24-2092

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

—against—

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare and Medicaid Services,

Defendants-Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT
NO. 23-CV-01103 (HON. MICHAEL P. SHEA)

BRIEF FOR *AMICUS CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PLAINTIFF-APPELLANT

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CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

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INTEREST 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 three 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. The Chamber's members include pharmaceutical manufacturers who are directly subject to, and will in the future be directly subject to, the price controls established by the Inflation Reduction Act's Drug Price Negotiation Program. More broadly, the Chamber has a strong interest

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amicus curiae* states that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The parties have consented to the filing of this brief.

in advocating against unconstitutional government programs that undermine incentives for private-sector innovation and investment. Accordingly, this brief focuses on background principles, crucial for the free-enterprise system, that apply far beyond the specifics of the Program at issue here.[2]

INTRODUCTION AND SUMMARY

Boehringer Ingelheim is correct: the provisions of the Inflation Reduction Act ("IRA") that create the Drug Price Negotiation Program coerce pharmaceutical companies into selling their products at below-market rates, in violation of the Takings Clause and the Due Process Clause of the Fifth Amendment.

The district court reached a different conclusion, based on a mistaken belief that participation in the Program is voluntary. But there is nothing voluntary about a government scheme that compels parties to

[2] The Chamber has joined other chambers of commerce in separate litigation, currently on appeal, raising constitutional challenges to the Program. *See Dayton Area Chamber of Com. v. Becerra*, No. 24-cv-3868 (6th Cir.). That case, which presents a somewhat different set of claims and issues than those raised in this case, was decided by the district court on standing and venue grounds, without reaching the merits. *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024).

sell to government programs at government-mandated prices by leveraging the government's regulatory power—including its power to exact crushing financial penalties. That is government coercion, plain and simple.

The district court's key error was to treat the penalty provisions of the IRA (discussed at SPA9–11) as being somehow distinct from the question of voluntariness (discussed at SPA21–30). Only by artificially separating the two could the district court frame the key issue in the case as "whether the government can use its power as a dominant buyer to demand lower prices from drug manufacturers." SPA21. That is an important question in its own right, but it is not the one presented in this case.

The central question here is whether the ordinary Due Process and Takings frameworks apply when the government combines together its power to exact monetary penalties *and* its regulatory power to design the government program *and* its market power, in a manner that coerces private parties to take the below-market price that the government is "offering." The answer must be that in such circumstances, the private party's conduct is coerced, both by design and in effect. And so the

ultimate answer is that the critical property-rights protections of the Fifth Amendment do not fall away due to any "voluntary" decision by the manufacturer. The Takings Clause and Due Process Clause instead continue to protect against improper government exactions.

Other features of the IRA confirm that the Program is not voluntary. Congress well understood that Medicare and Medicaid account for roughly half the U.S. pharmaceutical market, and that manufacturers would suffer serious harms to their mission of supporting patient health, and to their economic interests, if they were pushed out of that half of the market.

Congress also no doubt understood what the government essentially conceded and the district court recognized, SPA20 n.10: It is likely not practicable for manufacturers to stop selling to Medicare beneficiaries, for the simple reason that manufacturers do not sell directly to patients. Many actors have roles to play in the process that leads to an individual drug purchase, and intermediaries distribute drugs to patients. Understanding all of this, the drafters of the IRA designed the Program to give manufacturers like Boehringer only one

realistic option: stay, "negotiate," and "agree" to sell to Medicare beneficiaries at the government's prices.

If adopted by this Court, the district court's reasoning would have serious negative consequences for the pharmaceutical industry, but also far beyond. Enacted on a bare party-line vote, the Program upends the market-based system that had governed Medicare for decades, introducing price controls unchecked by judicial review of the agency's price-setting determinations or any legislative limits on how low the agency may force prices to go. If upheld, the Program will not only drastically undermine protections for property rights but also decrease incentives for innovation and access to capital in the pharmaceutical sector, with long-term impacts on patients.

What is more, by upending Medicare's longstanding system of market-based pricing and defying constitutional property-rights guarantees, the Program disrupts private parties' reliance interests and introduces inherent risk for any company that would consider partnering with the government in any important program. On the district court's understanding, a narrow majority in Congress may reorder such a program at any time while using the federal government's regulatory

weight, and power to exact crushing financial penalties, to lock the private party into continued, nominally "voluntary" participation. If that is how Congress may do business, and if the courts and the Constitution do not protect against it, the public-private partnership model is in big trouble: business leaders will be forced to recognize that partnering with the government carries immense downside financial risk.

