Case Nos. 24-1819, 24-1820, 24-1821

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS, LP, ET AL.,
Plaintiffs-Appellants
v.
XAVIER BECERRA, ET AL.,
Defendants-Appellees

On Appeal from the United States District Court
for the District of Delaware (Connolly, J.), No. 23-cv-00931

BRISTOL MYERS SQUIBB COMPANY,
Plaintiff-Appellant
v.
XAVIER BECERRA, ET AL.,
Defendants-Appellees

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant
v.
XAVIER BECERRA, ET AL.,
Defendants-Appellees

On Appeal from the United States District Court
for the District of New Jersey (Quraishi, J.), Nos. 23-cv-03335 & 23-cv-03818

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

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CORPORATE DISCLOSURE STATEMENT

Patients For Affordable Drugs is a 501(c)(3) non-profit corporation. No other entity has any ownership interest in it.

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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, and still today in this Court, pharmaceutical companies have treated Medicare Part D as if it was enacted for their benefit—as if it is a government handout for them, allowing them to line their pockets at the expense of taxpayers and patients. The Inflation Reduction Act ("IRA") delivered a long-

[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.

needed rebuttal. The IRA includes multiple, groundbreaking reforms designed to lower the high cost of prescription drugs and make them more accessible to patients, particularly seniors enrolled in Medicare. Most important here, the IRA granted Medicare—for the first time—the authority to negotiate with drug manufacturers regarding the prices Medicare pays for some of the highest-cost brand-name drugs. This authority, and the Negotiation Program that implements it, will provide people on Medicare with more affordable access to innovative, life-saving treatments.

The IRA as a whole, and the Negotiation Program in particular, is a historic reform and a monumental victory for the millions of Americans who depend on Medicare for their essential medications. It marks a critical shift in the system to make Medicare work for the patients it is supposed to serve instead of those who profit from it. The first round of negotiations, only recently concluded, provides 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.[2]

[2] 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).

P4AD files this brief to defend this historic program against a coordinated industry attack. This brief provides historical context for the Negotiation Program, highlights the IRA's extraordinary benefits to patients, and responds to statements by Appellants and their *amici* that misrepresent the IRA's impact on patients and their ability to access the medications and future innovation they need.

ARGUMENT

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

For decades, Medicare has set or negotiated prices for every good or service it pays for, including hospital care, medical devices, diagnostics, and physician visits—every good or service, that is, except for prescription drugs. In the IRA, Congress finally granted the Secretary of Health and Human Services the authority to also negotiate the prices Medicare will pay for some of the most expensive prescription drugs it covers. In the pre-IRA world, 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 make prescription drugs more affordable for millions of Americans by lowering out-of-pocket costs for Medicare beneficiaries. More broadly, the Negotiation Program

is projected to reduce Medicare spending by a whopping ***$100 billion*** by 2031 and by untold billions in years beyond.[3]

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

[3] 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.

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, as Appellants might suggest, about the constitutionality of the government negotiating drug prices with manufacturers?

No and no. The answer, as Rep. Walter Jones (R–NC) succinctly explained, is that "[t]he pharmaceutical lobbyists wrote the bill."[4] 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."[5] 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."[6]

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[4] *60 Minutes: Under The Influence* (CBS television broadcast Mar. 9, 2007) ("60 Minutes"), at 1:12, https://www.youtube.com/watch?v=RikKAelRX1w.

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

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

Then, after an all-night session of "arm-twisting"[7] by congressmen and staffers and an "extraordinary three-hour roll call"[8]—all part of what Rep. Jones described as "the ugliest night I have ever seen [in Congress]"[9]—House leaders secured enough votes to get the bill through by a margin of 220 to 215.[10]

Those most instrumental to the bill's passage went almost immediately to work for the pharmaceutical companies their efforts benefited. Rep. Billy Tauzin (R–LA), who led efforts to shepherd the bill through the House, promptly left to become the head of industry trade group PhRMA.[11] The Staff Director for the Health Subcommittee of the House Ways and Means Committee soon became a lobbyist for PhRMA, Pfizer, Lilly, and Merck.[12] The Chief of Staff for the House Committee on Energy and Commerce took a job lobbying for Novartis and Hoffmann-LaRoche.[13] Tom Scully, the administrator of the CMS—the person who forced Medicare's chief actuary to withhold the revised cost estimates—became a lobbyist for the

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

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

[9] 60 Minutes, *supra n.*4, at 1:35.

