24-2968

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

NOVARTIS PHARMACEUTICALS CORP.

Plaintiff- Appellants,

---v.---

U.S. SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendant- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY, No. 3:23-cv-14221

BRIEF OF LAW SCHOLARS AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE

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IDENTITY AND INTERESTS OF PROPOSED *AMICI CURIAE*[1]

Amici are law professors and scholars who focus their scholarship and teaching on intellectual property law, property law, regulatory law, and health law.[2] They write to address the plaintiff, Novartis Pharmaceuticals Corporation (Novartis), contention that the Medicare drug price negotiation program effectuates a taking of personal property in violation of the Fifth Amendment. Amici submit this brief to provide the Court with the historical and legal background necessary to understand two issues: first, the constitutionality of government price negotiations and price regulations; second, the federal government's use of patents. The amici explain how Courts have historically ruled on these questions, as well as the far-reaching consequences that a ruling in Novartis's favor would have on the federal government's ability to provide adequate healthcare to across the United States.

I. INTRODUCTION

Today, about three in ten Americans cannot afford their prescription drugs.[3]

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[1] No counsel for any party authored this brief in whole or in part. 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.

[2] Four professors in particular have guided the research, drafting, and editing of this brief: Amy Kapczynski, Christopher J. Morten, Aaron S. Kesselheim, & Ameet Sarpatwari.

[3] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, THE KAISER FAMILY FOUNDATION (Aug. 21, 2023),

High prices also drive-up insurance premiums and public spending, diverting resources from other priorities. The most decisive driver of high drug prices are the monopoly rights that governments grant to drug makers, allowing them to exclude competitors and raise prices.[4] Responding to this deadly dilemma, Congress passed the Inflation Reduction Act (IRA) and, with it, the Medicare drug price negotiation program.

This new program enables the Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), to negotiate with drug makers over the prices of a small number of drugs that the Medicare program purchases. In so allowing, this law modifies a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—the "non-interference" provision—that prevented the federal government from negotiating the prices of retail medicines it buys via Part D insurance plans that operate its Medicare Part D program. This non-interference provision—a product of extensive

https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

[4] Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 (11) JAMA INTERNAL MED. 1 (2017); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform*, 316 (8) JAMA 858 (2016).

pharmaceutical lobbying[5]—has been anomalous since its inception. The federal government negotiates prices and receives discounts on most contracts it enters, including for drugs it purchases for patients covered by the Veterans Health, Section 340B, and Medicaid programs. Yet, it is forbidden from doing the same for Medicare. The IRA's Medicare drug price negotiation program marks an attempt to bring Medicare in line with the other government-sponsored insurance programs, for a limited number of high-revenue drugs, many years after their makers put them on the market.

Novartis now argues that they have a constitutional right to the monopoly prices they have been charging the government. Pharmaceutical companies enjoy some of the highest profit margins in the United States—and will continue to do so even after full implementation of this program.[6] But this reality does not endow them with a Fifth Amendment *right* to a certain price or level of profits when

[5] *See* Judie Svihula, *Political Economy, Moral Economy and the Medicare Modernization Act of 2003*, 35 J. SOCIO & SOC. WELFARE 157, 161 (2008); *Drug Industry and HMOs Deployed an Army of Nearly 1,000 Lobbyists to Push Medicare Bill, Report Finds*, PUB. CITIZEN (June 23, 2004), https://www.citizen.org/news/drug-industry-and-hmos-deployed-an-army-of-nearly-1000-lobbyists-to-push-medicare-bill-report-finds.

[6] *See* Sean Dickson & Jeromie Ballreich, *How Much Can Pharma Lose? A Comparison of Returns Between Pharmaceutical and Other Industries*, WESTHEALTH POL'Y CTR. 3 (2019) ("[L]arge pharmaceutical manufacturers could endure significant revenue reductions . . . and still achieve the highest returns of any market sector.").

negotiating with the federal government for the purchase of goods—especially when those profits drain the public fisc, directly harm millions of Americans, and flow from government-granted privileges.[7]

The government may negotiate the prices of goods it purchases. The courts have long recognized that the federal government, like any private party, is authorized to negotiate the prices of the goods it purchases without running afoul of the Takings Clause. There is no constitutional entitlement to government purchase of goods at prices a seller unilaterally dictates. Nor is there any rule against the government, or any other purchaser, negotiating in bulk. Suppliers of government purchase orders must accept negotiated terms as a condition of their sales to federal programs. Novartis understands this: they voluntarily participate in the Veterans Health, Section 340B, and Medicaid programs, each of which requires them to negotiate prices and offer price discounts. This rule alone settles the question this case presents. Price negotiations that discipline public spending do

[7] *See Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657 (D. Conn. July 3, 2024) (Rejecting Boehringer's argument that the IRA constitutes an unjustified taking pursuant to the Fifth Amendment); *AstraZeneca Pharms. LP v. Becerra*, No. 23-cv-00931, 2024 WL 895036, at *16 (D. Del. Mar. 1, 2024) (holding that because "AstraZeneca's participation in Medicare is not involuntary, AstraZeneca does not have a protected property interest in selling drugs to the Government at prices the Government will not agree to pay. Accordingly, AstraZeneca' s due process claim fails as a matter of law."); *see also Dayton Area Chamber of Com. v. Becerra*, No. 2:23 CV 156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024) (dismissed on standing but raising similar arguments).

not give rise to a constitutional claim.

