No. 24-2968

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVARTIS PHARMACEUTICALS CORP., et al.,
Plaintiff-Appellant,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey
No. 3:23-cv-14221
Hon. Zahid N. Quraishi

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, DOCTORS FOR AMERICA, FAMILIES USA, AND PROTECT OUR CARE IN SUPPORT OF APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Public Citizen, Inc., Doctors for America, Families USA, and Protect Our Care are nonprofit, nonstock corporations. None of them have a parent corporation, and because they issue no stock, no publicly held corporation owns 10% or more of their stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

Other Authorities

Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016) 21, 22, 23, 24

Ashley Kirzinger et al., *Data Note: Prescription Drugs and Older Adults*, Kaiser Family Foundation (Aug. 9, 2019) 8

Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, Kaiser Family Foundation (Mar. 1, 2019) 8

Berkeley Lovelace, Jr., *1 in 5 older adults skipped or delayed medications last year because of cost*, NBC News (May 18, 2023)..... 10

Chris Melore, *Healthcare hell: 1 in 5 seniors skip paying rent, buying groceries to afford their cocktail of prescription meds*, StudyFinds (Nov. 15, 2022) 12, 13

Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Research Report (2021)..... 30, 31

Anthony W. Olson et al., *Financial hardship from purchasing prescription drugs among older adults in the United States before, during, and after the Medicare Part D "Donut Hole": Findings from 1998, 2001, 2015, and 2021*, 28 J. Managed Care & Specialty Pharm. 508 (May 2022)..... 9

S. Vincent Rajkumar, *The high cost of prescription drugs: causes and solutions*, 10 Blood Cancer J. (2020) 19

Christina Ramsay & Reginald D. Williams II, *Medicare Patients Pay More for Drugs Than Older Adults in Other Countries; Congress Has an Opportunity to Move Forward*, The Commonwealth Fund (Sept. 30, 2021) 11, 12

David M. Rind et al., Institute for Clinical & Economic Review, *Unsupported Price Increase Report: Unsupported Price Increases Occurring in 2021* (Dec. 6, 2022) 25

INTEREST OF AMICI CURIAE[1]

Public Citizen is a nonprofit consumer advocacy organization with members and supporters in all 50 states. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including issues concerning consumer health and safety. A central concern of Public Citizen is protecting and expanding access to affordable medicines for consumers, both domestically and globally. To advance that interest, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower pharmaceutical prices. Public Citizen has provided technical assistance concerning patent rules and access to medicines to dozens of governments and international organizations.

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics on the pressing issues of the day to improve the health of their patients, communities, and nation. A non-partisan, nonprofit, non-trade organization working on patients' behalf,

[1] This brief was not authored in whole or part by counsel for a party, and no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of the brief. Counsel for all parties have consented to its filing.

Doctors for America is continuously working to improve access to equitable, affordable, high-quality health care for patients across the country. For this reason, Doctors for America has a longstanding history of working to improve drug affordability by advocating for legislative, regulatory, and judicial changes to ensure that patients can access life-sustaining treatments.

Families USA is a non-partisan voice for health care consumers and is dedicated to achieving high-quality, affordable health care and improved health for all. On behalf of health care consumers, working people, and patients, Families USA has advocated for decades for legislation and rulemaking that improves the accessibility and affordability of prescription drugs. Families USA believes that ensuring drug affordability should be a key part of the Medicare Part D program and has urged policymakers to explore the root causes of high and irrational drug prices and to tackle the complex network of abusive practices that underpin the American pharmaceutical market.

Protect Our Care, a fiscally sponsored project of the New Venture Fund, is dedicated to making high-quality, affordable, and equitable health care a right, and not a privilege, for everyone in America. Protect

Our Care educates the public, influences policy, supports health care champions, and holds lawmakers accountable. Protect Our Care supported the development and enactment of the Inflation Reduction Act's provisions to make prescription drugs more affordable, including the Medicare drug price negotiation program. Protect Our Care is committed to the successful implementation of the Act to ensure that seniors and taxpayers benefit from more affordable prescription drugs.

Amici curiae share an interest in the promotion and implementation of policies that make medications more accessible and affordable to the patients who need them, thereby improving health outcomes, saving lives, and protecting the financial health of individuals and families. Because the Inflation Reduction Act's drug price negotiation program is an important step towards reining in the high cost of prescription drugs for patients enrolled in Medicare, amici are concerned that the arguments made by Novartis, if accepted by this Court, would result in substantial harm to the health and finances of seniors and other Medicare patients.

