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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-JBD

**PLAINTIFF'S COMBINED OPPOSITION TO DEFENDANTS' CROSS-  
MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF  
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

The government’s defense of the “Drug Price Negotiation Program” (the Program) of the Inflation Reduction Act (IRA) relies on re-writing the statute into something it is not. The government claims the Program is an unremarkable effort to impose “market discipline” by allowing the federal government to “decide how much it is willing to pay for certain prescription drugs.” Gov’t Br. at 1. In other words, the government portrays the Program as an ordinary price-setting regime. That may be the statute the government now *wishes* to defend, but it is not the one Congress enacted.

The reality is that the Program creates a forced-sale regime unique in American history. Through the Program, the government handpicks a subset of manufacturers that participate in the Medicare and Medicaid programs and dictates to them that *they must hand over their personal property* on the government’s selected terms, while, at the same time, speaking a government-approved message. That is not a run-of-the-mill “Medicare reimbursement cap[ ].” Gov’t Br. at 28. And, as much as the government tries to downplay its scope, its own tortured efforts to re-write the statute only underscore that the Program is indefensible.

The government’s principal argument is that because participation in Medicare is “voluntary,” the “consequences of that participation cannot be considered a constitutional violation.” Gov’t Br. at 12 (quoting *Dayton Area*

*Chamber of Com. v. Becerra*, No. 3:23-cv-156, —F. Supp. 3d—, 2023 WL 6378423, at \*11 (S.D. Ohio Sept. 29, 2023)). In other words, in the government’s view, when a party elects to participate in a program that Congress enacts through its Spending Clause powers, there are *no* constitutional limits on what the government may do to the program’s participants. That is as extraordinary—and wrong—as it sounds. If that were the law, then the government could force manufacturers to turn over their manufacturing plants and raw materials without any compensation, simply by framing those appropriations as a “condition” on the use of Medicare funds. Or the government could force universities to publicly support the President’s reelection campaign because they accepted federal funds.

Those actions are impermissible for an obvious reason: choosing to enter into a government program does not give the government *carte blanche* to violate the constitutional rights of the program’s participants. And once that sweeping premise is rejected, the government’s defense of the Program crumbles.

As to the Takings claim, the government first resorts to misdirection by arguing that Novartis is *not* actually required to turn over its property even if it stays in the Medicare and Medicaid programs. It purports to base this argument in the text of the statute, which it says requires Novartis only to provide “access” to the CMS-dictated price for ENTRESTO® *if* it chooses to sell its drugs to Medicare beneficiaries. Thus, the government now says, Novartis is free to stop selling

ENTRESTO® to Medicare beneficiaries, while otherwise remaining in the Medicare and Medicaid programs. But that interpretation is at odds with the plain language of the statute, as well as with the implementing agencies' own guidance. And it defies common sense. There is no reason for Congress and CMS both to have explained that manufacturers can avoid the financial demands of the Program only by withdrawing *all of their products* from both Medicare and Medicaid, without flagging the obviously preferable choice that a manufacturer could simply withdraw from just Medicare coverage the *one* selected product (which would remain covered by Medicaid). This new made-for-litigation interpretation, found only in Department of Justice briefs, should be rejected out of hand.

The government's "voluntariness" defense for the Takings claim fares no better. The Supreme Court has made unmistakably clear that a party's ability to avoid a physical taking by exiting the market does *not* insulate that taking from constitutional scrutiny. *Horne v. Dep't of Agric.*, 576 U.S. 350, 365-66 (2015); *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982). And even assuming the Program is viewed as a "condition" on participation in a government program, the "unconstitutional conditions" doctrine forbids the abuse of federal spending powers to coerce the abandonment of constitutional rights. The government's cited out-of-circuit cases emphasizing the voluntariness of Medicare participation in the context of *regulatory* takings are inapposite. Those cases stand

for the unremarkable proposition that a property owner has no established Fifth Amendment interest in making sales to the government at a particular rate. But the owner *does* have an established right not to have his personal property requisitioned. And if, as here, a law requires the handing over of property, it is no defense to label the unconstitutional taking a “condition” of participation.

The rest of the government’s arguments are equally flawed. The government argues that the statute’s speech regulation is permissible because it is “incidental” to the regulation of conduct. But that is incorrect. To the contrary, the statute’s compelled speech aspects are *wholly unnecessary* to effectuate the regulation of conduct. The Program would function precisely the same way without compelling its participants to describe themselves as engaging in a “negotiation” to determine a “maximum fair price.” Indeed, numerous government programs regulate similar conduct without any of the attendant theatre present here. Those compelled speech aspects of the Program are an independent and direct regulation of speech—and are subject to robust First Amendment scrutiny.

The government also tries to apply its “voluntariness” argument to the First Amendment context. But that only highlights the limitless nature of the government’s position. The notion that compelled speech is “voluntary” because the compelled party participates in a government program would devastate the First Amendment. Indeed, it would mean the government could compel pro-government

messages from any private individual or organization who received federal funds—and enforce those speech compulsions with enterprise-destroying penalties. That is plainly not the law.

Finally, the government does not truly defend the “excise tax” on the merits. Instead, it raises jurisdictional arguments, distorts the applicable case law, and attempts to rewrite the statute to obscure its obvious constitutional defects. The government first raises Article III standing and Anti-Injunction Act (AIA) arguments that seek to use the statute’s “tax” label and complex structure to shirk responsibility. But just calling something a “tax” does not automatically invoke jurisdictional barriers, like the AIA, that were not intended for this kind of punitive government conduct. The AIA does not bar suit against anything involving a “tax”; rather, it only prohibits claims that seek to restrain the “*assessment or collection of* [such a] tax.” 26 U.S.C. § 7421(a) (emphasis added). And here, the crippling “excise tax” is not designed to, and likely will never be, collected—as Congress itself anticipated. So Novartis’s lawsuit is not seeking to restrain the “assessment or collection of” a tax, as that purported “tax” could never realistically be paid; rather, Novartis’s suit seeks to restrain CMS’s use of the cudgel of an unconstitutional fine to coerce participation in the Program. The AIA cannot be read to make such coercion immune from suit. To hold otherwise would give the government unfettered discretion to impose unconstitutional penalties under the guise of “taxes”



that are too large to ever be paid—and then allow the government to forever immunize itself from having those defects reviewed simply by labeling those unconstitutional fines “taxes.”

The government also distorts the applicable case law to suggest that the “excise tax” cannot qualify as a “fine” that is subject to the Excessive Fines Clause. But courts have consistently found that exactions that are intended in part to punish fall within the Excessive Fines Clause, regardless of how they are characterized. The massive exaction imposed by the “excise tax” easily meets that test because it serves only to coerce manufacturers into agreeing to the government’s terms and punishing them severely if they do not.

Ultimately, this case is not about the government’s stated goal of lowering the cost of prescription drugs. A ruling in Novartis’s favor would not, as the government and its *amici* suggest, prevent Congress from addressing drug prices in any number of lawful ways. This case is about the means Congress chose to pursue that goal. Regardless of one’s view on the desirability of the Program as a policy matter, Congress’s chosen method transgresses vital constitutional limits on the government’s power. This Court must enforce those limits here.

## ARGUMENT

### I. THE PROGRAM EFFECTS PHYSICAL TAKINGS OF NOVARTIS'S PROPERTY WITHOUT JUST COMPENSATION

Novartis's Fifth Amendment argument is simple—and mostly undisputed. Novartis's prescription drugs are property. Through the IRA, the government takes those drugs by threatening to penalize Novartis with unprecedented crippling fines unless it provides Medicare beneficiaries "access" to its drugs at CMS's chosen prices. And those prices do not provide "just compensation" because they are capped at a fraction of the drugs' market prices. This scheme flouts the Fifth Amendment.

The government offers little response to the actual elements of Novartis's takings claim. The government does not dispute that physical doses of ENTRESTO® are protected property. And it does not dispute that the CMS-set prices do not provide Novartis just compensation.<sup>1</sup> Instead, the government

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<sup>1</sup> The government's vague suggestion (at 31 n.8) that CMS's set prices might occasionally provide just compensation—without any actual argument or caselaw citations—is not enough to preserve the issue. *See, e.g., Prometheus Radio Project v. FCC*, 824 F.3d 33, 53 (3d Cir. 2016) (issues "relegated to a footnote" are forfeited). And while some *amici* argue that the market prices are not "fair" because manufacturers enjoy a period of exclusivity under patent and FDA law, *see* Public Citizen Br. at 15-23; Economists Br. at 5-7, *amici* cannot raise issues the government forfeited. *See United States v. Alkaabi*, 223 F. Supp. 2d 583, 593 n.19 (D.N.J. 2002). Regardless, the Supreme Court has long endorsed "market price" as the measure of compensation for private property sold in an established market. *Kimball Laundry Co. v. United States*, 338 U.S. 1, 6 (1949). And, of course, it is entirely fair for a

principally relies on the contention that Novartis’s participation in the Medicare program is “voluntary.” But voluntariness in the abstract does not exempt government demands for property from the Takings Clause. Indeed, property owners almost always have some theoretical “option” to avoid handing over their property to the government—for example, they could sell that property to another buyer first—but that does not excuse the government’s taking. Here, none of the government’s proffered “choices”—paying a devastating fine, divesting Novartis’s interest in its drugs, or withdrawing entirely from half of the nation’s healthcare market—offers a viable legal pathway to excuse a physical taking.

The government also tries to justify the Program as a valid “condition” on participation in a federal spending program. But this requirement is nothing like a normal “condition” on the receipt of federal funds; it is a demand—backed by an onerous penalty—placed on some, but not all, of a program’s participants. The government fails to identify *any* similar requirement in any other program that has been deemed a “condition.” And, regardless, there are constitutional limits on the “conditions” the government may attach to spending programs like Medicare. One such limitation is that the government cannot condition receipt of a benefit on the relinquishment of a constitutional right, including Fifth Amendment property rights.

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market price to reflect the value of a seller’s groundbreaking—and hence patent-protected—innovation.

That rule applies with full force even when the government acts pursuant to the Spending Clause. The out-of-circuit and largely unreasoned cases the government cites emphasizing the voluntariness of Medicare participation in the context of alleged regulatory—not *per se*—takings say nothing about the question presented here.

Ultimately, the government’s “voluntariness” defense is all smoke and mirrors. When carefully analyzed, it devolves into a limitless warrant for the government to violate the constitutional rights of participants in federal programs. This Court cannot accept that rationale to save the IRA.

**A. The Program’s Compelled Sales Take Novartis’s Property**

The Program requires manufacturers to hand over their personal property at a government-set price. Unlike an ordinary price-setting regime, the Program does not offer manufacturers the option to say “no” to the price the government sets; manufacturers must actually sell to the government on the government’s terms.

