No. 25-902

In the Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORP., PETITIONER

v.

ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Tax Anti-Injunction Act, 26 U.S.C. 7421(a), and the tax exception to the Declaratory Judgment Act, 28 U.S.C. 2201(a), permit a district court to entertain a claim to enjoin enforcement of an excise tax before the tax has been collected.

2. Whether the government commits a physical taking when, pursuant to statute, a federal agency negotiates the price that Medicare will pay for certain prescription drugs.

3. Whether the government compels speech when participants in a government program must memorialize their decisions to participate in the program (as well as certain negotiated terms) in a contract.

ADDITIONAL RELATED PROCEEDINGS

United States District Court (D.N.J.):

Novartis Pharm. Corp. v. *Becerra*, No. 23-cv-14221 (Oct. 18, 2024)

United States Court of Appeals (3d Cir.):

Novartis Pharm. Corp. v. *HHS*, No. 24-2968 (Sept. 11, 2025)

Supreme Court of the United States:

Novartis Pharm. Corp. v. *Kennedy*, No. 25A587 (Nov. 20, 2025 and Dec. 11, 2025)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-17a) is reported at 155 F.4th 223. The opinion of the district court (Pet. App. 18a-29a) is available at 2024 WL 4524357.

JURISDICTION

The judgment of the court of appeals was entered on September 11, 2025. On November 20, Justice Alito extended the time within which to file a petition for a writ of certiorari to and including January 9, 2026. On December 11, 2025, Justice Alito further extended the time to and including January 23, 2026, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Congress created Medicare in 1965. Health Insurance for the Aged Act, Pub. L. No. 89-97, 79 Stat. 286. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. See *Becerra* v. *Empire Health Found.*, 597 U.S. 424, 428 (2022); 42 U.S.C. 1395 *et seq.* The Centers for Medicare & Medicaid Services (CMS) administers Medicare on behalf of the Secretary of Health and Human Services (HHS).

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. See Pet. App. 2a. As relevant here, Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. See *ibid.* CMS generally pays Part B providers at a rate of 106% of the average sales price for most drugs or biologicals. See 42 U.S.C. 1395w-3a(b)(1); see also *American Hosp. Ass'n* v. *Becerra*, 596 U.S. 724, 729 (2022).

Pharmaceutical manufacturers opt into participating in Medicare (and Medicaid). See 42 U.S.C. 1395cc. Their participation may also be terminated by one of two statutory procedures. If a manufacturer chooses to withdraw unilaterally, it may terminate its agreements "for any reason" after providing 11 to 23 months' notice. 42 U.S.C. 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Alternatively, CMS may terminate its agreements with a manufacturer "for a knowing and willful violation of the requirements of the agreement or other good cause shown" with only 30 days' notice. 42 U.S.C. 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i).

For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003,

when Congress enacted Medicare Part D to provide "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums" for Medicare enrollees. Pet. App. 32a (citation omitted); see 42 U.S.C. 1395w-101 *et seq.* Under Part D, CMS enters into contracts with private entities, known as "sponsors," 42 U.S.C. 1395w-112(b), and makes payments to them to provide prescription drug plans to Part D eligible individuals, see 42 U.S.C. 1395w-115. On average, the government subsidizes 74.5% of the expected cost of Part D benefits. See 42 U.S.C. 1395w-115(a).

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise becoming involved in the arrangements between drug manufacturers and insurance plans. Congress thus expressly provided that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and "may not institute a price structure for the reimbursement of covered part D drugs." *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 120 (3d Cir. 2025) (citation omitted).

The cost to the federal government of subsidizing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by those programs. See News Release, KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-KYRM. "Prescription drug expenditures" were "projected to continue rising during the" 2020s, "placing increasing fiscal pressure[ ]" on the federal budget. Office of the Assistant Sec'y for Planning & Evaluation,

HHS, *Report To Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 Report). Medicare Part D spending in particular was "projected to increase faster than any other category of health spending." S. Rep. No. 120, 116th Cong., 1st Sess. 4 (2019).

The high cost of prescription drugs and thus drug coverage also burdens Medicare beneficiaries by affecting their out-of-pocket payments and premiums. Beneficiaries generally pay 20% of their Part B prescription drug costs out of pocket after their deductible. See 42 U.S.C. 1395*l*(a)(1) and (b). And because Part B premiums are automatically set to cover 25% of aggregate Part B spending, see 2020 Report 11, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. Many Part D plans likewise require beneficiaries to pay cost-sharing amounts, *e.g.*, 42 C.F.R. 423.104(d)(2), and Part D premiums are similarly based on a plan's anticipated costs, see 42 C.F.R. 423.286.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 324, 116th Cong., 1st Sess. Pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in Medicare Part D." 2020 Report 7. By 2021, the top ten drugs by total spending accounted for 22% of spending under Part D. See Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

Those high costs are largely attributable to manufacturers' considerable latitude in dictating the prices that

Medicare pays for the most expensive drugs. Congress originally tied drug prices under Medicare Part B and Part D to the price that manufacturers charged private buyers. See 42 U.S.C. 1395w-3a(b), 1395w-111(i)(1) and (3). As a result, manufacturers of drugs with no generic competition could "effectively set[ ] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC.

