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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services et al.,

Defendants.

Case No. 3:23-CV-14221-ZNQ-DEA

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

ORAL ARGUMENT REQUESTED

Motion Day: March 18, 2024

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INTRODUCTION

This case challenges an unprecedented and unconstitutional attempt to compel the nation's drug manufacturers to hand over their products at any price the government demands. Instead of using the government's market power or granting CMS traditional price-setting authority to help lower drug prices in a lawful manner, Congress instead created a regime that compels manufacturers to transfer ownership of their most valuable drugs upon penalty of ruinous fines. It simultaneously compels the participants to publicly—and falsely—declare that they are engaged in a "negotiation" to establish the "maximum fair price." Despite its numerous intricacies, the crux of the "Drug Price Negotiation Program" (the "Program") is very simple: it requisitions property by threatening an enterprise-destroying fine, and then forces the affected parties to misrepresent the scope of the government's intrusion.

The Program is thus unconstitutional in three distinct ways. *First*, it effects a physical taking of private property for public use without just compensation, in violation of the Fifth Amendment. The Program does not merely set the price for the drug; rather, by virtue of its access requirement, it *compels a transfer* by requiring that manufacturers provide their drug to Medicare beneficiaries at prices the government dictates. And these compelled sales do not give manufacturers like Novartis Pharmaceuticals Corporation ("Novartis") the just compensation the Fifth

Amendment demands. To the contrary, the Program expressly *forbids* the government from paying the market value of patented drugs like Novartis's ENTRESTO®, instead mandating prices that *at most* are far below the market value—and can be as little as one penny, if the government so chooses. That forced transfer of property violates the Fifth Amendment.

Second, the Program forces manufacturers to espouse views with which they fundamentally disagree. Manufacturers must say that they are involved in a "negotiation"; that the price set by CMS is "fair"; and that it is actually 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 heightened public concern with which Novartis vehemently disagrees. This is not regulation of speech incidental to conduct—Congress can (and does) regulate similar conduct without compelling any such statements. Rather, these speech regulations exist solely to force manufacturers, including Novartis, to parrot the government's preferred narrative regarding the Program, despite Novartis's profound disagreement. The First Amendment prohibits private speech being compelled for that purpose.

Third, the Program imposes massive penalties on any manufacturer that refuses to comply with its demands. Those penalties take the form of a so-called "excise tax" running up to nineteen times the manufacturer's nationwide revenues

from the sale of the drug. This purported "tax" is so plainly punitive that the government itself does not anticipate deriving any revenue from it—because no manufacturer would or could ever pay it. In reality, this "excise tax" is a civil fine for refusal to participate in the government's scheme, and is so wildly disproportionate that it violates the Eighth Amendment's Excessive Fines Clause.

All of this amounts to a forced sales regime that is unique in American history. Never before has the government compelled private companies to hand over their products at a price and quantity of the government's demand. And, while the government hides behind the contention that this Program is "voluntary," the Supreme Court has squarely rejected the notion that physical takings can be justified simply because a participant has the supposed "freedom" to withdraw from the relevant market. Tellingly, all the out-of-circuit cases on which the government has relied in other litigation involved *regulatory*, not physical, takings. The Program is thus as unprecedented as it is misguided. It recklessly gambles with public health and violates core tenets of our constitutional order, for no purpose other than to advance the government's preferred narrative and then shield the government from any resulting political accountability for its decisions. It must be struck down.

BACKGROUND

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. One such drug is ENTRESTO®, a medication that treats heart failure by helping to improve the heart's ability to pump blood to the body. ENTRESTO® represents a significant advance in the treatment of heart failure, and provides a 20% relative risk reduction of cardiovascular death compared to patients receiving other heart failure medications. Vineis Decl. ¶¶ 6, 7 ("Decl."). To date, ENTRESTO® has helped approximately 2 million United States heart failure patients, including almost 600,000 Medicare beneficiaries in just the past twelve months. *Id.*

Developing a lifesaving drug such as ENTRESTO® entails enormous investments in time and expenses—on average, it takes nearly $3 billion, and ten to fifteen years, to develop just one new medicine. *See* Meron Decl. Ex. A, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016).[1] And given the nature of pharmaceutical research and the complexity of the regulatory process, manufacturers like Novartis

[1] All exhibits referenced herein are attached to the concurrently filed Declaration of Daniel Meron.

make these investments with no guarantee of a return. The vast majority of drugs never even secure Food and Drug Administration ("FDA") approval. *See* Ex. B, Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 EMBO Reports 837, 837 (2004); *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1302-03 (11th Cir. 2021). Even where a manufacturer like Novartis does secure approval, few drugs provide an economic return significant enough to allow for continued innovation. *See* Ex. C, John A. Vernon & Joseph H. Golec, Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence 7 (2008).

The Medicare program includes two parts relevant here. Medicare Part B insures Medicare beneficiaries with respect to a wide variety of outpatient healthcare services, including coverage for drugs administered by physicians. *See* 42 U.S.C. § 1395k(a)(1); *id.* § 1395x(s)(2)(A). 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 United States prescription drug market, accounting "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

Until Congress's passage of the Inflation Reduction Act ("IRA"), both parts of the Medicare program guaranteed manufacturers market-based pricing. Medicare Part B reimbursement is based on a drug's average sales price, which ensures that

reimbursement tracks market prices. *See* 42 U.S.C. § 1395w-3a. And Medicare Part D expressly prohibits the Department of Health and Human Services ("HHS") from "[i]nterfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs in order to ensure that market forces drive pricing. *Id.* § 1395w-111(i). Historically, plan sponsors "can and do negotiate prices with prescription drug manufacturers," and have market incentives to secure lower pharmaceutical prices. Ex. D, Ryan Knox, *More Prices, More Problems*, 18 Yale J. Health Pol'y L. & Ethics 191, 206-07 (2020).

B. The Inflation Reduction Act Mandates The Transfer Of Drugs At Prices Set By CMS

The Program upends that market-driven approach by compelling manufacturers such as Novartis to agree to the government's unilaterally set price, while also forcing them to endorse those prices as "maximum fair prices" arrived at via "negotiations." The Program functions in the following way:

CMS first identifies the drugs that account for the highest Medicare Part D expenditures and selects a subset of those drugs for negotiation. 42 U.S.C. § 1320f-1(b)(1)(A). Each year, starting in 2023, at least ten drugs will be selected, with the number of selected drugs rising to twenty in 2027. *Id.* §§ 1320f-1(a)(1), (a)(4).

