No. 25-902

In the Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORP.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONER

SAMIR DEGER-SEN
S.Y. JESSICA HUI
NIKITA KANSRA
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020

GREGORY G. GARRE
Counsel of Record
DANIEL MERON
CHRISTINA R. GAY
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2207
gregory.garre@lw.com

Counsel for Petitioner

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INTRODUCTION

Congress has many tools to encourage true negotiation over drug prices, but the Drug Price Negotiation Program (Program) is not one of them. What makes the Program different, and uniquely dangerous, is that Congress created an unprecedented model that it calls "negotiation," but which in reality amounts to a gun to the head. This scheme transgresses numerous constitutional limits—imposing ruinous fines, seizing property without just compensation, and forcing participants to become mouthpieces for the government's own message. That model is so unique, and so unconstitutional, that it warrants this Court's intervention before it begins to take root.

In that regard, the most notable thing about the government's response is that it does not dispute the importance of the constitutional questions presented, the regulatory overreach that embracing this unprecedented legislative model will unleash, or the alarming consequences of the decision below for the development of life-saving drugs. As the Chamber of Commerce explains, the Program will cause manufacturers to forgo development of roughly 140 drugs over the next decade—including life-saving medicines—and will eliminate tens of thousands, if not hundreds of thousands, of jobs. Chamber Amicus Br. 19; *see* Biotechnology Innovation Organization Amicus Br. 15, *Janssen Pharms., Inc. v. Kennedy*, Nos. 25-749, 25-751 (Jan. 22, 2026) (Program "poses an existential threat" to drug development).

Instead of denying importance, the government's principal response is to argue the merits. It insists that the Third Circuit correctly held that the Anti-

Injunction Act (AIA) bars all review of the Program's enterprise-destroying penalties because it is "unclear" whether the Excessive Fines Clause applies to penalties imposed on otherwise lawful conduct. But *Austin v. United States*, 509 U.S. 602 (1993), already answered that question. And the government's efforts to wave away the clear and lopsided circuit split this issue implicates are unavailing.

Nor does the government's plea for delay have any merit. The questions presented have already been thoroughly vetted in numerous lower-court decisions, and six petitions are currently pending before the Court. Granting certiorari now also would allow the pending petitions to be consolidated for briefing and argument at the beginning of next Term, a more advantageous schedule for this Court. Meantime, delaying review would inflict an extreme cost on patients, manufacturers, and the broader economy—as the Program's unique harms compound.

The petition should be granted.

ARGUMENT

I. THE DECISION BELOW UPHOLDING THE NOVEL PROGRAM CARRIES SWEEPING CONSEQUENCES THAT DEMAND REVIEW

The government argues the merits but ignores the far-reaching implications of the Third Circuit's decision upholding this unprecedented Program.

A. The Program Exacts Unconstitutional Fines From Its Coerced Participants

At the outset, the panel transformed the AIA from a channeling rule preventing delay in the payment of revenue-raising measures into a shield blocking any challenge to ruinous fines that will never raise any

revenue because they are enacted only to force entities to agree to the government's own terms. That ruling alone warrants review.

1. The government does not dispute that under its reading of the AIA—which makes Congress's use of the label "tax" dispositive—Congress could impose a trillion-dollar "tax" on the failure to recycle and thereby guarantee courts could never review its excessiveness. Pet.18. That follows directly from the panel's rule: the AIA would bar pre-enforcement review based solely on the "tax" label; the *Williams Packing* exception to the AIA would be unavailable because success on the merits is not "certain"; and no rational actor would ever incur such a staggering exaction to pursue a refund suit. *Id.* at 17-18.

The result is perverse: the more extreme the exaction, the more secure it is from any constitutional scrutiny. *Id.* at 16, 18. The government does not deny that is where its position leads. And it makes no attempt to explain how a regime that places the most excessive sanctions beyond judicial review comports with the Constitution or any sensible understanding of the AIA, much less with the "'strong presumption in favor of judicial review.'" *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 370 (2018). In embracing this position, the Third Circuit's decision is an open invitation to unchecked regulatory overreach. No decision of this Court has ever adopted such an extreme view of the AIA, and these problems alone warrant review.[1]

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[1] Each of the prior cases in which this Court applied the AIA involved a tax that would *actually be paid*—such that judicial review was delayed, not *denied*. *See National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544 (2012) (citing cases).

