

Nos. 24-1820(L) & 24-1821(M)

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRISTOL MYERS SQUIBB CO,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *et al.*

Defendants-Appellees,

JANSSEN PHARMACEUTICALS INC,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *et al.*

Defendants-Appellees,

On Appeal from the United States District Court
for the District of New Jersey, Nos. 3-23-cv-03335, 3-23-cv-03818
Hon. Zahid N. Quraishi

**BRIEF FOR *AMICUS CURIAE* THE CHAMBER OF
COMMERCE OF THE UNITED STATES OF AMERICA IN
SUPPORT OF APPELLANTS**

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CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America (“Chamber”) 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 Inflation Reduction Act's so-called "Drug Price Negotiation Program" (the "Program") sets a dangerous precedent for the American free-enterprise system. Whatever the industry that is targeted, confiscatory laws violate the fundamental constitutional rights of all Americans and undermine incentives for private-sector innovation, investment, and collaboration with the government. The Chamber has a

¹ 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.

strong interest in explaining these ramifications and in advocating for robust constitutional protections for private property.²

INTRODUCTION

The IRA's prescription-drug program poses a grave threat to the rights of American businesses and the interests of all those who depend on them. Although the law aims to restructure the workings of a single industry, the fundamental principles at stake reach far beyond that sector. The Chamber files this *amicus curiae* brief to highlight three of the Program's broader ramifications for the American system of free enterprise and property rights.

First, when the government confiscates companies' returns on their investments, it flouts basic constitutional protections for private property and thereby saps the entrepreneurial initiative that drives investment, innovation, and economic progress. Securing property rights was of

² The Chamber has joined with other chambers of commerce in a separate constitutional challenge to the Program, *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-156 (S.D. Ohio). That case, which presents a somewhat different set of claims and issues than those raised in these cases, is awaiting a decision on cross-motions for summary judgment. This *amicus curiae* brief covers different ground, focusing primarily on background principles, crucial for the entire private sector, that apply far beyond the specifics of the Program at issue here.

paramount importance to the Framers of the Constitution, and for good reason. Unjust deprivations of private property not only harm their immediate victims, but are detrimental to society as a whole because they undermine the rule of law and erode the foundations of national prosperity.

Second, for the Constitution's protections of private property and free enterprise to be effective, courts must police both direct and indirect means of expropriation. Even assuming that the Program can be framed as a condition on government benefits rather than a coercive mandate in its own right, the Supreme Court has emphasized the importance of substance over form, and the well-established unconstitutional-conditions doctrine has long restrained the government from withholding benefits to induce the surrender of constitutional rights. Despite this time-honored principle and its especially important role in preserving property rights and freedom of commerce, the district court in this case gave it short shrift, misconstruing it so badly as to render it a dead letter.

Third, the Program threatens the integrity of the public-private partnership model that has enabled the government to benefit from the unmatched dynamism, efficiency, and capital of private enterprise. The

government has long relied on partnerships with private companies to advance important policy priorities in critical fields, of which health care is only one. By upending Medicare’s established system of market-based pricing, reneging on longstanding statutory commitments, and defying basic constitutional guarantees, the Program disrupts critical reliance interests and degrades the government’s reputation as a reliable business partner. If allowed to stand, this bait-and-switch will further diminish the trust and confidence needed to facilitate investment in a wide range of important projects that depend on effective public-private collaboration.

ARGUMENT

I. Confiscatory Government Policies Violate Bedrock Constitutional Protections and Undermine Crucial Incentives for Investment and Innovation.

A. Property Rights Are Central to the Constitution’s Design and Historical Purpose.

Protection of private property is a fundamental principle of American freedom and constitutional government. The Bill of Rights protects private property not once but several times, in several different ways. Most prominently, the Takings Clause of the Fifth Amendment prohibits the government from taking property for public use without just

compensation. The Fifth Amendment also bars the deprivation of property without due process of law. Meanwhile, the Third and Fourth Amendments guard against government encroachment on property by, respectively, forbidding the forced quartering of soldiers (except by law during wartime) and prohibiting unreasonable searches and seizures. Beyond the Bill of Rights, the Patent and Copyright Clause and the Contracts Clause reflect a similar commitment to property rights and economic freedom. And fundamental structural features of the Constitution, such as the separation of powers, are designed in large part to prevent concentrations of power that threaten liberty and property. See Renée L. Lerner, *Enlightenment Economics and the Framing of the U.S. Constitution*, 35 Harv. J.L. & Pub. Pol’y 37, 37–46 (2012); The Federalist Nos. 48, 51 (James Madison).