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. 42 U.S.C. § 1320f(d)(2)(A); *id.* § 1320f-2(a). That initial "agreement," which the

manufacturer must sign on pain of ruinous fines, commits the manufacturer to "agreeing" that the price CMS eventually chooses—no matter how low—is the "maximum fair price" for the drug. *See* Ex. E, "Agreement" Between CMS and Novartis; Ex. F, Memorandum from M. Seshamani, CMS Deputy Admin., to Interested Parties on Medicare Drug Price Negotiation Program: Revised Guidance 118 (June 30, 2023) ("Revised Guidance"). 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 merely Medicare sales), which the Program terms an "excise tax." 26 U.S.C. § 5000D(b).

The penalty is designed to force a manufacturer to enter into the "agreement." The penalty is based on a formula for an "applicable percentage," which begins at 65% of the drug's total price and increases by 10% for each quarter the manufacturer is out of compliance until it reaches 95% of the total price. *Id.* § 5000D(d). Under the statutory formula, the penalty is "an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold." *Id.* § 5000D(a). Applying that statutory formula, for a drug sold for $100 and subject to the 65% applicable percentage, the penalty would be $186 (or 186% of the "pre-tax" price) per sale. Once that percentage goes up to 95%, the penalty would be $1,900 per sale—1,900% of the drug's daily revenue. *See* Ex. G, Cong. Rsch. Serv., R47202, Tax Provisions in the Inflation Reduction Act of 2022

(H.R. 5376) 4 tbl. 2 (2022).[2] In order to escape the Program and its gargantuan penalties, a manufacturer would need to exit Medicare and Medicaid entirely—not merely for the selected drug, but for *all* of its drugs. *See* 26 U.S.C. § 5000D(c). That is not a step Novartis could rationally take. Decl. ¶ 30.

Once a manufacturer has entered into the initial "agreement" in the face of ruinous monetary penalties, the manufacturer then has little say in the "negotiation" that follows. Manufacturers are forced to provide all "information that [CMS] requires to carry out the negotiation." § 1320f-2(a)(4)(B). And although the manufacturer can provide a "counteroffer"—based only on categories of evidence CMS specifies and not on those the manufacturer might believe is relevant—this does nothing to salvage the process, as CMS is under no obligation to consider that counteroffer. *See* 42 U.S.C. §§ 1320f-3(b)(2)(C)(ii), 1320f-3(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." 42 U.S.C. § 1320f-7. The Program provides no floor below which CMS

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[2] On October 2, 2023, the Internal Revenue Service ("IRS") issued a nonbinding notice announcing its intent, at some unspecified point in the future, to promulgate regulations implementing the "excise tax." Ex. H, IRS, Notice 2023-52 (Aug. 4, 2023) ("Notice"). As described *infra,* 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, and an intention to issue future regulations obviously can have no impact on the Court's construction of the statute today. *See infra* at 38-40.

may not set the price (with one limited exception not relevant here). 42 U.S.C. §§ 1320f-3(c), (b)(2)(F)(ii). While CMS is required to provide an explanation for this price, *see, e.g.*, Ex. F, Revised Guidance, at 69, there is no mechanism by which manufacturers can request the information that manufacturers believe is relevant be considered by CMS or included in that explanation.

The law does impose a ceiling on how *high* a price CMS can set. Under the Program, CMS is directed to use as the ceiling price the lowest number produced by two specified statutory methods. §§ 1320f-3(c)(1)(A), (b)(2)(F). These methods are expressly designed to yield prices that are well below market value. *See* Compl. ¶¶ 44-45; Ex. F, Revised Guidance, at 138-42.

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 is August 1, 2024. §§ 1320f(d)(5), 1320f-3(b)(2)(E). While CMS claims that manufacturers are bound to respond to CMS's "final offer" by "either accepting or rejecting [it]," Ex. F, Revised Guidance, at 158, manufacturers cannot in reality "reject" CMS's offer and walk away as in a normal negotiation. Decl. ¶¶ 16-17. If a manufacturer rejects CMS's final "maximum fair price" demand, it is subjected to the previously discussed, enterprise-destroying excise "tax" that starts at over 180% and runs up to 1900% (nineteen times) of the total revenue derived from sales of that drug in the United States. § 1320f-2(a)(1);

§ 5000D; *see* Ex. G, Cong. Rsch. Serv., R47202, at 29 tbl. A-2. No rational manufacturer could ever pay that penalty. Decl. ¶ 33. Congress was well aware of this reality; in fact, the Congressional Budget Office ("CBO") projected that this "tax" would raise exactly zero dollars. *See* Ex. I, Cong. Budget Off., Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 4-5 (Sept. 7, 2022).

The Program then requires manufacturers to provide "access" to their drugs at the "maximum fair price" to a wide array of individuals and entities: all eligible individuals dispensed drugs under Medicare Parts B and D; all "pharmacies, mail order services, and other dispensers" dispensing drugs to Medicare beneficiaries; and all "hospitals, physicians, and other providers of services and suppliers" dispensing or administering drugs to Medicare beneficiaries. § 1320f-2(a)(1)(A)-(B); § 1320f(c)(2). If a manufacturer does not do so, it is subject to civil monetary penalties at the extraordinary rate of ten times the alleged overcharge. § 1320f-2(a)(1); 42 U.S.C. § 1320f-6(a)-(b). The Program thus compels manufacturers to provide "access" to the selected drugs at whatever price the government selects, and at whatever quantities Medicare beneficiaries may be prescribed.

C. ENTRESTO® Has Been Selected For Negotiation

On August 29, 2023, CMS selected Novartis's ENTRESTO® for "negotiation." In 2022, ENTRESTO®'s gross sales in the United States totaled $4.9

billion, which means that the penalty for not reaching an agreement would quickly rise to an annual rate of $93.1 billion—almost double Novartis's total global annual net revenue. Decl. ¶¶ 8-11. Thus, under threat of this catastrophic penalty, Novartis was forced to sign the "agreement" with the Secretary on September 28, 2023, and enter into the so-called "negotiation" process established by the statute. *Id.* ¶ 10. Novartis will continue engaging in the "negotiation" process only because the excise tax would be devastating. *Id.* ¶ 11.

