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

BRIEF OF CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTERESTS OF *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Chamber's members have a strong interest in this case, which involves fundamental constitutional challenges to the Drug Price Negotiation Program (the Program) adopted as part of the Inflation Reduction Act (IRA). The Program is deeply flawed on several constitutional grounds, including but not limited to the Eighth Amendment. The Program uses the threat of breathtaking civil penalties and debarment to coerce private businesses to sell commercial goods to third parties at below-market prices set by agency bureaucrats. Government programs like that are rare in our history for a reason: they are dangerous to free markets and sound business enterprise. When threats like this emerge, the Chamber's consistent position is that close constitutional scrutiny from this Court is imperative.

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[1] No counsel for any party authored this brief in whole or in part. No entity or person, other than *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The parties were given timely notice of *amicus curiae*'s intent to file this brief.

SUMMARY OF ARGUMENT

This case, like others challenging the same Program, presents a profoundly important constitutional challenge to a convention-shattering federal statute.

The Inflation Reduction Act requires pharmaceutical companies to sell their most valuable products to Medicare beneficiaries at below-market prices set by the Government, or else face an astronomical daily "excise tax" on all sales of the product. These fines can rise to *nineteen times* the manufacturer's total nationwide revenue from the sale of the relevant drug—for Novartis, as much as $93.1 billion annually. Pet. i.

The only alternative to these forced sales or ruinous penalties is for a pharmaceutical company to stop selling *all* of its drugs to Medicare *and* Medicaid beneficiaries—which together make up roughly half of the national pharmaceutical market. No company could afford to do that. And if any could, the withdrawal of that company's products from the two largest government health insurance programs would be disastrous for the most vulnerable patients. Congress knew all of this going in, and it would not take the risk that any manufacturer would walk away.

So the IRA uses an iron triangle to lock manufacturers into the Program. The first side is built from the Government's power to establish and fund healthcare programs that by design have absorbed much of the marketplace for pharmaceuticals. The second is made from the Government's power to exclude individual manufacturers from that government-run swath of the marketplace. And the third is built from the Government's power to impose massive civil penalties for nonparticipation.

As Novartis persuasively explains in its Petition, the extreme penalties imposed by this law—the third side

of that iron triangle—violate the Excessive Fines Clause of the Eighth Amendment.[2] Erroneously, the Third Circuit refused to even address the merits of Novartis's Eighth Amendment challenge. It concluded that because Congress had labeled its nearly 12-figure penalty threat a "tax," the IRA's scheme of fines is insulated from judicial review under the Anti-Injunction Act (AIA). Subject to a series of exceptions, that law generally bars preemptive suits brought "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). Its purpose is not to preclude litigation, but to channel it. The upshot of that channeling function is generally to postpone taxpayer suits until after the tax has been paid. But here, Congress's expectation, as explained by the Congressional Budget Office and as further confirmed by a commonsense understanding of the implications of the scheme that Congress enacted, was that the IRA's "excise taxes" would raise *zero* revenue—because these penalties are so high that they cannot realistically be paid. The real purpose of the "excise tax" is to force manufacturers' "[]compliance" with the Program, which requires submitting to government-mandated prices. 26 U.S.C. § 5000D. And the real purpose of Novartis's suit is to challenge that coercive regime, not any "tax."

Further, far from supporting the AIA's channeling function, the upshot of the Third Circuit's position is to preclude judicial review of Novartis's constitutional claim altogether—contrary to the hard-worn understanding that the courts are open to hear constitutional claims even when the Congress has generally abrogated judicial review of a particular subject. See,

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[2] As Novartis's counsel explains, review from this Court is warranted as to all three of the questions presented in Novartis's petition for certiorari. In this brief, however, the Chamber focuses on the first question presented.

e.g., *Webster* v. *Doe*, 486 U.S. 592 (1988). That is true because the IRA's taxes, by design, are unpayable. No going concern could afford to pay a tax 19 times its annual revenue in one go, as Novartis would have to do on the Third Circuit's understanding. And it is inimical to liberty to suggest that such a back-breaking payment should be necessary to obtain Article III review of a substantial constitutional claim.