That would be bad policy in its own right. More importantly, that is not the policy choice the Nation made when it constrained the government's power to diminish property rights by enacting the Fifth Amendment. The decision below should be reversed.

ARGUMENT

I. THE INFLATION REDUCTION ACT UNCONSTITUTIONALLY COERCES COMPANIES INTO PARTICIPATING IN THE ACT'S DRUG PRICE "NEGOTIATION" PROGRAM.

A. Companies Are Coerced into Participating in the Program by the IRA's Monetary Penalties.

The district court upheld the constitutionality of the Program based on the mistaken belief that participation in the Program is voluntary. *See* SPA14, 29–30. But there is nothing voluntary about a law that

requires parties to sell their property to someone else, at a price set by the government, or else pay an unaffordable penalty.

And that is exactly what the IRA requires. Manufacturers who fail to "negotiate" a "maximum fair price" for a selected drug, 42 U.S.C. § 1320f-2(a), or fail to "agree to" the price determined by the government, *id.* § 1320f-2(a)(1), are subjected to a penalty (styled as an "excise tax") on sales of that drug, 26 U.S.C. § 5000D(a)–(b). The 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.[3] *See id.* § 5000D(a), (b)(1), (d); *see also* Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 29 (2022), https://tinyurl.com/4tp4pp7e. The penalty takes effect the day after the manufacturer fails to agree and continues to accrue daily until the manufacturer complies with the Program's requirements. 26 U.S.C. § 5000D(b)(1)(A), (b)(2)(A). Even manufacturers who commit to

[3] As the district court observed, while the parties "disagree as to the excise tax rates," they "agree as to the actual amount of the tax." SPA9 & n.3. That amount is exorbitant—for example, a manufacturer could be assessed a $19,000 penalty for a single sale of a drug with a list price of $1,000. *Id.*

"negotiate" or "agree to" a price would 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). In short, the IRA commands manufacturers to "negotiate" with the government, to "agree to" the government's price, and to offer selected drugs at that price—or else pay a penalty.

This is clear-cut coercion. A manufacturer who signs the mandated "agreements" with the government and offers the selected drug at the government's price does not freely choose to take these actions. Rather, the manufacturer comes to the "negotiating" table, acquiesces to the government's price, and provides access to the drug at that price because it is compelled to do so by the threat of monetary penalties if it refuses to take any of those actions. *See, e.g.*, *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("One who does a thing in order to avoid a monetary penalty does not agree; he yields to compulsion precisely the same as though he did so to avoid a term in jail.").

In the district court's mistaken view, this scheme is voluntary, because Boehringer can "opt out of Medicare and Medicaid"—thus avoiding both the penalties and the government-imposed price controls.

SPA14. The key flaw in the district court's reasoning is that when a company "withdraw[s] from Medicare and Medicaid," SPA14, to escape monetary penalties, that is not a *voluntary* withdrawal. It is a manufacturer "yield[ing] to compulsion" in the form of those very penalties. *Carter Coal*, 298 U.S. at 289.

Ironically, the district court got this basic point exactly right elsewhere in its opinion, when it rejected the government's argument that Boehringer could "avoid participating in the Program by divesting its interest in Jardiance[®]." SPA19. There, the district court correctly reasoned that "[t]he government cannot evade a Fifth Amendment challenge by requiring manufacturers to choose between losing any property rights they have through government appropriation and losing them through divestment." SPA19. But the district court should have equally recognized that the government engages in coercion when it forces manufacturers to choose between losing money through government-imposed penalties and losing money through divestment from Medicare. The government should not be able to evade a Fifth Amendment challenge in that way either. *See Frost v. R.R. Comm'n*, 271 U.S. 583, 593 (1926) (deeming law unconstitutional where it gave

regulated party "no choice, except a choice between the rock and the whirlpool—an option to forego a privilege which may be vital to his livelihood or submit to a requirement which may constitute an intolerable burden").