The Constitution’s meticulous safeguards for private property are no accident. Indeed, “the protection of property” was the Framers’ “central concern” at the Constitutional Convention of 1787, where “[o]ne delegate after another proclaimed its cardinal importance.” Bret Boyce, *Property as Natural Right and as a Conventional Right in Constitutional Law*, 29 Loyola L.A. Int’l Comp. L. Rev. 201, 245 (2007). Alexander

Hamilton explained that “[o]ne great obj[ect] of Gov[ernment] is personal protection and the security of Property.”¹ The Records of the Federal Convention of 1787, at 302 (Max Farrand ed., 1911). Gouverneur Morris similarly affirmed that “property was the main object of Society.” See *Madison Debates: Notes on the Debates in the Federal Convention: July 5, 1787*.³ And Madison extolled property rights as one of only two “cardinal objects of Government.” James Madison, Observations on Jefferson’s Draft of a Constitution for Virginia (Oct. 15, 1788), in 1 Founders’ Constitution ch. 17, doc. 25 (1986).⁴ As Madison explained, “[g]overnment is instituted to protect property of every sort,” and “that alone is a *just* government, which *impartially* secures to every man, whatever is his *own*.” James Madison, Property (1792), in 1 Founders’ Constitution ch. 16 doc. 23 (1986).⁵ In recognizing the central importance of property rights to a just government, the Framers were deeply influenced by the classical liberal political philosophy of John Locke, who

³ Available at https://avalon.law.yale.edu/18th_century/debates_705.asp.

⁴ Available at <https://press-pubs.uchicago.edu/founders/documents/v1ch17s25.html>.

⁵ Available at <https://press-pubs.uchicago.edu/founders/documents/v1ch16s23.html>.

identified the “preservation of . . . property” as the “great and *chief end*” of government. John Locke, *Second Treatise*, ch. IX, § 124 (1689) *in* 1 Founders’ Constitution ch. 16 doc. 3.⁶

The principle of just compensation for takings of property also has deep roots in the Anglo-American common law tradition. As Blackstone explained, “[s]o great . . . is the regard of the law for private property, that it will not authorize the least violation of it; no, not even for the general good of the whole community.” 1 William Blackstone, *Commentaries on the Laws of England* *139. If the legislature required property owners to surrender their property for the common good, Blackstone insisted, it must give them “a full indemnification and equivalent for the injury thereby sustained.” *Id.* Drawing on that tradition, founding-era cases such as *VanHorne’s Lessee v. Dorrance* described the principle of just compensation as fundamental to “reason, justice, and moral rectitude.” 2 U.S. (2 Dall.) 304, 310 (C.C.D. Pa. 1795); *see also Bowman v. Middleton*, 1 Bay 252, 252 (Ct. Com. Pl. S.C. 1792) (“It was against common right, as well as against Magna Charta, to take

⁶ Available at <https://press-pubs.uchicago.edu/founders/documents/v1ch16s3.html>.

away the freehold of one man and vest it in another . . . without any compensation.”)

B. Confiscatory Policies Threaten Investment, Innovation, and Economic Growth.

The Framers sought to protect property not only as a matter of basic fairness, but also for the practical reason that strong property rights would be essential to the new nation’s prosperity. Hamilton and Madison had read Adam Smith’s classic *Wealth of Nations*—published the same year as the Declaration of Independence—and carefully absorbed its economic lessons. Lerner, 35 Harv. J.L. & Pub. Pol’y at 39–40. As Madison wrote in Federalist No. 62: “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?” Farmers and manufacturers would have little incentive to improve and expand their operations if the fruits of their labor and capital could be taken from them without fair compensation. A stable rule of law with robust protections for private property, in contrast, would allow people to invest with confidence and incentivize them to “hazard [their] fortunes” on “new branch[es] of commerce.” *Id.*

History has borne out these economic lessons. In the nineteenth and twentieth centuries, while agricultural production and manufacturing flourished in the United States, it languished in countries that failed to respect property rights. At one extreme, for example, in the Soviet Union, policies such as forced collectivization of farms and requisitioning of grain at fixed government prices led to widespread famine and increasing dependency on foreign imports. See David Marcus, *Famine Crimes in International Law*, 97 Am. J. Int'l L. 245, 253 (2003); Viktor Kondrashin, *The Effect of Collectivization on the Fate of Russia in the 20th Century*, 92 Herald of Russian Acad. of Scis. S204, S204–S211 (2022). As one Russian scholar observed, “[t]he system tore the peasant away not only from the land but also from the ownership of the products produced,” leaving him “no incentive to show his abilities . . . or us[e] land and other resources prudently.” *Id.* at S210 (quotation marks omitted).