[10] Pear, *supra* n.8.

[11] 60 Minutes, *supra* n.4, at 9:33.

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

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

pharmaceutical industry just ten days after the President signed the bill.[14] 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.[15]

The fight did not stop there. Subsequent years saw 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 secretarial 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.

Against that backdrop, the Medicare negotiation provisions in the IRA represent a triumph of good lawmaking over moneyed interests. The IRA includes multiple reforms designed to lower the cost of prescription drugs and make them more accessible to patients, all enacted despite an intense, $372 million industry

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

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

lobbying campaign.[16] Through the Negotiation Program and the IRA's other reforms, Medicare will finally be structured in a way that puts the needs of patients above the profits and political power of drug companies.

II. The IRA's Prescription-Drug Provisions Will Help Millions of Americans Afford Their Prescription Drugs and Maintain Access to Life-Saving Treatments.

A. The IRA Delivers Life-Changing Benefits to Patients.

The IRA enhances affordability and promotes access by addressing exorbitant drug prices and ensuring that patients can continue to obtain—or afford for the first time—the medications they need. The IRA's 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] Those numbers substantially understate the long-term impact of both the IRA and the Negotiation Program, 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

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[16] *See* Inci Sayki, *Despite Record Federal Lobbying Spending, the Pharmaceutical and Health Product Industry Lost Their Biggest Legislative Bet In 2022*, Open Secrets (Feb. 2, 2023).

[17] CBO Estimate, *supra* n.3, at 5.

premiums, copays, deductibles, and coinsurance. The prices Medicare negotiates for the selected drugs directly impact patients' out-of-pocket responsibility. For example, three of the ten selected drugs—Enbrel, Imbruvica, and Stelara—are "on the specialty tier in virtually all Part D plans that cover these 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 cost 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 the widely used blood thinner Eliquis will be reduced by 56%; for many beneficiaries, this will lower the out-of-pocket cost of a 30-day supply from $130.25 to $57.75.

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,

[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.

the more each Part D beneficiary is required to pay in premiums.[19] As Medicare uses the Negotiation Program to cut spending by billions of dollars each year, everyone's Part D premiums will decrease as well.

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]

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

[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.*

Consider Aly Elbaga, an 84-year-old retired chemist living in Old Bridge, New Jersey. He has been on Eliquis for the past eight years and expects to stay on it for the rest of his life. 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.

Finally, consider Lynn Scarfuto, a retired nurse in Herkimer, New York who spent her career working with cancer patients to ensure they received the best treatment possible. After retirement, in a cruel twist of fate, she was diagnosed with chronic lymphocytic leukemia, and later, lung cancer. She has taken Imbruvica for more than ten years, during which time the price has more than doubled. Lynn has been fortunate enough to obtain grants from the PAN Foundation to assist with her out-of-pocket costs for Imbruvica, but without those grants, Lynn would not have been able to afford housing because of the crippling cost of her prescription drugs. Lynn believes that patients like her should not be forced to choose between being homeless and being healthy, or to rely on grants that are unpredictable and can come and go, especially when pharmaceutical companies are making billions in profits each year.