The district court thus erred in framing "[t]he question" in this case as "whether the government can use its power as a dominant buyer to demand lower prices from drug manufacturers." SPA21. The government here has not merely used its market power as a "dominant buyer" in the pharmaceutical market to "demand lower prices"; it has used its governmental power to impose monetary penalties to compel manufacturers to acquiesce to prices the government has set.

This feature of the Program makes it completely different from settings where the government truly acts as a market participant, wielding market power as any other private party could, and no more. To see the difference, compare this case with those the government relied on in advancing this government-as-market-participant theory to the district court. Gov't Cross-MSJ at 27–28, ECF No. 48-1. For example, in *Building & Construction Trades Department, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002), the court concluded that the federal

government acts in a "proprietary capacity" when it uses federal money to fund construction projects on private property, because the government "act[s] just as would a private entity," such as "private lender or a benefactor" of the project. *Id.* at 35. Here, by contrast, no private payer in the health insurance market could unilaterally exact fines and other monetary penalties for a drug manufacturer's refusal to accede to the payer's chosen price. In running the Program, the government does not "act just as would a private entity." SPA21. It deploys powers that are uniquely governmental.

The presence of coercive penalties also distinguishes this case from *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), and other cases holding that participation in Medicare is voluntary for healthcare providers. *See* SPA21–23. In *Garelick*, for example, anesthesiologists alleged that a law limiting the amount physicians could receive in reimbursements under Medicare Part B effected a taking of their property under the Fifth Amendment. 987 F.2d at 916. In rejecting the anesthesiologists' takings claim, the Second Circuit reasoned that "there is no legal compulsion to provide service and thus there can be no taking" when "a service provider voluntarily participates in a price-regulated program or activity." *Id.* at

916–17. And this Court determined that the doctors "voluntarily participate[d]" in Medicare, despite their insistence that foregoing participation in Medicare was "not an economically viable option" for providers. *Id.* As discussed below, the "economic hardship" that pressures manufacturers to stay in the Program is "equivalent to legal compulsion." *Id.* at 917; *infra* Part I.B. Moreover, *Garelick* did not involve any congressional use of "taxes," penalties, or fines to enforce price controls, so it has no bearing on the constitutionality of the Program, which *does* incorporate those classic elements of governmental compulsion.

This case is instead like those, relied on by Boehringer, in which a private party was compelled to comply with a government mandate on pain of a monetary penalty. Boehringer MSJ at 36–37, ECF No. 28-1. In *Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937), for example, cotton growers were required to sign an agreement with the Secretary of Agriculture setting production limits, or else pay a "tax" designed to "compel submission" to the cotton-production quotas. *See id.* at 484. Just as "[n]o farmer . . . was in position to refuse to sign the agreement which the act required and to accept his allotment as the Secretary made it," no

manufacturer is in a position to refuse to sign onto the Program. *Id.*; *see also United States v. Butler*, 297 U.S. 1, 70–71 (1936) (invalidating law that sought to restrict agricultural production by conditioning agricultural subsidies funded by a "so-called tax" on farmers on the farmers' agreement to join purportedly "voluntary" cooperatives); *Carter Coal*, 298 U.S. at 289 (concluding that purportedly voluntary "agreement" to participate in coal-regulation program "lack[ed] the essential element of consent" because "[o]ne who does a thing in order to avoid a monetary penalty does not agree"). The penalties manufacturers face if they choose not to participate in the Program coerce their participation. Because of those penalties, participation in the Program is not voluntary.

B. Other Features of the Program Confirm That It Is Not Voluntary.

For other reasons beyond the monetary penalties, manufacturers' participation in the Program is coerced, not voluntary. Indeed, the coercive components of the Program are a feature, not a bug: the Program cannot achieve the asserted goal of "improv[ing] access" to "brand name Part B and Part D drugs," CMS, *Medicare Drug Price*

Negotiation, https://tinyurl.com/4ka4n8bv (last visited Nov. 11, 2024), unless the drugs subjected to price-setting remain available to Medicare and Medicaid beneficiaries. Consistent with that, Congress took no chances—it locked manufacturers in.

