Docket Nos. 24-1819, 24-1820, & 24-1821

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP & ASTRAZENECA AB,
Plaintiffs-Appellants,
v.
XAVIER BECERRA, U.S. Secretary of Health & Human Services et al.
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Delaware (1:23-cv-00931), Hon. Colm F. Connolly

BRISTOL MYERS SQUIBB COMPANY, *Plaintiff-Appellant*,
v.
XAVIER BECERRA, U.S. Secretary of Health & Human Services et al.
Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC., *Plaintiff-Appellant*,
v.
XAVIER BECERRA, U.S. Secretary of Health & Human Services et al.
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey (3:23-cv-03818 & 3:23-cv-03335), Hon. Zahid N. Quraishi

BRIEF OF *AMICUS CURIAE* THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL MEDICINE, THE AMERICAN GERIATRICS SOCIETY, AND THE AMERICAN SOCIETY OF HEMATOLOGY IN SUPPORT OF APPELLEES

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici the American Public Health Association, the American College of Physicians, the Society of General Internal Medicine, the American Geriatrics Society, and the American Society of Hematology (the "Public Health *amici*") are some of the world's largest public health organizations, representing hundreds of thousands of doctors (and other clinicians), public health officials, and health professional trainees (including medical students) who have managed care for millions of Americans. They have been active for decades in tracking the effects of high prescription drug prices on public health and patient outcomes. They explain below why the Inflation Reduction Act's (IRA) Drug Price Negotiation Program (the "Program") is vital to maintaining and strengthening patient care and the Medicare program. *Amici* also explain why assertions by Plaintiffs-Appellants Bristol Myers Squibb ("BMS"), Janssen, and AstraZeneca Pharmaceuticals LP and AstraZeneca AB ("AstraZeneca")[2] regarding the negative effects of the Program are unsupported by the weight of independent public health research.

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[1] *Amici* certify that no party nor any party's counsel authored any part of this brief or contributed money to the preparation or submission of the brief. All parties have consented to this filing.

[2] The Plaintiffs have made nearly identical arguments about the public health effects of drug price negotiation. Public Health *amici* are providing the same information to this Court in all three appeals and, for the sake of efficiency, have submitted identical briefs in the three cases.

INTRODUCTION AND SUMMARY OF ARGUMENT

New pharmaceutical interventions can save millions of lives. They can also save money by treating illnesses before patients need expensive, invasive treatments. *Amici* believe private sector manufacturers advance public health by developing critical drugs, and that they should be encouraged to do so. However, if prescription drugs are unaffordable to patients or health insurance providers, like the federal government, they no longer advance public health. *Amici* have long advocated for evidence-based and value-oriented public policy regarding drug pricing.[3] Controlling unsustainable drug prices is necessary to preserve patient health and to ensure the longevity and sustainability of the social safety net.

For decades, Medicare did not cover prescription drug costs for older adults. Congress, in 2003, amended the Medicare statute to create Part D pharmacy benefits. "At the time, more than 14 million seniors in America had no access to drug coverage and more than one-third reported not taking their medicines as

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[3] *See, e.g.*, Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), https://tinyurl.com/4v7c35j8 [hereinafter *Ensuring Equitable Access*]; Hilary Daniel & Sue S. Bornstein, *Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians*, Annals Internal Med., 2019, https://tinyurl.com/3tsxa443.

prescribed due to cost."[4] Starting in 2006, older adults and people with certain disabilities could enroll in plans run by private companies that contracted with Medicare. These plans generally require that enrollees pay a premium, occasionally a deductible, and, for prescriptions, co-insurance or a co-payment. Part D benefits have allowed older adults, especially low-income people, to access critical care: "annual out-of-pocket drug costs dropped an average of 49% among those who previously did not have drug coverage."[5] In 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[6]

The federal government now accounts for roughly 45% of nationwide drug spending, principally through Medicare and Medicaid. Despite its key role in the market, Medicare has been prohibited by law from negotiating directly with drug manufacturers for the prices of the drugs it pays for. Drug prices—especially for drugs targeted at people over 65 who have guaranteed coverage through Medicare—have ballooned over the last two decades, which has bankrupted older Americans, and undercut the core public health objective of Part D: ensuring

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[4] Reshma Ramachandran et al., *Out-Of-Pocket Drug Costs for Medicare Beneficiaries Need to Be Reined In* (Jan. 7, 2022), https://tinyurl.com/33jjrr8b.

[5] *Id*.

[6] Kaiser Fam. Found., *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 19, 2022), https://tinyurl.com/ya3fhu69.

access to necessary medications. In response to these exponential increases in drug prices, and the attendant concerns for public health, Congress enacted the Program, which gives the Centers for Medicare & Medicaid Services (CMS) authority to directly negotiate with manufacturers of some of the costliest drugs on the market.

