EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP & ASTRAZENECA AB, *Plaintiffs*, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*, *Defendants.*	Civil Action No. 23-931-CFC

PROPOSED BRIEF OF 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 AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Democracy Forward Foundation

Ananda V. Burra*
Ben Seel*
Robin Thurston*
P.O. Box 34553
Washington, DC
(202) 448-9090
aburra@democracyforward.org
bseel@democracyforward.org
rthurston@democracyforward.org
* *pro hac vice* forthcoming

Block & Leviton LLP

Kimberly A. Evans (#5888)
Robert Erikson (#7099)
3801 Kennett Pike, Suite C-305
Wilmington, DE 19807
(302) 499-3600
kim@blockleviton.com
robby@blockleviton.com

Counsel for Amici Curiae

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IDENTITY AND INTERESTS 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 are some of the world's largest public health organizations, representing hundreds of thousands of doctors, public health officials, and health professional trainees (including medical students) who have treated and 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, which allows the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices for Medicare, 42 U.S.C. §1320f(a) (the "Program"), is vital to maintaining and strengthening patient care and the Medicare program. Contrary to what drug companies have argued, doctors and their patients do not support untrammeled price increases by drug manufacturers. *Amici* also explain why assertions by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB ("AstraZeneca") regarding the negative effects of these new rules on public health are exaggerated.

[1] *Amici Curiae* certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission.

INTRODUCTION

New pharmaceutical interventions for chronic or acute illnesses can save millions of lives. They can also save patients and insurance plans money by treating illnesses before patients must undergo more expensive, invasive treatments. Private sector drug manufacturers of course play a vital role in inventing, testing, and supplying these drugs, and they should be encouraged to do so. However, if prescription drugs are so expensive that they are unaffordable to patients or to health insurance providers like the federal government, they no longer advance societal and individual health. *Amici* have long advocated for evidence-based and value-oriented public policy regarding drug pricing.[2] Controlling unsustainable drug prices and fixing the market failures that contribute to the astronomical cost of prescription drugs are 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. Older adults had to find their own private plans to access care. Congress, in 2003,

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[2] *See, e.g.*, Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), https://tinyurl.com/4v7c35j8; Am. Coll. Physicians, *ACP: Passage of Inflation Reduction Act Improves Access to Health Care Services, Treatments*, https://tinyurl.com/44wmn2b6 (last visited Nov. 6, 2023); 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.

amended the Medicare statute to create Part D pharmacy benefits. *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 & 749 n.2 (3d Cir. 2017). "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 prescribed due to cost."[3] 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 charge enrollees a premium and, for each prescription filled, enrollees pay co-insurance or make a co-payment. Part D benefits 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."[4] Part D was incredibly successful and, in 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[5]

Medicare became one of the single largest underwriters of drug therapy in the United States but, unlike private health insurance providers, it was not allowed to negotiate directly with drug manufacturers for the prices of the drugs it was paying for. *See* 42 U.S.C. §§ 1395w-111(i). Drug prices—especially for drugs

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[3] Reshma Ramachandran, Tianna Zhou, & Joseph S. Ross, *Out-Of-Pocket Drug Costs for Medicare Beneficiaries Need to Be Reined In* (Jan. 7, 2022), .

[4] *Id*.

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

targeted at people over 65 who have Medicare's guaranteed coverage—have ballooned over the last two decades. They have put the system at peril, have bankrupted older Americans, and have undercut the core public health mission Congress was advancing through its 2003 revisions.

Fixing Part D is vital, and Congress finally acted by passing the Inflation Reduction Act. It empowered CMS to identify certain drugs that have long been on the market for negotiation, taking their total cost to Medicare and other considerations into account. *See id.* § 1320f. CMS is mandated to negotiate prices for these drugs over the course of multiple years. *Id.* §§ 1320f-1(a)-(b). Manufacturers can choose to withdraw their drugs from large government health insurance systems if they do not wish to negotiate prices. *See* Defs.' Br. at 8-9, 11-12, 46-47, D.I. 21-1; *see also Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-00156, --- F. Supp. 3d ---, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) ("participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice"). AstraZeneca and other drug companies are seeking to gut the law, which would stop these vital reforms. The Court should deny AstraZeneca's motion for summary judgment and grant Defendants' cross-motion for summary judgment.

ARGUMENT

I. America's Unsustainably High Prescription Drug Pricing Regime Has Substantial and Escalating Negative Effects on Public Health and Patient Outcomes.