The IRA's prescription-drug provisions will dramatically improve the lives of Aly, Trevor, Lynn, and millions others like them. Because of the Negotiation Program, the prices of their prescriptions will be substantially lower—56% lower

for Eliquis, 68% lower for Farxiga, and 38% lower for Imbruvica—delivering meaningful relief that will allow them to finally take that vacation, fix that roof, and relieve 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]

Other aspects of the IRA will save patients money as well. For example, the IRA will keep drug prices lower more generally by disincentivizing manufacturers from increasing their prices faster than the rate of inflation.[24] In addition, starting next year, the IRA will cap out-of-pocket expenses in Medicare Part D at $2,000, indexed annually for inflation thereafter.[25] The IRA also eliminated cost-sharing for many Medicare Part D vaccines. If the IRA had been in effect in 2021, 3.4 million patients would have saved a combined $234 million in out-of-pocket costs on these

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

[24] Juliette Cubanski, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

[25] *Id.*

vaccines alone.[26] Finally, the IRA places a $35 cap on out-of-pocket costs for insulin. An estimated 1.5 million Medicare beneficiaries who use insulin would have saved a combined $734 million in Part D if these caps had been in effect in 2020.[27] These out-of-pocket savings are financed in large measure by lowering prices via the Negotiation Program.

B. Contrary to Industry Claims, the IRA's Prescription-Drug Provisions Will Protect Patients and Promote Innovation.

Some amicus briefs question the IRA's benefits for patients, casting themselves as neutral observers with supposedly objective concerns about the Negotiation Program's impact on patients and innovation. *See, e.g.*, Brief of Amicus Curiae The Alliance For Aging Research, at 23 (claiming that the Negotiation Program "directly and potentially harmfully impacts patients, particularly older patients"); Brief of Amicus Curiae The Biotechnology Innovation Organization, at 23 (claiming that "patients will suffer"). **Make no mistake: These are not independent patient groups.** The Alliance for Aging Research (the "Alliance") has received hundreds of thousands of dollars in funding from PhRMA over the past

[26] U.S. Dep't of Health and Human Services, *The Inflation Reduction Act of 2022: One Year Anniversary Highlights from ASPE Drug Pricing Reports* (Aug. 16, 2023), https://aspe.hhs.gov/sites/default/files/documents/6354a76564a01bc0bec52b9956e74d9d/IRA-Medicare-Drug-Pricing-Highlights-from-ASPE-Reports%202022-2023.pdf.

[27] U.S. Dep't of Health and Human Services, *Report on the Affordability of Insulin* (Dec. 16, 2022), at 15.

several years, and its events are sponsored by both BMS and Johnson & Johnson (J&J), which is Janssen's parent company.[28] The Biotechnology Innovation Organization ("BIO"), for its part, is the world's largest trade association *for biotechnology companies*—not for patients. Its members include AstraZeneca, BMS, Boehringer Ingelheim, Janssen, J&J, Merck, Novartis, Novo Nordisk, and many other pharmaceutical companies.[29]

These briefs' claims about the IRA's impact on patients are inaccurate, unsupported, or supported only by studies funded by pharmaceutical companies. The Alliance's brief warns that "[p]atients could lose access to existing treatments" if a manufacturer chooses to withdraw all its drugs from Medicare instead of participating in the Negotiation Program. Alliance Br.9. That contention, of course, directly contradicts Appellants' insistence that the option to withdraw is "illusory and not in fact available" to them. BMS Br.34; *see* AstraZeneca Br.11. In any event, this hypothetical possibility has proven to be exactly that—hypothetical. Medicare reached agreements for all ten drugs selected for negotiations, at prices that "range

[28] Accountable.US, *Big Pharma Sees Amicus Support After Spending Nearly $4.8 Million on Contributions in Recent Years* (July 30, 2024), https://accountable.us/wp-content/uploads/2024/07/2024-07-30-Research-on-PhRMA-Contributions-to-3rd-Circuit-Amicus-Filers-FINAL.docx-2.pdf.

[29] Biotechnology Innovation Organization, *BIO Member Directory* (last accessed Aug. 23, 2024), https://www.bio.org/member/bio-member-directory.

from 38 to 79 percent discounts off of list prices."[30] No manufacturer withdrew from the market or removed drugs from the Medicare program.

