No. 24-2968

United States Court of Appeals for the Third Circuit

NOVARTIS PHARMACEUTICALS CORPORATION,

Appellant,

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES,

Appellees.

On Appeal from the United States District Court for the District of New Jersey in Civil Action No. 3:23-cv-14221-ZNQ-JBD

BRIEF OF APPELLANT NOVARTIS PHARMAECUTICALS CORP.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Rule 26.1, Appellant Novartis Pharmaceuticals Corp. makes the following disclosure.

1. Novartis Pharmaceuticals Corporation is a direct, wholly owned subsidiary of Novartis Finance Corporation, a New York corporation; and Novartis Pharmaceuticals Corporation is an indirect, wholly owned subsidiary of Novartis AG, a Swiss company.

2. No other publicly held corporation owns 10% or more of Novartis Pharmaceutical Corporation's stock.

Dated: December 30, 2024

s/ Daniel Meron
Daniel Meron

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INTRODUCTION

This appeal challenges an unprecedented effort by the government to requisition valuable drugs from manufacturers at prices well below market value, under threat of ruinous penalties. Misleadingly labelled the "Drug Price Negotiation Program" (the "Program"), the Program does not involve any true negotiation; instead, it threatens manufacturers with enterprise-destroying fines unless they "agree" to sell their products at a government-dictated "maximum fair price." 42 U.S.C. § 1320f-2(a)(1). These penalties can run up to *nineteen times* a manufacturer's total nationwide revenues from the sale of the drug—representing dollar fines that are unprecedented in modern legislative history and, by design, unpayable. For Plaintiff Novartis, that penalty would swiftly escalate to *$93.1 billion each year*. Although branded as a "tax" in an attempt to evade review, the Congressional Budget Office has estimated this "tax" would, in fact, raise zero revenue. Rather, in the words of the statute itself, it is designed to force manufacturers' "[]compliance" with the Program's requirements. 26 U.S.C. § 5000D.

The Eighth Amendment's Excessive Fines Clause forbids exactly this kind of governmental abuse. That Clause prohibits the government from punishing parties with monetary penalties that are disproportionate to the proscribed conduct. *See Austin v. United States*, 509 U.S. 602, 621 (1993). A fine that would effectively

bankrupt a business simply because it refused to agree to a government's demanded price for its products is an obvious and undeniable violation of the Eighth Amendment.

The district court below, however, declined even to address the merits of Novartis's Eighth Amendment claim—incorrectly concluding that the Anti-Injunction Act ("AIA") divested it of jurisdiction. That holding represents an unprecedented expansion of the AIA's narrow judicial-review bar. The AIA prevents pre-enforcement challenges made "for the purpose of restraining the assessment or collection of a[] tax." 26 U.S.C. § 7421(a). The statute thus "direct[s] courts" to focus on the *purpose of* a suit—"rather than the suit's downstream effects"—to determine whether the AIA applies. *CIC Servs., LLC v. IRS*, 593 U.S. 209, 228-29 (2021) (Kavanaugh, J., concurring).

Here, the "purpose" of Novartis's lawsuit is not to restrain the assessment or collection of a tax, because the statute is crafted in such a way as to ensure that no tax will ever be assessed or collected. The statute operates as intended when it is *not* raising revenue, but instead using the threat of an impossible-to-pay penalty to coerce conduct. The AIA is intended to protect the government fisc—not to shield from constitutional challenge a coercive penalty that has no revenue-raising purpose.

The district court's contrary holding would create a roadmap for the government to violate the Eighth Amendment with impunity.[1]

The Program is also unconstitutional in two other respects. *First*, the Program effects a physical taking of private property for public use without just compensation, in violation of the Fifth Amendment. The Program does not merely set the price for the selected drug; it mandates a *physical transfer* by compelling manufacturers to actually hand over their drugs to beneficiaries at government-dictated prices. Unlike a price-setting regime, the manufacturer cannot *decline* to sell its products at the dictated price.

The district court rejected Novartis's Fifth Amendment challenge, reasoning that these mandatory transfers were, in fact, "voluntary" because manufacturers could avoid the penalty by withdrawing *all* their medicines from the Medicare and Medicaid programs. That conception of "voluntariness" is flatly incompatible with settled precedent. As the Supreme Court has made clear, the fact that a party can avoid a physical taking by exiting a market altogether does not authorize the government to seize property without just compensation. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 364-65 (2015). If that were the law, the government could

[1] Although the Program has been subject to numerous constitutional challenges, including in four other cases pending in this Circuit, this case is the only one before this Court that raises an Eighth Amendment challenge to the penalty provision. This Court's careful review of that question is imperative.

force manufacturers to turn over their manufacturing plants and raw materials without any compensation, so long as a manufacturer had the option of leaving the Medicare and Medicaid programs entirely. But it has long been settled that entering a government program does not give the government carte blanche to violate participants' constitutional rights or to nationalize industries, even if doing so would save the Treasury money.

Second, the Program violates the First Amendment by coercing manufacturers into espousing views they fundamentally oppose. Manufacturers must declare that they are involved in a "negotiation"; that they "agree" with the government-set price; and that the government-set price represents the "maximum fair price" (and thus, implicitly, that the market-based prices the manufacturer currently charges are unfair)—all of which are viewpoints on matters of public concern with which manufacturers, like Novartis, vehemently disagree.

In rejecting this claim, the district court primarily held that the statute's speech regulation is permissible because it is merely "incidental" to the regulation of conduct. That is plainly incorrect. Speech restrictions qualify as "incidental" to conduct regulation only when they are *essential* to achieving the conduct-related objectives. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). But the compelled-speech aspects of the Program are wholly unnecessary to such purposes. In fact, numerous government programs regulate similar conduct without including

any of the attendant theater present here. The Program's compelled-speech aspects are a direct regulation of speech and demand robust First Amendment scrutiny.

The judgment below must be reversed.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. This Court has jurisdiction under 28 U.S.C. § 1291 because Novartis timely appealed (JA12-13) from a final judgment (JA11).

ISSUES PRESENTED

1. Whether the Program violates the Eighth Amendment by using the threat of excessive fines to coerce Novartis into complying with the government's Program. JA6-10.

2. Whether the Program violates the Fifth Amendment by taking Novartis's property without just compensation. JA5.

3. Whether the Program violates the First Amendment by compelling Novartis to deliver messages with which it disagrees. JA6.

RELATED CASES

This appeal has not previously been before this Court. Four cases raising constitutional challenges to the Program are currently pending in this Court: *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J.), No. 24-1821 (3d Cir.); *Bristol Myers Squibb Co. v. Becerra* (*"BMS"*), No. 3:23-cv-3335 (D.N.J.), No. 24-

1820 (3d Cir.); *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:23-cv-0931 (D. Del.), No. 24-1819 (3d Cir.); and *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J.), No. 24-2510 (3d Cir.). *BMS*, *Janssen*, and *AstraZeneca* were argued on October 30, 2024, and the Court has not yet issued a decision.

Outside the Third Circuit, the following cases also involve constitutional challenges to the Program: *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health & Human Services ("HHS")*, No. 3:23-cv-1103 (D. Conn.), No. 24-2092 (2d Cir.); *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C.); *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-0156 (S.D. Ohio), No. 24-3868 (6th Cir.); and *National Infusion Center Association v. Becerra*, No. 1:23-cv-0707 (W.D. Tex.).

STATEMENT OF THE CASE

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

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 and has developed a number of groundbreaking pharmaceutical drugs. JA89 (Vineis ¶3). One such drug is ENTRESTO®, a lifesaving medication that treats heart failure. As of November 2023, ENTRESTO® had helped approximately 2 million United States heart failure patients. JA91 (*id.* ¶7).

Developing a lifesaving drug such as ENTRESTO® requires massive investments of time and money—on average, nearly $3 billion, and ten to fifteen years, to develop just one new medicine. JA110-11. Given the nature of pharmaceutical research and the complexity of the regulatory process, manufacturers like Novartis make these investments with no guarantee of a return. Most drugs never even secure FDA approval. JA120. And even when approval is secured, few drugs generate enough economic return to allow for continued innovation. JA141. Manufacturers therefore must fund their research efforts from revenue obtained from a very few "blockbuster" drugs.

B. The Prescription Drug Market Historically Relied On Market-Based Pricing

The Medicare program includes two parts relevant here. Medicare Part B insures Medicare beneficiaries for outpatient healthcare services, including physician-administered drugs. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A).[2] Medicare Part D permits beneficiaries to choose from a variety of insurance plans offered by private insurers under contracts with the government, which provide coverage for self-administered drugs. Together, Medicare Parts B and D "dominate[]" the U.S. prescription drug market, accounting "for almost half the

[2] All citations are to Title 42 of the U.S. Code unless otherwise noted.

annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

Until Congress's passage of the IRA, both parts of the Medicare program guaranteed manufacturers market-based pricing for all of their drugs, in order to incentivize investment and innovation in new products. Medicare Part B reimbursement is based on a drug's average sales price, which ensures that reimbursement tracks market prices. § 1395w-3a. And Medicare Part D expressly prohibits HHS from "interfer[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 drive pricing. § 1395w-111(i). Historically, private plans "can and do negotiate prices with prescription drug manufacturers," and have market incentives to secure lower pharmaceutical prices. JA211.