BMS, Janssen, AstraZeneca, and other drug companies quickly sued to stop the Program, making misleading assertions about the public health effects of this reform. Public Health *amici* correct some of those erroneous assertions in this brief: Section I describes the scope of the challenge facing Medicare, including escalating prices for brand-name drugs that lead older Americans to choose between medicine and other basic needs, jeopardizing their health and the social safety net. Section II discusses how the Program addresses the escalating costs of a handful of ultra-expensive drugs and will meaningfully reduce the burden on older Americans. Section III debunks Plaintiffs' assertion that negotiated prices will inevitably lead to worse health outcomes and explains how the Program will likely substantially increase medication access and affordability without a meaningful drop in drug innovation or development.

ARGUMENT

I. AMERICA'S PRESCRIPTION DRUG PRICING REGIME HAS SUBSTANTIAL AND ESCALATING NEGATIVE EFFECTS ON PUBLIC HEALTH AND PATIENT OUTCOMES.

Medicare Part D, which has allowed beneficiaries to afford lifesaving medications and avoid even more expensive hospital visits, has become a vital part of the social safety net and improved older Americans' health outcomes.[7] Unfortunately, those advances are at risk from the never-ending increase in prescription drug prices.

A. MEDICARE PRESCRIPTION DRUG COSTS HAVE BECOME UNSUSTAINABLE.

Prescription drug costs have increased at rates far above inflation in recent years,[8] a trend that has been driven in large part by popular brand-name specialty drugs that account for billions of dollars in revenue to their manufacturers. From 2009-2018, the average price of these brand-name drugs "more than doubled in the Medicare Part D program and increased by 50 percent in Medicaid."[9] And the cost

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[7] *See* David M. Cutler et al., *Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012*, Health Affs., Feb. 2019, at 222-29, https://tinyurl.com/panjxufb.

[8] Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* (Jan. 2022), https://tinyurl.com/yck5mkbz ("[N]ationwide spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018.").

[9] *Id*.

to Medicare for top-selling name-brand drugs more than doubled again between 2018 and 2021.[10] Even if one considers only the drugs selected for negotiation under the Program, it is clear that their prices have increased far above inflation.[11]

The drugs at the heart of Plaintiffs' cases illustrate this increase. Xarelto (Janssen) and Eliquis (BMS) treat blood clotting problems and reduce the risk of stroke; Farxiga (AstraZeneca) treats diabetes and related conditions. They are marketed heavily to Medicare beneficiaries. Since 2011, when Xarelto was released, retail inflation was approximately 43%; Xarelto's price has increased 168%. Since 2012, when BMS's Eliquis was released, retail prices have increased by approximately 39%; Eliquis's price went up 124%. And since 2014, when AstraZeneca's Farxiga was approved, retail prices increased approximately 34%; Farxiga's price went up 81%.[12]

These staggering price increases cannot be justified as necessary to recover research and development (R&D) costs, which are far outpaced by the revenue

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[10] Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://tinyurl.com/ycytf6wm.

[11] Leigh Purvis, *Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market*, AARP Pub. Pol'y Inst. 1 (Aug. 2023), https://tinyurl.com/388becj2.

[12] Price increases from *id.* at 2, fig. 1. Inflation figures calculated from *CPI Inflation Calculator*, U.S. Bureau Lab. & Stat., https://tinyurl.com/4xdtjs4j.

brought in by these drugs. It cost roughly $5.4 billion to develop Farxiga and research additional indications for it.[13] Medicare pays roughly half of this total lifetime R&D spending, $3 billion, for this drug every year. Likewise, it cost roughly $7.9 billion to develop Xarelto; Medicare costs were over $6 billion in just one year, 75% of Xarelto's lifetime R&D cost. The numbers for Eliquis are even more jaw dropping. It cost roughly $4.3 billion to develop Eliquis and research additional indications. Gross Medicare costs for Eliquis from June 2022 to May 2023 were almost $16.5 billion. In other words, Medicare paid almost *four times* more than the lifetime R&D costs for Eliquis in just one year. Even if revenues from these successful drugs must offset the cost of developing drugs that fail, these returns are staggering.

[13] Drug development costs and revenue from ATI Advisory, *The First 10 Drugs to be Negotiated by Medicare* (Aug. 30, 2023), https://tinyurl.com/294sj44f. Medicare costs from *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, Ctrs. for Medicare & Medicaid Servs. (Aug. 2023), https://tinyurl.com/mrys5br6. Note that drug development costs are notoriously difficult to estimate because drug companies have historically refused to disclose detailed financial information. The Program now requires drug companies to disclose some of these figures during the negotiation process.

B. AMERICANS, ESPECIALLY OLDER ADULTS, CANNOT SUSTAIN THESE PRICES.

Although most high-priced medication costs are borne by American taxpayers through Medicare, a significant portion is also borne directly by older Americans and individuals with disabilities, whose cost-sharing can include burdensome monthly premiums and other costs, which are unaffordable for some.[14] In 2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[15] That figure had increased by 5 percentage points by summer 2023.[16] And more than a third of older Americans had medical debt recently,[17] a quarter of which is related to their prescription drugs.[18]

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[14] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5. For the standard framework for Medicare Part D plans after the Inflation Reduction Act, *see Part D Payment System*, MedPAC, https://tinyurl.com/37c87543 (last revised Oct. 2022).