Compounding its error, the Third Circuit signaled that, if it had reached the merits, it would have held that the IRA's penalties escape Eighth Amendment scrutiny because they are civil, not criminal. But this Court indicated decades ago that fines that serve to punish—whether civil or criminal—are subject to the Excessive Fines Clause. See *Austin* v. *United States*, 509 U.S. 602 (1993). Several courts of appeals have faithfully followed *Austin*. The Third Circuit and one other have now strayed from it, giving the Government permission to enact coercive schemes like the IRA while seeking to insulate those schemes' fines from judicial review.

Now is the right time for this Court to intervene. The constitutional questions raised by the Program are obviously and critically important. And so is the IRA itself. Before that law, Congress had for decades mandated market-based pricing for Medicare-covered prescription drugs. That free-market model helped fuel pharmaceutical manufacturers' investments in the discovery of novel and life-saving therapies. In replacing that model with forced sales at government-dictated "maximum fair prices" that are anything but maximum or fair, the IRA threatens the U.S. pharmaceutical sector's position as the world's leader in developing innovative medicines.

It is therefore no surprise that nearly every one of the manufacturers whose drugs were subjected to the

Program for the first year of price mandates (beginning just a few weeks ago, on January 1, 2026), brought constitutional challenges to the IRA regime. A number of those challenges are now before the Court or scheduled to arrive soon.[3] There is a real risk that, if these decisions are not reviewed by this Court now, the statutory regime will take root, and will do irremediable damage to investment in research and development in the U.S. pharmaceutical sector.

And the threat goes far beyond one industry. If the Court does not step in, legislatures and executive-branch officials will doubtless begin to explore other areas where they can use their coercive powers to compel businesses to sell goods and services to private parties at below-market rates.

The Court should grant review of one or more of the petitions presently before it that seek review of the Program's numerous constitutional infirmities. And upon doing so, the Court should reverse.

ARGUMENT

I. THE INFLATION REDUCTION ACT'S DRUG PRICE "NEGOTIATION" PROGRAM IMPOSES AN EXCESSIVE FINE IN VIOLATION OF THE EIGHTH AMENDMENT.

Participation in the Program is coerced by the threat of crushing fines. If a manufacturer refuses to sign an "agreement" to sell a Program-eligible product to

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[3] The Chamber joined other chambers of commerce in separate litigation that raised constitutional challenges to the Program. See *Dayton Area Chamber of Com.* v. *Kennedy*, No. 24-cv-3868 (6th Cir.). That case, which presented a somewhat different set of claims and issues than those raised in this case, was dismissed by the district court, and the dismissal was affirmed by the Sixth Circuit, on standing and venue grounds, without reaching the merits.

Medicare beneficiaries at the government-mandated price, the manufacturer must pay a daily penalty. See 42 U.S.C. § 1320f-2(a); 26 U.S.C. § 5000D(a)–(b). That penalty starts at 186 percent of the selected drug's price and rises to 1,900 percent, such that the fine for each sale of a $100 drug would be $1,900. 26 U.S.C. § 5000D(a)–(b), (d); Anthony A. Cilluffo et al., Cong. Rsch. Serv., No. R47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 29 (2022). The penalty takes effect the day after the manufacturer fails to sign the "agreement" and continues to accrue daily until the manufacturer complies with the statute's requirements. 26 U.S.C. § 5000D(b)(1)(A), (b)(2)(A). Manufacturers who commit to "negotiate" or who "agree to" a price will also face civil monetary penalties if they do not provide access to a price that is equal to or less than the "maximum fair price" to "eligible individuals," to "pharmacies, mail order services, and other dispensers," with respect to such individuals, and to "hospital[s], physician[s], or other provider[s] of services or supplier[s]," also with respect to such individuals. 42 U.S.C. § 1320f-6(a).

