UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, In his official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Defendants.

Case No. 3:23-cv-20814-ZNQ-JBD

[PROPOSED] BRIEF OF LAW SCHOLARS AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

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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, Novo Nordisk Inc., et al. (Novo), overarching contention that the Medicare drug price negotiation program constitutes an unconstitutional price control. Amici submit this brief to provide the Court with the historical and legal background regarding 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 Novo'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] 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

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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.

[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), 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).

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 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.[6] 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.

Novo now attempts to argue that its pharmaceutical manufacturer members 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

[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 infra* Section II.A.

continue to do so even after full implementation of this program.[7] 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 government-granted privileges.

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. 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. Novo 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.[8] This rule alone settles the question this case presents. Price negotiations that discipline public spending do not give rise to a constitutional claim.

The government may regulate prices within an industry. Novo also implies that the Medicare drug pricing negotiation program is unconstitutional because it has 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 not only has the right to negotiate in bulk for the

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[7] *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.").

[8] *See infra* Section II.A.

program as a whole, but it also holds the power to *set* prices in an industry like this one. The Supreme Court has declared the constitutionality of state and federal price regulations to be "settled beyond dispute."[9] Thus, even viewed as a mandatory price regulation—which it is not—the Medicare drug price negotiation program should not constitute an unconstitutional price control. For example, 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. Price regulations are a fair and logical trade for the privileges the government has granted drug makers.

Concluding that the Medicare drug price negotiation program is unconstitutional here would unravel the principal government healthcare programs. Finally, accepting Novo'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. Finding that companies and individuals hold constitutional rights to profit from their contracts with government health programs would jeopardize the continued operation

[9] *Fed. Commc'ns Comm'n v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987).

of such programs, miring the courts in a morass of lawsuits.

II. ARGUMENT

A. The government can and routinely does negotiate to form contracts for goods and services, including drugs.

Courts have consistently held that "no one has a 'right' to sell to the government that which the government does not wish to buy."[10] 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."[11] To assist in this "efficient procurement," the government holds the authority to (1) "determine those with whom it will deal,"[12] (2) "fix the terms and conditions upon which it will make needed purchases,"[13] and (3) negotiate the prices it will pay for goods and services.[14] Indeed, the federal government contracts in its commercial, not sovereign, capacity.[15] Novo appears

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

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

[12] *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) ("Courts should not . . . subject purchasing agencies of the Government to the delays necessarily incident to judicial scrutiny at the instance of potential sellers . . . [when a] like restraint applied to purchasing by private business would be widely condemned as an intolerable business handicap.").

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

[14] *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) (outlining that the "primary concern" in government contract negotiations should be "the overall price the Government will actually pay").

[15] *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).

to seek a constitutional right for drug makers to sell their drugs at profits levels they dictate—levels that routinely exceed those in all other industries.[16] But 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.[17] Many of these contracts were fixed-price vehicles that do not guarantee or even encourage profit.[18] 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.[19] Each program has a baseline statutory discount with options for the federal government or seller (e.g., a hospital) to negotiate further discounts.[20] Drug

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[16] *See Dickson & Ballreich, supra* note 7.

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

[18] *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) ("Under [fixed price] contracts, if the final total costs of the agreed upon services exceed the contracted price, the contractor takes the loss; conversely, he can profit if the costs are lower than the contract price.").

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

[20] *See* 38 U.S.C. § 8126(a)(2) ("[T]he price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price."); 42 U.S.C. § 256b(a)(1), (10) (requiring a price equal to the "average manufacturer price" paid under Medicaid minus the average rebate; noting that additional discounts are permitted); 42 U.S.C. §§ 1396r-8(a) (requiring drug manufacturer to "have in effect a rebate agreement" with HHS); (c)(1) (basic rebate for single source and innovator multiple source drugs must be equal to either 23% of the average manufacturer price, or the difference between the average manufacturer price and the best price, whichever is greater).

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).[21] These programs offer manufacturers the opportunity to negotiate drug prices in exchange for access to various government markets. 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.[22] Accepting Novo's argument that the drug price negotiation program constitutes an unconstitutional price control[23] 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.

i. Congress has long held the power to regulate prices within certain industries.