The government may regulate prices within an industry. Novartis also implies that the Medicare drug pricing negotiation program violates the Takings Clause because they have no realistic option but to participate in it due to the size of the Medicare market and the take-or-leave-it nature of the program. That too is false. The government holds the power to *set* prices in an industry like this one, without interference from the Takings Clause. Precedent teaches that price regulations are particularly justified and do not implicate the Takings Clause in industries that receive significant government privileges and are highly regulated. Here, drug makers' sales of patented and FDA-approved medicines meet both conditions. First, government-granted privileges, such as patents, data exclusivities, and tax credits, drive the profitability of the pharmaceutical industry. Second, the healthcare and pharmaceutical industry is arguably the most regulated in the country. As a result, Congress's authority to control drug prices extends far beyond that which the IRA achieves: even a mandatory price regulation affecting *all* drugs the industry sells, not just those purchased by Medicare, would be constitutional.

Finding a taking here would unravel the principal government healthcare programs. Finally, accepting Novartis's position would have far reaching ramifications for access to healthcare within the United States. Such a ruling would

not only jeopardize the continued operation of the Medicare program, but also undermine the cost containment measures—price negotiations—that enable the Medicaid and Veterans Health programs to function. Indeed, when raised, courts have uniformly rejected Taking Clause challenges to the price negotiations in these programs. This Court should follow suit and decline to overturn decades of settled precedent.

The amici request that this Court affirm the lower court's decision.

II. PROCEDURAL HISTORY

On September 1, 2023, Novartis filed a lawsuit against CMS for, among other things, violating the Fifth Amendment as an unconstitutional taking of physical property.[8] The parties filed cross motions for summary judgment and on October 18, 2024 the district court denied Novartis's motion and granted CMS's motion for summary judgment. In relevant part, the Court held the IRA does not violate the Fifth Amendment because the program is not a physical taking and

[8] Compl., *Novartis Pharmaceuticals Corp. v. Becerra et al*, 3:23-cv-14221, ECF No. 1, at 2.

Novartis's participating in Medicare is voluntary.[9] Novartis appealed on October 21, 2024.[10]

III. ARGUMENT

A. The government can and routinely does negotiate to form contracts for goods and services, including drugs, without implicating the Takings Clause.

Courts have consistently held that "no one has a 'right' to sell to the government that which the government does not wish to buy."[11] The government, "just like any other party participating in an economic market, is free to engage in the efficient procurement and sale of goods and services."[12] To assist in this "efficient procurement," the government holds the authority to (1) "determine those with whom it will deal,"[13] (2) "fix the terms and conditions upon which it will make needed purchases,"[14] and (3) negotiate the prices it will pay for goods

[9] Opinion re Summary Judgment, *Novartis Pharmaceuticals Corp. v. Becerra et al*, 3:23-cv-14221, ECF No. 79, at 5.

[10] Notice of Appeal, *Novartis Pharmaceuticals Corp. v. Becerra et al*, 3:23-cv-14221, ECF No. 81.

[11] *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980).

[12] *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417–18 (3d Cir. 2016).

[13] *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). *See J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"); *Curtiss-Wright Corp. v. McLucas*, 364 F. Supp. 750, 754 (D.N.J. 1973).

[14] *Perkins*, 310 U.S. at 127.

and services.[15] Such contracting does not implicate the Takings Clause. The federal government contracts in its commercial, not sovereign, capacity.[16] In so doing, the government "removes itself from the ambit of the Fifth Amendment as 'a takings claim cannot be based on the Government's acting in its proprietary capacity.'"[17]

Yet, Novartis seeks a constitutional right to sell its drug at profits levels it dictates—levels that routinely exceed those in all other industries. In its briefing, Novartis claims that the IRA's Medicare drug price negotiation program is a per se taking of their patented drugs.[18] Yet it can point to no reassignment of patent rights or warehouse seizure of ENTRESTO®.