[15] Alex Montero et al., *Americans' Challenges with Health Care Costs*, KFF (July 14, 2022), https://tinyurl.com/yck7juez.

[16] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://tinyurl.com/hun2y8bn.

[17] Noam N. Levey, *100 Million People in America Are Saddled with Health Care Debt*, KFF Health News (June 16, 2022), https://tinyurl.com/4hapcdbj.

[18] Lunna Lopes et al., *Health Care Debt in the U.S.: The Broad Consequences of Medical and Dental Bills*, KFF (June 16, 2022), https://tinyurl.com/bddpnkk6.

The most predictable and poignant effect of American's expensive prescription drug delivery system is cost-related nonadherence ("CRNA") to medications, where patients stop taking prescription drugs because of rising prices, even when those drugs are essential to their health.[19] In 2022, roughly a quarter of adults reported that they or someone in their family had "not filled a prescription, cut pills in half, or skipped doses of medicine in the last year because of the cost."[20]

Although Americans covered by Medicare are insulated from some of the challenges faced by uninsured Americans under 65, they are not immune. A recent analysis by the Office of Health Policy using the National Health Interview Survey reported that 6.6% of all adults over 65 (a total of 3.5 million people) found medication unaffordable, and 2.3 million of them did not take needed prescriptions due to cost.[21] "Black and Latino beneficiaries were 1.5 to 2 times as likely to experience medication-related affordability challenges as White beneficiaries in

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[19] Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 JAMA 61, 61-69 (2007), https://tinyurl.com/2p9yt463.

[20] Montero et al., *supra* note 15.

[21] Wafa Tarazi et al., *Prescription Drug Affordability among Medicare Beneficiaries*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't Health & Hum. Servs. 3 (Jan. 19, 2022), https://tinyurl.com/3uxmyfwr.

this age range," showing persistent disparities in US healthcare.[22] These figures would likely be higher still, except that some older people—8.5% according to one 2022 survey—forego other basic needs, such as food, in order to afford their prescription drugs.[23] Other older Americans are only able to avoid this impossible choice thanks to assistance from non-profits and state pharmacy assistance programs that try to provide a safety net for the most needy.

Beyond these direct effects, cost-related medication nonadherence has downstream effects on healthcare costs and patient wellbeing because financial barriers may prevent people from filling prescriptions for drugs that can prevent serious medical complications that are life-threatening, permanently disabling, and/or extremely costly to treat.[24] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[25] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in

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[22] *Id*. at 5.

[23] 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 Open, May 2023, at 1, https://tinyurl.com/4mccyu7x.

[24] *Id.* at 5.

[25] Goldman et al., *supra* note 19, at 65.

hospitalization rates for several conditions.[26] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare program and will lead to an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[27]

Older adults in other countries do not struggle so mightily. CRNA in the United States is two to four times higher than in other developed countries.[28] And, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[29]

Members of *amici* have observed and treated patients who ration their use of critical medications because of the high costs passed on to them. For instance:

- A doctor in Maryland: "I had a patient with a history of recurrent pulmonary emboli who needed to take Xarelto to prevent another

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[26] Aaron S. Kesselheim et al., *Prescription Drug Insurance Coverage and Patient Health Outcomes: A Systematic Review*, Am. J. Pub. Health, Feb. 2015, at 19, https://tinyurl.com/3ts9cew5.

[27] *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*, Council for Informed Drug Spending Analysis (Nov. 18, 2020), https://tinyurl.com/yc4tm4vv.

[28] Steven Morgan & Augustine Lee, *Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries*, BMJ Open, Jan. 2017, at 4, https://tinyurl.com/2u8tfn8e.

[29] *Id.*

recurrence. She could not afford to take the medication regularly due to her limited income. She was found dead in her home last week."

- A doctor in Georgia: A patient had "atrial fibrillation and his cardiologist and primary care physician agree[d] that Eliquis is safer for him than Warfarin. He cannot afford Eliquis under his Medicare plan. He shared with his primary care physician that if it were not for the samples sometimes made available to him through his doctors' offices, he wouldn't know what he would do to afford and receive the Eliquis as he is on a fixed income."
- A doctor in New Mexico: "I took care of a patient who didn't take his blood pressure medication on the day he was to see me because in order to be able to afford gas to the appointment, he had reduced how often he took his medication so it would last longer."
- A doctor in North Carolina: "Last week I was talking to an octogenarian patient on a fixed income. . . . She admitted she had started 'stretching' her supply [of Eliquis], skipping a few days each month, to make her supply last longer, and wanted my advice on how many days per month she could skip without putting herself at serious risk for a stroke. I had to tell her I wasn't really sure, and discouraged her from doing this, but I also tried to counsel her realistically,

knowing that she might continue doing this and [should] at least [be] spacing out her skipped days."