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Courts regularly resolve pre-enforcement constitutional challenges to federal statutes through summary judgment. *See, e.g.*, *Gen. Elec. Co. v. EPA*, 360 F.3d 188, 189 (D.C. Cir. 2004).

ARGUMENT

I. THE PROGRAM TAKES NOVARTIS'S PROPERTY WITHOUT JUST COMPENSATION

The Program violates Novartis's Fifth Amendment property rights by forcing Novartis to transfer ENTRESTO® to third parties on the government's terms, and capping Novartis's compensation at below-market prices. The Program thus goes far beyond merely regulating drug prices and constitutes a *per se* taking of Novartis's protected personal property.

A. The Program Effects A Taking Of Novartis's Property 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*, 141 S. Ct. 2063, 2071 (2021). When it "appropriate[s] personal property" in this way, the government "has a categorical duty to pay just compensation." *Horne v. Dep't of Agric.*, 576 U.S. 350, 358-59 (2015). "[J]ust compensation" means "the market value of the property at the time of the taking." *Id.* at 368-69. Only that remedy can put the owner "in the same position monetarily as he would have occupied if his property had not been taken." *United States v. Reynolds*, 397 U.S. 14, 16 (1970).

The Supreme Court's decision in *Horne* illustrates these principles. In *Horne*, 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. 576 U.S. at 361-62. The Court held that the statute effectuated a physical taking because the farmers were required to transfer title to their property, losing the "right to control their [raisins'] disposition." *Id.* at 358, 364.

The Program appropriates Novartis's medicines in much the same way. It deprives manufacturers of their right to control their personal property and compels sales on terms of the government's choosing. It is a classic, *per se* taking.

1. The Program's Compelled Sales Regime Is A *Per Se* Taking Of Protected Property

As a threshold matter, Novartis's drugs are undoubtedly "private property" protected by the Takings Clause. The drugs themselves are—until they are sold—the manufacturers' personal property, and are therefore protected from uncompensated takings. *See, e.g.*, *id.* at 358-59. And Novartis's patented pharmaceutical drugs, including ENTRESTO®, are also protected as a matter of intellectual property. A patent confers on the patentee "an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation." *Id.* at 359 (citation omitted).

Under the Program, Novartis *must* transfer its products to third parties at the dictated price; it cannot refuse to sell to them on those terms. *See* 42 U.S.C. § 1320f(c)(2)(A); *id.* § 1320f-2(a)(3). The Program expressly requires that Novartis "provid[e]" "access" to its drugs at the maximum fair price to Medicare beneficiaries and those who buy drugs on their behalf. § 1320f(c)(2)(A); § 1320f-2(a)(3); *see also* Ex. H, Notice, at 2 (recognizing that the Program requires manufacturers "to provide access to selected drugs" to eligible buyers).

In its briefing in other cases, the government has suggested that manufacturers can avoid the demands of the Program simply by not selling the selected drugs to Medicare beneficiaries. *See, e.g.*, Opp'n to Pl.'s Mot. for Summ. J. & Cross-Mot. at 23, 29, *Bristol Myers Squibb Co. v. Becerra*, No. 23-3335 (D.N.J. Oct. 16, 2023),

ECF No. 38-1. But it is not feasible for Novartis to avoid sales of ENTRESTO® to Medicare beneficiaries, as the Medicare Part D statute now requires that each selected drug be included in every Medicare Part D insurance plan formulary. *See* 42 U.S.C. § 1395w-104(b)(3)(I). Due to this statutory requirement and the nature of how the United States pharmaceutical supply chain operates, Novartis cannot avoid selling ENTRESTO® to Medicare beneficiaries. Manufacturers like Novartis sell their drugs directly to wholesalers, who in turn distribute those drugs to pharmacies. Decl. ¶¶ 24-25. The pharmacies are the ones who then decide whether to sell certain drugs to Medicare beneficiaries based on whether those drugs are covered by Part D plans—and here, ENTRESTO® always will be covered. And once a Medicare beneficiary seeks to fill his or her prescription for ENTRESTO®, the IRA requires Novartis to provide that drug to the pharmacy for dispensing to the beneficiary at the "maximum fair price." 42 U.S.C. §§ 1320f(c)(2)(A), 1320f-2(a)(3).

In short, every time a Medicare beneficiary requests the listed drug, it will be transferred to that beneficiary at the (below-market) "maximum fair price." This mechanism strips Novartis of its right to "control" the "use and dispos[ition]" of its property. *Horne*, 576 U.S. at 361-62.[3] Novartis must provide access to its drugs,

[3] Given the reality of how pharmaceutical sales occur, the only way a manufacturer could avoid having its own selected drug dispensed to Medicare beneficiaries would be to divest its interests in the drug to another, unrelated

and it will necessarily have a large share of those drugs transferred to Medicare beneficiaries at the government-prescribed price.

As in *Horne*, the Program uses the threat of penalties as a means of ensuring that manufacturers comply with the forced transfer of their property at below-market terms. *See id.* at 356. Failing to provide access to ENTRESTO® at CMS's chosen "maximum fair price" would trigger approximately *$93.1 billion* in annual penalties, almost double Novartis's total global annual net revenue. Decl. ¶ 11. That Novartis could hypothetically avoid giving up its property rights by incurring these crippling penalties does not change the fact that a taking has occurred. *See, e.g.*, *id.* (finding a physical taking even though the scheme alternatively provided for a civil penalty); *see also Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1234-35 (D.C. Cir. 2023) (that owners could pay a $250 fine instead of handing over their property did not "affect" the takings analysis because "[a] statute can effect a taking even if the property owner never actually forfeits property and is instead subject to a fine"). 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

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manufacturer. *See* Ex. F, Revised Guidance, at 131-32. But the fact that Novartis could theoretically *abandon* its property—at a price that would be discounted to reflect the cost of the unlawful takings yet to come—does not change the takings analysis. Either way, Novartis is forced to transfer "title" and "lose[s] any right to control" its property. *Horne*, 576 U.S. at 364.

[property] or making a payment equal to the [property's] value.'" *Id.* at 9 (quoting *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013)).