Other federal agencies, including the Departments of War and Veterans Affairs, operate their drug benefit programs differently and have not been subject to skyrocketing costs. As a condition on Medicaid participation, manufacturers that wish to sell drugs to the government through these programs have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. See 38 U.S.C. 8126(a)-(h); 42 U.S.C. 1396r-8(a)(1) and (6). Consequently, manufacturers often sell drugs to these agencies for roughly half as much as they charge Medicare Part D. See Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16, 18 (Feb. 2021), https://perma.cc/YY2E-GM97.

b. In the Inflation Reduction Act of 2022 (Act), Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1833-1864 (26 U.S.C. 5000D, 42 U.S.C. 1320f to 1320f-7), Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, as the Department of War, the Department of Veterans Affairs, and other agencies have done for decades. The Negotiation Program applies only to manufacturers

that choose to participate in Medicare and Medicaid, and even then, it governs only the prices that Medicare pays for certain drugs. See CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 120-121 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance); see also 26 U.S.C. 5000D(c)(1); 42 U.S.C. 1320f-1(b) and (d). The Program does not dictate the prices paid by other buyers of those drugs.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (or 11 years, for biological products). See 42 U.S.C. 1320f-1(d) and (e). After selecting the drugs, CMS signs a Manufacturer Agreement with each manufacturer that is willing to engage in the negotiation process. See 42 U.S.C. 1320f-2.

The object of the negotiations is to reach an agreement on what the Act calls a "maximum fair price" that Medicare will pay for each selected drug. See 42 U.S.C. 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, 42 U.S.C. 1320f-3(c), and directed CMS to "aim[ ] to achieve the lowest maximum fair price" that the manufacturer will accept, 42 U.S.C. 1320f-3(b)(1). The statute requires CMS to "consider several factors during negotiations, including the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities,

FDA product approvals, sales data, and alternative treatments." *AstraZeneca*, 137 F.4th at 121 (citing 42 U.S.C. 1320f-3(e)). If negotiations prove successful, the manufacturer signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. 42 U.S.C. 1320f-3; see 42 U.S.C. 1320f-2; Revised Guidance 159. CMS must then publish the maximum fair price. See 42 U.S.C. 1320f-4(a)(1).

Congress specified that, for drugs selected for the first negotiation cycle, any negotiated prices take effect for Part D on January 1, 2026. 42 U.S.C. 1320f(b)(1) and (2).[1] To ensure that negotiated prices could be implemented by that date, Congress established interim deadlines to govern the process. 42 U.S.C. 1320f(d). And to ensure that litigation would not disrupt negotiations, Congress expressly prohibited judicial review of certain agency decisions, including the selection of drugs for negotiation and the determination of a maximum fair price. 42 U.S.C. 1320f-7.

A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is voluntary, the manufacturer can withdraw from Medicare and Medicaid, and thus not be subject to any of the Negotiation Program's requirements. See 26 U.S.C. 5000D(c); Revised Guidance 120-121. Alternatively, a manufacturer can transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare and Medicaid. See Revised Guidance 131-

[1] The prices negotiated for the first two years of the Negotiation Program apply only to drugs covered by Part D; for Medicare Part B, drug selection and negotiations occur later, and any negotiated prices will take effect in 2028. See 42 U.S.C. 1320f-1(a)(3).

132. A manufacturer that pursues neither of those options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. See 26 U.S.C. 5000D; see also *Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); IRS, Notice 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

c. In addition to the statutory requirements detailed above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first three negotiation cycles. Act § 11001(c), 136 Stat. 1854; 42 U.S.C. 1320f note. In June 2023, "[a]fter receiving more than 7,500 public comments," CMS published a revised guidance document that applies for the 2026 drug-pricing period. *AstraZeneca*, 137 F.4th at 121. Among other things, that guidance explains how CMS determines which drugs may be selected for negotiation and the procedures for participating in the negotiation process. See Revised Guidance 94-96. And that guidance provides a process for manufacturers to contest putative errors made by CMS in certain calculations. See *id.* at 128-129.