INTRODUCTION AND SUMMARY OF ARGUMENT

For many years, seniors have struggled to pay the high cost of prescription medications. High prescription drug prices force many seniors to cut back on other expenses—including necessities such as mortgages and groceries—to pay for the drugs they need. Others have had to forgo medications that they cannot afford, risking adverse health effects and premature death. Enacted in August 2022, the Inflation Reduction Act of 2022 (IRA) contains several reforms designed to lower the high cost of prescription drugs and make them more accessible to patients, including seniors enrolled in Medicare. *See* Pub. L. No. 117-169, §§ 11001–11003, 136 Stat. 1818, 1833–1861, *codified at* 42 U.S.C. §§ 1320f et seq. and 26 U.S.C. § 5000D. One such reform is the IRA's drug price negotiation program, which provides a pathway to lower the prices for a particular set of high-cost drugs—so-called single-source drugs, for which no generic equivalent is currently on the market. The program relies on a process in which the Department of Health and Human Services (HHS) and the manufacturer of selected drugs negotiate the prices at which drugs subsidized by Medicare will be made available to Medicare providers and drug plans.

Seeking to protect its ability to extract huge profits from Medicare subsidies by maintaining exceedingly high prices for its single-source drugs, Novartis challenges the IRA program on various legal grounds, including under the Takings Clause. Novartis's Takings Clause claim, however, is based on the notion that through the IRA program, "the government … requisition[s] valuable drugs from manufacturers at prices well below market value." Novartis Br. 1; *see also id.* at 12 (stating that the IRA program "yields prices that are well below market value"). Underlying this claim is the notion that the drug's "market" price is whatever price Novartis would otherwise charge Medicare; anything below that amount, it suggests, results in an unconstitutional taking. Novartis's theory, however, is built on the premise that the price drug companies prefer to charge Medicare patients is the "market" price from which any reduction in price under the program must be evaluated. That premise is wrong. And absent any showing that the drug prices negotiated under the IRA program necessarily fall short of the drug's fair market value, Novartis's Takings Clause challenge must be rejected.

ARGUMENT

I. The high cost of prescription drugs harms patients' health and quality of life.

"Medicare is the single largest purchaser of prescription drugs in the [United States], and those drugs account for more than 1 in 4 health care dollars spent by Medicare." Benjamin N. Rome et al., *Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022*, JAMA Health Forum, at 2 (Jan. 27, 2023).[2]

Medicare provides drug coverage to seniors through two programs: Part B and Part D. Medicare Part B compensates medical providers for drugs administered by health care professionals in medical facilities and doctor's offices. *See* Ctrs. for Medicare & Medicaid Servs. (CMS), No. 11315-P, *Drug coverage under different parts of Medicare* 1 (Mar. 2023).[3] HHS does not currently negotiate the prices for drugs covered under Part B. Instead, Medicare reimburses providers based on a statutory formula

[2] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2800864.

[3] https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf.

that typically results in payment of the average sales price plus 6%. *See* 42 U.S.C. § 1395w-3a(b), (c).

Part D was enacted in 2003 to address seniors' access to outpatient prescription drugs not covered by Part B. *See* Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071, *codified as amended at* 42 U.S.C. §§ 1395w-101 et seq. Under the Part D program, Medicare contracts with private plan sponsors to provide a prescription drug benefit. Prior to the enactment of the IRA, Part D relied on direct negotiations between drug manufacturers and Part D plans to set drug prices; HHS was barred from participating in those negotiations. *See* 42 U.S.C. § 1395w-111(i) (providing that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," and "may not require a particular formulary" or "institute a price structure for the reimbursement of covered part D drugs," except as provided in specified statutory provisions).

Despite the coverage benefits offered under Medicare Parts B and D, Medicare beneficiaries continue to face extremely high drug prices

that make access difficult for many consumers, harming their finances, their health, and their ability to enjoy life. Of those adults taking prescription drugs, nearly one in four (24%) report difficulty in affording their prescription drugs, and nearly three in ten (29%) report not taking their medicines as prescribed because of cost. Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, Kaiser Family Found. (Mar. 1, 2019).[4] Nearly one in ten adults (8%) say that their health condition worsened due to not taking their prescription medication as recommended. *Id.*

High drug prices impact seniors in particular. As of 2019, "[n]early nine in ten (89%) adults 65 and older report[ed] they are currently taking any prescription medicine," and "a majority of older adults [had] prescription drug coverage through Medicare Part D." Ashley Kirzinger et al., *Data Note: Prescription Drugs and Older Adults*, Kaiser Family Found. (Aug. 9, 2019).[5] But despite the benefits provided by Part D and

[4] https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.

