No. 25-761

IN THE
Supreme Court of the United States

NOVO NORDISK INC., ET AL.,
Petitioners,

v.

ROBERT F. KENNEDY, 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 PETITIONERS

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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, which was adopted as part of the Inflation Reduction Act (IRA). The Chamber and its members are concerned that this legislative scheme is deeply flawed on several constitutional grounds. It 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 petition, like others challenging the same scheme, 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 "enterprise-crippling" daily tax on all sales of the product. *Bristol Myers Squibb Co.* v. *Kennedy*, 155 F.4th 245, 269–70 (3d Cir. 2025) (Hardiman, J., dissenting). 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—who 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 in. 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. Further, Congress barred judicial review of the Government's decisions under the IRA about what prices to set, and much more.

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

Yet the Third Circuit upheld the scheme. As the petition's second question presented emphasizes, Pet. i, the Third Circuit was constrained by *Bristol Myers Squibb*, which had held a month earlier that the sales the IRA compels are a "voluntary exchange" between the companies and the Government. 155 F.4th at 255; *see also* Pet. App. 7–8 (citing *Bristol Myers Squibb*). Relying on that precedent, the Third Circuit below held that the IRA "provides an escape hatch" for manufacturers that wish to avoid the forced sales (and astronomical penalties). *Id.* at 7. But the "hatch" requires manufacturers to exit wholesale from Medicare *and* Medicaid. *Id.* at 7–8. Beyond reference to its decision in *Bristol Myers Squibb*, the Third Circuit did not acknowledge the reality that withdrawal from half the domestic market would destroy a manufacturer's business. In *Bristol Myers Squibb*, a divided panel downplayed that consequence as an "economic factor[]" that "may . . . influence" a manufacturer's "choice to do business with the government" but did not render that choice involuntary. 155 F.4th at 257. The Second Circuit recently reached a similar conclusion. *See Boehringer Ingelheim Pharms., Inc.* v. *HHS*, 150 F.4th 76, 88–90 (2d Cir. 2025); *see also Boehringer Ingelheim Pharms., Inc.* v. *HHS*, No. 25-799 (U.S.).

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 the ordinary constitutional protections

for private property fall away when the Government pressures property owners to sell their products by combining its market and regulatory powers.

Now is the right time for this Court to intervene. The constitutional questions raised by the IRA regime are obviously and critically important. Before the enactment of that law, Congress had for decades provided for market-based pricing of Medicare-covered prescription drugs. That free-market model helped fuel manufacturers' investments in the discovery of novel and life-saving therapies. In replacing that model with forced sales at unreviewable 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 "negotiation" 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 irremediable damage to investment in research and development in the U.S. pharmaceutical sector.

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[2] The Chamber joined other chambers of commerce in separate litigation that raised constitutional challenges to the IRA's price "negotiation" regime. *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.

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, exempt from judicial review. Many sectors—from healthcare to technology to aerospace—depend on government funding or purchasing. In upholding this scheme, 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 penalties and other 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 "negotiation" scheme's numerous constitutional infirmities. And upon doing so, the Court should reverse.

ARGUMENT

I. THE INFLATION REDUCTION ACT'S DRUG PRICE "NEGOTIATION" SCHEME IS UNCONSTITUTIONALLY COERCIVE, NOT VOLUNTARY.

The Third Circuit wrongly concluded that participation in the IRA's "Drug Price Negotiations" is "voluntary" for manufacturers. But the statutory title (*see* 42 U.S.C. § 1320f(a)) is intentionally misleading: the IRA's scheme forces manufacturers to engage in a stylized process of "negotiation" that is a negotiation only in name. Participation is coerced. 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. Neither option is real; there is no "escape hatch" from participation. Pet. App. 7. As the petition explains, because the IRA's drug-pricing scheme is coercive, not voluntary, it triggers scrutiny under the Constitution's provisions protecting private property. Pet. 25–30. The scheme also transgresses the separation of powers. *Id.* at 15–22.

Relying on its earlier decision in *Bristol Myers Squibb*, the Third Circuit nevertheless accepted CMS's "argument that its price-control program is . . . voluntary" and "concluded that no analysis was required to determine whether forcing manufacturers to relinquish their rights . . . was consistent with the Constitution." Pet. 28 (cleaned up); *see* Pet. App. 7–8 (discussing *Bristol Myers Squibb*, 155 F.4th at 254–59). 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.