The Revised Guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. See Revised Guidance 120-121, 129-131; accord CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, at 257-260 (Sept. 30, 2025), https://perma.cc/37EL-GRUW. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare

agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. Revised Guidance 33-34. The Treasury Department and the Internal Revenue Service (IRS) issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. That interpretation took effect immediately. See *id.* at 5. The Treasury Department and the IRS have reiterated that understanding of the application of the tax in a proposed rule. See 90 Fed. Reg. at 32-34, 36.

2. In August 2023, CMS selected ten drugs with the highest Medicare expenditures for the first negotiation cycle. See 42 U.S.C. 1320f-1(a); HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The ten drugs selected accounted for more than $50 billion of gross Medicare Part D prescription drug costs between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those drugs in 2022 alone. See *HHS Selects the First Drugs for Medicare Drug Price Negotiation*, *supra*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94 (*Selected Drugs for IPAY 2026*). Each manufacturer of a selected drug executed a Manufacturer Agreement with CMS to negotiate the price of its drug, and negotiations proceeded over the spring and summer of 2024. See CMS,

Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026 (Oct. 3, 2023), https://perma.cc/3222-VPEE.

In accordance with the schedule established by Congress, CMS presented the manufacturers with initial offers. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8 (*Negotiated Prices for IPAY 2026*). The manufacturers responded with counteroffers. *Ibid.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Ibid.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Ibid.* All told, CMS reached price agreements for five of the selected drugs in connection with these meetings. CMS sent final written offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the ten selected drugs. *Ibid.* None of the ten manufacturers has withdrawn from the Negotiation Program, and the manufacturers have been responsible for effectuating the negotiated prices since January 1, 2026. *Ibid.*

3. Petitioner Novartis Pharmaceuticals manufactures pharmaceuticals, including the drug Entresto, which is used to treat heart failure. See Pet. App. 7a, 20a-21a. Entresto was one of the drugs selected for the first round of the Negotiation Program. See *Selected Drugs for IPAY 2026*, *supra*. In 2023, more than 660,000 Medicare Part D enrollees used Entresto; that year, CMS covered more than $3.4 billion in costs for that drug. *Negotiated Prices for IPAY 2026*, *supra*.

Petitioner entered into a Manufacturer Agreement and ultimately agreed to a negotiated price for Entresto with CMS. See *ibid.*

Petitioner sued in the United States District Court for the District of New Jersey to challenge the Negotiation Program. Pet. App. 20a-21a. Petitioner alleged that the Program violated the Eighth Amendment's Excessive Fines Clause, the Fifth Amendment's Takings Clause, and the First Amendment's Free Speech Clause. *Id.* at 7a, 21a. The district court denied petitioner's motion for summary judgment and granted the government's cross-motion for summary judgment. *Id.* at 18a-29a.

The district court concluded that petitioner's excessive-fines claim is barred by the Tax Anti-Injunction Act. Pet. App. 29a. The court reasoned that petitioner's suit falls within the Anti-Injunction Act's express prohibition on suits "for the purpose of restraining the assessment or collection of any tax," *id.* at 25a (quoting 26 U.S.C. 7421(a)), and rejected petitioner's argument that the *Williams Packing* exception—which requires a plaintiff to show irreparable harm and certainty of success on the merits—permitted its suit to proceed, *id.* at 26a; see *Enochs* v. *Williams Packing & Navigation Co.*, 370 U.S. 1 (1962). The district court explained that "a refund suit is an adequate remedy" to contest a "divisible tax," so any harm would not be irreparable. Pet. App. 27a; see *id.* at 27a-28a. And it explained that petitioner's novel excessive-fines challenge to a tax "lacking any connection to criminal conduct" was not certain to succeed on the merits. *Id.* at 28a; see *id.* at 28a-29a.

The district court also rejected petitioner's takings and compelled-speech arguments, relying on its earlier rulings rejecting parallel challenges from other

manufacturers. Pet. App. 22a-25a; see *Bristol Myers Squibb Co.* v. *Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024); and *Novo Nordisk Inc.* v. *Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024).

4. The court of appeals affirmed in an opinion authored by Judge Hardiman and joined by Judges Phipps and Freeman. Pet. App. 1a-17a.

The court of appeals held that petitioner had standing to challenge the excise tax, Pet. App. 8a-11a, but that the Anti-Injunction Act barred that challenge, *id.* at 11a-16a. The court explained that "the excise tax is a 'tax' within the meaning of the Anti-Injunction Act" because Congress had exercised its "wide latitude" to apply that label. *Id.* at 12a (citing *National Fed'n of Indep. Bus.* v. *Sebelius*, 567 U.S. 519, 544 (2012)). It also reasoned that "the purpose of [petitioner's] Eighth Amendment claim is to 'restrain[ ] the assessment or collection of [the] tax,'" because petitioner "sought declaratory and injunctive relief that would run against the assessment and collection of the excise tax *itself*." *Id.* at 12a-13a (quoting 26 U.S.C. 7421(a)) (second and third set of brackets in original). And the court rejected as irrelevant petitioner's argument that Congress did not intend for the excise tax to raise revenue, explaining that "the Anti-Injunction Act 'draws no distinction between regulatory and revenue-raising tax rules.'" *Id.* at 14a (quoting *CIC Servs., LLC* v. *IRS*, 593 U.S. 209, 225 (2021)).

