the Double Jeopardy Clause, that the tax was punitive because it amounted to eight times the market value of the product taxed, and was designed not only to raise revenue but also to facilitate anticrime initiatives). "A 'tax' that is five times the value of the item taxed," for example, "is remarkably

high and is more consistent with punishing ownership of the item than with raising revenue." *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004).

66. By these or any standards, the so-called "excise tax" imposed by the Program is harshly punitive. As noted above, the penalty begins at 186% of sales revenue, and if the manufacturer fails to accede to CMS's price demands within 271 days, the penalty escalates to fully *nineteen times* the manufacturer's nationwide revenues from the drug's sales, including its revenue from private sales that are wholly outside of the Medicare program. 26 U.S.C. § 5000D(d); *see also* Tax Provisions in the Inflation Reduction Act of 2022, at 4 ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance.").

67. That is not an "excise tax" in any meaningful sense of the term. In 2022, the federal government collected approximately $88 billion in total from *all* federal excise taxes. *Historical Tables* tbl. 2.1, President's Budget, Off. of Mgmt. & Budget, https://www.whitehouse.gov/omb/historical-tables/ (last visited Aug. 22, 2023). So, the $44.65 billion excise tax imposed on Novartis would be more than half of the federal government's current excise tax collections and *greater* than total fuel and other surface transportation taxes collected from all sources. *Id.* tbl. 2.4. It would also amount to the single largest annual tax bill ever paid by a single company in United States history.

68. A "tax" of that scale—a tax that is not intended or expected to raise any revenue because it is so severe—is unquestionably punitive for purposes of the Excessive Fines Clause. *See Bajakajian*, 524 U.S. at 329 (observing that deterrence has "traditionally been viewed as a goal of punishment"). Indeed, the excise tax is so large that incurring it would be financially ruinous for Novartis, who could not possibly pay the full weight of the excise tax for long without declaring bankruptcy.

69. This penalty is also grossly disproportionate to the "offenses" that trigger it.

70. First, the excise tax punishes manufacturers' failure to agree on contractual terms with the government. *See* 26 U.S.C. § 5000D(b)(1)-(4). But a business's refusal to agree to a counterparty's terms of sale is not normally considered misconduct *at all*, let alone an "offense" warranting the effective destruction of the business. Yet, that is what a $44.65 billion penalty would bring about given Novartis's total Fiscal Year 2022 net sales of $50.5 billion and net income of $6.9 billion. There is ordinarily nothing wrongful or unlawful about a seller refusing to sell its products at a particular price—much less in refusing to affirmatively "agree" that such a price is fair. To the contrary, the ability to say no is the cornerstone of a free market economy. A seller's failure to agree to a price term is certainly far less "grave" than the reporting offense at issue in *Bajakajian*,

which the Supreme Court held could not constitutionally trigger forfeiture of $357,144. *See* 524 U.S. at 337.

71. Second, the excise tax punishes manufacturers for failing to provide certain proprietary data to the Secretary. *See* 26 U.S.C. § 5000D(b)(4). The fine is grossly disproportionate to these reporting failures as well. In *Bajakajian*, the Supreme Court found that failure to comply with mere reporting requirements could not constitutionally justify the imposition of a monetary penalty (in the form of forfeiture) that was orders of magnitude less severe than the excise tax here. *See* 524 U.S. at 337. The Program's imposition of a significantly greater severe penalty is perforce unconstitutional under *Bajakajian*.

E. The Program Compels Speech

72. Finally, the Program unconstitutionally compels speech by forcing manufacturers to engage in sham negotiations, sign sham agreements, and ultimately endorse the opinion that the prices they are compelled to accept by government fiat represent the "maximum fair price" for their drugs.

73. These aspects of the scheme serve no purpose other than to compel manufacturers to deliver Congress's desired political message with which the manufacturers profoundly disagree. If Congress wished to impose a price-control or rate-setting scheme, it could have done so in a straightforward and politically accountable manner. But instead, it adopted a convoluted process that requires

manufacturers, including Novartis, to give the false impression that a "negotiation" has taken place and to agree that the prices the government will pay for their pharmaceutical drugs under the Program reflect the "maximum fair prices" for those drugs. The *only* purpose of this structure is to shift responsibility from the government to manufacturers for any adverse consequences from the Program.