There is no right to a fixed level of profits. The government frequently negotiates prices before entering contracts. In 2022, the government spent $694 billion on contracts.[19] Many of these contracts were fixed-price vehicles that do not

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[15] *See Honolulu Rapid Transit Co. v. Dolim*, 459 F.2d 551, 553 (9th Cir. 1972) ("[T]he Supreme Court has left no doubt that the Federal Government enjoys power to conclude commercial bargains;" (citing *Albrecht v. United States*, 329 U.S. 599, 603–04 (1947))); *see also* Price Negotiation, 48 C.F.R. § 15.405 (2022).

[16] *See Hughes Commc'ns Galaxy, Inc. v. United States*, 271 F.3d 1060, 1070 (Fed. Cir. 2001); *St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1385 (Fed. Cir. 2008).

[17] *Klump v. United States*, 50 Fed. Cl. 268, 272 (2001) (citation omitted), *aff'd*, 30 F. App'x 958 (Fed. Cir. 2002). Contractors seeking to allege a breach of contract also have remedies based on the contract, not based on constitutional rights. *See Hughes Commc'ns*, 271 F.3d at 1070.

[18] Novartis S.J. Br. at 13.

[19] *See A Snapshot: Government-Wide Contracting*, GOVERNMENT

guarantee or even encourage profit.[20] The IRA's drug price negotiation program is simply another example of the government negotiating with a private vendor in a commercial capacity to purchase goods.

In fact, the government *already negotiates* drug prices and sets parameters on the prices it will pay for drugs across several federal programs, including the Veterans Health Administration, Section 340B, and Medicaid programs. Under each of these programs, the government contracts with a manufacturer to provide drugs.[21] Each program has a baseline statutory discount with options for the federal government or seller (e.g., a hospital) to negotiate further discounts.[22] Drug makers do not have to supply medicines to the government. However, if they opt not to sell to the Veterans Health Administration or the 340B program, the government can limit the drug maker's access to Medicaid (and by extension, Medicare Part B).[23]

ACCOUNTABILITY OFFICE (May 2023), https://gaoinnovations.gov/Federal_Government_Contracting.

[20] *Id*. (noting that majority of contracts awarded in fiscal year 2022 were fixed price); *United States v. White*, 765 F.2d 1469, 1472 (11th Cir. 1985).

[21] *See* 38 U.S.C. § 8126 (Veterans Health Administration); 42 U.S.C. §§ 256b (Section 340B), 1396r-8 (Medicaid).

[22] *See* 38 U.S.C. § 8126(a)(2); 42 U.S.C. § 256b(a)(1), (10); 42 U.S.C. §§ 1396r-8(a) (requiring drug manufacturer to "have in effect a rebate agreement" with HHS); (c)(1).

[23] *See* 38 U.S.C. § 8126(a)(4); 42 U.S.C. §§ 1396r-8(a)(1), (a)(5)(A). *See also Eli Lilly & Co. v. United States Dep't of Health & Human Servs*., No. 21-cv-00081, 2021 WL 5039566, at *2 (S.D. Ind. Oct. 29, 2021) (340B program "requires, as a condition of Plaintiffs' participation in Medicaid and Medicare Part

These programs offer manufacturers the opportunity to negotiate drug prices in exchange for access to various government markets.

Courts have routinely and uniformly held that the structure and requirements of these programs do not effectuate a taking. For example, courts have emphasized that the 340B program is voluntary, even if withdrawal from one program means the drug company will be prohibited from selling its drugs to another government program.[24] "[E]conomic hardship is not equivalent to legal compulsion for purposes of takings analysis."[25] Indeed, one court described the manufacturers' per se physical takings argument in a 340B case as borderline nonsensical.[26]

The IRA's Medicare drug price negotiation program sets up a structure similar to the existing drug purchase programs under 340B, Medicaid, and the

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B, that pharmaceutical manufacturers such as Plaintiffs sell their outpatient drugs at a heavily discounted price to "'covered entities'").

[24] *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs*., 570 F. Supp. 3d 129, 209–10 (D.N.J. 2021), *aff'd in part, rev'd in part sub nom. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023); *Eli Lilly & Co. v. United States Dep't of Health & Human Servs*., No. 21-cv-00081, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021).

[25] *Eli Lilly & Co.*, 2021 WL 5039566 at *21 (*quoting Garelick v. Sullivan*, 987 F. 2d 913 (2d Cir. 1993)) (quotations omitted).

[26] *See Sanofi-Aventis*, 570 F. Supp. 3d at 208 (D.N.J. 2021) ("Such an argument makes little sense given how the 340B Program works. HHS does not acquire title to Sanofi's drugs. . . obtain them for a third party. . . or compel Novo to surrender them . . . . [T]here is no 'government-authorized invasion.'") (quoting *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2074 (2021)).

Veterans Health Administration.[27] The takings analysis here should not differ. Accepting Novartis's argument that price negotiations constitute a taking would open the door for nearly all contract negotiations and "[g]overnment contract breaches [to] give rise to compensation under the Fifth Amendment."[28] Such a view would not only undermine settled contract law involving voluntary, bargained-for exchanges, but also upend hundreds of government contracts at an industry's whim.

