

**United States Court of Appeals
for the Third Circuit**

NOVARTIS PHARMACEUTICALS CORPORATION,

Appellant,

v.

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

Appellees.

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

**REPLY BRIEF OF APPELLANT NOVARTIS
PHARMACEUTICALS CORP.**

Samir Deger-Sen
Nikita Kansra
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020

Daniel Meron
Cherish A. Drain
Graham B. Haviland
Christina R. Gay
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004-1304
Tel.: (202) 637-2200
Email: daniel.meron@lw.com

March 12, 2025

Counsel for Appellant Novartis Pharmaceuticals Corp.

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
ARGUMENT	4
I. THE PROGRAM IMPOSES AN EXCESSIVE FINE IN VIOLATION OF THE EIGHTH AMENDMENT	4
A. The Excise Tax Imposes An Excessive Fine In Violation Of The Eighth Amendment	5
B. The AIA Does Not Bar Novartis’s Challenge.....	9
C. The Injury Inflicted By CMS Is Redressable.....	14
II. THE PROGRAM VIOLATES THE FIFTH AMENDMENT’S TAKINGS CLAUSE	17
A. The Program’s Compelled Sales Take Novartis’s Property	17
B. The Government’s “Voluntary” Defense Cannot Save The Program	19
III. THE PROGRAM COMPELS SPEECH IN VIOLATION OF THE FIRST AMENDMENT	23
A. The Program’s Compelled Speech Is Not “Voluntary”	24
B. The Program Compels Speech, Not Simply Conduct.....	25
CONCLUSION.....	27

TABLE OF AUTHORITIES

Page(s)

CASES

<i>Agency for International Development v. Alliance for Open Society International, Inc.</i> , 570 U.S. 205 (2013).....	3
<i>Austin v. United States</i> , 509 U.S. 602 (1993).....	4, 6
<i>Axson-Flynn v. Johnson</i> , 356 F.3d 1277 (10th Cir. 2004)	24
<i>Barr v. American Association of Political Consultants, Inc.</i> , 591 U.S. 610 (2020).....	10
<i>Bob Jones University v. Simon</i> , 416 U.S. 725 (1974).....	11
<i>C.N. v. Ridgewood Board of Education</i> , 430 F.3d 159 (3d Cir. 2005)	24
<i>Carter v. Carter Coal Co.</i> , 298 U.S. 238 (1936).....	5
<i>CIC Services v. IRS</i> , 593 U.S. 209 (2021).....	2, 9, 10, 12
<i>Circle Schools v. Pappert</i> , 381 F.3d 172 (3d Cir. 2004)	27
<i>Constitution Party of Pennsylvania v. Aichele</i> , 757 F.3d 347 (3d Cir. 2014)	14
<i>Durham v. Martin</i> , 905 F.3d 432 (6th Cir. 2018)	14
<i>Expressions Hair Design v. Schneiderman</i> , 581 U.S. 37 (2017).....	25

	Page(s)
<i>Horne v. Department of Agriculture</i> , 576 U.S. 350 (2015).....	3, 18, 19, 20
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	14
<i>Miller v. Mitchell</i> , 598 F.3d 139 (3d Cir. 2010)	24
<i>Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare</i> , 742 F.2d 442 (8th Cir. 1984)	21
<i>Mullaney v. Anderson</i> , 342 U.S. 415 (1952).....	16, 17
<i>Northern California Small Business Assistants Inc. v. IRS</i> , 153 T.C. 65 (2019).....	7
<i>National Federation of Independent Business v. Sebelius</i> , 567 U.S. 519 (2012).....	6
<i>Pacific Gas & Electric Co. v. Public Utilities Commission of California</i> , 475 U.S. 1 (1986).....	27
<i>Ruckelshaus v. Monsanto</i> , 467 U.S. 986 (1984).....	22
<i>Southeast Arkansas Hospice, Inc. v. Burwell</i> , 815 F.3d 448 (8th Cir. 2016)	22
<i>Silbaugh v. Chao</i> , 942 F.3d 911 (11th Cir. 2019)	16
<i>Sims v. State of Florida, Department of Highway Safety & Motor Vehicles</i> , 862 F.2d 1449 (11th Cir. 1989)	16
<i>Swan v. Clinton</i> , 100 F.3d 973 (D.C. Cir. 1996).....	16, 17

	Page(s)
<i>Tahoe-Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency</i> , 535 U.S. 302 (2002).....	21
<i>Timbs v. Indiana</i> , 586 U.S. 146 (2019).....	5
<i>Toth v. United States</i> , 143 S. Ct. 552 (2023).....	6
<i>United States v. Bajakajian</i> , 524 U.S. 321 (1998).....	5, 7
<i>United States v. RR No. 1, Box 224</i> , 14 F.3d 864 (3d Cir. 1994)	7
<i>United States v. Schwarzbaum</i> , 127 F.4th 259 (11th Cir. 2025).....	5
<i>United States v. Toth</i> , 33 F.4th 1 (1st Cir. 2022).....	6
<i>Valancourt Books, LLC v. Garland</i> , 82 F.4th 1222 (D.C. Cir. 2023).....	22

STATUTES

26 U.S.C. § 5000D(a).....	8
26 U.S.C. § 5000D(c)(2).....	8
26 U.S.C. § 5000D(g)	9
26 U.S.C. § 7421(a)	2
38 U.S.C. § 8126(a)	27
42 U.S.C. § 1320f-2(a)(3)	17
42 U.S.C. § 1320f-5(a)(6).....	15
42 U.S.C. § 1320f-6(a).....	20