This forced-sale aspect distinguishes the Program from a genuine rate-setting regime. When the government engages in true rate setting, the result is a regulatory cap on what the seller may charge—but that does not mean the seller has to sell at that price. *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992). Thus, a challenge to that cap would properly be evaluated as a potential regulatory taking. Here, however, the Program goes much further because it does not just set a price, but it compels manufacturers to *provide* "*access*" to their drugs at that government-set price. § 1320f-2(a)(3) (emphasis added); § 1320f(c)(2)(A). In other words, the Program forces manufacturers to hand over their property. That is a quintessential taking.

2. The Program's Government-Dictated Compensation Is Constitutionally Inadequate

Because the Program appropriates manufacturers' patented personal property for public use, the government must pay "just compensation" equivalent to the "market value of the property at the time of the taking." *Reynolds*, 397 U.S. at 16; *United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 (1979). But the Program actually ensures that the government does *not* pay just compensation. The statutory ceiling, which is the lowest number yielded by alternative calculations, ensures a price well below the going market rate. Under one calculation, CMS must extract at

least a 25% discount (and almost certainly far steeper discounts) off of the average price paid by pharmaceutical drug buyers other than the federal government. *See* 42 U.S.C. § 1320f-3(c)(1)(C). In other words, CMS would force Novartis to turn over to the government a supply of ENTRESTO® at a minimum of 25% *less* than its current market price. That is, by definition, not just compensation. *See, e.g.*, *Reynolds*, 397 U.S. at 16; *see also Horne*, 576 U.S. at 362-63.

The same is true for the other "ceiling" arrived at by the alternative calculation. That method uses the average Part D net price from the latest year with complete data—which, for the first year of the Program, is 2022—as the highest price CMS can offer. § 1320f-3(c)(2)(A); Ex. F, Revised Guidance, at 138-39. But this number does not take into account inflation from the years between selection and implementation—which means Novartis would be forced to sell ENTRESTO® in 2026 based on the unadjusted *2022* Part D net price. This alone guarantees that the price set by CMS will be below the going market price. And, of course, CMS is free to—and almost certainly will—go far below whichever ceiling applies, given Congress's directive that CMS "achieve the lowest" possible price for each selected drug, § 1320f-3(b)(1), with no floor and no prospect of judicial review, 42 U.S.C. § 1320f-7. Indeed, there is nothing in the statute that would prevent CMS from unilaterally determining that the "maximum fair price" for a drug is one penny.

II. THE PROGRAM CANNOT BE UPHELD AS PART OF A VOLUNTARY EXCHANGE

The government cannot defend its physical taking of Novartis's property by arguing that Novartis "voluntarily" accepts forced below-market requisitioning of its products by electing to participate in the Medicare and Medicaid markets. *First*, the Program cannot be justified on the ground that manufacturers could theoretically avoid the taking by withdrawing from Medicare. The Supreme Court has time and again rejected the premise that the government can justify a *physical* taking on the ground that a party could withdraw from the relevant market. *Second*, the Program likewise cannot be justified as a "condition" on Medicare participation, because it is not applied to all participants nor actually tied to the receipt of a government benefit. Rather, it is selectively imposed on certain companies, who receive no additional benefit for handing over their drugs. And, in any event, even if the taking could be viewed as a "condition" of Medicare participation, it would plainly run afoul of the unconstitutional conditions doctrine, because it is unduly coercive.

A. Voluntariness Arguments Do Not Apply To *Per Se* Takings Claims

Any potential defense by the government that Novartis could avoid the Program's forced-sales requirements by leaving the Medicare and Medicaid markets would fail here because such voluntariness arguments are "insufficient to defeat a physical taking claim." *Yee*, 503 U.S. at 531 (citing *Loretto v. Teleprompter*

Manhattan CATV Corp., 458 U.S. 419, 439 n.17 (1982)) (a landlord's ability to control his property "may not be conditioned on his forfeiting the right to compensation for a physical occupation").

In *Horne*, the government tried this exact argument—attempting to recast its physical appropriation of raisins as voluntary because growers could, in theory, avoid it by forfeiting the right "to participate in the raisin market." 576 U.S. at 356-57, 365. The Supreme Court rejected the government's reformulation, explaining that "property rights cannot be so easily manipulated" and the ability to participate in a particular market cannot be held "hostage, to be ransomed by the waiver of constitutional protection." *Id.* at 365-67. This Court should do the same here. Congress can no more require manufacturers to abandon a vast swath of the United States prescription drug market to avoid a physical taking of their property than it can tell farmers to stop selling raisins in order to avoid having to turn over a portion of their crop to the government. Either way, the government is unlawfully holding access to a market "hostage" to compel a party to physically hand over its property.

Indeed, treating these forced sales as avoidable based on the theoretical ability to abandon the sale of drugs to Medicare and Medicaid beneficiaries would render the *per se* takings framework a nullity. Consider *Loretto*, the seminal physical-takings case. *See* 458 U.S. at 435-38. There, the Supreme Court had little trouble concluding that the attachment of a cable box to Loretto's apartment building was a

per se, unlawful taking—even though the imposition could have just as easily been cast as "avoidable" due to Loretto's "choice" to enter the rental property market.

That the Program effectuates a physical taking of Novartis's property distinguishes this case from those where courts outside of the Third Circuit have found that participation in a particular market excused a *regulatory* taking or a particular rate-setting regime. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). In each case, the law at issue simply set the price a provider could charge for a particular service, and so was properly evaluated as a regulatory taking. None of those cases involved a forced sale provision like 42 U.S.C. § 1320f(c)(2)(A). And, in any event, each of those cases predate *Horne*—which made clear that, when it comes to physical takings, a property owner's ability to exit a particular market before a taking occurs *cannot* render an appropriation of its property voluntary as a matter of law.

