**Case No. 25-50661**

**UNITED STATES COURT OF APPEALS**
**FOR THE FIFTH CIRCUIT**

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NATIONAL INFUSION CENTER ASSOCIATION, *on behalf of itself and its members*; GLOBAL COLON CANCER ASSOCIATION, *on behalf of itself and its members*; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *on behalf of itself and its members*,
*Plaintiffs-Appellants*,

*v.*

ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services, In his Official Capacity; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, Administrator of the Centers for Medicare and Medicaid Services, In his Official Capacity; CENTERS FOR MEDICARE AND MEDICAID SERVICES,
*Defendants-Appellees.*

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On Appeal from the United States District Court
for the Western District of Texas (Ezra, J.), No. 1:23-cv-707

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# AMICUS BRIEF OF PATIENTS FOR AFFORDABLE DRUGS IN SUPPORT OF DEFENDANTS-APPELLEES

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September 24, 2025

**SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES**

*Nat'l Infusion Center Ass'n, et al. v. Kennedy, et al.*, No. 25-50661

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

- Amicus Curiae Patients For Affordable Drugs is a 501(c)(3) non-profit corporation. No other entity has any ownership interest in it.
- Amicus Curiae is represented by Michael Lieberman and Rucha Desai of Fairmark Partners, LLP.

September 24, 2025

/s/ *Michael Lieberman*
Michael Lieberman

*Counsel of Record for Amicus Curiae Patients for Affordable Drugs*

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### Cases



### Statutes



### Other Authorities

## STATEMENT OF INTEREST

Patients For Affordable Drugs (P4AD) is the only national patient advocacy organization focused exclusively on achieving policy changes to lower the price of prescription drugs. P4AD is bipartisan, independent, and does not accept funding from any organization that profits from the development or distribution of prescription drugs. Since its founding, P4AD has advocated to empower Medicare to negotiate prices directly with pharmaceutical companies for a better deal for both patients and taxpayers in the United States. P4AD is pleased to file this amicus brief to defend the Inflation Reduction Act's drug price negotiation program—a historic measure that will strengthen the health, well-being, and financial security of individuals and families across the country while ensuring innovation in new drug development.[1]

## INTRODUCTION AND SUMMARY OF ARGUMENT

For too many years, pharmaceutical companies and their lobbyists have treated Medicare Part D as if it were enacted for their benefit—as if it were a government handout for them, allowing them to line their pockets at the expense of taxpayers and patients. The Negotiation Program delivers a long-needed rebuttal: it restores power over Medicare administration to where it belongs, authorizing the

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

Executive Branch to use its bargaining power to reduce needless Government spending on prescription drugs. This dealmaking authority allows HHS and CMS to cut needless spending and deliver savings to American taxpayers and patients, in addition to making life-saving treatments more accessible to seniors enrolled in Medicare. As Secretary Kennedy noted at his confirmation hearing, "[l]owering the cost of prescription drugs for Americans is a top priority of President Trump and his Administration," and the Negotiation Program equips the Administration with a critical tool to deliver on that commitment.[2]

Appellants portray Medicare drug pricing before the Negotiation Program as if it were some carefully designed, "time-tested," and "market-based" system. Appellants' Br. at 1. That could not be further from the truth. The system in effect before the Negotiation Program—one that barred the government from using its purchasing power to save itself and American taxpayers money on prescription drugs—was the product of an intense, overnight lobbying campaign, not anyone's belief that it was actually good policy.

That system did not work, at least not for anyone other than pharmaceutical companies. The Negotiation Program marks a critical shift in the system to make Medicare work for the patients it is supposed to serve instead of those who profit

[2] Hearing to Consider the Nomination of Robert F. Kennedy, Jr., of California, to be Secretary of the Health and Human Services: Follow-up Questions for the Record, S. Comm. on Fin., 119th Cong. (Jan. 29, 2025).

from it. The first round of negotiations provided the ultimate confirmation: the manufacturers of all ten selected drugs agreed to engage in negotiations that meaningfully lowered the prices they charge to Medicare, some by as much as 79%. These prices are expected to save people on Medicare $1.5 billion in out-of-pocket costs in the first year of the Program alone, with taxpayers expected to save $6 billion.[3]