The 2003 reforms to Medicare sought to address a key gap in the social safety net: until the creation of Medicare Part D, Medicare beneficiaries had to pay out of pocket for prescription drugs taken outside a doctor's office. These costs were a crushing burden for many low- and moderate-income people. By covering prescription drugs for them, Medicare Part D allowed beneficiaries to afford lifesaving medications and avoid even more expensive hospital visits; it became a vital part of the social safety net and improved older Americans' health outcomes.[6]

Unfortunately, those advances in public health are at risk from the unsustainable increase in prescription drug prices in the two decades since Medicare Part D was introduced. Part D spending between 2007 (a year after Part D came into force) and 2023 has more than doubled.[7] These cost increases have been markedly greater for a small group of ultra-expensive drugs, often taken for common conditions like diabetes and hypertension. These drugs—including

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[6] *See* David M. Cutler et al., *Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012*, 38 Health Affs., no. 2, Feb. 2019, at 222-29, https://tinyurl.com/panjxufb.

[7] *See* Dana P. Goldman & Geoffrey F. Joyce, *Medicare Part D: A Successful Start with Room for Improvement*, JAMA Network, Apr. 23, 2008, https://tinyurl.com/59nctjfj.

AstraZeneca's Farxiga—are prescribed in large quantities (and marketed heavily) to older Americans. This is a uniquely American problem. Drug prices in the U.S. are multiple times the prices in other comparable countries.[8]

A. Medicare prescription drug costs have become unsustainably high.

Prescription drug costs, driven in part by per unit drug price hikes, have increased at rates far above inflation in recent years. According to a report published by the Congressional Budget Office (CBO) in 2022, "nationwide spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018."[9] Prescription drug expenditures per capita increased from $140 in 1980 to $1,073 in 2018 and $1,631 in 2020.[10]

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[8] *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/4t8t6fs7; Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, Commonwealth Fund (Oct. 2017), https://tinyurl.com/yc4nfmfd; Irene Papanicolas, Liana R. Woskie, & Ashish K. Jha, *Health Care Spending in the United States and Other High-Income Countries*, 319 JAMA Network 1024-39 (2018), https://tinyurl.com/4jaebbbc. While use of prescription drugs in the United States is high, it is not an outlier compared with nine other high-income nations. *See* 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, at 825.

[9] Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* (Jan. 2022), https://tinyurl.com/yck5mkbz (these numbers were expressed in 2018 dollars).

[10] *Id.*; *Drug Expenditure Dynamics 1995–2021: Country Detail Appendices*, IQVIA (Nov. 16, 2021), https://tinyurl.com/437spyj3.

These cost increases are particularly burdensome for Medicare Part D as it is one of the largest single underwriters of drug therapy in the United States. In 2023, Part D benefits are estimated to total $120 billion, or 14% of net Medicare outlays.[11] Although the introduction of a number of generic drugs into the marketplace has worked to modulate some of these cost increases, by 2018 per enrollee spending on Medicare Part D averaged about $2,700 per year.[12] Notably, these high per capita costs have persisted, despite 90 percent of Medicare Part D prescriptions being for low-cost generics, and despite the average price for generics *dropping* between 2009 and 2018.[13]

These high levels of spending are driven in large part by the widespread and long term use of so-called "blockbuster" or specialty drugs that account for billions of dollars in revenue to their manufacturers.[14] The CBO estimates that, "[o]ver the

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[11] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5; Cong. Budget Off., *Medicare: Baseline Projections* 2 (2022), https://tinyurl.com/28fu8xzp.

[12] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9.

[13] *Id*. The Federal Trade Commission has investigated so-called "Pay for Delay" schemes, where branded drug manufacturers enter into settlements with manufacturers of generic medicines to keep generic alternatives off the market. *See* Fed. Trade Comm'n, *Pay-for-Delay: When Drug Companies Agree Not to Compete*, https://tinyurl.com/9u24eu2k (last visited Nov. 6, 2023).

[14] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9; Juliette Cubanski et al., *No Limit: Medicare Part D Enrollees Exposed to High Out of-Pocket Drug*

2009–2018 period, the average price of a prescription for a brand-name drug more than doubled in the Medicare Part D program and increased by 50 percent in Medicaid."[15] The American Association for Retired Persons (AARP) has calculated that between 2007 and 2017, the average annual cost of chronic therapy increased by more than $51,000 per specialty drug.[16] Had specialty drug prices merely tracked general retail inflation, their average annual cost would have gone up by only about $2,000 during this period; a saving of almost $50,000 per drug.[17]

Costs Without a Hard Cap on Spending, Kaiser Fam. Found. 3-4 (Nov. 2017), https://tinyurl.com/2rypz7yr.

