No. 25-799

IN THE

Supreme Court of the United States

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Petitioner,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second 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 Chamber and its members are concerned that the Program is deeply flawed on several constitutional grounds. 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 tax on all sales of the product. The only alternative to these forced sales or 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 penalties for non-participation.

The IRA's combined use of these mechanisms to compel forced property transfers at below-market prices without just compensation violates the Due Process and Takings Clauses of the Fifth Amendment, among other constitutional provisions.

Yet the Second Circuit upheld the Program on the ground that manufacturers' "participation . . . is voluntary and thus does not entail an unlawful deprivation of rights." Pet. App. 8a. Ignoring the IRA's crippling "excise tax," *id.* at 25a, the Second Circuit reasoned that the Program was not "coercive" because manufacturers could "simply opt out of Medicare and Medicaid" to avoid the forced sales. *Id.* at 26a. The court brushed aside the reality that "opt[ing] out" would destroy any manufacturer's domestic business, holding that "the choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even substantially worse, economic outcomes." *Id.* A divided panel of the Third Circuit recently reached a similar conclusion on similar reasoning. See *Bristol Myers Squibb Co.* v. *Sec'y U.S. Dep't of Health & Hum. Servs.* (*BMS*), 155 F.4th 245, 255, 269 (3d Cir. 2025); see also *Bristol Myers Squibb Co.* v. *Kennedy*, No. 25-751 (U.S.) (cert. petition filed Dec. 19, 2025); *Novo Nordisk Inc.* v. *Sec'y U.S. Dep't of Health & Hum. Servs.*, 154 F.4th 105, 110 (3d Cir. 2025) (relying in part on *BMS* to uphold the Program); *Novo Nordisk Inc.* v. *Kennedy*, No. 25-761 (U.S.) (cert. petition filed Dec. 22, 2025).

There is nothing "voluntary" about a government scheme that coerces private parties to sell their products to third parties at government-mandated prices by leveraging a power—to exact "excise taxes"—that no other market participant (however dominant) possesses. Nor do ordinary constitutional protections fall away when the Government pressures property owners to sell their products by combining its market and regulatory powers.

All of that was lost on the Second Circuit (and on the majority of a Third Circuit panel as well). Judge

Hardiman's dissenting opinion in *BMS* was correct: the "negotiation" process contemplated by the IRA is illusory, culminating in an "offer" that manufacturers "couldn't refuse." 155 F.4th at 281 (Hardiman, J., dissenting) (cleaned up) (quoting *The Godfather* (Paramount Pictures 1972)).

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.[2] 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

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[2] The Chamber joined other chambers of commerce in separate litigation that raised constitutional challenges to the Program. *See Dayton Area Chamber of Com.* v. *Becerra*, 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.

irremediable damage to investment in research and development in the U.S. pharmaceutical sector.

The threat goes far beyond one industry, however. The decision below gives the Government a blueprint for forcing others to give up their constitutional rights. Many sectors—from healthcare to technology to aerospace—depend on government funding or purchasing. In upholding the Program, the Courts of Appeals have said that the Government may coerce these actors into giving up their property (or other rights) as long as it does so by using a combination of monetary penalties and monopsony power. 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 IS UNCONSTITUTIONALLY COERCIVE, NOT VOLUNTARY.

The Second Circuit wrongly concluded that participation in the IRA's "Drug Price Negotiations" is "voluntary" for manufacturers. Pet. App. 25a. But that is not the case. Even the statutory title (see 42 U.S.C. § 1320f(a)) is misleading: the IRA forces manufacturers to engage in a stylized process of "negotiation" that is a negotiation only in name. If a manufacturer refuses to accede to the price that the Government sets at the end of the stylized process, the manufacturer must

either pay ruinous monetary penalties or exit half the U.S. pharmaceutical market. In our constitutional system, this is not a "voluntary" "choice between only bad options—opting into a government program with price controls or bowing out of the program entirely," Pet. App. 27a; it is no choice at all. As the petition explains, because the IRA's drug-pricing scheme is coercive, not voluntary, it requires close scrutiny under the Constitution's provisions protecting private property. Pet. 14–21. For the reasons discussed below, this Court should intervene to vindicate the important constitutional rights at issue here.