The government argues (at 28-29) that the IRA does not actually “force[] manufacturers to surrender their drugs,” so the scheme should be considered a “regulatory” taking instead of a “physical” taking. That is because, in the government’s view, the statute 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.” On this reading, 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. That remarkable interpretation conflicts with the plain language of the statute, creates superfluity, and cannot be squared with previous statements by CMS and the IRS. This effort to re-write the statute to save a regime that the government knows is indefensible should be firmly rejected.

Start with the text. The IRA requires that Novartis “shall ... provide” third parties in Medicare “access to the maximum fair price ... with respect to” ENTRESTO®. 42 U.S.C. § 1320f-2(a)(3). The government responds (at 29-30) that this language requires Novartis only to provide “access” to a *discounted price*, not “access” to a *drug*. It thus argues (at 29-30) that the Program obligates Novartis only to charge the maximum fair price *if* Novartis chooses to sell ENTRESTO® to Medicare beneficiaries—but it does not obligate Novartis to make any such sales in the first instance.

That reading defies common sense. Any reader of ordinary English would understand “access” to a particular price to encompass “access” to the underlying product as well. To provide “access” to something means to enable someone to “make use of” it. *Access*, Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/access> (accessed Feb. 23, 2024). If, after signing the agreement with CMS, Novartis were simply to refuse to transfer

ENTRESTO® to any Medicare beneficiary, Novartis would not be allowing anyone “to make use of” the purported “maximum fair price.” It would be like 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. That is not a plausible reading of the word “access.”

While the phrase “access to price” is somewhat unwieldy, that is because it is trying to convey, simultaneously, two different promises: (1) the manufacturer will sell the product to Medicare beneficiaries; and (2) when it does, those sales will be at the purported maximum fair price. It tortures the plain meaning of the statute to suggest that it allows a manufacturer to *not* provide “access” to *anyone* in the Program.

The other provisions of the IRA confirm this understanding. 26 U.S.C. § 5000D(c) makes clear that Novartis has the “option” to suspend 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. It would make no sense for the IRA to expressly suspend its crippling tax only if a manufacturer withdrew *all* products from both programs, yet implicitly permit manufacturers to circumvent the statute’s all-or-nothing choice by declining to sell *only* the selected drug and only to Medicare. 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”).

The government’s new-found position also flies in the face of 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., CMS, Medicare Drug Price Negotiation Program: Revised Guidance (“Revised Guidance”) at 6, 129-130 (June 3, 2023)*. The IRS has taken a similar position, acknowledging in its own guidance that the Program requires manufacturers “to provide *access to selected drugs*.” IRS Notice § 3.02 (emphasis added).

The contradictory “convenient litigating position” the government’s litigation counsel took in this brief—a brief that was not cosigned by CMS, the agency responsible for enforcing this statute—lacks any persuasive value and should be rejected. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)

(refusing to defer to government’s litigating counsel’s position); *Abbott Lab’ys v. United States*, 573 F.3d 1327, 1332-33 (Fed. Cir. 2009) (distinguishing between the views of the agency itself and litigating counsel).

The government obliquely suggests (at 30) that its interpretation is supported by the notion that the civil monetary penalty provided for in 42 U.S.C. § 1320f-6(a), which attaches to failures to “provide access to a price that is equal to or less than maximum fair price,” would come out to \$0 if a manufacturer did not sell its drug to Medicare beneficiaries because this penalty is a multiple of the total Medicare sales. But even if true, there are numerous *other* provisions in the IRA that would provide onerous penalties for any breach of Novartis’s “access” duty. The statute imposes a crippling excise tax for “noncompliance” with the Program, 26 U.S.C. § 5000D(b)(2)—a term that would make no sense if Novartis were not legally obligated to comply in the first instance. And the statute also provides for a civil monetary penalty of \$1,000,000 per day that a manufacturer breaches “requirements determined by [CMS] to be necessary for purposes of administering the program.” 42 U.S.C. §§ 1320f-2(a)(5), 1320f-2(a)(4), 1320f-6(c). CMS has suggested in its Revised Guidance that one such requirement is that manufacturers provide “access” to their selected drugs. Revised Guidance at 45, 72, 82-85, 119, 168, 172; *see also id.* at 94 (CMS’s Revised Guidance “specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation”). At most,



therefore, the government has shown that one of several statutory penalties could be avoided by a manufacturer stopping sales of a single drug. That says absolutely nothing about what the statute means.

Indeed, in the end, even the government itself does not endorse its own position. Elsewhere in its brief, the government identifies as the available “options” for avoiding the Program (i) divesting a manufacturer’s interest in its drug, (ii) paying a crippling excise tax, or (iii) withdrawing from Medicare and Medicaid *entirely*. *See, e.g.*, Gov’t Br. at 2, 7-8, 24 (“A manufacturer that does not wish to [participate in the Program]” can “continue selling its drugs to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales,” “transfer its interest in the selected drug to another entity,” or “withdraw from the Medicare and Medicaid programs.”). And in its briefs in other related cases, the government has acknowledged that the manufacturers’ “obligation” under the IRA is “to ultimately *provide their drugs* at the negotiated prices.” Opp’n to Pl.’s Mot. for Summ. J. & In Supp. of Defs.’ Cross-Mot. at 34, *Merck v. Becerra*, No. 1:23-cv-01615-CKK (D.D.C. Sept. 2023), ECF No. 25 (emphasis added).

In any event, the government also cannot set forth any plausible way for Novartis to actually 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. 42 U.S.C. § 1395w-104(b)(3)(I)(i). As Novartis explained in its opening brief, 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. *See* Novartis Br. at 14 (citing Vineis Decl. ¶¶ 24-25). The government had no response to this point in its brief and did not explain how a manufacturer could stop a selected drug from being sold to Medicare beneficiaries while nonetheless staying in the program. Nor could it. As CMS has confirmed, this formulary-inclusion provision exists to ensure “*access to selected drugs.*” Revised Guidance at 82, 83, 84, 85 (emphasis added).

**B. The Government’s “Voluntary” Defenses Cannot Save The Program**

Once the government’s effort to re-write the statute is rejected, its defense to Novartis’s Takings Clause claim disintegrates. The government’s principal argument is that the taking here is permissible because Novartis voluntarily participates in the Medicare program. But that cannot be correct. Voluntary participation in a government program does not give the government carte blanche to commit constitutional violations against participants. The government could not, for example, requisition a pharmaceutical manufacturer’s means of production as a

product of its “voluntary choice” to stay in Medicare and Medicaid. And while the government attempts to excuse its taking as a “condition” on participation in a federal spending program, this is not a condition at all—it is a mandate on a subset of participants, backed by an unconstitutionally onerous penalty; and, in any event, the unconstitutional conditions doctrine forbids attempts to accomplish indirectly via “conditions” what the government cannot lawfully do directly.

1. Voluntary Participation In A Government Program Does Not Justify A *Per Se* Taking

The government argues (at 8) that there is no taking because Novartis could avoid handing over its property by opting instead to (i) pay a crippling excise tax for each day of “[n]oncompliance” with the Program’s obligations, (ii) divest Novartis’s interest in ENTRESTO® to a separate entity, or (iii) withdraw each of Novartis’s drugs from the Medicare and Medicaid programs. Because there is no “legal compulsion” to participate in the Program given these other options, the government argues, the “consequences of that participation cannot be considered a constitutional violation” as a matter of *law*. Gov’t Br. at 12-16, 28 (citing *Dayton Area Chamber of Com.*, 2023 WL 6378423, at \*11).

But none of this makes Novartis’s participation in the Program “voluntary” in a legally relevant sense. As the Supreme Court has held on numerous occasions, the fact that a property owner can *avoid* a taking by withdrawing from a relevant market does not insulate the government’s action from constitutional scrutiny. *See Horne*,

576 U.S. at 365; *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612-13 (2013). That is for good reason. A property owner will virtually always have some theoretical “option” to refuse to hand over its property. But that alone cannot excuse a governmental taking of physical property. *See, e.g., Horne*, 576 U.S. at 365 (recognizing that raisin growers could change their business model to avoid the taking). Here, each of the government’s “options” are just different ways of saying—as in *Horne*—that a manufacturer can avoid a taking by abandoning their participation in a market.

Start with the first option: paying a crippling excise tax for each day of noncompliance. The government does not seriously defend this option, 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. *See, e.g., id.* at 370 (demand for raisins enforced through penalties was *per se* taking). 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*, 570 U.S. at 612). Here, the government goes even farther by giving manufacturers the “choice” of either surrendering their property or paying the government far *more* than its value in penalties.

As for the second option, the government's view is apparently that manufacturers can abandon their interests in their property before the government takes it, and thereby escape the taking. This works no better than the "option" of paying a monetary fine. 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. *Valancourt*, 82 F.4th at 1234-35 (quoting *Koontz*, 570 U.S. at 613); *see also* Novartis Br. at 14 n.3. 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.

The third option—exiting Medicare and Medicaid *entirely* for *all* of Novartis's products—is the only one the government meaningfully attempts to defend, but it is just as impermissible. It is just another way of saying that Novartis can leave the relevant marketplace to avoid the taking. But, as Novartis explained in its opening brief, the Supreme Court's decision in *Horne* establishes that a property owner's theoretical ability to leave a particular marketplace in order to avoid a physical taking does not excuse a physical taking of property. *See* Novartis Br. at 18-22.

Indeed, the arguments the government makes here are remarkably similar to those it made in *Horne*. In *Horne*, the government argued that its raisins appropriation was a voluntarily accepted condition because the growers were not

legally compelled to participate in the raisins market. 576 U.S. at 365-67. In response, the petitioners pointed out that the government’s “voluntariness” defense would allow it to “require drug manufacturers to turn over every third batch of their medicines or car manufacturers to let the government drive off with every other car off the assembly line, as a condition to doing ordinary business in the market”—which could not possibly be the law. Reply Brief for Petitioners at \*9, *Horne*, No. 14-275, 2015 WL 1731465 (Apr. 15, 2015). The Supreme Court agreed with the petitioners, and in doing so made clear that physical property may *never* be held “hostage” as a “condition” for participating in a market—regardless whether the property owners “voluntarily [chose] to participate in [that] market.” *Horne*, 570 U.S. at 365-67. That holding is fatal to the IRA. If “legal compulsion” was required to have a *per se* takings claim (as the government now argues), *Horne* would have come out the opposite way.

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) than suggesting that 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. And the consequences of such reorientation would be far more catastrophic than in *Horne*: Tens of millions of Americans would lose access to their needed drugs.

The Supreme Court's holding in *Horne* is not an outlier. In *Loretto*, the Supreme Court likewise held that a property owner's ability to participate in a particular marketplace "may not be conditioned on his forfeiting the right to compensation for a physical occupation" as a matter of law. 458 U.S. at 439 n.17. Otherwise, the government could "require a landlord to devote a substantial portion of his building to vending and washing machines" in the form of a condition without providing compensation, or even "requisition a certain number of apartments as permanent government offices." *Id.* But that sort of physical requisitioning in return for market participation is *never* permissible, as numerous cases make clear. *See id.* at 434-40; *see also Yee v. City of Escondido*, 503 U.S. 519, 531-32 (1992) (*Loretto* forecloses conditions defense when statute "effect[s] a physical taking"); *Gulf Power Co. v. United States*, 187 F.3d 1324, 1331 (11th Cir. 1999) (government's voluntariness defense was "foreclosed by *Loretto*" because statute effectuated a "per se taking"); *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*).