2. Rather than confront the stakes of the decision, the government simply declares the AIA holding correct, and the circuit conflict it implicates nonexistent. Neither assertion holds up.

As Novartis explained (at 17, 19-21), in *Williams Packing* this Court recognized that the AIA does not bar injunctions against the enforcement of "taxes" when the plaintiff will otherwise suffer "irreparable injury" and can demonstrate "certainty of success on the merits." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (citing *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 6-7 (1962)). If that exception is to mean anything, it must apply here. The government is defending a *$93.1 billion* penalty on the entirely lawful decision not to sign an agreement to hand over property. That fine is obviously excessive, and the use of ruinous financial penalties to compel speech is clear irreparable harm.

The government simply repeats (at 19-20) the panel's mistaken premise that certainty on Novartis's Eighth Amendment claim is impossible because this Court has "reserved" the question whether the Excessive Fines Clause reaches civil penalties unconnected to criminal conduct. Pet.App.15a. But this Court's precedents leave no such gap. *Austin v. United States* squarely holds that the question is "*not*" "whether [a penalty] is civil or criminal, but rather whether it is punishment." 509 U.S. 602, 609-10 (1993) (emphasis added); *see id.* at 610 ("'civil proceedings may advance punitive as well as remedial goals'"). And "punishment" is not limited by "the division between the civil and the criminal law." *Id.* at 610; *see id.* at 614 n.7 (reviewing Founding-era definitions of "fine"); Chamber Amicus Br. 8-9.

The government never grapples with *Austin*. Instead, it observes (at 20) that the Court's Excessive Fines Clause cases have involved penalties that bore some connection to criminal proceedings. But that simply reflects the unremarkable fact that governments have not, until now, attempted to impose massive punitive exactions on "otherwise lawful choices." BIO 20. Seeking to impose such penalties in the absence of any connection to criminal proceedings is *more,* not less, problematic.

The government's efforts (at 23-24) to wish away the circuit split on this important question fare no better. As Novartis explained, at least five circuits have faithfully followed *Austin* and held that the Excessive Fines Clause reaches punitive civil penalties even when they are unconnected to criminal proceedings. Pet.19-20; *see* Chamber Amicus Br. 12-13. Until now, only the First Circuit had disagreed—and its outlier position has produced a clear circuit "split" recognized by judges, scholars, and Members of this Court. Jessica L. Asbridge, *Tax Forfeitures and the Excessive Fines Muddle*, 118 Nw. U.L. Rev. Online 170, 174 (2023); *see* Pet.20-21 (discussing conflict).

In response, the government asserts (at 23) that these decisions simply "resolved statute-specific questions." Not true. Courts are divided on a fundamental point of law: whether the Excessive Fines Clause requires a criminal nexus. Pet.19-20 & n.2. As Justice Gorsuch recognized, the First Circuit's insistence that it does "clashes with the approach many other courts have taken" and is "difficult to reconcile with" precedents like *Austin*. *Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari).

The government tries (at 23) to sidestep the split by insisting it is not "presented" because this case involves the *Williams Packing* exception to the AIA, rather than the underlying merits of Novartis's Eighth Amendment claim. But *Williams Packing* turns on the merits—it asks whether the plaintiff has "certainty of success on [them]." *Bob Jones*, 416 U.S. at 737. And the Third Circuit denied relief for exactly that reason, concluding that it remains unclear—even after *Austin*—whether the Excessive Fines Clause extends to civil penalties unconnected from criminal conduct. Pet.App.15a-16a. That premise squarely implicates the divide among the circuits.[2]

This case crystallizes the need for resolution of this conflict. The panel's rule invites governments to leverage this supposed uncertainty not only to "impose exorbitant civil penalties" on otherwise lawful conduct, *Toth*, 143 S. Ct. at 553 (Gorsuch, J., dissenting)—but then to shield them from judicial scrutiny entirely with a "tax" label. That regime should not take root without this Court's sanction.