A. Participation Is Coerced By Monetary Penalties.

As an initial matter, participation in the Program is coerced by the threat of crushing monetary penalties. If a manufacturer refuses to sign an "agreement" to sell a Program-eligible product to 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); 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). See Pet. App. 15a; Pet. 10 (noting that Boehringer signed an agreement "under protest to avoid [a penalty] that would have started at over $500 million per week and increased to more than $5.5 billion per week"). Manufacturers who commit to "negotiate" or who "agree to" a price will also face punitive

civil monetary penalties if they do not provide access at 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).

Because of these penalties, a manufacturer who signs the mandated "agreements" with the Government and offers the selected drugs at the Government's price does not freely choose these actions. Rather, the manufacturer comes to the table, acquiesces to the Government's price, and provides access to the drug at that price because the manufacturer is compelled to do so by the threat of impossibly high monetary penalties if it refuses. In short, the IRA commands manufacturers to "negotiate" with the Government, "agree to" the Government's price, and offer selected drugs at that price—or else pay a crushing penalty. There is no real choice here.

The Second Circuit ignored apt precedent from this Court holding that the Government cannot do this: it cannot compel parties to choose between relinquishing property and paying coercive penalties. In *Carter* v. *Carter Coal Co.*, 298 U.S. 238 (1936), for example, the Court held that Congress could not "coerce" coal producers to agree to Government-set coal prices and labor rules by subjecting producers who did not agree to a tax that was ten times higher than the tax for producers who did comply. *Id.* at 281–82, 289. "One who does a thing in order to avoid a monetary penalty does not agree," the Court said; "he yields to compulsion precisely the same as though he did so to avoid a term in jail." *Id.* at 289. In other words, the presence of monetary penalties in such a scheme renders the

regulated party's choice to comply *in*voluntary. To give another example: in *Union Pacific Railroad Co.* v. *Public Service Commission*, 248 U.S. 67 (1918), this Court rejected a State's argument that a company had "voluntarily" purchased a certificate to issue bonds, where the State had threatened "grave penalties" and "purported to invalidate the bonds" if the company did not buy the certificate. *Id.* at 70. A State cannot, the Court explained, "impose an unconstitutional burden by the threat of penalties worse than [the burden] in case of a failure to accept it, and then . . . declare the acceptance voluntary." *Id.* But that is exactly what the IRA does.

The Second Circuit ignored these precedents, much as it failed to come to terms with the IRA's penalties. In holding that participation in the Program is "voluntary," the Second Circuit—without explanation—"[p]ut[] aside the excise tax." Pet. App. 26a. Later in its decision, the Second Circuit explained (deep in a nearly 400-word footnote) why it thought the IRA's sky-high penalties could be divorced from its analysis. *Id.* at 31a–32a n.11. There, the court maintained that, "in negotiating prices for pharmaceuticals for Medicare beneficiaries, the government acts as a market participant" that "leverages its purchasing power to get a better bargain," just "[l]ike any other private party." *Ibid.* The Second Circuit acknowledged that the presence of "civil fines" or other coercive "tools 'that no private actor could wield'" could render the government a "market regulator" rather than a "market participant." *Ibid.* (quoting *United Haulers Ass'n, Inc.* v. *Oneida-Herkimer Solid Waste Mgmt. Auth.*, 438 F.3d 150, 157 (2d Cir. 2006), *aff'd*, 550 U.S. 330 (2007)). But in the Second Circuit's view, the presence of monetary penalties did not change the overall constitutional analysis here, because a statutory scheme's use of

penalties and other regulatory coercive tools "is 'evaluate[d] separately' from [the Government's] activity as a market participant." *Ibid.* (quoting *United Haulers Ass'n*, 438 F.3d at 157).