[5] https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

other reforms, in 2019, nearly one in four (23%) of seniors continued to find it "difficult to afford their prescription drugs." *Id*. (emphasis removed).[6] Much of that difficulty is attributed to large and rapid price increases in the preceding years. Prescription drug prices rose "faster than prices for overall U.S. goods and services in most years from 2000 to 2020," mainly due to price increases for existing brand-name drugs and adoption of expensive new brand-name drugs. Cong. Research Serv., R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy* 8–9 (2021).[7] Accordingly, while prior reforms had stabilized consumers' out-of-pocket spending on prescription drugs generally, by the end of the last decade, "the number of consumers with high out-of-pocket costs—such as those with serious conditions or those prescribed specialty drugs—ha[d] increased." *Id*. at 13. According to one study, "Part

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[6] *See also* Anthony W. Olson et al., *Financial hardship from purchasing prescription drugs among older adults in the United States before, during, and after the Medicare Part D "Donut Hole": Findings from 1998, 2001, 2015, and 2021*, 28 J. Managed Care & Specialty Pharm. 508, 509 (May 2022), https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.5.508 ("Financial hardship from purchasing prescription drugs is still experienced by many older adults after the full implementation of the [2003 law] and [the Affordable Care Act].").

[7] https://crsreports.congress.gov/product/pdf/R/R44832/7.

D enrollees paid $16.1 billion out of pocket in 2019, up 27% over the previous five years." *Id.* at 13 n.43.

These high costs deter seniors from taking the medication they need to maintain or improve their health. According to a 2023 study, "[a]bout 1 in 5 adults ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost." Berkeley Lovelace, Jr., *1 in 5 older adults skipped or delayed medications last year because of cost*, NBC News (May 18, 2023)[8] (discussing Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network (May 18, 2023)).[9] Similarly, a 2022 HHS report found that "[m]ore than 5 million Medicare beneficiaries struggle to afford prescription medications. Among adults 65 and older, Black and Latino beneficiaries are most likely to experience affordability problems. Medicare beneficiaries with

[8] https://www.nbcnews.com/health/health-news/1-5-older-adults-skipped-delayed-medications-last-year-cost-rcna84750.

[9] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012.

lower incomes and those under age 65 also had above-average rates of not taking needed medications due to cost." Wafa Tarazi et al., HHS, *Prescription Drug Affordability among Medicare Beneficiaries* 1 (Jan. 19, 2022).[10] And a 2020 report estimated that, by 2031, "112,000 seniors each year could die prematurely because drug prices and associated cost-sharing are so high that they cannot afford their medication." Council for Informed Drug Spending Analysis, *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost* (Nov. 18, 2020).[11]

This situation need not exist—and does not in other countries: "Seniors in the U.S. have the highest rate among 11 high-income countries (Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States) of not taking prescription drugs because of cost." Christina Ramsay & Reginald D. Williams II, *Medicare Patients Pay More for Drugs Than Older Adults in Other Countries; Congress Has an*

[10] https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf.

[11] https://www.cidsa.org/publications/xcenda-summary.

Opportunity to Move Forward, The Commonwealth Fund (Sept. 30, 2021).[12]

Beyond the health costs, high drug prices impose financial costs on seniors, who are often retired and living on fixed incomes, and who often struggle to pay for prescription drugs. *See, e.g.*, Matt Sedensky & Carla K. Johnson, *Deal on Capitol Hill could ease seniors' health costs*, Associated Press (July 28, 2022).[13] And paying for drugs often requires sacrificing other essential needs. A 2022 survey of 2,000 seniors, for instance, found that "35 percent have cut down on costs in other aspects of their life in order to have enough money to afford their healthcare needs," and about 20% have "cut down on paying for necessities like the rent or mortgage payments … and groceries … in order to pay for medical costs." Chris Melore, *Healthcare hell: 1 in 5 seniors skip paying rent, buying groceries to afford their cocktail of prescription meds*, StudyFinds

[12] https://www.commonwealthfund.org/blog/2021/medicare-patients-pay-more-drugs-older-adults-other-countries-congress-has-opportunity.

[13] https://apnews.com/article/health-seniors-medicare-prescription-drug-costs-drugs-8aaa8fd3959c1da5fba5b5a352b6afb0.