Under these programs, the government "does not directly purchase drugs" for its own use; rather, it acts as a sovereign, using tax revenue to "subsidize[] a portion of the costs of providing prescription drugs to Medicare beneficiaries." *United States ex rel. Behnke v. CVS Caremark Corp.*, No. 14-cv-824, 2024 WL 1416499, at *4 (E.D. Pa. Apr. 2, 2024). These subsidies, though complex in structure, essentially function as reimbursements from the government to beneficiaries

(through private insurers) to offset a portion of the costs beneficiaries incur purchasing prescription drugs.

C. The Inflation Reduction Act's Fines

The Program upends the traditional market-driven approach by (1) allowing government agencies to unilaterally set the price for certain drugs, (2) compelling those drugs' manufacturers to sell their products at that price, and (3) forcing the manufacturers to publicly endorse those prices as "maximum fair prices" arrived at via "negotiations."

CMS first identifies the drugs that account for the highest Medicare Part D expenditures and selects a subset of those drugs for negotiation. § 1320f-1(b)(1)(A). Each year, starting in 2023, at least ten drugs are selected, with the number of additional selected drugs rising to twenty in 2027. § 1320f-1(a)(1), (a)(4). Within 10 years, as many as 180 drugs will be covered by the Program.

After a drug is chosen, the manufacturer has only 30 days to enter into an initial "agreement[]" with CMS to participate in the Program's "negotiation" process. §§ 1320f(d)(2)(A), 1320f-2(a). That "agreement" commits the manufacturer to publicly "agreeing" that the price CMS eventually chooses—no matter how low—is the "maximum fair price" for the drug. JA259-62.

If a manufacturer refuses to sign the initial agreement by the statutory deadline, the statute imposes a swiftly increasing penalty based on all United States

sales of the listed drug (not just Medicare), which the Program terms an "excise tax." *See* 26 U.S.C. § 5000D(b). 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. JA468-69 (tbl. 2).[3] For Novartis, this would mean that the penalty for not reaching an agreement to "negotiat[e]" over the "maximum fair price" for ENTRESTO® would quickly rise to an annual rate of *$93.1 billion*—

[3] On October 2, 2023, the IRS issued a nonbinding notice announcing its intent, at some unspecified point in the future, to promulgate regulations implementing the "excise tax." JA500-05 ("IRS Notice"). This notice purports to limit application of the "excise tax" to Medicare sales and apply a lower penalty rate. But in addition to being nonbinding, these aspects of the notice are at odds with the language of the statute—the *actual* binding authority. An executive agency cannot rectify an unconstitutional statute by mere assertion. Moreover, an intention to issue future regulations on the calculation of the excise tax—still unfulfilled more than a year later, even though the IRS has since issued regulations on how to report and pay the "tax," 89 Fed. Reg. 55045, 55049 (July 3, 2024)—obviously can have no impact on the Court's construction of the statute today.

almost double Novartis's total global annual net revenue. JA91-92 (Vineis ¶¶8-11). It is undisputed that this not a penalty that Novartis could afford to incur. *See id.*

The only statutory mechanism to avoid these penalties is for a manufacturer to "opt out of Medicare [and Medicaid] . . . *entirely*"—not merely for the selected drug, but for all of its drugs—"meaning [CMS] will not reimburse patients or providers for any of the drugs that the manufacturer sells (whether or not those drugs are part of the [Program])." *Nat'l Infusion Ctr. Ass'n v. Becerra* (*NICA*), 116 F.4th 488, 495 (5th Cir. 2024).

Once a manufacturer has entered into the initial "agreement," the manufacturer then has little say in the "negotiation" that follows. Although the manufacturer is allowed to provide a "counteroffer," CMS is under no obligation to consider it. § 1320f-3(b)(2)(C)(ii), (e).

At the end of this process, CMS has the unfettered discretion, unchecked by any processes of administrative or judicial review, to unilaterally set a "maximum fair price." § 1320f-7. The Program provides no floor below which CMS may not set the price (with one limited exception not relevant here). § 1320f-3(c), (b)(2)(F)(ii). The law does however impose a ceiling on how *high* a price CMS can set. Specifically, CMS is directed to use as the ceiling price the lowest number produced by two specified statutory methods. § 1320f-3(c)(1)(A), (b)(2)(F). These

methods are expressly designed to yield prices that are well below market value. JA51-52 (Compl. ¶¶44-45).

The Program next 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 was August 1, 2024. §§ 1320f(d)(5)(C), 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]," JA421, manufacturers cannot in reality "reject" CMS's offer and walk away as in a normal negotiation. JA93-94 (Vineis ¶¶16-18). If a manufacturer rejects CMS's final "maximum fair price" demand, "the consequences are severe": it is subjected to the previously discussed 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. *NICA*, 116 F.4th at 495, 500; § 1320f-2(a)(1). Congress was well aware that no manufacturer could afford to pay such a tax; in fact, the Congressional Budget Office ("CBO") projected that this "tax" would raise zero dollars. CBO, Cost Estimate, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 at 4-5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

The Program then requires manufacturers to provide "access" to their drugs at the "maximum fair price" to a wide array of individuals and entities, including all

eligible individuals dispensed drugs under Medicare Parts B and D. §§ 1320f-2(a)(1)(A)-(B), 1320f(c)(2). If a manufacturer does not do so, it is subject to a different but equally harsh sanction—civil monetary penalties at the extraordinary rate of ten times the alleged overcharge. §§ 1320f-2(a)(1), 1320f-6(a)-(b).

D. ENTRESTO® Was Selected For "Negotiation"

On August 29, 2023, Novartis's ENTRESTO® was selected for "negotiation" by CMS. Novartis signed the "agreement" with the Secretary on September 28, 2023, and entered into the "negotiation" process established by the statute in order to avoid the ruinous penalties described. JA91 (Vineis ¶10). At the close of the "negotiation" process, Novartis "acceded to a 'maximum fair price' for [ENTRESTO®] . . . only to avoid other untenable options including catastrophic fines or the removal of all [its] products from both Medicare and Medicaid." Novartis Statement on Maximum Fair Price for Entresto (Aug. 15, 2024), https://www.novartis.com/node/662816/printable/pdf.

E. Procedural History

Novartis filed suit in September 2023, seeking declaratory and injunctive relief. Novartis alleged the Program violates (1) the Eighth Amendment by using the threat of excessive fines to coerce Novartis into complying with the Program; (2) the Fifth Amendment by appropriating Novartis's property rights in

ENTRESTO®; and (3) the First Amendment by compelling Novartis's speech about the Program.

The district court heard oral argument in Novartis's case at the same time as three other cases challenging the Program: *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 3:23-cv-3818; *BMS v. Becerra*, No. 3:23-cv-3335; and *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814. *Janssen* and *BMS* involve overlapping First and Fifth Amendment claims, while *Novo Nordisk* involves an overlapping First Amendment claim. None of the other three cases includes an Eighth Amendment claim. The district court reached decisions in each case at different times, granting summary judgment to the government in this case on October 18, 2024.

As to Novartis's Eighth Amendment claim, the court concluded the Anti-Injunction Act ("AIA") divested it of jurisdiction to adjudicate its merits. JA8-10. The AIA bars pre-enforcement challenges "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). Novartis argued that the AIA is inapplicable because the "purpose" of its challenge is not to restrain the "assessment or collection of" any tax that is expected to be paid, but to prevent CMS's use of the unconstitutional fine to coerce Novartis's participation in the Program. The district court rejected this argument in a single sentence in a footnote, stating only that "Congress labeled the excise tax a 'tax,'" without addressing the

purpose of Novartis's suit, or engaging with the rest of the statutory language. JA7 n.6.

The court also determined that Novartis failed to meet either prong of the *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1 (1962), exception to the AIA, which applies when a plaintiff will otherwise suffer irreparable injury and it is clear the plaintiff will prevail on the merits. JA7-8. Novartis contended it would suffer irreparable harm absent the lawsuit by being forced to engage in compelled speech and/or by having to suffer enterprise-destroying penalties. But the court saw Novartis's harm as only "minimal and reparable" due to the IRS's purported informal policy of "'exercis[ing] forbearance with respect to collection'" while a refund suit is pending. JA9. This policy, the district court reasoned, made a refund suit an "adequate remedy," even though the tax would still be *accruing* during that suit—and would have to be paid in full in the event Novartis lost. JA8. The court also concluded that Novartis could not demonstrate certainty of success on the merits, simply because its Eighth Amendment claim was "novel." JA9. The court did not engage with any of the substantive arguments, observing only that Novartis had "not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes." *Id.* On that basis, the court found *Williams Packing* inapplicable.

Drawing heavily from its previous rulings in the *BMS*, *Janssen*, and *Novo Nordisk* cases, the district court also rejected Novartis's claims under the Fifth and First Amendments. As to the Fifth Amendment claim, the court concluded that the Program does not effect a physical taking because participation in the Program "is voluntary." JA5. In the court's view, because Novartis is not "'legally compelled'" to participate in Medicare and "'there is no physical appropriation taking place,'" the Program's forced sales do not effectuate takings. *Id*. The court highlighted that, "'[u]nlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [Plaintiff's] facility at eight o'clock one morning" to haul away pills.'" *Id*. And it concluded that "[t]here is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs." *Id.*

Regarding the First Amendment, the court reiterated its conclusion from *BMS* and *Janssen* that the Program "regulates commercial conduct, not speech." JA6. In the Court's view, any "'speech'" aspects of the Program, are "'merely incidental mechanisms used during the price-setting process.'" *Id.*

STANDARD OF REVIEW

This Court reviews a decision granting summary judgment *de novo*. *TitleMax of Del., Inc. v. Weissmann*, 24 F.4th 230, 236 n.3 (3d Cir. 2022).

