24-2092

United States Court Of Appeals
for the
Second Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellants,

v.

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,

Defendant- Appellees.

On Appeal From The United States District Court
for the District Of Connecticut

Case No. 3:23-cv-01103

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's, Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), 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 the constitutionality of government price negotiations and price regulations. The amici explain how Courts have historically ruled on these questions, as well as the far-reaching consequences that a ruling in Boehringer's favor would have on the federal government's ability to provide adequate healthcare across the United States.

I. INTRODUCTION

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

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[1] Amici and their counsel are the sole authors of this brief. No party or counsel for a party authored any piece of this brief or contributed any money intended to fund its preparation or submission. The parties do not object 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 (Oct 04, 2024).

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 in 2022 passed the Inflation Reduction Act (IRA) and, with it, created the Medicare drug price negotiation program.

This new law 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 pharmaceutical lobbying[5]—has been anomalous since its inception. The federal

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[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).

[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*

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 has been fully 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.

Boehringer now argues that it has a constitutional right to the monopoly prices it has 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 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

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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.").

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. Boehringer understands this: it voluntarily participates in the Veterans Health, Section 340B, and Medicaid programs, each of which requires the company to negotiate prices and offer price discounts. This rule alone settles the question this case presents. Price negotiations that discipline public spending do not give rise to a constitutional claim.

Finding a taking here would unravel the principal government healthcare programs. Accepting Boehringer'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

[7] In *Dayton Area Chamber of Com. v. Becerra*, the Court denied the plaintiffs' motion for preliminary injunction, concluding that the plaintiffs failed to show "that no set of circumstances exist where the [Medicare drug price negotiation program] would be constitutionally valid," as is required to "demonstrate a strong likelihood of success on the merits of a constitutional challenge at the preliminary injunction stage." No. 3:23-CV-156, 2023 WL 6378423, at *10 (S.D. Ohio Sept. 29, 2023). There, the plaintiffs alleged the drug price negotiation program violated the Fifth Amendment Due Process Clause. *Id.*

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

In August 2023, Boehringer filed a lawsuit against CMS, for, among other things, violating the Fifth Amendment as an unconstitutional taking of physical property.[8] Parties filed cross motions for summary judgment and on July 3, 2024, the district court denied Boehringer's motion and granted CMS's.[9] In relevant part, the Court held that the IRA does not violate the Fifth Amendment because the program is not a physical taking and Boehringer's participation in Medicare is voluntary.[10] Boehringer appealed on July 26, 2024.[11]

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

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[8] Ruling on Mot. for Summary Judgment, *Boehringer v. Becerra*, No. 3:23-cv-01103-RNC (D. Conn.), ECF No. 122, at 47.

[9] *Id*. at 29.

[10] *Id*. at 29.

[11] Appellant Opening Brief, *Boehringer v. Becerra*, No. 2402092 (2nd Cir) ECF 46.1, at 5.

government that which the government does not wish to buy."[12] 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."[13] To assist in this "efficient procurement," the government holds the authority to (1) "determine those with whom it will deal,"[14] (2) "fix the terms and conditions upon which it will make needed purchases,"[15] and (3) negotiate the prices it will pay for goods and services.[16] Such contracting does not implicate the Takings Clause. The federal government contracts in its commercial, not sovereign, capacity.[17] In so doing, the government "removes itself from the ambit of the Fifth Amendment as 'a takings

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

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

[14] *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). *See J.H. Rutter Rex Mfg. Co., Inc. 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).

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

[16] *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;" concluding "transaction had 'passed out of the range of the Fifth Amendment' and was a situation where '[p]arties . . . bargain between themselves as to compensation'") (citing *Albrecht v. United States*, 329 U.S. 599, 603–04 (1947)); *see also* Price Negotiation, 48 C.F.R. § 15.405 (2022).

[17] *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).

claim cannot be based on the Government's acting in its proprietary capacity.'"[18]

Yet, Boehringer appears to seek a constitutional right to sell its drugs at profits levels it dictates—levels that routinely exceed those in all other industries. In its briefing, Boehringer claims that the IRA's Medicare drug price negotiation program is a per se taking of its drug.[19] Yet Boehringer points to no warehouse seizure of Jardiance tablets. Rather, Boehringer's chief concern is that its compensation will be capped, so it argues, "well below market-based prices."[20] The true "taking" at issue is a reduction of its profits.