(Nov. 15, 2022).[14] The high prices have a particularly damaging impact on the many seniors of limited means who must "decid[e] whether they will buy groceries or pay for a prescription." Andrea Baer, *Why are seniors struggling to afford their medications?*, PAN Found. (July 2, 2019).[15]

II. Prices negotiated under the IRA program do not result in an unconstitutional taking.

To address the high cost of prescription drugs, and the concomitant high cost in terms of health and quality of life, Congress in the IRA created a program to lower the prices of a particular set of high-cost drugs, known as single-source drugs. The IRA program relies on a negotiation between HHS and drug manufacturers to determine the prices at which drugs subsidized by Medicare will be made available to providers and drug plans that participate in the Medicare program.

Novartis's Takings Clause claim rests on the premise that through the IRA program, "the government … requisition[s] valuable drugs from manufacturers at prices well below market value." Novartis Br. 1; *see*

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[14] https://studyfinds.org/healthcare-hell-seniors-prescription-medication/.

[15] https://www.panfoundation.org/why-are-seniors-struggling-to-afford-their-medications/.

also id. at 12 (stating that the IRA program "yields prices that are well below market value"). This premise is doubly flawed.

First, the IRA program does not mandate that manufacturers give drugs to Medicare; it mandates a *negotiation* of the price of designated drugs, which the manufacturer may choose to forgo by not participating in Medicare and Medicaid. That the government is leveraging manufacturers' desire for federal subsidies for their drugs does not transform a negotiation into a taking. Indeed, drug companies regularly negotiate prices with other government entities, both in the United States and abroad.

Second, although Novartis does not state the fair market price of any drug or explain how such a price should be calculated, it suggests that the price that a drug company charges buyers in the Medicare program (absent negotiation) is the drug's "market value." "Fair market value," however, is the price determined by a willing buyer and a willing seller. In a monopoly system where a seller has an exclusive product, however, the sales price—absent negotiation—is not set by the "fair market value," but by the seller's effort to maximize profit. Indeed, drug companies charge different amounts to different buyers and in different

countries. Because Novartis's Takings Clause claim fails to appreciate the dynamics that inform pricing in the market for brand-name prescription drugs, Novartis's assertion that the price negotiated under the IRA program results in an unconstitutional taking fails.

A. Drug companies set prices for brand-name prescription drugs under monopolistic conditions.

The products at issue under the IRA program are brand-name prescription drugs currently on the market without generic alternatives. Because of the power afforded by the market exclusivity of these products, combined with the pre-IRA bar on Medicare negotiating prices, the manufacturers of those drugs have, to date, been able to set prices for Medicare with minimal constraints. Drug manufacturers price drugs "to maximize profits." HHS, *Prescription Drugs: Innovation, Spending, and Patient Access* 27 (Dec. 7, 2016).[16] And "[o]nce a drug is approved, the brand-name manufacturer sets its initial price in the United States at what the manufacturer estimates that the market will bear." Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An*

[16] https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//192456/DrugPricingRTC2016.pdf.

Overview of the Landscape and Avenues for Improvement, 30 Stan. L. & Pol'y Rev. 421, 453 (2019).

1. During the period of market exclusivity, a brand-name drug is protected from generic drug competition. Two exclusivity periods are potentially available. First, a company that has a patent on its drug generally has the exclusive right to make or sell the drug for 20 years after the filing date of the patent application. *See* 35 U.S.C. § 154(a).[17] A patent is awarded by the U.S. Patent and Trademark Office, *see* 35 U.S.C. §§ 101–103, and can be sought by a company at any time during the development of a drug. *See* Food & Drug Admin. (FDA), *Frequently Asked*

[17] Drug companies sometimes use "patenting practices" that extend the exclusivity period. Cong. Research Serv., R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing* 6 (2021), https://crsreports.congress.gov/product/pdf/R/R46679. These practices include: (1) "obtain[ing] new patents to cover a product as older patents expire to extend the period of exclusivity without significant benefits for consumers"; (2) "attempting to switch or 'hop' consumers to a slightly different product covered by a later-expiring patent, just as the patent covering a current product nears expiration"; (3) "acquir[ing] many overlapping patents on a single product, creating so-called 'patent thickets'"; and (4) "'pay-for-delay' or 'reverse payment' settlements," where companies "settle litigation that results when a generic [drug] seeks to compete with a patented branded product" by "transfer[ing] value from the brand to the generic in return for the generic delaying its market entry." *Id.* at 43 (citations omitted).

Questions on Patents and Exclusivity.[18] Second, after a drug company receives FDA approval of a new drug application, allowing a company to market the product for specified uses, the company is entitled by statute to an exclusivity period, the length of which depends on the type of drug and other factors. For example, the exclusivity period for a drug that contains a new chemical active ingredient is generally 5 years, 21 U.S.C. § 355(c)(3)(E)(ii), and the exclusivity period for new biologics is 12 years, 42 U.S.C. § 262(k)(7)(A). As the FDA has explained, "[s]ome drugs have both patent and exclusivity protection while others have just one or neither. Patents and exclusivity may or may not run concurrently and may or may not cover the same aspects of the drug product." FDA, *Frequently Asked Questions*.