The purportedly "market-based" system that Appellants seek to restore never existed in the first place. In a market-based system, all buyers get to participate in the price-setting process, with the competing forces of supply and demand resulting in a market-clearing price. Before the Negotiation Program, however, the market excluded the largest and most powerful buyer—the Government—from this process, forcing it to accept whatever prices *other* buyers were able to negotiate. Pharmaceutical companies, moreover, are no ordinary sellers—they are monopolists, *i.e.*, holders of government-granted patents on their prescription drugs. In other words, the previous system combined monopolist sellers with an artificially constrained pool of buyers—a structure designed not to achieve market outcomes, but to maximize pharmaceutical profits at the expense of the very entity that granted these companies their monopoly power in the first place.

[3] Fact Sheet, THE WHITE HOUSE, *Biden-Harris Administration Announces New, Lower Prices for First Ten Drugs Selected for Medicare Price Negotiation to Lower Costs for Millions of Americans* (Aug. 15, 2024).

## ARGUMENT

### I. The Negotiation Program Ends A Handout to Drug Companies Secured by Industry Lobbyists 20 Years Ago.

Medicare has historically set or negotiated prices for every good or service it buys, including hospital care, medical devices, diagnostics, and physician visits—every good or service, that is, except prescription drugs. With the Negotiation Program, Congress finally granted the Secretary of Health and Human Services the authority to also negotiate the prices Medicare pays for some of the most expensive prescription drugs it covers. In the previous system, the Secretary was prohibited from using the government's purchasing power to negotiate more favorable prices for prescription drugs; instead, Medicare was required to pay whatever prices were agreed to by each patient's private plan sponsor. As detailed below, allowing the Secretary to use the government's purchasing power to negotiate lower prices will cut needless government spending and make prescription drugs more affordable for millions of Medicare beneficiaries. The Negotiation Program is projected to reduce Medicare spending by a whopping ***$100 billion*** by 2031 and by untold billions in years beyond.[4]

These obvious benefits raise an obvious question: Why wasn't the Secretary already allowed to negotiate the prices the government pays for prescription drugs,

[4] Cong. Budget Off., *Cost Estimate* ("CBO Estimate") (Sep. 7, 2022) at 5, https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

which Medicare has long been able to do for every other purchase it makes? The answer is a so-called "non-interference" provision that was slipped into the Medicare Modernization Act of 2003. That Act created Medicare Part D, which for the first time provided prescription-drug coverage to millions of Medicare-eligible Americans. But one provision of the Act undermined the rest—it prohibited the Secretary from "interfer[ing] with the negotiations between drug manufacturers and [private insurance plans]" and from "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. §1395w-111(i) (2003). This meant that the federal government, despite being the largest purchaser of prescription drugs in the United States, was forbidden from using its bargaining power to secure lower prices for itself and for Medicare recipients, and instead had to pay whatever prices prevailed in the rest of the market.

This, of course, raises only more questions. Allowing the federal government to negotiate lower prices for itself seems like a no-brainer, and yet Congress expressly prohibited it despite granting similar authority for other Medicare purchases. Was there some drug-specific fiscal or policy benefit that explains the prohibition on using the government's bargaining power to trim billions from the deficit and help millions of Americans better afford their prescription drugs? Was there some doubt about the legality of the government acting like any other market participant?

No and no. The answer, as Rep. Walter Jones (R–NC) succinctly explained, is that "[t]he pharmaceutical lobbyists wrote the bill."[5] Pharmaceutical lobbyists insisted on adding the so-called "non-interference" provision at the last minute because, as Rep. Dan Burton (R–IN) put it, "the drug companies … wanted to make as much money as possible, and if there's negotiation, like there is in other countries around the world, then they're going to have their profit margin reduced."[6] After discovering the "non-interference" provision, Medicare's chief actuary revised the cost estimate for the bill upwards by $140 billion, but he was coerced into withholding that revision from Congress—specifically, he was directed by the then-Administrator of the Centers for Medicare and Medicaid Services ("CMS") to "withhold the [updated] numbers from Congress if he wanted to keep his job."[7] Then, after an all-night session of "arm-twisting"[8] by congressmen and staffers and an "extraordinary three-hour roll call"[9]—all part of what Rep. Jones described as "the

[5] *60 Minutes: Under The Influence* (CBS television broadcast Mar. 9, 2007) ("60 Minutes"), at 1:12, https://www.youtube.com/watch?v=RikKAelRX1w.