There is no right to a fixed level of profits. The government frequently negotiates prices before entering into contracts. In 2022, the government spent $694 billion on contracts.[21] Many of these contracts were fixed-price vehicles that do not guarantee or even encourage profit.[22] The IRA's drug price negotiation

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[18] *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.

[19] Brief and Special Appendix for Plaintiff-Appellant, *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Dep't of Health & Hum. Servs. et al*, 24-2092, ECF No. 46-1 (2nd Cir.), at 3.

[20] *Id.* at 23, n.7.

[21] *See A Snapshot: Government-Wide Contracting*, GOVERNMENT ACCOUNTABILITY OFFICE (May 2023), https://gaoinnovations.gov/Federal_Government_Contracting.

[22] *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).

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.[23] Each program has a baseline statutory discount with options for the federal government or seller (e.g., a hospital) to negotiate further discounts.[24] 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).[25] 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

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

[24] *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).

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

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.[26] "[E]conomic hardship is not equivalent to legal compulsion for purposes of takings analysis."[27] Indeed, one court described the manufacturers' per se physical takings argument in a 340B case as borderline nonsensical.[28]

The IRA's Medicare drug price negotiation program sets up a structure similar to the existing drug purchase programs under 340B, Medicaid, and the Veterans Health Administration.[29] The takings analysis here should not differ. Accepting Boehringer's argument that a government price negotiation program constitutes a per se taking of a drug maker's medicine would open the door for nearly all contract negotiations and "[g]overnment contract breaches [to] give rise

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[26] *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.*,2021 WL 5039566, at *21.

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

[28] *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)).

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

to compensation under the Fifth Amendment."[30] 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 regulate drug prices directly, 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."[31] 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 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.[32] The pharmaceutical industry is also highly regulated. And caselaw affirms Congress's authority and special latitude to impose conditions on

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

[31] *Exxon Corp. v. Eagerton*, 462 U.S. 176, 191 (1983) (internal citation and quotations omitted).

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

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.[33]

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*.[34] 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.[35] Even where the oysters had been "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."[36]

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[33] 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.

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

[35] *Id*. at 394, 396, 398; *Leonard v. Earle*, 141 A. 714, 715–16 (1928), *aff'd*, 279 U.S. 392 (1929). *See Horne v. Dep't of Agric.*, 576 U.S. 350, 366–67 (2015) (describing both decisions).

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

The Supreme Court's recent decision in *Horne v. Department of Agriculture* did not disturb *Leonard*—it affirmed *Leonard's* logic.[37] 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.'"[38] 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."[39] And without patents, brand manufacturers like Boehringer would lose the power to reap the benefit—high profits—it contends 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 market access it bestows on regulated companies.[40] 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

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[37] *Horne*, 576 U.S. at 366–67.

[38] *Id.* at 367.

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

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

EPA's competitive use or disclosure of that data constituted a taking.[41]

As to the first question, the Supreme Court noted that the state conceded that the data were "cognizable as a trade-secret property right under Missouri law," and concluded that trade secrets could be protectable property interests under the Takings Clause.[42] 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."[43] 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."[44] Not only were the companies seeking 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

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[41] *Id*. at 1000.

[42] *Id.* at 1003–04.

[43] *Id*. at 1007 (concluding Monsanto was "aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest").

[44] *Horne*, 576 U.S. at 366.

insecticides in *Monsanto*. Just as the EPA regulates the issuance of a "license to sell dangerous chemicals,"[45] 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.[46] By granting a pharmaceutical company's new drug application, the FDA grants a "valuable Government benefit"[47]: 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 and the direct funding of disease and drug research via the National Institutes of Health, among other mechanisms.[48] Next, the FDA's licensing requirements—

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[45] *Id.*

[46] *Cf. Id.* at 366 (distinguishing *Monsanto*: "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.").