[15] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9; *see also* Erin Trish, Jianhui Xu, & Geoffrey Joyce, *Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase*, 35 Health Affs. no. 9, Sept. 2016, at 1564, https://tinyurl.com/dcwffu3j ("Annual total drug spending per specialty drug user studied increased considerably [between 2008 till 2012], from $18,335 to $33,301, and the proportion of expenditures incurred while in the catastrophic coverage phase increased from 70 percent to 80 percent.").

[16] Leigh Purvis & Stephen W. Schondelmeyer, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, AARP Pub. Pol'y Inst. at 7 (June 2021), https://tinyurl.com/46k6565c.

[17] *Id*. at 1 ("Between 2016 and 2017, retail prices for 97 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, increased by an average of 7.0 percent. In contrast, the general inflation rate was 2.1 percent over the same period. . . . Retail prices for 27 chronic use specialty drugs that have been on the market since the beginning of the study (i.e., between January 2006 and December 2017) increased cumulatively by an average of 226.4 percent over 12 years. In contrast, general inflation in the US economy rose 25.1 percent during the same 12-year period.").

This disproportionate growth has continued since the AARP's 2017 study: KFF estimated that between 2018 and 2021 gross Medicare spending for the top selling Part D drugs more than doubled.[18]

The Drug Negotiation Program intervenes in the unsustainable growth in prices of drugs already on the market. The AARP found that prices for drugs chosen for negotiation under the Program increased far above inflation, unmoored to any additional costs associated with research and development.[19]

The drug at the heart of AstraZeneca's case illustrates this problem. Farxiga treats diabetes and is indicated for the treatment of heart failure and chronic kidney disease. The cumulative rate of retail inflation between 2014 (when Farxiga was approved) and the present is approximately 32%.[20] In contrast, Farxiga's price

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[18] Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, Kaiser Fam. Found. (July 12, 2023), https://tinyurl.com/ycytf6wm. The Office of Health Policy with the Department of Health and Human Services estimated that there were 1,216 products whose prices increased more than general inflation between July 2021 and July 2022. The average price increase was 31.6%, though some prices increased as much as 500%. *See* Arielle Bosworth et al., *Issue Brief, Price Increases for Prescription Drugs, 2016-2022*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't Health & Human Servs. 1 (Sept. 30, 2022), https://tinyurl.com/44tmd4rr.

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

[20] *CPI Inflation Calculator*, U.S. Bureau Lab. & Stat., https://tinyurl.com/4xdtjs4j.

went up 81%.[21] It cost roughly $2 billion to develop Farxiga and to get it approved by the FDA; after it was already on the market, Farxiga's manufacturers spent another $3.4 billion to identify which other conditions Farxiga may be able to treat.[22] Gross Medicare costs for Farxiga from June 2022 to May 2023 were over $3 billion; it thus pays roughly half of the lifetime R&D spending for Farxiga *every year*.[23] Farxiga has earned over $15.8 billion globally.[24]

[21] @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinyurl.com/3m64hu2x.

[22] ATI Advisory, *The First 10 Drugs to be Negotiated by Medicare* 7 (Aug. 30, 2023), https://tinyurl.com/294sj44f.

[23] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, Ctrs. for Medicare & Medicaid Servs. 1 (Aug. 2023), https://tinyurl.com/mrys5br6.

[24] ATI Advisory, *supra* note 22, at 7.

The table below summarizes available data for the drugs chosen for negotiation.

Prescription Drugs Chosen for Negotiation: Price Hikes, Revenue, and Research

Drug	**Year of FDA approval**	**Percentage increase in price since approval**[25]	**Medicare Part D Gross Cost (June 2022-May 2023)**[26]	**Global lifetime sales (2021)**[27]	**Total R&D costs (2021)**[28]
Enbrel	1998	701%	$2.8 bn	$132.5 bn	unknown[29]
Novolog[30]	2000	628%	$2.6 bn	$42.8 bn	unknown
Januvia	2006	275%	$4.1 bn	$54.1 bn	$5.3 bn
Stelara	2009	184%	$2.6 bn	$54.8 bn	$2.1 bn
Xarelto	2011	168%	$6.0 bn	$54.3 bn	$7.8 bn
Eliquis	2012	124%	$16.5 bn	$57.1 bn	$4.3 bn
Imbruvica	2013	108%	$2.7 bn	$36.8 bn	$1.4 bn
Jardiance	2014	97%	$7.1 bn	$18.3 bn	$3.5 bn
Farxiga	2014	81%	$3.3 bn	$15.8 bn	$5.2 bn
Entresto	2015	78%	$2.9 bn	$14.3 bn	$4.8 bn

[25] Purvis, *supra* note 19, at 2, fig. 1; @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinyurl.com/3m64hu2x.