SUMMARY OF ARGUMENT

I. The Eighth Amendment's Excessive Fines Clause forbids the government from imposing fines that are grossly disproportionate to the "offenses" that triggered them. The Program violates this restriction by threatening to levy draconian penalties on any manufacturer that dares to defy its pricing demands. Those penalties are "[f]ines" for Eighth Amendment purposes because they "'cannot fairly be said solely to serve a remedial purpose.'" *Austin*, 509 U.S. at 621-22. These penalties serve solely to force manufacturers to comply with the Program—a purpose that is not remedial at all. And they are grossly disproportionate to the "offenses" that trigger them—the entirely innocent conduct of failing to agree on contractual terms with the government.

The district court did not reach the merits of Novartis's claim, because it wrongly concluded that any pre-enforcement challenge to this fine was jurisdictionally barred by the AIA. But the AIA does not bar pre-enforcement challenges to anything labelled a "tax"; it bars only suits with the "*purpose of* restraining the assessment or collection of a[] tax." 26 U.S.C. § 7421(a) (emphasis added). Novartis's suit does not have that purpose. The district court failed to engage with the full text of the AIA, which, by its plain language, requires examining the nature of the *lawsuit*—not the label on the exaction—to determine whether it applies. The district court's broad and untenable interpretation of the AIA—which

would allow the government simply to label any coercive fine a "tax" to insulate it from judicial review—demands correction.

II. The Takings Clause requires the government to pay fair market value when it takes private property for public use. In *Horne*, the Supreme Court found a physical taking when the government required raisin growers to surrender part of their crop under threat of fines. 576 U.S. at 370. By that same logic, the government cannot compel manufacturers to sell their products below fair market value under the threat of enterprise-destroying penalties. Forcing sales at dictated discounts is a straightforward, *per se* taking.

The district court wrongly concluded that no taking occurs because Novartis has "options" to "avoid" the taking—such as divesting its interest in ENTRESTO® or exiting the Medicare and Medicaid markets *entirely*. However, *Horne* specifically rejected the notion that a property owner's theoretical ability to avoid a taking by exiting a federally-regulated market is a valid defense against a *per se* takings claim. As the Court recognized, a person's participation in a market—even a federally-regulated one—does not mean the government has unrestricted authority to infringe the participant's constitutional rights. The district court's contrary holding was plainly wrong and must be reversed.

III. The First Amendment's compelled-speech doctrine prohibits the government from forcing businesses to communicate messages against their will.

The Program does just that by compelling Novartis—under threat of severe penalties—to publicly endorse the government's misleading narrative that it "negotiated" and "agree[d]" to a "maximum fair price" for ENTRESTO®.

The district court's contrary reasoning was flawed many times over. It confused the Program's direct speech compulsion with the incidental effects of genuine price regulation. It mistakenly viewed the coerced "agreements" as non-expressive "commercial contracts." And it wrongly asserted that Novartis's ability to spread its own message about the Program somehow eliminated the First Amendment harm, despite clear Supreme Court and Third Circuit precedent holding the opposite. The First Amendment holding must likewise be reversed.

ARGUMENT

I. THE PROGRAM IMPOSES AN EXCESSIVE FINE IN VIOLATION OF THE EIGHTH AMENDMENT

The Program violates the Eighth Amendment by using a draconian fine, the sole purpose of which is to coerce manufacturers into "compliance" with the statute's commands. The district court's decision to dismiss this claim on jurisdictional grounds, based solely on the IRA's labeling of the fine as a "tax," is indefensible—and clears the way for unchecked governmental overreach masquerading as "taxation."

A. The Program Imposes Grossly Disproportional Fines

The Eighth Amendment bars (1) "fine[s]" that are (2) "grossly disproportional to the gravity of [the] offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *see* U.S. Const. amend. VIII. The Program's "excise tax" easily meets both criteria.

1. A monetary sanction is a "fin[e]" within the meaning of the Eighth Amendment if it "serv[es] in part to punish." *Austin v. United States*, 509 U.S. 602, 610 (1993). A purely remedial sanction, on the other hand, that "compensates [the] [g]overnment for lost revenues" is not brought about to "[d]eter[] and to "punish[]" and does not qualify as a "fine" for Eighth Amendment purposes. *Bajakajian*, 524 U.S. at 327-29. Because "'sanctions frequently serve more than one purpose,' … the Excessive Fines Clause applies" if "the law 'cannot fairly be said *solely* to serve a remedial purpose.'" *Tyler v. Hennepin County*, 598 U.S. 631, 648 (2023) (Gorsuch, J., concurring).

Here, there can be no dispute that the "excise" tax is intended to punish—or deter—behavior rather than to raise revenues. That much is obvious from the face of the statute, which imposes a penalty so high that it cannot ever realistically be paid. *See Stevens v. City of Columbus*, No. 20-cv-1230, 2021 WL 3562918, at *4 (S.D. Ohio Aug. 12, 2021) ("Because the would-be fine [i]s at least partially punitive (since it seeks to enforce compliance), the fine is punitive."), *aff'd,* 2022 WL

2966396 (6th Cir. July 27, 2022); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("It is very clear that the 'excise tax' is not imposed for revenue but exacted as a penalty to compel compliance with the regulatory provisions of the act."). Indeed, the CBO has projected that this "tax" would raise zero dollars. *Supra* at 12. As in *Carter*, the sheer magnitude of this so-called "tax" confirms that its "purpose" is not to raise revenues, but to coerce behavior—specifically, to force "an agreement," when "of course, it is not, for it lacks the essential element of consent." 298 U.S. at 289; *see Hill v. Wallace*, 259 U.S. 44, 66 (1922) (striking down statute where "[t]he manifest purpose of the tax is to compel Boards of Trade to comply with regulations").

Indeed, the "excise tax" provision is explicitly titled "Designated drugs during *noncompliance periods*," and it is expressly triggered by "*noncompliance periods*" when manufacturers fail to comply with the Program's various demands, such as that they "negotiat[e]" with CMS and "agree[]" to the agency's "maximum fair price." 26 U.S.C. § 5000D (emphasis added). "Economic penalties" such as this one that are "imposed to deter willful noncompliance with the law" are just "fines by any other name." *Tyler*, 598 U.S. at 649-50.

2. The fine is also disproportionate to the "gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. In evaluating proportionality, courts consider "(1) the degree of the defendant's reprehensibility or culpability;

(2) the relationship between the penalty and the harm to the victim caused by the defendant's actions; and (3) the sanctions imposed in other cases for comparable misconduct." *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 425 (2001).

The "excise tax" fails this test because it imposes an enormous penalty for totally innocent conduct. Refusing to negotiate or agree to proposed terms for a sale *is not wrongful at all*—even if the government might benefit financially from compliance. *See, e.g.*, *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, 715 F. Supp. 3d 1133, 1158 (D. Minn. 2024) (monetary award under False Claims Act was excessive fine because of relatively low "degree of moral turpitude" underlying defendants' conduct). It goes without saying that the most severe monetary penalty the federal government has ever imposed is grossly disproportionate to that alleged "wrong-doing." *Bajakajian*, 524 U.S. at 336-37.[4]

B. The AIA Does Not Bar Novartis's Challenge

The district court sidestepped the merits, dismissing Novartis's Excessive Fines Clause claim as jurisdictionally barred under the AIA. The district court erred

[4] In the district court, the government relied on a nonbinding IRS intent to issue regulations that have never been issued and that sets forth an interpretation of the penalty that cannot be reconciled with the statute's plain text. *See supra* at 10 n.3. But even assuming the government imposed only the amount described in that guidance, Novartis still would be facing a fine exceeding *$2 billion* annually for the simple act of not agreeing to proposed "contractual" terms. JA91 (Vineis ¶8).

in applying the AIA to this suit in the first place, and it was equally mistaken in concluding the challenge falls outside the *Williams Packing* exception.

1. The AIA Does Not Bar Pre-Enforcement Challenges That Do Not Have The Purpose Of Restraining Revenue Collection

The AIA prohibits pre-enforcement "suit[s] *for the purpose of* restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a) (emphasis added). The plain language thus directs courts to focus on the "purpose of" the "*suit*," not merely the label of the exaction, to determine whether the AIA applies. *CIC Servs., LLC v. IRS*, 593 U.S. 209, 217-18 (2021) (emphasis added); *see id.* at 228-29 (Kavanaugh, J., concurring) (the AIA's plain text "direct[s] courts to look at the stated object of a suit rather than the suit's downstream effects"). And it also makes clear that only exactions that will be "assess[ed] or collect[ed]" to yield public revenue count as "taxes" for AIA purposes. 26 U.S.C. § 7421(a); *see, e.g.*, *Tax*, *Black's Law Dictionary* (12th ed. 2024) (defining "tax" to be a "charge, usu[ally] monetary, imposed by the government . . . to yield public revenue").