Participation in the IRA's forced-sale regime is coerced by the threat of crushing monetary penalties. If a manufacturer refuses to sign an "agreement" to sell an eligible product at the government-mandated price to private participants in Medicare, 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 Bristol Myers Squibb*, 155 F.4th at 272–73 (Hardiman, J., dissenting); Decl. of Karen M. Hauda at 19–20, *Novo Nordisk Inc.* v. *Becerra*, No. 3:23-cv-20814-ZNQ-JBD (D.N.J. Dec. 8, 2023), ECF No. 29 (noting that if Novo Nordisk did not sign an "agreement," penalties on sales of covered products would escalate to exceed "400 million dollars per day"). Manufacturers who commit to "negotiate" or who "agree to" a price will face civil monetary penalties if they do not "provide access to a price that is equal to or less than the maximum fair price[.]" 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 to take 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 an "enterprise-crippling" penalty. *Bristol Myers Squibb*, 155 F.4th at 269–70 (Hardiman, J., dissenting). There is no real choice here.

The Third 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. Likewise, 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*. That is exactly what the IRA does.

B. The Illusory Exit Option Confirms That Manufacturers' Participation Is Not "Voluntary."

Over a forceful dissent, the Third Circuit has concluded that these penalties do not matter, because manufacturers "are not *legally* compelled to participate in Medicare" and can avoid the penalties by withdrawing *all* of their drugs (not just those selected for "negotiation") from Medicare *and* Medicaid. *Bristol Myers Squibb*, 155 F.4th at 256 (emphasis added). But withdrawal is not a realistic option.

For one, at least for the manufacturers selected for the first year of IRA "negotiations," the statutory scheme made it literally "*impossible*" for manufacturers to exit in this way. *Id.* 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 exacerbate the separation-of-powers problems highlighted in the petition and underscore that the scheme Congress enacted was not one from which the companies could walk away. *Id.* at 276–79. In short, the Third Circuit was wrong to conclude that there is an "escape hatch" from the devastating penalties that the statute imposes for leaving. Pet. App. 7.

Moreover, the Third 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 and stopping sales to more than 140 million individuals. *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.

In *Bristol Myers Squibb*, the majority brushed aside these existential threats as mere "economic factors" that "may have a strong influence on a company's choice to do business with the government" but that do not make that choice involuntary. 155 F.4th at 257–58. Once again, this Court's precedent says otherwise. Most recently, in *National Federation of Independent Business* 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's scheme is an unconstitutional "gun to the head." *Id.* at 581–82.

The Third Circuit majority in *Bristol Myers Squibb* dismissed *NFIB*, citing its "explicit and repeated focus on federalism and the states' role as distinct sovereigns." 155 F.4th at 259–60. That description of *NFIB* is literally true, but it 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").

The panel majority in *Bristol Myers Squibb* was also wrong to suggest that applying *NFIB* "to the government's dealings with private parties" would mean that "the government could [*n*]*ever* renegotiate or discontinue contracts." 155 F.4th at 259 n.15 (emphasis added). That policy argument is unsound. *NFIB* has not sounded the death knell for cooperative federal-state programs under the Spending Clause or otherwise. Likewise, it would not impede federal contracting to recognize that a government program can be (or can become) unconstitutionally coercive when it forces private parties to give up their constitutional rights by combining the governmental power to impose monetary penalties with the power to regulate and control large federal benefits programs. Recognizing this would just underscore what has always been true: Some governmental acts are coercive; and when the Government employs power coercively, it must operate within constitutional bounds.

In the end, every step of *NFIB*'s coercion analysis applies equally well to the IRA. *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 IRA's "negotiation" scheme amounts to "economic dragooning that leaves" manufacturers "with no *real* option but to acquiesce[.]" *Id.* at 582 (emphasis added).

Contrary rulings blessing the scheme should not go unexamined by this Court.

C. The Unavailability Of Judicial Review Compounds The Constitutional Problem.

Novo Nordisk's petition highlights another feature of the IRA that deepens the constitutional problem with the IRA's forced-sale provisions: the bar on judicial review of the responsible agency's price-setting decisions. Pet. 2, 16–18. Under the threat of an "enterprise-crippling" penalty, *Bristol Myers Squibb*, 155 F.4th at 269–70 (Hardiman, J., dissenting), and facing an illusory option to exit from Medicare and Medicaid, manufacturers are coerced into "agreeing" to sell selected drugs at below-market rates set by the Government. But unlike most other schemes in which a federal agency action sharply affects the rights of individuals or businesses, the IRA prohibits regulated parties from seeking recourse in the courts to vacate the agency's unlawful or arbitrary rules and price-setting decisions.

The Third Circuit interpreted the IRA's judicial review bar broadly, 42 U.S.C. § 1320f-7, to foreclose review of several of the Government's substantive regulations (issued as "guidance") and determinations made in its drug selection and price-setting "negotiation" with Novo Nordisk. *See* Pet. App. 9–13. That interpretation grants the Government unreviewable discretion to issue substantive regulations that allow it to select a collection of a manufacturer's most valuable products, label them eligible for "negotiation" as a single "drug," 42 U.S.C. § 1320f-7(1)–(4), and set a "maximum fair price" as low as zero dollars that applies to all of the products, *id.* § 1320f-3(b)(2)(B), (b)(2)(C)(ii)(II), (d), (e) (lacking any price floor, apart

from a narrow, temporary exception for certain "small biotech" drugs).