For centuries, the government has implemented—and the Supreme Court has upheld—price regulations for commodities, public utilities, and services. Starting in England, "from time immemorial," it was "customary" "to regulate ferries, common carriers, hackmen, bakers, millers,

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[21] *See* 38 U.S.C. § 8126(a)(4) (limiting Medicaid participation for manufacturers who do not meet requirements of Veterans Health Administration drug contract process); 42 U.S.C. §§ 1396r-8(a)(1), (a)(5)(A) (limiting Medicaid and Medicare Part B reimbursement to drug manufacturers that have a "rebate agreement" with HHS and that participate in the 340B program). *See also Eli Lilly & Co. v. U.S. Dep't of Health & Hum. 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'").

[22] *See* P.L. 117-169, § 11101 (enacted in Aug. 2022) (requiring a rebate for single-source drugs and biological products if the price of the product increases faster than inflation).

[23] Novo Memo. of Law in Supp. of Pls' Mot. for Summ. J. at 2-3, *Novo Nordisk Inc. et al. v. Becerra et al.*, Civ. A. No. 3:23-cv-20814 (D.N.J. Dec. 8, 2023), ECF No. 28-1.

wharfingers, innkeepers . . . and in so doing to fix a maximum charge to be made for services rendered, accommodations furnished, and articles sold."[24] The colonies continued this practice, with at least eight of the thirteen colonies adopting "expansive" price controls affecting "substantially everything in use at the time."[25] Price controls even extended to patented products. Borrowing from English common law and statutory obligations that a patentee would not use their exclusivity to "be 'mischievous to the State' by raising the prices of commodities,"[26] some colonies granted patents with "working clauses" that stipulated price as a condition.[27]

The Supreme Court first affirmed the constitutionality of price regulations in *Munn v. Illinois*.[28] There, the Court held that price regulations on goods and services "of public consequence" that were "clothed with a public interest"—a categorization encompassing public utilities and transportation—did not offend the constitution.[29] The Court's decision in *Nebbia v. New York* extended the scope of regulable businesses.[30] *Nebbia* clarified that Congress may regulate the price of commodities sold by private businesses, such as milk, if the "conditions or practices of an industry . . . produce[d] waste harmful to the public [or] threaten[ed] . . . to cut off the supply of

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[24] *Munn v. People of State of Illinois*, 94 U.S. 113, 125 (1876).

[25] Breck P. McAllister, *Price Control by Law in the United States: A Survey*, 4 L. & CONTEMP. PROBS. 273, 274, 276 n.11 (1937) (identifying price controls for wages, agricultural products, tobacco, and liquor, and building materials).

[26] An Act Concerning Monopolies, 21 Jac. I, c. 3, § 6 (1623) (Eng.).

[27] Oren Bracha, *The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care*, 38 LOY. L.A. L. REV. 177, 211-16 (2004). Therefore, in Britain and the colonies at the time of the Founding, a patent grant did not convey any private right to profits or immunity from price regulation.

[28] *Munn*, 94 U.S. at 135 (upholding rate controls on railroads and grain warehouses).

[29] *Id.* at 126.

[30] *Nebbia v. People of New York*, 291 U.S. 502, 516 (1934).

a commodity needed by the public."[31]

To ensure equitable access to public utilities post-*Munn*, the federal government and nearly every state established public-service commissions that set utility rates.[32] And Congress concurrently passed antitrust legislation—including the Sherman Antitrust Act—to restrain unchecked monopoly prices.[33] Finally, to limit profiteering and price gouging during the wartime and economic crises of the mid-twentieth century, the government imposed systemic price freezes and price maximums on nearly all commodities, services, rents, and wages.[34] Even these broad

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[31] *Id.*

[32] *See* William Boyd, *Just Price, Public Utility, and the Long History of Economic Regulation in America*, 35 YALE J. REG. 721, 755 (2018). At the federal level, Congress authorized the Interstate Commerce Commission in 1887 to regulate railroad (and later trucking) rates, *see* McAllister, supra note 25, at 280; the Federal Power Commission in 1920—with subsequent grant of authority in the Federal Power Act of 1935 and the Natural Gas Act of 1938—to regulate rates for electricity and gas, *see* Nelson Lee Smith, *Rate Regulation by the Federal Power Commission*, 36 AM. ECON. REV. 405, 406-08 (1946); the Federal Farm Board in 1929 to regulate agricultural prices, *see* Nathan R.R. Watson, *Federal Farm Subsidies: A History of Governmental Control, Recent Attempts at a Free Market Approach, the Current Backlash, and Suggestions for Future Action*, 9 DRAKE J. AGRIC. L. 281, 286-88 (2004); the Federal Communications Commission in 1934 to regulate telephone and telegraph rates, *see* Carl I. Wheat, *The Regulation of Interstate Telephone Rates*, 52 HARV. L. REV. 846, 848-49 (1938); and the Civil Aeronautics Authority in 1938 to regulate air fares, *see* William C. Wooldridge, *The Civil Aeronautics Board as Promoter*, 54 VA. L. REV. 741, 741-43, 747-51 (1968).