[6] *Id.* at 7:00.

[7] *Id.* at 7:35.

[8] *Id.* at 2:45.

[9] Robert Pear, *Medicare Debate Turns To Pricing Of Drug Benefits*, N.Y. TIMES, Nov. 24, 2003.

ugliest night I have ever seen [in Congress]"[10]—House leaders secured enough votes to get the bill through by a margin of 220 to 215.[11]

Those most instrumental to the bill's passage went almost immediately to work for the pharmaceutical companies their efforts benefited. The representative who led efforts to shepherd the bill through the House promptly left to become the head of industry trade group PhRMA.[12] The Staff Director for the Health Subcommittee of the House Ways and Means Committee soon became a lobbyist for PhRMA, Pfizer, Lilly, and Merck.[13] The Chief of Staff for the House Committee on Energy and Commerce took a job lobbying for Novartis and Hoffmann-LaRoche.[14] The administrator of CMS—the person who forced Medicare's chief actuary to withhold the revised cost estimates—became a lobbyist for the pharmaceutical industry just ten days after the President signed the bill.[15] In all, at least 15 congressmen, staffers, and federal officials who were instrumental to the bill's passage left government to work for the pharmaceutical industry.[16]

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[10] 60 Minutes, *supra* n.5, at 1:35.

[11] Pear, *supra* n.9.

[12] 60 Minutes, *supra* n.5, at 9:33.

[13] *Id.* at 11:47.

[14] *Id.* at 12:10.

[15] *Id.* at 8:08.

[16] *Id.* at 12:36.

In subsequent years, legislators introduced multiple proposals to eliminate the "non-interference" provision, but each time, lobbyists convinced enough members to oppose it or vote it down. In 2007, for example, the House approved the Medicare Prescription Drug Price Negotiation Act of 2007, which would have repealed part of the noninterference provision to allow negotiation of Part D prices. After aggressive industry opposition and a presidential veto threat, however, the Act was never put to a vote in the Senate. In 2019, the House passed the Elijah E. Cummings Lower Drug Costs Now Act, but that bill, too, languished in the Senate amid intense industry opposition.

The point here is not to indict or embarrass past members of Congress. The point is that this history directly undermines Appellants' romanticization of the pre-Negotiation system as reflecting some fundamental constitutional principle or "time-tested" and efficient market mechanism. The non-interference provision was an artificial constraint that departed from both normal market practices and standard government procurement methods—every other major government health program routinely negotiates drug prices, as do private insurers and pharmacy benefit managers. The Negotiation Program does not give the Executive Branch some unprecedented power to override natural market mechanisms, but rather restores to Medicare the same negotiating authority that other government purchasers have always possessed and that the Constitution has never been thought to prohibit.

Through the Negotiation Program, Medicare will finally be structured in a way that puts responsible Government spending and the needs of patients above the profits and political power of drug companies.

## II. The Negotiation Program Will Help Millions of Americans Afford Their Prescription Drugs and Maintain Access to Life-Saving Treatments.

With the Negotiation Program and associated enactments, Congress addressed exorbitant drug prices and ensured that patients can continue to obtain—or afford for the first time—the medications they need. These prescription drug provisions are projected to lower drug costs by approximately $237 billion through 2031, with about $100 billion of those savings coming from the Negotiation Program.[17] And those numbers substantially understate the long-term impact, as even greater savings to taxpayers will come in years after 2031.

Much of these savings will be passed through to the individual patients who rely on these drugs. While Medicare pays most of the cost of prescription drugs, Part D beneficiaries remain responsible for out-of-pocket payments, including deductibles, copays, and coinsurance. The prices Medicare negotiates for the selected drugs directly impact patients' out-of-pocket responsibility. For example, three of the ten drugs selected in the first round of negotiations—Enbrel, Imbruvica, and Stelara—are "on the specialty tier in virtually all Part D plans that cover these

[17] CBO Estimate, *supra* n.4, at 5.

drugs, with median coinsurance of 30-33%."[18] Accordingly, the price reductions that Medicare negotiated for those drugs—overall savings of $4,751 for a 30-day supply of Enbrel; $5,615 for a 30-day supply of Imbruvica, and $9,141 for a 30-day supply of Stelara—will be enjoyed proportionally by patients because their out-of-pocket costs will now be based on the much lower negotiated price. The same is true for every drug that has been or will be selected for negotiation. For example, patient out-of-pocket costs for Entresto will be reduced by 53%; for many beneficiaries, this will lower the out-of-pocket cost of a 30-day supply from $157 to $74.