As already discussed, the district court's conclusion that participation is voluntary rested on its mistaken view that "manufacturers seeking to escape the Program can opt out of Medicare and Medicaid." SPA15. To avoid the mandate to negotiate, the government's price controls, and the mandatory "excise tax," a manufacturer would be required to "terminat[e] . . . *all* applicable agreements" with the Department of Health and Human Services ("HHS") governing Medicare and Medicaid coverage for *all* of the manufacturer's drugs—not just the selected drug. 26 U.S.C. § 5000D(c) (emphasis added).

The facts of this case illustrate just how coercive that feature of the Program is in real-world application. To "escape the Program," SPA15, Boehringer would need to terminate its Medicare and Medicaid agreements with the government, which cover not only Jardiance, but more than 20 total Boehringer products, Boehringer MSJ at 35 (citing

Marsh Decl.). No drug manufacturer can realistically be expected to curtail millions of Medicare and Medicaid patients' access to medical treatments, including treatments that are completely unrelated to the treatment for which the government has set its price.[4] For Boehringer, for example, this would result in more than 1.3 million Americans losing insurance coverage for Jardiance alone. Boehringer MSJ at 35 (citing Marsh Decl.). For many of these patients, Jardiance is a critical—even lifesaving—medicine, helping to treat conditions from type 2 diabetes to heart failure to end-stage kidney disease. As Boehringer explained to the district court, ending its Medicare and Medicaid agreements with the government would thus "compromise [Boehringer's] core values of 'improving human health and responsibility to the community,'" Boehringer MSJ Reply at 12, ECF No. 92 (quoting Marsh Decl.). The district court simply ignored this consequence. SPA21.

[4] Moreover, as Boehringer has explained, the Medicare statute forbade Boehringer and other manufacturers from withdrawing from the Program in time to avoid the deadline for signing a manufacturer "agreement" and participating in the "negotiation" process. Br. for Pl.-Appellant 55 n.25. This is an independent reason why the Program is coercive and presents no voluntary "choice" to manufacturers.

In addition, terminating Boehringer's Medicare and Medicaid contracts for all of its products would drive a wedge between Boehringer and nearly half of the U.S. healthcare market. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023) ("Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs." (citing Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 8 (2022))). In 2022, for example, 55% of Boehringer's net sales came from Medicare and Medicaid. Boehringer MSJ at 35 (citing Marsh Decl.). The district court brushed aside these market realities, but they render the choice between participating in the Program and "withdrawing from Medicare and Medicaid" illusory, SPA15; *see also Butler*, 297 U.S. at 71 (concluding that a scheme was not "voluntary" because it amounted to "coercion by economic pressure," making "[t]he asserted power of choice . . . illusory"); *cf. Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 500 (5th Cir. 2024) (observing that a drug manufacturer might accede to the Program's price controls simply "because doing so is preferable to losing the Medicare market for all of its drugs"). As discussed, these realities were not lost on Congress in enacting the IRA.

Recently, in *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), the Supreme 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 by Congress to lock States into the expanded Medicaid program while pretending to give them a choice. This Court should do the same here. As in *NFIB*, the Program "is a gun to the head": It leaves manufacturers with no meaningful choice but to participate in the Program. *Id.* at 581–82.

The district court dismissed *NFIB* because it involved a federal-state program, not government "dealing[s] with private parties." SPA29. But the *NFIB* Court's coercion analysis did not hinge on the coerced parties' identities as states. Every step of the Court's analysis applies equally well to similarly situated private parties. And in the end, here as there, the Program amounts to "economic dragooning that leaves"

manufacturers "with no real option but to acquiesce." *NFIB*, 567 U.S. at 582.

At all events, the Court should recognize that the district court's effort to distinguish *NFIB* gets things exactly backwards. States are 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 against government exactions. The district court erred in reaching the opposite conclusion.

II. A DECISION UPHOLDING THE DRUG PRICE "NEGOTIATION" PROGRAM WOULD THREATEN INVESTMENT, INNOVATION, AND PUBLIC-PRIVATE PARTNERSHIPS.

A. A Decision Upholding the Program Would Undermine Crucial Incentives for Investment and Innovation.

If sustained, the district court's failure to protect individual property rights would have serious consequences. A decision upholding the Program would undercut protections for property rights and incentives for innovation in the pharmaceutical sector and beyond. The resulting decline in innovation and economic growth would harm

businesses and individual citizens, including patients (in the health care context), workers, and families.