The court of appeals further rejected petitioner's contention that its suit could proceed under the *Williams Packing* exception. Pet. App. 15a-16a. The court explained that it "need not consider whether [petitioner] would suffer irreparable injury because it

cannot demonstrate 'certainty of success on the merits,'" *id.* at 15a (citation omitted), given that this Court has "reserved the question of whether the Excessive Fines Clause applies to civil penalties imposed without any connection to criminal conduct," *ibid.*

The court of appeals also held that petitioner's takings and compelled-speech arguments failed as well, under circuit precedent. Pet. App. 16a (citing *Bristol Myers Squibb Co.* v. *HHS*, 155 F.4th 245, 254-270 (3d Cir. 2025)).

ARGUMENT

This petition presents another set of challenges to the Medicare Drug Price Negotiation Program.[2] Petitioner reasserts its contentions that the Negotiation Program threatens excessive fines in violation of the Eighth Amendment, takes its property without just compensation in violation of the Fifth Amendment, and compels its speech in violation of the First Amendment. See Pet. 15-33; see Pet. App. 2a.

Petitioner's excessive-fines claim is barred by the Tax Anti-Injunction Act and the tax exception to the Declaratory Judgment Act. And petitioner's takings and compelled-speech claims fail for the same reasons as the government explained in *Janssen* and *BMS*. See Br. in Opp. at 14-26, *Janssen Pharm., Inc.* v. *HHS*, Nos. 25-749 and 25-751 (filed Mar. 25, 2026) (*Janssen/BMS*

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[2] See *AstraZeneca Pharm. LP* v. *Kennedy*, petition for cert. pending, No. 25-348 (filed Sept. 19, 2025); *Janssen Pharm., Inc.* v. *Kennedy*, petition for cert. pending, No. 25-749 (filed Dec. 19, 2025); *Bristol Myers Squibb Co.* v. *Kennedy*, petition for cert. pending, No. 25-751 (filed Dec. 19, 2025); *Novo Nordisk Inc.* v. *Kennedy*, petition for cert. pending, No. 25-761 (filed Dec. 22, 2025); *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, petition for cert. pending, No. 25-799 (filed Jan. 5, 2026).

Br. in Opp.). The court of appeals thus correctly rejected those claims. Pet. App. 11a-17a. That decision does not conflict with any decision of this Court or of any other court of appeals. The petition should be denied.

1. The court of appeals correctly rejected petitioner's excessive-fines, takings, and compelled-speech claims.

a. ***Excessive Fines.*** Petitioner errs (Pet. 16-22) in claiming that the Anti-Injunction Act poses no barrier to its Eighth Amendment claim. As the court of appeals correctly held, "the Tax Anti-Injunction Act and the Declaratory Judgment Act preclude [the Court's] review," Pet. App. 11a, because—among other reasons—petitioner "sought declaratory and injunctive relief that would run against the assessment and collection of the excise tax *itself*," *id.* at 13a.

i. With limited exceptions, the Anti-Injunction Act bars any "suit for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. 7421(a). The Anti-Injunction Act deprives federal courts of jurisdiction over such suits. *Bob Jones Univ.* v. *Simon*, 416 U.S. 725, 749 (1974). "Because of the Anti-Injunction Act, taxes can ordinarily be challenged only after they are paid, by suing for a refund." *National Fed'n of Indep. Bus.* v. *Sebelius*, 567 U.S. 519, 543 (2012) (*NFIB*). By contrast, the Anti-Injunction Act does not preclude review of a suit that "challenges, in both its substantive allegations and its request for an injunction, a regulatory mandate"—for example, "a reporting requirement"—"separate from any tax." *CIC Servs., LLC* v. *IRS*, 593 U.S. 209, 225 (2021).