Here, the antecedent "option" of Novartis being forced to leave the Medicare and Medicaid markets entirely—for all its products, not just ENTRESTO®—in order to avoid the taking would be just as harmful as forcing the grape producers in *Horne* to reorient their business away from raisins. Medicare and Medicaid "dominate[]" the United States prescription drug market and for some drugs account for an overwhelming majority of sales. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th

696, 699 (3d Cir. 2023); *see also* Decl. ¶ 30. Abandoning these markets is not a step Novartis can rationally take, and doing so would upend deeply settled expectations in its property. *See, e.g.*, *Union Pac. R. R. Co. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70 (1918) (economic "duress" negates a purported "choice" where it is "practically impossible *not* to comply with the terms of the law" (emphasis added)); *Tenoco Oil Co. v. Dep't of Consumer Affs.*, 876 F.2d 1013, 1027 (1st Cir. 1989) (holding that the supposed freedom to temporarily leave the gasoline market was illusory due to fixed costs, overhead, and salaries). It also would leave millions of patients without access to their medications—a devastating result that neither the government nor Novartis actually wants to happen here.

Indeed, the government's argument ultimately boils down to the absurd contention that *any* taking by the government is voluntary so long as the property owner had some prior opportunity to avoid it—no matter how onerous that option is. Under the government's logic, instead of the price-setting scheme it created, Congress in the IRA could have directed the Secretary to seize without just compensation the manufacturing plants and raw materials of the 10 highest spend drugs and then produce those drugs itself—and the nationalization of those factories would not even implicate the Takings Clause because it would be a "condition" of the manufacturers' participation in Medicare and Medicaid. Under that view, there would be no limit to what the government could expropriate, so long as it frames the

taking of property as a condition of selling something—no matter how unrelated—in a market regulated by the government. That is preposterous. Physical takings must be accompanied by just compensation—no matter how they "come[] garbed." *Cedar Point*, 141 S. Ct. at 2072.

B. There Is No Voluntary Exchange Here

The government also cannot defend its requisitioning of Novartis's property as a valid "condition" for participation in Medicare or Medicaid. *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). While the government can impose conditions that "place[] a direct *restriction*," *Gruver v. Louisiana Board of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020) (emphasis added), on the receipt of government benefits, such as conditions attached to "a license to sell dangerous chemicals," *Horne*, 576 U.S. at 366-67, that principle has no application here. The Program does not operate like a condition because its obligations are not a general prerequisite for participation in Medicare. Rather, they are a unique burden placed on a small subset of Medicare participants, and they are enforced not by "direct[ly] restrict[ing]" Medicare participation, *Gruver*, 959 F.3d at 183, but by a separate fine.

That there is no exchange—voluntary or otherwise—is fatal to any possible "conditions" argument by the government. There is no possible lawful "condition" when, as here, the property owner does not receive any "special government benefit" in "*exchange*" for handing over its property. *Horne*, 576 U.S. at 365-66 (emphasis

added); *see also Cedar Point*, 141 S. Ct. at 2079-80 (rejecting argument that government could "require property owners to cede a right of access as a condition of receiving certain benefits" because access rule was not "germane to any benefit provided to [the property owners] or any risk posed to the public").

The D.C. Circuit's post-*Horne* decision in *Valancourt Books v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023) (Srinivasan, J.), is instructive. There, the Court held that the Copyright Act's requirement that copyright holders deposit copies of their works with the government on pain of fines was an unconstitutional taking. *Id.* at 1231. In doing so, it rejected the government's argument that taking the books could be excused as part of a "voluntary exchange" for copyright protection, because the owners did not need to deposit their works to secure or retain the benefits of copyright. *Id.* at 1232-33. Copyright protection would apply regardless. The government accordingly could not point to a "single *incremental* benefit" owners received from handing over their works—which meant this deposit requirement could not "represent a voluntary exchange for a benefit." *Id.* at 1233 (emphasis added). Instead, there was "no benefit at all" and thus no "*quid pro quo*." *Id.*

The same is true here: Novartis receives no incremental benefit from giving the government its drugs pursuant to the Program. As in *Valancourt*, the requirement that Novartis turn over its property is enforced by separate penalties; failure to comply with the Program's new obligations does not cause a manufacturer

to lose coverage under Medicare or Medicaid, *even for the selected product*. Thus, the Program's demands are not a "condition" of participation in the Medicare or Medicaid markets—they are merely requirements backed by a penalty.

In addition, the fact that the Program revises the terms of Novartis's Medicare and Medicaid agreements *after* such agreements already have been signed confirms that the Program's demands are not part of a "voluntary exchange" for Novartis's participation in those markets. Manufacturers like Novartis "could hardly [have] anticipate[d]" the Program's bait-and-switch when they joined Medicare and Medicaid years ago or, more critically, when they spent billions of dollars to develop their products—long before the IRA was enacted—under the expectation that they would be able to determine the prices at which they would offer the few products that made it to the market. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579-80, 583-85 (2012) ("*NFIB*") (holding that threats to withhold "existing Medicaid funds" and "terminate other significant independent grants" if States would not accept "new conditions" was unlawful). Having used promises of market pricing to attract manufacturers to federal healthcare programs and then gain control of the prescription drug market, the government cannot now leverage that control to revise the terms of the original bargain and, in doing so, coerce Novartis to give up its right to "control" the "disposition" of its property. *Horne*, 576 U.S. at 361-62.

C. Regardless, The Purported Conditions Are Unlawful

Finally, even if complying with the Program could be viewed as a "condition" on receiving Medicare and Medicaid benefits, that still would not save the Program. That is because the "unconstitutional conditions doctrine" forbids the government from using its market power to "coerc[e] people into giving [] up" their constitutional rights, including "the Fifth Amendment right to just compensation." *Koontz*, 570 U.S. at 604; *see also Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002) ("The 'unconstitutional conditions' doctrine is based on the proposition that government incentives may be inherently coercive."). In the Takings Clause context, the government can condition receipt of certain government benefits on the forfeiture of a property right only when there is an "essential nexus" and "rough proportionality" between the taken property and the social costs of the owner receiving that government benefit. *Dolan v. City of Tigard*, 512 U.S. 374, 375, 386 (1994); *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987) (same); *see also Cedar Point*, 141 S. Ct. at 2079-80. Even if one were to view the relinquishment of property as a "condition" of participation in the Medicare and Medicaid programs, that purported "condition" would flunk both prongs of the *Nollan* and *Dolan* test.