- A doctor in Delaware: "Patients consistently resist trying to get us to change them from Lisinopril to Entresto despite what the data shows when it comes to readmissions and quality of life. It is the same issue with Jardiance. If we convince them, it often means they are giving up something else in their life given many are on a limited income."

II. THE PROGRAM IS A VITAL FIRST STEP IN ENSURING OLDER AMERICANS CAN AFFORD THEIR MEDICATION.

The Program is a measured attempt to bolster public health and ensure care for all of us as we age, by permitting the federal government to negotiate prices for the drugs it covers. *Amici* are under no illusions that negotiation alone will rein in drug prices, but this approach at least allows the government to leverage its purchasing power to reduce Medicare program costs—as any market participant would—while also allowing plan sponsors (insurance companies) to maintain the power to negotiate for most drugs covered by Part D. Moreover, the government routinely negotiates prices on goods it purchases from private companies—

including for products for which it is the sole or primary purchaser, such as defense equipment[30]—and it already negotiates rates in several other areas of Medicare.

Two other federal programs that provide prescription drug coverage and allow for direct negotiation illustrate the value of drug price negotiation between the government and drug manufacturers. The Veterans Health Administration (VHA) provides care directly to millions of veterans. It purchases drugs directly from manufacturers and, in 2017, paid an average of 54% less per unit of medicine than Medicare, including for brand name drugs.[31] In more than half the 399 drugs analyzed, the VHA paid less than half the price per unit Medicare paid; for 106 drugs, the VHA paid less than 25% of what Medicare paid.[32]

Similarly, the Department of Defense (DoD) uniform drug formulary, which provides prescription drug coverage for roughly 9.5 million active-duty and retired military personnel, their dependents, and others, negotiates prices. Within two years of it being implemented in 2005, DoD saved roughly $1 billion through the

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[30] Nat'l Acads. of Scis., Eng'g, & Med., *Making Medicines Affordable: A National Imperative* 52 (Norman R. Augustine et al. eds., 2018), https://tinyurl.com/2zjvmfk2.

[31] U.S. Gov't Accountability Off., *GAO-21-111, Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, at 1 (2020), https://tinyurl.com/bdusnnrt.

[32] *Id*. at 7.

drug formulary, representing an approximately 13% reduction in drug expenditures.[33]

Even Medicaid, which does not have the kind of direct negotiation and unified formulary system as DoD and the VHA, has been able to obtain substantially larger rebates than Medicare through statutory and State-run rebate programs, and it has substantially lower net costs for brand-name drugs.[34] The CBO has estimated that the average price of top-selling brand-name drugs in Medicare Part D is almost three times higher than in Medicaid.[35]

The United States is one of only two developed countries that allows the drug industry to set its own drug prices independent of government authority.[36] Drug prices in the US are between 2 and 2.5 times higher than in other comparable

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[33] Shana Trice et al., *Formulary Management in the Department of Defense*, J. Managed Care Pharmacy, Mar. 2009, at 133, https://tinyurl.com/yc5zp35h.

[34] Off. Inspector Gen., Dep't Health & Hum. Servs., *OEI-03-13-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (2015), https://tinyurl.com/2f936cpc.

[35] Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 15 (2021), https://tinyurl.com/mpr7edhz.

[36] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, Annals Internal Med., 2016, at 50.

countries and Medicare's inability to negotiate drug prices, as compared to the ability of other public health systems, is a key reason for higher prices.[37]

Lower prices under the Program will have substantial benefits for Medicare beneficiaries. KFF has estimated that many older Americans would save over 60% of their out-of-pocket costs under the new standards set by the IRA.[38] *Amici* like the Alliance for Aging Research misunderstand how Medicare beneficiaries receive care when they contend that "the Program is only intended to save the federal government billions of dollars each year without regard to the effects on patients' health or their out-of-pocket costs." Br. of Amicus Curiae Alliance for Aging Research, *Bristol Myers Squibb v. Becerra* (24-1820), ECF No. 71 ("Alliance Br."), at 4.[39] While it is true the IRA created a new $2,000 out-of-

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[37] *See* Andrew W. Mulcahy et al., *U.S. Prescription Drug Prices Are 2.5 Times Those in Other OECD Countries*, Rand Corp. (2021), https://tinyurl.com/bdh43w7r; Kaiser Permanente Inst. for Health Pol'y, *Pharmaceutical Pricing: Lessons from Abroad* (2015), https://tinyurl.com/3nbaj9a6.

[38] Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023), https://tinyurl.com/3adurnbk. Other estimates put the savings at 30% of out-of-pocket costs. *CMS Releases 2025 Medicare Part D Bid Information and Announces Premium Stabilization Demonstration*, Ctrs. for Medicare & Medicaid Servs. (July 29, 2024), https://tinyurl.com/2mwuzbcc.