Protection of private property rights is a fundamental principle of our constitutional order, fully embraced in the Bill of Rights. Most relevant to Boehringer's claims, the Takings Clause of the Fifth Amendment bars the government from taking private property for public use without just compensation. And the same Amendment forbids the deprivation of property without due process of law.

The Constitution enduringly protects these rights, regardless of what policy goals a majority of Congress might embrace at any given moment. It does so based on the recognition that a stable rule of law, complete with robust protections for private property, is critical to economic prosperity and the common good. As James Madison explained: "What farmer or manufacturer will lay himself out for the encouragement given to any particular cultivation or establishment, when he can have no assurance that his preparatory labors and advances will not render him a victim to an in-constant government?" The Federalist No. 62 (James Madison). Farmers, manufacturers, and businesses alike would have little incentive to invest in their own

operations if their return on that investment could be taken from them without fair compensation. By contrast, a rule of law with robust protections for private property allows citizens and businesses to invest with confidence and incentivizes them to "hazard [their] fortunes" on "new branch[es] of commerce." *Id.*

Stable, reliable incentives for investment and innovation are especially important in industries like the pharmaceutical sector. Drug development and manufacturing are high-risk endeavors that require massive capital outlays over long periods of time. The process of developing a new drug involves years and years of research followed by a lengthy and complex FDA approval process. Most of these efforts fail before they reach the clinical trial phase, and almost 90% of drugs that do enter clinical trials ultimately fail to receive FDA approval. *See* Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* at 2 (Apr. 2021), https://tinyurl.com/237rx2hp. All of this work is cost-intensive: Estimates that account for unsuccessful clinical trials place the median research and development costs per FDA-approved drug at $1.1 billion. *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) (analyzing the years 2009 to 2018). And only a tiny fraction of FDA-approved drugs generate enough revenue to cover even their own development costs. *See* Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 665 (2016).

Despite the uncertainty, expense, and time-investment required to develop new drugs, the U.S. pharmaceutical sector has long invested with confidence in new drug development, because our system of laws has generally guaranteed strong protections for private property. But when the government upends a decades-old regime respecting manufacturers' property rights and enacts a policy that confiscates the returns on private-sector investment, it diminishes resources and incentives for further investment.

In the case of the IRA, the negative impacts of this are predictable. In one recent survey, over three-quarters of pharmaceutical companies report that, because of the IRA's price-setting provisions, they anticipate cutting projects in the early stages of clinical development; two-thirds will not pursue projects not yet in the clinical phases. PhRMA, *Inflation Reduction Act's Unintended Consequences*, https://tinyurl.com/4avptkjh

(last visited Nov. 11, 2024); *see also* Suchita Shah et al., *Boston Consulting Grp., Navigating the Inflation Reduction Act's Impact on Drug Pricing and Innovation* (Sept. 14, 2023), https://tinyurl.com/y2ktpyy ("Several companies have already abandoned clinical trials or assets, and many more have said that the IRA influences their clinical development decisions."). Reductions like these in research and development will harm workers in an important U.S. industry: Models predict a loss of between 66,800 and 135,900 jobs in the biopharmaceutical industry from the Program. *See* Daniel Gassull et al., Vital Transformation, *IRA's Impact on the US Biopharma Ecosystem* at 29–30 (June 1, 2023), https://tinyurl.com/cbdy6a4x. And the consequences for patients are potentially devastating: By one estimate, the Program will result in approximately 140 drugs over the next 10 years never being developed. *Id*. at 2, 16. The IRA's provisions thus pose threats both to a basic principle of our constitutional order and to innovation in a critical industry that saves lives.

B. A Decision Upholding the Program Would Threaten Public-Private Partnerships in a Range of Sectors.

The Program also jeopardizes essential partnerships between private companies and the government. The government often relies on public-private partnerships to advance important policy objectives. Medicare is one such program, enlisting private companies, alongside the government, in providing essential health benefits to millions of Americans. For private-sector manufacturers, the Program represents a bait-and-switch that threatens to deter businesses across the economy from partnering with the government to improve the lives of Americans.