Even less extreme confiscatory policies hamper economic progress. In developing countries, a lack of security against expropriation has historically been one of the main obstacles to investment and economic growth. See Angus Maddison, *Economic Progress and Policy in*

Developing Countries 221–22 (2006) (noting historical “risk of expropriation with inadequate compensation” in countries such as Egypt, Algeria, and Indonesia, “either because of nationalist policies against foreign investors, or of socialist policies against private capitalists”). A globalized economy creates new opportunities for investment from a wider range of sources, but also enables the flight of capital away from jurisdictions with unfavorable regulatory climates. *See id.*; Matthew S. Bethards, *Condemning A Patent: Taking Intellectual Property by Eminent Domain*, 32 AIPLA Q.J. 81, 116–19 (2004) (“Multinational firms will become less willing to invest in a sector where the government is disposed to taking things for what the firms view to be less than fair”).

The greater the “threat of confiscatory policies,” the less likely potential investors will be to risk their capital, even on projects that would otherwise yield high returns. *See* Margarita Kalamova & Nick Johnstone, *Environmental Policy Stringency and Foreign Direct Investment* 12 (OECD Env’t Working Paper No. 33, 2011). “Unless the government can credibly commit to not make use of the opportunities to expropriate, or can compensate investors upfront, investors will not invest if they anticipate that, at least, part of the returns on their

investments are confiscated.” *Id.*; see, e.g., Pham van Thuyet, *Legal Framework and Private Sector Development in Transitional Economies: The Case of Viet-nam*, 27 *Law & Pol’y Int’l Bus.* 541, 572–73 (1996) (describing a typical “incentives package” for foreign direct investment, including “a guarantee against nationalization or expropriation”).

When the government confiscates the returns on private-sector investment, it dampens incentives for further investment—even in other industries—because it sets a precedent that may later be repeated. In the academic literature on the just-compensation principle, the losses in social welfare due to these diminished incentives are sometimes referred to as “demoralization costs.” See Michael A. Heller & James E. Krier, *Deterrence and Distribution in the Law of Takings*, 112 *Harv. L. Rev.* 997, 1003 (1999). As described in an influential article by Frank Michelman, “demoralization costs” consist of “lost future production” caused not only by the demoralization of the uncompensated victim of a taking, but also by the impaired incentives of “other observers disturbed by the thought that they themselves may be subjected to similar treatment on some other occasion.” Frank I. Michelman, *Property, Utility, and Fairness: Comments on the Ethical Foundations of “Just Compensation” Law*, 80

Harv. L. Rev. 1165, 1214 (1967); *see, e.g.*, Valerie Jaffee Washburn, *Regular Takings or Regulatory Takings?: Land Expropriation in Rural China*, 20 Pac. Rim L. & Pol’y J. 71, 98 (2011) (referring to the effects of land expropriation on agricultural productivity as “a clear example of Michelman’s ‘impaired incentives’”). Members of the U.S. business community outside the pharmaceutical sector cannot but observe what Congress did to private businesses in the IRA, and to reflect on its implications for businesses in other sectors.

Stable, reliable incentives for investment and innovation are especially important in endeavors that, like pharmaceutical development and manufacturing, require large capital outlays over a lengthy period of time. *See generally* Amicus Br. of Biotechnology Innovation Organization. The process of developing new drugs—conducting cutting-edge research, navigating the lengthy FDA approval process, and bringing the drugs to patients in need—is remarkably time-consuming, uncertain, and expensive. Of the tiny fraction of medicines approved for patient use, an even smaller fraction generate enough revenue to cover 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). When the IRA’s prescription-drug program forces takings without just compensation, it undercuts the strong property-rights protections and critical incentives needed for growth and innovation—not only in the pharmaceutical sector and in the capital investment community that supports that sector, but throughout the economy as a whole. Ultimately, that decline in growth and innovation harms individual Americans—especially, in the health-care context, patients and their families.