[39] While positioning itself as an independent voice on drug pricing, *see* Alliance Br. at 3 n.3, the Alliance fails to mention that senior executives from BMS and Johnson & Johnson (Janssen) sit on its board. Board members and their companies

pocket cost cap that prevents catastrophic financial outcomes, Medicare beneficiaries may still be responsible for costs (including co-insurance) *up to* $2,000. Reaching that cap is still a substantial burden, especially for those with incomes below $30,000 (the median annual income for Medicare beneficiaries) and no savings (approximately 12% of Americans over 65).[40] Medicare beneficiaries also pay premiums to the insurance companies that administer Medicare, and those premiums are set in part based on the total cost of drugs used by beneficiaries; these premiums are unaffected by the out-of-pocket cap.[41] It is simply not true that the Program will have no effect on older Americans' budgets.

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give the Alliance substantial funding. *See Board of Directors*, All. for Aging Rsch., https://tinyurl.com/yrtrzx88 (last visited Sept. 10, 2024).

[40] Dena Bunis, *AARP Research: Prescription Drugs That Cost Medicare the Most*, AARP (March 8, 2022), https://tinyurl.com/nbuckbb3.

[41] *See* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Part D Premiums*, KFF (Aug. 1, 2024), https://tinyurl.com/mua82sd3. The IRA limits the increase of these premiums up to a point, but increases are inevitable without cost reductions.

III. PUBLIC HEALTH RESEARCH SHOWS THAT THE PROGRAM IS UNLIKELY TO HAVE MEANINGFUL NEGATIVE EFFECTS ON DRUG AVAILABILITY OR PATIENT OUTCOMES.

The nonpartisan CBO estimated that the Program will lead to only 13 fewer drugs in the next 30 years, for an overall reduction of 1% in volume.[42] The Brookings Institute has similarly found that the Program is unlikely to substantially change the future development of medications, based on drug manufacturers' own public market activity.[43] Indeed, even after negotiated prices were finalized, drug companies informed their investors that they saw few substantial effects to their bottom lines from the Program.[44] This is unsurprising, in part, because the Program does not apply to new drugs and continues to grant drug companies almost unfettered discretion to price these drugs at exorbitant rates. Indeed, the limited scope of the Program—affecting a handful of drugs from the biggest companies in the world—means that it does not interfere with the sites of greatest innovation: novel interventions from government-funded academic research and small pharmaceutical companies. Plaintiffs and their supporting *amici* speculate

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[42] Cong. Budget Off., *Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14*, at 15 (2022), https://tinyurl.com/4jdersf7.

[43] Richard G. Frank & Ro W. Huang, *Early Claims and M&A Behavior Following Enactment of the Drug Provisions in the IRA* (Aug. 23, 2023), https://tinyurl.com/yjv3y48t.

[44] *Id.*

that lower prices will trigger lost profits, drug shortages, and reduced drug research funding, with consequent adverse public health outcomes. But they cannot substantiate their dire predictions with credible evidence.

A. LOWER DRUG PRICES ARE UNLIKELY TO LEAD TO LESS RESEARCH AND DEVELOPMENT.

Increased drug prices do not necessarily lead to increased R&D intensity (the percentage of revenue spent on research) by big companies, or increased public health outcomes.[45] As one study put it: "If research and development costs justified drug prices, an association between the 2 variables would be found," but it was not.[46] For one thing, we now know that large drug companies do not regularly prioritize R&D spending.[47] A substantial portion of revenue goes to direct-to-customer marketing and lobbying, rather than research and development.[48] A 2015

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[45] Aylin Sertkaya et al., *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, JAMA Network Open, June 2024, https://tinyurl.com/yzbfr9ky; Mujaheed Shaikh et al., *Revisiting the Relationship Between Price Regulation and Pharmaceutical R&D Investment*, 19 Applied Health Econ. & Health Pol'y 217 (2021), https://tinyurl.com/dexsm5hw.

[46] Olivier J. Wouters et al., *Association of Research and Development Investments with Treatment Costs for New Drugs Approved From 2009 to 2018*, JAMA Network Open, Sept. 2022, at 7, https://tinyurl.com/58zbnnfp.

[47] *See, e.g.*, Accountable US, *The Pharmaceutical Firms with Drugs on Medicare's Price Negotiation List* (May 9, 2024), https://tinyurl.com/ufwesxpw (listing spending by large drug companies in areas like advertising and lobbying, and comparing that with research and development funding).

[48] Daniel, *supra* note 36, at 59; *Ensuring Equitable Access*, *supra* note 3, at 3.

study from the National Bureau of Economic Research estimated that nearly one third of the growth in drug spending is attributable to an increase in advertising.[49] Other estimates suggest that marketing and administration can contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[50] Similarly, for many companies, shareholder payouts were larger on average than the amounts spent on R&D.[51] Drug companies would likely be able to offset reduced revenue from lower prices by reducing non-R&D spending like advertising and shareholder payouts.