The Alliance contends that patients could still lose access to the selected drugs because Part D plans might disincentivize their use in favor of higher-priced drugs that generate greater rebates. Alliance Br.10-11. In reality, the IRA is designed to prevent any such result. First, the IRA *requires* Part D plans to include *all* selected drugs on their formularies (including all dosage forms and strengths), ensuring that no patients lose access. 42 U.S.C. §1395w-104(b)(3)(I). The Negotiation Program will actually *increase* access for patients, as any Part D plans that previously excluded the selected drugs from their formularies now must include them.[31] Second, CMS has made clear that it will "use its comprehensive formulary review process to assess any practices that may undermine beneficiary access," including "any instances where Part D sponsors place selected drugs on non-preferred tiers" or "impose more restrictive utilization management."[32] By refusing to approve

[30] Press Release, U.S. Department of Health and Human Services, *Negotiating for Lower Drug Prices Works, Saves Billions* (Aug. 15, 2024).

[31] *See* Cubanski, *supra* n.24.

[32] Memorandum from Meena Seshamani to Interested Parties, *Medicare Drug Price Negotiation Program: Revised Guidance* ("Revised Guidance") (Jun. 30, 2023) at 82, 176, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

formularies with these features, CMS will ensure that patients have unfettered access to the selected drugs when their doctors prescribe them.[33]

BIO's brief suffers from similar flaws. One of the factors that CMS considers when negotiating the maximum fair price for a selected drug is the "[r]esearch and development costs of the manufacturer for the drug." 42 U.S.C. §1320f-3(e)(1)(A). In arguing that the IRA will harm patients by disincentivizing innovation, BIO claims that CMS will consider only "R&D costs of that medication alone," rather than including R&D costs for "drugs that never make it out of preliminary research phases or clinical trials." BIO Br.14. In reality, however, CMS does include "[f]ailed or abandoned product costs" in calculating R&D, including "research costs on drugs with the same … active ingredient or mechanism of action as the selected drug that did not make it to clinical trials" and costs "for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval."[34]

BIO claims that "patients will suffer because biopharmaceutical companies will have no choice but to reduce their R&D spend because of the inadequate revenue the Program provides." BIO Br.23. This suggestion ignores how these companies actually spend their money. In 2023, for example, both BMS and J&J spent more on stock buybacks and dividends than they did on R&D: BMS paid its

[33] *Id.* at 176-77.

[34] *Id.* at 190-91.

shareholders $9.9 billion while spending $9.3 billion on R&D; J&J paid its shareholders $16.8 billion while spending $15.1 billion on R&D.[35] Indeed, 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.[36] This makes intuitive sense, as "many innovative emerging pharmaceutical manufacturers bring new drugs to market prior to collecting any revenues."[37] 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.

Even more exaggerated is BIO's claim that "the conservative estimate is that the Program's revenue reductions will result in roughly 139 drugs over the next 10 years never being developed." BIO Br.23. BIO's source for this supposedly "conservative" estimate is a report issued by an organization called Vital Transformation—a report that BIO's brief cites 12 times. Vital Transformation is funded by the pharmaceutical industry. Its clients include BMS, Janssen, J&J,

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[35] 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.

[36] Richard G. Frank & Kathleen Hannick, *5 things to understand about pharmaceutical R&D*, Brookings (June 2, 2022).

[37] *Id.*

PhRMA, Novartis, Pfizer, and more.[38] The place to look for an actually objective analysis of the Negotiation Program's effects on new drug development is the report issued by the non-partisan Congressional Budget Office ("CBO"). The CBO's estimate belies the industry's hyperbolic claims: "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."[39] Put another way, the CBO forecasts just a 1% reduction in the number of new drug approvals over the next 30 years.[40]

Moreover, a full understanding of the IRA's 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."[41] 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

[38] Vital Transformation BVBA, *About Us*, https://vitaltransformation.com/about-us (last accessed Aug. 15, 2024).

