IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

DAYTON AREA CHAMBER OF COMMERCE, *et al*, *Plaintiffs*, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*, *Defendants.*	Civil Action No. 3:23-cv-00156 Judge Michael J. Newman Magistrate Judge Peter B. Silvain, Jr.

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

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SUMMARY

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 outline the substantial public health research on high drug pricing in the United States and provide the Court with data on the expected public health effects of the Inflation Reduction Act's Medicare drug price negotiation program. *Amici* represent the interests of thousands of clinicians and public health professionals who have seen the tragic effects of high prescription drug prices on their patients, and they provide the Court with both anecdotal and research data on the human costs of the current prescription drug pricing system.

This brief proceeds in three parts, addressing respectively the effects of high drug prices, the importance of the negotiation program, and the expected effects of this program on drug availability and patient outcomes. Section I, from pages 4 through 14, describes the current drug pricing structure and uses public health research to describe how drug prices have increased at unsustainable rates since the creation of Medicare Part D and have put substantial pressure on Medicare recipients. Section I.A, from pages 5 through 9, describes how prices for a small number of so-called "specialty" drugs have far outpaced retail inflation over the last few decades and have led to ballooning system-wide costs, even though a greater percentage of prescriptions today are for low-cost generic medications. The drugs that have been added to the negotiation program so-far illustrate this broader problem, with prices outpacing research and development expenditure. Section I.B, from pages 9 through 14, describes how high drug prices create hardship for millions of Americans and contribute to cost-related medication nonadherence, the phenomenon where patients stop taking medications or reduce dosages because of high cost, thereby hurting their health. This section includes anecdotes from doctors who have treated patients facing just these kinds of hard choices, humanizing what is often a faceless tragedy.

Section II, from pages 14 through 18, addresses how drug negotiation may reduce drug prices and improve outcomes in the US healthcare system. It discusses how other governmental health programs like those run by the Veterans Health Administration and the Department of Defense provide healthcare with lower prescription drug costs, in part thanks to their ability to negotiate prices with drug companies. Indeed, health systems in other countries that allow drug price negotiations have markedly lower drug prices than in the United States.

Section III, from pages 18 through 24, addresses the primary public health argument against drug price negotiation: that this new program will undermine innovation. First: reputable estimates suggest that new drug development will reduce by only 1% due to this program. The public health benefits of lower prices and consistent medication management will easily make up for this projected reduction. Second: research suggests that a large portion of expenditure in bringing drugs to market relates to extremely expensive direct-to-consumer marketing and lobbying, not research and development. Reductions in drug company profits may be set off by reducing marketing overhead. Third: US private drug research is disproportionately focused on identifying new indications for existing drugs and differentiating similar therapies, rather than innovative new therapies. Reductions in private research do not necessarily correspond to harm to public health innovation. Finally: A large part of the most innovative research in the country is funded by the government and universities. The current drug development ecosystem thus rewards private companies for relatively low-risk high-reward investments and charges the American people twice for the most innovative drugs: first for the underlying basic research funded by organizations like the National Institutes of Health and then through high prices paid by Medicare.

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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 leading 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 Plaintiffs and drug companies have argued, doctors and their patients do not support untrammeled price increases by drug manufacturers. *Amici* also explain why assertions by Plaintiffs Dayton Area Chamber of Commerce, Ohio Chamber of Commerce, Michigan Chamber of Commerce, and the Chamber of Commerce of the USA ("Plaintiffs") regarding the negative effects of these new rules on public health are exaggerated.[2]

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

[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.

[2] *Amici* do not take a position on Defendants' motion to dismiss and issues of standing and venue in this case.

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.[3] 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, 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."[4] Starting in 2006, older adults and people with certain disabilities could enroll in plans run by private companies that contracted with Medicare. These

[3] *See, e.g.*, Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), https://tinyurl.com/4v7c35j8; Am. Pub. Health Ass'n, *APHA Applauds Senate Passage of Inflation Reduction Act* (Aug. 8, 2022), https://tinyurl.com/3etz4e7d; Am. Pub. Health Ass'n, *Ensuring That Trade Agreements Promote Public Health* (Nov. 13, 2015), https://tinyurl.com/b2et6uvp; Am. Pub. Health Ass'n, *Creating the Healthiest Nation: Advancing Health Equity*, https://tinyurl.com/5xn4ue8n (last visited Oct. 23, 2023); Am. Pub. Health Ass'n, *Regulating Drugs for Effectiveness and Safety: A Public Health Perspective* (Nov. 8, 2006), https://tinyurl.com/5n7zv9bd; 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); William Fox, *ACP Comments on CMS' Proposed Changes to Medicare Advantage and Part D*, Am. Coll. Physicians (Feb. 13, 2023), https://tinyurl.com/5a8bxdf7; Ryan D. Mire, *Internal Medicine Physicians Call Inflation Reduction Act a Win for Health in U.S.*, Am. Coll. Physicians (Aug. 15, 2022), https://tinyurl.com/4rhr7skw; Ryan D. Mire, *ACP Letter in Support of Provisions of the Inflation Reduction Act*, Am. Coll. Physicians (Aug. 2, 2022), https://tinyurl.com/4rzhymm3; 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; Am. Coll. Physicians, *Address Prescription Drug Costs*, https://tinyurl.com/4hyh2326 (last visited Oct. 23, 2023).