These penalties are so high that they are unpayable, and Congress knew as much. For Novartis, the penalty for not reaching an agreement to "negotiat[e]" over the "maximum fair price" for its selected drug, ENTRESTO®, would escalate to an annual amount of $93.1 billion. C.A. App. 91–92. That is nearly double Novartis's entire annual net revenue worldwide. *Ibid.* Recognizing that no manufacturer could afford to pay such a "tax," the CBO projected that the IRA's "excise taxes" would not raise even one penny of revenue. Cong. Budget Off., *Cost Estimate, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14*, at 4–5 (Sept. 7, 2022), https://tinyurl.com/23ffrtrv.

A. The Program's Fines Violate The Eighth Amendment.

1. The Eighth Amendment prohibits "fine[s]" that are "grossly disproportional to the gravity of [the] offense." *United States* v. *Bajakajian*, 524 U.S. 321, 334 (1998); see U.S. Const. amend. VIII. By any reasonable measure, the Program's "excise tax" is a "grossly disproportional" "fine" within the meaning of that Clause.

First, the Program imposes a "fine." For Eighth Amendment purposes, a monetary exaction is a "fin[e]" if it "serv[es] in part to punish." *Austin*, 509 U.S. at 610. A scheme whose goal is "[d]eterrence" punishes. See *Bajakajian*, 524 U.S. at 327–29 ("Deterrence . . . has traditionally been viewed as a goal of punishment."). By contrast, an assessment that "compensates [the] Government for lost revenues" is "remedial" and falls outside the Clause. *Id.*

The Program's "excise tax" is clearly intended to deter and punish, *not* to raise revenue. The "tax" applies only during statutorily defined "noncompliance periods"—that is, periods when manufacturers have not complied with the Program's mandates, including to "negotiat[e]" and "agree[]" to the Government's "maximum fair price." 26 U.S.C. § 5000D. "Economic penalties imposed to deter willful noncompliance with the law are fines by any other name." *Tyler* v. *Hennepin Cnty.,* 598 U.S. 631, 649–50 (2023) (Gorsuch, J., concurring); see also *United States* v. *Schwarzbaum*, 127 F.4th 259, 270–74 (11th Cir. 2025) (holding that "substantial" penalties imposed to "promote compliance" were fines). The unpayable nature of the IRA's "tax"—further confirmed by the CBO's conclusion that it will raise no revenue—makes clear that the "tax's" purpose is not revenue-raising but instead the deterrence of noncompliance (in other words, coercion through a

scheme of punishments). See *Carter* v. *Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("It is very clear that the 'excise tax' is not imposed for revenue but exacted as a penalty to compel compliance with the regulatory provisions of the act."); *Hill* v. *Wallace*, 259 U.S. 44, 66 (1922) (striking down statute where "[t]he manifest purpose of the tax is to compel Boards of Trade to comply with regulations").

Second, the Program's "fine" is obviously disproportionate to the "gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. The penalty is astronomical, yet it is triggered by a manufacturer's refusal to engage in a coerced Government "negotiation" or to accept the Government's coerced price. Refusals of this kind do not amount to wrongful conduct at all. To the contrary, it is broadly the right of citizens and enterprises in a free society to stand aside and allow the Government to do business with someone else.

2. Without engaging any of these arguments, the Third Circuit nevertheless deemed it "far from certain that Novartis" could prevail "on the merits of its claim." Pet. App. 15a–16a. In the Third Circuit's view, this Court "has reserved the question of whether the Excessive Fines Clause applies to civil penalties imposed without any connection to criminal conduct." *Ibid*. That is mistaken. In *Austin*, the Government argued that the Excessive Fines Clause reaches only sanctions that look like "criminal" punishments. *Austin*, 509 U.S. at 607. This Court rejected that framing, holding the question is "not, as the United States would have it, whether [a penalty] is civil or criminal, but rather whether it is punishment." *Id.* at 610. That rule applies here. Because the "excise tax" is "essentially punitive in nature," *Vermont Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784 (2000), the Clause applies to invalidate the Program's

excessive penalties – and the "agreements" that those penalties coerce.