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

[48] *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 Indust*ry, 2010–2019, 4 JAMA HEALTH F. 1, 1 (2023) (finding

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 the average and marginal cost of manufacturing their medications.[49] 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.[50]

In addition to these exclusivities, statutory purchasing obligations for

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that between 2010 and 2019, NIH provided funding that contributed to almost every drug approved during that period).

[49] 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). *See* Erin H. Ward, Kevin J. Hickey & Keith T Richard, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, CONG. RSCH. SERV., R46679, 12–14, 29 (2021).

[50] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 6–8 (Aug. 2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-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).

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.[51] Other laws and regulations require government insurance programs to cover certain classes of drugs, including many branded pharmaceuticals.[52]

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. Such price regulation is not only authorized by Congress and the courts, but it also provides essential benefits to the public at 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

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

[52] *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).

market of about 67 million people.[53] In 2021, Medicare Part D spending exceeded $200 billion.[54] And this figure continues to rise.[55] Despite this spending, as noted above, consumers in this program struggle to pay for drugs. The program currently has no structural price controls and, without the IRA's drug price negotiation program, limited negotiating power.[56] Medicare Part B does not negotiate at all, paying for drugs at the average sales price in the private market, plus 6%.[57] With no ability to negotiate, the government and seniors—via the Medicare program—have been held hostage by drug makers' high prices (and profits).[58]

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[53] *See* Nancy Ochieng, et al., *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, KAISER FAMILY FOUNDATION (Sep. 23, 2024), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries.

[54] *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).

[55] *See Baseline Projections: Medicare*, CONG. BUDGET OFF. (May 2023); *see also* David Austin & Tamara Hayford, *Prescription Drugs: Spending, Use, and Prices* 8, CONG. BUDGET OFF. (Jan. 2022).

[56] *See* 42 U.S.C. § 1395w-101(a)(1) (2018).

[57] *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. The 6% fee can be reduced a bit during federal budget sequestration.

[58] *See* 42 U.S.C. § 1395w-111 (2018); U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-111, PRESCRIPTION DRUGS: DEPT. OF VETERANS AFFAIRS PAID ABOUT HALF AS MUCH AS MEDICARE PART D FOR SELECTING DRUGS IN 2017 (Dec. 15

The Supreme Court has held that in highly regulated industries, especially when price regulations are present in some domains, the "foreseeab[ility]" of price regulations negates certain constitutional claims.[59] The pharmaceutical industry is one of the most regulated industries 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.

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

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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).

[59] *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 regulations"—because of the expansive "regime of rent regulations"—price controls "result[ing] in a loss does not constitute a taking").

single[] out the property owner to bear a burden that should be borne by the public as a whole."[60]

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.[61] In recent years, 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.[62] Pharmaceutical companies, by contrast,

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

[61] *See, e.g.*, *Hegeman Farms v. Baldwin*, 293 U.S. 163, 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). *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 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.").

[62] *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989); *Pittsburgh & Lake Erie 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* 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

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.[63]

Even if the utility rule applied to pharmaceutical manufacturers, they would only be entitled to a "just and reasonable" compensation.[64] "Just and reasonable" compensation is a minimal standard for rate-setting.[65] Sellers are entitled to a rate that reflects their original capital investments and expenditures and allows them to reasonably attract future capital.[66] The complexity of making these determinations

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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.").

[63] *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").

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

[65] *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)).

[66] *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

means that courts give the government discretion in setting rates, regardless of the methodology employed, "if the total effect of the rate order cannot be said to be 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 constitute 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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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.").

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

[68] *See In re 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

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

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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., *MACPAC Releases 2022 Edition of MACStats: Medicaid and CHIP Data Book*, MACPAC (Dec. 14, 2022), https://www.macpac.gov/news/macpac-releases-2022-edition-of-macstats-medicaid-and-chip-data-book.

[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.

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 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

[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.'").

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.

IV. CONCLUSION

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

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(5) and 32(a)(7)(B)(ii) because this brief contains 6,077 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Times New Roman in 14-point font.

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CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on January 28, 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 six paper copies of the foregoing brief will be sent to the Clerk's office.

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