The government attempts (at 21-22) to limit *Horne* to cases involving government regulations instead of the spending of government funds, but that distinction has no basis in the Court’s decision. The Spending Clause simply locates the government’s authority for a particular act; it does not somehow insulate the government’s actions from constitutional scrutiny or change the limits on what conditions the government can lawfully impose on receipt of its benefits. *See infra* at 28-30.

Furthermore, as Novartis explained in its opening brief, the upshot of accepting the government’s “voluntariness” argument here would be that the government could “seize without just compensation the manufacturing plants and raw materials of the 10 highest spend drugs and then produce those drugs itself” simply by claiming that participation in the Medicare market is “voluntary.” Novartis Br. at 21. But that is the argument the Supreme Court already rejected in *Horne* and *Loretto*. The government did not respond to this point in its opposition, and that silence is deafening.

2. The Government’s Non-Binding Authorities Are Inapposite Or Inconsistent With Supreme Court Precedent

To support its claim that it has the unbounded authority to impose whatever conditions it wants on a federal spending program, the government relies entirely on non-binding, outdated, and largely unreasoned cases making broad statements that participation in Medicare is voluntary. *See* Gov’t Br. at 2, 12-14, 23-24. To the



extent these cases actually stand for the government's proposition that spending conditions are entirely immunized from constitutional review, they are unpersuasive and should not be followed. None of these cases is from the Third Circuit. This Court is instead bound by *Horne* and the other precedent discussed above.

Besides, each of these cases is readily distinguishable. All were addressing a “voluntariness” argument in the context of deciding whether a particular price-setting regime gave rise to a *regulatory* taking or a due-process violation. *See, e.g., Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (analyzing whether statute gave rise to a “regulatory taking”); *Baker Cnty. Med. Servs., Inc. v. U.S. Att’y Gen.*, 763 F.3d 1274, 1276-79 (11th Cir. 2014) (same); *cf. Dayton Area Chamber of Com.*, 2023 WL 6378423 (due-process challenge to Program’s price-setting procedures). None involved an alleged *physical* taking of property.

And that distinction is crucial: As the Supreme Court has explained, regulatory takings cases should not be used as “controlling precedents” when evaluating a physical takings claim. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Plan. Agency*, 535 U.S. 302, 323 (2002); *see also, e.g., Yee*, 503 U.S. at 522 (articulating the two “distinct” lines of Takings Clause cases). The government itself emphasizes the “settled difference” between regulatory and *per se* takings cases. Gov’t Br. at 2, 28-29. And some of the regulatory takings cases the government cites for its “voluntary” argument even themselves recognized that the bottom-line

result would be different if the plaintiffs had argued that the statute at issue required property owners to hand over their property instead of simply setting a rate of compensation. *See Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 125 (1st Cir. 2009) (analyzing statute “under the law of regulatory takings, not the law of physical takings” because it did not “directly appropriate” property but rather set a rate); *Garelick*, 987 F.2d at 916 (recognizing that the Takings Clause requires compensation when companies “are compelled to employ their property to provide services to the public,” which was not the facts of that case).

A regulatory takings claim is premised on the idea that the government has regulated a particular “use” of private property to such an extent that its regulation is “tantamount to a direct appropriation,” based on factors like the regulation’s interference with the property owner’s reasonable “investment-backed expectations” for how it planned to use its property and the “character” of the government’s regulation. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124, 131 n.7 (1978). The regulatory takings cases the government cites are best read as holding that when a price-setting regulation impacts only one “use” of a piece of property—the “use” of voluntarily selling that product to the government—such a regulation will not effectuate a taking *at all* because the property owner has no “reasonable expectation” that the government will buy its products at whatever price it demands. *See, e.g., Hempstead Gen. Hosp. v. Whalen*, 474 F. Supp. 398, 410 (E.D.N.Y. 1979)

(distinguishing between price-setting regimes that cause a property owner to “lose a potentially profitable sale” and government actions that cause an owner to lose an “existing right of property”), *aff’d*, 622 F.2d (2d Cir. 1980); *Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (weighing the fact that participation was “voluntary” when performing factual regulatory takings analysis); *cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007-08 (1984) (regulation did not undercut “reasonable investment-backed expectations” when property owner “voluntarily” participated in scheme).

But a physical seizure of property is different and does not depend on the extent of the regulatory scheme or its impact on the owner’s reasonable expectations. Such a claim simply asks whether property was appropriated without compensation. *See, e.g., Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021) (“[P]hysical appropriations constitute the ‘clearest sort of taking’” and are assessed “using a simple, *per se* rule: The government must pay for what it takes.” (citation omitted)).

The government’s contention (at 22-24) that manufacturers have no property interest in making sales to the government thus misses the point. Novartis is not arguing that it has a right to force the government to buy its products at any particular price. Rather, it is arguing that it cannot be *forced to sell* its products at the government-dictated price. So although Congress is free to impose “limits on how much federal agencies pay for prescription drugs,” Gov’t Br. at 1, or to authorize

agencies to “negotiate prices” like other market participants, *id.*, it is *not* free to use draconian penalties or the threat of exclusion from half the nation’s drug market to force manufacturers to *hand over* their personal property at a government-dictated price.

The government’s argument that these forced sales would simply place manufacturers in a position similar to “public utilities” is similarly unpersuasive. Gov’t Br. at 30-31 (citing *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307-15 (1989)). For one thing, Novartis is not a public utility. Any “evolution of takings jurisprudence,” *id.* at 30, to treat public utilities differently stems from “th[e] partly public, partly private status of utility property.” *Duquesne*, 488 U.S. at 307. But Novartis is a purely private company—and the same is true for the ENTRESTO® products it markets. The government cites no support for its suggestion that Novartis or its property should be classified as a public utility for Takings Clause purposes.

In any event, the *per se* physical takings rule applies with full force even when the government takes a public utility’s property. *Duquesne*’s discussion of utilities was not in the context of a physical takings claim. So “[n]othing in *Duquesne* suggests a utility’s property is less subject to protection against permanent, physical occupation than anyone else’s property.” *Gulf Power*, 187 F.3d at 1330 (holding that the *Loretto* rule applies to physical takings of the property of public utilities). And it is by now well-established that even a public utility’s property is protected

from “physical occupation.” *FCC v. Fla. Power Corp.*, 480 U.S. 245, 252 (1987) (citing *Loretto*, 458 U.S. at 436); *see also, e.g., St. Louis v. Western Union Tel. Co.*, 148 U.S. 92, 102-04 (1893).

In the end, by relying only on regulatory takings cases evaluating the voluntariness of Medicare participation, the government has all but conceded that it cannot lawfully impose a *physical* seizure of property as a condition on accepting federal funds.

3. Regardless, The Program’s Forced Sales Would Be An Unconstitutional Condition

Even if this Court disagrees that this sort of physical requisitioning is always unlawful under *Horne* and *Loretto*, that would not change the result. The government’s voluntariness defense hinges on its taking being a “proper condition” on Novartis’s participation in the Medicare and Medicaid markets. Gov’t Br. at 20, 28; *see id.* at 14 (“If a provider dislikes the conditions offered by the government, it can simply withdraw from the program.” (citation omitted)); *id.* at 2, 8, 16, 23, 25-26, 28 (describing the Program’s demands as “conditions Congress imposed on future Medicare spending”). The government argues (at 23) that “conditions that Congress sets for participation in federal spending programs” are always lawful, without any need to “further analyze[] the propriety of the condition.” (citation omitted). That is simply incorrect.

As an initial matter, the Program’s mandates are not actually “conditions” on Novartis’s participation in the Medicare and Medicaid markets. *See* Novartis Br. at 22-24; *see also Cedar Point*, 594 U.S. at 161-63 (access regulation was not a “condition of receiving certain benefits” but was instead a *per se* physical taking because it amounted to a “simple appropriation of private property”). It is not the case that every Medicare participant must agree to a maximum fair price as a condition of participating in Medicare. Rather, a *subset* of manufacturers have been picked out and told that they—and they alone—will have their property requisitioned at a government-set price, or pay a devastating penalty. And failure to comply with the Program’s obligations would not actually cause those handpicked manufacturers to lose coverage under Medicare or Medicaid, *even for their selected products*. *See* Novartis Br. at 22-24. They would remain within those programs, receiving the same existing market prices—but now would be subject to a massive penalty. That is in no sense a condition of coverage or a limit on reimbursement. It is just a requirement backed by a penalty. The government cites *no* case where such a regime has been analyzed as a “condition.” And the government offered no substantive response on this point whatsoever in its brief. Its reply brief is “too late” to do so. *Garza v. Citigroup Inc.*, 881 F.3d 277, 284 (3d Cir. 2018).

Even if this demand for property could be viewed as a “condition” on participation in the federal healthcare programs, that would not save the Program.

Under the unconstitutional conditions doctrine, “the government may not deny 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). This principle “vindicates the Constitution’s enumerated rights by preventing the government from coercing people into giving them up.” *Koontz*, 570 U.S. at 604. The key issue in every unconstitutional conditions case is whether the condition imposed by the government would violate the Constitution if imposed *directly* (i.e., not simply as a condition for receipt of a government benefit). *See, e.g., Rutan v. Republican Party of Ill.*, 497 U.S. 62, 77-78 (1990); *Frost v. R.R. Comm’n of Cal.*, 271 U.S. 583, 593 (1926) (“[C]onstitutional guaranties” are safeguarded not only “against direct assault” but also against “the indirect, but no less effective process of requiring a surrender, which, though in form voluntary, in fact lacks none of the elements of compulsion”). If a “condition” on the voluntary receipt of a benefit could not be imposed directly, it flunks the unconstitutional conditions test, regardless whether the rightsholder was “legally compelled” to accept that benefit and comply with the condition.

The government argues (at 22) that because manufacturers have “no right” to Medicare funds, this “reasoning does not apply” when Congress acts pursuant to its Spending Clause powers. That’s wrong. In *Koontz*, the government made a similar argument that, because it could deny a government benefit outright, it could refuse

to grant that benefit if the petitioner refused to cede a constitutional right. 570 U.S. at 608. But the Supreme Court soundly rejected this argument, emphasizing that “[v]irtually all of [the Supreme Court’s] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind,” yet the Court has “repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights.” *Id.* (citing *Regan*, 461 U.S. 540 (tax benefits); *Mem’l Hosp. v. Maricopa Cnty.*, 415 U.S. 250 (1974) (healthcare benefits); *Perry v. Sindermann*, 408 U.S. 593 (1972) (public employment); *United States v. Butler*, 297 U.S. 1, 71 (1936) (crop payments); *Frost*, 271 U.S. 583 (business license)). Instead, the law is clear that “the government may not deny a benefit to a person on a basis that infringes his constitutionally protected [right] even if he has no entitlement to that benefit.” *United States v. Am. Libr. Ass’n*, 539 U.S. 194, 210 (2003).