	Page(s)
42 U.S.C. § 1395cc	26
42 U.S.C. § 1395w-102(b).....	27
42 U.S.C. § 1396-r-8(b)	26
42 U.S.C. § 1396-r-8(c)	26

OTHER AUTHORITIES

Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47)	15
Fed. R. Civ. P. 21	16
Erin M. Hawley, <i>The Equitable Anti-Injunction Act</i> , 90 Notre Dame L. Rev. 81 (2014)	12
Erica York, Tax Foundation, <i>Lawmakers’ Tax Rate to Help Pay for Reconciliation is 1,900 Percent</i> (Aug. 31, 2021), https://taxfoundation.org/blog/hr3-tax-pay-for-reconciliation	8

INTRODUCTION

The government’s defense of the “Drug Price Negotiation Program” (the Program) relies on rewriting the statute into something it is not. The government depicts the Program as a run-of-the-mill, price-setting mechanism that does no more than “establish[] limits on the amounts that federal agencies will pay for prescription drugs.” Gov’t Br. 1. But that characterization depends on ignoring or disguising the Program’s most troubling features. The reality is that the Program threatens manufacturers with enterprise-destroying fines to coerce them into “agreeing” to transfer their drugs to third-parties at a government-dictated amount that it forces manufacturers to say is the “maximum fair price.” In a true price-setting mechanism, a manufacturer can *decline* to sell at the price the government sets. Under the IRA, by contrast, refusal results in a multi-billion-dollar fine that is unprecedented in modern legislative history.

The Eighth Amendment’s Excessive Fines Clause prohibits imposing such a devastating penalty for innocent conduct. The government hardly disputes that a fine that would effectively bankrupt a business because it refused to agree to the government’s demands is grossly disproportionate to the “offenses” that triggered it. Instead, the government focuses on jurisdiction, claiming that the Anti-Injunction Act (AIA) bars this challenge because Congress labeled these exactions “taxes.” That argument flouts the AIA’s plain text, which requires that a suit have the

“*purpose of restraining*” tax assessment or collection. 26 U.S.C. § 7421(a) (emphasis added). This lawsuit cannot have that purpose because no one—neither the government nor the manufacturer—expects any tax to ever be paid. The same amount of tax would thus be “assessed or collected” regardless of the lawsuit. The only thing that Novartis’s suit will change is that CMS will be unable to use the threat of the fine to unconstitutionally compel Novartis’s conduct. And contrary to the government’s assumption, Novartis’s Eighth Amendment challenge seeks invalidation of the entire statute, not just the fine. Under settled precedent, the AIA has no role to play in a case like this. *See CIC Services v. IRS*, 593 U.S. 209, 218-19 (2021).

The government’s contrary position has extraordinary implications. Its understanding of the AIA would allow it to shield any exorbitantly high penalty from judicial review, forever, simply by labeling it a “tax.” Congress could punish even the most innocent conduct with unpayable fines, and foreclose any judicial review by channeling lawsuits into “refund” actions that, by definition, could never occur. The Excessive Fines Clause cannot so easily be circumvented.

The Program also violates the Fifth Amendment by mandating physical transfers of Novartis’s property at below-market rates. The government principally argues that such a physical taking is lawful because Novartis has the “option” to exit the Medicare and Medicaid markets entirely. But that argument is inconsistent with

Horne v. Department of Agriculture, which makes clear that the “option” to exit a market does not legitimize a physical taking. 576 U.S. 350, 364-65 (2015). And the government again ignores the frightening consequences of its position, which would grant the government a limitless warrant to infringe on the constitutional rights of participants in federal programs. The government does not dispute, for example, that, under its rule, it could force manufacturers to turn over their manufacturing plants and raw materials so long as they receive federal funds. That is not the law.

Finally, the Program violates the First Amendment by requiring Novartis to speak about the government-set prices, including by declaring them “fair” and even the “*maximum* fair prices”—a statement which clearly conveys to the public that the prices Novartis previously charged were *unfair*. The government again responds that this compelled speech is simply a “voluntary” condition of Novartis’s participation in Medicare. But it has long been settled that the government cannot “condition” participation in a federal program on speaking the government’s message. See *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 218 (2013). Were it otherwise, the government could force students to publicly support a president’s reelection campaign simply because they receive federal student aid. And the government’s assertion that this speech is simply incidental to the conduct of making agreements is flat-out false. The Program does not need

loaded language conveying value judgments about its results in order to function. The sole purpose of this compelled speech is to mislead the public.

Ultimately, this case presents an important test of the vitality of our constitutional order. At every turn, the government pushes beyond established doctrine and claims novel authority to impose vast penalties, appropriate property, and compel speech—sometimes without any judicial review at all. Regardless of one’s view of the desirability of the Program as a policy matter, these claimed powers sweep too far. This Court should reverse the district court’s judgment.

ARGUMENT

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

The Program imposes a crippling “excise tax”—a 1,900% tax on all sales of a manufacturer’s drug, which, for Novartis, would swiftly escalate to *\$93 billion* annually. The government does not dispute that this tax serves no revenue-raising purpose. Thus, it is clear that the tax is designed at least 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 supposed “offense” of refusing the price dictated by CMS.