B. The Anti-Injunction Act Does Not Strip The Courts Of Jurisdiction To Review This Challenge To The Program.

Aside from this passing remark, the Third Circuit dodged the merits of Novartis's Excessive Fines Clause challenge. The court concluded that the AIA stripped the federal courts of jurisdiction to hear that challenge and thus insulated the IRA's enforcement mechanism from constitutional scrutiny. But the AIA does not apply here.

1. The AIA prohibits pre-enforcement "suit[s] for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). Restraining the assessment or collection of a tax is not what Novartis's suit seeks.

To begin, the IRA's penalties are not a tax at all, much less a "tax" within the text of the AIA. A "tax" is a "charge . . . imposed by the government . . . to yield public revenue." *Tax*, *Black's Law Dictionary* (12th ed. 2024). As explained above, Congress understood that the IRA's penalties would yield no revenue. A levy designed not to raise revenue but to coerce compliance is a penalty, not a tax.

Nor is the "purpose" of this suit to "restrain[]" tax "assessment or collection." 26 U.S.C. § 7421(a). This Court has emphasized that "[t]he purpose" of a suit under the AIA "is 'the end or aim to which [it] is directed,'" not its downstream effects. *CIC Servs., LLC* v. *IRS*, 593 U.S. 209, 217–18 (2021). Here, the relief sought targets the Government's coercive "negotiation" scheme and its use of punitive exactions to force participation—not "any impending or eventual tax

obligation." *CIC Servs.*, 593 U.S. at 219. No "tax" has been triggered or assessed here, and Novartis "stands nowhere near the cusp of tax liability." *Id.* at 221; see also *Harper* v. *Rettig*, 46 F.4th 1, 8–9 (1st Cir. 2022) (AIA did not apply where plaintiff "stands nowhere near the cusp of tax liability" and "target" of lawsuit was not tax "assessment and collection" but IRS's "'separate legal' wrong" of retaining records).

2. The Third Circuit's application of the AIA elevated form over substance. This Court has instructed that the AIA analysis turns on "the substance of the suit," including the "claims brought" and the "injuries alleged." *CIC Servs.*, 593 U.S. at 218 (quotes omitted). Ignoring this instruction, the Third Circuit started with formalism: "Because Congress labeled the exaction a 'tax,'" the panel below held, "it is a tax within the meaning of the Anti-Injunction Act." Pet. App. 12a (quoting 26 U.S.C. § 5000D(a), (c), (f)(2)). And because the complaint sought some relief (a declaratory judgment) against the provisions of the IRA that establish the "excise tax," the court decided that Novartis's suit was necessarily aimed at restraining tax collection. *Id.* at 13a–14a ("[A]t bottom, its claim is that the excise tax violates the Excessive Fines Clause—not that some other part of the statute does so.").

When the Third Circuit finally (and briefly) confronted the full "substance of the suit," *CIC Servs.*, 593 U.S. at 212, it strained to explain how the suit's "purpose" was "restraining" any "assessment or collection." The Third Circuit acknowledged that Novartis's suit also sought injunctive relief against agreements that Novartis had been coerced into signing by the IRA's excessive fines. In the Third Circuit's view: "By seeking to enjoin CMS from 'forcing' it to participate in the Program, Novartis effectively sought to enjoin CMS from collecting information about excise tax liability

and sharing it with the IRS for collection." Pet. App 14a. That gets the Program, and Novartis's suit, exactly backwards: The statute does not use the Program to facilitate tax collection; it uses the "tax" to compel participation in the Program.