The government offers a fallback (at 20-21): that Novartis suffers no irreparable harm because it could

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[2] That split may well deepen. During oral argument last October in a pending Fifth Circuit challenge, members of the panel expressed serious concerns about the Program's constitutionality under the Eighth Amendment and the applicability of the AIA to preclude pre-enforcement review. *See, e.g.*, Oral Argument at 12:49-56, *National Infusion Ctr. Ass'n v. Kennedy* (*NICA*), No. 25-50661 (5th Cir. Oct. 7, 2025) (Judge Higginson) (noting that "the idea that you can punish something because it's not criminal" is "topsy-turvy"); *id.* at 35:04-37 (Judge Wilson) (observing that the tax is "prohibitive"). A decision in *NICA* almost certainly is near. This Court could relist this case to ensure it has the benefit of *NICA* before acting on this petition.

pay a single instance of the "divisible" tax, file a refund suit, and then the government would forbear from collecting the rest while that suit is pending. The Third Circuit did not adopt this theory—and for good reason. It rests on an IRS policy that the government admits (at 21) the agency only "generally" follows—and one the government pointedly does not commit to applying here. Regardless, even if the government temporarily forbears from *collection*, the penalties would keep *accruing*—rapidly reaching enterprise-destroying levels during the course of any refund suit. No rational manufacturer would risk such financial ruin by flouting the statute. And that coercive dilemma is what constitutes the irreparable harm: comply and endure compelled speech and transfers of property, or refuse and face existential penalties.[3]

The government is equally unpersuasive in its attempt to defend (at 14-18) the panel's conclusion that the AIA applies at all. Its argument is pure

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[3] The government tries to shrink (at 21 n.3) Novartis's exposure from $93.1 billion to roughly $3 billion. The amount is massive either way. But as Judge Hardiman explained, the $3 billion figure rests on two sleights of hand. The government first swaps in the tax-inclusive rate—which calculates the tax as a percentage of the *total* sale price including the tax—for the tax-exclusive rate, which is the "ordinary way to express an excise tax rate." Pet.App.72a n.1 (Hardiman, J., dissenting). Then it narrows the tax base to Medicare Part D sales alone—rather than all domestic sales—based on an IRS Notice that flouts the statutory language, which applies to "the sale . . . of *any* designated drug." 26 U.S.C. § 5000D(a) (emphasis added); *see National Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 495 (5th Cir. 2024); Pet.App.6a. The government's attempt to torture the statutory language to lower the fine Congress imposed just underscores how indefensible the statute actually is.

formalism: Because Novartis alleges that something Congress called a "tax" is unconstitutional, the AIA bars review. BIO 16-17. But the AIA's plain text bars only suits brought "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). And that "purpose" turns on "the substance of the suit"—"the injuries alleged" and whether the plaintiff faces an "impending or eventual tax obligation." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 218-19 (2021). Here, the government does not dispute that no tax will *ever* be "assess[ed] or collect[ed]," injunction or not. 26 U.S.C. § 7421(a); Pet.22. And that should end the analysis. As the Chamber of Commerce explains, the AIA is a channeling rule that routes disputes over actual tax liabilities into refund suits—not a device for barring judicial review altogether. Chamber Amicus Br. 3, 11.

The government answers a strawman. It emphasizes (at 18) that regulatory taxes are still taxes. Of course a "tax" can deter conduct. But the point is that the AIA presupposes a tax *that will actually be collected*. Pet.22. *CIC Services* confirms as much, directing courts to ask whether a suit would "disrupt[] the flow of revenue" before applying the AIA's bar. 593 U.S. at 212. There is no flow to disrupt here: The Congressional Budget Office projected this ruinous "tax" will raise zero revenue (because no one could ever pay such amounts). Pet.10. And while the government says (at 18) the "'[CBO] is not Congress,'" it never disputes the CBO's projection or explains how the AIA's "pay-now-sue-later" mechanism could operate when no one will ever pay.

In sum, the panel's AIA ruling cries out for review.

B. The Program Unconstitutionally Seizes Property And Compels Speech

The Court should also decide whether the Program violates the Fifth and First Amendments. Pet.22-32. The government stresses (at 23) the absence of a circuit split on those questions, but these issues are certworthy because the panel's divided decision conflicts with this Court's precedents and carries alarming and far-reaching consequences—consequences the government simply ignores.

The panel's Fifth Amendment reasoning—that because manufacturers are purportedly free to exit the government-subsidized Medicare market, any physical taking of their property is categorically immune from constitutional scrutiny—effectively suspends constitutional protections for participants in government-stabilized markets. Pet.23-24. The government does not dispute that premise. Nor does it engage Novartis's examples showing what that means in practice—the government could seize landlords' property simply because they participate in rent-assistance programs, or compel drug manufacturers to surrender their manufacturing plants so long as they have the "option" of leaving Medicare. *Id.* at 23. That cannot possibly be true.