First, the supposed condition lacks the requisite nexus to the allegedly impacted benefits, because it leverages not just the drug at issue, but the entirety of a manufacturer's participation in Medicare. And, even worse, it also leverages the

manufacturer's participation in *Medicaid*—and the provision of lifesaving drugs to over 87 million of the lowest-income and most vulnerable Americans. The Program provides no explanation (nor has CMS offered one) as to how forcing Novartis to hand over discounted ENTRESTO® bears any "nexus" to retaining Medicare coverage for Novartis's *other* distinct products. Nor has it offered any explanation for why Medicaid is implicated at all. There simply is no "reasonable relationship" between the supposedly voluntary condition of handing over ENTRESTRO® and the participation rights afforded by Novartis's existing Medicare and Medicaid agreements. *Dolan*, 512 U.S. at 395. As the Supreme Court has explained, threatening to withhold an *unrelated* benefit to compel surrender of property is not a condition, but "extortion." *Id.* at 387; *see also Harris v. McRae*, 448 U.S. 297, 317 n.19 (1980) (recognizing that a "substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits from an otherwise eligible candidate" based on exercise of constitutional right).

Second, the required "condition" of terminating Medicare and Medicaid coverage for all of a manufacturer's products to avoid the demands of the Program is grossly disproportionate to the government's interests in reducing the prices of specific prescription drugs offered under Medicare plans. *See, e.g.*, *FCC v. League of Women Voters*, 468 U.S. 364, 400 (1984) (invalidating condition that required radio station receiving "only 1% of its overall income" from government grants to

abstain from "all editorializing"). The Program involves only one Novartis drug—ENTRESTO®—and only because of that drug's use in one Medicare program—Medicare Part D. *See* 42 U.S.C. §§ 1320f-1(b)(2), (d)(1)(A). Yet the Program purportedly conditions Novartis's ability to offer all its other products in every part of Medicare and Medicaid. 26 U.S.C. § 5000D. That is not remotely proportional.

Accordingly, treating the Program as a mere condition on federal funds or participation in a marketplace would not save it—that construction would merely render it unlawful "coercion" to pressure manufacturers to "giv[e] … up" their constitutional rights. *Koontz*, 570 U.S. at 604. However framed, the Program is simply a way for the government to take the manufacturers' private property without paying just compensation.

III. THE PROGRAM UNCONSTITUTIONALLY COMPELS SPEECH

In addition to unconstitutionally taking Novartis's property, the Program also forces the company to sign a compelled "agreement," wrongly declare that it is engaging in a "negotiation," and ultimately endorse and espouse the contention that the price it is forced to accept is the "maximum fair price" for its drug—and thus that the price it has been charging up to that point is unfair. Those speech-related aspects to the Program are wholly unnecessary. They serve solely to force the manufacturers to promote the government's preferred narrative while disguising, and misleading the public about, the true nature of the Program.

The First Amendment protects both the right to speak and the right to refrain from speaking. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *see also Janus v. Am. Fed'n of State, City & Mun. Emps.*, 138 S. Ct. 2448, 2463-64 (2018). And laws compelling private speech, like the Program does here, are subject to strict scrutiny. *Wooley*, 430 U.S. at 714-15. "[S]uch laws 'are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.'" *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018).

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

Compelled speech lies at the heart of the Program. Congress adopted this convoluted process, rather than straightforward price-setting, to give the false impression that a "negotiation" has taken place and to force the manufacturers to state that they agree that the prices the government will pay reflect the "maximum fair prices" for their drugs. The purpose of this structure is to force manufacturers to endorse the government's claim that they are simply "negotiating" with manufacturers rather than dictating the price at which they must sell, and thus shift responsibility for any of the potential negative consequences of that dictate from the government to manufacturers.

From top to bottom, the Program is designed to compel manufacturers to engage in forced messaging, namely that this process constitutes a "negotiation,"

reflects Novartis's "agreement" and results in the "maximum fair price" for the product. *First*, Congress forced manufacturers like Novartis to represent that they voluntarily engaged in a "negotiation" when, in reality, the government unilaterally sets the price. 42 U.S.C. § 1320f-2(a); § 5000D. Congress expressly provided that manufacturers must enter into agreements imposing the obligation to "*negotiate* to determine … a maximum fair price" for a drug. § 1320f-2(a)(1) (emphasis added). And Novartis has been forced to convey this exact idea in the agreement it was compelled to sign. Ex. E, Agreement, at 2; *see also id.* at 1 (claiming Program "sets forth a framework under which manufacturers and CMS *may negotiate* to determine a price" (emphasis added)). Congress has also obligated manufacturers to actively participate in this "negotiation" process by signing the agreement, providing information purportedly used in that process, 42 U.S.C. § 1320f-3(b)(2)(A), and either being forced to publicly accept the government's first offer or being forced to counteroffer, § 1320f-3(b)(2)(C). Those actions are purely performative, completely unnecessary in light of the government's unfettered power to unilaterally set the price, and imposed solely to force Novartis to convey a message with which it profoundly disagrees.

Second, Congress compelled manufacturers to state that they "agree" to the price CMS ultimately sets, even though there can be no genuine "agreement" in the face of the Program's massive penalties. The IRA purports in various of its phases

to provide that manufacturers will "agree" to a "maximum fair price." § 1320f-(a)(1). Novartis's initial "agreement" with CMS thus compelled Novartis to state that it was entering an "agreement" with the aim of ultimately "agree[ing] to" a maximum fair price. Ex. E, Agreement, at 2; *see also id.* at 1 (titled "Medicare Drug Price Negotiation Program Agreement"). And after the "negotiation" process ends, Novartis will be forced to represent again that it agrees to a price. *Id.* at 2; § 1320f-2(a)(1). But these "agreements" are being entered into only under the threat of billions of dollars of penalties. § 5000D. Novartis is in no way voluntarily agreeing to negotiate, or to the price set by CMS.

Third, Congress required manufacturers to sign an "agreement" that purported to accept a "maximum fair price." 42 U.S.C. § 1320f(c)(3); *id.* § 1320f-2(a)(1). In choosing that language, Congress not only requires manufacturers to agree that CMS's set price is reflective of the drug's value—a contention that Novartis disputes—it actually forces manufacturers to convey that the current market prices charged by manufacturers, including those agreed to in genuine negotiations with private insurers, are *unfair*. 42 U.S.C. § 1320f(c)(3). Indeed, the agreement Novartis was forced to sign refers to the "maximum fair price" nearly two dozen times. *See generally* Ex. E, Agreement.