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

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."[5] Part D was incredibly successful and, in 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[6]

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 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). As this Court has already held, manufacturers can choose to withdraw their drugs from large government health insurance systems if they do not wish to negotiate prices. *See Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-00156, --- F. Supp. 3d ---, 2023 WL

[5] *Id.*

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

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"). Plaintiffs and major drug companies are seeking to gut the law, which would stop these vital reforms. The Court should deny Plaintiffs' 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.[7]

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.[8] 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 are prescribed in

[7] *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.

[8] *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.

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.[9]

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."[10] Prescription drug expenditures per capita increased from $140 in 1980 to $1,073 in 2018 and $1,631 in 2020.[11]

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.[12] Although the introduction of a number of generic drugs into the marketplace has worked to modulate some of these cost

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[9] *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; Matthew McGough et al., *How Does Health Spending in the U.S. Compare to Other Countries?*, Health Sys. Tracker (Feb. 9, 2023), https://tinyurl.com/3jpr6tnc; 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. After adjustment for differences in purchasing power, outpatient prescription drug spending among Organisation for Economic Co-operation and Development countries averaged $564 per person in 2017, with spending highest in the United States ($1,220), Switzerland ($963), and Japan ($838). *See* Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 2 (Nov. 8, 2022). Reports show that use of prescription drugs in the United States is high, but 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.

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

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

[12] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 6; Cong. Budget Off., *Medicare: Baseline Projections* 2 (2022), https://tinyurl.com/28fu8xzp.

increases, by 2018 per enrollee spending on Medicare Part D averaged about $2,700 per year.[13] 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.[14]

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.[15] The CBO estimates that, "[o]ver the 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."[16] 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.[17] Had specialty drug prices merely tracked general retail inflation, their average annual cost would have gone up by only about $2,000 during this

[13] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10.

[14] *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).

[15] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10; Juliette Cubanski et al., *No Limit: Medicare Part D Enrollees Exposed to High Out of-Pocket Drug Costs Without a Hard Cap on Spending*, Kaiser Fam. Found. 3-4 (Nov. 2017), https://tinyurl.com/2rypz7yr.

[16] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10; *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.").

[17] 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.

period; a saving of almost $50,000 per drug.[18] This disproportionate growth has continued since the AARP's 2017 study: KFF, formerly known as the Kaiser Family Foundation, estimated that between 2018 and 2021 gross Medicare spending for the top selling Part D drugs more than doubled.[19]

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.[20]

Amici understand that Plaintiffs' standing to bring these claims is premised on two drug company members: AbbVie and Pharmacyclics. *See* Amended Complaint, ECF No. 57 ("Compl."), ⁋⁋ 37-53. While *amici* do not take a position on the Parties' dispute on standing, AbbVie and Pharmacyclics's drug, Imbruvica, illustrates the problem of unmoored drug price increases. Imbruvica is a blood cancer drug that cost $352 million to bring to FDA approval; after it was already on the market, Imbruvica's manufacturers spent another $1.2 billion to

[18] *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.").

[19] 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.

[20] 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.

identify additional indications and modes of delivery.[21] Gross Medicare costs for Imbruvica from June 2022 to May 2023 were over $2.6 billion; it thus pays roughly twice the *lifetime* R&D spending for Imbruvica *every year*.[22] The cumulative rate of retail inflation between 2013 (when Imbruvica was approved) and the present is approximately 34%.[23] In contrast, Imbruvica's price went up 108%.[24] Researchers in 2018 found that Imbruvica's manufacturers tripled the cost of a single pill when it became clear that patients could be treated with lower doses.[25] Imbruvica has earned over $36.8 billion globally.[26]

[21] ATI Advisory, *The First 10 Drugs to be Negotiated by Medicare* 8 (Aug. 30, 2023), https://tinyurl.com/294sj44f.