[26] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026, supra* note 23, at 1 (costs rounded). These costs do not necessarily incorporate data regarding rebates or other confidential price adjustments that are not available to the public.

[27] ATI Advisory, *supra* note 22.

[28] *Id*.

[29] Certain information is not available for drugs tested before recent clinical trial reporting requirements.

[30] Includes sales for Fiasp.

B. Americans, especially older adults, cannot sustain these high prices.

Even though most of the cost of high-priced medication is borne by Medicare, a significant portion is also borne by older Americans and individuals with disabilities, whose cost-sharing can include significant monthly premiums and other costs.[31] In addition to these premiums, many drug plans have annual deductibles that beneficiaries must pay. After the initial coverage phase when Medicare beneficiaries pay either a co-payment (usually for medications on lower tiers) or a co-insurance (for higher tier or specialty medications), they reach the 'donut hole' or coverage gap and pay 25% of a drug's list price until an out-of-pocket maximum is reached.[32] During the coverage gap phase, plan reimbursements are often reduced with the switch from flat co-payments to 25% co-insurance, which means patient contributions often increase.[33] Before the

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[31] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5; Juliette Cubanski & Anthony Damico, *Key Facts About Medicare Part D Enrollment and Costs in 2023*, Kaiser Fam. Found. (July 26, 2023), https://tinyurl.com/2tby57ue. 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).

[32] *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.

[33] Louise Norris, *How Did the Medicare Donut Hole Change for 2023?* (Jan. 10, 2023) https://tinyurl.com/4r92uedt.

Part D amendments in the IRA, patients with extremely high drug costs—generally associated with taking one or more specialty drugs—entered the "catastrophic phase" of coverage. A December 2020 study by KFF reported that "over one million Part D enrollees had out-of-pocket spending in the catastrophic phase in 2017, with average annual out-of-pocket costs exceeding $3,200."[34] For context, the median annual income of Medicare beneficiaries was just below $30,000 and 12% of Americans over 65 have no savings or are in debt.[35] Today, "catastrophic coverage" for ultra-high cost enrollees accounts for nearly half of total Medicare Part D spending, up from 14% in 2006.[36] In some cases, the movement of patients into "catastrophic" levels in Medicare Part D could be traced to the increase in price of just one or a few drugs.[37] More than a third of older people have had

[34] Juliette Cubanski et al., *Options to Make Medicare More Affordable for Beneficiaries Amid the COVID-19 Pandemic and Beyond*, Kaiser Fam. Found. 4 (Dec. 8, 2020), https://tinyurl.com/52n7hj82.

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

[36] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5.

[37] *See* 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, at 825 (analyzing the effects of increasing prices of multiple sclerosis drugs).

medical debt recently.[38] Twenty-four percent of people over 65 with medical debt trace it to prescription drugs.[39] One in six older adults in the United States report difficulty affording out-of-pocket costs for drugs.[40]

Of course, the effects of high drug prices are not limited to older Americans: According to polls conducted by KFF in 2022, "[a]bout half of U.S. adults say that it is very or somewhat difficult for them to afford their health care costs (47%)."[41] Thirty percent of people experiencing medical debt reported it was due to their need for prescription drugs.[42] Fears about medical costs and debt have topped peoples' list of financial worries for many years.[43]

The impact of an expensive prescription drug delivery system is most poignant when reviewing cost-related nonadherence (CRNA) to medications.

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

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

[40] 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.

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

[42] Lopes et al., *supra* note 39.

[43] Montero et al., *supra* note 41.

CRNA is the widely reported phenomenon where patients stop taking prescription drugs because of rising prices, even where the drugs are "essential" to their health.[44] In 2022, "[a]bout a quarter of [US] adults [said] they or [a] family member in their household have not filled a prescription, cut pills in half, or skipped doses of medicine in the last year because of the cost, with larger shares of those in households with lower incomes, Black and Hispanic adults, and women reporting this."[45]

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 found that 6.6% of all adults over 65 (a total of 3.5 million people) faced affordability problems due to prescription costs, and 2.3 million of these older adults did not take needed prescriptions due to cost.[46] The same survey found that "Black and Latino beneficiaries were 1.5 to 2 times as likely to experience medication-related affordability challenges as White beneficiaries in this age

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[44] Dana P. Goldman, Geoffrey F. Joyce, & Yuhui Zheng, *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, JAMA Network, July 2007, at 61-69, https://tinyurl.com/2p9yt463.