And that rule still applies when, as here, the voluntarily accepted “benefit” involves the government’s funds. The government’s argument (at 20, 22-23) that conditions imposed on “spending programs” are “subject to a fundamentally different form of constitutional review” is flatly incorrect. Multiple cases from the Supreme Court and the Third Circuit have applied the exact same unconstitutional conditions doctrine described above when evaluating a purported “condition” on the use of federal funds. For example, in *FCC v. League of Women Voters of Cal.*, the



Court invalidated a condition denying federal public broadcasting funds to stations that engage in editorializing. 468 U.S. 364 (1984). Treating this condition as coercive, the majority repeatedly referred to it as a “ban” or “restriction” rather than an offer to the stations to choose between entirely private funding and a federal subsidy. *Id.* The Court gave no weight to the fact that the prohibition was predicated upon the provision of federal funds that a broadcaster did not have a “right” to.

Similarly, in *Koslow v. Commonwealth of Pennsylvania*, the Third Circuit made clear that just “[b]ecause the federal government is not required to provide states with funds does not mean it may condition distributions on arguably unconstitutional grounds.” 302 F.3d 161, 173 (3d Cir. 2002) (citing *Speiser v. Randall*, 357 U.S. 513, 526 (1958) (the government may not act indirectly “to produce a result which [it] could not command directly”)). The proper analysis in the Spending Clause context, as elsewhere, is whether the condition, if imposed directly, would be constitutional on its own terms. *Id.*; see, e.g., *Agency for Int’l Dev. v. All. For Open Soc’y Int’l, Inc.*, 570 U.S. 205, 221 (2013) (funding condition violated unconstitutional conditions doctrine); *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 59-60 (2006) (federal statute requiring universities accepting federal funds to permit on-campus military recruiting did not violate unconstitutional conditions doctrine because federal government could directly require all universities to permit on-campus military recruiting).

That accords with common sense. The Department of Education could not seize a private university's land and buildings as a condition of continuing to receive federal funds, for example. The government's characterization of the taking here as a "condition" thus does not rehabilitate the constitutional deficiency.

4. The Government Has Not Attempted To Meet Any Exception To The Background Unconstitutional Conditions Rule

To be sure, as Novartis acknowledged in its opening brief, there are two narrow exceptions to the default unconstitutional conditions rule in the Takings Clause context: when a property owner voluntarily relinquishes use of its property in "exchange" for "a valuable Government benefit," *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984), or when a voluntarily accepted condition meets the *Nollan/Dolan* test, *see, e.g., Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 547 (2005). Those are the only two exceptions the Supreme Court has carved out to the general rule that takings must be accompanied by just compensation even when framed as a condition on the "voluntary" receipt of some benefit. *See, e.g., Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 47 (1st Cir. 2002) (explaining that the background rule is that the government "cannot condition" the ability to sell a product on an "unconstitutional taking," except when it comes to the *Ruckelshaus* and *Nollan/Dolan* exceptions); *Cedar Point*, 594 U.S. at 150-51 (considering only these two tests when rejecting a "conditions" argument).

The government *agrees* that these two tests are inapplicable because they apply only in narrow contexts. *See* Gov’t Br. at 20-23 (arguing that the *Ruckelshaus* voluntary exchange test applies only to regulations); *id.* at 27 (arguing that *Nollan/Dolan* apply only to land-use permitting decisions). But the result of that concession is that *Koontz*’s general rule applies—i.e. that unlawful takings remain unlawful even when imposed indirectly, or as a purported condition.

Instead of attempting to meet these tests, the government proposes (at 24-26) an alternative. It cites language from *Valancourt* granting that, “perhaps,” a forfeiture “might arguably be voluntary” if the owner had a “simple, seamless, and transparent” opt-out mechanism that was “known and costless.” 82 F.4th at 1235.

This fallback argument fails for multiple reasons. First, this language was dicta. In *Valancourt*, the D.C. Circuit recognized that it “need not resolve” whether a “known and costless” opt-out option could make the statute constitutional because no such mechanism existed in that case. *Id.* And neither the Supreme Court nor the Third Circuit has carved out this alternate pathway. *See supra* at 16-22.

Second, the Program would not come close to meeting this proposed test in any event. For starters, even more so than in *Valancourt*, no such “costless” mechanism exists here. Withdrawing from the Medicare and Medicaid markets entirely is the opposite of “costless”; it would be a devastating blow to a manufacturer, as the government intended. In *Valancourt*, the D.C. Circuit found

that a mere \$125 fee made the opt-out insufficient. *See* 82 F.4th at 1236-37. Here, a manufacturer must surrender not only coverage of the selected drug but also coverage for every other product it sells—actions that would almost certainly amount to an existential threat to the manufacturer. That would be like the statute at issue in *Valancourt* requiring a copyright owner to divest *all* of its copyrights if it failed to deposit one single book, which would obviously cost more than a \$125 fine.

In addition, this opt-out is not “transparent.” As in *Valancourt*, the “statute itself gives no indication” that withdrawing from Medicare can be readily “effectuate[d].” *Id.* at 1236. To the contrary, Congress expressly *blocked* manufacturers from withdrawing without providing up to 23 months’ notice. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). The government responds that CMS has found a convoluted way to bypass that statutory limit: If manufacturers wish to withdraw, the agency will “terminate” the manufacturers’ agreements earlier. Gov’t Br. at 16-17. But this rewrite is part of a pattern: The government recognizes the statute is unconstitutional as written, so it has developed a workaround “only in the course of litigation,” reflecting a “post hoc” tactic “by an agency seeking to defend past [congressional] action against attack.” *Valancourt*, 82 F.4th at 1237-38 (citation omitted). This rewrite stands in evident conflict with the statute and thus further shows that the government itself is aware that there are serious constitutional problems with the statute as written. And, regardless, this rewrite certainly cannot

be deemed a “simple, seamless, and transparent” opt-out mechanism for the manufacturers. *Id.* at 1235.

## **II. THE PROGRAM VIOLATES THE FIRST AMENDMENT**

The government’s various arguments responding to Novartis’s First Amendment claim are all equally misdirected. The government first contends (at 32) that “[s]igning an agreement with CMS is not speech, nor is it expressive conduct” and instead is speech “incidental to the . . . regulation of conduct.” In other words, the government seems to contend that, because manufacturers are forced to sign an agreement (a purported regulation of conduct), any speech required by that agreement is somehow immune from First Amendment scrutiny. That is plainly incorrect. The statute’s speech provisions are wholly unnecessary to effectuate the Program. The government could have created a system of price-regulation without requiring manufacturers to represent that they are in a “negotiation” for a “maximum fair price”—just like it has done in other statutes. The Program’s speech compulsion is direct, not incidental, regulation of speech.

The government also asserts (at 35-37) that, if compelled speech is at issue, it is permitted to require it as a condition of participation in the government’s spending program. That too runs headlong into Supreme Court precedent that recognizes the government is prohibited from imposing limitations on First Amendment rights as a condition of receiving a governmental benefit.

Notably, the government offers no argument for why the forced speech aspects of the Program would survive any form of heightened scrutiny or even tries to articulate any governmental interest they serve. That omission is telling. The reality is that the government has no argument on that front—the substance of the Program looks *exactly the same* when shorn of the forced speech aspects. The only possible governmental interest that is served by that compelled speech is to mislead the public into thinking the Program is something it is not, thereby furthering the government’s own preferred political narrative. Neither of these is a legitimate purpose.

**A. The Program Compels Speech**

1. The Forced Speech Here Is Not Incidental To A Conduct Regulation

The government asserts (at 32-33) that any speech is incidental to the signing of a commercial contract and so does not fall within the bounds of speech or expressive conduct. But a look at each of the compelled speech requirements at issue here directly refutes that argument. The compelled speech is *not* necessary to implement the forced-sales requirement, and thus is not “incidental” to the regulation of conduct.

In assessing whether a statute directly regulates speech and protected expression or only “imposes . . . an incidental burden on [them],” courts look to 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,” the effect on speech is not merely “incidental.” *Id.*; *see also United States v. Hansen*, 599 U.S. 762, 783 (2023) (impact on speech is “incidental” where, to the extent statute reached speech at all, the speech was “integral to unlawful conduct”). Here, the statute *directly* compels speech—it is directed at the content of Novartis’s speech, and in a way that is wholly unnecessary to regulate the relevant conduct.

As an initial matter, the government’s argument that the speech regulation here is “incidental” to the signing of a commercial “contract” assumes that the *only* way to establish the Program was via a contract. But the government nowhere defends that assumption. Congress could have, via statutory provisions, imposed the requirement to sell at a government-set price and provided that the excise “tax” was triggered by sales above that price. It was Congress’s own choice to utilize a “contract” to implement the requirement. So, even if the mechanism of using a “contract” led to the constitutional violations here, that does nothing to excuse them.

Further, even if some kind of contract had been necessary, Congress certainly did not need to mandate one that compels misleading representations. Here, the Program does so in at least three ways.

First, Congress forced manufacturers to represent that they voluntarily engaged in a “negotiation” when, in reality, the government compels their

participation and unilaterally sets the price. 42 U.S.C. § 1320f-2(a). The Program would function the same way absent a requirement to represent the process as a “negotiation.” The government would still be forcing manufacturers to sell their drugs at a government-set price. The word “negotiation” (and subsequent compelled performance of that “negotiation”) simply does not need to exist as any part of this scheme. And it is plainly misleading; no one would consider an exchange between a party with unilateral authority to dictate terms to be a “negotiation.”

Second, Congress compelled manufacturers to state that they “agree” to the price ultimately set by CMS, notwithstanding the fact that manufacturers are not actually agreeing but instead acquiescing to the price under the duress of massive penalties. Again, this compelled representation of “agreement” is unnecessary to the forced-sales requirement. Congress could have simply set the price without requiring manufacturers to attest that they agree to it, and the Program would function in the exact same way.

Finally, Congress required manufacturers to agree that the price chosen by CMS represents the “maximum fair price” for their drugs, which conveys both that the CMS selected price is reflective of the drug’s value and that any current commercial prices are unfair. 42 U.S.C. § 1320f(a)(3). And, once again, that language is completely unnecessary. *See, e.g., id.* § 256b(a)(1) (340B Program statute straightforwardly calls government-set price the “ceiling price”).