2. During a drug's exclusivity period, drug companies have a monopoly with respect to the drug. For that reason, the price that a monopolist would charge buyers absent price negotiations is not the drug's "fair market value." "Fair market value" is "a price as would be fixed by negotiation and mutual agreement, after ample time to find a

[18] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity.

purchaser, as between a vendor who is willing (but not compelled) to sell and a purchaser who desires to buy but is not compelled to take the particular ... piece of property." *BFP v. Resol. Tr. Corp.*, 511 U.S. 531, 538 (1994) (alteration in original; citation omitted); *see also* Value, *Black's Law Dictionary* (12th ed. 2024) (defining "fair market value" as "[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction; the point at which supply and demand intersect"). In a monopoly system, however, "the practical suppression of effective business competition … creates a power to control prices to the public harm." Monopoly, *Black's Law Dictionary* (12th ed. 2024) (quoting 54A Am. Jur. 2d *Monopolies, Restraints of Trade, and Unfair Trade Practices* § 781 (1996)). Because "fair market value" presumes market conditions involving "negotiation and mutual agreement," *BFP*, 511 U.S. at 537 (citation omitted), the price charged by a monopolistic seller absent any negotiation is not the measure of fair market value.

For pharmaceuticals, the pricing power afforded by monopoly is far greater than for other tangible products, for at least three reasons. First, the "pharmaceutical industry is … a high-fixed low-cost marginal cost

industry," where the manufacturing (marginal) cost of drugs is slight relative to the fixed cost. Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, Health Affairs Blog (Nov. 13, 2017) (explaining that "the cost of producing an extra unit of a product that is on the market is frequently 'pennies a pill'").[19] Second, the demand side for drugs is different than for other products. Because prescription medicines are necessary to people's health and well-being, some "patients and their families are willing to pay any price in order to save or prolong life." S. Vincent Rajkumar, *The high cost of prescription drugs: causes and solutions*, 10 Blood Cancer J. 2 (2020).[20] Third, the drug companies' pricing power during the exclusivity period is amplified by laws requiring insurance coverage of many prescription drugs. For example, Medicare Part D plans are generally required to cover "at least two Part D drugs that are not therapeutically equivalent and bioequivalent" within each therapeutic category and class of Part D drugs. 42 C.F.R. § 423.120(b)(2)(i); *see also*

[19] https://www.healthaffairs.org/content/forefront/pharmaceutical-industry-profits-and-research-and-development.

[20] https://www.nature.com/articles/s41408-020-0338-x.

42 U.S.C. § 1395w-104(b)(3)(G). In addition, Part D plans are required to cover all FDA-approved "[a]nticonvulsants," "[a]ntidepressants," "[a]ntineoplastics" (cancer-treatment drugs), "[a]ntipsychotics," "[a]ntiretrovirals" (HIV-treatment drugs), and "[i]mmunosuppressants for the treatment of transplant rejection." 42 U.S.C. § 1395w-104(b)(3)(G)(iv)(I)–(VI). Although the federal government does not mandate prescription drug coverage by state Medicaid programs, state Medicaid programs receiving federal rebates for prescription drugs are required to cover all FDA-approved drugs, subject to certain exceptions. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 Minn. L. Rev. 2307, 2316–17 (2018) (discussing public payer coverage requirements for prescription drugs); *see also* 42 U.S.C. § 1396r-8(k)(2).

For these reasons, drug companies during the exclusivity period can impose prices that are orders of magnitude higher than the marginal cost of producing the drug. Indeed, the pre-IRA Medicare Part D purchasing scheme, which barred negotiations by HHS, illustrates these unrestrained monopoly price-setting dynamics. Although other countries have similar patent laws and regulatory exclusivity periods comparable to those in the United States—for example, the exclusivity period in the

European Union can run up to 11 years[21]—the U.S. "practice is distinct from that of other high-income countries, which to differing degrees have government-affiliated organizations that negotiate a price based on evaluation of the drug's clinical and cost-effectiveness," resulting in "most brand-name drugs cost[ing] far more in the United States than in other comparable settings around the world." Kesselheim et al., *Pharmaceutical Policy*, 30 Stan. L. & Pol'y Rev. at 453.