That cannot be right. It cannot be that, so long as the penalties a statutory scheme imposes are not themselves unconstitutional, those penalties are irrelevant to the question whether a statutory scheme coerces private parties.[3] The IRA's crippling civil penalties are plainly relevant to whether participation in the Program is coerced.

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[3] Nor does the circuit precedent the Second Circuit cited support the proposition that the penalties here may be set to the side in analyzing the constitutional questions. That precedent offers only the uncontroversial proposition that when considering whether a local scheme violates the dormant aspect of the Commerce Clause, separate parts of a regulatory program may be analyzed separately, because "a state may act as a market participant with respect to one portion of a program while operating as a market regulator in implementing another." *United Haulers Ass'n*, 438 F.3d at 158. The Second Circuit never explained its evident view that this Commerce Clause analysis can be ported over wholesale to the Fifth Amendment Takings Clause and Due Process contexts. But even if it could be, the Second Circuit never explained how the penalties imposed on manufacturers who refuse to comply with the Program's strictures could be seen as separate from the rest of the Program. In addition, Petitioner also brought an unconstitutional conditions claim, and that doctrine necessarily requires considering how the constituent parts of a governmental scheme relate to one another, and to the whole. That is how the doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz* v. *St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

B. The Illusory Exit Option Confirms That The Program Is Not "Voluntary."

Regardless of the penalties, the Second Circuit was wrong that the manufacturers' purported ability to "opt out of Medicare and Medicaid" fixes the constitutional problems. Pet. App. 26a. The Second Circuit's reasoning just shifts, rather than eliminates, the coercion problem: A manufacturer that exits has done so in order to avoid having to make forced sales of its goods, or pay astronomical penalties. As *Carter Coal* says, that kind of scheme is a form of coercion: "One who does a thing in order to avoid a monetary penalty does not agree"; rather, "he yields to compulsion[.]" 298 U.S. at 289.

Further, the unconstitutional coercion here is compounded by the costs that the statute exacts as the price for avoiding the monetary penalty. Those costs are so high that they make the exit option "illusory." *United States* v. *Butler*, 297 U.S. 1, 71 (1936). Withdrawing wholesale from Medicare and Medicaid would mean abandoning nearly half of the U.S. pharmaceutical market. See *Sanofi Aventis U.S. LLC* v. *HHS*, 58 F.4th 696, 699 (3d Cir. 2023) ("Through Medicare and Medicaid, [the Government] pays for almost half the annual nationwide spending on prescription drugs." (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022))). That would destroy any manufacturer's U.S. business. And it would leave the over one-fifth of Americans insured by Medicare or Medicaid without insurance coverage for *any* of the manufacturer's products. No manufacturer would choose to so sharply curtail patient access to its treatments.

The Second Circuit brushed aside these existential threats as part of an alternative "route" for

manufacturers that merely "entail[s] worse, even substantially worse, economic outcomes" than does participation in the IRA scheme. Pet. App. 26a. Applying *Garelick* v. *Sullivan*, 987 F.2d 913 (2d Cir. 1993), and cases from other circuits that "have recognized in various contexts that participation in Medicare and Medicaid is voluntary," Pet. App. 23a n.7, the Second Circuit suggested that no amount of "economic hardship" imposed by a statute could render participation in a federal program involuntary so long as a statute did not contain a provision that created a "legal compulsion" to participate in Medicare. *Id.* at 24a–25a.

Even if that were correct, the Second Circuit's reasoning would not solve the constitutional problems. The statutory scheme made it literally "*impossible*" for manufacturers selected for the first year of IRA "negotiations" to exit by withdrawing from Medicare and Medicaid. *BMS*, 155 F.4th at 272 (Hardiman, J., dissenting). That is because the statute required manufacturers to "provide notices of termination by January 29, 2022, *before the Act became law*." *Id.* The Government's "efforts to rewrite" this statutory timeline "by making promises in nonbinding guidance documents" only underscore that the scheme Congress enacted was not one from which the companies could walk away. *Id.* at 276–79. In short, the Program does work "legal compulsion" of the kind contemplated by the Second Circuit.