Thus, the government's assertion that the compelled speech here is all just part and parcel of the signing of a "contract" is false. Congress could have, for example, made manufacturers sign an agreement that simply states "the manufacturer acknowledges that it must sell the drug for no more than X dollars." It could have referred to the final amount as the "maximum allowable price," or even the "ceiling price," as it has done in other contexts. Instead, the government required manufacturers to opine that it is the "maximum *fair* price," thereby forcing manufacturers to carry the government's preferred messages for it. The government cannot immunize that compelled speech from challenge simply by placing it within a contract.

Consider this scheme: The government enacts a statute stating that manufacturers must sell their drugs at the government's chosen rate or be required, under threat of penalty, to withdraw all of their drugs from Medicare and Medicaid. That statute would achieve all of the non-speech related purposes that Congress sought to accomplish here: availability of the drug at no more than the maximum price the government wishes to pay. Separately, the government enacts a statute requiring manufacturers to issue a document stating that the price selected by the government was the product of negotiation and represents the maximum fair prices for their drugs. No one would seriously contend that the latter is not compelled speech and subject to First Amendment scrutiny. But that is exactly what happened

here. The fact that the government has intermingled a forced-sales regime with a series of provisions compelling speech does not make the latter regulation “incidental” to conduct.

The government’s lead case, *Rumsfeld*, 547 U.S. at 62, just underscores how inapposite the incidental-to-speech doctrine is to the facts in this case. The statute at issue in *Rumsfeld* specified that, for a law school to receive federal funding, it “must offer military recruiters the same access to its campus and students that it provides to the nonmilitary recruiter receiving the most favorable access.” *Id.* at 55. The challengers argued that if the law schools chose to send emails announcing the availability of recruiters, they would be “compelled,” as a downstream consequence, to send a similar email for military recruiters. But the statute did not specifically require the law schools to say or convey any particular messages. *Id.* at 62. That is totally unlike the Program here, which *directly* compels manufacturers to express particular sentiments—such as that they are involved in a “negotiation” and have agreed to a “maximum fair price.” Those features are not downstream consequences of conduct regulation; they are the direct and intended consequences of a statute that targets speech.

For similar reasons, the government’s reliance (at 33) on *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019), is misplaced. In *Nicopure*, the challengers argued that a ban on e-cigarette manufacturers offering e-cigarettes for zero dollars

(i.e., providing free samples) constituted a prohibition of speech because the samples were a means of communicating “product-specific information” about the e-cigarettes to the public. *Id.* at 291. In other words, the challengers “appear[ed] to be urging [the court] to afford constitutional protection to the informational value of customers’ experience trying out vaping, including the experience of sampling the available flavors and sensations.” *Id.* That “extraordinary” position, the court explained, “would extend First Amendment protection to every commercial transaction on the ground that it ‘communicates’ to the customer ‘information’ about a product or service.” *Id.*

That is nothing like this case. Novartis is not arguing that the conduct of being subject to the forced-sales regime is itself “communicative.” Rather, here, the statute affirmatively requires manufacturers to engage in speech that characterizes the Program a certain way—as a “negotiation” to reach an “agreement” on the “maximum fair price.” Indeed, *Nicopure* is not even a compelled speech case—the manufacturers there were not required to do anything affirmative at all; their challenge was limited to a ban on the conduct of free sampling, which they claimed was itself “communicative.” This case is more akin to a ban on free-sampling coupled with a requirement that manufacturers state that the free-sampling is a dangerous practice. In other words, it is a regulation of conduct coupled with a *wholly independent and unnecessary* set of speech provisions that are designed to

publicly *characterize* the regulated conduct in a certain way—in this case, as a “negotiation” to establish the *only* allegedly “fair” outcome—a position with which Novartis fundamentally disagrees. As Novartis has explained, other programs accomplish a virtually identical regulation of conduct (signing contracts that establish prices paid under government programs) without any of these speech-related provisions. *See* Novartis Br. at 30-31. The only possible purpose of the speech provisions is to co-opt the manufacturers into presenting a charade. And the fact that *Rumsfeld* and *Nicopure* are the government’s *best* cases speaks volumes. No court has ever described the kind of speech regulation at issue here as “incidental.”

Indeed, the logical consequence of the government’s position is that, whenever the government thinks that a statutory requirement should be implemented through a contract between itself and a private party, it can require the contracting party to say just about anything in that contract—and claim that those words are all speech “incidental” to conduct regulation. That cannot be the law.

## 2. The Statute Itself Requires Compelled Speech

The government also appears to argue (at 33-34) that there is no compelled speech issue here because the “decision to sign the negotiation agreement ‘is not inherently expressive’ . . . . [and] the agreement uses statutory terms merely as a way

of ensuring that the signatories share the same understanding of their respective obligations.”

As an initial matter, the compelled speech flows from the statute, not merely the agreement. The statute requires manufacturers like Novartis to affirmatively *misrepresent* that they willingly engaged in a negotiation, 42 U.S.C. § 1320f-2(a), compels manufacturers to participate in that process, *id.* § 1320f-3(b)(2)(A), requires them to state they “agree” to the price set by CMS, *id.* § 1320f(a)(2), and mandates that they represent that the price chosen by CMS is the “maximum fair price,” *id.* §§ 1320f(c)(3), 1320f-2(a)(1). Whether or not the agreement also reflects those terms is beside the point: The statute establishes the forced speech at issue here—not just the signing of an agreement.<sup>2</sup>

In any event, the government cites nothing to support its argument. And, again, it is virtually limitless in its scope. Under the government’s rationale, it can always co-opt private entities into agreements that communicate government-approved messages—such as that a particular price is the “maximum fair price”—under the guise that the message is “merely” a “statutory term” and compulsion is required to ensure that the parties have a “shared understanding” of their “obligations.” Gov’t Br. at 34. But the words “maximum fair price” have an actual

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<sup>2</sup> For that reason, the government could not fix the constitutional problem by simply modifying the language in the agreement.

meaning in the real world—and they inherently communicate that meaning to the public. If a manufacturer signs an “agreement” as to the “maximum fair price,” they are communicating that they agree both that the price is “fair,” and that the prior higher price was “unfair.” *See, e.g., New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 177-78 (2d Cir. 2020); *cf. John Doe No. 1 v. Reed*, 561 U.S. 186, 194-95 (2010) (signing a document can convey the messages in the document).<sup>3</sup> While this is the message that the government wishes to promote, it is one with which Novartis profoundly disagrees and should not be forced to parrot. Compelled speech dressed up in the form of an agreement is still compelled speech.

Nor does it matter that the Agreement contains disclaimers purportedly countering the compelled speech. *See* Gov’t Br. at 33-34 (contending that provision stating “[in] signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS’ views” sanitizes the compelled speech). As the Supreme Court has made clear time and again, 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.).

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<sup>3</sup> The government’s cited cases, neither of which involve agreements, offer it no support. *See Turner Broad. Sys. v. FCC*, 512 U.S. 622, 661-62 (1994) (reviewing a rule that required cable systems to set aside a portion of their channels for local broadcasters); *City of Dallas v. Stanglin*, 490 U.S. 19, 25-26 (1989) (reviewing city ordinance that restricted admission to certain dance halls to persons between the ages of 14 and 18).

The Third Circuit has likewise dismissed the contention that a disclaimer remedies First Amendment infringement, holding that a “general disclaimer . . . does not erase” the violation where an entity is “still compelled to speak the [government’s] message.” *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). To hold otherwise would mean the government could “infringe on anyone’s First Amendment interest at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer.” *Id.* That “idea is contrary to the First Amendment’s plain language.” *Id.*; *see also Telescope Media Grp. v. Lucero*, 936 F.3d 740, 757 (8th Cir. 2019).

Moreover, the disclaimer here—that the agreement “reflects the parties’ intention that such terms be given the meaning specified in the statute and does not reflect any party’s views regarding the colloquial meaning of those terms,” Novartis Br., Ex. E (“Agreement” Between CMS And Novartis) at 3—is no disclaimer at all. Novartis disagrees completely with the statutory language *itself*, which does not give some special meaning to the terms “negotiation” or “maximum fair price.” A disclaimer that the terms should be given their “specified” statutory “meaning” and not their “colloquial” ones thus makes no sense; the statutory meaning of those terms *is* the colloquial one. The disclaimer in no way communicates to the public that the prices are *not* truly “negotiated,” or that the manufacturer does *not* “agree” to them or believe the resulting price is the “maximum fair” one. If anything, the disclaimer

just—at best—layers more confusion onto the message that manufacturers are forced to convey, and—at worst—only reinforces it.

Indeed, one need only look to recent press releases to see that the government continues to tout the Program as a “negotiation” that prevents manufacturers from charging unfair prices—in direct conflict with the assertion in the government’s brief that manufacturers are not forced to communicate its preferred message. The government has repeatedly portrayed the process as a “negotiation” in recent public facing announcements. *See* <https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/12/14/remarks-by-president-biden-on-progress-to-lower-prescription-drug-costs/> (“In every other industry, people negotiate prices every time. But with Big Pharma, it’s been us[ed] to get[ting] its own way—no negotiation, suppressing competition instead of innovation.”); <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/> (“[T]he Administration has announced 10 prescription drugs for which Medicare will *negotiate prices directly with participating manufacturers.*” (emphasis added)). The government has likewise portrayed the prices it will set as “fair” and in contrast to reportedly “exorbitant” prices. *See* <https://www.hhs.gov/about/news/2024/02/01/biden-harris-administration-make-first-offer-drug-price-negotiation-program-launches-new-resource-hub-help-people>



-access-lower-cost-drugs.html (“Today is another milestone on the march to ensure people with Medicare get fair prices for prescription drugs. I am confident that this process will lead to lower prices, putting an end to exorbitant price gouging by pharmaceutical companies,” said HHS Secretary Xavier Becerra.”); <https://www.whitehouse.gov/briefing-room/statements-releases/2024/02/01/biden-takes-on-big-pharma-and-is-lowering-prescription-drug-prices/> (“President Biden’s drug price negotiation program finally takes on Big Pharma’s exorbitant price gouging of seniors[.]”).

In short, the government’s contention that the statute is saved by two sentences in the agreement or by manufacturers’ ability to elsewhere disclaim the forced messaging conflicts with decades of case law—and is belied by the government’s own messaging on the Program. The reality is that manufacturers have been coopted into the government’s public relations campaign, deliberately designed to characterize the Program as something that it is not, and then forced to denounce themselves to the public by falsely stating that the commercial prices they had been charging up until that point were “unfair.” That is flatly prohibited by the First Amendment.