II. The Unconstitutional-Conditions Doctrine Is a Vital Protection for American Business and Private Property.

Confiscation does not always take the form of direct mandates. Instead of directly “order[ing]” someone to hand over property, officials may “attempt[] to pressure that person” indirectly by withholding government benefits, privileges, or permits. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013). But “our Constitution deals in substance, not form,” *Sheetz v. County of El Dorado*, 601 U.S. 267, 281 (2024) (Gorsuch, J., concurring), and it “nullifies sophisticated as well as simple-minded modes’ of infringing on constitutional protections,” *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995) (quoting *Lane v. Wilson*, 307 U.S. 268, 275 (1939)). As the Supreme Court has long

recognized, “[t]he indirect way in which [a property right] has been destroyed does not alter the principle; for what cannot lawfully be done directly, cannot be done indirectly.” *Proprietors of Charles River Bridge v. Proprietors of Warren Bridge*, 36 U.S. 420, 456 (1837).

One expression of that fundamental principle is what has come to be known as the “unconstitutional conditions doctrine.” *Koontz*, 570 U.S. at 604. Under that “well-settled” doctrine, *id.* (quotation marks omitted), the government “may not deny a benefit to a person on a basis that infringes his constitutionally protected interests,” *Sheetz*, 601 U.S. at 275–76 (quoting *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)). Although the unconstitutional-conditions doctrine has been applied in “a variety of contexts,” *Koontz*, 570 U.S. at 604, it has long been an especially important protection for free enterprise and property rights. See Jan G. Laitos, *Causation and the Unconstitutional Conditions Doctrine: Why the City of Tigard’s Exaction Was a Taking*, 72 *Denv. U. L. Rev.* 893, 894–95 (1995) (“[P]roperty rights protected by the Fifth Amendment are a category of rights for which the unconstitutional conditions doctrine is particularly relevant”); Christopher M. Kieser, *What We Have Here Is a Failure to Compensate: The Case for a Federal*

Damages Remedy in Koontz “Failed Exactions,” 40 Wm. & Mary Env’t L. & Pol’y Rev. 163, 165 (2015) (noting that the right not to have property taken without just compensation “has been robustly protected by the unconstitutional conditions doctrine”).

For example, in the seminal case *Frost v. Railroad Commission*, 271 U.S. 583 (1926), the Supreme Court struck down a state’s attempt to condition the privilege of using public highways on a private company’s submission to common-carrier regulations. Under the Constitution’s protections for private property, the Court noted, “a private carrier cannot be converted against his will into a common carrier by mere legislative command.” *Id.* at 592. The question, then, was “whether the state may bring about the same result by imposing the unconstitutional requirement as a condition precedent to the enjoyment of a privilege.” *Id.* The Court rejected that end-run around the Constitution. “Having regard to form alone,” the Court explained, the state law was “an offer to the private carrier of a privilege” upon “a condition which the carrier is free to accept or reject.” *Id.* at 593. “In reality,” however, the carrier had “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.” *Id.* Allowing such a condition to stand would leave “constitutional guaranties, so carefully safeguarded against direct assault . . . open to destruction by the indirect, but no less effective, process of requiring a surrender” of a valuable privilege, “which, though in form voluntary, in fact lacks none of the elements of compulsion.” *Id.*

Frost followed a long line of cases invalidating conditions on economic freedoms on similar grounds. *See id.* at 594–98. For instance, in *Union Pacific Railroad Co. v. Public Service Commission*, 248 U.S. 67 (1918), the Court invalidated a fee levied on an out-of-state corporation’s bond issuance as a condition of the corporation’s doing business in the state. Although the company had nominally agreed to pay the fee, it “gave notice that it paid under duress to escape the statutory penalties.” *Id.* at 68. The Court held that economic “duress” negated the purported “choice,” explaining that the government could not “impose an unconstitutional burden by the threat of penalties worse than [that burden]” and “then to declare the acceptance voluntary.” *Id.* at 70.