[45] Montero et al., *supra* note 41.

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

range."[47] In 2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[48] By the summer of 2023, that figure had increased by 5 percentage points.[49] These figures would likely be higher still, except that some older people—8.5% according to one 2022 survey—choose the rock instead of the hard place and forego other basic needs, such as food, in order to afford their prescription drugs.[50]

Older adults in other countries do not struggle so mightily. Cost-related medication nonadherence in the United States is two to four times higher than in other developed countries.[51] Public health researchers have estimated that, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and

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[47] *Id*. at 5.

[48] Montero et al., *supra* note 41; *see also* 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 2023, at 3, https://tinyurl.com/4mccyu7x (estimating "20.2% [of older adults] reported any cost-related medication nonadherence").

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

[50] 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 2023, at 1; *see also* Karthik W. Rohatgi et al., *Medication Adherence and Characteristics of Patients Who Spend Less on Basic Needs to Afford Medications*, J. Am. Bd. Fam. Med., June 2021, https://tinyurl.com/ybzbf9nf.

[51] Morgan & Lee, *supra* note 40, at 4.

older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[52]

Beyond these direct effects, CRNA has downstream effects on healthcare costs and patient wellbeing because the same financial barriers that prevent people from filling prescriptions for "drugs taken for symptom relief" also "impede the use of essential, preventative medications" that would save them from death or serious injury.[53] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[54] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[55] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare

[52] *Id.* at 1.

[53] *Id.* at 5; *see also* Jessica Williams et al., *Cost-related Nonadherence by Medication Type Among Medicare Part D Beneficiaries with Diabetes*, Med. Care, Feb. 2013, at 1, https://tinyurl.com/ycynd88h (finding more frequent CRNA for cholesterol-lowering medication as compared to medications for symptom relief).

[54] Goldman, Joyce, & Zheng, *supra* note 44, at 7.

[55] Aaron S. Kesselheim et al., *Prescription Drug Insurance Coverage and Patient Health Outcomes: A Systematic Review*, Am. J. Pub. Health, Feb. 2015, at e19, https://tinyurl.com/3ts9cew5.

program and will lead to an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[56]

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 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 Florida: "I have patients who are stable on their oral anticoagulant like Xarelto or Eliquis and then they hit the doughnut hole [gap in coverage in Medicare] and have to stop their medications. They run the risk of blood clots and stroke but they can't afford [their medications]."
- 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'

[56] *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*, *supra* note 32.

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 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 The Health Of Americans And The Medicare Program.

The drug price negotiation program in the Inflation Reduction Act is a measured attempt to bolster public health and to ensure care for all of us as we age by permitting the federal government, which foots the bill for 45% of nationwide spending on retail prescription drugs, to negotiate prices for the drugs it will pay for.[57] Allowing Medicare to negotiate the price of drugs in the Part D program has

[57] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9; Erin Trish, Jianhui Xu, & Geoffrey Joyce, *Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase*, 35 Health Affs. no. 9, Sept. 2016, at 1569 ("the large price increases in specialty drugs

been debated since the creation of Part D in 2003. *Amici* advocated for the repeal of Medicare's "non-interference" provisions specifically because of that provision's negative effects on public and patient health.

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 to maintain the power to negotiate for the vast majority of drugs covered in the program. As the National Academies of Sciences, Engineering, and Medicine have noted, there is nothing unusual about the federal government negotiating prices on goods it purchases from private companies; it routinely does so for a wide variety of other products for which it is the monopsonist (the sole or primary purchaser), for instance, for purchasing defense equipment.[58] Indeed, the federal government negotiates rates in several other areas of Medicare. The benefit of drug price negotiation to the public will be substantial: KFF has estimated that many older Americans would save over 60% of their out-

observed [between 2008 and 2012] could have been partly a response by manufacturers to more generous coverage in the doughnut hole").

[58] 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.

of-pocket costs under the new standards set by the IRA.[59] AstraZeneca's dramatic characterization of drug price negotiation as "government-imposed price controls.," D.I. 16 ("Compl.") ¶ 94, notwithstanding, the Program will restore a semblance of freedom to a market that has for many years been shielded from market forces by the largest purchaser's inability to negotiate the prices it pays.