The tax exception to the Declaratory Judgment Act similarly bars courts from issuing declaratory

judgments "with respect to Federal taxes." 28 U.S.C. 2201(a). "There is no dispute * * * that the federal tax exception to the Declaratory Judgment Act is at least as broad as the Anti-Injunction Act." *Bob Jones*, 416 U.S. at 732 n.7; cf. *Jefferson Cnty.* v. *Acker*, 527 U.S. 423, 433 (1999) ("[T]here is 'little practical difference' between an injunction and anticipatory relief in the form of a declaratory judgment" against a taxing provision) (citation omitted).

ii. A claim is thus barred by the Anti-Injunction Act—and therefore by the tax exception to the Declaratory Judgment Act—if (a) the exaction at issue is a "tax" within the meaning of those statutes, and (b) the purpose of the claim is to "restrain[ ] the assessment or collection" of that tax. 26 U.S.C. 7421(a); see 28 U.S.C. 2201(a). Because both conditions are met with respect to petitioner's excise-tax claim, the court of appeals correctly held that the claim could not proceed. Pet. App. 11a-16a.

First, "the excise tax is a 'tax' within the meaning of the Anti-Injunction Act." Pet. App. 12a. In determining whether a payment qualifies as a "tax" for purposes of the Anti-Injunction Act, courts defer to the language Congress used to describe the exaction at issue. That is because the challenged statute and the "Anti-Injunction Act * * * are creatures of Congress's own creation"—thus, "[h]ow they relate to each other is up to Congress." *NFIB*, 567 U.S. at 544. As "the best evidence of Congress's intent is the statutory text," *ibid.*, Congress's decision to call something a tax—or not—is all but conclusive, see *id.* at 564 (where Congress calls something a "tax," it "intend[s] the Anti–Injunction Act to apply").

Here, statutory text and structure leave no doubt that Congress considered the excise tax to be a "tax" and thus subject to the Anti-Injunction Act. The Act's provision concerning the excise tax is codified in the Tax Code (Title 26 of the U.S. Code), see 26 U.S.C. 5000D; the tax is enforced by the IRS; and, most importantly, Congress describes the exaction as a "tax." See 26 U.S.C. 5000D(a) ("There is hereby imposed on the sale by the manufacturer * * * of any designated drug * * * a tax * * * ."); 26 U.S.C. 5000D(a)(1) (referring to "such tax"); 26 U.S.C. 5000D(a)(2) (same); 26 U.S.C. 5000D(c) ("Suspension of tax"); 26 U.S.C. 5000D(f)(2) (referring to "the tax imposed by this section"). "Because Congress labeled the exaction a 'tax,' it is a tax within the meaning of the Anti-Injunction Act." Pet. App. 12a (citing 26 U.S.C. 5000D(a), (c), and (f)(2)).

NFIB confirms that result. There, the Court considered whether the Anti-Injunction Act barred a suit challenging the payment levied on those without health insurance. *NFIB*, 567 U.S. at 543-546. The Court concluded that it did not: the Affordable Care Act "describe[d] the payment as a 'penalty,' not a 'tax,'" and "that label [was] fatal to the application of the Anti-Injunction Act." *Id.* at 564. The Court explained that it had consistently deferred to congressional labels in determining whether the Anti-Injunction Act applies—even when it ultimately disagreed with the label. See *ibid.* For instance, in *Bailey* v. *George*, 259 U.S. 16 (1922), the Court held that the Anti-Injunction Act barred a claim challenging a "tax" intended to discourage the use of child labor. *Id.* at 20. But on the same day, the Court also held that this "so-called" child labor tax was, constitutionally speaking, not a tax. *Child Labor Tax Case*, 259 U.S. 20, 38 (1922). Similarly, in

NFIB, the Court held that the Affordable Care Act individual mandate penalty was not a tax for purposes of the Anti-Injunction Act but then upheld Congress's imposition of the penalty under the taxing power. See 567 U.S. at 564, 574. The Court has "thus applied the Anti–Injunction Act to statutorily described 'taxes' even where that label was inaccurate." *Id.* at 544.

Second, "the purpose of [petitioner's] Eighth Amendment claim is to 'restrain[ ] the assessment or collection of [the] tax.'" Pet. App. 12a (quoting 26 U.S.C. 7421(a)) (second and third set of brackets in original). In addressing that question, courts "inquire not into a taxpayer's subjective motive, but into the action's objective aim." *CIC Servs.*, 593 U.S. at 217. That aim is "best assessed" by "look[ing] to the face of the taxpayer's complaint" and, "most especially * * * to the 'relief requested.'" *Id.* at 217-218 (citation omitted). If the relief requested runs against implementation or collection of the tax itself, the suit is prohibited. See *id.* at 219.