B. Congress has the authority to directly regulate drug prices, and even a price regulation applied to the whole pharmaceutical industry would be constitutional.

1. Price regulation in the pharmaceutical industry is particularly justified—and does not implicate the Takings Clause—because the industry is supported by many government privileges, subject to significant monopoly pricing problems, and highly regulated.

Price regulations achieve the "broad societal interest" of "protecting consumers from excessive prices."[29] Price regulation is particularly justified and does not implicate the Takings Clause in industries that (1) benefit from significant government privileges and (2) are highly regulated. The sales of medicines within the pharmaceutical industry to the government meet both conditions. Myriad

[27] *See* P.L. 117–169, § 11101 (enacted in Aug. 2022).

[28] *See Hughes Commc'ns*, 271 F.3d at 1070.

[29] *Exxon Corp. v. Eagerton*, 462 U.S. 176, 190–91 (1983) (internal citation and quotations omitted).

government-granted privileges—in the form of monopoly power, tax credits, and research funding—have made the pharmaceutical industry one of the most profitable in the world.[30] The pharmaceutical industry is also highly regulated. And caselaw affirms Congress's authority and special latitude to impose conditions on industries that benefit from such government privileges and regulations. As such, Congress could lawfully implement a price regulation affecting *all* drugs on the market, not just those sold to Medicare. Here, the Medicare drug price negotiation program, even if viewed as a mandatory price regulation, survives any takings challenge.[31]

Where the federal government grants an individual or industry a special privilege, it is entitled to impose conditions thereon. *And such conditions do not give rise to takings claims*. The Supreme Court affirmed this principle in *Leonard v. Earle*.[32] In 1929, *Leonard* affirmed that a Maryland law requiring oyster packers to give the state ten percent of their collected oyster shells—a valuable commodity—did not constitute a takings.[33] Even where the oysters had been

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[30] *See Dickson & Ballreich*, *supra* n.6.

[31] Price negotiation and regulation of medicines is the norm among peer nations. *See, e.g.*, Leah Z. Rand & Aaron S. Kesselheim, *Getting the Price Right: Lessons for Medicare Price Negotiation from Peer Countries*, PHARMACOECONOMICS, Sept. 11, 2022.

[32] *Leonard v. Earle*, 279 U.S. 392 (1929).

[33] *Id.* at 394, 396, 398 (1929); *Leonard v. Earle*, 141 A. 714, 715–16 (1928),

"taken and reduced to possession by an individual," the Court held that the packer's "ownership may be regulated and restrained by appropriate legislation enacted for considerations of state or the benefit of the community."[34]

The Supreme Court's decision in *Horne v. Department of Agriculture*—Novartis's principal authority—did not disturb *Leonard*—it affirmed *Leonard's* logic.[35] As *Horne* explained, "[t]he oysters, unlike raisins, were 'feræ naturæ' that belonged to the State under state law, and "[n]o individual ha[d] any property rights in them other than such as the state may permit him to acquire."[36] The same can be said of patented medications: no individual holds a right to a patent "other than such as the state may permit him to acquire."[37] And without patents, brand manufacturers like Novartis would lose the power to reap the benefit—high profits—they contend has been taken by the Medicare drug price negotiations.

Over fifty years after *Leonard*, in *Ruckelshaus v. Monsanto*, the Supreme Court reiterated the government's authority to set conditions on the benefits of

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aff'd, 279 U.S. 392 (1929). *See Horne v. Dep't of Agric.*, 576 U.S. 350, 366–67 (2015) (describing both decisions).

[34] *Leonard*, 141 A. at 716.

[35] *Horne*, 576 U.S. at 366–67.

[36] *Id.* at 367.

[37] *Id.*; *see* U.S. Const. Art. I § 8, Cl. 8 (Congress hold the power—but the not the obligation—to grant patents).

market access it bestows on regulated companies.[38] There, the Court considered, *inter alia*, (1) whether the appellee, Monsanto, had "a property interest" "protected by the Fifth Amendment's Taking Clause in the health, safety, and environmental data" it submitted to the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and (2) if so, whether the EPA's competitive use or disclosure of that data constituted a taking.[39]

As to the first question, the Supreme Court noted that the state conceded that the data was "cognizable as a trade-secret property right under Missouri law," and concluded that trade secrets could be protectable property interests under the Takings Clause.[40] As to the second, the Court concluded that Monsanto's "voluntary submission of data . . . in exchange for the economic advantages of a registration can hardly be called a taking."[41] As articulated in *Horne*, Monsanto and other similarly situated insecticide manufacturers "were not subjected to a taking because they received a 'valuable Government benefit' in exchange—a license to sell dangerous chemicals."[42] Not only were the companies seeking

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[38] *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

[39] *Id*. at 1000.