Rather than seriously defend the penalty on its merits, the government resorts to a series of jurisdictional arguments that misrepresent Novartis’s lawsuit and have startling implications. Indeed, the government does not dispute that its jurisdictional

arguments would allow it to shield *any* exorbitantly high penalty from judicial review altogether simply by labeling that penalty a “tax.” The AIA simply was not intended to give the government such unchecked power.

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

1. The Program’s exorbitant penalties are “fines” within the scope of the Excessive Fines Clause because they are at least “partially punitive.” *Timbs v. Indiana*, 586 U.S. 146, 154 (2019). These penalties go beyond merely “compensat[ing] [the] [g]overnment for lost revenues,” *United States v. Bajakajian*, 524 U.S. 321, 329 (1998), instead deterring behavior by “compel[ling] compliance with” the IRA’s “regulatory provisions,” *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936); *see* Novartis Br. 20-22. This deterrent purpose places the Program’s exactions squarely within the scope of the Eighth Amendment. *See United States v. Schwarzbaum*, 127 F.4th 259, 270-74 (11th Cir. 2025) (“substantial” penalties imposed by IRS to “promote compliance” with tax laws were fines).

The government does not actually dispute that these penalties aim to deter and therefore qualify as “punishment.” Instead, it argues (at 35-36) that the penalties cannot be “fines” because they “lack[] any connection to a criminal offense.” But this is the same argument the government pressed—and the Supreme Court rejected—in *Austin*. Novartis Br. 31-32. In *Austin*, the Court was emphatic: “[T]he question is not, as the United States would have it, whether [a penalty] is civil or

criminal, but rather whether it is punishment.” 509 U.S. at 610. And a fine has the hallmark of punishment when it “cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes.” *Id.* at 610-11. The government sidesteps *Austin* because its argument conflicts with it—and with numerous other binding precedents rejecting the government’s preferred civil/criminal divide. *Novartis Br. 31* (citing cases).

The government argues (at 35-36) that because those cases ultimately bore *some* connection to criminal offenses, they implicitly hold the Clause applies *only* in such circumstances. That is a non-sequitur. *Austin* and its progeny set forth a specific test—whether the penalty is intended in part to punish—that has nothing to do with whether the proceeding is connected to a criminal offense. 509 U.S. at 609-10. The government’s effort to resuscitate the argument it lost in *Austin* is baseless.¹

Like the district court, the government also fixates (at 36) on the penalty’s “tax” label—but offers no justification for why the label is constitutionally significant. Nor could it: The Supreme Court has already held that Congress cannot avoid constitutional scrutiny of a “severe financial punishment” by “describing it as” a “tax.” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012); *see N.*

¹ The lone out-of-circuit case the government cites (at 36) emphasizing a lack of connection to criminal proceedings—*United States v. Toth*, 33 F.4th 1 (1st Cir. 2022)—is unpersuasive: It relied on outdated precedents and is “difficult to reconcile with” the Supreme Court’s more recent guidance. *Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari).

Cal. Small Bus. Assistants Inc. v. IRS, 153 T.C. 65, 87-90 (2019) (Gustafson, J., concurring in part) (explaining why “income tax[es]” can qualify as “fines”).

2. As for the excessive nature of this fine, the government invents a new test. It argues (at 37) that the fine is not excessive because it “bears a close and proportional relationship to the burdens on the fisc.” That is not the standard. The test is whether the fine is “grossly disproportionate” to “the gravity of *the offense* that it is designed to punish,” *Bajakajian*, 524 U.S. at 334 (emphasis added), considering the offense’s “seriousness” and the “moral gravity” of the defendant’s behavior, *United States v. RR No. 1, Box 224*, 14 F.3d 864, 875 (3d Cir. 1994).

On these points, the government is silent. Understandably, because the IRA imposes a massive penalty for innocent conduct that normally would not be considered an “offense” at all: refusing to negotiate over or agree to terms for a sale. Novartis Br. 22. It would be extraordinary to hold that harm to the fisc alone—especially alleged harm concededly not related to any illegality—qualifies as the kind of “grave offense” warranting an enterprise-destroying penalty.

In any event, the government’s argument fails on its own terms because the government does not demonstrate how this “tax” actually has a “close and proportional relationship” to the purported burdens on the fisc. Gov’t Br. 37. If Congress truly intended to impose a penalty “proportional” to its alleged losses, it could have levied a fine equal to the difference between the dictated “maximum fair

price” and the sales price. Instead, it set a penalty that is hundreds of times more than that amount, and that applies to sales to private parties that do not harm the fisc. This penalty thus bears no relation to the government’s purported financial burden.²

Citing brand-new proposed regulations, the government tries to minimize the significance of the penalty by arguing (at 12-13, 37) that the tax is calculated on the basis of sales to Medicare, not *all* sales of the selected drug. Even if that were correct, which it is not, the fine for Novartis still would amount to approximately \$44 billion annually. JA91. So this argument does nothing to alter the fact that the tax is exorbitant. Regardless, this position flouts the statutory language, which imposes the tax on all “sale[s]”—without exception—“of any designated drug during” a “noncompliance period[.]” 26 U.S.C. § 5000D(a). And it would render broad swaths of the IRA nonsensical or superfluous—for instance, the provision “suspend[ing]” the tax when manufacturers have *exited* Medicare, *id.* § 5000D(c)(2),