[33] *See generally* Boyd, *supra* note 32, at 723 & n.2.

[34] During World War II, for example, the temporary Office of Price Administration set maximum prices on nearly ninety percent of commodities and imposed rent control over "practically the entire country." *See* Note, *Price and Sovereignty*, 135 HARV. L. REV. 755, 758 (2021); Bernard F. Grainey, *Price Control and the Emergency Price Control Act*, 19 NOTRE DAME L. REV. 31, 32-33 (1943). Episodic price freezes affecting most commodities, services, rents, and wages would be implemented through the 1970s, as authorized by the 1950 Defense Production Act and the 1970 Economic Stabilization Act. *See* John N. Drobak, *Constitutional Limits on Price and Rent Control: The Lessons of Utility Regulation*, 64 WASH. U. L. REV. 107, 117 (1986); Richard H. Field, *Economic Stabilization Under the Defense Production Act of 1950*, 64 HARV. L. REV. 1, 4-8 (1950).

mandates survived constitutional challenges at the Court.[35]

This price-setting authority is so well-settled that the Supreme Court has upheld price regulations affecting a broad range of industries and services, including essential[36] and recreational commodities,[37] public utilities,[38] rent,[39] and labor.[40] Such regulations are deemed to be constitutional even if they have the potential to limit a seller's profits[41] or to reduce the value of

[35] The Supreme Court rejected constitutional challenges to the expansive rent and commodity price controls during World War II in *Bowles v. Willingham*, 321 U.S. 503 (1944) and *Yakus v. United States*, 321 U.S. 414, 420 (1944), respectively. Constitutional challenges to similarly broad-reaching price regulations in the 1950s and 1970s were rejected by lower courts and did not reach the Supreme Court. Drobak, 64 WASH. U. L. REV. at 117 & n.45; *see, e.g.*, *United States v. Excel Packing Co.*, 210 F.2d 596 (10th Cir. 1954), *cert. denied*, 343 U.S. 817 (1954) (rejecting challenges to the constitutionality of the 1950 Defense Production Act).

[36] *See, e.g.*, *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381 (1940) (upholding maximum prices for interstate sale of coal); *German Alliance Insurance Co. v. Lewis*, 233 U.S. 389, 405-12 (1914) (rejecting plaintiff's contention that price controls of fire insurance rates were a "taking of private property"); *Yakus*, 321 U.S. 414 (upholding price controls on meat).

[37] *See, e.g.*, *Townsend v. Yeomans*, 301 U.S. 441 (1937) (upholding maximum prices on the sales of leaf tobacco); *Seagram & Sons v. Hostetter*, 384 U.S. 35 (1966) (upholding price regulations affecting the sale of liquor).

[38] *See, e.g.*, *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 582 (1942) ("The price of gas distributed through pipelines for public consumption has been too long and consistently recognized as a proper subject of regulation."); *Simpson v. Shepard (U.S. Reps. Title: Minnesota Rate Cases)*, 230 U.S. 352, 433 (1913) (holding, in a case involving railroad rates, that "[t]he rate-making power is a legislative power"); *Spring Valley Waterworks v. Schottler*, 110 U.S. 347, 354 (1884) (holding that "it is within the power of the government to regulate the prices at which water shall be sold").

[39] *See Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (holding that rent control did not "involve[] a 'taking' of property").

[40] *See West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937) (upholding minimum-wage legislation).

[41] *See, e.g.*, *Hegeman Farms Corp. v. Baldwin*, 293 U.S. 163, 170 (1934) (holding that regulation of milk prices that "deprive [a seller] of a profit . . . is not enough to . . . [allow] revision by the courts").

the regulated good.[42] Indeed, by 1987, the Supreme Court declared the constitutionality of state and federal price regulation to be "settled beyond dispute."[43] Lower courts have adopted this posture, including in cases involving regulations of hospital and insurance rates.[44]

ii. Price regulation in the pharmaceutical industry is particularly justified 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."[45] Price regulation is particularly justified in industries that (1) benefit from significant government privileges and (2) are highly regulated. Price regulations in such industries are not only logical, but often essential to protect the public from price gouging. Here, 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.[46] 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

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[42] *See, e.g.*, *Andrus v. Allard*, 444 U.S. 51, 66 (1979) ("When we review regulation, a reduction in the value of property is not necessarily equated with a taking.").