To be sure, enabling drug companies to charge above marginal-cost prices is the reason for an exclusivity period—so that the companies can recoup the substantial costs of research and development, including the cost of clinical trials and other costs incurred to bring a drug to market. *See* Cong. Research Serv., *Drug Prices*, at Summary; *see also* Frank & Ginsburg, *Pharmaceutical Industry Profits*; Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and*

[21] Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity,* 17 Developing World Bioethics 11, 13 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/pdf/DEWB-17-11.pdf (discussing the European Union's data exclusivity period).

Prospects for Reform, 316 JAMA 858, 863 (2016).[22] However, the purpose of the government-conferred monopoly does not justify the exorbitant prices that companies charge Medicare enrollees and that Congress sought to rein in through the IRA program. In any event, the IRA price-negotiation program applies only to drugs that have generated the highest level of revenue—far exceeding any plausible estimate of the cost of research and development—and only after those drugs have had lengthy periods of exclusivity: For a drug to qualify for selection to participate in the IRA program, at least 7 years must have elapsed since FDA approval of the drug, and for a biologic to qualify, at least 11 years must have elapsed since FDA licensure of the biologic. *See* 42 U.S.C. § 1320f-1 ("Selection of negotiation-eligible drugs as selected drugs"); *see also* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 98–99 (June 30, 2023).[23]

[22] https://jamanetwork.com/journals/jama/article-abstract/2545691.

[23] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

B. A company's preferred price for a brand-name prescription drug is not necessarily a "fair" price.

Without guardrails like price negotiation, the monopoly power exercised by drug companies enables exorbitant pricing that does not reflect the cost of research and development. Indeed, pharmaceutical companies spend on average only approximately one-quarter of their revenues (net of expenses and rebates) on research and development. Cong. Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021).[24] As HHS has explained, although "[d]rug manufacturers often point to high drug development costs as a justification for high drug prices[,] … [i]n reality, the prices charged for drugs are unrelated to their development costs." HHS, *Prescription Drugs* at 27; *see* Kesselheim et al., *The High Cost of Prescription Drugs*, 316 JAMA at 863 (stating "there is no evidence of an association between research and development costs and [drug] prices"). Instead, companies price drugs during the exclusivity period at the highest levels they believe the market will bear, *see* Kesselheim et al., *The High Cost of Prescription*

[24] https://www.cbo.gov/publication/57126.

Drugs, 316 JAMA at 863, resulting in prices that cannot be called either "fair market value" or "fair" to patients.

Drug-company spending confirms that the prices charged to Medicare cannot be justified by pointing to companies' research and development costs. For example, "counter[ing] the claim that the higher prices paid by US patients and taxpayers are necessary to fund research and development," "the premiums pharmaceutical companies earn from charging substantially higher prices for their medications in the US compared to other Western countries generates substantially more than the companies spend globally on their research and development." Nancy L. Yu et al., *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, Health Affairs Blog (Mar. 7, 2017) (emphasis added).[25]

Notably, although manufacturers commonly increase the price for a particular drug annually, the increases do not reflect improvements in the drug's net health benefit or new costs incurred by the manufacturer for that drug. According to a study of 2021 drug prices, "[o]f the 10 drugs

[25] https://www.healthaffairs.org/content/forefront/r-d-costs-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices.

assessed due to net price increases, seven were judged to have price increases unsupported by new clinical evidence." David M. Rind et al., Inst. for Clinical & Econ. Review, *Unsupported Price Increase Report: Unsupported Price Increases Occurring in 2021*, at ES2 (Dec. 6, 2022).[26] "The unsupported net price increases of these seven drugs produced a total of $805 million incremental added costs to US payers in 2021." *Id.*

Inflation costs also do not justify the annual increases in drug prices, which have risen at a rate vastly exceeding the inflation rate. For example, a study conducted by researchers at the University of Pittsburgh found that from 2007 to 2018, list prices for brand-name drugs, adjusted to account for inflation, increased by 159 percent, or 9.1 percent per year, and that "net prices increased every year by an average of 4.5 percentage points, or 3.5 times faster than inflation." Inmaculada Hernandez et al., *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018*, 323 JAMA 854, 861 (2020).[27] Another study found that "[f]rom 2008 to 2021, launch prices for new

[26] https://icer.org/wp-content/uploads/2022/04/UPI_2022_National_Report_120622.pdf.