² The government tries to downplay the tax’s coerciveness by suggesting (at 37) that the rate tops out at 95%, not 1900%. Setting aside the fact that a 95% tax would still be wildly excessive, this is just sleight of hand. The government is conflating the tax-*inclusive* rate (what the IRA calls the “applicable percentage,” 26 U.S.C. § 5000D(a)), with the tax-*exclusive* rate (the typical way to express excise taxes). A tax-inclusive rate calculates the tax as a percentage of total sales price *plus* the tax, while the tax-exclusive rate bases it on the pre-tax price. The tax-exclusive rate is what matters to manufacturers, as it reflects the burden of the tax relative to earnings. See Erica York, Tax Foundation, *Lawmakers’ Tax Rate to Help Pay for Reconciliation is 1,900 Percent* (Aug. 31, 2021), <https://taxfoundation.org/blog/hr3-tax-pay-for-reconciliation>. Here, everyone agrees that the tax-*exclusive* rate is 1900%. JA468, 493 (Congressional Research Service report).

as well as the exclusion for exports, *id.* § 5000D(g), given that Medicare is a domestic program. Ultimately, the fact that the government is willing to torture the statutory language to *lower* the fine that Congress imposed just underscores how indefensible the statute actually is.

B. The AIA Does Not Bar Novartis’s Challenge

The government ultimately anchors its Eighth Amendment defense in the district court’s mistaken conclusion that the AIA bars this suit. But this position conflicts with the AIA’s text and purpose, and has alarming implications.

1. The government seemingly concedes that if Congress had labeled the excise tax a “fine” or “penalty,” the AIA would not apply. But it contends that Congress’s labeling is decisive; thus, once a provision is termed a “tax,” any lawsuit seeking to enjoin that tax is barred by the AIA. This is true, the government claims, even if the fine (1) lacks any revenue-raising purpose and (2) is set so prohibitively high that it can never be paid or function as a genuine tax. That approach completely untethers the AIA from its core purpose, and means that the *more* excessive a fine is, the *less* able a court is to review it. No authority supports that senseless rule.

To the contrary, in *CIC Services v. IRS*, the Supreme Court clarified that courts must look beyond the “tax” label to the “injuries alleged”—analyzing whether the plaintiff faces an “impending or eventual tax obligation”—to determine whether a suit has the “purpose of” restraining tax collection and will “disrupt[] the flow of

revenue to the Federal Government.” 593 U.S. 209, 212, 218-19 (2021). That is because the purpose of the AIA is simply to “protect[] the Government’s ability to collect a consistent stream of revenue.” *Id.* at 212.

Here, Novartis’s alleged injury does not stem from a tax being “assessed or collected” because, with or without an injunction, no tax will ever be levied or paid. Rather, Novartis’s injury arises from CMS’s use of an exorbitantly high “tax” as a cudgel during negotiations. *Infra* at 14-15. As in *CIC Services*, the relief Novartis seeks is not against “any impending or eventual tax obligation.” 593 U.S. at 219. And like the plaintiff in *CIC Services*, Novartis “stands nowhere near the cusp of tax liability.” *Id.* at 221. All of this is evident from the “face” of Novartis’s complaint, *id.* at 218, which highlights that the “tax” was designed *never* to be collected, JA38, 56, and seeks relief against CMS’s use of the fine to coerce Novartis’s participation in the Program, *infra* at 14-15.

Importantly, Novartis seeks not only to enjoin the fine but also, as in *CIC Services*, to enjoin the enforcement of the statute *itself*. JA61, 86; *see CIC Servs.*, 593 U.S. at 219. That is because the law and the fine are inextricably linked, as the IRA functions solely *through* the threat of the fine. *See, e.g., Barr v. Am. Ass’n of Pol. Consultants, Inc.*, 591 U.S. 610, 628 (2020) (statutory provision cannot be severed when remainder of statute would not be “fully operative” as law).

Far from being “foreclosed by decades of Supreme Court precedent,” Gov’t Br. 26, Novartis’s position is firmly supported by it. The cases the government cites (at 26-28) simply confirm that an exaction with *both* regulatory *and* revenue-raising purposes can qualify as a “tax” for AIA purposes. However, these cases involved exactions that aimed, at least in part, to raise revenue—making it logical for the AIA to apply to safeguard revenue collection. *See* Petitioner Br. 27, *Bob Jones Univ. v. Shultz*, 416 U.S. 725 (1973) (No. 72-1470), 1973 WL 172321 (arguing government was “primarily”—not entirely—“interested in conformance rather than payment”).

No case has ever held that the AIA bars a suit implicating a “tax” that is not expected or intended to generate *a single penny* of revenue, which Congress acknowledged is true with the IRA’s “tax.” Novartis Br. 12. On the contrary, *Bob Jones University v. Simon* strongly suggested the outcome would have been different if “revenues w[ould] be unaffected” by the lawsuit. 416 U.S. 725, 739 n.10 (1974). That was not true in *Bob Jones* because the requested injunction—preventing the IRS from revoking a Section 501(c)(3) exemption—would have resulted in the Treasury receiving around two million dollars less in tax payments. *Id.* at 738, 746. But *Bob Jones* repeatedly emphasized that the AIA applies only to “truly revenue raising tax statutes,” *id.* at 743, and exactions “which clearly are intended to raise revenue,” *id.* at 741 n.12.