Two other federal government programs that provide prescription drug coverage and allow for direct negotiation illustrate the value of drug price negotiation. *See* 38 U.S.C. §§ 8126(a)-(h). The Veterans Health Administration (VHA) provides care to veterans, covering several million people. It purchases drugs directly from manufacturers and has a national formulary, unlike Medicare or Medicaid. The Government Accountability Office (GAO) found that, in 2017, the VHA paid an average of 54% less per unit of medicine than Medicare, including for brand name drugs.[60] In more than half the 399 drugs the GAO 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.[61]

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[59] Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023), https://tinyurl.com/3adurnbk.

[60] 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.

[61] *Id*. at 7.

Another example is the Department of Defense (DoD) uniform drug formulary (TRICARE formulary), which provides prescription drug coverage for roughly 9.5 million active-duty and retired military personnel, their dependents, and others. Within two years of being implemented in 2005, the DoD drug formulary led to roughly $1 billion in cost savings, representing approximately a 13% reduction in drug expenditures.[62] In its most recent report from 2022, the Defense Health Agency estimated $1 billion annual savings in retail pharmacy refunds on most brand-name retail drugs and reported a very low rate of annual growth in costs in recent years.[63]

Even Medicaid, which does not have the kind of direct negotiation and unified formulary system as TRICARE 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.[64] The

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[62] Shana Trice et al., *Formulary Management in the Department of Defense*, J. Managed Care Pharmacy, no. 2, March 2009, at 133, https://tinyurl.com/yc5zp35h.

[63] Analytics & Evaluation Div., Def. Health Agency, *The Evaluation of the TRICARE Program: Fiscal Year 2022 Report to Congress* 51 (2022), https://tinyurl.com/4jf5ucyw.

[64] 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.

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.[65]

The importance of negotiation to reducing prices is also illustrated by the differences in drug prices between the US and other similarly situated countries. The United States is the only country in the 34-member Organisation for Economic Co-operation and Development (OECD) that lacks some degree of government oversight or regulation of prescription drug pricing, and it is the only developed country other than New Zealand that allows the drug industry to set its own drug prices independent of government authority.[66] Studies show that drug prices in the US are between 2 and 2.5 times more expensive than in other comparable

[65] Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 15 (2021), https://tinyurl.com/mpr7edhz; *see also* Marc-André Gagnon & Sidney Wolfe, *Mirror, Mirror on the Wall: Medicare Part D Pays Needlessly High Brand-Name Drug Prices Compared with Other OECD Countries and with U.S. Government Programs* 11 (2015), https://tinyurl.com/2zuydwj7 (noting that the VA and Medicaid often pay the similar prices for drugs, while Medicare Part D pays almost twice as much).

[66] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 50; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 2 (Nov. 8, 2022).

countries.[67] Medicare's inability to negotiate drug prices, as compared to the ability of other public health systems, is a key reason for higher US drug prices.[68]

III. Public Health Research Shows That The Program Is Unlikely To Have Substantial Negative Effects On Drug Availability Or Patient Outcomes.

AstraZeneca and other drug companies opposed to the negotiation program are correct that the United States leads the world in bringing drugs to market. But their claim that the Program will make it uneconomical to continue this pace of innovation, and thereby irretrievably hurt public health, is insufficiently supported.

First: While it is true that developing new pharmaceuticals is an expensive and risky enterprise, it is not clear that the price reductions that result from the Program will lead to substantial reduction in the number of high-impact drugs brought to market. The CBO estimates that the Program will lead to only 13 fewer drugs being brought to market in the next 30 years, for an overall reduction of 1% in volume.[69] The Brookings Institute has similarly found that the Program is unlikely to substantially change the future development of medications, based on

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[67] Andrew W. Mulcahy et al., *U.S. Prescription Drug Prices Are 2.5 Times Those in Other OECD Countries*, Rand Corp. (2021).

[68] *See* Kaiser Permanente Inst. for Health Pol'y, *Pharmaceutical Pricing: Lessons from Abroad* (2015), https://tinyurl.com/3nbaj9a6.

[69] 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.

drug manufacturers' public market activity.[70] This is unsurprising, in part, because the Program does not apply to new drugs on the market and continues to grant pharmaceutical companies almost unfettered discretion to price new drugs at exorbitant rates, which they may well continue to do.[71]

Nevertheless, even without changing the price of new drugs, the public health benefits from lower drug prices for drugs that have been on the market for several years are likely to be orders of magnitude greater than the harm caused by this 1% reduction in new drugs. Making existing drugs more affordable will enable more patients—especially older people with fixed, and often limited, incomes—to actually take and maintain existing necessary medication.