As the Supreme Court has explained, "[t]he *purpose of* a measure is 'the end or aim to which [it] is directed,'" not its eventual downstream impact. *CIC Servs.*, 593 U.S. at 217. That "'end'" or "aim" is "best assessed" by "the face of the taxpayer's complaint" and, "most especially," the "thing sought to be enjoined." *Id.* at 217-18. Unless "the target of a requested injunction is a tax obligation" and "runs against the 'collection or assessment of [a] tax,'" the lawsuit "can go forward"—

regardless of whether the exaction is labeled a "tax." *Id.* at 216, 218; *see, e.g.*, *Harper v. Rettig*, 46 F.4th 1, 8-9 (1st Cir. 2022) (AIA did not apply where plaintiff "stands nowhere near the cusp of tax liability" and "target" of lawsuit was not tax "assessment and collection" but IRS's "'separate legal' wrong" of retaining records). That is because the AIA's primary function is to "'protect[] the . . . Government's ability to collect a consistent stream of revenue, by barring litigation to enjoin or otherwise obstruct the collection of taxes.'" *CIC Servs.*, 593 U.S. at 212.

Novartis's challenge is not aimed at restraining the "assessment or collection of" any "tax" that the government intends to assess or collect. Instead, its target is to restrain CMS's use of the specter of an unconstitutional fine to coerce its participation in the Program. *See* JA86 (Compl. ¶23) (seeking to "[e]njoin Defendants from forcing Novartis . . . to 'agree' to prices set by the Program").

Below, the government suggested that the effect of Novartis's lawsuit is to restrain the assessment or collection of the "tax" because an injunction would prohibit the government from assessing or collecting any excise tax. But, as discussed above, the government has no intention of ever actually assessing or collecting the "tax." The "excise tax" was purposefully set at such an exorbitantly high level as to ensure no manufacturer could ever afford not to comply with the Program's commands. Any assessment of that "tax" would mean the Program has

failed to operate as intended. That is why the CBO has predicted that the tax will *never* be assessed or collected. *Supra* at 12.

A lawsuit that challenges a provision that is intended to generate no revenue obviously does not have the "purpose" of preventing tax collection. With or without Novartis's lawsuit, a tax will never be levied. Rather, the object of Novartis's lawsuit is to prevent the government from using the tax to unlawfully coerce participation. No plausible purpose of the AIA supports barring a lawsuit in circumstances where, even absent the suit, the "tax" is not expected or intended to generate revenue. *See* Erin M. Hawley, *The Equitable Anti-Injunction Act*, 90 Notre Dame L. Rev. 81, 124 (2014) ("[W]hile the pay-now, litigate-later system makes sense when applied to revenue-raising measures, the government's fiscal interests in summary and stringent enforcement do not apply when the measure accomplishes a regulatory purpose.").

In a single sentence in a footnote, the district court held that the AIA's jurisdictional bar applied to Novartis's challenge because "Congress labeled the excise tax a 'tax'." JA7 n.6. That reasoning is fatally incomplete. As explained above, the AIA does not block every suit involving what Congress conveniently labels a "tax"; rather, it only prohibits pre-enforcement challenges that have the "*purpose of* restraining the *assessment or collection of* a[] tax." 26 U.S.C. § 7421(a) (emphasis added). The district court entirely overlooked this distinction—and,

indeed, failed to engage with the statutory text or purpose at all. Moreover, the district court failed to explain why Congress's chosen label should dictate the AIA's applicability, when the exaction is not intended to and never will result in *any* payment to the fisc. The Supreme Court has never held that Congress's choice of a "tax" label controls for AIA purposes where a penalty was not designed to generate any revenue.

The district court's sweeping and unreasoned holding also creates a situation ripe for abuse, since it means that simply by Congress *labelling* a penalty a "tax," any Eighth Amendment challenge would be practically impossible to mount. Congress could, for example, impose a trillion-dollar "tax" on individuals who choose not to recycle. Under the district court's logic, affected individuals would first have to *pay* that tax in order to initiate a refund suit challenging the provision. And if they simply complied with the law (as anyone surely would), they would lose the ability to challenge it at all. That cannot be the law.

2. Regardless, Novartis's Challenge Meets The *Williams Packing* Exception

Even assuming that this were a suit to restrain assessment or collection of a bona fide tax, which it is not, the challenge here fits comfortably within the AIA's equitable *Williams Packing* exception. Under *Williams Packing*, a plaintiff may obtain an injunction against enforcement of a "tax" when the plaintiff will otherwise suffer irreparable injury and can demonstrate a "certainty of success on the merits."

Bob Jones Univ. v. Simon, 416 U.S. 725, 737 (1974). Here, Novartis would indisputably suffer irreparable injury by being forced either to engage in speech it disagrees with or pay ruinous penalties. And the government has never offered a serious basis to reject the Excessive Fines claim on the merits. The district court's contrary conclusions do not withstand scrutiny.

1. The government below did not contest that Novartis would face irreparable harm if forced to choose between paying a "tax" of 1,900%—or even 95%—on all sales of ENTRESTO® or even just Medicare sales, or capitulating to the Program's forced-sales and forced-speech demands. Nor could it, as Novartis plainly suffers irreparable harm from being coerced by a multi-billion dollar fine into echoing the government's preferred messages. The law is well-settled that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). And the imposition of a financially ruinous penalty would likewise have irreversible effects on Novartis's business, including by potentially forcing it to redirect its investment efforts. *See Doran v. Salem Inn, Inc*., 422 U.S. 922, 932 (1975) (finding irreparable injury where petitioners would suffer "a substantial loss of business and perhaps even bankruptcy"); JA91-92, 97 (Vineis ¶¶11, 28). And the same is true if Novartis were to withdraw all of its products from Medicare and Medicaid, in order to avoid the fine—which would cause tremendous loss of reputation and goodwill, while also

causing devastating harm to the many patients who rely on ENTRESTO® to combat their heart disease. *See Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 805 (3d Cir. 1998) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill"); JA92, 98 (Vineis ¶¶12, 31-32). Whichever option Novartis chooses, the harm will be vast and irreversible.

The district court nonetheless concluded that any such harm would not be irreparable because the excise tax is "divisible." JA8. The court reasoned that, since the tax is imposed on each transaction, Novartis could incur the tax on a single transaction and the government would then "'exercise forbearance'" while a refund suit is pending, based on a policy that IRS "typically" follows. *Id.*

The district court's conclusion was deeply misguided. As an initial matter, even if this "policy" could serve to reduce the financial penalty, irreparable harm lies not just in the magnitude of the penalty, but in the speech it compels itself. *See, e.g.*, *Cuviello v. City of Vallejo*, 944 F.3d 816, 832 (9th Cir. 2019); *Bery v. City of New York*, 97 F.3d 689, 693-94 (2d Cir. 1996) (both recognizing irreparable harm from speech restrictions without regard to amount of financial penalties involved). Reducing the size of the fine—through forbearance or otherwise—does nothing to change the fact that Novartis suffers irreparable harm from being compelled to speak the government's preferred messages.

In any event, the forbearance policy does not actually mitigate the financial *risk*—and therefore the coercive effect—of the fine. There is significant doubt about whether the IRS would—or even could—follow this so-called forbearance "policy." The government below merely hinted that the IRS "typically" refrains from collecting the full balance of divisible taxes like this one, but provided little support for the notion that such a policy would apply here. And even if the government's position had been more definitive, convenient litigating positions do not constitute formal, enforceable policy.

Moreover, this "divisibility" argument is irrelevant either way. Even if the IRS were to exercise forbearance in *collecting* the bulk of the penalty, that penalty would still be *accruing* to the tune of billions of dollars each year before a decision is reached—which could take months, if not years. Practically speaking, Novartis cannot run the risk of such enterprise-destroying fines—meaning it would still be impossible for Novartis or any manufacturer to challenge this fine, even if the IRS promises to collect only a small portion of it before the lawsuit. The government well knows that it is utterly unrealistic to expect a company to gamble its entire business on the outcome of a refund suit; that was the entire stated point of setting the penalties at these levels. The government's purported "forbearance" thus has no effect on the irreparable harm Novartis suffers.

By the government's logic, it could force homeowners with federally guaranteed mortgages to sell their homes to the government at 75% of market value, threatening a $1 million daily fine for noncompliance. Then, as long as the government claims the first day's fine is just $1 and promises to forbear from collecting the rest to allow a challenge, the scheme would be deemed constitutional. No reasonable homeowner would ever take that gamble and challenge the fine. Neither can Novartis. The end result is that a patently unconstitutional mandate is foreclosed entirely from judicial review.

2. The district court also sidestepped the merits, instead making the erroneous (and irrelevant) observation that Novartis's right to relief is not clear "because [Novartis's] claim is novel, and [Novartis] has not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes." JA9. This reasoning conflates two distinct issues: that Congress chose to label this "fine" a "tax," and that this "fine" is unconnected to criminal conduct. But the law clearly holds that neither factor alone prevents this exaction from being considered a "fine" for Eighth Amendment purposes. Combining these two elements does not change that. And the unprecedented nature of the government's overreach cannot possibly be what shields it from constitutional scrutiny.

a. On the district court's criminal/civil distinction, Novartis cited a number of cases applying the Excessive Fines Clause to civil penalties bearing no connection to criminal conduct—all of which the district court ignored. For example, at least four courts of appeals have held that civil penalties obtained in a False Claims Act qui tam action are "fines for the purposes of the Excessive Fines Clause" because "they are at least in part punitive." *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1308 (11th Cir. 2021); *see United States v. Mackby*, 261 F.3d 821, 830-31 (9th Cir. 2001); *United States v. Aleff*, 772 F.3d 508, 512 (8th Cir. 2014); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387 (4th Cir. 2015). And many other courts have applied the Excessive Fines Clause to cases that had no connection at all to criminal proceedings. *See, e.g. Pimentel v. City of Los Angeles,* 974 F.3d 917, 921-22, 925 (9th Cir. 2020) (analyzing whether $63 parking fine is "grossly disproportional to the underlying offense of overstaying the time at a parking space").