Furthermore, all Part D beneficiaries share the financial burden of high-priced prescription drugs regardless of whether they take any of those drugs themselves. This is because Medicare Part D premiums are calculated based on overall programmatic costs—*i.e.*, the more Medicare spends on prescription drugs overall, the more each Part D beneficiary is required to pay in premiums.[19] As the Government's brief explains, "higher total spending on prescription drug coverage results in higher premiums for individual enrollees." Gov't Br. at 6. The Negotiation

[18] *See* Juliette Cubanski, et al., *How Medicare's New Drug Price Negotiation Program Could Expand Access to Selected Drugs*, KAISER FAM. FOUND. (Sep. 26, 2023), https://www.kff.org/medicare/issue-brief/how-medicares-new-drug-price-negotiation-program-could-expand-access-to-selected-drugs.

[19] Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* (Feb. 2023), at 25.

Program will cut spending by billions of dollars each year and everyone's Part D premiums will decrease accordingly.

While the financial savings are massive, the Negotiation Program's impact goes far beyond money in pockets. Prescription drugs, and especially the brand-name drugs likely to be chosen for the Negotiation Program, are so expensive that Medicare beneficiaries are not always able to fill their prescriptions. A 2022 study found that more than ***one in five*** Medicare beneficiaries aged 65 or older did not adhere to their medications as prescribed because doing so would have been too expensive.[20] These patients reported skipping or delaying prescription refills, skipping doses, or taking smaller doses than their doctors prescribed.[21] More than half of all respondents in the study used one of several cost-coping strategies, with nearly one in ten reporting that they made the impossible choice to go without basic life essentials, such as food and/or housing, to pay for their medication.[22]

Consider Aly Elbaga, a retired chemist living in Old Bridge, New Jersey. He has been on Eliquis—another drug that was part of the first round of Medicare Negotiation—for the past eight years and expects to stay on it for the rest of his life.

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[20] 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).

[21] *Id.*

[22] *Id.*

Aly has long struggled to afford the costs of his prescription drugs, which eat up nearly half of his monthly income. Instead of enjoying his well-earned retirement, Aly cannot afford vacations or other leisure activities, and he struggles even to buy himself new clothing, shoes, or other basic necessities. He sometimes has no choice but to skip doses of his medication to ensure that he has enough money to pay for rent, food, and car insurance. Aly understands that pharmaceutical companies are entitled to make a profit on the life-saving drugs they make, but is frustrated that Eliquis and other drugs are so much cheaper in other countries. Given that the companies still make profits from their sales in other countries, Aly does not understand why they should get to make even more money in the United States. As Aly put it: "How greedy can you be?"

Or consider Trevor Watts. Trevor is a retired glazier living in Roseburg, Oregon who now dedicates his time to volunteering with Habitat for Humanity. He was diagnosed with Type 2 Diabetes at the age of 62, and Farxiga is vital for managing his condition. Before the Negotiation Program, his coinsurance responsibility for Farxiga was as high as $161 per thirty-day prescription. Paying those costs means forgoing other necessities. He has been forced to delay trips to visit family members, visits to the dentist, and repairs on a three-year-old leak in his roof that would drip water into his entryway but for a tarp covering the hole. Some months, he has to choose between buying presents for his grandchildren and filling

his prescriptions. Trevor believes that access to affordable medication is crucial so that he and everyone else can afford groceries and other everyday essentials without worrying about whether they can also afford their life-saving medications.