[43] *Fed. Commc'ns Comm'n v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987).

[44] *See, e.g.*, *United Wire Metal and Machine Health and Welfare Fund, v. Morristown Memorial Hosp.*, 995 F. 2d 1179 (3d Cir. 1993) (holding that a New Jersey law setting hospital rates was constitutional and not a taking); *Whitney v. Heckler*, 780 F.2d 963 (11th Cir. 1986) (rejecting a takings challenge to a freeze on physician rates for Medicare).

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

[46] *See Dickson & Ballreich, supra* note 7.

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 constitutional challenge.[47]

Where the federal government grants an individual or industry a special privilege, it is entitled to impose conditions thereon. The Supreme Court affirmed this principle almost a century ago in *Leonard v. Earle*.[48] 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.[49] 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."[50] Indeed, before the Supreme Court, the oyster packers did "not deny the power of the state to declare their business a *privilege* and to demand therefor reasonable payment of money."[51] The government gave the packers a valuable benefit: the privilege to collect and sell the public goods. In exchange, the packers had to compensate "the State, as owner of the oysters" with ten percent of their shells.[52]

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[47] 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 (finding that the governments in "[h]igh-income peer countries . . . negotiate [drug] prices with manufacturers" using various approaches, including "maximum price setting.").

[48] 279 U.S. 392 (1929).

[49] *Leonard v. Earle*, 279 U.S. 392, 394, 396, 398 (1929); *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).

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

[51] *Leonard*, 279 U.S. at 396 (emphasis added).

[52] *Horne*, 576 U.S. at 367 (*quoting Leonard*, 141 A., at 717) (internal quotations omitted).

Over fifty years later, 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.[53] 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.[54] Under FIFRA, companies are required to submit certain data to the EPA as part of their applications for registration to sell insecticides and other dangerous chemicals.[55] Pursuant to the 1978 FIFRA amendments, the EPA could then use that data when considering other companies' applications or disclose the data to the public under certain circumstances.[56]

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.[57] 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."[58] Monsanto could not "successfully" challenge the federal government's ability "to regulate the marketing and use of pesticides . . . for

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

[54] *Id.* at 1000.

[55] *Id.* at 991-92.

[56] *Id.* at 992-93.

[57] *Id.* at 1003-04.

[58] *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").

such restrictions are the burdens we all must bear in exchange for 'the advantage of living and doing business in a civilized community.'"[59] 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."[60] 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.

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,"[61] 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.[62] By granting a pharmaceutical company's new drug application, the FDA grants a "valuable Government benefit"[63]—permission to sell the drug. In exchange, the federal government is free to impose conditions and regulations without violating the Constitution.

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

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[59] *Id.* at 1007 (*quoting Andrus v. Allard*, 444 U.S. 51, 67 (1979).

[60] *Horne v. Dep't of Agric.*, 576 U.S. 350, 365-66 (2015).

[61] *Horne*, 576 U.S. at 365-66.

[62] *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.")

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

research via the National Institute of Health, among other mechanisms.[64] 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.[65] 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, such as on the dosage strength of the drug,[66] methods of using the drug,[67] mode of administering the drug,[68] and manufacturing processes.[69] These secondary patents further

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[64] *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).

[65] 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).

[66] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 142-143 (E.D.N.Y. 2018).

[67] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5-6 (1st Cir. 2020).

[68] *In re Loestrin 24 Fe Antitrust Litigation*, Op. and Order on Def's Mot. to Dismiss, No. 13-2472, ECF No. 299, (R.I. 2017); *id.*, Op. and Order on Summ. J. and Order re Mot. to Exclude Expert Ops., No. 13-2472, ECF No. 1380 (R.I. 2019).