#### **B. The Government Cannot Condition Funds On Compelled Speech**

The government also responds to Novartis’s First Amendment claim with the same “voluntariness” argument it makes with respect to the Takings claim. In the

government's telling (at 35-37), because it deems the Program "voluntary," the government is permitted to attach any speech requirement to the use of federal funds. That voluntariness argument is no more persuasive in the First Amendment context. To the contrary, the Supreme Court has made clear that the government cannot "deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit." *Agency for Int'l Dev.*, 570 U.S. at 214 (2013). In deciding whether a condition on federal funds infringes freedom of speech, "the relevant distinction" is between conditions that "define" and "specify the activities Congress wants to subsidize" and those that "seek to leverage funding to regulate speech." *Id.* at 214-15. For example, in *Agency for International Development*, the Supreme Court ruled that a requirement that federal funds may not "be used by an organization 'that does not have a policy explicitly opposing prostitution and sex trafficking'" constituted an unconstitutional condition. *Id.* at 208, 221 (quoting 22 U.S.C. § 7631(f)). The Court contrasted that situation with the circumstance in *Rust v. Sullivan*, 500 U.S. 173 (1991). *Agency for Int'l Dev.*, 570 U.S. at 217. In *Rust*, the "challenged regulations were simply 'designed to ensure that the limits of the federal program are observed,' and 'that public funds [are] spent for the purposes for which they were authorized.'" *Id.* (quoting *Rust*, 500 U.S. at 193). The limitation there defined the "program" itself. By contrast, the condition in *Agency for International Development* went "beyond

defining the limits of the federally funded program to defining the recipient” and so qualified as an unconstitutional condition. *Id.* at 218.

The same is true here. The compelled speech provisions are not necessary to define what Congress intends to fund—they are not, for example, restrictions on how government money is to be utilized or restrictions on what activities the government wants to subsidize. Instead, they seek to “leverage” the threat of exclusion from Medicare and Medicaid to force manufacturers to present the Program to the public in a manner they fundamentally disagree with. That is a condition placed “on the *recipient* of the subsidy rather than on a particular program or service.” *Rust*, 500 U.S. at 197; *see also Agency for Int’l Dev.*, 570 U.S. at 218-19.

In response, the government asserts that the conditions are permitted because they “pertain to the nature of a government program.” Gov’t Br. at 36. That contention cannot be squared with the statute or the agreement. For the reasons discussed above, *see supra* at 35-41, the compelled speech here is completely ancillary to the Program, and the Program’s forced-sale mandate would function in precisely the same way without the compelled speech. The government’s contention that the agreements are simply meant to “ensure . . . Medicare funds are ‘spent for the purposes for which they were authorized’” is thus blatantly incorrect. Gov’t Br. at 37 (quoting *Rust*, 500 U.S. at 193, 196). The compelled speech requirements have nothing to do at all with ensuring the proper use of Medicare funds. There are plenty

of other ways in which Congress could have ensured that funds are properly spent without the sham negotiation and agreement.

At bottom, the government’s counterarguments are premised on the erroneous notion that the compelled speech requirements are a necessary or inherent part of the Program. But the government disregards that, absent the compelled speech requirements, the Program would function in precisely the same way. That reality eviscerates the government’s arguments that the forced speech is merely “incidental” to the conduct requirements and that the government can impose the forced speech provisions as a condition of participation in its spending program. The Program violates the First Amendment.

### **III. THE PROGRAM’S “EXCISE TAX” IS AN EXCESSIVE FINE THAT VIOLATES THE EIGHTH AMENDMENT**

The Program imposes a crippling “excise tax”—a 1,900% tax on *all sales* of a manufacturer’s drug, regardless of whether the sales are to Medicare beneficiaries. The government cannot seriously dispute that this “tax” exists “in part to punish.” *Austin v. United States*, 509 U.S. 602, 610 (1993). And the billions of dollars in penalties it imposes are grossly disproportionate to the purported “offense”—the mere choice to decline the price dictated by CMS.

Instead of defending the excise tax on the merits, the government raises a series of jurisdictional arguments that misrepresent the statutory scheme and the nature of the penalty, and that try to rewrite the statute. These arguments fail.

**A. The Court Has Jurisdiction Over The Excessive Fines Claim**

1. The Injury Inflicted By CMS And HHS Is Redressable

The government first insists (at 37-41) that Novartis’s injury is not redressable without joining IRS and Secretary of the Treasury as defendants. But that fundamentally misconstrues Novartis’s claim, and the nature of the statutory scheme. It is CMS’s referral that acts as the statutory trigger for the imposition of the excise tax. And it is CMS and HHS that are injuring Novartis by leveraging the excise tax in their implementation of the Program. An injunction or declaratory relief against CMS and HHS would thus fully redress Novartis’s injury, and this suit appropriately targets the governmental actors that are, in fact, responsible for the unconstitutional coercion.

A party has standing to bring a claim when it is “likely, as opposed to merely speculative, that the[ir] injury will be redressed by a favorable decision.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotation marks omitted). “Redressability is not a demand for mathematical certainty.” *Toll Bros. v. Twp. of Readington*, 555 F.3d 131, 143 (3d Cir. 2009); *Massachusetts v. EPA*, 549 U.S. 497, 525 (2007) (A plaintiff “need not show that a favorable decision will relieve his every injury” for an injury to be redressable. (quoting *Larson v. Valente*, 456 U.S. 228, 244 n.15 (1982))). Redressability is satisfied as long as an injury is not caused

by “the actions of other actors alone.” *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 367 (3d Cir. 2014).

Even if Treasury and IRS are the governmental actors that would ultimately levy the excise tax, CMS’s and HHS’s decisions are a necessary part of the causal chain for the tax to be imposed. An injunction or declaratory relief in this case thus redresses Novartis’s injury because IRS and Treasury “could take no action without” CMS and HHS doing so first. *Id.*; *see also Durham v. Martin*, 905 F.3d 432, 434 (6th Cir. 2018) (“Plaintiffs suing public officials can satisfy the causation and redressability requirements of standing by demonstrating a *meaningful nexus* between the defendant and the asserted injury.” (emphasis added) (internal quotation marks omitted)).

CMS is charged under the statute with “sharing with the Secretary of the Treasury . . . such information as is *necessary* to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code.” 42 U.S.C. § 1320f-5(a)(6) (emphasis added). And the “tax” provision itself indicates that the applicability of the tax is based on various kinds of agreements with and determinations made by HHS. 26 U.S.C. § 5000D(b), (c).

Accordingly, as CMS has explained, the excise tax is triggered only when manufacturers are “referred to IRS” for their failure to sign an agreement or accept CMS’s dictated price. Revised Guidance at 91-92. And it is CMS that is responsible for monitoring “manufacturer compliance” with the “Negotiation Program”—with the application of the tax depending entirely on what determination CMS makes about a manufacturer’s compliance and what information CMS chooses to convey. *Id.* at 119. CMS is thus plainly “necessary” to the enforcement of the excise tax. Absent a referral by CMS, based on information that is only in CMS’s possession, there can be no excise tax. Accordingly, injunctive relief preventing the referral of Novartis to IRS would be “likely” to redress Novartis’s injury. *Lujan*, 504 U.S. at 561. There is simply no realistic basis to think that IRS or Treasury would or could impose the excise tax, notwithstanding an injunction prohibiting CMS from referring a manufacturer for the tax. *See Aichele*, 757 F.3d at 367; *see also id.* at 366-68 (“[T]here is room for concurrent causation.”).

The government does not even address CMS’s role in imposing the excise tax. Instead, it relies (at 40) principally on *Haaland v. Brackeen*, 599 U.S. 255 (2023), for the proposition that Novartis was required to sue IRS and Treasury. But the reasoning of *Brackeen* is not at all applicable here. In that case, the plaintiffs conceded that state courts *exclusively administered* the relevant statute and carried out its mandates, yet they sued only federal defendants that had no role in their

alleged injuries. *Id.* at 292-93. The plaintiffs argued that their injuries were redressable solely because state courts were “likely to defer to a federal court’s interpretation of federal law,” even if they were not bound by the judgment. *Id.* at 293-94. The Supreme Court rejected this argument because redressability is satisfied only when a court can “afford relief through the exercise of its power” rather than just through “the persuasive or even awe-inspiring effect of the opinion explaining the exercise of its power.” *Id.* (citation omitted).

That holding is inapplicable here because CMS has an integral role in the causal chain of enforcing the excise tax. A judgment against Defendants would therefore afford meaningful “relief through the exercise of [this Court’s] power.” *Id.* at 294.

In any event, the relevant “injury” here is not just the ultimate imposition of an excise tax, but the *threat* of that excise tax—which is too big ever to be imposed—to coerce a manufacturer’s compliance. In other words, the injury stems from the fact that *CMS* has and will continue to use the specter of the unconstitutional penalty to force Novartis to engage with the Program and, ultimately, accept the price that *CMS* demands. *See, e.g.*, Novartis Br., Ex. E at 3 (CMS agreement indicating that excise tax will be imposed for “failure to meet the requirements of the Negotiation Program, including violations of this Agreement”). Indeed, if the system works as intended, IRS and Treasury will have no role to play whatsoever—as Congress itself



acknowledged, the tax is so large that no manufacturer would ever realistically pay it. *See* Novartis Br. at 37; Vineis Decl. ¶ 33. The injury inflicted by the tax therefore is not its ultimate levy by IRS or Treasury, but its use as a cudgel by CMS. And a declaratory judgment stating that the tax represents an unconstitutional fine would redress *that* injury by preventing CMS from improperly leveraging it.

The government is thus simply wrong when it claims a declaratory judgment in this case would not “conclusively resolve[] the legal rights of the parties.” Gov’t Br. at 40 (quoting *Brackeen*, 599 U.S. at 293). A declaratory judgment properly addresses a “case or controversy” if it resolves “some dispute which *affects the behavior of the defendant towards the plaintiff.*” *Rhodes v. Stewart*, 488 U.S. 1, 4 (1988) (emphasis in original); *see ACandS, Inc. v. Aetna Cas. & Sur. Co.*, 666 F.2d 819, 823 (3d Cir. 1981) (court has jurisdiction where “[a] determination of legal obligations would strongly affect present behavior, have present consequences and resolve a present dispute”). That is the case here. A declaratory judgment would “affect [CMS’s] behavior,” *Rhodes*, 488 U.S. at 4, by forcing it to truly negotiate without relying upon the excise tax.

In any event, to the extent the Court disagrees, it has the authority to add any necessary parties under Rule 21 of the Federal Rules of Civil Procedure. Under this Rule, “the court may at any time, on just terms, add or drop a party,” Fed. R. Civ. P. 21, and this authority can be used even on appeal, or when issues have been

resolved in district court. *See Mullaney v. Anderson*, 342 U.S. 415, 417 (1952); *Sims v. State of Fla., Dep't of Highway Safety & Motor Vehicles*, 862 F.2d 1449, 1460 (11th Cir. 1989). If needed to afford Novartis relief, adding IRS and Treasury here would be appropriate given that the United States Attorney's Office for this district has already been served—which puts the federal government *as a whole* (including members of each executive agency) “on notice of the claim,” even if the plaintiff “named the wrong defendant”—and the Department of the Treasury has no doubt been consulted in this litigation. *Silbaugh v. Chao*, 942 F.3d 911, 913-14 (11th Cir. 2019) (allowing plaintiff to amend complaint to sue the Secretary of Transportation instead of members of the Federal Aviation Administration where Secretary should have been on notice of the claim); *see also Barvick v. Cisneros*, 941 F. Supp. 1015, 1017 n.2 (D. Kan. 1996) (considering complaint to include proper federal agency defendants not initially named as defendants where those additional defendants “had notice of the action” and “participated in its defense”).