[22] *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.

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

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

[25] Washington Post, *Science Hinted That Cancer Patients Could Take Less of a $148,000-a-Year Drug. Its Maker Tripled the Price of a Pill*, Los Angeles Times (Apr. 18, 2018, 11:25 AM), https://tinyurl.com/3xd25y73.

[26] ATI Advisory, *supra* note 21, at 8.

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**[27]	**Medicare Part D Gross Cost (June 2022-May 2023)**[28]	**Global lifetime sales (2021)**[29]	**Total R&D costs (2021)**[30]
Enbrel	1998	701%	$2.8 bn	$132.5 bn	unknown[31]
Novolog[32]	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

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.[33] In addition to these premiums, many drug plans have annual deductibles that beneficiaries must pay. After the initial

[27] Purvis, *supra* note 20, at 2, fig. 1; @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinyurl.com/3m64hu2x.

[28] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026, supra* note 22, 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.

[29] ATI Advisory, *supra* note 21.

[30] *Id*.

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

[32] Includes sales for Fiasp.

[33] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 6; 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).

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.[34] 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.[35] Prior to the 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."[36] 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.[37] More than a third of older people have had 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] Today, "catastrophic

[34] *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.

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

[36] 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.

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

[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.

coverage" for ultra-high cost enrollees accounts for nearly half of total Medicare Part D spending, up from 14% in 2006.[41] 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.[42]

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%)."[43] Thirty percent of people experiencing medical debt reported it was due to their need for prescription drugs.[44] Fears about medical costs and debt have topped peoples' list of financial worries for many years.[45]

The impact of an expensive prescription drug delivery system is most poignant when reviewing cost-related nonadherence (CRNA) to medications. 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.[46] 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

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[41] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 6.

[42] *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).

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

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

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

[46] 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.

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."[47]

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.[48] 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 range."[49] In 2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[50] By the summer of 2023, that figure had increased by 5 percentage points.[51] 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.[52]

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

[48] 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.

[49] *Id*. at 5.

[50] Montero et al., *supra* note 43; *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").

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

[52] 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.

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.[53] Public health researchers have estimated that, "[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."[54]

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.[55] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[56] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[57] 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.[58]

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

[54] *Id.* at 1.

[55] *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).

[56] Goldman, Joyce, & Zheng, *supra* note 46, at 7.

[57] 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.

[58] *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*, *supra* note 34.

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' 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.[59] Allowing Medicare to negotiate the price of drugs in the Part D program has 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.[60] 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-of-pocket costs under the new standards set by the IRA.[61] Plaintiffs' dramatic characterization of drug price negotiation as "disastrous" and "unprecedented" "central planning and socialized medicine" that "disrupts the entire

[59] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10; 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 observed [between 2008 and 2012] could have been partly a response by manufacturers to more generous coverage in the doughnut hole").

[60] 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.

[61] 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.

pharmaceutical development ecosystem" and sets up CMS as "interested party, judge, jury, and executioner" Compl. ¶¶ 1, 2, 24, 59, 110, 150, notwithstanding, the Program will restore some 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 between the government and drug manufacturers. *See* 38 U.S.C. §§ 8126(a)-(h). The Veterans Health Administration (VHA) operates as a closed system and provides care directly to veterans, covering several million people. It purchases drugs and other pharmaceuticals directly from manufacturers and has a national formulary that does not exist in 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.[62] 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.[63]

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.[64] In its most recent report

[62] 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.

[63] *Id*. at 7.

[64] 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.

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.[65]

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.[66] 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.[67]

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.[68] Studies show that drug prices in the US are

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

[66] 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.

[67] 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).

[68] 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).

between 2 and 2.5 times more expensive than in other comparable countries.[69] Medicare's inability to negotiate drug prices, as compared to the ability of other large public health systems, is a key reason for higher US drug prices.[70]

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

Plaintiffs and 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.[71] The Brookings Institute has similarly found that the Program is unlikely to substantially change the future development of medications, based on drug manufacturers' public market activity.[72] This is unsurprising, in part, because the Program

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

[70] *See* Kaiser Permanente Inst. for Health Pol'y, *Pharmaceutical Pricing: Lessons from Abroad* (2015), https://tinyurl.com/3nbaj9a6; Dana O. Sarnak, et al., *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, Commonwealth Fund (Oct. 2017).

[71] 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.

[72] 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.

does not apply to new drugs on the market and continues to grant companies almost unfettered discretion to price new drugs at exorbitant rates, which they may well continue to do.[73]

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 proportion of pharmaceutical costs are for direct-to-customer marketing and lobbying, rather than research and development.[74] 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.[75] Other estimates suggest that marketing and administration can

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

[74] 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).