[40] *Id.* at 1003–04.

[41] *Id*. at 1006–07 (concluding Monsanto was "aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest").

[42] *Horne*, 576 U.S. 350, 365–66.

licenses to sell insecticides required to share certain information with the government, but the government was also entitled to give that information to the public. Thus, the government is free to impose conditions on the benefits it gives; doing so is not a taking.

The pharmaceutical regulatory system is on all fours with the regulation of insecticides in *Monsanto*. Just as the EPA regulates the issuance of a "license to sell dangerous chemicals,"[43] the FDA regulates the sale of pharmaceuticals, requiring manufacturers to apply, submit safety and efficacy clinical trial data, and receive FDA approval before marketing their (potentially dangerous) drugs.[44] By granting a pharmaceutical company's new drug application, the FDA grants a "valuable Government benefit"[45]—permission to sell the drug. In exchange, the federal government is free to impose conditions and regulations without violating the Taking Clause.

The government also grants drug makers significant benefits that enable their high prices and profits throughout drug development, manufacturing, and sales. First, the government subsidizes new drug development through tax credits

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[43] *Id.*, 576 U.S. at 365–66.

[44] *Cf. Horne*, 576 U.S. at 366 (distinguishing *Monsato*: "Raisins are not dangerous pesticides; they are a healthy snack. A case about conditioning the sale of hazardous substances on disclosure of health, safety, and environmental information related to those hazards is hardly on point.").

[45] *Monsanto*, 467 U.S. at 1007.

and the direct funding of disease and drug research via the National Institute of Health, among other mechanisms.[46] Next, the FDA's licensing requirements—demanding submission of clinical trial data—create barriers to entry, limiting the number of competitors that can enter the market.

Concurrent patent and regulatory exclusivities then permit the approved drug makers to exclude others from the market, setting prices far above those they could obtain in the face of generic competition and far above the average and marginal cost of manufacturing their medications.[47] In addition to the twenty-year term of patent exclusivity a manufacturer usually obtains on its drug's active ingredient, pharmaceutical companies frequently obtain a range of "secondary" patents that further extend the pharmaceutical company's monopoly.[48]

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[46] *See* David Austin & Tamara Hayford, *Research & Development in the Pharmaceutical Industry* 18–20, CONG. BUDGET OFF. (2021); Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010–2019*, 4 JAMA HEALTH F. 1, 1 (2023) (finding that between 2010 and 2019, NIH provided funding that contributed to almost every drug approved during that period).

[47] According to the FDA, where only one generic is allowed onto the market, that generic will price its competitor product 39% lower than the brand, on average; with six or more generic drugs on the market, the discount off the brand-drug price increases to 95%. Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. FOOD & DRUG ADMIN. 2–3 (Dec. 2019).

[48] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 6–8 (Aug. 2018),

In addition to these exclusivities, statutory purchasing obligations for Medicare and other federal prescription drug programs guarantee drug makers a robust market. The statutes establishing Medicaid, Medicare, Section 340B, and the Veterans Administration drug program *require* the federal government to purchase or otherwise provide drugs for each program's beneficiaries.[49] Other laws and regulations require government insurance programs to cover certain classes of drugs, including many branded pharmaceuticals.[50]

The protections and benefits the government grants to the pharmaceutical industry permit the former great latitude to regulate the fruits of the latter—i.e., medicines. Drug companies can no more claim a "taking" of their products than could packers over their oysters or insecticide manufacturers over their knowingly disclosed trade secrets. Rightly so. Such price regulation is not only authorized by Congress and the courts, but it also provides essential benefits to the public at

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https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-OverpatentedOverpriced-Report.pdf (finding the top 12 drugs by gross U.S. revenue were associated with an average of 71 patents each); Amy Kapczynski, Chan Park & Bhavan Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 6–7 (2012) (secondary patents extend market exclusivity by several years).

[49] *See* 42 U.S.C. § 1396d(12); 42 U.S.C. § 256b(1) ("The Secretary shall . . ."); 42 U.S.C. § 1395w-3b; 42 U.S.C. § 1395w-101(a)(1) (2018) ("[E]ach part D eligible individual . . . is entitled to obtain qualified prescription drug coverage . . . ."); 38 U.S.C. § 8126(a).

[50] *See, e.g.*, 42 U.S.C. §§ 1395w-102, 104(b)(3) (describing general Part D formulary requirements); 42 C.F.R. § 423.120 (2024); 42 U.S.C. § 1396r-8(d)(1).

large. Indeed, without price regulation in this setting, we face a predictable problem of high—and rising—monopoly prices, unjustified by investment, that put patients and the system at risk.