Further, a large part of drug cost increases is not driven by innovative R&D, but by the manipulation of patents and other anticompetitive activities by large drug companies to protect their market dominance. For example, under so-called 'Pay for Delay' schemes, branded drug manufacturers enter into settlements with manufacturers of generic medicines to keep generic alternatives off the market.[52]

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[49] Abby Alpert et al., *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D*, at 33 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3.

[50] *Ensuring Equitable Access*, *supra* note 3, at 10.

[51] Richard G. Frank & Kathleen Hannick, *5 Things to Understand About Pharmaceutical R&D*, Brookings Inst. (June 2, 2022), https://tinyurl.com/5a67arcp.

[52] *See* Fed. Trade Comm'n, *Pay-for-Delay: When Drug Companies Agree Not to Compete*, https://tinyurl.com/9u24eu2k (last visited Sept. 10, 2024).

These schemes lead to higher costs for consumers and insurers, and higher profits for branded and generic manufacturers, without therapeutic improvements.[53] Following a legal crackdown on Pay for Delay schemes, drug research output increased, especially for more innovative drugs, even when these higher profits were reduced.[54] Indeed, although Plaintiffs and their supportive *amici* make much of the harm their reduced market exclusivity would cause to innovation, research suggests precisely the opposite: when market exclusivity is reduced, "firms pursue *higher-quality* innovation."[55]

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[53] Notably, generic manufacturer Teva Pharmaceuticals, an *amicus* in support of plaintiffs that argues drug price negotiation will hurt the generics industry, has been investigated and fined for colluding with other manufacturers to maintain high prices. *See, e.g.*, Press Release, Fed. Trade Comm'n, *FTC Settlement of Cephalon Pay for Delay Case* (May 28, 2015), https://tinyurl.com/3mucnzfz (regarding Pay for Delay); Press Release, Dep't of Just., *Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars* (Aug. 21, 2023), https://tinyurl.com/5fe9dkjc (regarding price fixing for a cholesterol drug).

[54] Xuelin Li et al., *Paying Off the Competition: Contracting, Market Power, and Innovation Incentives* 3 (Nat'l Bureau Econ. Rsch., Working Paper No. 28964, 2024), https://tinyurl.com/2xp7t7sz.

[55] *Id.* at 4 (emphasis in original).

B. SMALLER R&D BUDGETS ARE UNLIKELY TO LEAD TO SUBSTANTIALLY FEWER NEW DRUGS.

Even if R&D funding intensity by the biggest drug companies does decline, the evidence still does not suggest that fewer drugs will ultimately be approved by the FDA.[56] Drug development costs vary wildly between firms, and "firms rarely disclose verifiable information about the expenses related to individual drug candidates," as they are now required to do to CMS.[57] Much cutting-edge research is done by small pharmaceutical companies rather than major players, which means that blanket claims that lower drug prices necessarily lead to fewer marketable drugs should be viewed with skepticism.

Drug manufacturers' claims about private innovation and market prices for drugs also ignore the large share of R&D carried out or funded by the government and universities. In fact, publicly-supported research is substantially *more* likely to

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[56] *See* Frank & Hannick, *supra* note 51 (observing that, while "annual R&D budgets for PhRMA members have been on the rise, growing from $37.5 billion in 2000 to $83.0 billion in 2019 . . . , the 5-year average for new drug approvals went from 36.8 in 2000, . . . declined for nearly a decade hitting a low in 2009 with 22 new drugs, before the 5-year average steadily increased to 44 new drugs in 2019").

[57] Olivier J. Wouters & Aaron S. Kesselheim, *Quantifying Research and Development Expenditures in the Drug Industry*, JAMA Network Open, June 2024, at 1, https://tinyurl.com/3kskhes8 (noting that the main studies on drug trial costs by Joseph A. DiMasi, cited in industry-friendly briefs before this Court, "relied on a sample provided confidentially by large pharmaceutical firms to an industry-funded research group," and cannot be independently validated).

lead to innovative drug development resulting in measurable increases in patient health outcomes.[58] Between 1988 and 2005, federal research funding contributed to 45% of all drugs approved by the FDA and to 65% of drugs that received priority review.[59] From 2010 through 2019, every one of the 356 new drugs approved by the FDA was the result of research funded by the National Institutes of Health (NIH).[60] Major innovative drugs have been discovered in public universities funded through grants from the NIH.[61]

In fact, government funding supported research led to most of the drugs currently subject to negotiation.[62] For instance, the NIH sponsored foundational

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[58] *See* Kerstin N. Vokinger et al., *Therapeutic Value of First Versus Supplemental Indications of Drugs in US and Europe (2011-20): Retrospective Cohort Study*, BMJ Open, July 2023, https://tinyurl.com/5xfs593m (using French data, as collection of US data on effectiveness is inconsistent).