[75] 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)).

contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[76] 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 insurance.[77] 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.[78] 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.[79] Recent studies suggest that more than 60% of research and development spending is post-approval research into additional indications

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

[77] 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; *see also* U.S. Gov't Accountability Off., GAO-21-380, *Medicare Spending on Drugs with Direct-to-Consumer Advertising* (2021), https://tinyurl.com/bdhtv42c.

[78] 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.

[79] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 76, at 10.

for approved drugs, rather than into new drugs.[80] AbbVie and Pharmacyclics have been accused of creating a "patent thicket" or "patent wall" around Imbruvica since its first patent in 2006, delaying generic competition.[81] This strategy has extended market exclusivity by more than 9 additional years, into 2036.[82]

The current market thus incentivizes less breakthrough research, rather than more. 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.[83] Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[84] Even if the Program were to lead to less research funds for 'me-too' drugs, it may divert that funding towards more innovative drug development.

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

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[80] ATI Advisory, *supra* note 21. AbbVie and Pharmacyclics have been criticized for focusing research on extending the patent protections for Imbruvica with additional indications, rather than putting funding towards genuine research needs. *See* I-MAK, *Imbruvica's Patent Wall* (July 2020), https://tinyurl.com/48sftsjv.

[81] *See* I-MAK, *Imbruvica's Patent Wall* 4-5 (July 2020), https://tinyurl.com/48sftsjv (describing a "drip feed" patenting strategy to extend patent protection for Imbruvica, netting the companies tens of billions of dollars in additional profits).

[82] *Id.*

[83] 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 such 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.

[84] *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. Notably, large pharmaceutical companies accounted for most pharmaceutical revenues, whereas small drug companies accounted for more than 70% of the total pharmaceutical R&D pipeline in 2018. *See* IQVIA Inst., *The Changing Landscape of Research and Development* (Apr. 2019), https://tinyurl.com/2p943hre.

government investments in basic research and play a key role in spurring new innovations and breakthroughs.[85] 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.[86] 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.[87] From 2010 through 2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[88]

Insulin is a great example of this kind of process. 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-fee.[89] Despite being the product of public and academic research a century ago, insulin prices have skyrocketed in recent years. Amongst the most expensive of these insulin-based treatments are Fiasp and Novolog, both of which are on the list of drugs eligible for negotiation under the Program. Combined, they accounted for $2.6 billion in total Medicare Part D spending between June 2022 and May 2023,

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[85] 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.

[86] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 76, 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.

[87] Daniel, *supra* note 85, 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).

[88] 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.

[89] Hilary Daniel, Josh Serchen, & Thomas G. Cooney, *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.

despite being built on a base of publicly supported research.[90] AbbVie and Pharmacyclics's Imbruvica is similar. Early research into its effectiveness against leukemia was funded by the Intramural Research Program of the NIH, the National Cancer Institute, the Center for Cancer Research, the National Institute of Allergy and Infectious Disease, and the National Human Genome Research Institute.[91]

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.[92]

There is thus no 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.

Plaintiffs recently 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* Sept. 15, 2023, Oral Argument on Plaintiffs' Motion for a Preliminary

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[90] Jeannie Baumann, Celine Castronuovo, & John Tozzi, *Insulin Makers Facing Price Talks Appear Poised to File Lawsuits*, Bloomberg Law (Aug. 31, 2023, 5:01 AM), https://tinyurl.com/2j44msz6.

[91] *See* Rachel E. Davis et al., *Chronic Active B Cell Receptor Signaling in Diffuse Large B Cell Lymphoma*, 463 Nature 88 (2010), https://tinyurl.com/3n4jka3v (discussing the effectiveness of targeting Bruton's tyrosine kinase with PCI-32765, later called Ibrutinib and branded as Imbruvica); *see also* Sarah E.M. Herman et al., *Bruton Tyrosine Kinase Represents a Promising Therapeutic Target for Treatment of Chronic Lymphocytic Leukemia and Is Effectively Targeted By PCI-32765*, 117 Blood 6,287 (2011), https://tinyurl.com/2d6c9tju (industry sponsored research citing this publicly-funded basic research).

[92] Notably, the drug negotiation program allows CMS to take prior financial support for development of the drugs selected for negotiation into account when considering fair prices. *See* 42 U.S.C. § 1320f-3(e); Compl. ¶ 105.

Injunction, ECF No. 54. *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,

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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 does not exceed the page requirements mandated by local rules.

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