An apt example is Medicare without the IRA's drug price negotiation program. Medicare makes up the largest portion of the federal government's drug purchase obligation: the program's current regulatory structures require the government to provide coverage for pharmaceuticals, where prescribed, to a market of 65 million people.[51] In 2021, Medicare Part D spending exceeded $200 billion.[52] And this figure continues to rise.[53] Despite this spending, as noted above, consumers in this program struggle to pay for drugs.[54] The program currently has no structural price controls and, without the IRA's drug price negotiation program, minimal negotiating power.[55] Medicare Part B does not negotiate at all, paying for

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[51] *See* Gabrielle Clerveau, et al., *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, KAISER FAMILY FOUNDATION (Aug. 14, 2023), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries.

[52] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105270, MEDICARE PART D: CMS SHOULD MONITOR EFFECTS OF REBATES ON PLAN FORMULARIES AND BENEFICIARY SPENDING (September 2023).

[53] *See Baseline Projections: Medicare*, CONG. BUDGET OFF. (May 2023) (charting projected growth in Medicare Part D budget between 2023–2033); *see also* David Austin & Tamara Hayford, *Prescription Drugs: Spending, Use, and Prices* 8, CONG. BUDGET OFF. (Jan. 2022).

[54] *See* discussion *supra* in Introduction.

[55] *See* 42 U.S.C. § 1395w-101(a)(1).

drugs at the average sales price set by the drug makers, plus 6%.[56] With no ability to negotiate, the government and seniors—via the Medicare program—are held hostage by the prices (and profits) drug makers unilaterally demand.[57]

The Supreme Court has held that in highly regulated industries, especially where price regulations are present in some domains, the "forseeab[ility]" of price regulations negates certain constitutional claims.[58] As described above, the

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[56] *See Medicare Part B Drug Average Sales Price*, CMS.GOV (Sept. 6, 2023 4:51 PM), https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price. Medicare Part B is Medicare's medical insurance benefit. In addition to physician visits and hospital services, it often covers drugs that must be administered in an in-patient setting.

[57] *See* 42 U.S.C. § 1395w-111 (2018); U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-111, PRESCRIPTION DRUGS: DEPARTMENT OF VETERANS AFFAIRS PAID ABOUT HALF AS MUCH AS MEDICARE PART D FOR SELECTED DRUGS IN 2017 (Dec. 15 2020) ("Department of Veterans Affairs (VA) paid, on average, 54 percent less per unit for a sample of 399 brand-name and generic prescription drugs in 2017 as did Medicare Part D, even after accounting for applicable rebates and price concessions in the Part D program."); *see also* Aaron S. Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858 (2016) (noting that U.S. drug prices are not based on the price of research and development, but instead on what the market will bear).

[58] *See, e.g., Energy Reserves Group, Inc. v. Kansas Power and Light Co.*, 459 U.S. 400, 413, 416, 419 (1983) (concluding that in a "heavily regulated industry," price regulation was "foreseeable as the type of law that would alter contract obligations" and was constitutionally permissible under Contracts Clause). *See also 74 Pinehurst LLC v. New York*, 59 F.4th 557, 567–68 (2d Cir. 2023) (holding that because a "reasonable investor" in the housing market "would have anticipated [that] their rental properties would be subject to regulation"—because of the expansive "regime of rent regulations"—price controls "result[ing] in a loss does not constitute a taking").

pharmaceutical industry is arguably the most regulated industry in the country, and government price negotiations and regulations are part and parcel of federal healthcare programs, including through the Veterans Health Administration, Section 340B, and Medicaid programs.

In sum, even if applied to the entire pharmaceutical industry, which this *Medicare* drug price negotiation program is not, price regulation would be justified. It would not implicate the Takings Clause because it would not "unfairly single[] out the property owner to bear a burden that should be borne by the public as a whole."[59]

2. There is no legal mandate to sell medicines, and even if there were, only a minimal "just compensation" requirement would apply.

In certain industries, the government legally *mandates* that a seller serve the market at fixed prices. Historically, courts have exercised some judicial oversight over those rates, but that oversight is the exception, not the rule.[60] In recent years,

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[59] *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 522–23 (1992).

[60] *See, e.g., Hegeman Farms v. Baldwin,* , 293 U.S. 163 at 170 (1934) ("The appellant would have us say that . . . [a government-regulated price] must be changed whenever a particular dealer can show that . . . its application to himself is to deprive him of a profit. This is not enough to subject administrative rulings to revision by the courts."); *Aetna Ins. Co. v. Hyde*, 275 U.S. 440, 447–48 (1928) ("Jurisdiction of this Court to set aside state-made rates as confiscatory will be exercised only in clear cases; and the burden is on one seeking that relief to bring forward and satisfactorily prove the invalidating facts."). *See generally* John N. Drobak, *From Turnpike to Nuclear Power: The Constitutional Limits on Utility Rate Regulation*, 65 B.U. L. REV. 65, 125 (1985) ("The Supreme Court has

caselaw requiring just compensation for such services pertains only to rate-regulated utilities. This is because utility providers are *required*, by law, to serve the market; they cannot pull out.[61] Pharmaceutical companies, on the other hand, *voluntarily* choose to sell their drugs on the market, without any obligation to participate. As a result, they are not entitled to judicial oversight of government price regulations.[62]

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established a limited role for the judiciary in its constitutional review of [utility] ratemaking, consistent with the judiciary's limited role in reviewing other kinds of economic regulation.").