For decades, Congress induced pharmaceutical manufacturers to invest in selling products to Medicare (and in *developing* such products) with promises of market-based pricing and non-interference by government entities. 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.* It did so by expressly prohibiting the government from setting drug prices or

"interfer[ing]" in market-based negotiations between manufacturers and pharmacies and prescription drug plan sponsors. *Id.* § 1395w-111(i)(1). Thus, before the enactment of the IRA, pharmaceutical manufacturers and other private parties negotiated drug prices for Medicare under Part D without any interference by the government. More broadly, Congress's decision 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.

The IRA upends that bargain. Enacted after the government had achieved dominance in the prescription drug market, 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, the IRA directs HHS to mandate the prices of essential and widely used medicines. And it uses as leverage the manufacturer's ability to sell any of its products (even those unrelated to the selected drug) to Medicare and Medicaid patients.

By upending the market-based pricing system that had governed Medicare for many years and reversing the government's commitments to its private-sector partners, while also locking manufacturers into the

Program, the IRA threatens the government's ability to attract and retain willing partners in a range of industries. As the Supreme Court has recognized in the related context of government contracting, if the federal government does not act as "a reliable contracting partner" that honors its commitments, then partnerships will "become more cumbersome and expensive for the Government, and willing partners more scarce." *Salazar v. Ramah Navajo Chapter*, 567 U.S. 182, 191–92 (2012). This is because potential partners "would bargain warily—if at all—and only at a premium large enough to account for the risk" of the government failing to keep its promises. *Id.* From the private sector's standpoint, governmental partnerships demand significant investments of time, money, and resources to comply with congressional mandates and regulatory requirements. Of course, businesses assume a level of risk in these partnerships, as they do in every other endeavor. But the unique risk posed by private-public partnerships—if the district court's view is accepted—is that whenever the winds shift, the government may restructure such a deal unilaterally while using coercive regulatory tools, such as financial penalties, to prevent the business from walking away. Indeed, CMS has unabashedly announced its sole power to amend its

"agreement" with drug manufacturers at any time. *See* JA299. Private counterparties lack that power.

If allowed to stand, the IRA's model for coercion threatens the government's ability to rely on private industry to help address major challenges. During the COVID-19 pandemic, the government depended heavily on companies in the pharmaceutical and healthcare industries for initiatives such as Operation Warp Speed, which supported the development of multiple life-saving vaccines. *See* Press Release, White House, *FACT SHEET: President Biden Announces Increased Vaccine Supply, Initial Launch of the Federal Retail Pharmacy Program, and Expansion of FEMA Reimbursement to States* (Feb. 2, 2021), https://tinyurl.com/745rvda8 (noting that a "public-private partnership with 21 national pharmacy partners" was a "key component" of the government's strategy "to expand equitable access to vaccines for the American public"). Whatever the next public health emergency, there is little doubt that the government will again seek to draw heavily on private industry to meet the challenge.

Outside of public health, the government depends on private-sector partnerships in pursuing other policy priorities, such as affordable

housing, infrastructure, and protecting national security. As the Department of Housing and Urban Development (HUD) has explained, in the realm of affordable housing, "most HUD programs are structurally public-private partnerships" or "have some public-private aspects." HUD, Off. of Pol'y & Rsch., *The Evolution of HUD's Public-Private Partnerships: A HUD 50th Anniversary Publication* 1 (2015), https://tinyurl.com/mtutkv65. These partnerships "enable government to share risks with the private sector, leverage investments for far greater effect, take advantage of efficiencies outside government, and employ broader knowledge and skills." *Id.* at 2. Similarly, the Department of Homeland Security has made "partnerships between the public and private sectors" the "foundation and the lifeblood" of "maintaining critical infrastructure security and resilience" in the cyber realm. Cybersecurity & Infrastructure Sec. Agency, *Partnerships and Collaboration*, https://tinyurl.com/bduhncdn (last visited Nov. 11, 2024). If permitted to stand, the IRA threatens investment, innovation, and public-private collaboration in the pharmaceutical sector and across the economy.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment of the district court.

November 12, 2024

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CERTIFICATE OF SERVICE

I hereby certify that, on November 12, 2024, an electronic copy of the foregoing Brief for *Amicus Curiae* the Chamber of Commerce of the United States of America in Support of Plaintiff-Appellant was filed with the Clerk of Court using the ECF system and thereby served upon all counsel appearing in this case.

November 12, 2024

/s/ Kwaku A. Akowuah

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