2. The Anti-Injunction Act Does Not Bar The Excessive Fines Claim

The government next offers up another jurisdictional defense—that this suit is barred by the Anti-Injunction Act (AIA). The AIA generally prohibits suits brought “for the purpose of restraining the assessment or collection of any tax.” 26 U.S.C. § 7421. This is subject to two exceptions: (1) when a plaintiff will suffer irreparable injury and can establish a certainty of success on the merits, *Enochs v.*

*Williams Packing & Navigation Co.*, 370 U.S. 1 (1962), and (2) when Congress has provided no alternative remedy, *South Carolina v. Regan*, 465 U.S. 367, 374 (1984).

The government argues (at 44) that any challenge here is barred because the Excessive Fines “claim squarely targets the tax,” and so must be dismissed. But even if the government is correct that this should be considered a “tax” for AIA purposes, that would not automatically mean the AIA bars this claim. The AIA does not bar suit against anything involving a tax; rather, it only prohibits claims that seek to restrain the “*assessment or collection of* [such a] tax.” 26 U.S.C. § 7421(a) (emphasis added). As discussed above, the challenge here does not seek to restrain the “assessment or collection of” any tax that could ever realistically be paid. Rather, it seeks to restrain CMS’s use of the specter of an unconstitutional fine to coerce participation in the Program. *See* Compl. ¶¶ 123 (requesting that the court “[e]njoin Defendants from forcing Novartis . . . to ‘agree’ to prices set by the Program”); *supra* at 50-54 (describing target of declaratory relief).

As the Supreme Court has explained, the purpose of the AIA 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., LLC v. I.R.S.*, 593 U.S. 209, 212 (2021) (citation omitted); *see also id.* at 228-29 (Kavanaugh, J., concurring) (“[T]he Anti-Injunction Act is best read as directing courts to look at the stated object of a suit rather than the suit’s downstream

effects.”). But the tax here was never expected or intended to generate revenue, as Congress itself has acknowledged. It is a straightforward *penalty* that serves only a deterrent function. Because Novartis’s “claim has no implication[s] for tax assessment or collection,” the AIA “does not apply.” *Z St. v. Koskinen*, 791 F.3d 24, 30 (D.C. Cir. 2015) (internal quotation marks omitted); *cf. Bob Jones Univ. v. Simon*, 416 U.S. 725, 740 (1974) (holding challenge fell within the scope of the AIA because relevant IRS action was not “unrelated to the protection of the revenues”). Holding otherwise would create a situation ripe for abuse: Congress could, in any situation, just slap the label of a “tax” on an abusively large penalty and forever insulate it from judicial review.

None of the cases relied upon by the government (at 43-45) requires a contrary result because none involves a tax that will never realistically raise revenues and thus could not possibly implicate the concerns of the AIA. For example, in *In re Juntoff*, 76 F.4th 480 (6th Cir. 2023), the tax at issue was the *lower* of 2.5% of a taxpayer’s income or the nationwide average premium for certain health insurance plans. *Id.* at 482. That is a far cry from the penalty imposed here.

In any event, even assuming *arguendo* that this were a suit to restrain assessment or collection of a bona fide tax, the challenge here fits comfortably within the AIA’s equitable *William Packing* exception. Under *Williams Packing*, a plaintiff may obtain an injunction against enforcement of a “tax” when the plaintiff will suffer

irreparable injury and can demonstrate a “certainty of success on the merits.” *Bob Jones Univ.*, 416 U.S. at 737 (citing *Enochs*, 370 U.S. at 6-7). Here, Novartis would indisputably suffer irreparable injury by being forced to “agree” to a price dramatically below market value or by paying ruinous penalties. And, as discussed below, the government has virtually no argument on the merits of the Excessive Fines claim. *See infra* Part III.B.

The government does not contest that Novartis would face irreparable harm if it were to pay an excise tax of 1,900% on all sales (or even of just the Medicare sales that the government argues are subject to the penalty tax, contrary to the statutory terms). Nor could it since the penalty would quickly rise to a level where it would impose over \$90 billion in penalties each year, which is nearly double Novartis’s Fiscal Year 2022 net sales of \$50.5 billion. Vineis Decl. ¶ 11.<sup>4</sup> Instead, the government principally argues (at 45-46) that Novartis will not be deprived of access to judicial review because the excise tax is a “divisible tax.” Because the tax arises on each transaction, the government insists that Novartis can incur the tax on a *single* transaction, and that the government will then “exercise forbearance” while the refund suit is pending based on a policy that IRS “typically” follows. *Id.* at 46 (citing IRS Policy Statement 5-16, IRM 1.2.1.6.4(6)).

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<sup>4</sup> Even under the government’s misreading of the statute, *see infra* at 68-69, the penalty would amount to billions of dollars each year.

That does not even remotely solve the problem. Even if IRS were to, at its discretion, exercise forbearance in *collecting* the bulk of the penalty, that penalty would still be *accruing* to the order of \$90 billion each year. And it is that fact that prevents Novartis from ever being able to challenge the tax. Under the government’s theory, Novartis would essentially be forced to sell a single dose of ENTRESTO® to provide a basis to challenge the “tax” but then would need to pull the drug from the market while the challenge was pending to keep the tax from accruing. In other words, Novartis would need to pull its product off the market, leading to the same constitutional infirmities addressed earlier in the brief. This would not only cause irreparable harm to Novartis through the loss of reputation and goodwill, but devastating harm to the many patients who rely on ENTRESTO® to combat their heart disease.

This case is thus completely different from *Bob Jones*, because no manufacturer has a “full, albeit delayed opportunity to litigate” its constitutional challenges to the excise tax. 416 U.S. at 746. Instead, there will be effectively “no access at all to judicial review” of the constitutionality of the “excise tax” if the AIA is construed to bar Novartis’s claims. *Id.*

The second *Williams Packing* requirement is also met because it is “clear” that Novartis will succeed on the merits. *Id.* at 737 (quoting *Enochs*, 370 U.S. at 7). The IRA’s 1,900% penalty for the “offense” of refusing to “agree” to provide access

to the CMS-dictated price is grossly disproportionate, and the government cannot prevail on the merits in opposing the excessive fines claim. *See infra* Part III.B; *Novartis Br.* at 35-40. The government suggests (at 46-47) that the alleged novelty of an excessive fines challenge to a tax means that there is no “certainty of success on the merits.” But many “novel” laws are also clearly unconstitutional—and this is one of them. Indeed, under the government’s rationale, it will never be “clear” that a new—and therefore previously unchallenged—tax is unconstitutional, and thus any challenge to an exaction labeled a “tax” would be unable to satisfy the *Williams Packing* exception. That makes no sense. And the novelty here actually supports *Novartis*’s position on the merits: This is simply not a run-of-the-mill “tax” of the type the AIA was meant to address.

**B. The Excise Tax Imposes An Excessive Fine In Violation Of The Eighth Amendment**

On the merits of the Excessive Fines claim, the government has remarkably little to say. There can be no serious dispute that the extraordinary penalty Congress chose to enact is (1) intended, at least in part, to punish and (2) is grossly excessive to the “offense” that triggers it. It thus violates the Excessive Fines Clause.

1. The So-Called “Excise Tax” Is Punitive In Character

The “excise tax” is clearly punitive in part, which is all that is required to make it a “fine” within the meaning of the Eighth Amendment. *Austin*, 509 U.S. at 609. The Supreme Court has made clear that the purpose of the Excessive Fines

Clause was “to limit the government’s power to punish,” *id.*, and that “civil proceedings may advance punitive as well as remedial goals,” *id.* at 610 (quoting *United States v. Halper*, 490 U.S. 435, 447 (1989)).

Here, the “excise tax” is intended to punish. That much is obvious from the face of the statute—it imposes a prohibitively high rate, *and*, unlike an ordinary excise tax, it “seeks to bring Plaintiffs into compliance with the regulations.” *Stevens v. City of Columbus*, No. 2:20-cv-01230, 2021 WL 3562918, at \*4 (S.D. Ohio Aug. 12, 2021), *aff’d*, 2022 WL 2966396 (6th Cir. 2022); *see 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.”). The “excise tax” provision is titled “Designated drugs during *noncompliance periods*,” and it is expressly triggered by “*noncompliance periods*” where manufacturers fail to comply with the Program’s various demands, such as its requirement that they “negotiate” 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 v. Hennepin Cnty.*, 598 U.S. 631, 649-50 (2023) (Gorsuch, J., joined by Jackson, J., concurring).

In addition, this “excise tax” imposes an exaction of 1,900% on any drug sales above the CMS-dictated price, a penalty that would financially ruin any



manufacturer that incurred it. Veneis Decl. ¶ 33; Novartis Br. at 35-40. The label used for the penalty is immaterial, as is its civil character. The *purpose* is what counts. See *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-86 (2000) (looking at False Claims Act’s damages provision and concluding it was punitive in nature). Here, the magnitude of the excise tax and the broader statutory structure make clear that it was intended to punish and deter.

The government first tries (at 49) to avoid this conclusion by suggesting that a penalty must have either a “connection to a criminal offense or criminal proceedings” or certain “unusual features” to constitute a penalty. But it is well-settled that the constitutional prohibition on excessive fines “is not confined to exactions imposed as an aspect of the criminal law enforcement process” and “[a] 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). Indeed, 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).

Indeed, it would be perverse if the Clause only proscribed penalties on criminal acts (that are always at least to some degree wrongful), but placed no limits

on the government’s power to punish even innocent conduct via civil fines. 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. That cannot be the law.

The government makes much of the fact that the Supreme Court’s leading Excessive Fines cases arose in the context of criminal and civil forfeiture proceedings. Gov’t Br. at 48-52. But nothing in those cases suggests that the Excessive Fines Clause is *limited* to those contexts. Quite the opposite. In *Austin*, for example, the Supreme Court explained that “a civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes, is punishment, as we have come to understand the term.” 509 U.S. at 610 (citation omitted).

Indeed, the Supreme Court has expressly held in other contexts that civil penalties levied by the government can be “essentially punitive in nature” where they serve to “deter future, unlawful conduct, not to ameliorate the liability of wrongdoers.” *Vermont Agency*, 529 U.S. at 784-86 (citation omitted). And reflecting the “punitive” nature of monetary awards under the False Claims Act, four courts of appeals have uniformly held that such awards are fines for the purposes of the Excessive Fines Clause. *See Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1308 (11th Cir. 2021) (collecting cases).