The district court's reliance on a purported "civil/criminal" distinction is also irreconcilable with Supreme Court and Third Circuit precedent. In *Austin*, for instance, the Supreme Court unanimously rejected the government's attempt to limit the Excessive Fine Clause to "criminal" cases, explaining that the question for Excessive Fines Clause purposes "is not, as the United States would have it, whether [the penalty] is civil or criminal, but rather whether it is punishment." 509 U.S. at

610. The Court underscored that the Eighth Amendment serves "to limit the government's power to punish," a power that "'cuts across the division between the civil and the criminal law.'" *Id.* at 609-10.

This Court has likewise made clear that the prohibition on excessive fines "is not confined to exactions imposed as an aspect of the criminal law enforcement process," so "civil imposition . . . which is adjudged 'excessive,' [falls] within the purview of the constitutional bar." *Myrie v. Comm'r, N.J. Dep't of Corr.*, 267 F.3d 251, 262 (3d Cir. 2001); *see also Grashoff v. Adams*, 65 F.4th 910, 916 (7th Cir. 2023) (acknowledging that the Excessive Fines "inquiry does not depend on whether the sanction arises in the civil or criminal context").

Indeed, as Justice Gorsuch has noted, the Excessive Fines Clause "would mean little if the government could evade constitutional scrutiny under the Clause's terms by the simple expedient of fixing a 'civil' label on the fines it imposes and declining to pursue any related 'criminal' case." *Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari). And the implication would be that the *same* penalty could be struck down as unconstitutional if it were deemed excessive in relation to culpable criminal conduct, but valid as to *less* culpable—or completely innocent—civil conduct. The civil/criminal distinction that the district court relied upon is thus flatly incorrect.

b. Nor does it matter that the civil penalty here was labelled a tax. As the Supreme Court has explained, "Congress cannot change whether an exaction is a tax or a penalty for constitutional purposes simply by describing it as one or the other." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012). This principle applies even when Congress explicitly labels a penalty a "tax" for AIA *statutory* purposes; that "tax" can still be deemed a "fine" for Eighth Amendment *constitutional* purposes. *Id.* As the Supreme Court has reiterated, when the government amplifies the "penalizing features of [a] so-called tax," that "tax" may "lose[] its character as such and become[] a mere penalty with the characteristics of regulation and punishment," subject to Eighth Amendment scrutiny. *Dep't of Revenue of Mont. v. Kurth Ranch*, 511 U.S. 767, 779 (1994) (citing cases "examin[ing] taxes for constitutional validity"). This so-called "tax" catapults over that line.

At bottom, the mere presence in the statute of this purported "tax" inflicts vast and irreversible harm on Novartis, and the government has advanced no serious argument on the merits. Even if the AIA governed this suit, it would fit comfortably within the *Williams Packing* exception.

II. THE PROGRAM VIOLATES THE FIFTH AMENDMENT'S TAKINGS CLAUSE

A. The Program Appropriates Novartis's Property Rights Without Just Compensation

The Fifth Amendment's Takings Clause prevents the government from taking "private property . . . for public use, without just compensation." U.S. Const. amend. V. A physical appropriation of property is the "'clearest sort of taking.'" *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021). When it "appropriat[es] personal property" in this way, the government "has a categorical duty to pay just compensation," or the "'market value of the property at the time of the taking.'" *Horne v. Dep't of Agric.*, 576 U.S. 350, 358-59, 368-69 (2015).

The Supreme Court's decision in *Horne* controls this case. There, a statute directed farmers to "turn over a percentage of their raisin crop" under pain of penalties, subject to the right to recover some proceeds if the government resold the raisins. *Id.* at 361-62. When the Hornes declined to comply, "[t]he Government sent trucks . . . to pick up the raisins," the Hornes "refused entry," and the Government then imposed fines for "disobeying." *Id.* at 356. Even though the government never physically seized the Horne's raisins, the Court held that the statute effectuated a "clear physical taking" because the farmers lost their "right to control their [raisins'] disposition." *Id.* at 358, 361, 364.

The Program appropriates Novartis's medicines in much the same way. The drugs themselves are—until they are sold—Novartis's personal property, and are therefore protected from uncompensated takings. *See, e.g.*, *id.* at 358-59. And under the Program, Novartis *must physically transfer* its products to third parties at the dictated price; it cannot refuse to sell to them, and thereby forfeit the money from the sale. §§ 1320f(c)(2)(A), 1320f-2(a)(3). This is because the Program requires manufacturers to provide "access" to their drugs at the "maximum fair price" to all eligible individuals dispensed drugs under Medicare Parts B and D, among others. §§ 1320f-2(a)(1)(A)-(B), 1320f(c)(2).

Moreover, just as in *Horne*, the Program uses the threat of penalties as a means of ensuring that manufacturers comply in the forced transfer of their property at below-market terms. *See* 576 U.S. at 355-56. As noted, failing to provide access to ENTRESTO® at CMS's chosen "maximum fair price" would trigger approximately *$93.1 billion* in annual penalties, an amount almost double Novartis's total global annual net revenue. The end result is a forced transfer: Novartis must provide its property to Medicare participants on terms the company would never voluntarily accept, upon pain of bankrupting the business with a ruinous fine. That is, of course, nothing like an ordinary market transaction.

It also stands in stark contrast to rate setting. When the government engages in true rate setting, the result is a regulatory cap on what the seller may charge. The

seller is left with a choice between retaining their property, or selling it at the government-set price. But, here, critically, there is no choice to retain the property in question—the manufacturer *must sell* the drug at the dictated price. That is a quintessential taking.

B. Novartis's Purported Options To Avoid The Taking Are Legally Irrelevant

1. The district court's main response was that the taking here would be permissible because Novartis "voluntarily" participates in the Medicare program. JA5 n.4. In the district court's view, Novartis could avoid handing over its property by opting instead to (i) pay the crippling excise tax, (ii) divest Novartis's interest in ENTRESTO® to a separate entity, or (iii) withdraw *all* of Novartis's drugs from the Medicare and Medicaid programs. *Bristol Myers Squibb Co. v. Becerra* (*BMS-Janssen*), 2024 WL 1855054, at *4-9 (D.N.J. Apr. 9, 2024), *appeal filed*, No. 24-1821 (3d Cir. May 6, 2024). Because Novartis is not "*legally* compelled" to participate in the Program given these other options, the district court concluded, the consequences of that participation cannot be considered a constitutional violation as a matter of law. *Id.* at *5.

But *Horne* makes clear that none of these options makes Novartis's participation in the Program "voluntary" in a legally relevant sense. Start with the first option: paying a crippling excise tax for each day of noncompliance. The government did not seriously defend that option in the district court, and for good

reason. The Supreme Court has held that government action backed by a fine still constitutes a physical taking, even if the taking is not "legally" compelled. *Horne*, 576 U.S. at 356, 370. Were the law otherwise, "the government could avoid the strictures of the Takings Clause by purporting to 'simply give the owner a choice of either surrendering [property] or making a payment equal to the [property's] value.'" *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023) (quoting *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013)).

The second option works no better. Transferring one's property to someone else "'burdens ownership of property'" just as much as paying a fine or handing over the property to the government. *Id.* at 1234-35. Either way, the government is forcing the owner to give up "title" and "any right to control" its property, which means a physical taking has occurred. *Horne*, 576 U.S. at 364.

This leaves the third option, which is the only one that the government meaningfully attempted to defend below: exiting Medicare and Medicaid entirely for all of Novartis's products. But this is just as impermissible as the other two. It is simply another way of saying that Novartis can leave the relevant marketplace to avoid the taking. But the Supreme Court has held on numerous occasions that the fact a property owner can avoid a taking by exiting a relevant market is not a valid defense to a *per se* takings claim. *See Koontz*, 570 U.S. at 612-13.

Indeed, the arguments the district court accepted mirror those the government advanced—and the Supreme Court *rejected*—in *Horne*. In *Horne*, the government contended that its raisins appropriation was not a *per se* taking because producers were subjected to it "only by voluntarily entering the commercial market for raisins." *Horne* Respondent's Br. 30 (No. 14-275), 2015 WL 1478016. Because that market was federally regulated and heavily subsidized, the government argued, it could lawfully impose any participation conditions, including takings deemed necessary to "stabilize the market." *Id.* at 16, 28.

Justice Sotomayor, in her dissenting opinion, accepted this reasoning, asserting that "insofar as the Hornes wish to sell some raisins in a market regulated by the Government and at a price supported by governmental intervention, the Order requires that they give up the right to sell a portion of those raisins at that price and instead accept disposal of them at a lower price." *Horne*, 576 U.S. at 384-85. That is *exactly* the same, flawed argument the district court accepted here.

But Justice Sotomayor's dissent was just that—a dissent, not the law. The *Horne* majority made clear that physical property may *never* be held "hostage" as a "condition" for market participation—regardless whether property owners "voluntarily cho[se] to participate in [that] market" and irrespective of how regulated that market may be. *Id.* at 365-67; *see also Sierra Med. Servs. All. v. Kent*, 883 F.3d 1216, 1225 (9th Cir. 2018) ("voluntary participation in a market" does not "defeat a

takings claim" under *Horne*). That holding is fatal to the IRA. If "legal compulsion" was required to have a *per se* takings claim (as the district court here concluded), *Horne* would have come out the opposite way. Instead, *Horne* underscores that the government cannot simply mandate that a participant exit a market to avoid a *per se* taking.