This type of performative, forced messaging is not a run-of-the-mill conduct regulation that only incidentally affects speech. A comparison with the 340B Drug

Pricing Program demonstrates that the government's regulation of speech is not "incidental," but rather the *goal* of these provisions. Under the 340B Program, HHS enters into agreements with manufacturers that specifies they must offer their drugs for sale to certain entities at a price below the statutorily defined "ceiling price." 42 U.S.C. § 256b(a)(1). But the statute and the agreement do not force manufacturers to say they "negotiated" for the relevant price, or otherwise portray that "ceiling price" as the product of "negotiation."[4] Rather, the agreement simply memorializes in writing that the manufacturer is obligated to charge a *government-set* price. The 340B statute straightforwardly acknowledges that the ceiling price is set by the government and that it is "the maximum price that covered entities may permissibly be *required to pay*." § 256b(a)(1) (emphasis added). Congress has elsewhere similarly used neutral terms like "average sales price," 42 U.S.C. § 1395w-3a(c)(1); "wholesale acquisition cost," § 1395w-3a(c)(6)(B); and "widely available market price," § 1395w-3a(d)(5)(A). The Program, by contrast, sweeps well beyond that type of neutral language. Congress's deviation from that standard practice reinforces that its goal here was forced messaging, not merely conduct regulation.

The government's attempt to conceal its imposition of governmental price controls by portraying CMS's unilaterally imposed price as the subject of a joint

[4] Ex. J, Health Res. & Serv. Admin., Healthcare Sys. Bureau OMB NO. 0915-0327.

"agreement" between manufacturers and regulators cannot withstand constitutional scrutiny. It is fundamental that "the government may not compel a person to speak its own preferred messages." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023) (collecting cases). Indeed, when the government "requires the utterance of a particular message favored by the government," it "seeks not to advance a legitimate regulatory goal, but to … manipulate the public debate through coercion." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994).

The Program's compulsion of speech cannot survive strict scrutiny (or indeed any level of scrutiny), because those speech compulsions serve *no* valid purpose, let alone a compelling one.[5] The government may have an interest in minimizing what it pays for prescription drugs. But requiring manufacturers to express "agreement" with the prices CMS sets, and to pretend that this is an actual negotiation process, is unnecessary to achieving *that* goal. Setting aside its other fatal constitutional

[5] The Program should be subject to strict scrutiny, *see supra* at 28, but the requirement that manufacturers state falsely that they "agree" with prices unilaterally set by CMS cannot be upheld under any level of constitutional scrutiny. As to intermediate scrutiny, the forced messaging at issue here does not serve an important government objective, and it is not substantially related to the only government objective that could legitimately be claimed: the amount of payment for drugs. The forced messaging also fails even rational basis review—regardless of what interest the government claims it seeks to advance, it has "no legitimate reason to force" businesses to convey "false information." *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Ent. Merch. Ass'n*, 564 U.S. 786 (2011).

infirmities, the Program would work exactly as intended without these compelled speech provisions. The only interest served by these provisions is to promote the fiction that the Program establishes a market-based negotiation process rather than a potentially unpopular price control. That is not a legitimate governmental interest, let alone a compelling or substantial one.

Nor are the compelled speech provisions of the "negotiation" process narrowly tailored to any compelling government interest. After all, as explained above, Congress could have enacted the same basic Program, along the lines of 340B, without requiring manufacturers to engage in any forced messaging at all. *See R.A.V. v. City of St. Paul*, 505 U.S. 377, 395 (1992) (narrow tailoring requires that a statute be "*necessary* to serve the asserted compelling interest").

B. CMS's Inconsistent Disclaimer Reinforces Rather Than Resolves The Compulsion

Even the government seems to recognize that the statute, as written, violates the Constitution. In an attempt to save the statute, CMS added a disingenuous disclaimer to the Agreement, stating that it does not reflect an "endorsement of CMS['s] views" and that signing it should not be taken as agreement that "fair" means "fair" in the "colloquial" sense. Ex. E, Agreement, at 4. It goes on to state that terms should be "given the meaning specified in the statute." *Id.* But the statute uses those terms to convey their ordinary meanings, and the "definition" provided in the statute simply says that a price set under the statute should be understood as

the "maximum fair price." § 1320f(c)(3). The statute plainly requires manufacturers to purport to "agree" to a price that is set solely by the government and then endorse the government's claim that this is the "maximum fair price."

The disclaimer also raises the obvious question of why Congress would use—and force the manufacturers to parrot—the words "fair" "agreement" and "negotiation" if that is not in fact what Congress meant. The question answers itself. Those words were carefully chosen by Congress to deliver the message intended by their ordinary meaning. Nothing the agency can do or has done can alter that reality.

Not only does the disclaimer run headlong into the statute, it is also inconsistent with how the Program is described in the rest of the agreement. *See supra* at 29-30 (discussing the terms of the agreement and its references to "negotiation" and "maximum fair price"). The purported disclaimer does nothing to resolve the compelled speech requirement imposed by the statute and made clear in the remaining text of the agreement. In any event, adding a "disclaimer" cannot cure a compelled speech problem, because 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, 15 n.11 & 16 (1986) (plurality op.).

Nor is it any answer, as the government may contend, that Novartis could potentially announce its disagreement through speech in other places. *Reno v. ACLU*, 521 U.S. 844, 880 (1997) ("[O]ne is not to have the exercise of his liberty of

expression in appropriate places abridged on the plea that it may be exercised in some other place." (citation omitted)); *Pac. Gas.*, 475 U.S. at 16; *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 257-58 (1974). And, from a practical standpoint, speech by an individual entity like Novartis is unlikely to reach the same audience as the repeated statements by the government regarding Novartis's purported "voluntary" agreement to the government's unilaterally set price.

Finally, to the extent that the government advances a voluntariness argument, it disregards that Congress cannot use funding conditions to "requir[e] recipients to profess a specific belief" or "the Government's view on an issue of public concern." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 218 (2013); *see supra* at 25 (discussing the unconstitutional conditions doctrine). Because the Program compels manufacturers to speak the government's own preferred messages, it violates the First Amendment.