Petitioner's Eighth Amendment claim is unmistakably directed toward the excise tax itself. The claim, as stated in the complaint, is that the "[Negotiation] Program's excise tax is * * * unconstitutional under the Excessive Fines Clause of the Eighth Amendment." C.A. App. 84. As relief, petitioner asked the district court to "[d]eclare that the Program's 'excise tax' violates the Excessive Fines Clause," *id.* at 86, such that it cannot be enforced. The complaint thus explicitly asks the court to review and pass judgment upon the tax's constitutionality so as to block its enforcement. See *CIC Servs.*, 593 U.S. at 219 (explaining that a lawsuit that "target[s]" a tax is subject to the Anti-Injunction Act). Because petitioner "sought declaratory and injunctive

relief that would run against the assessment and collection of the excise tax *itself*," Pet. App. 13a, the Anti-Injunction Act bars its claim.

iii. Though petitioner suggests that the excise tax is a penalty simply "labeled a 'tax,'" Pet. 16, it does not appear to seriously dispute the court of appeals' holding that the first prong of the Anti-Injunction Act test is satisfied. Instead, petitioner argues that its suit was not actually "brought '*for the purpose of* restraining the assessment or collection of any tax.'" Pet. 21 (quoting 26 U.S.C. 7421(a)); see Pet. 21-22. In petitioner's view, its "alleged injury does not stem from a tax being 'assessed or collected' because, with or without its requested injunction, no tax will ever be levied or paid" due to the excise tax being "exorbitantly high." Pet. 22.

The court of appeals correctly rejected petitioner's "invitation to elevate the statute's supposed purpose over its plain text." Pet. App. 14a. As the court explained, this Court "has been clear that the Anti-Injunction Act 'draws no distinction between regulatory and revenue-raising tax rules.'" *Ibid.* (quoting *CIC Servs.*, 593 U.S. at 225). Petitioner's argument also confuses purposes and effects. The excise tax is still a tax even if, by petitioner's telling, a manufacturer would not engage in the conduct that would cause the harm the excise tax is designed to remedy. Cf. *United States* v. *Sanchez*, 340 U.S. 42, 44 (1950) (tax is valid "even [if it] definitely deters the activities taxed"). Moreover, petitioner's reliance (Pet. 2, 10) on a Congressional Budget Office estimate that the excise tax would raise no revenue is misplaced. "[T]he [Congressional Budget Office] is not Congress, and its reading of the statute is not tantamount to congressional intent." *Sharp* v. *United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009).

Petitioner separately argues (Pet. 17-18) that its suit can proceed under an exception to the Anti-Injunction Act that this Court recognized in *Enochs* v. *Williams Packing & Navigation Co.*, 370 U.S. 1 (1962). Under that exception, the Anti-Injunction Act does not apply (1) if the plaintiff will suffer irreparable injury, and (2) "if it is clear that under no circumstances could the Government ultimately prevail," even "under the most liberal view of the law and the facts." *Id.* at 6-7; *Bob Jones*, 416 U.S. at 737. "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Alexander* v. *Americans United, Inc.*, 416 U.S. 752, 758 (1974). The court of appeals correctly held that petitioner "cannot demonstrate 'certainty of success on the merits,'" and that failure is dispositive. Pet. App. 15a (quoting *Bob Jones*, 416 U.S. at 737). But petitioner fails to establish the irreparable-injury prong as well.

First, petitioner has fallen well short of establishing a "certainty of success on the merits." *Bob Jones*, 416 U.S. at 737. Petitioner incorrectly suggests that the "premise underlying" the court of appeals' *Williams Packing* ruling was "that this Court has 'reserved' the question whether civil penalties can qualify as 'fines.'" Pet. 19 (quoting Pet. App. 15a). Rather, as the court of appeals recognized, it is "far from certain that [petitioner] would win on the merits of its claim at the time the District Court considered" it because this Court "has reserved the question of whether the Excessive Fines Clause applies to civil penalties *imposed without any connection to criminal conduct*." Pet. App. 15a-16a (emphasis added; citing *Browning-Ferris Indus. of Vermont, Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 262-264 (1989)).

Indeed, this Court's cases applying the Excessive Fines Clause have involved a forfeiture ordered as a sanction for criminal conduct after an adjudication of guilt in a criminal proceeding, see *United States* v. *Bajakajian*, 524 U.S. 321, 325-326, 328 (1998); *Alexander* v. *United States*, 509 U.S. 544, 547-548 (1993), or a civil action brought after the property owner had already been convicted of a crime, seeking forfeiture of property used in the commission of the crime, see *Timbs* v. *Indiana*, 586 U.S. 146, 148-149 (2019); *Austin* v. *United States*, 509 U.S. 602, 604-605 (1993); see also *United States* v. *Jalaram, Inc.*, 599 F.3d 347, 354 (4th Cir. 2010) ("[T]he [Supreme] Court consistently focused on whether the forfeiture stemmed, at least in part, from the property owner's criminal culpability."); *United States* v. *Toth*, 33 F.4th 1, 16 (1st Cir. 2022) (rejecting excessive-fines challenge where "civil penalty [was] not tied to any criminal sanction"), cert. denied, 143 S. Ct. 552 (2023). The excise tax here, by contrast, lacks any connection to criminal conduct. Liability does not depend on the commission of any crime; it is instead triggered by the otherwise lawful choices of the taxpayer in connection with drug sales to Medicare.