The Negotiation Program will dramatically improve the lives of Aly, Trevor, and millions of others like them. Because of the Negotiation Program, the prices of their prescriptions will be substantially lower—56% lower for Eliquis and 68% lower for Farxiga—delivering meaningful relief that will allow them to afford the medicines they need and allay some of the daily concern about making ends meet. For many Medicare patients, the IRA's prescription-drug provisions will make a literal life-or-death difference: One study estimates that Medicare negotiation, by lowering out-of-pocket costs, will result in "656,967 fewer deaths over 7 years (an average of 93,852 lives saved annually) due to the effects of improved adherence."[23]

Appellants' brief makes unsubstantiated claims that the Negotiation Program will "dramatically slow innovation, reduce the availability of new medicines, and undermine public health, causing grave harm to patients, pharmaceutical manufacturers, and healthcare providers." Appellants' Br. at 4. Appellants cite nothing in support of these dramatic claims, and in fact the evidence is to the contrary. The non-partisan Congressional Budget Office ("CBO") debunked

[23] Xcenda, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, (Sept. 21, 2020), at 15.

Appellants' claim that the Negotiation Program is likely to "dramatically slow innovation." The CBO forecasts just a 1% reduction in new drug approvals over the next 30 years, estimating that "the number of drugs that would be introduced to the U.S. market would be reduced by about 1 over the 2023-2032 period, about 5 over the subsequent decade, and about 7 over the decade after that."[24]

Moreover, a full understanding of the impact on innovation "requires considering not merely the number of new drugs that might come to market… but the clinical value those new drugs deliver to patients, as well as other policies… designed to reward and promote clinically valuable innovation."[25] The Negotiation Program promotes innovation in myriad ways, which together will provide benefits to patients that far outweigh any marginal reduction in new drug development. For example, the IRA's negotiation framework is designed to provide higher reimbursement for products that provide greater clinical benefits for patients. Specifically, CMS will offer a higher price during negotiations for truly innovative drugs than for drugs that provide only marginal clinical benefits when compared with existing treatments, 42 U.S.C. §1320f-3(e)(2), creating powerful incentives to innovate and making it likely that any reduction in new drug approvals will be limited to drugs that would have had minimal clinical impact anyway.

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[24] CBO Estimate, *supra* n.4, at 15.

[25] Rachel Sachs, Richard G. Frank, et al., *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 Health Affs. Scholar 1, 2 (2023).

Furthermore, by limiting the profits that companies can make from a drug at the end of its exclusivity period, the Negotiation Program "realign[s] incentives in a way that increases rewards to companies that engage in the creation of entirely new products" instead of "activities aimed at extending exclusivity" for old ones.[26] Companies have historically used several tactics to extend exclusivity periods past the expiration of their initial patents, including "filing dozens or even hundreds of patents on the same drug," making small changes and then applying for a patent extension, or paying would-be generic competitors to stay out of the marketplace.[27] Because the Negotiation Program "reduces the monopoly pricing that companies can expect to recoup many years after a drug has entered the market," it increases payoffs to companies that create entirely new products relative to the payoffs for repurposing old ones.[28]

Various other provisions enacted alongside the Negotiation Program likewise encourage innovation. For example, drugs with only a single orphan indication are exempted from the Negotiation Program, ensuring continued incentives for innovation in rare diseases. 42 U.S.C. §1320f-1(e)(3)(A). There are also special protections for small biotechnology companies, which are often instrumental in new

[26] *Id.* at 2.

[27] Ryan Cooper, *How Big Pharma Rigged the Patent System*, THE AM. PROSPECT (June 6, 2023), https://prospect.org/health/2023-06-06-how-big-pharma-rigged-patent-system/.

[28] Sachs, *supra* n.25, at 2.

drug development, thereby helping safeguard their ability to pursue innovative treatments. *Id.* §1320f-1(d)(2).

Appellants' suggestion that the Negotiation Program will lead to reductions in R&D spending ignores that pharmaceutical companies typically spend nearly as much on shareholder compensation as they do R&D.[29] In fact, studies show that R&D is funded primarily by debt rather than retained earnings, and that earnings are more often distributed to shareholders than allocated to R&D.[30] This makes intuitive sense, as "many innovative emerging pharmaceutical manufacturers bring new drugs to market prior to collecting any revenues."[31] The notion that marginal decreases in revenue would leave pharmaceutical companies "no choice" but to cut back on R&D is simply untrue; they would just choose to invest in their businesses and their patients rather than focusing on short-term enrichment of their shareholders.

## III. Pharmaceutical Companies Do Not Have A Constitutional Right To Sell Drugs To The Government At Whatever Prices They Want.