74. That type of forced messaging denies manufacturers the protections of the First Amendment. The First Amendment protects both the right to speak and the right to refrain from speaking. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *see also Janus v. Am. Fed'n of State, City & Mun. Emps.*, 138 S. Ct. 2448, 2463-64 (2018) ("Compelling individuals to mouth support for views they find objectionable violates [a] cardinal constitutional command" and "seriously impinges on First Amendment rights."). Under the First Amendment, the government may not "interfere with 'an uninhibited marketplace of ideas.'" *303 Creative LLC v. Elenis*, 143 S. Ct. 2298, 2311 (2023) (quoting *McCullen v. Coakley*, 573 U.S. 464, 476 (2014)).

75. Laws compelling private speech are subject to strict scrutiny under the First Amendment. *Wooley*, 430 U.S. at 714-15. "[S]uch laws 'are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.'" *Nat'l Inst. of Fam. & Life*

Advocs. v. Becerra ("*NIFLA*"), 138 S. Ct. 2361, 2371 (2018) (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)).

76. Yet the forced negotiation process prescribed by the Program requires manufacturers, including Novartis, to deliver political messages with which they vehemently disagree: that the current market prices for their selected drugs are unfair, that the price dictated by the government is not only fair but the "maximum" price that is fair, and that the manufacturers voluntarily agreed to sell their drugs at those prices as the result of a "negotiation." All are positions on matters of public concern that Novartis strongly disagrees with and does not wish to express.

77. This compelled speech is present at every step of the Program. Start with the first step: manufacturers are compelled to "enter into" an "agreement[]" with CMS forcing them into "negotiation[s]." 42 U.S.C. § 1320f-2(a); 26 U.S.C. § 5000D. CMS has even publicized a template of that "agreement" for public consumption. *See* Revised Guidance at 120. Similarly, at the culmination of the "negotiation," the manufacturers must "agree to" whatever final "fair price" CMS offers, 42 U.S.C. § 1320f-2(a)(1), by executing a "Negotiated Maximum Fair Price Addendum," Medicare Drug Price Negotiation Program Agreement at 7, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template .pdf ("Template Agreement"). The substance of that "agreement," too, is published for the public. *See* 42 U.S.C. § 1320f-4(a); Revised

Guidance at 162-63. Yet both "agreements" are legally coerced by threat of sanctions. If the manufacturer does not enter into them by the statutory deadlines, every subsequent day counts as a "noncompliance" period and triggers an enormous penalty. 26 U.S.C. § 5000D.

78. The Template Agreement released by CMS repeats this same misleading language. It is entitled "Medicare Drug Price Negotiation Agreement," conveying both that the manufacturer is participating in a "negotiation" and that the parties reached an "agreement." Template Agreement at 1. Its opening clauses recite that the parties will "negotiate to determine a price," and that the manufacturer contemplates reaching "agreement with CMS." *Id.* The contract goes on to use the terms "agree," "agreement," and "maximum fair price" dozens of times across a mere five pages. *See id.* at 1-5. The Addendum, too, is styled as a "Negotiated Maximum Fair Price Addendum," and repeats that the parties "engaged in negotiation" and "agree" to the CMS-dictated price. *Id.* at 7.

79. But Novartis does not "agree" that the Program involves a "negotiation" or results in the "maximum fair price" for its products. Novartis instead believes that CMS's discounted prices will harm the public by eviscerating the incentives to develop new lifesaving drugs. Nonetheless, it is required to say the opposite by signing both agreements.

80. In requiring manufacturers to affirm that the prices "agreed" to by the government and the manufacturers are the "maximum fair prices," the government forces manufacturers such as Novartis to convey at least three messages. First, it forces manufacturers to say that the price set by CMS is a "fair" one. That, of course, implies endorsement of the amount of the price as reflective of the drug's value. Second, it also requires manufacturers to agree that CMS's set price is the "*maximum*" fair price that can be charged for the drug—meaning that the current market prices charged by manufacturers, including those agreed to in genuine negotiations with private insurers, are *unfair*. Third, it forces manufacturers to claim that they *voluntarily* agreed to the price selected—instead of accurately reflecting that the price was set unilaterally by CMS.