But even accepting the Third Circuit's framing, the connection between Novartis's challenge and tax assessment and collection is far too remote. As even the Government acknowledged in *CIC Services*, where there is "'too attenuated a chain of connection' between an upstream duty and a 'downstream tax,' a court should not view a suit challenging the duty as aiming to 'restrain the assessment or collection of a tax.'" 593 U.S. at 221. Here, "[b]etween the upstream [agreement] and the downstream tax, the river runs long." *Id.* The Third Circuit erred in "characteriz[ing] this suit's purpose as enjoining a tax." *Id.*

* * *

In the end, the AIA's aim is to "protect[] the . . . Government's ability to collect a consistent stream of revenue." *CIC Servs.*, 593 U.S. at 212. That is why the AIA channels tax suits through a "pay-now-sue-later procedure," under which a taxpayer pays the tax and then brings a refund suit against the tax. *Id.* at 222. But that procedure cannot work here, where the "tax" is so excessive that it will never be paid (and, accordingly, can reliably be predicted to produce zero revenue). The Third Circuit's decision to apply the AIA in this case thus did what the Act never meant to do: insulate unconstitutional, punitive fines from judicial review.

C. This Court Should Clarify That The Anti-Injunction Act Does Not Apply Here And That The Excessive Fines Clause Applies To Punitive Civil Fines.

This case presents an opportunity for this Court to clarify that neither the AIA nor the Eighth Amendment permits Congress to shield crushing monetary sanctions from constitutional scrutiny. The Court should take the opportunity, particularly in the face of "a world filled with more and more civil laws bearing more and more extravagant punishments." *Sessions* v. *Dimaya*, 584 U.S. 148, 184 (2018) (Gorsuch, J., concurring in part and concurring in the judgment).

CIC Services was clear: whether the AIA applies turns not on labels but on the "substance of the suit." *CIC Servs.*, 593 U.S. at 218. Yet the Third Circuit treated Congress's use of the word "tax" and the complaint's request for relief against "tax"-related statutory provisions as effectively dispositive. And then the court constructed a strained, attenuated causal chain linking Novartis's suit to the assessment or collection of the "tax."

The Third Circuit's approach cannot be reconciled with *CIC Services*, which demonstrates that the AIA is not a blanket prohibition on pre-enforcement judicial review of government action that touches on taxation. Rather, the statute permits suits that are not, in substance, about interfering with tax collection. The Third Circuit's decision impermissibly walks back *CIC Services*.

The Third Circuit's decision also walks back *Austin*. Like *CIC Services*, *Austin* was clear: the Excessive Fines Clause applies whenever a monetary sanction "serv[es] in part to punish." 509 U.S. at 610. So clear

that five Circuits applying *Austin* have held that the Excessive Fines Clause applies to civil monetary penalties that are in part punitive, even if those penalties are not tied to criminal conduct. *Schwarzbaum*, 127 F.4th at 270, 274–75; *Grant ex rel. United States* v. *Zorn*, 107 F.4th 782, 797 (8th Cir. 2024); *Grashoff* v. *Adams*, 65 F.4th 910, 916 (7th Cir. 2023); *United States ex rel. Drakeford* v. *Tuomey*, 792 F.3d 364, 387 (4th Cir. 2015); *United States* v. *Mackby*, 261 F.3d 821, 829 (9th Cir. 2001). Only the First Circuit—now joined by the Third Circuit's suggestion in the decision below—clings to the view that civil penalties are immune from scrutiny under the Eighth Amendment when untethered to a crime. *United States* v. *Toth*, 33 F.4th 1, 16 (1st Cir. 2022); see also *Toth* v. *United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari) (Mem.) (explaining that the First Circuit's decision "clashes with the approach many other courts have taken"). This Court should make clear once and for all that the Excessive Fines Clause prohibits punitive civil penalties just as much as it prohibits punitive criminal penalties.