Appellants' due process arguments are premised in large part on the idea that the Negotiation Program will deprive pharmaceutical companies of "market-based reimbursement" for their drugs. Appellants' Br. at 7, 8; *see also* Appellants' Br. at 52

[29] Protect Our Care, In 2023, Big Drug Companies Raked in $684 Billion and Spent $106 Billion Rewarding Shareholders (Feb. 2024), at 3, https://www.protectourcare.org/wp-content/uploads/2024/02/greedwatch2023.pdf.

[30] Richard G. Frank & Kathleen Hannick, *5 Things to Understand About Pharmaceutical R&D*, BROOKINGS (June 2, 2022).

[31] *Id.*

(arguing that the Negotiation Program "deprives manufacturers of their protected interest in the 'treasured' common-law right to offer access to their products at market prices."). Appellants appear to use the term "market prices" to mean the prices at which pharmaceutical companies sold their drugs before the Negotiation Program. But the markets for those drugs have long been distorted, such that historic prices do not reflect any objective conception of "market-based reimbursement." In reality, the fair market price for these drugs *is* the price that results from the Negotiation Program, not previous prices that reflected companies' unchecked exploitation of their government-granted monopoly power in a market that artificially blocked the largest buyer from exercising its purchasing power.

### A. Appellants Have a Misguided Conception of "Fair Market Value."

The pre-Negotiation prices of the selected drugs were by no means "market-based." This is so for at least two reasons. *First*, pharmaceutical companies enjoy government-granted monopolies over their products—*i.e.*, patents. Monopolists do not charge "fair" market prices; they charge monopoly prices. Indeed, the very definition of monopoly power is "the ability to control prices," *i.e.*, the ability to charge *more* than the price that would prevail in a fair and competitive market. *Roy B. Taylor Sales v. Hollymatic Corp.*, 28 F.3d 1379, 1386 (5th Cir. 1994).

Appellants' position that a monopoly price is the only "fair" price, or that companies have a constitutional right to keep charging the government monopoly

prices, has no basis in law or reality. The companies did not have a constitutional right to receive their patents in the first place, *see* U.S. Const. Art. I, §8 (allowing but not requiring Congress to grant patents), and Congress could cancel the patents tomorrow without raising any Takings Clause concerns, *Christy, Inc. v. United States*, 141 Fed. Cl. 641, 660 (2019) ("Patent rights are not cognizable property interests for Takings Clause purposes."). Congress's constitutional authority to cancel the patents confirms the constitutionality of the Negotiation Program. In effect, what the Negotiation Program does is marginally reduce the maximum value of a drug patent: Whereas pharmaceutical companies could previously charge monopoly prices for their drug's entire exclusivity period, now the drug *might* be selected for the Negotiation Program and thus *might* see its price reduced at the end of its patent period.[32] Given that Congress could *cancel* a patent without raising Takings Clause concerns, it follows *a fortiori* that it can constitutionally enact legislation that leaves the patent intact but potentially limits the price the government will pay several years down the road.

*Second*, even setting patents aside, pre-Negotiation prices do not reflect "fair market value" because for the past twenty years, the market for those drugs has artificially excluded the buyer with the most purchasing power and the greatest ability to exert downward pressure on prices—*i.e.*, the government. As Rep. Burton

[32] *See* Sachs, *supra* n.25, at 2.

said all those years ago, "if there's negotiation, … then [drug companies are] going to have their profit margin reduced."[33] It is a bizarre conception of "fair market value" that is based on a market that has excluded the buyer with the most purchasing power for two decades.

### B. The Negotiation Program Will Result in the Government Paying a Fair Market Price.

The actual fair market price for prescription drugs are prices that result from negotiations between seller and buyer—*i.e.*, from the Negotiation Program. Nothing the government can do as part of the Negotiation Program differs materially from what private parties can do in their contract negotiations. Appellants make much of the "civil penalties" for noncompliance, *id.*, but "a private party could easily insert similar enforcement mechanisms in a private … contract." *Antilles Cement Corp. v. Fortuño*, 670 F.3d 310, 330 (1st Cir. 2012). The excise tax is akin to liquidated damages provisions—*e.g.*, if the manufacturer charges more than the parties' negotiated price, the government is entitled to liquidated damages calculated as a percentage of the manufacturer's overcharge. 26 U.S.C. §5000D. Any private party could require the payment of liquidated damages for a contract violation.