[69] *See, e.g.*, *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 823 (N.D. Ill. 2020).

extend the pharmaceutical company's monopoly.[70] The availability of these secondary patents also enables drug makers to engage in a range of (often anticompetitive) behaviors that further delay generic drug competition such as pay-for-delay, product hopping, and market allocation.[71]

On top of patent protections, Congress has created several regulatory exclusivities for new drugs—a benefit unique to the pharmaceutical industry.[72] Like patents, these regulatory exclusivities enable brand drug makers to delay generic competition and continue supra-competitive pricing.

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.[73] Other laws and regulations require government insurance programs to cover certain

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[70] *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-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).

[71] *See, e.g.*, *F.T.C. v. Actav*is, Inc., 570 U.S. 136, 141 (2013) (holding that pay-for-delay settlements can violate antitrust laws); *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 870 (N.D. Cal. Aug. 13, 2021) (denying motion to dismiss claims that "name-brand manufacturer's volume-limited licenses were [not] plausibly anticompetitive market allocations."). *See generally* Robin C. Feldman & Mark A. Lemley, *Atomistic Antitrust*, 63 WM. & MARY L. REV 1869,1907-14 (2022) (describing how a range of patent-related anticompetitive actions work in concert to delay generic-drug entry).

[72] *See* ERIN H. WARD, KEVIN J. HICKEY & KEITH T. RICHARDS, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 12-14, 29 (2021).

[73] *See* 42 U.S.C. § 1396d(12); 42 U.S.C. § 256b(1) ("The Secretary shall . . ."); 42 U.S.C.

classes of drugs, including many branded pharmaceuticals.[74]

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. 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 market of 65 million people.[75] In 2021, Medicare Part D spending exceeded $200 billion.[76] And this figure continues to rise.[77] Despite this spending, as noted above,

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§ 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).

[74] *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).

CMS requires Part D plans to include at least two drugs in a particular class or formulation on the Part D formulary, where available. These requirements often limit the government's ability to negotiate, especially with manufacturers of single-source brand drugs. *See Chapter 6- Part D Drugs and Formulary Requirements*, *included in* MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL (Jan. 15, 2016).

[75] *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.

[76] *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 (Sept. 2023). Medicare Part D is Medicare's prescription drug benefit. Generally, it covers drugs patients purchase through retail or mail order pharmacies.

[77] *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,

consumers in this program struggle to pay for drugs.[78] The program currently has no structural price controls and, without the IRA's drug price negotiation program, minimal negotiating power.[79] Medicare Part B does not negotiate at all, paying for drugs at the average sales price set by the drug makers, plus 6%.[80] 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.[81]

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.[82] As described above, the pharmaceutical industry is arguably the most

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Prescription Drugs: Spending, Use, and Prices 8, CONG. BUDGET OFF. (Jan. 2022) (describing inflation-adjusted growth in Part D spending between 2009 and 2018).

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

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

[80] *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.

[81] *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).

[82] *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").

regulated industry in the country, and government price negotiations are part and parcel of federal healthcare programs. Even if applied to the entire drug industry, which this *Medicare* drug price negotiation program is not, price regulation would be justified. The beneficiaries of the government's extraordinarily valuable privileges, especially in highly regulated industries, must adhere to the conditions it sets, not wield their privilege to harm the public.

C. A ruling that the Medicare drug price negotiation program constitutes an unconstitutional price control 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.[83] But, due to their reach, these programs strain state and federal budgets. In 2021, Medicare alone accounted for 21% of all U.S. healthcare spending and 10% of the federal budget.[84] Medicare's costs are predicted to rise to 18% of the federal budget in 2032.[85] The

[83] *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.75. *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.

[84] *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.

[85] *Id.*

Medicaid program cost $728 billion, excluding administrative costs, in fiscal year 2021,[86] about 17% of national health expenditures that year.[87]

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 an unconstitutional price control 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 regarding programs never-before questioned. For example, such a ruling could open the courts to takings challenges in which the 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.[88] For example, takings challenges to EMTALA have failed on the grounds that participation in Medicare (and by extension in EMTALA) is voluntary.[89] A holding that the IRA's Medicare drug price negotiations

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[86] *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.

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

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

[89] *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

are coerced could open the door to a similar holding with respect to EMTALA. Every unpaid emergency room visit could be grounds for constitutionality 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.

III. CONCLUSION

For these reasons, amici respectfully request that the Court reject Novo's claim that the IRA Medicare drug price negotiation program constitutes an unconstitutional price control.

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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.'").

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CERTIFICATE OF SERVICE

I, Donald A. Ecklund, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: February 2, 2024

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