The Program’s “tax” bears no resemblance to the dual-purpose taxes the government has previously enacted, which, although steep, are payable and indeed paid. Take the federal excise tax on cigarettes, which is currently about \$1 a pack. While this tax is clearly designed to deter smoking, it simultaneously generates significant revenue for the government from people continuing to purchase cigarettes. But if instead the government were to impose a \$100 million “tax” on cigarettes, it would be evident that the intent was not to collect any revenue—and it would be unreasonable to think a challenge would fall within the scope of the AIA, and be shielded from judicial review indefinitely.

The reason is clear: the AIA’s “familiar pay-now-sue later procedure,” *CIC Servs.*, 593 U.S. at 222, makes no sense in the context of an *unpayable* fine. By definition, such fines cannot (1) raise revenue, or (2) be subject to refund actions. In such a circumstance, the AIA serves no function other than to permanently bar judicial review of an unconstitutional action. It would be startling if this little-known statutory provision, which “garnered no attention in floor debates” and was not even mentioned in the “most influential” tax treatises at the time, silently gave the government such unfettered power. Erin M. Hawley, *The Equitable Anti-Injunction Act*, 90 Notre Dame L. Rev. 81, 123 (2014).

2. In any event, this case falls within the AIA’s equitable *Williams Packing* exception, which allows for injunctions against enforcement of “taxes” when the

plaintiff will otherwise suffer “irreparable injury” and can demonstrate a “certainty of success on the merits.”” Novartis Br. 26-27.

Here, Novartis would indisputably suffer irreparable injury by being forced either to engage in speech with which it disagrees or pay ruinous penalties. *Id.* at 26-30. The government ignores essentially all of Novartis’s irreparable-harm arguments, choosing instead to focus solely on (at 30) a policy IRS “generally” follows: levying a tax on one single transaction, and then exercising forbearance on the rest while a refund suit is pending. Notably, the government does not specifically commit to that process here, nor even explain how it could work in practice. Regardless, this argument cannot save the Program because the enterprise-destroying penalty would still be *accruing* while that refund suit was pending. Novartis Br. 28-30. And, for that reason, no rational manufacturer could ever dare face financial ruin by flouting the statute (even if it could trust that the government would abide by a voluntary policy that it only half-commits to in its briefing here)

Novartis also is “certain[.]” to succeed on the merits, as this “fine” is undeniably punitive in nature and grossly disproportionate by any measure. *Supra* at 5-9. The government responds (at 30) by repeating its argument that the “tax” is not a “fine” because it “lack[s] any connection to criminal conduct.” As discussed, this civil/criminal distinction is foreclosed by decades of Supreme Court precedent—making this a clear-cut case where Novartis is unassailably correct on

the merits. *Supra* at 5-6. The government also suggests (at 30) that the mere novelty of Novartis’s challenge *alone* precludes a certainty of success. But a statute obviously can be both unprecedented and patently unlawful. Any “novelty” in this challenge arises solely from the fact that no Congress has ever tried to do something as remarkable as impose a multi-billion-dollar fine on innocent conduct.

C. The Injury Inflicted By CMS Is Redressable

The government also argues (at 31) that Novartis’s injury is not redressable without joining the IRS and Treasury as defendants. This is wrong too, as Novartis’s Excessive Fines Clause challenge targets the *entire* statute, not just the fine. Regardless, CMS plays a crucial role in developing and enforcing the “excise tax.”

A party has standing if it is “‘likely’” their injury “will be ‘redressed by a favorable decision.’” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). A plaintiff suing a public official “can satisfy the ... redressability requirement[] ... by demonstrating ‘a meaningful nexus’ between the defendant and the asserted injury.” *Durham v. Martin*, 905 F.3d 432, 434 (6th Cir. 2018). Redressability is satisfied as long as the 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) (emphasis added).

Here, Novartis’s Eighth Amendment injury is not attributable to the IRS at all, let alone solely attributable to it, because the IRS will *never* assess or collect any tax from Novartis. Rather, Novartis’s injury stems from *CMS*’s implementation of the

IRA—a statute that can function as intended only *through* the cudgel of the fine. The excessive nature of the fine renders *both* the fine *and* the statute unconstitutional. For that reason, Novartis seeks an injunction against the enforcement of the *entire* statute as violative of the Eighth Amendment, not just against the enforcement of the fine. JA86; *see* JA61. And because CMS is responsible for implementing the statute, Novartis has not sued the wrong party.

Even if Novartis were simply seeking to enjoin the fine, CMS still would be a proper defendant because it plays a “meaningful” role in the development and enforcement of any potential tax by communicating, monitoring, and referring violations. *See, e.g.*, 42 U.S.C. § 1320f-5(a)(6); JA293, 304, 391, 430-32. The statute explicitly tasks CMS with “sharing with the Secretary of the Treasury [] such information as is necessary to determine the tax imposed by section 5000D.” 42 U.S.C. § 1320f-5(a)(6). And CMS has stated in its guidance that “[m]anufacturers of selected drugs without an Agreement in place are *referred to IRS*” for imposition of the tax. JA354-55 (emphasis added).

Thus, when Novartis filed its lawsuit, it was clear that an injunction against CMS would prevent the levying of any tax because, without CMS, the IRS would lack necessary information to identify violations. This situation arguably changed when, months after Novartis filed this lawsuit, the IRS issued regulations requiring that manufacturers “self-report” tax liability. Excise Tax on Designated Drugs;

Procedural Requirements, 89 Fed. Reg. 55507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47). However, it remains doubtful, as a practical matter, that the IRS could or would impose the excise tax without CMS’s involvement, especially since CMS has maintained its role in monitoring compliance, and there would be no legal obligation for manufacturers to comply with this self-reporting scheme if the taxes were declared unconstitutional.