[39] CBO Estimate, *supra* n.3, at 15.

[40] *Id.*

[41] Rachel Sachs, Richard G. Frank, et al., *A holistic view of innovation incentives and pharmaceutical policy reform*, 1 Health Affs. Scholar 1, 2 (2023)

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.

Furthermore, by limiting the profits that companies can make from a drug at the end of its exclusivity period, the IRA "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.[42] 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.[43] 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

[42] *Id.* at 2.

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

companies that create entirely new products relative to the payoffs for repurposing old ones.[44]

Various other provisions of the IRA likewise encourage innovation. For example, the IRA exempts drugs with only a single orphan indication from the Negotiation Program, ensuring continued incentives for innovation in rare diseases. 42 U.S.C. §1320f-1(e)(3)(A). The IRA also contains special protections for small biotechnology companies, which are often instrumental in new drug development, thereby helping safeguard their ability to pursue innovative treatments. *Id.* §1320f-1(d)(2).

In sum, the "oversimplified vision of 'innovation' and the IRA's relationship to it presented by many of the law's detractors," including Appellants and their *amici*, "simply do not match the nuanced vision of innovation encompassed either in the IRA or in adjacent policies."[45] That "oversimplified" vision also does not accord with on-the-ground facts: the pharmaceutical industry is currently experiencing a surge in investment, with a staggering $6.8 billion in venture capital investments in the first three months of 2024, indicating strong investor confidence

[44] Sachs, *supra* n.41, at 2.

[45] *Id.*

in the industry's ability to continue innovating and developing new drugs in a post-IRA world.[46]

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

Appellants' legal claims are largely premised on the idea that the Negotiation Program will deprive them of "fair market value" for their drugs. Appellants appear to use the term "fair market value" to mean the price at which they sold Eliquis, Xarelto, and Farxiga to Medicare before the Negotiation Program. But the market for these drugs has long been distorted in Appellants' favor, so the prices that have historically prevailed do not reflect any objective conception of "fair market price." In reality, the "fair market prices" for Eliquis, Xarelto, and Farxiga are the prices that resulted from the Negotiation Program, not prices reflecting Appellants' previously unchecked exploitation of their government-granted monopolies.

A. Appellants Have a Misguided Conception of "Fair Market Price."

The pre-IRA prices for Eliquis, Xarelto, and Farxiga were by no means the "fair market prices" for those drugs. This is so for at least two reasons. *First*, Appellants enjoy government-granted monopolies over Eliquis, Xarelto, and Farxiga—*i.e.*, patents. Monopolists do not charge "fair market prices"; they charge

[46] Gwendolyn Wu, *Private Biotech Funding Rises as Venture Firms Deploy Cash*, BioPharma Dive (Apr. 8, 2024), https://finance.yahoo.com/news/private-biotech-funding-ticks-venture-160000703.html.

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 competitive market. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005).

Appellants' position that a monopoly price is the only "fair" price, or that they have a constitutional right to charge the government monopoly prices, has no basis in law or reality. Appellants 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 those 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 Appellants' 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.[47] Given that Congress could *cancel* a patent without raising Takings Clause

[47] *See* Sachs, *supra* n.41, at 2.

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-IRA prices do not reflect "fair market value" because for the past twenty years, the market for these 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 said all those years ago, "if there's negotiation, … then [drug companies are] going to have their profit margin reduced."[48] 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 prices" for prescription drugs are prices that result from negotiations between seller and buyer—*i.e.*, from the Negotiation Program. Appellants claim that CMS is not a typical buyer and so can extract an *un*fair price in these negotiations. Specifically, they argue that "CMS is not a mere market participant because it exercises significant *regulatory* authority" in the context of the Negotiation Program, Janssen Br.36, or that "the Program is a quintessential exercise

[48] 60 Minutes, *supra* n.4, at 7:00.

of sovereign power, not ordinary market forces," BMS Br.48. These contentions miss the mark. Nothing the government can do as part of the Negotiation Program differs materially from what private parties can do in their contract negotiations.