81. This compelled speech is no accident: Congress plainly wished to conceal its imposition of governmental price controls by portraying CMS's unilaterally imposed price with respect to each listed drug as the subject of a joint "agreement" between manufacturers and regulators, and thus the product of free and fair negotiations. Even before the IRA was passed, its supporters engaged in this pretense by repeatedly asserting that the statute does no more than allow "the Medicare Program to negotiate prices with the pharmaceutical industry" the same way that "[p]rivate insurance companies … try to get a better deal for their members." 186 Cong. Rec. S4006 (daily ed. Aug. 4, 2022); *see also* 186 Cong. Rec.

H7561-02 (daily ed. Aug. 12, 2022); 186 Cong. Rec. S4070-02 (daily ed. Aug. 6, 2022). But, as discussed above, the Program's provisions for "negotiation"—which rest on the compelled assent of manufacturers and their "endorsement" of prices dictated by the government—bear no resemblance to negotiations between private entities. Private insurers obviously cannot impose ruinous taxes on manufacturers who simply disagree with the prices demanded by the insurer, nor can private insurers prevent manufacturers from walking away from the table.

82. It is fundamental that "the government may not compel a person to speak its own preferred messages." *303 Creative*, 143 S. Ct. at 2312; *see also Turner Broad. Sys, Inc. v. FCC*, 512 U.S. 622, 641 (1994) ("At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence."). Indeed, when the government "requires the utterance of a particular message favored by the Government," it "seeks not to advance a legitimate regulatory goal, but to … manipulate the public debate through coercion." *Id.*

83. Nor is it any answer that manufacturers—having been pressed to pledge their agreement to the government's pricing decisions at the conclusion of "negotiations"—might also be able to express disagreement with those decisions through other speech in other places. *Reno v. ACLU*, 521 U.S. 844, 880 (1997) ("[O]ne is not to have the exercise of his liberty of expression in appropriate places

abridged on the plea that it may be exercised in some other place." (citation omitted)); *Pac. Gas & Elec. Co. v. Pub. Utils. Com'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality op.) ("Were the government freely able to compel corporate speakers to propound political messages with which they disagree, this protection would be empty, for the government could require speakers to affirm in one breath that which they deny in the next."); *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 257-58 (1974) (same).

84. Tellingly, even the government appears to understand that the statute, as written, violates the First Amendment. CMS has attempted to save the statute by adding a disingenuous disclaimer to the Template Agreement, stating that the agreement does not reflect an "endorsement of CMS'[s] views" and that signing it should not be taken as an agreement that "fair" means "fair" in the "colloquial" sense. Template Agreement at 4. The Template Agreement says that terms should instead be "given the meaning specified in the statute." *Id.* But the statute uses those terms to convey their ordinary meanings, and the "definition" provided in the statute simply says that a price set under the statute should be understood as the "maximum fair price." 42 U.S.C. § 1320f(c)(3). The statute plainly requires manufacturers to "agree" to a price that is set solely by the government and then agree that this is the "maximum fair price." Those words were carefully chosen by Congress to deliver

the message intended by their ordinary meaning. Nothing the agency can do or has done can alter that fact.

85. Not only is the disclaimer in direct conflict with the plain text of the statute and its structure (which as discussed was designed to force manufacturers to convey messages with which they disagree), it is also inconsistent with how the Program is described in the rest of the agreement. *See supra* at 37 ¶ 78 (discussing the terms of the agreement and its references to "negotiation" and "maximum fair price"). The purported disclaimer does nothing to resolve the compelled speech requirement imposed by the statute and made clear in the remaining text of the agreement. In any event, adding a "disclaimer" cannot suffice to cure a First Amendment compelled speech problem, because the government cannot "require speakers to affirm in one breath that which they deny in the next." *Pac. Gas*, 475 U.S. at 15 n.11 & 16 (plurality op.).