Of course, this Court's precedent also suggests the Second Circuit's reasoning is incorrect. Most recently, in *National Federation of Independent Businesses* v. *Sebelius* (*NFIB*), 567 U.S. 519 (2012), this Court struck down a federal healthcare program with similarly coercive features, holding that Congress could not compel a State to expand Medicaid coverage by "threatening to withhold all of [its] Medicaid grants." *Id.* at 575.

There, Congress had sought to leverage billions of dollars of federal grants on which States had long relied—and that the States could not afford to lose—to pressure States to acquiesce to new conditions on the original Medicaid program. The Court rejected that attempt to lock States into the expanded Medicaid program while pretending to give them a choice. As in *NFIB*, the IRA is an unconstitutional "gun to the head." *Id.* at 581–82.

The Second Circuit dismissed *NFIB* as "very clearly derived from federalism concerns, i.e., the scope of the federal government's authority to regulate the states." Pet. App. 26a–27a. True enough, *NFIB* involved the States and mentioned federalism. But the Second Circuit's narrow understanding of *NFIB* does not answer several points. In that case, only 10% of budget revenue was at issue for States, yet this Court concluded that the economic effect was too coercive because it left the States with "no real option." 567 U.S. 582. Here, the comparative coercion being imposed on private companies is much greater: nearly 50% of the U.S. pharmaceutical market. And States are among the Nation's most powerful political actors. If (as *NFIB* held) the Constitution protects States against coercive congressional directives, then surely the Constitution protects with no less force the "person[s]"—individuals and businesses alike—whose property rights the Fifth Amendment protects. U.S. Const. amend. V; cf. *Medina* v. *Planned Parenthood S. Atl.*, 606 U.S. 357, 374 n.5 (2025) (observing that this Court's "spending-power cases have applied similar principles to state and private recipients of federal aid"). Moreover, just as in *NFIB*, Congress has created a scheme that "threaten[s] political accountability" by misleadingly stylizing the IRA's coercive price-setting regime as a

voluntary "negotiation." Pet. App. 27a (quoting *NFIB*, 567 U.S. at 578).

In the end, every step of *NFIB*'s coercion analysis applies equally well to this Program. See *NFIB*, 567 U.S. at 580–81 (inquiring whether a party's acceptance of a federal program "remain[ed] [its] prerogative . . . not merely in theory but in fact" (citation omitted)). The Program amounts to "economic dragooning that leaves" manufacturers "with no *real* option but to acquiesce[.]" *Id.* at 582 (emphasis added). Contrary rulings blessing the Program should not go unexamined by this Court.

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, is 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.

All agree: "the United States can do business with whomever it wishes, and it may offer whatever prices it deems proper." *BMS*, 155 F.4th at 269 (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. Worse, the IRA does this while barring judicial review, Pet. App. 17a–18a, and without other procedures to ensure that the Government is acting within constitutional bounds. That combination makes the IRA unique, and uniquely dangerous. Under the IRA "negotiation" regime, the Government is not acting in a procurement capacity or as a mere market participant. Contra *id.* at 31a n.11. The Government is exercising regulatory power backed by civil monetary penalties to mandate private sales at a price chosen by the Government—all while claiming that because those sales are connected to a government insurance program, no constitutional constraints apply.

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. Under the guise of a "negotiation" that is anything but voluntary, the IRA directs the Department of Health and Human Services to mandate the prices of 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 coercive and 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 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"—not to

mention the avoidance of political accountability—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 debarment or destroy-the-company 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.

Under the Second Circuit's reasoning, these schemes would be "voluntary"—and thus constitutional. The specter of these programs threatens not only the constitutional rights of businesses across industries with significant government spending, 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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