Unless this Court intervenes, the decision below draws the Government a blueprint for coercing private parties using ruinous (and obviously disproportionate) financial penalties and then evading judicial review. All the Government needs to do is enact a regulatory scheme that coerces compliance through crippling *civil* penalties labeled a "tax," and then invoke the AIA to block any pre-enforcement challenge. And even if a regulated party were to overcome the AIA obstacle, its claim would automatically fail on the merits, because the exaction is labeled as "civil." With these moves, the Government would forever insulate crippling sanctions from meaningful judicial review. Neither *CIC Services* nor *Austin* permits that result.

II. THIS COURT'S INTERVENTION IS WARRANTED BECAUSE THE STATUTE IS NOVEL, CONSTITUTIONALLY DEFECTIVE, AND EXCEPTIONALLY IMPORTANT.

Some statutes are game-changers. They are such clear departures from the norm and so impactful that they call out for the Court to have the last word on their constitutional validity. The Inflation Reduction Act is one such statute. That law, and the decision below upholding it, are of great importance for pharmaceutical companies, the patients who depend on their medicines, and the public as a whole.

A. The IRA Is Exceptionally Important Because It Adopts A Revolutionary Approach To Coerce Price Regulation.

"[T]he United States can do business with whomever it wishes, and it may offer whatever prices it deems proper." *Bristol Myers Squibb Co.* v. *Sec'y U.S. Dep't of Health & Hum. Servs.* (*BMS*), 155 F.4th 245, 269 (3d Cir. 2025) (Hardiman, J., dissenting). Separately, the Government may use civil monetary penalties to enforce compliance with regulatory requirements, as it has in many other programs. See Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Revised Guidance* 78 (June 30, 2023), https://tinyurl.com/3vh3ykxr.

What the Government may not do—and, typically, has not done—is combine these coercive tools into a single scheme that forces private parties to sell their property to third parties at government-dictated below-market prices. Under the IRA "negotiation" regime, the Government is not acting in a procurement capacity or as a mere market participant. The Government is exercising regulatory power backed by civil monetary penalties to mandate private sales at a price

chosen by the Government—all while asserting that the exactions are shielded from judicial review because Congress branded them as "taxes."

The Government itself recognized the IRA's novelty when the statute was enacted. The Centers for Medicare & Medicaid Services, for example, described the Program as "historic." See Ctrs. for Medicare & Medicaid Servs., *CMS Releases Revised Guidance for Historic Medicare Drug Price Negotiation Program* (June 30, 2023), https://tinyurl.com/22hsndtz. It also touted the Program's deployment of "new" "negotiation" tools "for the first time in history." *Id.*; Ctrs. for Medicare & Medicaid Servs., *Fact Sheet: Medicare Drug Price Negotiation Program Revised Guidance* (June 2023), https://tinyurl.com/mpdt9ffc. Here, as in many settings, the lack of "historical precedent" for the way the IRA amalgamates powers (and then shields the exercise of those powers from judicial review) to coerce participation is a strong indicator of "constitutional problem[s]." *Free Enter. Fund* v. *Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010).

That is particularly true for a statute that disguises those tools as a mere procedure for "negotiation," obscuring Congress's accountability for the coercion. "[I]n Orwellian fashion," *BMS*, 155 F.4th at 285–86 (Hardiman, J., dissenting), the statute forces manufacturers to sign "Agreements" that falsely represent that they have "agreed" to "negotiate" "maximum fair prices," even though the manufacturers are "agreeing" only under protest and do not, in fact, believe that the prices set in the "negotiation" are "fair."

B. The IRA Is Exceptionally Important Because It Transforms Medicare.

Even if the Program were not novel, it would merit the Court's attention. Medicare is critical—not only to

the tens of millions of elderly and disabled Americans it insures, but also to the U.S. healthcare system and to the U.S. economy as a whole. Medicare "provide[s] health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation's population." *Azar* v. *Allina Health Servs.*, 587 U.S. 566, 569 (2019). And at over $850 billion, Medicare is the second-largest federal program by spending; only Social Security is larger. See Cong. Budget Off., *The Federal Budget in Fiscal Year 2024: An Infographic* (Mar. 20, 2025), https://www.cbo.gov/publication/61181. Through Medicare and the health insurance program for indigent Americans, Medicaid, the Government "dominates" the prescription drug market in the United States. *Sanofi Aventis*, 58 F.4th at 699.