The government offers (at 22) that the Program does not actually "'physically appropriate'" property but instead only "'alters what Medicare will offer to pay for certain drugs.'" But as Judge Hardiman explained, the statute requires manufacturers to "provide 'access'" to their drugs at below-market prices; manufacturers cannot simply refuse to sell to Medicare beneficiaries. Pet.App.92a-95a (dissenting)

(quoting 42 U.S.C. § 1320f-2(a)). That is not mere price-setting; it is a forced transfer of property.

As for the First Amendment, the government does not dispute the breadth of the panel's ruling: the government may compel speech from federal-program participants on virtually any topic, so long as the speech mandate is styled as part of the program. Pet.32. That is a positively "Orwellian" result. Pet.App.103a (Hardiman, J., dissenting). Indeed, as Novartis explained, if this were the law, the government could require banks to state that prior interest rates were "exploitative" or landlords to label past rents "unjust." Pet.30. The government offers no response—and no limiting principle. A ruling that vests the government with such unchecked power to script private speech warrants review, too.

II. THE COURT'S REVIEW IS NEEDED NOW—NOT AFTER THE PROGRAM TAKES ROOT AND ITS IRREVERSIBLE HARMS DEEPEN

On the Program's importance, the government buries its head in the sand. It does not dispute Judge Hardiman's assessment that the constitutionality of the Program is of "great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." Pet.App.110a (dissenting). It does not deny that the Program's billions of dollars of threatened exactions will fundamentally and irretrievably alter manufacturers' investment decisions. Pet.34. Nor does it contest the Chamber of Commerce's evidence that "'[e]arly-stage funding for certain [drug] products has fallen nearly 70% since the IRA was introduced'"—a decline that will translate into "'approximately 140 drugs over the next ten years'" never being developed and "'between

66,800 and 135,900 jobs'" lost. Chamber Amicus Br. 19.

These undisputed consequences are "potentially devastating to pharmaceutical companies' collective mission of tackling the world's most complex diseases"—threatening their "continued ability to invest in our economy and . . . create new technologies and products that benefit all Americans." *Id.* at 20-21; *see* Pet.35-36. The Program's constitutionality is therefore of "exceptional importance" not just to drug manufacturers, but also to "the millions of patients who will lose out on the life-changing—or even life-saving—therapies that might have been developed and brought to market, but for the Program's innovation-stunting effects." National Ass'n of Manufacturers Amicus Br. 22, 24, *Janssen Pharms., Inc. v. Kennedy*, Nos. 25-749, 25-751 (Jan. 22, 2026).

The government emphasizes (at 25) the absence of a circuit split on the Program itself. But the Third Circuit was itself divided on the Program's constitutionality, with a forceful dissent from Judge Hardiman, *see* Pet.App.67a-110a, and Fifth Circuit judges have expressed additional concerns, *supra* 6 n.2. In any event, the constitutional issues presented implicate other circuit conflicts, *see supra* 5-6, and the importance of the issues warrants certiorari even in the absence of a direct circuit conflict.

Nor is there any reason to postpone review. The lower courts have already extensively ventilated these issues. And given the "critically high stakes," delay would impose a steep and unnecessary cost: lost innovation, lost jobs, and lost therapies—costs that compound each year as the Program expands. Biotechnology Innovation Org. Amicus Br. 15, *Janssen*, Nos. 25-749, 25-751 (Jan. 22, 2026); *see*

Pet.33-35. Moreover, six cases are currently pending before this Court challenging the Program. Granting certiorari now also would allow the Court to consider these important issues at the outset of next Term, maximizing the time for a decision.

Finally, the government does not dispute that this case—and others—present a clean vehicle for addressing the constitutionality of the Program. Pet.36. Indeed, it raises no vehicle objection at all. And this case is a uniquely favorable vehicle because it also raises an Eighth Amendment challenge.

CONCLUSION

The petition should be granted.

Respectfully submitted,

SAMIR DEGER-SEN
S.Y. JESSICA HUI
NIKITA KANSRA
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020

GREGORY G. GARRE
Counsel of Record
DANIEL MERON
CHRISTINA R. GAY
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2207
gregory.garre@lw.com

Counsel for Petitioner

April 21, 2026