In fact, to the extent that CMS's conduct deviates from the conduct that would be expected from a private market participant, those deviations actually work *in the*

[33] 60 Minutes, *supra* n.5, at 7:00.

*pharmaceutical companies' favor*. When private market participants negotiate prices, they "seek to maximize profits by … minimizing costs" to the greatest extent possible. *Palmyra Park Hosp., Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1300 (11th Cir. 2010). The government's incentives are different. Contrary to Appellants' claim that CMS has "no meaningful constraints," Appellants' Br. at 11, CMS must follow Congress's direction to consider several factors *other* than simply aiming for the lowest possible price. For example, CMS must consider the "the extent to which the manufacturer has recouped research and development costs," 42 U.S.C. §1320f-3(e)(1)(A), and whether a selected drug "address[es] unmet medical needs" for patients, *id*. §1320f-3(e)(2)(D). If a drug is truly innovative or if a manufacturer has not recouped its R&D costs, CMS may offer more than a similarly situated private party would.[34]

More broadly, it would be catastrophic for the federal government if manufacturers withdrew all their products from the Medicare and Medicaid markets. Accordingly, when CMS determines its offers under the Negotiation Program, it must consider not only dollars and cents like a market participant would, but also the public good, knowing that the public good will be best served if negotiations are

[34] Memorandum from Meena Seshamani to Interested Parties, *Medicare Drug Price Negotiation Program: Revised Guidance*, at 150-51 (Jun. 30, 2023).

successful, companies continue participating in Medicare, and incentives for innovation remain strong.

### C. Appellants Seek Special Treatment For Their Industry Not Afforded Anyone Else.

The government has long negotiated or set the prices of goods and services in many other industries in which it is a buyer. For example, the U.S. Department of Veterans Affairs ("VA") negotiates with drug manufacturers to get lower prices. The 1992 Veterans Health Care Act required that any drug manufacturer wishing to participate in Medicaid enter into agreements under which the VA, the Department of Defense, the Public Health Service, and the Coast Guard are entitled to a minimum discount of 24 percent off the average sales price to non-federal purchasers and may negotiate even lower prices from there.[35] Like those statutory provisions, the Negotiation Program gives manufacturers a choice between selling their drugs at prices the government is willing to pay or taking their business elsewhere.

As another example, the Medicare fee-for-service program for medical services sets provider pay by regulation.[36] In this program, there is no negotiation at all. Instead, Medicare offers hospitals a predetermined amount for inpatient and

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[35] Mike McCaughan, Prescription Drug Pricing at 2 (Aug. 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/healthpolicybrief_174.pdf.

[36] Cong. Budget Off., *The Prices that Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services* (Jan. 2022), https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf.

outpatient services "on a take-it-or-leave-it-basis," and "[p]roviders that do not want to accept those rates can decline to participate."[37] What providers cannot do, however, is deny services to Medicare patients because they believe Medicare reimbursements are not sufficient; providers participating in Medicare must provide all offered services to Medicare beneficiaries.

Appellants do not and cannot explain why these longstanding programs have existed without issue for decades if, as it argues, government negotiation of prices creates a constitutional problem. Instead, Appellants and the other companies that have unsuccessfully challenged the Negotiation Program are seeking a special rule that applies only to them—in their view, drug companies are constitutionally entitled to a different system than any other industry, one that allows them to enjoy the fruits of their lobbying campaign in perpetuity, with the federal government permanently disabled from negotiating lower prices for the drugs it buys. But Appellants identify no feature of constitutional law that entitles the pharmaceutical industry to special treatment or allows courts to pick winners and losers in the marketplace. Congress may have the power (for better or worse) to pass special-interest legislation, but courts have no corollary authority to apply the Constitution differently to different industries.

[37] *Id.*

Rather than engage in negotiations with their largest purchaser—a negotiation that is routine in any other industry and with any private purchaser—Appellants and the companies they represent ask this Court for the right to sell drugs at a price higher than the government is willing to pay. The Constitution does not afford it that right.

## CONCLUSION

This Court should affirm the judgment below.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) because it contains 5,065 words, not counting portions of the brief listed in Federal Rule of Appellate Procedure 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared in Times New Roman 14-point font.

/s/ *Michael Lieberman*

Michael Lieberman

## CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in these cases are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Michael Lieberman

Michael Lieberman