The Program transforms Medicare. Until the IRA, both Medicare Part B and Part D operated based on market-based pricing. Part B reimbursement rates, for example, have been based on an "average sales price" formula. 42 U.S.C. § 1395w-3a. Part D was predicated on market-based pricing, too. When Congress established the Medicare Part D benefit for self-administered prescription drugs in 2003, it enacted an explicit "Non-interference clause." 42 U.S.C. § 1395w-111(i). That clause's stated purpose was to "promote competition" within the framework of a government healthcare program. *Id.* The clause did so by expressly prohibiting the Government from setting drug prices or "interfer[ing]" in negotiations between manufacturers, pharmacies, and prescription drug plan sponsors. *Id.* § 1395w-111(i)(1). In other words, even as Congress created Part D to bring self-administered prescription drugs within the ambit of Medicare, Congress ensured that Part D would not disrupt the free-market ecosystem that had driven massive investments in pharmaceutical research and development

before 2003. This feature of Part D was crucial to manufacturers, which continued their investments in reliance on Congress's legal guarantee of market-based pricing. That guarantee bolstered expenditures of billions of dollars on developing drugs that have improved, and continue to improve, the lives of Medicare beneficiaries and other Americans. See *infra* at 18–19.

The IRA breaks this bargain. Enacted after the Government had achieved dominance in the prescription drug market by creating and managing Medicare and Medicaid, the Program reneges on the Government's promise of a market-based Medicare drug-benefit program. The IRA replaces that framework with a regime in which manufacturers must pay crushing penalties unless they "agree" to the Government's mandated "maximum fair prices" for essential and widely used medicines. Although the Government must consider certain factors in arriving at these prices, the IRA does not impose any floor on HHS's price selection. 42 U.S.C. § 1320f-3(b)(2)(B), (b)(2)(C)(ii)(II), (e). The price-setting mandate applies to ten medications in 2026, twenty-five in 2027, forty in 2028, and twenty additional drugs in each subsequent year. In that way, the Program is swallowing an increasing share of the market year over year. Finally, as already discussed, to force manufacturers to accept the below-market prices the Government sets, the IRA leverages both the Government's power to exact statutory penalties and the Government's dominance of the pharmaceutical market through Medicare *and* Medicaid.

Together, these changes result in "a shift in kind, not merely degree," to Medicare. *NFIB*, 567 U.S. at 583. (And indeed to Medicaid, too, as illustrated by the consequences for beneficiaries of a manufacturer's hypothetical withdrawal from both Medicare and Medicaid in order to avoid participation in the Program.) This

transformation is reason enough for this Court to take notice—even though to be clear, the Program would have been just as unconstitutional had it been established contemporaneously with Medicare and Medicaid.

This Court's intervention is also necessary because, as discussed, Congress achieved this transformation of a massive federal program through unconstitutional means. There are ways to lower prescription drug prices, including the prices that Medicare pays for prescription drugs, that would comply with the Constitution. Such mechanisms would preserve market participants' freedom of action and would not involve grossly disproportionate fines or other undue coercion. But as Petitioner explains, and as is further explained *supra*, Congress opted in the IRA for the "shorter cut than the constitutional way" to reduce prescription drug prices. *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 416 (1922). This Court has made clear that "convenience and efficiency" cannot justify departure from constitutional limits. *INS* v. *Chadha*, 462 U.S. 919, 944–45 (1983). And the Court has weighed in to protect these limits when Congress deploys constitutionally problematic means to transform the largest and most important federal programs. See, e.g., *NFIB*, 567 U.S. at 575–76, 580. When this Court does so, it reinforces the foundational principle that "[t]he Framers created a Federal Government of limited powers, and assigned to this Court the duty of enforcing those limits." *Id.* at 588. The Court should do so again here.