86. The Program's compulsion of speech cannot survive strict scrutiny. First, its speech requirements do not advance any legitimate or compelling governmental interest. To be sure, the government may have an interest in minimizing what it pays for prescription drugs, which it could in theory have furthered through straightforward price setting. But requiring manufacturers to express "agreement" with the prices CMS sets, and to pretend that this is an actual negotiation process, is totally unnecessary to achieving *that* goal. The only interest

served by forcing manufacturers to express "agreement" with CMS's prices is to promote the fiction that the Program establishes a market-based negotiation process rather than a potentially unpopular price control in order for Congress to shift accountability for any resulting harms such price controls will inflict from Congress to manufacturers. But under the First Amendment, Congress's desire to maintain a fiction of negotiation is not a legitimate governmental interest, let alone a compelling or substantial one. Nor is the "negotiation" process narrowly tailored: After all, Congress could have simply engaged in price setting without the illusion of manufacturer "agreement."

87. Second, the requirement that manufacturers state falsely that they "agree" with prices unilaterally set by CMS cannot be upheld under any level of constitutional scrutiny. Regardless of what interest the government claims it seeks to advance, it has "no legitimate reason to force" businesses to convey "false information." *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Ent. Merchs. Ass'n*, 564 U.S. 786 (2011).

88. Because the Program's "negotiation" process compels manufacturers to speak the government's own preferred message, it violates the First Amendment.

F. Novartis Did Not Voluntarily Submit To The Program By Participating In Medicare

89. The government cannot defend its physical taking of Novartis's property by arguing that because Novartis "voluntarily" participates in the Medicare

market, it thus necessarily "voluntarily" accepts forced below-market sales of its products to Medicare beneficiaries. Novartis did not voluntarily accept this "condition" when deciding to participate in Medicare, and its continued participation is not a voluntary choice but is instead compelled by statute for at least the first year of the Program. More fundamentally, the Supreme Court has time and again rejected the premise that the government can lawfully physically appropriate property merely by framing that appropriation as a "condition" to participation in a particular market.

90. Novartis has no legal ability to exit Medicare and Medicaid and thereby escape the Program's price-control regime in time to avoid the first year of the Program, so any argument that it has voluntarily handed over its property for this period fails out of the gate. The Medicare statute delays a manufacturer's ability to exit from Part D of Medicare—and thus compels it to participate in Part D—for between 11 and 23 months after the manufacturer terminates its agreements with CMS. *See* 42 U.S.C. § 1395w–114a(b)(4)(B). To avoid being penalized for failure to sign the October 1 "agreement," then, Novartis would have needed to terminate all of its Medicare contracts by January 31, 2022—months before the IRA was enacted, and nearly two years before the point at which ENTRESTO® was selected for the initial list. Novartis therefore has no legal ability to avoid the Program's requirement that it sell ENTRESTO® at below-market rates to Medicare beneficiaries.

91. Once again, the government appears to recognize that the statute, as written, effectuates an involuntary *per se* physical taking without just compensation. In its most recent Guidance, CMS tries to create the foundation for an argument that the government's taking of property is "voluntary" despite this statutory lock-in period by claiming the authority to terminate a manufacturer's Medicare agreements with only 30 days' notice, on demand by the manufacturer that it be permitted to exit the Medicare and Medicaid programs. Revised Guidance at 120-21, 130-31. But that authority is nowhere to be found in the Medicare statute. 42 U.S.C. § 1395w-114A(b)(4)(B) provides only two pathways to termination: termination by the *manufacturer* for any reason, which takes effect no sooner than 11 months following termination, or termination by the *Secretary* "for a knowing and willful violation of the requirements of the agreement or other good cause," which takes effect 30 days following notice of termination. A termination of the agreement at the sole initiative of the manufacturer, taking effect on demand, subject to no requirement other than expression by the manufacturer of the desire to terminate, is clearly an at-will termination by the manufacturer, not by the government for cause. Accordingly, such a termination requires at least 11 months' notice under the terms of the statute. *See id.* § 1395w-114a(b)(4)(B)(ii)(I). CMS lacks the authority to rewrite this statutory text, and its attempts to do so merely confirm that the Program is unlawful.