In any event, if the Court has any concern on this front, it can simply add the necessary parties under Rule 21 of the Federal Rules of Civil Procedure. Under this Rule, a court may “at any time, on just terms, add or drop a party,” Fed. R. Civ. P. 21, including on appeal and even when issues have been resolved in the district court. *See, e.g., Mullaney v. Anderson*, 342 U.S. 415, 416-17 (1952) (adding parties); *Sims v. State of Fla., Dep’t of Hwy. Safety & Motor Vehicles*, 862 F.2d 1449, 1460 (11th Cir. 1989) (same). Novartis raised this argument below, *see* Pl.’s Opp. to Mo. Summ. J. 54-55, Dkt. No. 57, yet the government completely ignores it in its brief.

If needed to afford Novartis relief, adding IRS and Treasury here would be appropriate given that the United States Attorney’s Office has already been served—meaning the federal government *as a whole* (including members of each executive agency) are “on notice of the claim.” *Silbaugh v. Chao*, 942 F.3d 911, 913-14 (11th Cir. 2019); *see Swan v. Clinton*, 100 F.3d 973, 980 & n.3 (D.C. Cir. 1996) (amending complaint to include proper federal-agency defendants). And the Treasury no doubt

has been consulted in this litigation. Since the new defendants are all government officers who, “if added, would be sued in their official capacity and would be represented by the Attorney General and United States Attorney as are [the existing defendants],” there is no “concern[] that they might suffer prejudice by being added as defendants at this point in the proceedings.” *Swan*, 100 F.3d at 980 n.3. To dismiss the claim for lack of standing now “and require [Novartis] to start over in the [d]istrict [c]ourt would entail needless waste and runs counter to effective judicial administration.” *Mullaney*, 342 U.S. at 417. And this situation is a paradigmatic case for applying Rule 21, because it is *post-filing* developments that would make the addition of other defendants necessary.

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

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

The Program also violates the Fifth Amendment’s Takings Clause by commanding Novartis to physically transfer ENTRESTO® products to Medicare beneficiaries at whatever price CMS dictates, under threat of severe penalties. 42 U.S.C. § 1320f-2(a)(3); *see* Novartis Br. 34-36. The government claims (at 39-41, 43) there is no *per se* taking because CMS does not physically “sen[d] trucks” to Novartis’s warehouse to “haul away” ENTRESTO® products. But the Supreme Court has held time and again that the government need not physically seize property to effect a *per se* taking; compelling an owner to transfer possession to a third party,

on pain of fines, is sufficient. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015); Novartis Br. 40.

The government also attempts to downplay (at 46-50) the Program as merely an “offer” from the government to purchase products on specific terms, akin to offers made by agencies like the Department of Defense. But unlike genuine offers from the government to buy products, the Program imposes an “access” requirement that *mandates* the transfer of products whenever a manufacturer has Medicare or Medicaid agreements in place. Novartis Br. 35. Moreover, under the Program, the government does not “offer” to purchase drugs; it acts as a sovereign, providing a subsidy to influence prices in *private* transactions. *Id.* at 41.

Next, the government (at 44-45) hints at the idea that manufacturers are not actually required to sell the selected drugs to Medicare beneficiaries, even if they remain within the Medicare or Medicaid programs. This argument featured prominently in the government’s papers below, but now receives only passing mention. For good reason: As Novartis explained, this argument cannot be reconciled with the statute’s plain text, which mandates that Novartis “shall ... provide” third parties in Medicare “access to the [maximum fair price] with respect to” ENTRESTO®. Novartis Br. 44-46. Meeting this “access” requirement would be impossible without providing “access” to ENTRESTO® through sales. The

government never once references this textual argument, and offers no response to any of Novartis’s other arguments on this point. *Id.*

In fact, elsewhere in its brief (as CMS did in its guidance), the government lists *only three* options to avoid the Program’s penalties—entirely “withdraw[ing] from Medicare and Medicaid,” “transfer[ring] [] ownership of the selected drug to another entity,” or paying the “excise tax”—omitting the single-drug, single-program withdrawal option altogether. Gov’t Br. 10-11; *see id.* at 46. This confirms it is not actually an option for manufacturers.

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

The government ultimately stakes its position on the notion that there are no limits on what it may do to participants of federal programs, because participation in such programs is voluntary. Gov’t Br. 41-42, 46-53.

But that argument cannot withstand *Horne*. In *Horne*, the Supreme Court rejected the government’s argument that the fact “growers voluntarily ch[ose] to participate in the raisin market” could insulate the raisin-reserve program from Fifth Amendment scrutiny. 576 U.S. at 365. Voluntary participation in a government program simply does not give the government carte blanche to commit constitutional violations against participants. Novartis Br. 37-39.

The government contends (at 50-51) that the unconstitutional confiscation of raisins in *Horne* differs from the Program because the only way growers could avoid

surrendering their raisins or paying a fine was by exiting the raisin market *entirely*. But that is not an accurate description of *Horne*. In *Horne*, the farmers were growers of *grapes* who had the option to orient their businesses toward a federally supported market (raisins) or other alternative markets (such as table grapes, juice, or wine). The Court rejected the notion that their ability to reorient their businesses could excuse a physical taking. 576 U.S. at 365-66. The same reasoning applies here: Suggesting that a manufacturer reorient its business away from the Medicare and Medicaid markets is no more constitutionally acceptable than suggesting farmers shift their business to wine production instead of raisins.