Second: Drug manufacturers' claim that negotiated drug prices will automatically lead to less money available for research is difficult to substantiate considering their longstanding opposition to price and cost transparency, which limits public access to their research costs. The public must trust that drug manufacturers are unilaterally setting the correct price for their drugs, without competition, negotiation, or transparency. For instance, an unknown but large

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[70] 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.

[71] Deena Beasley, *U.S. New Drug Price Exceeds $200,000 Median in 2022*, Reuters (Jan. 5, 2023), https://tinyurl.com/4hmk7vjk.

proportion of pharmaceutical costs are for direct-to-customer marketing and lobbying, rather than research and development.[72] A 2015 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.[73] 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.[74] The US is one of the only countries that allows such a vast scale and scope of direct-to-consumer advertising. Research has shown that direct to consumer advertising increased substantially after the introduction of Medicare Part D and may have been targeted to reach older Americans who were newly covered by governmental prescription drug

[72] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 3 (Nov. 8, 2022).

[73] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 33 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3; *see also* Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, JAMA Network, Jan. 2019, https://tinyurl.com/4hctxutv (noting that between 1997 and 2016, spending on marketing almost doubled, from $17.7 to $29.9 billion (in 2016 dollars)).

[74] Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 10 (Nov. 8, 2022).

insurance.[75] Even if the Program results in lower prices for certain drugs, any difficulty bringing new viable products to market may just as likely be attributable to self-imposed marketing overhead.

Third: New pharmaceutical development in the United States, and especially private corporate research priorities, does not always align with the goal of long-term effective increases in public health. In particular, the US regulatory system for pharmaceutical drugs does not require drug developers to routinely evaluate the marginal benefit of new and expensive treatments over longstanding alternatives.[76] Driven by a wish for higher investment returns, pharmaceutical research and development often focuses on relatively low risk research into marginal changes to differentiate similar drugs, instead of higher risk research into new scientific paradigms that could reduce morbidity and mortality.[77] Recent studies suggest that

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[75] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 17-18 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3.

[76] Some studies have suggested that the lower average healthcare spending seen in other countries may stem in part by their more careful striction on the use of new drugs that have unproven marginal clinical advantages over longstanding generic alternatives. *See* Panos Kanavos, *Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*, Health Affs., Apr. 2013, https://tinyurl.com/4xr32ka2.

[77] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 74, at 10.

more than 60% of research and development spending is post-approval research into additional indications for approved drugs, rather than into new drugs.[78]

The current market thus incentivizes less breakthrough research, rather than more. AstraZeneca refers to the Program reducing its incentive to find new indications for its existing drugs repeatedly. *See, e.g.*, Compl. ¶¶ 10, 11, 20, 36, 100-02. This is also evident in the number of so-called 'me-too' drugs—that is, drugs that are similar to products already on the market and provide little, if any, added benefit.[79] Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[80] Even if the Program were to lead to less research funds for 'me-too' drugs, it may divert funding towards new innovative drug development.

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[78] ATI Advisory, *supra* note 22.

[79] Marc-André Gagnon & Sidney Wolfe, *Mirror, Mirror on the Wall: Medicare Part D Pays Needlessly High Brand-Name Drug Prices Compared With Other OECD Countries and with U.S. Government Programs* 2 (2015) (noting that Medicare prices for "me-too" drugs are significantly higher than older, equally effective versions, but that Medicare continues to pay higher prices and thereby incentivizes the continued production of drugs with marginal value to patients); *see also* Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, J. L., Med. & Ethics, 2013, https://tinyurl.com/yckypnhf.

[80] *See* Ashish Arora, Sharon Belenzon, & Andrea Patacconi, *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.

Fourth: Drug manufacturers' claims about private innovation and market prices for drugs ignore the large share of research and development carried out or funded by governments and universities. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring new innovations and breakthroughs.[81] Major innovative drugs have been discovered in public universities funded through grants from the NIH, and patent rights have been purchased after drug discovery by private companies, generating enormous revenues for drug companies.[82] 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.[83] From 2010 through

[81] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11.

[82] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 74, at 2. Studies have suggested that between 6% and 10% of "new molecular entities" (new innovative drugs) were first patented by public sector or academic institutions and that 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*, 115 Proc. Nat'l Acad. Scis., no. 10, Mar. 2018, at 2332, https://tinyurl.com/bdhu39t9.