[27] https://jamanetwork.com/journals/jama/article-abstract/2762310.

drugs increased exponentially by 20% per year" and that "[p]rices increased by 11% per year even after adjusting for estimated manufacturer discounts and changes in certain drug characteristics." Benjamin N. Rome et al., *Trends in Prescription Drug Launch Prices, 2008–2021*, 327 JAMA 2145, 2145 (2022).[28] During those same years, the annual inflation rate did not exceed 5 percent, and for all but two of those years, the annual inflation rate was below 3 percent. *See* Bureau of Labor Statistics, *CPI for All Urban Consumers (CPI-U)* (database statistics for the consumer price index from 2008 to 2021).[29]

C. Outside of Medicare, drug companies negotiate prices and charge different prices to different buyers.

That a brand-name manufacturer's preferred Medicare price is not properly deemed a fair market price of the drug is further confirmed by the fact that manufacturers do not generally set a uniform price for the "market"; they negotiate different prices with different buyers. In this

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[28] https://jamanetwork.com/journals/jama/fullarticle/2792986.

[29] https://data.bls.gov/toppicks?survey=cu. Select "U.S. city average, All items–CUUR0000SA0" and click "Retrieve Data"; click "More Formatting Options" and (1) select "12-Month Percent Change," (2) choose year range from 2008 to 2021, (3) select "Annual Data" for time period, and (4) click "Retrieve Data."

regard, the Medicare program, lacking the ability to negotiate, has been an outlier, and the prices charged to Medicare have not been reflective of fair market value. The IRA program, by requiring negotiation, will bring prices more in line with those paid by other large-scale buyers. For example, for drugs with no therapeutic alternatives or where the price of the alternative is above the statutory ceiling under the IRA program, CMS will use "the maximum price a drug manufacturer is allowed to charge the 'Big Four' federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard" as its starting point to determine its initial offer for the price negotiation. CMS, *Revised Guidance* at 147 n.66.

Other government agencies and programs responsible for purchasing and reimbursing the cost of prescription drugs do not simply accept prices dictated by the manufacturer. For example, the VA, unlike Medicare and Medicaid, determines which drugs it will cover and can negotiate prices with manufacturers. *See* Gov't Accountability Office (GAO), GAO-21-111, *Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*,

Highlights (2020)[30]; *see also* Health Affairs, *Prescription Drug Pricing: Veterans Health Administration* 2 (Aug. 2017).[31] As a result, prices paid by the VA are substantially lower than those paid under Medicare Part D for the same drug. For example, the 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." GAO, *Prescription Drugs* at Highlights. The GAO also reported that "233 of the 399 drugs in the sample were at least 50 percent cheaper in VA than in Medicare, and 106 drugs were at least 75 percent cheaper." *Id*. The VA achieves these lower prices through a combination of statutory fixed discounts (including the Federal Ceiling Price, which, like the IRA program, is based on percentages of the non-federal average manufacturer price, *see* 38 U.S.C. § 8126(b)) and bulk negotiating power, GAO, *Prescription Drugs* at 9–10.[32]

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[30] https://www.gao.gov/assets/gao-21-111.pdf.

[31] https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/healthpolicybrief_174-1525355141023.pdf.

[32] Moreover, within Medicare, fee-for-services prices paid to hospitals and physicians are set by statute and regulations—not by the provider—

Likewise, manufacturers do not set prices under the Medicaid Drug Rebate Program (MDRP), which requires prescription drug manufacturers to provide a discount of at least 23.1% of the average manufacturer price, or a greater discount to match the best price available to the manufacturer's most favored commercial customer, subject to certain exceptions. *See* 42 U.S.C. § 1396r-8(c)(1). If price increases outpace inflation, the statute requires an additional rebate. *Id.* § 1396r–8(c)(2). In addition to statutory discounts, state Medicaid programs negotiate supplementary rebates, sometimes through

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and are generally updated annually by regulation. *See* Cong. Research Serv., R46797, *Finding Medicare Fee-For-Service (FFS) Payment System Rules: Schedules and Resources* (2024), https://crsreports.congress.gov/product/pdf/R/R46797 (collecting statutory and regulatory requirements for different fee-for-service payment systems); *see also* CMS, *Medicare Fee-for-Service Payment Regulations*, https://www.cms.gov/medicare/regulations-guidance/fee-for-service-payment-regulations (collecting all fee-for-service payment regulations by provider type). CMS determines rates for physician reimbursement under Medicare Part B according to "the Resource Based Relative Value Scale," which "weight[s] services according to the resources used in delivering the service": the physician work required to provide the service, the expenses related to the practice, and malpractice insurance expenses. HHS, No. 04-0008, *Determinants of Increases in Medicare Expenditures for Physicians' Services* 79 (Oct. 2003), https://www.ncbi.nlm.nih.gov/books/NBK43879/pdf/Bookshelf_NBK43879.pdf.