In any event, manufacturers like Novartis have no feasible way to prevent their drugs from being sold to Medicare beneficiaries *even if* they wished to sell exclusively to private buyers. As Novartis explained, manufacturers sell their drugs to wholesalers, who then sell the drugs to pharmacies, who then decide who receives the drug. Novartis Br. 45; JA96. Even setting aside the Program's formulary provision, if a Medicare beneficiary were willing to pay, she could obtain ENTRESTO® at the commercial price from a pharmacy—subjecting Novartis to the IRA's steep civil penalties. 42 U.S.C. § 1320f-6(a). The only way for Novartis to avoid the Program would be to stop selling ENTRESTO® *altogether*.

The government suggests (at 45 n.3) that Novartis could, perhaps, solve this problem by becoming its own wholesaler or entering into contracts with every

pharmacy to control who obtains Novartis’s drugs. But requiring that Novartis completely overhaul its business model, and the pharmaceutical supply chain, is unrealistic. This “option” is akin to the business-changing alternatives the Court rejected as insufficient in *Horne* and *Loretto*. Novartis Br. 39. And the fact that this is the only “option” the government suggests highlights that there is no real-world possibility of Novartis selling its drugs to *anyone* while avoiding the Program. Thus, even if the relevant test were whether Novartis is unable to sell its products at all, that test would be satisfied here.

Finally, the government cites (at 41-42) non-binding, outdated, and largely unreasoned cases making broad statements that participation in Medicare is voluntary. But 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. *See, e.g., Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 444-47 (8th Cir. 1984) (price cap “d[id] not involve a forced taking of property”). None involved an alleged *physical* taking of property.

That distinction is crucial. As the Supreme Court has emphasized time and again, regulatory-takings cases are not “controlling precedents” for physical-takings claims. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Plan. Agency*, 535 U.S. 302, 323 (2002). These regulatory-takings cases simply recognize that property

owners have no “reasonable expectation” that the government will purchase products at any price the plaintiff demands. *See, e.g., Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016).

Regardless, the government fails to address Novartis’s argument that any “voluntariness” argument still hinges on the taking being a *condition on* Novartis’s participation in the Medicare and Medicaid markets. Novartis Br. 42-43. The “voluntariness” cases cited by the government are best understood as applying the principle from *Ruckelshaus v. Monsanto* that the government can, under certain circumstances, validly “condition” the receipt of a governmental benefit on meeting specific requirements. 467 U.S. 986, 1007-08 (1984). However, this requires that the taking be a “condition” that is part of a “voluntary exchange.” *Id.* at 1007. Even the government seems to acknowledge (at 51) that a *per se* taking remains unlawful when “the government [i]s not offering anything in exchange.”

But here, as in *Horne*, the government is not “offering anything in exchange” for its taking. Gov’t Br. 51. Medicare will continue to cover Novartis’s drugs—even ENTRESTO®—if Novartis fails to sign agreements or provide “access” to it. Novartis Br. 43. Instead, should Novartis fail to comply, it faces a ruinous penalty while continuing to receive the same existing government “benefits.” This setup underscores that the Program’s demands are not “conditions” of receiving Medicare benefits in any legally relevant sense. *See Valancourt Books, LLC v. Garland*, 82

F.4th 1222, 1232-35 (D.C. Cir. 2023) (requirement backed by fine not “condition” subject to *Ruckelshaus*). In other words, the government’s argument is *not* that Congress may place conditions on participation in federal programs; it is that participation in federal programs permits the government to violate the constitutional rights of participants—because any such violation is consented to. No case supports that broad—and frightening—proposition.

Indeed, as with the Eighth Amendment challenge, the government entirely ignores the far-reaching implications of its arguments. The government does not dispute that, under such a rationale, it could force manufacturers to surrender their plants and raw materials without compensation, provided they had the “option” of leaving Medicare. *Novartis* Br. 3-4. Or it could force universities to publicly support the president’s reelection campaign because they accept federal funds. Those are not possibilities this Court should endorse.

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

The Program violates the First Amendment by compelling *Novartis* to convey to the public that it believes the government’s unilaterally set price is the “maximum *fair* price” and that *Novartis* “agree[d]” to it after genuine “negotiation[s].” *Novartis* Br. 46-48 (emphasis added). The government makes two arguments in response, but neither is persuasive.

A. The Program’s Compelled Speech Is Not “Voluntary”

First, the government retreats to its theory that the Program is a “voluntary” exchange and any compelled speech is simply the “associated terms” for “payment.” Gov’t Br. 54-56, 62-64. But by that logic, manufacturers could be forced to say *anything* because such speech is part of an “exchange” for participation in a federal program. The government could, as a purported condition of participation, compel manufacturers to declare that the current president “saved” the healthcare industry or was responsible for lowering drug costs. The government cannot seriously defend such a position.

And the government’s related contention (at 54-55) that manufacturers are simply “weigh[ing] the financial upside against the cost of the associated obligations” is positively Orwellian. If Novartis does not engage in this compelled speech, it must pay enterprise-destroying penalties. “‘Indirect discouragement’ ... such as ... ‘fines, injunctions[,] or taxes’” is sufficient to show compulsion. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004); see *Miller v. Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010). For this reason, the Program bears no similarity to typical government contracting, in which the contractor can walk away and face zero consequences. *Contra* Gov’t Br. 59. Nor does it resemble *C.N. v. Ridgewood Board of Education*, where the government imposed no “disincentive or penalty” if the plaintiff refused to speak. 430 F.3d 159, 189 (3d Cir. 2005).