[83] Daniel, *supra* note 81, at 11 (citing Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 Health Affs., no. 2, Feb. 2011, at 332-39).

2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[84]

For instance, the active compound in Farxiga, dapagliflozin, has been studied by university-affiliated scientists around the world and foundational research was sponsored by the NIH.[85] Other drugs AstraZeneca cites in its complaint like Lynparza (olaparib) have similar antecedents. Olaparib was developed by a public sector research institute in the United Kingdom, the Institute for Cancer Research.[86] Several of the initial studies were funded by grants from charitable organizations that fund cancer research. Other researchers were granted millions of dollars from the US Army and the NIH, as well as grants and support from private non-profit universities and the European Union. Overall, public funding contributed hundreds of millions of dollars to olaparib's development. The same is true of Soliris (eculizumab), at one point the most expensive drug in the world. Research into eculizumab was built on public research at universities,

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[84] Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 Proc. Nat'l Acad. Scis., no. 10, Mar. 2018, at 2329.

[85] *See, e.g.*, Ernest M. Wright, *Renal Na^+-Glucose Cotransporters*, 280 Am. J. Physiology – Renal Physiology (2001), https://tinyurl.com/53262fnn (describing the kidney's role in glucose absorption and laying the basis for Sodium-glucose co-transporter inhibitors like Farxiga).

[86] Louise Schmidt et al., *Counting the Cost of Public and Philanthropic R&D Funding: The Case of Olaparib*¸ 15 J. Pharm. Pol. & Prac. 2 (2022), https://tinyurl.com/mvtwuv8d.

and clinical trials continue to be supported by the NIH.[87] Research has shown similar findings for other "orphan" drugs of the kind AstraZeneca identifies in its papers.[88]

Under the current system, U.S. taxpayers end up paying twice for pharmaceutical products: by funding basic research and then by paying high prices through government health programs. Where funding for research and development comes from public programs, there is little reason to believe reduction in prices charged by manufacturers will result in substantially reduced effective and impactful innovation.

There is thus no reason to credit AstraZeneca's 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.

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[87] *See* Cancer Inst., *A Study Evaluating the Safety, Pharmacokinetics, and Efficacy of Crovalimab Versus Eculizumab in Participants with Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated with Complement Inhibitors*, https://tinyurl.com/5n97c4kh (last visited Nov. 6, 2023); Kelly Crowe, How Pharmaceutical Company Alexion Set the Price of the World's Most Expensive Drug, CBC News (June 25, 2015, 5:00 AM), https://tinyurl.com/32ew9a82.

[88] Louise Schmidt & Claudia Wild, *Assessing the Public and Philanthropic Financial Contribution to the Development of New Drugs: A Bibliographic Analysis*, 4 Sci., Tech., & Pub. Pol. 8 (2020), https://tinyurl.com/bdh3rmhy.

Recently, an industry group suing in the Southern District of Ohio argued that doctors and patients will be harmed by the Drug Negotiation Program and suggested that doctors supported efforts by the drug companies to gut the Program. *See* Oral Argument on Plaintiffs' Motion for a Preliminary Injunction, D.I. No. 54, *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-00156 (S.D. Ohio, argued Sept. 15, 2023). *Amici* wish to make it clear that they do support this Program and do not support the manufacturers' efforts to gut drug price negotiation.

CONCLUSION

The Court should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion for summary judgment.

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Respectfully submitted,

Democracy Forward Foundation

Ananda V. Burra*
Ben Seel*
Robin Thurston*
P.O. Box 34553
Washington, DC
(202) 448-9090
aburra@democracyforward.org
bseel@democracyforward.org
rthurston@democracyforward.org

Block & Leviton LLP

/s/ Kimberly A. Evans
Kimberly A. Evans (#5888)
Robert Erikson (#7099)
3801 Kennett Pike, Suite C-305
Wilmington, DE 19807
(302) 499-3600
kim@blockleviton.com
robby@blockleviton.com

* *pro hac vice* forthcoming

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation set forth in the Court's local rules and court procedures because it contains 7,476 words, exclusive of the matters designated for omission, according to the word count function of Microsoft Word 365.

Dated: November 8, 2023

/s/ Kimberly A. Evans
Kimberly A. Evans (#5888)
3801 Kennett Pike, Suite C-305
Wilmington, DE 19807
(302) 499-3600
kim@blockleviton.com