Appellants point to the IRA's "excise tax" and "steep penalty," Janssen Br.36; AstraZeneca Br.12, 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). These taxes and penalties are akin to liquidated damages provisions—*e.g.*, if the manufacturer charges more than the negotiated price, the government is entitled to liquidated damages calculated as 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. *Cf. Mabey Bridge & Shore, Inc. v. Schoch*, 666 F.3d 862, 873 (3d Cir. 2012) (government's authority to institute "disgorgement proceedings and debarment from public contracts" did not convert government from market participant to regulator).

The same is true for provisions allowing CMS to require manufacturers to "comply with any requirements [CMS] 'determine[s] … to be necessary' to administer the Program" or to "amend the Manufacturer Agreement's terms without Janssen's consent." Janssen Br.36-37. Any party can ask its contractual counterparty to comply with the requirements it deems necessary to the contractual relationship; that is, indeed, the whole point of having a contract. And CMS's right

to amend the Manufacturer Agreement applies only when necessary "to reflect changes in law, regulation, or guidance," JA680, *i.e.*, to ensure that no party is required to violate the law to fulfill its contractual obligations. Appellants identify no legal impediment to a private entity negotiating the same provision into its contracts.

Finally, Appellants claim that a private entity "would face serious antitrust scrutiny if it leveraged [its market] power to tie the purchase of *all* Janssen's drugs to a favorable price on a single drug." Janssen Br.37-38; *see* BMS Br.48. This contention is both irrelevant and incorrect. It is irrelevant because the question is whether the government is exercising *sovereign power—i.e.*, power that market participants simply do not have, like the power to "implement[] a criminal prohibition punishable by time in prison." *Am. Trucking Ass'ns v. City of L.A.*, 569 U.S. 641, 651 (2013). The answer here is no, as any market participant could present the same choice the government presents here: "Give me a better deal or we'll take all our business elsewhere."

In any event, there is no antitrust problem. Even accepting the premise that the government exercises monopsony power, the Sherman Act allows monopsonists to demand monopsony prices as long as they do not use their power to demand lower prices in markets in which they are not monopsonists. *See Kartell v. Blue Shield*, 749 F.2d 922, 927 (1st Cir. 1984) ("Mere monopoly pricing is not a violation of the

Sherman Act."). Here, the government is negotiating lower prices for the selected drugs independently and is not using its purchasing power over those drugs to demand concessions in any other market.

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 Appellants' 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 AstraZeneca's claim that CMS has an "interest in negotiating the lowest price possible, no matter how 'fair,'" AstraZeneca Br.13-14, 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.[49]

[49] Revised Guidance, *supra* n.32, at 150-51.

More broadly, while BMS likens the Negotiation Program to "a gun to the head," BMS Br.42, it is really more like a double-edged sword: 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 successful, companies continue participating in Medicare, and incentives for innovation remain strong.

C. Appellants Seek Special Treatment 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.[50] Like those statutory provisions,

[50] Mike McCaughan, *Prescription Drug Pricing* at 2 (Aug. 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/healthpolicybrief_174-1525355141023.pdf.

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.[51] In this program, there is no negotiation at all. Instead, Medicare offers hospitals a predetermined amount for inpatient and 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."[52] 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 they argue, government negotiation of prices creates a constitutional problem. Instead, Appellants and the other companies challenging 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

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[51] *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.

[52] *Id.*

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 that 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.

Rather than submit to negotiations with their largest purchaser—a negotiation that is routine in any other industry and with any private purchaser—pharmaceutical manufacturers 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 them that right.

CONCLUSION

This Court should affirm the judgments 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 6,487 words, not counting portions of the brief listed in Federal Rule of Appellate Procedure 32(f) and L.A.R. 29.1(b). 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.

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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third 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.

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