C. This Court Should Weigh In Because The IRA Threatens Private Investment In Medical Innovation On A Massive Scale.

This Court's intervention is also needed to address the threats the IRA poses to U.S. businesses in the pharmaceutical sector and beyond.

Pharmaceutical product development and manufacturing are high-risk endeavors that require massive capital outlays over decades. See Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 845 (2020) (estimating the median research and development cost per-FDA-approved drug to be $1.1 billion). Thanks in part to Medicare's market-based drug pricing system, however, this country's pharmaceutical industry has overcome these structural barriers, and has long led the world in pharmaceutical innovation. See Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical R&D Investment*, Nature Revs. Drug Discovery (Aug. 6, 2024).

The IRA threatens this critical investment and innovation—and, thereby, the many millions of patients in the United States and around the world who benefit from the dynamism and productivity of the U.S. pharmaceutical sector. Early-stage funding for certain products has fallen "nearly 70%" since the IRA was introduced. PhRMA, *The Inflation Reduction Act and Medicare Drug Price "Negotiation"*, https://tinyurl.com/2z9n232h (last visited Jan. 21, 2026). Funding cuts will drastically reduce clinical trial activity in the biopharmaceutical sector. See Meir Pugatch & David Tortensson, *From Innovation Oasis to Research Desert* 4, U.S. Chamber of Com. (Dec. 11, 2023), https://tinyurl.com/4xmfrxem. The result, by one estimate, is that approximately 140 drugs over the next ten years will never be developed. See Daniel Gassull et al., *IRA's Impact on the US Biopharma Ecosystem* 2, 16, Vital Transformation (June 1, 2023), https://tinyurl.com/cbdy6a4x. And models predict a loss of between 66,800 and 135,900 jobs in the biopharmaceutical industry. See *id.* at 29–30.

Outcomes like this are the predictable result of a bait-and-switch maneuver that upends a decades-old market-based regime and substitutes one that confiscates the returns on private-sector investment. In the case of the IRA, the consequences are potentially devastating to pharmaceutical companies' collective mission of tackling the world's most complex diseases.

If the Program stands, there is no reason to expect that in future years, Congress, state legislatures, and executive-branch officials will stop at transforming the pharmaceutical industry. The twenty-first century Government's power to regulate commerce, buy, and spend is so great that the Government dominates many markets, not just the markets for medicines. The Government spends billions of dollars every year on non-pharmaceutical healthcare services for senior, low-income, and disabled Americans. See Ctrs. for Medicare & Medicaid Servs., *Table 19: National Health Expenditures by Type of Expenditure and Program* (2023), https://tinyurl.com/ybk65b8d. And the Government is itself a monopsony buyer of technology and other goods—from weapons systems to airplanes—essential to our national defense. See, *e.g.*, *BMS*, 155 F.4th at 257; Andrew P. Hunter et al., *Defense Acquisition Trends, 2015* 44, Ctr. for Strategic & Int'l Stud. (Jan. 1, 2016), https://tinyurl.com/murwzpf9.

Following the IRA's model, the Government could exact property from, or infringe other rights enjoyed by, businesses in these industries. The model is to impose destroy-the-company monetary penalties as alternatives to compliance with the demand to give up property, or other rights. Indeed, the Government need not stop at industries that it currently dominates. Using its spending and regulatory powers, Congress could create subsidy, benefit, or other programs that

make the Government the dominant player in a market, and from there, enact a scheme modeled on the one at issue here. A similar penalty-backed scheme could be deployed elsewhere, and then shielded from review by labeling the coercive fines "taxes."

The specter of these programs threatens not only the constitutional rights of businesses across industries, but also those industries' continued ability to invest in our economy and innovate to create new technologies and products that benefit all Americans.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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