[59] Daniel, *supra* note 36, at 60.

[60] Joel Lexchin, *Therapeutic Benefit from New Drugs from Pharmaceutical Companies*, 184 JAMA Internal Med. 52 (2023).

[61] *Ensuring Equitable Access*, *supra* note 3, at 2. Between 6 and 10% of "new molecular entities" (new innovative drugs) were first patented by public sector or academic institutions and up to 40% of new molecular entities were first synthesized or purified in academic institutions. *See* Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, Proc. Nat'l Acad. Scis., Mar. 2018, at 2332.

[62] Tarazi et al., *supra* note 21, at 1.

research into dapagliflozin, the active compound in AstraZeneca's Farxiga.[63] Insulin is also illustrative. It was developed in a non-commercial laboratory in the early 20th century and its patent was sold to the University of Toronto for $3, which in turn allowed manufacturers to license it royalty-free.[64] Even so, drug companies have dramatically increased the prices for insulin-based treatments in recent years, despite building their products on publicly supported research.

When so much funding for research comes from public programs—a fact Plaintiffs and their supporting *amici* ignore—there is little reason to believe reduction in prices charged by big pharma companies will result in substantially reduced effective innovation. Instead, the Program will spare U.S. taxpayers from paying exorbitant prices through government health programs for pharmaceutical products developed through foundational basic research they also funded.[65]

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[63] *See, e.g.*, Ernest M. Wright, *Renal Na^+-Glucose Cotransporters*, 280 Am. J. Physiology – Renal Physiology F10 (2001), https://tinyurl.com/53262fnn (NIH-funded study laying the basis for sodium-glucose co-transporter inhibitors like Farxiga).

[64] Hilary Daniel et al., *Policy Recommendations to Promote Prescription Drug Competition: A Position Paper from the American College of Physicians*, Annals Internal Med., Sept. 2020, at 1006, https://tinyurl.com/y56byn7y.

[65] Notably, the drug negotiation program allows CMS to take prior public financial support for development of the drugs selected for negotiation into account when considering fair prices.

C. FEWER NEW DRUGS FROM BIG PHARMACEUTICAL COMPANIES ARE UNLIKELY TO LEAD TO MEANINGFULLY WORSE PUBLIC HEALTH OUTCOMES.

Plaintiffs and their supporting *amici* also fail to grapple with the fact that many privately funded drugs do not make significant contributions to public health advances because the US regulatory system for pharmaceutical drugs does not link prices to public health, or require drug companies to evaluate the marginal benefit of new and expensive treatments over longstanding alternatives. Privately funded drug R&D often focuses on differentiating similar drugs, instead of higher risk research into new scientific paradigms that could reduce morbidity and mortality.[66] Simply put, the majority of new drugs approved provide little additional clinical value compared to already approved alternatives, leading to the proliferation of so-called 'me-too' drugs.[67] And recent studies suggest that more than 60% of R&D spending is post-approval research into additional indications for approved drugs, rather than into new drugs.[68] These additional indications—which drug companies

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[66] *Ensuring Equitable Access*, *supra* note 3, at 10.

[67] *See* Lexchin, *supra* note 60 (analyzing French data on effectiveness as US data collection is inconsistent); *see also* Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, 41 J. L., Med. & Ethics 571, 571 (2013).

[68] ATI Advisory, *supra* note 13.

claim are uniquely at risk under the Program—have on average substantially lower therapeutic value than new drugs.[69]

The current market thus has limited incentives for breakthrough research. Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[70] Even if it were to lead to less research funds for 'me-too' drugs, since CMS now requires manufacturers to provide data on therapeutic value during the negotiation process, the Program may divert funding towards more innovative drug development through value-based pricing.[71]

Amici are unaware of any peer-reviewed or rigorous independent research undergirding claims, like those in the Alliance for Aging Research *amicus* brief, that the Program will lead to dozens of fewer drugs or hundreds of millions of life years lost in the US.[72] Many briefs cite, directly or indirectly, to a series of seemingly independent studies by a single lead researcher, Professor Tomas

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[69] Vokinger et al., *supra* note 58, at 3.

[70] *See* Ashish Arora et al., *Killing the Golden Goose? The Decline of Science in Corporate R&D* (Nat'l Bureau Econ. Rsch., Working Paper No. 20902, 2015), https://tinyurl.com/bdeuzpt8.

[71] Rachel Sachs et al., *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, Health Affs. Scholar, July 2023, at 2, https://tinyurl.com/36hamdfr.

[72] *See* Alliance Br. at 14.