With the New Deal and a rising tide of economic interventions by federal, state, and local governments, unconstitutional-conditions

questions became even more salient. See Adam B. Cox & Adam M. Samaha, *Unconstitutional Conditions Questions Everywhere: The Implications of Exit and Sorting for Constitutional Law and Theory*, 5 J. Legal Analysis 61, 69 (2013) (noting that “unconstitutional conditions questions have been considered pressing since at least the New Deal”). The modern regulatory and welfare state tends to “generate, or at least increase the frequency of” such questions because “[t]he more goods, services, and exemptions that may be offered by the government at the behest of ordinary politics, the greater is the opportunity for government officials to condition those benefits on the sacrifice of constitutional rights.” *Id.*

The Court confronted one such scheme in *United States v. Butler*, 297 U.S. 1 (1936), which invalidated part of the Agricultural Adjustment Act of 1933. The Act sought to restrict agricultural production in ways Congress otherwise could not have done by conditioning agricultural subsidies—funded by a “so-called tax” on farmers—on the farmers’ agreement to join purportedly “voluntary” cooperatives. *Id.* at 58–59, 70–71. The Court concluded that the scheme was “not in fact voluntary” because it amounted to “coercion by economic pressure,” rendering “[t]he

asserted power of choice . . . illusory.” *Id.* at 71 (citing *Frost*, 271 U.S. 583); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (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 unconstitutional-conditions doctrine continues to be a crucial protection for property rights today. The Supreme Court has recently and repeatedly reaffirmed that the doctrine applies with full force to conditions designed to induce the relinquishment of land or personal property. *See, e.g., Sheetz*, 601 U.S. at 275–76 (monetary exaction); *Koontz*, 570 U.S. at 612 (monetary exaction); *Dolan v. City of Tigard*, 512 U.S. 374, 386 (1994) (public easement); *Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825, 834–37 (1987) (public easement). As the Court has explained, “[b]y conditioning” a government benefit on a taking of private property, “the government can pressure an owner” into “voluntarily” giving up property “for which the Fifth Amendment would otherwise require just compensation.” *Koontz*, 570 U.S. at 605. So long as the benefit is important enough, the government can “leverage[e]” its

“monopoly” over the benefit “to exact private property without paying for it.” *Sheetz*, 601 U.S. at 275. And because of the government’s monopoly power, “the owner is ‘likely to accede to the government’s demand, no matter how unreasonable.’” *Id.* (quoting *Koontz*, 570 U.S. at 605). The unconstitutional-conditions doctrine restrains the government from making such “[e]xtortionate demands” by ensuring that any condition (1) has an “essential nexus” to the benefit and (2) is “rough[ly] proportional” to it. *Koontz*, 570 U.S. at 605–06.

Despite the fundamental importance of the unconstitutional-conditions doctrine and its particular relevance in protecting property rights, the district court’s discussion of it here was cursory and confused. Without undertaking the requisite nexus-and-proportionality analysis, the court deemed the doctrine irrelevant because the court had “already found” that the Program did not constitute an unlawful taking. JA25. But that gets the proper approach backwards. When the government tries to defend a potential taking by framing it as a voluntary condition, the unconstitutional-conditions doctrine is part and parcel of the analysis needed to determine whether a taking occurred in the first place. *See Koontz*, 570 U.S. at 604–06; *Dolan*, 512 U.S. at 391; *Nollan*, 483 U.S. at

834–37. Only after applying the doctrine can the court distinguish reasonable demands from “out-and-out . . . extortion.” *Koontz*, 570 U.S. at 604–06 (quoting *Nollan*, 483 U.S. at 837). The district court’s circular reasoning left the doctrine no work to do, reducing it to a redundant afterthought. As the Supreme Court observed nearly a century ago, “[i]t is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence.” *Frost*, 271 U.S. at 594.

III. The Program’s Bait-and-Switch Threatens the Integrity of Public-Private Partnerships in a Wide Range of Sectors.

In addition to undermining incentives for private-sector investment and innovation, the IRA’s prescription-drug program jeopardizes the integrity of partnerships between private companies and the government. The government often relies on public-private partnerships, in health care and many other sectors, to harness the power of private-sector competition and innovation and to advance important policy objectives. Yet for private-sector participants in Medicare, the Program is a massive bait-and-switch. For decades, Congress enticed pharmaceutical companies to invest in selling products to Medicare (and in developing such products) with promises of market-based pricing and

non-interference by government entities. Then, when the government had achieved dominance in the prescription-drug market, Congress enacted the IRA—reneging on its promises, disrupting important reliance interests, and parlaying its monopsony power into a confiscatory scheme. If allowed to stand, that gambit will threaten the norms of trust and reciprocity that underlie public-private cooperation and deter businesses from partnering with the government in a wide variety of contexts.