If anything, the cost of withdrawal here is even more onerous than in *Horne*, because a manufacturer must withdraw *all* of its products from the relevant market, rather than just the one subject to the taking. It would be akin to the government in *Horne* suggesting that a farmer could avoid the taking of raisins, only by ceasing sales of all its *other* crops as well. And while the government may suggest that a manufacturer can re-orient its business away from the Medicare and Medicaid markets, that is no different (and no more realistic or constitutionally acceptable) than suggesting the farmers in *Horne* could re-orient their business to use their grapes for wine instead of raisins. *See Horne*, 576 U.S. at 365.

2. The district court dismissed the central reasoning in *Horne* based on a series of misplaced distinctions. First, it asserted that the law in *Horne* required growers "to stop selling raisins altogether" to avoid a taking, while the Program affects only manufacturers' "sales to Medicare," not all sales. *BMS-Janssen*, 2024 WL 1855054, at *6. But the growers in *Horne* were not "manufacturers" of raisins—they grew grapes, and sought to sell those grapes into the federally regulated raisins market.

So they *could* sell the same grapes to other buyers "'as table grapes or for use in juice or wine'"—just as Novartis can (by the government's telling) sell the same ENTRESTO® products outside the federally regulated market. *Horne*, 576 U.S. at 365. But *Horne* rejected this "'[l]et them sell wine'" defense as "wrong as a matter of law." *Id.*

The district court also suggested that no taking occurs because the government does not "'sen[d] trucks'" to Novartis's facility or require it "'to physically transmit or transport drugs.'" JA5. That is a distinction without a difference. Any law that appropriates property rights constitutes a physical taking, however the appropriation "comes garbed." *Cedar Point*, 594 U.S. at 149; *see also Ark. Game & Fish Comm'n v. United States*, 568 U.S. 23, 31 (2012) (recognizing "the nearly infinite variety of ways in which government actions or regulations can affect property interests"). And *Horne* did not turn on the fact that the government sent trucks to the facility—as those trucks were *sent away* by the growers. *See Horne*, 576 U.S. at 356. Nothing in Takings jurisprudence suggests a distinction between having to pay an enterprise-destroying penalty for refusing to hand something over, and having that property ripped from one's hands.

Likewise, the district court's conclusion that there is "'no statutory provision that imposes a requirement that pharmaceutical manufacturers must *set aside, keep,* or *otherwise reserve* any of their drugs'" is another red herring. JA5. Due to the

Program's "access" requirement, manufacturers must transfer available units at government-dictated prices to beneficiaries upon request. § 1320f-2(a)(3). There is no legal difference between a set-aside or a forced sale for Takings Clause purposes.

Finally, the district court also stated that, unlike in *Horne*, the government here does not wield sovereign power, but is merely acting as a "market participant" that purchases drugs from manufacturers. *BMS-Janssen*, 2024 WL 1855054, at *8. That too is wrong. The government does not buy drugs from manufacturers in these transactions. *Supra* at 8. Rather, it operates as a sovereign, providing a subsidy to beneficiaries (through private health plans) and to healthcare providers to offset their costs of purchasing prescription drugs from manufacturers. These reimbursements are designed to impact prices in purchase transactions between private parties—not the prices paid by the government for a good it purchases for its own use. That is functionally no different to *Horne*, where the government engaged in direct interventions in the market to regulate and subsidize prices. *See supra* at 38. And the situation is no more a case of "market participation" than if, for example, the government implemented an affordable-housing program requiring landowners to relinquish their property to lower-income individuals, compensating them at only half the property's value. In both instances, the government is not purchasing a good for itself, but is exercising its regulatory power to mandate a transfer of property

between private parties on terms and compensation it dictates—a purely sovereign role.

Moreover, through the Program specifically, the government exercises sovereign power far different than a purchaser or ordinary market participant. For example, the government taxes private parties who refuse to comply with the Program's terms and imposes civil monetary penalties on sales above the prices it sets. The government also orders private parties to "compl[y] with" any "requirements" the government "determine[s] . . . to be necessary" to administer the Program. § 1320f-2(a)(5); *see* § 1320f-6. And the government asserts authority to amend the agreements' terms without manufacturers' consent, whenever it chooses. Market participants cannot do any of these things; only regulators can. *See, e.g.*, *Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 569 U.S. 641, 651-52 (2013) (An agency is not acting as a market participant where it "employs . . . coercive mechanism[s], available to no private party.").

In short, none of the district court's purported distinctions with *Horne* holds up to scrutiny. *Horne* unequivocally rejects the avoidance-as-voluntariness rationale at the heart of the district court's opinion.

3. Even if this Court disagrees that this sort of physical requisitioning is always unlawful under *Horne*, the district court's reasoning fails even on its own terms. The district court's voluntariness argument hinges on the government's

taking being a "condition" on Novartis's participation in the Medicare and Medicaid markets. *BMS-Janssen*, 2024 WL 1855054, at *8. However, the Program's mandates are not "conditions" on participation in a government program; they are requirements, backed by penalties. *See Valancourt*, 82 F.4th at 1233-34 (deposit requirement backed by fine was not a "condition" where owners "retain copyright regardless"). If manufacturers refuse the Program's forced-sales demands, they still remain in the Medicare and Medicaid programs, even as to the selected drug (which would then be reimbursed at its full market price). The consequence of such noncompliance is imposition of draconian penalties, not removal from the programs.

Regardless, such "conditions" still would fail under the unconstitutional-conditions doctrine, which prohibits the government from "deny[ing] a benefit to a person because he exercises a constitutional right." *Regan v. Tax'n with Representation of Wash.*, 461 U.S. 540, 545 (1983). Appropriating Novartis's medicines for below-market compensation remains unlawful even if characterized as a "condition."

C. The Government's Attempts To Rewrite The Statute Are Unconvincing

In an implicit acknowledgement that the statute Congress enacted is indefensible on its own terms, the government's briefs in this litigation attempted to rewrite the statute. Below, the government argued that Section 1320f-2(a)(3) does not actually require Novartis to provide "access" to ENTRESTO®, but rather only

"access to the price" that the government has declared to be the "maximum fair price" *if* Novartis choses to sell ENTRESTO® to Medicare beneficiaries. So, in the government's view, Novartis would not violate the statute if it simply declines to sell ENTRESTO® to Medicare beneficiaries, while otherwise remaining in the Medicare and Medicaid programs.

The district court did not adopt this argument—and for good reason. The government's interpretation flies in the face of the statute's plain language. To provide "access" to something means to enable someone to "make use of" it. *Access*, *Merriam Webster Dictionary* (2024, online). Any reader of ordinary English would understand "access" to a particular "price" to encompass "access" to the underlying *product* as well. After all, one cannot "make use of" a product's price if they are otherwise denied access to the product itself. If, after signing the agreement with CMS, Novartis were simply to refuse to transfer ENTRESTO® to any Medicare beneficiary, Novartis would obviously not be allowing anyone "access to"—or "use of"—the purported "maximum fair price." Indeed, it would be akin to a store promising that it "shall . . . provide" "access to a military discount with respect to" a product, only to turn away every military customer at the door. The government's reading is textually indefensible.

Other provisions of the IRA reinforce this interpretation. Section 5000D(c), for example, makes clear that Novartis has the "option" to avoid the IRA's penalties

only by withdrawing *all* of Novartis's products from Medicare *and* Medicaid entirely. The IRA nowhere suggests, as an alternative (and obviously preferable) choice, withdrawing just the *one* selected product from Medicare coverage only. Indeed, if the statute already allowed single-drug, single program withdrawal, then 26 U.S.C. § 5000D(c) would serve no purpose at all. That superfluity problem is reason enough to reject the government's argument. *See, e.g.*, *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (explaining a court's duty to "give effect, if possible, to every clause and word of a statute").

Nor did the district court set forth any plausible way for Novartis to avoid sales of ENTRESTO® to Medicare beneficiaries while nonetheless staying in the Medicare and Medicaid programs. The statute requires that selected drugs "shall" be included in *every* Medicare Part D drug formulary, which strips the manufacturer of the ability to withhold such drugs from coverage. § 1395w-104(b)(3)(I)(i). Due to this statutory requirement and the nature of how the United States pharmaceutical supply chain operates, Novartis cannot simply choose to stop selling ENTRESTO® to Medicare beneficiaries at below-market rates while remaining in the Medicare program. JA96 (Vineis ¶25).

The government's (re)interpretation of the statute also conflicts with statements that the implementing agencies themselves have already made. Perhaps most telling, CMS *nowhere* mentioned the purported option of stopping sales of only

the selected drug in its 198 pages of guidance detailing the alleged "options" manufacturers have to avoid the demands of the Program. Instead, CMS identified as viable options only divesting a manufacturer's interest in its drug, withdrawing from Medicare and Medicaid *entirely*, or paying the so-called "excise tax." *See, e.g.*, JA269, 392-93. The IRS has taken a similar position, acknowledging in its own guidance that the Program requires manufacturers "to provide *access to selected drugs*." JA502 (IRS Notice § 2.01) (emphasis added). The government's made-for-litigation rewrites do nothing to salvage a plainly unconstitutional taking.