To be sure, "Congress can . . . make exceptions to the historic practice whereby courts review agency action." *Bowen* v. *Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 672–73 (1986). But this Court has also made clear that Congress's power to make exceptions is "[s]ubject to constitutional constraints." *Id.* One area where judicial review bars merit close constitutional scrutiny is when they prevent courts from providing a meaningful check on agency decisions that exercise law-making powers and take actions that affect concrete, individual rights. And for good reason: just as "judicial review" can "give assurance that the action of the [Executive] is taken within its statutory authority," the lack of such review undermines that assurance. *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 533 (1935); *see also Am. Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946) ("Private rights are protected by access to the courts[.]"); *United States* v. *Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) ("Judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." (cleaned up) (citing cases)). So when Congress takes the unusual steps of delegating to an agency sweeping powers and then withdrawing judicial review from the agency's actions exercising those new powers, it can call the validity of the underlying legislative scheme into question.

The Third Circuit held that manufacturers' inability to seek the protection of the courts simply did not matter to whether the statute violates the Constitution's separation of powers and the Fifth Amendment's Due Process Clause. *See* Pet. App. 16–17 (incorporating opinion in *AstraZeneca Pharms. LP* v. *HHS*, 137 F.4th 116, 125–26 (3d Cir. 2025)). But the availability of judicial review bears on whether an agency may exercise

delegated authority to impose new rules and price controls that deprive a company of property without due process of law. In upholding a World War II–era price-setting scheme against a due-process challenge in *Bowles* v. *Willingham*, 321 U.S. 503 (1944), this Court explained that the *mere postponement* of judicial review until *after* the Government sets the price "is not a denial of due process," provided that there is an "opportunity given for the ultimate judicial determination" and provided that that opportunity "is adequate." *Id.* at 520–21.

It is no answer to *Bowles* that the scheme there regulated "private . . . transactions," whereas the IRA's scheme regulates private transactions where purchases are subsidized through a federal program, Medicare. *AstraZeneca Pharms.*, 137 F.4th at 126; *see* Pet. App. 16–17. Contrary to the Third Circuit, the IRA scheme does not "only set[] prices for drugs that [the Government] pays." *AstraZeneca Pharms.*, 137 F.4th at 126. After the Government sets the price under the IRA's scheme, that statute requires manufacturers to provide "access" to that price to "eligible individuals," to "pharmac[ies], mail order service[s], or other dispenser[s]," as well as to "hospitals, physicians, and other providers of services and suppliers." 42 U.S.C. § 1320f-2(a)(3). The statute thus expressly states that the Government is setting the prices a manufacturer must offer to another private party as part of a forced sale. What is more, under Medicare Part D, the Government never buys or even directly reimburses drugs. Rather, CMS pays private health insurers—known as "plan sponsors"—according to a complex statutory formula that does not turn directly on the actual or "negotiated" prices paid in individual drug sales. 42 U.S.C. § 1395w-115(a), (b). The Third Circuit's

attempt to distinguish *Bowles* ignores these critical considerations.

In sum, any purported constraints on the agency's power to set prices under the IRA (and there are few in the statute, *see* Pet. 7–8) mean little if no "court[] [can] ascertain whether the will of Congress has been obeyed" in any given instance. *Yakus* v. *United States*, 321 U.S. 414, 425 (1944). Thus, by insulating from judicial review "key determinations" about drug eligibility and price setting, the IRA creates an unprecedented delegation of legislative authority that goes far beyond the most sweeping delegations permitted even during wartime emergencies. It also creates "a substantial risk that [manufacturers] will be erroneously deprived of important property interests"—after being coerced into giving up those interests. *Nat'l Infusion Ctr. Ass'n* v. *Becerra*, 116 F.4th 488, 503 (5th Cir. 2024).

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.

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." *Bristol Myers Squibb*, 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, 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. The Government is exercising unconstrained power to mandate private sales at a price chosen by the Government alone 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 IRA's price-setting scheme 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 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," *Bristol Myers Squibb*, 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." *Id.* at 270.

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

Even if the IRA 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 IRA 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 that draws upon real-world sales data—the starting point is "the manufacturer's sales to all purchasers." 42 U.S.C. § 1395w-3a(c)(1)(A). 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). Congress's choice to maintain Medicare as a market-oriented program led manufacturers to invest billions of dollars in developing drugs that improve the lives of Medicare beneficiaries. *See infra* at 16–17.

The IRA breaks that bargain. Enacted after the Government had achieved dominance in the prescription drug market by creating and managing Medicare and Medicaid, the IRA 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 IRA 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.) This transformation is reason enough for this Court to take notice—even though to be clear, this legislative scheme 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 Petitioners explain, 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 this legislative scheme 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 Bristol Myers Squibb*, 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 Third 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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