92. In addition, these representations are made in nonbinding agency guidance that could change at any point. That the Revised Guidance purports to be "final" is cold comfort to manufacturers like Novartis; CMS previously issued parts of its Initial Guidance as "final" only to turn around and change course in the Revised Guidance.

93. The government's bait and switch of moving from market-based pricing to compelled below-market price controls is all the more improper because it leverages not only Medicare participation, but also Medicaid participation—and the provision of lifesaving drugs to over 87 million of the lowest-income and most vulnerable Americans—to force manufacturers to submit to CMS's demands. Even if Novartis's participation in Medicare were understood to voluntarily subject it to possible future price setting *for Medicare*, there is no logical relationship between a manufacturer's participation *in Medicaid* and the prices provided to Medicare beneficiaries. By choosing to participate in *Medicaid*, a manufacturer does not and reasonably cannot be understood to voluntarily accept regulation of its drug prices by Medicare—a completely different program. Forcing a manufacturer to exit Medicaid in order to avoid the Program is nothing other than a transparent punishment to compel participation. It is not a means of providing a voluntary "choice."

94. In addition, the Supreme Court has rejected similar attempts by the government to recast a physical appropriation of property as a "condition" on participation in the marketplace to evade application of the *per se* physical takings doctrine. "Let them leave Medicare" is essentially the same "[l]et them sell wine [instead of raisins]" argument the government urged, and the Supreme Court rejected, in *Horne*, 576 U.S. at 365. Congress can no more require manufacturers to abandon a vast swath of the United States prescription drug market as the price for avoiding a physical taking of their property than it can tell raisin producers to sell their grapes for other purposes in order to avoid having to turn over a portion of their crop to the government. *See id.* (holding that the government may not "hold hostage, to be ransomed by the waiver of constitutional protections" the right to engage in interstate commerce); *see also Loretto*, 458 U.S. at 439 & n.17 (holding that "a landlord's ability to rent his property may not be conditioned on his forfeiting the right to compensation for a physical occupation").

95. Such voluntariness arguments are "insufficient to defeat a physical taking claim." *Yee v. City of Escondido*, 503 U.S. 519, 531 (1992) (citing *Loretto*, 458 U.S. at 439 n.17) (distinguishing between the regulation of the use of property and the "compelled physical occupation" that amounts to a *per se* taking). Because the Program forces Novartis to physically surrender its prescription drugs, the fact that the Program leverages participation in Medicare and Medicaid does not make

Novartis's actions "voluntary." The government can no more force Novartis to physically turn over its prescription drugs than it can seize Novartis's manufacturing facilities—such physical invasions are *per se* takings and the Constitution prohibits Congress from conditioning participation in government programs such as Medicare and Medicaid on a manufacturer's agreement to have its property physically taken.

96. Finally, even if the statute provided a way for Novartis to terminate all of its Medicare and Medicaid agreements prior to suffering the statute's unconstitutional effects, and even if doing so would not be an unconstitutional condition—and it is—doing so would not be a tenable option for Novartis, which renders any "asserted power of choice … illusory." *United States v. Butler*, 297 U.S. 1, 71 (1936). These two programs account "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023); *cf. Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) ("Medicare stands as the largest federal program after Social Security" and "touches the lives of nearly all Americans"). Novartis could not rationally cut itself off from half of the United States prescription drug market; that step would cost it billions of dollars in revenue and leave tens of millions of patients without access to their medications. *See, e.g.*, *Tenoco Oil Co. v. Dep't of Consumer Affs.*, 876 F.2d 1013, 1027 (1st Cir. 1989) (holding that the supposed freedom to temporarily leave the

gasoline market is illusory where entities have fixed costs, overhead, and salaries, which makes such a course economically prohibitive).