III. THE PROGRAM COMPELS SPEECH IN VIOLATION OF THE FIRST AMENDMENT

Finally, the Program is unconstitutional in a third respect. It coerces Novartis into signing what is termed an "agreement," falsely claiming participation in a genuine "negotiation," and endorsing the notion that the government-dictated price is the "maximum fair price"—essentially forcing Novartis to denounce its current pricing as unfair. These speech mandates serve solely to promote the government's narrative and mislead the public about the Program's true nature. The district court's contrary holding was rife with errors. The court mistakenly characterized the Program as regulating only conduct, wrongly asserted that the terms in the agreements are "not expressive," erroneously believed that the ability to engage in counter-speech nullifies the First Amendment violations, and repeated the same

flawed "voluntariness" argument from the Fifth Amendment context. The decision below should be reversed on this ground as well.

A. The Program Forces Novartis To Deliver Messages With Which It Disagrees

The First Amendment safeguards both the right to speak and the right to remain silent. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 585 U.S. 878, 892 (2018). Laws that compel private speech, like the Program, are subject to strict scrutiny and are presumed unconstitutional unless the government demonstrates they are "'narrowly tailored to serve compelling state interests.'" *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018).

Compelled speech forms the backbone of the Program. The statute creates a convoluted process of sham negotiations designed to create a misleading impression that the Program is a genuine "negotiation" rather than compelled sales at the government's price. For example, as described above, Congress forces manufacturers like Novartis to represent to the public that they voluntarily engaged in a "negotiation" over the "maximum fair price" when, in reality, the government unilaterally sets the ultimate price. § 1320f-2(a); 26 U.S.C. § 5000D; *see also* § 1320f-2(a)(1) (emphasis added). And Congress compels manufacturers to sign documents stating that they "agree" to the "maximum fair price" CMS sets after those pretend "negotiation[s]" conclude. §§ 1320f-2(a)(1), 1320f(c)(2). Signing

these documents conveys clear messages to the public: that these are genuine, good-faith negotiations; that this voluntary give-and-take culminated in a true "agreement"; that the "agreed-on" price reflects the selected drug's value; and that manufacturers' previous and current market prices, even those resulting from genuine negotiations, are *unfair*.

Of course, Novartis does not genuinely "agree" with any of this. It has been coerced into signing these "agreements" because, otherwise, it would be deemed in "noncompliance" with the Program, facing untenable penalties that quickly balloon to nineteen times ENTRESTO®'s total sales. 26 U.S.C. § 5000D. The Program thus violates Novartis's right to refrain from speaking.

B. The District Court Misapplied First Amendment Doctrine In Upholding The Program

The district court had four justifications for upholding the Program's compelled-speech regime, but none is persuasive.

1. The district court first held that the Program "regulates commercial conduct, not speech," because the "'primary purpose of the Program is to determine the price manufacturers may charge'" and "'[a]ny "speech" aspects of the Program, such as the agreements and negotiations, are merely incidental mechanisms used during the price-setting process.'" JA6. In other words, the district court seemed to believe that, because manufacturers are forced to sign an agreement to particular

prices (a purported regulation of conduct), any implicated speech is somehow immune from First Amendment scrutiny. That is plainly incorrect.

In determining whether a statute directly regulates speech or only "imposes . . . an incidental burden," courts examine what the statute regulates "on its face." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). Where a statute "does not simply have an effect on speech, but is directed at certain content," its effect on speech is not merely "incidental." *Id.*; *see also United States v. Hansen*, 599 U.S. 762, 783 (2023) (impact on speech incidental where statute "stretches no further than speech integral to unlawful conduct"). Here, on its face, the Program *directly* compels speech—it does not simply cap the price of ENTRESTO®, but orders Novartis to *speak about* the price CMS has imposed. That compelled speech is in no way "integral" to a purported governmental goal of simply regulating drug prices.

The Supreme Court's decision in *Expressions Hair Design v. Schneiderman* is directly on point. 581 U.S. 37 (2017). In that case, the Court drew a clear line between restrictions that regulate "how sellers may *communicate* their prices" (which are *not* incidental restrictions) and those that simply set price limits (which *are* incidental). *Id.* at 47-48 (emphasis added). The Court explained that, unlike typical price caps, laws regulating "the *communication* of prices" have speech as their *object*, thus triggering strict scrutiny. *Id.* at 48 (emphasis added). That is

exactly the case with the Program. It is far from a "typical price regulation," *id.* at 47, as it mandates communications that "characteriz[e]" "product price[s]," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019), including statements about the nature of the process used to adopt those prices and their perceived fairness—statements with which Novartis profoundly disagrees.

The district court's conclusion that this compelled speech was "incidental" to its conduct regulation assumes that the *only* way to implement a drug-pricing scheme was through these statements. JA6. But Congress could have just as easily—and more straightforwardly—established a price regulation system without compelling manufacturers to make *any* statement about the prices, as it has done before. Alternatively, Congress could have used more neutral, purely descriptive terms like "maximum allowable price" or even the "ceiling price" that arguably do not convey any message beyond the conduct they are describing. But that is not what happened here. Instead, Congress required manufacturers to opine that its set price is the "maximum *fair* price"—an obviously loaded term that conveys the government's preferred message on a highly contentious political issue.

2. The district court also incorrectly held that agreements made pursuant to the Program are "not expressive" because the agreements merely incorporate "statutory terms of art." *BMS-Janssen*, 2024 WL 1855054, at *11. In the court's view, because the statute defines terms such as "maximum fair price," and because

the agreements incorporate those terms, agreements made under the Program do not implicate the First Amendment. That is wrong multiple times over. As the D.C. Circuit has explained, if the government could use politically charged statutorily defined terms to compel speech, "there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015).

The sole case the district court cited for this theory—*Meese v. Keene*, 481 U.S. 465 (1987)—offers no support. In *Meese*, a statute used the term "'political propaganda'" to identify certain expressive materials. *Id.* at 469-72. A person who exhibited covered films challenged the statute for implying he disseminated "'political propaganda,'" but the court upheld the statute because it neither required nor prohibited any speech. *Id.* at 480-84. This case is fundamentally different. Novartis is not challenging Congress' use of the term "maximum fair price" in the IRA; it is challenging the IRA's mandate that Novartis *itself* attest that whatever price CMS sets is the "maximum fair price." As the D.C. Circuit explained, *Meese* "'did not suggest, much less hold,'" that Congress can "'skew public debate by forcing companies to use [its] preferred language'" merely by assigning that language a "statutory definition." *Nat'l Ass'n of Mfrs.*, 800 F.3d at 529-30.

3. The district court next held that "nothing in the statute prevents Plaintiffs from publicly criticizing the Program or the final drug prices," deeming this

constitutional challenge a "public relations problem[]." *BMS-Janssen*, 2024 WL 1855054, at *12. But the notion that the ability to engage in counter-speech negates a First Amendment violation is fundamentally at odds with decades of established precedent. The Supreme Court has repeatedly recognized that the government cannot "require speakers to affirm in one breath that which they deny in the next." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion). "Otherwise," governments could "infringe on anyone's First Amendment interests at will." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). The court's limitless view would permit *any* compelled-speech regime, no matter how severe the constitutional harm, so long as some outlet for counter-speech exists.

4. Finally, the district court also repeated its conclusion that manufacturers' participation in the Program is voluntary. *BMS-Janssen*, 2024 WL 1855054, at *9. That argument is flawed for the all same reasons discussed in the Fifth Amendment context. *See supra* at 36-43. Indeed, the notion that voluntary participation in a program can excuse a constitutional violation carries even *less* force in the First Amendment context.

When assessing whether a condition on federal funds infringes on freedom of speech, "the relevant distinction" is between conditions that "specify the activities Congress wants to subsidize" and those that "seek to leverage funding to regulate speech." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc. ("USAID")*, 570

U.S. 205, 214-15 (2013). For example, in *USAID*, the Supreme Court invalidated a requirement that federal funds not "be used by an organization 'that does not have a policy explicitly opposing prostitution and sex trafficking.'" *Id.* at 208, 221. The Court contrasted this with the regulations in *Rust v. Sullivan*, 500 U.S. 173 (1991), which "were simply 'designed to ensure that the limits of the federal program are observed.'" 570 U.S. at 217 (quoting *Rust*, 500 U.S. at 193).

This case is more like *USAID* than *Rust*. The Program's compelled-speech provisions do not define what Congress intends to fund, but instead seek to leverage the threat of exorbitant fines to force manufacturers to speak the governments' preferred message. They are an impermissible mandate placed "on the *recipient* of the [government's benefits] rather than on a particular program or service." *Rust*, 500 U.S. at 197; *see USAID*, 570 U.S. at 218-19.

In any event, Novartis's compelled speech is not voluntary in any relevant sense, as Novartis could *not* have exited the Medicare and Medicaid programs before the Program's compelled-speech provisions kicked in. As in *Valancourt*, the "statute itself gives no indication" that withdrawing could have been "effectuate[d]" in time to avoid the Program's compelled-speech demands. 82 F.4th at 1236. To the contrary, Congress expressly *blocked* manufacturers from withdrawing from those programs without providing up to 23 months' notice. *See* § 1395w-114a(b)(4)(B)(ii). This means that to avoid penalties for refusing to sign the initial

agreement by October 1, 2023, Novartis would have had to act by January 31, 2022—before the IRA was even enacted.