The government frequently seeks out public-private partnerships to advance significant policy goals. A notable recent example is the government’s partnerships with companies in the pharmaceutical and healthcare industries, through initiatives such as Operation Warp Speed, to combat the COVID-19 pandemic. As the government explained at the time, “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.”⁷ Whatever the next public-

⁷ 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://www.whitehouse.gov/briefing-room/>

health emergency, there is little doubt that the government will again need to depend heavily on private industry to meet the challenge.

The federal government also depends on private-sector collaboration for other key priorities such as developing the nation's infrastructure, protecting national security, and promoting affordable housing. As the Department of Transportation has emphasized, “[e]arly involvement of the private sector can bring innovation, efficiency, and capital to address complex transportation problems.”⁸ DOT “encourages” state and local governments to consider such partnerships, including arrangements in which private companies take on “project risks such as design, construction, finance, long-term operation, and traffic revenue.”⁹ Similarly, the Department of Homeland Security has made “partnerships between the public and private sectors” the “foundation and the lifeblood”

statements-releases/2021/02/02/fact-sheet-president-biden-announces-increased-vaccine-supply-initial-launch-of-the-federal-retail-pharmacy-program-and-expansion-of-fema-reimbursement-to-states/.

⁸ U.S. Dep’t of Transp., *Public-Private Partnerships (P3)* (Jan. 3, 2024), <https://www.transportation.gov/buildamerica/p3>.

⁹ *Id.*

of “maintaining critical infrastructure security and resilience.”¹⁰ For example, one recent initiative aims to foster partnerships with chemical companies to address cybersecurity threats. As the White House observed in a press release describing the initiative, “[t]he majority of chemical companies are privately owned, so we need a collaborative approach between the private sector and government.”¹¹

As for affordable housing, the Department of Housing and Urban Development has stated that “most HUD programs are structurally public-private partnerships” or “have some public-private aspects.”¹² HUD favors public-private partnerships because they “enable government to share risks with the private sector, leverage investments

¹⁰ Cybersecurity & Infrastructure Sec. Agency, *Partnerships and Collaboration*, <https://www.cisa.gov/topics/partnerships-and-collaboration> (last visited July 10, 2024).

¹¹ Press Release, White House, FACT SHEET: Biden-Harris Administration Expands Public-Private Cybersecurity Partnership to Chemical Sector (Oct. 26, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/26/fact-sheet-biden-harris-administration-expands-public-private-cybersecurity-partnership-to-chemical-sector/>.

¹² U.S. Dep’t of Hous. & Urban Dev., Off. of Pol’y & Rsch., *The Evolution of HUD’s Public-Private Partnerships: A HUD 50th Anniversary Publication 1* (2015), https://www.huduser.gov/hud50th/HUD2-048-Public-Private_Partnership_508.pdf.

for far greater effect, take advantage of efficiencies outside government, and employ broader knowledge and skills.”¹³

Public-private partnerships are also playing a major role in the implementation of the Biden Administration’s trillion-dollar Infrastructure Investment and Jobs Act. The Chamber believes that the use of public-private partnerships is essential to modernizing America’s infrastructure and economy, including in emerging fields of science and technology.¹⁴ As the U.S. Chamber of Commerce Foundation recently noted in a letter to *Foreign Affairs*, private business is a critical element of national power, and public-private partnerships will only grow in importance as policymakers grapple with new frontiers such as digital

¹³ *Id.* at 2.