Second, a refund suit is an adequate remedy, so petitioner cannot establish that it will suffer irreparable harm absent preemptive injunctive relief. "This is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." *Bob Jones*, 416 U.S. at 746. A manufacturer that wishes to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. See 26 U.S.C. 7422; 28 U.S.C. 1346(a)(1), 1491. And a taxpayer need only pay "the excise tax on a single transaction" before challenging the tax in court. *Rocovich* v.

United States, 933 F.2d 991, 995 (Fed. Cir. 1991); see *Flora* v. *United States*, 362 U.S. 145, 171-175 nn.37-38 (1960). While such a suit is pending, the IRS generally does not collect the remainder of the excise tax that would otherwise be due. IRS, *Internal Revenue Manual* § 1.2.1.6.4(6), 2007 WL 9790655. Manufacturers have an obvious ability to pay a single instance of the divisible excise tax; but even if it posed a hardship, that would not justify equitable relief against enforcement. See *Flora*, 362 U.S. at 175 & n.38 (applying holding to divisible excise tax).[3]

b. ***Takings Clause.*** Petitioner also errs in arguing that the Negotiation Program "effects a physical taking by requiring manufacturers to transfer their drugs to third parties at below-market, government-dictated prices." Pet. 22; see Pet. 22-27.

As explained more fully in the government's brief in opposition in *Janssen* and *BMS*, the "'essential question' in physical takings cases is 'whether the government has physically taken property for itself or someone else.'" *Janssen/BMS* Br. in Opp. at 15 (quoting

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[3] Petitioner misstates (Pet. 8, 17, 18, 28) the amount of its potential tax liability. Section 5000D imposes a tax on the amount charged by the manufacturer. The IRS considers the amount charged to include the tax unless the manufacturer indicates otherwise, consistent with a longstanding IRS regulation for calculating many manufacturer excise taxes. IRS Notice 3-4; see 26 C.F.R. 48.4216(a)-2(a). Thus, if petitioner charged $628 for Entresto, it would remit to the government between $408.20 and $596.60 and keep the balance of the payment. Petitioner's assertion that it faces $93.1 billion in tax liability is thus without basis. See *Negotiated Prices for IPAY 2026*, *supra* (even at 95% applicable percentage, petitioner's 2023 Part D sales would have resulted in payment of less than $3.26 billion in tax with more than $171 million kept by petitioner).

Cedar Point Nursery v. *Hassid*, 594 U.S. 139, 149 (2021)); see *id.* at 14-20. Here, "there is no taking" because "the Negotiation Program does not physically appropriate or otherwise compel the transfer of [petitioner's] property and [petitioner's] loss of some profitability for [its] selected drugs does not support a takings claim." *Id.* at 16. Moreover, "the Negotiation Program simply alters what Medicare will offer to pay for certain drugs," and "the financial incentives of obtaining revenue from Medicare and Medicaid participation or of avoiding the excise taxes do not render participation in the Negotiation Program involuntary." *Id.* at 16-17. The court of appeals correctly rejected petitioner's takings claim. Pet. App. 16a; *Bristol Myers Squibb*, 155 F.4th at 255-263.

c. ***Compelled Speech.*** Petitioner finally errs in contending that the Negotiation Program "directly compels speech." Pet. 27; see Pet. 27-32.

As the government explained more fully in *Janssen* and *BMS*, petitioner's compelled-speech claim "fails at the outset for similar reasons as the Takings Clause claim"—specifically "the government is not actually compelling [petitioner's] speech" because its "participation in the Negotiation Program and in ensuing contracts memorializing specific terms, like [its] participation in Medicare and Medicaid, is voluntary." *Janssen/BMS* Br. in Opp. at 20-21. Petitioner's claim "independently fail[s]" because the Program "regulates non-expressive conduct, 'with only an incidental effect on speech.'" *Id.* at 21 (quoting *Bristol Myers Squibb*, 155 F.4th at 263). The Negotiation Program's structure in requiring manufacturers who choose to participate in government programs to memorialize certain terms in an agreement is also "unremarkable," as "[h]ealthcare

providers and other entities regularly execute similar agreements with the government to memorialize their acceptance of the terms of participation across a range of federal healthcare programs." *Id.* at 22-23. The court of appeals correctly rejected petitioner's compelled-speech claim. Pet. App. 16a; *Bristol Myers Squibb*, 155 F.4th at 263-269.