97. In addition, the purported "choice" the Program offers is ultimately no choice at all because, as in *National Federation of Independent Businesses* ("*NFIB*"), manufacturers "could hardly [have] anticipate[d]" the Program's bait-and-switch both when they joined Medicare and more critically when they spent billions of dollars to develop their products—long before the IRA was enacted—under the expectation that they would be able to determine the prices at which they would offer the few products that actually made it to the market. *NFIB v. Sebilius*, 567 U.S. 519, 581, 583-84 (2012). Having used promises of market pricing to attract manufacturers to federal healthcare programs and then gain control of the prescription drug market, the government cannot now leverage that control to coerce manufacturers to give up their property without just compensation. In offering manufacturers a "choice" between submitting to CMS's demands or withdrawing *all of their drugs* from half of the United States prescription drug market—a choice that exists "in theory" but not "in fact," *id.* at 581 (citation omitted)—Congress is engaged in an act of "economic dragooning" that puts a "gun to the head" of the manufacturers, *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (citation omitted). *See also NFIB*, 567 U.S. at 575-76, 579-82, 586 (noting that the fact that Congress threatened to withhold "existing Medicaid funds" and "terminate other

significant independent grants" if States would not accept "new conditions" was a signal that Congress was using its power over those benefits as a "means of pressuring" recipients); *cf. Swift & Courtney & Beecher Co. v. United States*, 111 U.S. 22, 28-30 (1884) (holding that plaintiff's payment of a tax was not voluntary where its only alternatives were "to submit to an illegal exaction or discontinue its business").

98. The purported "conditions" are all the more improper here because the markets for some drugs are overwhelmingly made up of Medicare and Medicaid patients. For ENTRESTO® in particular, the vast majority of its sales—more than 70%—come from Medicare and Medicaid. Congress's "condition" forcing Novartis to abandon its Medicare and Medicaid patients would in fact force Novartis to entirely remove the drug from sale in the United States.

99. In light of this reality, it is obvious that Congress did not actually intend that manufacturers exit the Medicare and Medicaid markets in order to avoid the Program. Drugs subject to the Program's negotiation regime are, by design, the drugs that are most widely used by Medicare patients, so if manufacturers ceased selling those drugs to Medicare in order to avoid the Program's "conditions," it would be catastrophic for tens of millions of Medicare patients and their families. This stark reality confirms that the purpose and effect of the Program is not to apply a condition on participation in Medicare and Medicaid at all, but rather to coerce

manufacturers to stay *within* the programs, while forcing their highest-selling products to be purchased at a below-market price—a classic, *per se* taking.

CLAIMS

CLAIM I
Uncompensated Physical Takings (Fifth Amendment)

100. Novartis re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

101. The Fifth Amendment requires the government to pay "just compensation" when it takes private property for public use. U.S. Const. amend. V.

102. Novartis's patented pharmaceutical products, including ENTRESTO®, are personal property protected by the Takings Clause of the Fifth Amendment.

103. The Program requisitions Novartis's personal property and transfers it to third parties. These forced sales of ENTRESTO® deprive Novartis of its "rights 'to possess, use, and dispose of'" the drugs it manufactures, which means they are a classic, *per se* taking. *Loretto*, 458 U.S. at 435 (quoting *Gen. Motors Corp.*, 323 U.S. at 378).

104. Because the Program "appropriate[s] [Novartis's] personal property," the government has a "categorical duty to pay just compensation," *Horne*, 576 U.S. at 358, which by law is "the fair market value" of the medicines it has taken, *Reynolds*, 397 U.S. at 16. The Program, however, *forbids* CMS from paying the fair market value of the selected drugs. By one calculation, CMS will not pay anything

more than *40-75%* of the actual fair market value of the selected drugs—and CMS will in all likelihood attempt to set prices even lower than that. The Program therefore is expressly designed *not* to provide the just compensation the Fifth Amendment requires.

105. Declaratory relief is "appropriate" in this case, 28 U.S.C. § 2201, because the Program does not provide "advance assurance of adequate compensation in the event of a taking," *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978).

106. In addition, declaratory relief is appropriate because it would "resolve the uncertainty" that "gave rise to the controversy"; promote "the convenience of the parties" relative to "other remedies" that may be available; and further "the public interest." *Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 140 (3d Cir. 2014); *see also Cedar Point*, 141 S. Ct. at 2070 (declaring judgment in favor of plaintiffs who "requested declaratory and injunctive relief prohibiting the Board from enforcing the regulation against them").