To be sure, the government can sometimes validly “condition” receipt of federal funds on speech when those speech-mandates “set the terms of and define the scope of government programs.” Gov’t Br. 62. But the Program’s compelled-speech provisions do not “define” what Congress will fund, as Novartis’s drugs remain covered by Medicare regardless whether Novartis complies. *Supra* at 18-19. Put another way, an alternate version of the Program that sets prices *without* these agreements would result in the *exact same* government spending. Instead, these mandates seek to leverage the threat of exclusion from Medicare and Medicaid to force manufacturers to speak the government’s preferred messages.

B. The Program Compels Speech, Not Simply Conduct

Second, the government argues that the Program amounts only to a regulation of conduct because it just sets the “amount that a [manufacturer] c[an] collect” from Medicare. Gov’t Br. 55, 57-59. That is wrong, and the government’s own principal authority—*Expressions Hair Design v. Schneiderman*, 581 U.S. 37 (2017)—explains why, by underscoring the distinction between regulations that simply set price limits (lawful) and those that regulate “how sellers [] communicate their prices” (unlawful). Novartis Br. 49-50 (quoting *Expressions*, 581 U.S. at 47-48). This case falls in the latter category: The Program does not simply “regulate the amount that [Novartis] c[an] collect” for its drugs, but also requires Novartis to “communicate” *about* those prices. *Expressions*, 581 U.S. at 47-58.

Indeed, by requiring Novartis to attest that the price set through the Program is the “maximum fair price” for ENTRESTO®, the IRA forces Novartis to attest that the market prices it has charged (and continues to charge in private markets) are *unfair*. Novartis Br. 46-48. And Novartis must endorse the government’s preferred framing of the Program as involving a “negotiation” resulting in an “agreement”—even though it strongly disagrees with that characterization.³ *Id.*

While run-of-the-mill commercial contracts do not ordinarily implicate the First Amendment, Gov’t Br. 54-55, 58-59, that is because they do not require value-judgment statements about the fairness of or process behind acceptance of an offer (nor are they compelled by threat of sanctions). These features distinguish the Program from the other healthcare-program contracts cited by the government (at 54, 59), which speak only to the price at which drugs will be sold. None requires participants to communicate that the price-setting process involves a negotiation and the resulting price is “fair,” let alone the “*maximum* fair price.” *See* 42 U.S.C. § 1395cc (Medicare provider agreements); *id.* § 1396-r-8(b)-(c) (Medicaid rebate

³ The government’s attempt (at 59-60) to reframe the compelled speech as simply employing “statutory terms of art” is unconvincing. If the statute declared that the mandated “fair price” was “established by the President in his wisdom,” no one would argue that requiring manufacturers to echo such language in a government-mandated contract was consistent with the First Amendment. What matters is the real-world meaning and impact of the words used.

agreements); *id.* § 1395w-102(b) (Medicare Part D coverage); 38 U.S.C. § 8126(a) (Department of Defense, Veterans Affairs, and Coast Guard contracts).

Nor does it matter that the Agreement contains disclaimers purportedly countering the compelled speech. Gov’t Br. 61. The Supreme Court has made clear that the government cannot “require speakers to affirm in one breath that which they deny in the next.” *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.*, 475 U.S. 1, 16 (1986). And this Court has likewise dismissed the notion that a “disclaimer” remedies First Amendment violations where an entity is “still compelled to speak the [government’s] message.” *Circle Schs. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). That is fatal to the government’s disclaimer argument.

CONCLUSION

The Court should reverse the judgment below.

Dated: March 12, 2025

Samir Deger-Sen
Nikita Kansra
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020

Respectfully submitted,

s/ Daniel Meron

Daniel Meron (DC Bar #450419)
Cherish A. Drain
Graham B. Haviland
Christina R. Gay
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004-1304
Tel.: (202) 637-2200
Email: daniel.meron@lw.com

Counsel for Appellant Novartis Pharmaceuticals Corp.

COMBINED CERTIFICATIONS

I. CERTIFICATE OF BAR MEMBERSHIP

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

II. CERTIFICATE OF WORD COUNT

I hereby certify that the foregoing brief complies with the word limit in Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 6,497 words as counted using the word-count feature in Microsoft Word, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 and 14-point Times New Roman font.

III. CERTIFICATE OF IDENTICAL BRIEFS

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

IV. CERTIFICATE OF VIRUS CHECK

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

Antivirus (last updated March 12, 2025), and according to that program no virus was detected.

Dated: March 12, 2025

Respectfully submitted,

Samir Deger-Sen
Nikita Kansra
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020

s/ Daniel Meron
Daniel Meron (DC Bar #450419)
Cherish A. Drain
Graham B. Haviland
Christina R. Gay
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004-1304
Tel.: (202) 637-2200
Email: daniel.meron@lw.com

Counsel for Appellant Novartis Pharmaceuticals Corp.

CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2025, I caused a copy of the foregoing Reply Brief of Appellant Novartis Pharmaceuticals Corp. to be served by electronic means, via the Court's CM/ECF system, on all counsel registered to receive electronic notices.

s/ Daniel Meron

Daniel Meron