[61] *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) ("[P]ublic utilities . . . are under a state statutory duty to serve the public."); *Pittsburgh & Lake Erie R.R. Co. v. Ry. Labor Execs' Ass'n*, 491 U.S. 490, 515 (1989) (Stevens, J., concurring) ("Regulated utilities do not have the same freedom to respond to market pressures that unregulated firms have. They may not raise rates or cut services . . . without permission from a regulatory agency . . . [and] they may neither enter nor leave the market without agency approval."); *see also* Jim Rossi, *The Common Law "Duty to Serve" and Protection of Consumers in an Age of Competitive Retail Public Utility Restructuring*, 51 VAND. L. REV. 1233, 1248–50 (1998) (describing long-standing decisions recognizing common-law and statutory "duty to serve" for public utilities and common carriers); Thomas W. Merrill, *Constitutional Limits on Physician Price Controls*, 21 HASTINGS CONST. L.Q. 635, 639 (1994) ("The Supreme Court has made it clear that the Takings Clause imposes significant limits on the power of government to regulate certain prices, most prominently, the rates charged by common carriers and public utilities. On the other hand, other types of price controls . . . have never been thought to raise questions under the Takings Clause.").

[62] *See Yee*, 503 U.S. at 531 ("Because they voluntarily open their property to occupation by others, petitioners cannot assert a per se right to compensation based on their inability to exclude particular individuals"); *Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (upholding World War II rent controls against takings challenge because statute did not require landlords "to offer any accommodations for rent").

Even if the utility rule applied to pharmaceutical manufacturers, they would only be entitled to a "just and reasonable" compensation.[63] "Just and reasonable" compensation is a minimal standard for rate-setting.[64] Sellers are entitled to a rate that reflects their original capital investments and expenditures and allows them to reasonably attract future capital.[65] The complexity of making these determinations means that courts give the government discretion in setting rates, regardless of the methodology employed,[66] "if the total effect of the rate order cannot be said to be

[63] *See Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 602–03 (1944).

[64] *See Duquesne*, 488 U.S. at 310–11; *see also id.* at 315–16 ("'It has repeatedly been stated that no single method need be followed by the Commission in considering the justness and reasonableness of rates.'. . . The designation of a single theory of ratemaking as a constitutional requirement would unnecessarily foreclose alternatives which could benefit both consumers and investors." (quoting *Wisconsin v. FPC*, 373 U.S. 294, 309 (1963)).

[65] *See Hope*, 320 U.S. at 602–03 ("[T]he return to the equity owner should be commensurate with returns on investments . . . . That return, moreover, should be sufficient to assure confidence in the financial integrity of the enterprise, so as to maintain its credit and to attract capital."); *see also Duquesne*, 488 U.S. at 302, 312 (holding that a reduced rate did not constitute a takings and emphasizing that the challenger failed to argue the reduced rate "jeopardize[d] the financial integrity of the companies, either by leaving them insufficient operating capital or by impeding their ability to raise future capital.").

[66] *See* William Boyd, *Just Price, Public Utility, and the Long History of Economic Regulation in America*, 35 YALE J. REG. 721, 767 (2018) (noting that after *Hope*, "in the vast majority of cases, the courts simply deferred to the commissions, no longer twisting themselves into knots trying to make the methods of valuation at the heart of ratemaking comport with received notions of property and its constitutional protections.").

unreasonable."[67] Such compensation certainly does not require that the regulated business earn a profit.[68]

The Medicare drug price negotiation program is a *price* negotiation, not a rate negotiation.

C. A ruling that the Medicare drug price negotiations constitutes a per se taking would upend the Medicare, Medicaid, and Veterans Administration programs.

Federal and state healthcare programs provide a key safety net for more than one in three Americans.[69] But, due to their reach, these programs strain state and

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[67] *Duquesne*, 488 U.S. at 310 (quoting *Hope*, 320 U.S. at 602).

[68] *See Permian Basin Area Rate Cases*, 390 U.S. 747, 769 (1968) ("Regulation may, consistent with the Constitution, limit stringently the return recovered on investment."); *Fed. Power Comm'n v. Sierra Pac. Power Co.*, 350 U.S. 348, 355 (1956) (holding that a rate "may not be said to be either 'unjust' or 'unreasonable' simply because it is unprofitable to the public utility").