Philipson at the University of Chicago.[73] Yet, much of this research was funded by industry and none appears to be peer-reviewed.[74] Indeed, Professor Philipson's IRA-specific papers are often not even new research, but rather rely on his own earlier non-peer reviewed studies or drug company statements. This fits a pattern of pharma-friendly briefs in these cases relying on industry or industry-hired

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[73] *See, e.g.*, Alliance Br. at 14. Other briefs that cite Professor Philipson include those by Daniel E. Troy (*Bristol Myers Squibb v. Becerra* (24-1820), ECF No. 57, at 12), the Buckeye Institute (ECF No. 67, at 6), the National Association of Manufacturers (ECF No. 58, at 29), and the Pioneer Public Interest Law Center (ECF No. 62, at 6) (citing a news article discussing Professor Philipson's work). These briefs and the one from Teva Pharmaceuticals (ECF No. 69, at 11, 16) occasionally cite to a study from USC's Shaeffer Institute: Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, USC Shaeffer Ctr. for Health Pol'y & Econ. (Apr. 13, 2023), https://tinyurl.com/msefpyfj, and one from the Center for Strategic and International Studies: Baily Crane, *The Effect of Reference Pricing on Pharmaceutical Innovation*, Ctr. for Strategic & Int'l Stud. (July 12, 2023), https://tinyurl.com/ym6ty78n. Those studies themselves rely on Professor Philipson's work for the impact of the IRA on drugs and life years lost.

[74] Professor Philipson has disclosed funding from Gilead and PhRMA in some of his studies. *See, e.g.*, Tomas J. Philipson et al., *The Potentially Larger Than Predicted Impact of the IRA on Small Molecule R&D and Patient Health*, Univ. of Chi., at n.1 (Aug. 25, 2023), https://tinyurl.com/4dj67tab; Tomas J. Philipson et al., *The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act*, Univ. of Chi (Oct. 5, 2023), https://tinyurl.com/bacxcysw. And he has previously been criticized for not disclosing when his work is funded, in part, by drug companies. *See* Annie Waldman, *Big Pharma Quietly Enlists Leading Professors to Justify $1,000-Per-Day Drugs*, ProPublica (Feb. 23, 2017), https://tinyurl.com/vd65sf57 (reporting that Professor Philipson, and the consulting company he co-ran, was paid by drug companies to defend prices he had, in some cases, advised on—a conflict he occasionally failed to disclose). That consulting company included companies now subject to Medicare drug pricing as its clients.

consultants' statements to come up with the number of drugs they speculate will be lost thanks to the Program.[75] In short, much of the evidentiary basis for the claim that the Program will cost hundreds of millions of life years derives from work funded by pharmaceutical companies, and then cited by pharmaceutical companies and their allies as independent academic analyses without disclosing that funding.

There is little reason to credit Plaintiffs' claim that the Program will cause the sky to fall. The federal government can use its purchasing power, like other market participants, to command a better price for the goods it purchases without threatening pharmaceutical innovation. In turn, those reduced prices may bolster public and individual health outcomes and help maintain the viability of the public health safety net for older Americans.

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[75] *See, e.g.*, Daniel Gassull et al., *IRA's Impact on the US Biopharma Ecosystem*, Vital Transformation 7 (June 1, 2023), https://tinyurl.com/2aa7z8fe (cited by Biotechnology Innovation Organization, AstraZeneca); Jordan Cates et al., *Medicare Price Negotiation: A Paradigm Shift In Part D Access and Cost*, Milliman (Sept. 12, 2023), https://tinyurl.com/pjpvtuyt (cited by Alliance for Aging Research); *Patient Options to Therapeutic Options*, Hayden Consulting Grp. (Sept. 4, 2023), https://tinyurl.com/4ntnrsht (cited by Pioneer Public Interest Law Center); Kylie Stengel et al., *Impact of H.R.3 as Passed by the House on Federal Spending and Drug Manufacturer Revenues*, Avalere (June 19, 2020), https://tinyurl.com/mufa39du (cited by Pioneer Public Interest Law Center and Teva).

CONCLUSION

For the foregoing reasons, Public Health *amici* respectfully request that the Court affirm in these three cases.

Dated: September 16, 2024

Respectfully submitted,

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CERTIFICATES OF COMPLIANCE

1. In accordance with Third Circuit Rules 28.3(d) and 46.1(e), I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. In accordance with Third Circuit Rule 31.1(c), I certify that the texts of the electronic brief and paper copies are identical, and that Microsoft Defender was run on the file and did not detect a virus.

3. In accordance with Federal Rules of Appellate Procedure 29(a)(4)(G) and 32(g)(1), I certify that this brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7) because it contains 6,380 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f), according to the word count of Microsoft Word. This brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in Times New Roman 14-point font, a proportionally spaced typeface.

Dated: September 16, 2024

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief was filed with the Clerk of the Court for the United States Court of Appeals for the Third Circuit through the appellate CM/ECF system on September 16, 2024, which will serve a notice of electronic filing to all registered counsel of record. I also certify that seven paper copies of the foregoing brief will be sent to the Clerk's Office via overnight delivery.

Dated: September 16, 2024

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