IV. THE PROGRAM IMPOSES EXCESSIVE FINES

Finally, the Program is unconstitutional in a third respect. It uses a draconian fine—an "excise tax" in name only—to coerce manufacturers into "agreements" to "negotiate" and, ultimately, to give into its pricing scheme for drugs. That escalating "excise tax" begins at 186% and, after 271 days, reaches 1900% (19 times) of a drug's total national sales revenues. 26 U.S.C. § 5000D(b)(1)-(4). For Novartis, the excise tax would quickly reach $93.1 billion each year. Decl. ¶ 11. This penalty is

financially catastrophic given Novartis's total Fiscal Year 2022 net sales of $50.5 billion and net income of $6.9 billion. *Id.* That punishment violates the Constitution because it is grossly disproportionate to the "offenses" triggering the fine.

A. The Program Imposes Grossly Disproportional Fines

The Eighth Amendment bars "fines" that are "grossly disproportional to the gravity of [the] offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *see* U.S. Const. amend. VIII. 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), for example by "deter[ring]" conduct with more than a merely "remedial purpose," *Bajakajian*, 524 U.S. at 329. 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 Cnty.*, 598 U.S. 631, 648 (2023) (Gorsuch, J., concurring) (emphasis added) (quoting *Austin*, 509 U.S. at 610).

The Program's so-called "excise tax" is a fine within the meaning of the Excessive Fines Clause because it is punitive and intended to punish and coerce. In similar contexts, courts have considered the size and purpose of a fine in determining whether it has a punitive character and found taxes of five- and eight-times the value of the taxed product to be punitive. *See Dep't of Revenue of Mon. v. Kurth Ranch*, 511 U.S. 767, 780 (1994) (tax of eight-times value); *Dye v. Frank*, 355 F.3d 1102,

1105 (7th Cir. 2004) (tax of five-times value). The penalty here is far more severe—it quickly escalates to fully *nineteen times* the manufacturer's nationwide revenues from the drug's sales if the manufacturer fails to accede to CMS. 26 U.S.C. § 5000D(d); *see also* Ex. G, Cong. Rsch. Serv., R47202, at 4 tbl. 2 ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance."). A "tax" of that scale is unquestionably punitive for purposes of the Excessive Fines Clause. *See Bajakajian*, 524 U.S. at 329 (deterrence has "traditionally been viewed as a goal of punishment").

The penalty is so substantial that incurring it would be financially ruinous for Novartis, which could not possibly pay the full weight of the excise tax for long without declaring bankruptcy. Accordingly, the "so-called tax" is sufficiently coercive and divorced from the raising of revenue that it has "lost its character as such and becomes a mere penalty." *Kurth Ranch*, 511 U.S. at 779-80 ("Whereas fines, penalties, and forfeitures are readily characterized as sanctions, taxes are typically different because they are usually motivated by revenue-raising, rather than punitive, purposes."); *NFIB*, 567 U.S. at 565 (looking to a provision's "practical characteristics" to determine whether it imposed a penalty or a tax).

It is also disproportionate to the gravity of the offense that it is designed to punish. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality," so the "amount of the [fine] must bear

some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. 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 draconian punishments for totally innocent conduct—failing to agree on contractual terms with the government. *See* 26 U.S.C. § 5000D(b)(1)-(4). It goes without saying that the most severe monetary penalty that the federal government has ever imposed is grossly disproportionate to that alleged "wrong-doing." *See Bajakajian*, 524 U.S. at 337.

B. The IRS's Nonbinding Notice Does Not Render The Excise Tax Constitutional

As with CMS's attempt to cure the statute's defects under the First Amendment, the IRS has now attempted to fix the unconstitutional "excise tax." The IRS recently issued a non-binding Notice announcing its intention to propose a rulemaking to limit the scope of the penalty. *See* Ex. H, Notice. That non-binding Notice offers no present basis for defending the Program. And even if the rulemaking were someday adopted, its proposed provisions lack any grounding in the statutory text. An agency may not "rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S.

302, 328 (2014). The government's attempt to administratively create a more defensible statute fails.

First, the Notice asserts that the excise tax would be imposed only on "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare." Ex. H, Notice § 3.01. The statute contains no such limitation. It "impose[s]" the penalty "on the sale by the manufacturer, producer, or importer of any designated drug during [a noncompliance period]." § 5000D(a). Moreover, CMS itself has acknowledged that the Program leverages participation in Medicaid to ensure compliance with the mandate. *See* Ex. F, Revised Guidance, at 120-121. Yet under the interpretation in the IRS Notice, a manufacturer that exited Medicare but not Medicaid would owe zero tax whatsoever. That is not consistent with the understanding of Congress or CMS, which both made clear that a manufacturer has to exit *both* Medicare and Medicaid to avoid the penalty. § 5000D(c); Ex. F, Revised Guidance, at 120-121.

Second, the Notice presumes that the amount charged for a drug subject to the excise tax includes both the "price" of the drug and the excise tax itself, such that a drug initially priced at $100 would be understood to actually cost only $5 with a massive $95 tax tacked onto it. Ex. H, Notice §3.02. There is no basis for that bizarre presumption. The price of ENTRESTO® was established before the Program—and obviously did not include any tax. And Novartis is, in fact, statutorily

barred from increasing its price to incorporate any tax payments. *See* 42 U.S.C. § 1395w-114b(b)(1)(A). Yet, under the government's reading, once a tax has been levied, the price of the drug inexplicably declines by the taxed amount. That is utter sophistry—and only underscores that even the government cannot defend the magnitude of the tax on its own terms.

In any event, even under the rules articulated in the Notice, the fine is grossly excessive. The government pretends as if taking 95% of a drug's value is not an excessive fine. But that formula applied to Novartis would still result in a fine of over *$2 billion.* That is excessive by any measure.

Ultimately, this case illustrates why the bar on excessive fines is "fundamental to our scheme of ordered liberty." *Timbs v. Indiana*, 139 S. Ct. 682, 689 (2019). "Exorbitant tolls" are not only wrongful, they also threaten to "undermine other constitutional liberties." *Id.* The "excise tax" here was enacted for just such a purpose—to coerce manufacturers into complying with the government's forced taking and compelled speech regime. The result is a reticulated vice of constitutional violations. This Court's intervention is urgently needed.

CONCLUSION

For the foregoing reasons, the Court should declare the Program unconstitutional and enjoin Defendants from enforcing it against Novartis.

Dated: November 22, 2023

Respectfully submitted,

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