107. Accordingly, the Court should declare that the Program effects a taking of Novartis's private property without "just compensation" under the Fifth Amendment.

CLAIM II
Excessive Fines Clause (Eighth Amendment)

108. Novartis re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

109. The Eighth Amendment bars the imposition of excessive fines. U.S. Const. amend. VIII. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334.

110. The Program's draconian "excise tax"—imposed for a failure to "agree" with the government's maximum fair price—is clearly punitive, and therefore falls within the scope of the Excessive Fines Clause. This penalty reaches up to *nineteen times* a manufacturer's nationwide revenues from the drug's sales. The penalty is so severe that the government anticipates (correctly) that no manufacturer will ever incur the penalty because the consequences of doing so would be ruinous for every pharmaceutical manufacturer in the world.

111. The Program's exorbitant penalty provisions are grossly disproportionate to the "offenses" that trigger those provisions. The failure to reach an agreement with a contractual counterparty is not fairly considered wrongful at all, let alone an "offense" that ought to incur tens of billions of dollars in fines. 26 U.S.C. § 5000D(b)(1)-(3). Nor is a pharmaceutical manufacturer's failure to

provide certain proprietary data to the Secretary an offense that warrants such a massive penalty. *See id.* § 5000D(b)(4). This conduct is certainly far less "grave" than the reporting offense that the Supreme Court in *Bajakajian* held could not constitutionally trigger forfeiture of $357,144. *See* 524 U.S. at 337.

112. The Program's excise tax is therefore unconstitutional under the Excessive Fines Clause of the Eighth Amendment.

CLAIM III
Compelled Speech (First Amendment)

113. Novartis re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

114. The First Amendment bars the government from "compel[ling] a person to speak its own preferred messages" in whatever form that compulsion may take, whether by "compel[ling] a person to speak its message when he would prefer to remain silent or . . . forc[ing] an individual to include other ideas with his own speech that he would prefer not to include." *303 Creative*, 143 S. Ct. at 2312. Laws compelling private speech "are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." *NIFLA*, 138 S. Ct. at 2371 (quoting *Reed*, 576 U.S. at 163); *see also Wooley*, 430 U.S. at 714-15.

115. The Program established by the IRA compels speech by forcing Novartis—like other pharmaceutical manufacturers—to convey the message that the

rates set by CMS are the product of "negotiation," to represent falsely that it has "agreed" on a price when that price is actually dictated by CMS, and to endorse the view that CMS's selected price is the "maximum fair price" for its drug. Novartis does not wish to do or say any of the foregoing.

116. Nor can the government show a legitimate or compelling state interest for forcing Novartis to engage in this speech. The only plausible reason that the government would have resorted to this convoluted process—rather than empowering CMS to decree prices in the open—is to force manufacturers like Novartis to convey the preferred policy message that Congress has dictated. The creation of that appearance is not a legitimate or compelling government interest.

117. The Program's requirement that manufacturers state falsely that they "agree" with prices unilaterally set by CMS cannot be upheld under any level of constitutional scrutiny. Regardless of which interests the government might claim it seeks to advance, it has "no legitimate reason to force" businesses to convey "false information." *Video Software Dealers Ass'n*, 556 F.3d at 967.

118. The Program's compelled speech provisions therefore violate the First Amendment. That constitutional defect warrants declaratory and injunctive relief. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.").

PRAYER FOR RELIEF

Novartis respectfully requests that this Court:

119. Declare that the Program compels speech in violation of the First Amendment;

120. Declare that the Program's "excise tax" violates the Excessive Fines Clause;

121. Declare that the Program effects a taking without providing for just compensation in violation of the Fifth Amendment;

122. Declare void any agreement that Novartis may be unconstitutionally coerced into entering before this case is adjudicated;

123. Enjoin Defendants from forcing Novartis to sign an initial "manufacturer agreement" or to "agree" to prices set by the Program;

124. Award Novartis reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

125. Grant any other relief the Court finds just and appropriate.

Dated: September 1, 2023

Respectfully submitted,

s/ *Gregory Mortenson*

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