To be sure, CMS has said in nonbinding guidance that if manufacturers wish to withdraw, *the agency* will "terminat[e]" the manufacturers' agreements earlier. JA296, 383-84. But this rewrite stands in evident conflict with the statute, which suspends the excise tax only when *a manufacturer* terminates its Medicare and Medicaid agreements, 26 U.S.C. § 5000D(c), and the IRA requires termination "[b]y a *manufacturer*" to be delayed 11 to 23 months, § 1395w-114a(b)(4)(B)(ii) (emphasis added). CMS cannot usurp legislative authority to alter statutory language, and its attempt to do so raises serious separation-of-powers concerns. The government's attempt to rewrite the statute "in the course of litigation" just underscores the statute is indefensible as written. *Valancourt*, 82 F.4th at 1237-38.

C. The Court Cannot Sever The Offending Elements Of The Program

The remedy for the Program's First Amendment problems is straightforward and mandatory: Strike down the IRA's drug-pricing provisions in their entirety. This Court cannot remedy the constitutional problem by simply instructing the government to use different language in the "agreements"—or to eliminate the "agreements" altogether—as that compelled speech flows from the *statute*. The statute itself mandates, among other things, that manufacturers falsely assert that they willingly engaged in a negotiation, § 1320f-2(a), that they "agree[]" to the price

set by CMS, § 1320f(a)(2), and that the price chosen by CMS is the "maximum fair price," §§ 1320f(c)(3), 1320f-2(a)(1). Novartis would be in violation of these statutory terms if it failed to sign agreements with Congress's preferred messaging.

Nor can this Court sever the speech elements from the statute. The Supreme Court has consistently refused to sever unconstitutional provisions when doing so would require it to "write words into the statute" or "foresee which of many different possible ways the legislature might respond to the constitutional objections." *Randall v. Sorrell*, 548 U.S. 230, 262 (2006). And severance is not an option when it is impossible to ascertain whether "'the statute created in [the] absence [of the unconstitutional provisions] is legislation that Congress would . . . have enacted.'" *Seila Law LLC v. Consumer Fin. Protection Bureau*, 591 U.S. 197, 234 (2020).

Here, the complex series of "agreements" and manufacturer statements about the Program are intricately "interwoven" throughout the Program, not confined to one single provision. *Wallace*, 259 U.S. at 70 (declining to sever despite severability clause because the unconstitutional section was "so interwoven" with other sections). For instance, the "[m]anufacturer agreements"—which are described in detail in 42 U.S.C. § 1320f-2—are one of the four key elements of the Program listed in 42 U.S.C. § 1320f(a); serve as the trigger for calculating certain rebates in 42 U.S.C. § 1320f-1(f)(4); require certain monitoring by the Secretary under 42 U.S.C.

§ 1320f-5(b); and form the basis for penalties under 42 U.S.C. § 1320f-6(a), (c), as well as under 26 U.S.C. § 5000D(b)(1)(A), (b)(2)(A), (b)(3)(A).

This case is thus a far cry from those where courts have severed unconstitutional provisions. In *Barr v. American Association of Political Consultants, Inc.*, for instance, the Court simply removed seventeen words from a single exception in one statutory provision. 591 U.S. 610, 631 (2020). Here, by contrast, "severing" the free-speech offending provisions would require rewriting multiple provisions across different sections of the U.S. Code.

Moreover, there is no reason to think Congress intended for this Court to undertake the endeavor of dismantling such a deliberately complex legislative framework if it concludes there are First Amendment problems. *See Seila Law*, 591 U.S. at 234. After all, the network of "agreements" and manufacturer statements was no accident; it was a calculated strategy by Congress to portray the Program as a genuine negotiation—which may have had important consequences for public support of the legislation. *See, e.g.*, The White House, Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/27/remarks-by-president-biden-on-medicare-and-the-inflation-reduction-act/ (stating that IRA simply gave the government "the power to negotiate lower prescription drug prices" when signing the bill). It is not this Court's role to speculate whether Congress

would have enacted a different statute that accomplishes its goals in a different way. The statute must be struck down.

CONCLUSION

The Court should reverse the judgment below.

Dated: December 30, 2024

Respectfully submitted,

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COMBINED CERTIFICATIONS

I. CERTIFICATE OF BAR MEMBERSHIP

I, Daniel Meron, counsel for appellant, hereby certify pursuant to Third Circuit Rule 28.3(d) that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

II. CERTIFICATE OF WORD COUNT

I hereby certify that the foregoing brief complies with the word limit in Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 12,986 words as counted using the word-count feature in Microsoft Word, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 and 14-point Times New Roman font.

III. CERTIFICATE OF IDENTICAL BRIEFS

Pursuant to Third Circuit Rule 31.1(c), I certify that the text of the electronic and hard copy forms of this brief are identical.

IV. CERTIFICATE OF VIRUS CHECK

Pursuant to Third Circuit Rule 31.1(c), I certify that a virus check of the electronic PDF version of this brief was performed using Microsoft Defender

Antivirus (last updated December 30, 2024), and according to that program no virus was detected.

Dated: December 30, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2024, I caused a copy of the foregoing Brief of Appellant to be served by electronic means, via the Court's CM/ECF system, on all counsel registered to receive electronic notices.

s/ Daniel Meron
Daniel Meron

STATUTORY ADDENDUM

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26 U.S.C. § 5000D

§ 5000D. Designated drugs during noncompliance periods

(a) In general

There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in 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.

(b) Noncompliance periods

A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of--

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

(c) Suspension of tax

(1) In general

A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period—

(A) beginning on the first date on which--

(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

(B) ending on the last day of February following the earlier of—

(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

(2) Applicable agreement

For purposes of this subsection, the term "applicable agreement" means the following:

(A) An agreement under—

(i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

(ii) the manufacturer discount program under section 1860D-14C of such Act.

(B) A rebate agreement described in section 1927(b) of such Act.

(d) Applicable percentage

For purposes of this section, the term "applicable percentage" means—

(1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

(4) in the case of sales of such drug during any subsequent day, 95 percent.

(e) Definitions

For purposes of this section—

(1) Designated drug

The term "designated drug" means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

(2) United States

The term "United States" has the meaning given such term by section 4612(a)(4).

(3) Other terms

The terms "initial price applicability year", "price applicability period", and "maximum fair price" have the meaning given such terms in section 1191 of the Social Security Act.

(f) Special rules

(1) Coordination with rules for possessions of the United States

Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

(2) Anti-abuse rule

In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).

(g) Exports

Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

(h) Regulations

The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.

26 U.S.C. § 7421

§ 7421. Prohibition of suits to restrain assessment or collection

(a) Tax

Except as provided in sections 6015(e), 6212(a) and (c), 6213(a), 6232(c), 6330(e)(1), 6331(i), 6672(c), 6694(c), 7426(a) and (b)(1), 7429(b), and 7436, no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed.

(b) Liability of transferee or fiduciary

No suit shall be maintained in any court for the purpose of restraining the assessment or collection (pursuant to the provisions of chapter 71) of–

(1) the amount of the liability, at law or in equity, of a transferee of property of a taxpayer in respect of any internal revenue tax, or

(2) the amount of the liability of a fiduciary under section 3713(b) of title 31, United States Code, in respect of any such tax.

42 U.S.C. § 1320f

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f–1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f–2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f–3 of this title;[1]

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1320f–4 and 1320f–5 of this title.

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

The term "initial price applicability year" means a year (beginning with 2026).

(2) Price applicability period

The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

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[1] So in original. Probably should be followed by ''and''.

(3) Selected drug publication date

The term "selected drug publication date" means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

(4) Negotiation period

The term "negotiation period" means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1320f-2 of this title with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term "manufacturer" has the meaning given that term in section 1395w-3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term "maximum fair price eligible individual" means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f-1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

(d) Timing for initial price applicability year 2026

Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting "September 1, 2023" for ", with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year".

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug"; and

(B) in subparagraph (B), by substituting "August 1, 2024" for "November 1 of the year that begins 2 years prior to the initial price applicability year".

(3) Section 1320f-1 of this title shall be applied—

(A) in subsection (b)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available"; and

(B) in subsection (d)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year".[2]

(4) Section 1320f-2(a) of this title shall be applied by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug".

(5) Section 1320f-3(b)(2) of this title shall be applied—

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[2] So in original. Probably should read as follows: "during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date)''.

(A) in subparagraph (A), by substituting "October 2, 2023" for "March 1 of the year of the selected drug publication date, with respect to the selected drug";

(B) in subparagraph (B), by substituting "February 1, 2024" for "the June 1 following the selected drug publication date"; and

(C) in subparagraph (E), by substituting "August 1, 2024" for "the first day of November following the selected drug publication date, with respect to the initial price applicability year".

(6) Section 1320f-4(a)(1) of this title shall be applied by substituting "September 1, 2024" for "November 30 of the year that is 2 years prior to such initial price applicability year".

42 U.S.C. § 1320f-2

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f-3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1320f-3 of this title, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order

services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1320f-3(f) of this title), and for section 1320f-1(f) of this title, with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of Title 38) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1320f-1(f) of this title, including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

(b) Agreement in effect until drug is no longer a selected drug

An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1320f-1(c) of this title.

(c) Confidentiality of information

Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) Nonduplication with 340B ceiling price

Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

42 U.S.C. § 1320f-6

§ 1320f-6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1320f(c)(2) of this title and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f-1(f)(4) of this title shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1320f-2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f-2(a)(4) of this title, shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f-5(a)(7) of this title shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.