purchasing pools where states join together for greater negotiating leverage. *See* Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, Kaiser Family Found. (Apr. 29, 2020)[33]; *see also* Sachs, *Delinking Reimbursement*, 102 Minn. L. Rev. at 2317 (stating that "states are empowered to seek additional rebates on top of" the ones required by statute). For top-selling drugs, the statutory discounts and negotiations have resulted in average net prices in Medicaid that are 35 percent of the average net price in Medicare Part D. *See* Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 18 (Feb. 2021).[34]

Moreover, manufacturers charge substantially lower prices to peer countries than they charge for the same drugs in the United States. For example, a RAND study found that U.S. prices for drugs in 2018 were 256% of those in 32 comparison countries. *See* Andrew W. Mulcahy et al.,

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[33] https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-payment-supplemental-rebates-and-rebate-management/.

[34] https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf.

International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies, RAND Research Report 36 (2021).[35] For brand-name drugs, U.S. prices were even higher than those in comparison countries, with U.S. prices at 344% of those in comparison countries. *Id*. Other studies similarly have found that U.S. prices for brand-name drugs "were more than two to four times higher" than prices in peer countries. GAO, GAO-21-282, *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France* (Mar. 2021) (comparing 2020 drug prices in the U.S. against those in Australia, Canada, and France)[36]; *see also* H.R. Comm. on Ways & Means, *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices* 4 (Sept. 2019) [hereafter, *Painful Pill*] (comparing 2017 and 2018 drug prices in the U.S. against those in

[35] https://www.rand.org/pubs/research_reports/RR2956.html. The 32 comparison countries are Australia, Austria, Belgium, Canada, Chile, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United Kingdom. *Id.* at 17.

[36] https://www.gao.gov/assets/gao-21-282.pdf.

11 other foreign regions and finding that "U.S. drug prices were nearly four times higher than average prices compared to similar countries" (formatting omitted)).[37] A House report analyzing 2017 and 2018 prices found that "[t]he greatest disparity was with Japan, where the average drug price was only 15 percent that of the U.S., meaning that the U.S. on average spends seven times what Japan pays for the same drugs." *Painful Pill* at 4.

For example, Humira, the "best-selling prescription drug in the world, … is over 500 percent more expensive in the U.S." than in 11 other foreign peer regions. *Id.* at 18. In 2018, the average price of Humira in the United States was $2,346.02 per dose. *Id.* The next highest price was in Denmark, where the same drug cost $787.10, and the combined mean price in the 11 other regions was $450.60. *Id.*

Novartis likewise charges higher prices in the United States than in other comparison countries. For example, in 2021, the estimated U.S. net price for Novartis's drug Entresto was $9.57 per dosage unit. Evan D.

[37] These 11 foreign regions are the United Kingdom, Japan, Ontario, Australia, Portugal, France, the Netherlands, Germany, Denmark, Sweden, and Switzerland.

Gumas et al., *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*, The Commonwealth Fund (Jan. 4, 2024).[38] That same year, in Switzerland, Japan, the United Kingdom, Australia, Germany, France, and Canada, the prices ranged from $4.51 to $1.25, with an average of $3.22—approximately one third of the price charged in the United States for the same drug. *Id.* The recently announced negotiated price for Entresto brings the Medicare cost closer to the international average: From $628 for a 30-day supply in 2023 ($20.93 per day) to $295 beginning in 2026 ($9.83 per day)—a 53% savings.[39] Even with these and the other negotiated cost reductions, Medicare will still pay two to five times more than Australia, Japan,

[38] https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally.

[39] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, at 2 (Aug. 2024), https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

Canada, and Sweden for nine of the ten drugs involved in the first year of the program.[40]

* * *

Novartis does not contest that it wants to sell brand-name drugs to Medicare participants and beneficiaries. It does not contest that it will be paid for purchases of the drugs. Instead, it argues that Medicare will pay less than the average amount that it *prefers* to charge in the United States—although not necessarily less than the amount that it charges other buyers in the United States or internationally. But Novartis is wrong that its desire to impose a high monopolistic price on Medicare, the world's largest drug purchaser, without negotiations, means that purchase below that price necessarily constitutes an unconstitutional taking. Novartis's Takings Clause claim thus fails to take account of the pricing dynamics in the market for brand-name prescription drugs and should be rejected.

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[40] Deena Beasley, *US will still pay at least twice as much after negotiating drug prices*, Reuters (Sept. 3, 2024), https://www.reuters.com/world/us/us-will-still-pay-least-twice-much-after-negotiating-drug-prices-2024-09-03/.

CONCLUSION

This Court should affirm the judgment of the district court.

February 26, 2025

Respectfully submitted,

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