[69] *See Health Insurance Coverage of the Total Population*, KAISER FAMILY FOUNDATION (2021), https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. In 2017, the Veterans Health Administration provided care to 9 million veterans and their families. In 2022, TRICARE, DoD's insurance program, covered approximately 9.5 million service members and their families. As noted above, Medicare provides coverage to 65 million people, and in 2022, Medicaid or CHIP covered almost 90 million Americans. *See* Mike McCaughan, *Veterans Health Administration*, HEALTH AFFAIRS (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/; *Patients by TRICARE plan*, HEALTH.MIL, https://www.health.mil/Military-Health-Topics/MHS-Toolkits/Media-Resources/Media-Center/Patient-Population-Statistics/Patients-by-TRICARE-Plan; Gabrielle Clerveau, et al., *supra* n.86. *MACPAC Releases 2022 Edition of MACStats: Medicaid and CHIP Data Book*, MACPAC (Dec. 15, 2022), https://www.macpac.gov/news/macpac-releases-2022-edition-of-macstats-medicaid-and-chip-data-book.

federal budgets. In 2021, Medicare alone accounted for 21% of all U.S. healthcare spending and 10% of the federal budget.[70] Medicare's costs are predicted to rise to 18% of the federal budget in 2032.[71] The Medicaid program cost $728 billion, excluding administrative costs, in fiscal year 2021,[72] about 17% of national health expenditures that year.[73]

Price caps and negotiated discounts on healthcare services enable federal and state healthcare programs to offer coverage to millions of Americans. A ruling that these programs' statutory discounts constitute takings would imperil these programs' continued operation. For patients, this would translate into reduced access to healthcare. For courts, it would mean a flood of litigation over the level of payment necessary to compensate takings by voluntary and mandatory programs never-before questioned. Courts would be asked to take on the administrative role of rate-setter, weighing the cost and benefits of each government contract for

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[70] *See* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, KAISER FAMILY FOUNDATION (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing.

[71] *Id.*

[72] *See* Elizabeth Williams et al., *Medicaid Financing: The Basics*, KAISER FAMILY FOUNDATION (Apr. 13, 2023), https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics.

[73] *See NHE Fact Sheet*, CMS.GOV, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

healthcare services.

But the Medicare, Medicaid, and Veteran Health Administration programs would not be the only areas of healthcare affected. All Americans are entitled to emergency room treatment, irrespective of insurance status, based on the federal Emergency Medical Treatment and Labor Act (EMTALA). This law requires hospitals with emergency departments that receive Medicare funding to accept all patients in critical condition, regardless of their ability to pay.[74] Takings challenges to EMTALA have failed on the grounds that participation in Medicare (and by extension in EMTALA) is voluntary.[75] A holding that the IRA's Medicare drug price negotiations are coerced could open the door to a similar holding with respect to EMTALA. Every unpaid emergency room visit could be grounds for a takings lawsuit in which a court would have to evaluate the degree of government compensation necessary—an unimaginably complex task given the byzantine world of medical billing and government reimbursement rates.

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[74] *See* 42 U.S.C. § 1395cc(a)(1)(I)(i); 42 U.S.C. § 1395dd.

[75] *See, e.g.*, *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F. 2d 1362, 1376 (5th Cir. 1991); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F. 3d 1274, 1279–80 (11th Cir. 2014) (quoting *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("Just as physicians who voluntarily treat Medicare beneficiaries cannot establish the legal compulsion necessary to challenge Medicare reimbursement rates as a taking, so too is the Hospital precluded from challenging the rate at which it is compensated for its voluntary treatment of federal detainees, a regulated industry in which the Hospital as a 'regulated group is not required to participate.'").

IV. CONCLUSION

For these reasons, amici respectfully request that the Court affirm the District Court's decision.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this brief:

(i) Complies with the type-volume limitation of Rule 32(a)(7) because it contains 6475 words, excluding the parts of the brief exempted by Rule 32(f); and

(ii) Complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2016 and is set in Times New Roman font in a size equivalent to 14 points or larger.

Pursuant to Third Circuit Local Appellate Rule 31(c), I certify that the text of this electronic brief is identical to the text of the paper copies and that Microsoft Defender Antivirus has been run on the file and no virus was detected.

Pursuant to Third Circuit Local Appellate Rules 28.3(d) and 46.1(e), I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Date: February 25, 2025

/s/ *Hannah W. Brennan*
Hannah W. Brennan

CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on 25th day of February, 2025, I electronically filed this Amicus Curiae Brief with the Court to all counsel of record via the CM/ECF system. I further certify that seven paper copies of the foregoing brief will be sent to the Clerk's office.

Date: February 25, 2025

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