For the same reason, the government is wrong (at 53) to rely on the fact that the “Supreme Court has never applied [*Austin*’s] deterrent-in-part test in the tax context.” The reasoning of that case applies with equal force regardless of whether an exaction is labeled a “tax” or not. Taxes can plainly constitute “penalties” just as much as any other exaction. *Carter*, 298 U.S. at 289 (holding that the “excise tax” at issue “is not imposed for revenue but exacted as a penalty to compel compliance”). And “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).

Moreover, the government’s own cases acknowledge that a civil tax can constitute punishment where, for example, the taxes are “excessive *in relation to their revenue-building purpose*.” *United States v. Beatty*, 147 F.3d 522, 526 (6th Cir. 1998) (emphasis added); *see also United States v. Toth*, 33 F.4th 1, 17 (1st Cir. 2022) (concluding that civil penalty at issue was not excessive because it was associated with “a fraud and loss” and “it was very difficult for law enforcement to police the use of [foreign financial] accounts” subject to the relevant reporting requirement); *United States v. Alt*, 83 F.3d 779, 782 (6th Cir. 1996) (suggesting tax could be a fine if it did not “remotely approximate the amount of money that the Government would be entitled to were it simply trying to recoup a loss”). The excise tax here is so large

that it has no revenue-building purpose whatsoever, as Congress itself acknowledged. *See* Novartis Br., Ex. I (CBO Report) at 4-5.

Similarly, the cases the government cites (at 56) for the proposition that taxes are inherently remedial do not govern here because they involve taxes that differ in critical ways from the IRA's excise tax. In *Helvering v. Mitchell*, 303 U.S. 391 (1938), the Supreme Court held that a tax penalty was remedial because it served to “reimburse the Government for the heavy expense of investigation and the loss resulting from the taxpayer’s fraud.” *Id.* at 401. Here, there is no expense of “investigation.” And the magnitude of the penalty goes far beyond any “loss” that the government might experience. *See infra* at 66-67.

The rest of the allegedly “insurmountable wall” of cases the government refers to (at 56) likewise do not hold that tax penalties are inherently remedial; rather, they simply found the *specific taxes at issue* to be remedial because they were calibrated to make the government whole. *See Dewees v. United States*, 272 F. Supp. 3d 96, 101 (D.D.C. 2017) (upholding tax “designed to mitigate the harm suffered by the Government”), *aff'd*, 767 F. App'x 4 (D.C. Cir. 2019). This just goes to show how extraordinary the IRA's excise tax is when compared to run-of-the-mill revenue-raising taxes, or even the vast majority of regulatory taxes. Here, the penalty is “preset by Congress and compulsory irrespective of the magnitude of the financial injury to the United States, if any.” *Yates*, 21 F.4th at 1308. And it is set at a high

multiple of not only the sale price, but of any conceivable “harm” to the government. *See infra* at 67; *cf. Vermont Agency*, 529 U.S. at 786 (“[t]he very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers” (citation omitted)). It is a stark outlier from any “tax” Congress has ever before imposed.

## 2. The 1,900% Fine Is Excessive

A penalty is unconstitutionally excessive if it is “grossly disproportionate” to the gravity of the offense. *United States v. Bajakajian*, 524 U.S. 321, 326, 334 (1998). The IRA imposes a tax of up to 1,900% on *every sale* of ENTRESTO® if Novartis does not agree to CMS’s dictated price. 26 U.S.C. § 5000D(a); *see also Cong. Rsch. Serv.*, No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) at 4 (Aug. 10, 2022), <https://crsreports.congress.gov/product/pdf/R/R47202>; Compl. ¶ 40. That tax will soon start to accrue at an annual rate of \$93.1 billion. Such an exaction is grossly disproportionate by any measure, and the government does not seriously contest that it would be excessive if it ever reached that magnitude.

The government also fails to meaningfully engage with the gravity of the “offense” triggering the excise tax. It concedes (at 57-58) that conduct underlying the excise tax would not normally be considered an “offense,” and does not suggest that a manufacturer declining to sign an agreement or accept a dictated price is

wrongful. Instead, the government suggests (at 59) that the punishable conduct is harmful because “the fisc will likely incur significant losses” if a manufacturer “declines to agree to a maximum fair price.” But it would be extraordinary to say that harm to the government’s fisc alone—especially a harm concededly not related to any kind of fraud or illegality—qualifies as the kind of “grave offense” that would warrant an enterprise-destroying tax. Refusing to negotiate or to agree to proposed terms for a sale is not *wrongful* at all—even if the government might benefit financially from compliance. See *Novartis Br.* at 37-38; see also, e.g., Order, *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-cv-3003, —F. Supp. 3d—, 2024 WL 489708 (D. Minn. Feb. 8, 2024) (monetary award under the False Claims Act was an excessive fine because of the relatively low “degree of moral turpitude” underlying the defendants’ conduct).<sup>5</sup> In any event, the government also fails to show that its harsh penalty has any logical relationship to the purported “significant losses” it invokes to justify the magnitude of the exaction. Gov’t Br. at 59.

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<sup>5</sup> The government does not appear to contest that this is “totally innocent conduct,” but suggests that “most taxes would be unconstitutionally disproportionate” under *Novartis’s* theory “because they are assessed following innocuous conduct like working or shopping.” Gov’t Br. at 57-58. Not so. The taxes the government appears to have in mind—like income taxes and modest excise taxes—are not remotely similar in magnitude to that imposed by the IRA and plainly not intended to punish the taxpayer. The government has not pointed to a single other “tax” that even remotely approaches the magnitude of this one.

Next, the government tries to re-write the statute to minimize the scale of the fine. Those tortured efforts are yet another sign that the government itself realizes the statute is indefensible on its own terms.

*First*, the government relies on an IRS notice regarding “forthcoming proposed regulations,” IRS Notice § 3.02, to argue that the excise tax applies “only to those drugs dispensed, furnished, or administered to Medicare beneficiaries.” Gov’t Br. at 55 n.12. But the relevant question is what the *statute* means, and the government does not even attempt to explain how this interpretation could possibly flow from the statutory language, which imposes the tax “on the sale . . . of any designated drug during” a “noncompliance period.” 26 U.S.C. § 5000D(a); *see also* Novartis Br. at 39. This is just another “convenient litigating position”—papered over by a nonbinding IRS notice—that should be rejected because it has no basis in the language of the statute. *Christopher*, 567 U.S. at 155; *see also Jennings v. Rodriguez*, 583 U.S. 281, 298 (2018) (rejecting application of constitutional avoidance canon where competing interpretation was not “plausible”).

Indeed, the government notice is flatly at odds with the statutory text. The statute specifies that the tax will be “suspen[ded]” during periods when manufacturers have exited not only Medicare, *but also Medicaid*. 26 U.S.C. § 5000D(c)(2). In other words, under the plain text of the statute, if a manufacturer exited only Medicare and not also Medicaid, the tax would not be suspended. But

under the government’s concocted-for-litigation position, there would be no tax left to “suspend” once a manufacturer exited just Medicare—and because leaving Medicare would *itself* be sufficient to avoid the tax, there would be no reason for a manufacturer to *also* have to leave Medicaid. *See* Novartis Br. at 39. That incongruity alone proves that Congress meant what it said: the excise tax applies to “all” sales, not just to sales to Medicare beneficiaries.<sup>6</sup>

*Second*, the government relies on the nonbinding IRS notice to argue that the excise tax will be presumed to be part of the amount charged for a drug, such that if (for example) a drug is sold for \$100, the manufacturer would keep the \$5 allocated to the “price” of the drug and then have to pay the government the \$95 allocated to the excise tax. *See* Gov’t Br. at 55 & n.12 (citing IRS Notice § 3.02).

But that is a total fiction. No one would seriously believe that a manufacturer has silently elected to cut their prices by 95% and the government cannot simply dictate in this context that it do so; this would raise even *great* Takings Clause issues than the ones noted above. Such a presumption is simply a transparent effort to manufacture a lower—and less flagrantly unconstitutional—tax figure than the one the statute actually calls for.

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<sup>6</sup> Further, Congress’s use of the term “suspen[ded]” confirms that even when a manufacturer exits *both* Medicare and Medicaid, there remains a tax that would apply absent such “suspension.” This just cements that the excise tax applies to “all” sales.



In any event, the presumption is incoherent, because if a manufacturer had truly slashed prices in that way, then the resulting price would surely be lower than the maximum fair price—and would, accordingly, not trigger a tax at all. The government instead wants the “price” of the drug for the purposes of whether a violation has occurred to mean one thing, but then for that “price” to mean something completely different when assessing the amount of the tax. That violates the “normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.” *Sullivan v. Strop*, 496 U.S. 478, 484 (1990) (citation and internal quotation marks omitted).

Moreover, even under the government’s incorrect understanding of the relevant “price,” the excise tax would still reach 1,900%. After all, if a manufacturer charges purchasers \$5 for a drug and pays a \$95 tax, then the tax amounts to 1,900% of the price. The government arrives at the 95% figure only by using the *sum* of the price and the tax itself as the point of reference for determining the tax rate. The government cannot have it both ways. Even if the government is correct that the excise tax is based on the \$5 “price,” then *that* number must provide the basis for the calculation of the tax rate, which is 1,900%.<sup>7</sup>

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<sup>7</sup> The government’s approach is also contrary to normal tax principles because it conflates the “tax-inclusive rate” referred to in the IRA as the “applicable percentage,” *see* 26 U.S.C. § 5000D(a), with the “tax-exclusive rate” normally used to measure taxes. *See* Tax Policy Ctr., *Tax Policy Center Briefing Book: What Is the*

The bottom line is that regardless of how the “price” is calculated for purposes of the excise tax, the tax rate is a very high multiple of price, such that the fine is excessive. If Congress had wanted to impose a remotely proportional penalty, it could have done so. Setting aside whether the failure to agree to a dictated price is an offense worthy of punishment, Congress could have recouped any “losses” by levying a fine equal to the difference between the dictated price and the drug’s sale price and applying it only to Medicare sales. Gov’t Br. at 56, 59. But it did not do so. It levied a fine that is far greater than, and bears no relation to, any alleged loss.<sup>8</sup> That is a blatantly unconstitutional penalty, and the government’s efforts to rewrite the statute in litigation only highlight that.

### CONCLUSION

For the foregoing reasons, as well as those set forth in Novartis’s opening brief, the Court should declare the Program unconstitutional and enjoin Defendants from enforcing it against Novartis.

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*Difference Between a Tax-Exclusive and Tax-Inclusive Sales Tax Rate?* (May 2020), <http://tinyurl.com/32ejney2> (“Sales tax rates are typically quoted in tax-exclusive terms.” (emphasis added)).

<sup>8</sup> For example, consider a drug initially priced at \$100, for which CMS demanded a \$60 price. If the manufacturer did not sign the final agreement and charged \$70 for the drug, Medicare would pay \$10 more for the drug than if it had paid the dictated price. But the sale would yield a \$1,330 penalty—133 times greater than the “loss.” And even applying the government’s erroneous 95% tax rate, it would yield a \$665 penalty—6.6 times greater than the “loss.”

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