2. Review is also unwarranted because the court of appeals' decision does not conflict with the decision of any other court of appeals. To the contrary, the courts of appeals have uniformly upheld the constitutionality of the Negotiation Program. See *Bristol Myers Squibb*, 155 F.4th 245; *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116 (3d Cir. 2025); *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, 150 F.4th 76 (2d Cir. 2025); *Novo Nordisk Inc.* v. *HHS*, 154 F.4th 105 (3d Cir. 2025). Petitioner rightly does not attempt to assert a conflict of authority on its takings or compelled-speech claims. It instead argues that a circuit conflict exists on whether "the Excessive Fines Clause applies to civil monetary penalties that are at least partly punitive or deterrent, even when they are not connected to criminal conduct." Pet. 19-20.

But there is no circuit split on that question. Rather, various courts of appeals have resolved statute-specific questions about mandatory payments. See, *e.g.*, Br. in Opp. at 19-20, *Toth* v. *United States*, 143 S. Ct. 552 (2023) (No. 22-177). More importantly, petitioner's alleged conflict is not presented in this petition. The relevant question for purposes of *Williams Packing* is whether petitioner has "certainty of success on the merits." *Bob Jones*, 416 U.S. at 737. The applicability of the exception does not turn on the underlying merits question, which the courts below lacked jurisdiction to reach. Said differently, even if this Court were to reverse the

judgment below, it would not resolve the merits of petitioner's Excessive Fines Clause challenge, which is not encompassed within the questions presented. Pet. i; see *Wood* v. *Allen*, 558 U.S. 290, 304 (2010) (citing Sup. Ct. R. 14.1(a)).[4]

Even if a circuit split existed on that merits question and even it were somehow implicated in this case, a conflict of authority among the courts of appeals would further weaken petitioner's effort to invoke *Williams Packing*. After all, a unanimous circuit opinion rejecting petitioner's position, see *Toth*, 33 F.4th at 16, demonstrates that the government's defense of the excise tax does not "complete[ly] lack" merit, *Shannon* v. *United States*, 521 F.2d 56, 61 (9th Cir. 1975); cf. *Morgan* v. *Swanson*, 659 F.3d 359, 372 (5th Cir. 2011) (opinion of Benavides, J.) ("when the federal circuit courts are split on the issue," the law is not clearly established for purposes of qualified immunity).

3. Petitioner stresses the importance of the questions presented, relying on the size of the government programs at issue, as well as the purported "profound and irreparable harm on regulated entities." Pet. 33; see Pet. 32-37. But as explained elsewhere, petitioner's "parade of horribles misapprehends the nature of" the Negotiation Program. *Janssen/BMS* Br. in Opp. at 32. And "whatever harms exist for drug manufacturers pale in comparison to the problems for everyday Americans' out-of-pocket prices that Congress designed the Negotiation Program to address." *Id.* at 33.

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[4] Because this case does not implicate the underlying merits of the Excessive Fines issue, this Court need not hold this petition pending the Court's decision in *Pung* v. *Isabella*, No. 25-95 (filed July 22, 2025). See Pet. 21 n.3.

Petitioner's additional stated concerns do not support this Court's review.

4. The Court's review of the questions presented at this time would be premature. Courts have thus far unanimously rejected constitutional challenges to the Negotiation Program. See p. 23, *supra*. Further percolation is warranted because two other courts of appeals are poised to consider challenges to the Negotiation Program, including one case concerning the same Anti-Injunction Act issue implicated here. See *National Infusion Ctr. Ass'n* v. *Kennedy*, 798 F. Supp. 3d 748, 765-769 (W.D. Tex. 2025), appeal pending, No. 25-50661 (5th Cir. argued Oct. 7, 2025); see also *Teva Pharm., USA, Inc.* v. *Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), appeal pending, No. 25-5425 (D.C. Cir. oral argument scheduled for May 5, 2026). If those courts of appeals were to deem the Negotiation Program unconstitutional, this Court could consider addressing those cases at a later juncture. And if the government continues to prevail across courts of appeals, there will continue to be no need for this Court's intervention.

At a minimum, the Court may wish to consider all pending petitions regarding the constitutionality of the Negotiation Program together, when they are fully briefed. See *AstraZeneca Pharm. LP* v. *Kennedy*, petition for cert. pending, No. 25-348 (filed Sept. 19, 2025); *Janssen Pharm., Inc.* v. *Kennedy*, petition for cert. pending, No. 25-749 (filed Dec. 19, 2025); *Bristol Myers Squibb Co.* v. *Kennedy*, petition for cert. pending, No. 25-751 (filed Dec. 19, 2025); *Novo Nordisk* v. *Kennedy*, No. 25-761 (filed Dec. 22, 2025); *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, petition for cert. pending, No. 25-799 (filed Jan. 5, 2026).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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APRIL 2026