¹⁴ See U.S. Chamber of Commerce, *U.S. Chamber Mobilizes Entrepreneurs for New Coalition to Protect U.S. Innovation from Government Confiscation* (Mar. 20, 2024), <https://www.uschamber.com/intellectual-property/u-s-chamber-mobilizes-entrepreneurs-for-new-coalition-to-protect-u-s-innovation-from-government-confiscation>; U.S. Chamber of Commerce, *U.S. Chamber Hosts NATO Summit Defense Industry Forum to Enhance Crucial Private-Public Partnerships for Boosting Defense Production and Collaboration* (July 9, 2024), <https://www.uschamber.com/international/u-s-chamber-hosts-nato-summit-defense-industry-forum-to-enhance-crucial-private-public-partnerships-for-boosting-defense-production-and-collaboration>.

ecosystems, biotechnology, artificial intelligence, and quantum computing.¹⁵

These partnerships do not appear out of thin air simply because the government asks for help. When private companies participate in government-funded programs, they make substantial investments of time, money, and resources to comply with congressional mandates and regulatory requirements. They assume a certain level of risk in exchange for compensation guarantees and legal protections that are commensurate with that risk. To put their livelihoods (and lenders' and shareholders' capital) on the line, businesses must have confidence that the government will honor its statutory and constitutional obligations.

Failure to adhere to that basic bargain will have predictable consequences. As the Supreme Court has recognized in a related context, if the federal government fails to act as “a reliable contracting partner” that honors its commitments, then such collaborations will “become more cumbersome and expensive for the Government, and willing partners

¹⁵ U.S. Chamber of Commerce Foundation, *Business Is a Critical Element of U.S. National Power* (Nov. 28, 2023), <https://www.uschamberfoundation.org/emerging-issues/business-is-a-critical-element-of-u-s-national-power>.

more scarce.” *Salazar v. Ramah Navajo Chapter*, 567 U.S. 182, 191–92 (2012) (citing *United States v. Winstar Corp.*, 518 U.S. 839, 883 (1996) (plurality opinion)). That 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 reneging. *Id.* Just as private parties “must turn square corners when . . . deal[ing] with the Government,” it is “also true, particularly when so much is at stake, that the [g]overnment should turn square corners in dealing with the people.” *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 24 (2020) (quotation marks omitted). If the government backtracks on its statutory commitments and flouts constitutional constraints, private businesses will decline to participate or will be forced to raise their prices for participating in programs that depend on private-sector collaboration.

The IRA’s prescription-drug program upends the market-based pricing system that had governed Medicare for many years. Consider the Medicare Part D benefit for self-administered prescription drugs, which Congress established in 2003. In Part D’s “non-interference clause,” with the stated purpose of “promot[ing] competition,” Congress expressly prohibited HHS from setting drug prices or “interfer[ing]” in market-

based negotiations between manufacturers and pharmacies and prescription drug plan sponsors. 42 U.S.C. § 1395w-111(i). Part D's sponsors, responding to concerns that government price-setting would "destroy" innovation, 149 Cong. Rec. S15631 (daily ed. Nov. 23, 2003) (statement of Sen. Frist), noted that this non-interference provision was a "fundamental protection" against "price fixing by the CMS bureaucracy," *id.* at S15624 (statement of Sen. Grassley). Accordingly, before Congress enacted the IRA, pharmaceutical manufacturers and private counterparties negotiated drug prices under Part D without interference by the government. Congress's establishment of a market-oriented model led manufacturers to invest billions of dollars in developing innovative drugs that serve Medicare beneficiaries.

The Program eviscerates that fundamental commitment. Instead of respecting the basic terms of the government's longstanding bargain with pharmaceutical companies and allowing market forces to work, the Program seeks to bludgeon pharmaceutical companies into submission with enormous penalties, *see, e.g.*, 26 U.S.C. § 5000D, and to micromanage the pricing of dozens of the most widely used drugs in the country. In effect, the Program replaces a public-private partnership

with a command-and-control scheme. If permitted to stand, that dramatic transformation will undermine incentives for investment, innovation, and public-sector collaboration not only in the pharmaceutical field, but across the entire economy.

CONCLUSION

For the reasons set forth above and in Plaintiffs' briefs on appeal, this Court should reverse the district court's decisions upholding the Program.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. Pursuant to Local Rule 28.3(d), I hereby certify that I am a member of the bar of this Court.

2. This brief complies with the type-volume requirements of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 5,125 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

3. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) and 3d Cir. L.A.R. 32.1(c) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 ProPlus in Century Schoolbook 14-point font.

4. Pursuant to Local Rule 31.1(c), I hereby certify that the text of the electronic brief is identical to the text in the paper copies, and that it has been scanned for viruses using McAfee Endpoint Security, Version 10.7.1, and no virus was detected.

Dated: July 19, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system. I certify that all participants in the appeal are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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