Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 1 of 43 PageID #: 942

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP & ASTRAZENECA AB, *Plaintiffs*, V.

Civil Action No. 23931-CFC

XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al. Defendants.*

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' CROSSMOTION 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) 4489090 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-**3**05 Wilmington, DE 19807 (302)499-3600 kim@blockleviton.com robby@blockleviton.com

Counsel for Amici Curiae

TABLE OF CONTENTS

	Page
Table of Authorities	iii
Identity and Interests of Amici Curiae	1
Introduction	2
Argument	5
I. America's Unsustainably High Prescription Drug Pricing Reg Substantial and Escalating Negative Effects on Public Health an Outcomes	d Patient
A. Medicare prescription drug costs have become unsustainal	bly.high6
B. Americans, especially older adults, cannot sustain these hi	gh price1s2
II. The Program Is A Vital First Step In Ensuring The Health Of And The Medicare Program	
III. Public Health Research Shows That The Program Is Unlike Substantial Negative Effects On Drug Availability Or Patient Out	
Conclusion	
Certificate of Compliance	33

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 4 of 43 PageID #: 945

TABLE OF AUTHORITIES

Page(s)

С

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, https://tinyurl.com/2p9yt463..15, 17

Hilary Daniel & Sue S. Bornstein, <i>Policy Recommendations for Public Health</i> <i>Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper</i> <i>from the American College of Physicians</i> , Annals Internal Med2019, <u>https://tinyurl.com/3tsxa443</u> 2, 6, 13
Irene Papanicolas, Liana R. Woskie, & Ashish K. Jhaulth Care Spending in the United States and Other High-Income Countries, 319 JAMA Network (2018), available at https://tinyurl.com/4jaebbbc
Jessica Williams et al., Cosrelated Nonadherence by Medication Type Among Medicare Part D Beneficiaries with Diabetes, Med. Care, Feb. 2013, https://tinyurl.com/ycynd88h
Juliette Cubanski & Anthony Damic <i>Key Facts About Medicare Part D</i> Enrollment and Costs in 2023, Kaiser Fam. Found. (July 26, 2023), https://tinyurl.com/2tby57ue
Juliette Cubanski & Tricia Neuman, Small Number of Drugs Account for a Large Share of Medicare Part D Spending, Kaiser Fam. Found. (July 12, 2023), https://tinyurl.com/ycytf6wm
Juliette Cubanski, Tricia Neuman, & Meredith Freed, <i>Explaining the Prescription Drug Provisions in the Inflation Reduction Act</i> , Kaiser Fam. Found. (Jan. 24, 2023), <u>https://tinyurl.com/3adurnbk</u>
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. (Nov. 2017).https://tinyurl.com/2rypz7yr
Juliette Cubanski et al., Options to Make Medicare More Affordable for Beneficiaries Amid the COVID-19 Pandemic and Beyond, Kaiser Fam. Found. (Dec. 8, 2020) <u>https://tinyurl.com/52n7hj82</u>
Kaiser Fam. Found., An Overview of the Medicare Part D Prescription Drug Benefit (Oct. 19, 2022), https://tinyurl.com/ya3fhu693,.7, 12-13
Kaiser Permanente Inst. for Health Pol'y, <i>Pharmaceutical Pricing: Lessons from</i> <i>Abroad</i> (2015), <u>https://tinyurl.com/3nbaj9a6</u>
Karthik W. Rohatgi et al., <i>Medication Adherence and Characteristics of Patients</i> <i>Who Spend Less on Basic Needs to Afford Medications</i> , J. Am. Bd. Fam. Med., June 2021, <u>https://tinyurl.com/ybzbf9nf</u>

Kelly Crowe, How Pharmaceutical Company Alexion Set the Price of th	ne World's
Most Expensive Drug, CBC News (June 25, 2015, 5:00 AM),	
https://tinyurl.com/32ew9a82	

- 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. (June 2021), https://tinyurl.com/46k6565c......8

9

,

Nat'l Acads. of Scis., Eng'g, & MedMaking Medicines Affordable: A National Imperative (Norman R. Augustine et al. eds., 2018), https://tinyurl.com/2zjvmfk2
Nat'l Cancer Inst., A Study Evaluatinghe Safety, Pharmacokinetics, and Efficacy of Crovalimab Versus Eculizumab in Participants with Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated with Complement Inhibitors, https://tinyurl.com/5n97c4k (last visited Nov. 6, 2023)
Noam N. Levey, 100 Million People in America Are Saddled with Health Care Debt, KFF Health News (June 16, 2022), https://tinyurl.com/4hapcdb14
Off. Inspector Gen., Dep't Health & Hum. Serv@EI-03-13-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin (2015), https://tinyurl.com/2f936cp.c
Oral Argument on Plaintiffs' Motion for a Preliminary Injunction, D54, Dayton Area Chamber of Commerce v. Becerra, No. 23cv-00156 (S.D. Ohio, argued Sept. 15, 2023)
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, <u>https://tinyurl.com/4xr32ka2</u>
Part D Payment System, MedPAC, <u>https://tinyurl.com/37c875</u> 4last revised Oct. 2022)
Reshma Ramachandran, Tianna Zhou, & Joseph S. Rosof @wcket Drug Costs for Medicare Beneficiaries Need to Be Reined In (Jan. 7, 2022), https://tinyurl.com/33jjrr8b
Richard G. Frank & Ro W. Huang, <i>Early Claims and M&A Behavior Following</i> <i>Enactment of the Drug Provisions in the IRA</i> (Aug. 23, 2023), <u>https://tinyurl.com/yjv3y48t</u>
Shana Trice et al <i>Formulary Management in the Department of Defense</i> , J. Managed Care Pharmacy, no. 2, March 2009, https://tinyurl.com/yc5zp225h
Stacie B. Dusetzina et al., CoRelated Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022, JAMA Network, May 2023, https://tinyurl.com/4mccyu7x16

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 11 of 43 PageID #: 952

I

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. *Almaxie* long advocated for evidencebased and valueriented public policy regarding drug pricing. 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,

² See, e.g., Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescripe*

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 Ameri**ba**d no access to drug coverage and more than **ethe**rd reported not taking their medicines as prescribed due to cost.⁹ 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 **ein**surace or make a epayment. PartD benefits allowed older adults, especially lowincome people, to access critical care: "annualow#tocket 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 f⁶lans.

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. §§ 1395vf 11(i). Drug prices-especially for drugs

⁴ Id.

³ Reshma Ramachandran, Tianna Zhou, & Joseph S. Rosof *Omacket Drug* Costs for Medicare Beneficiaries Need to Be Reined In (Jan. 7, 2022), .

⁵ Kaiser Fam. Found., *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 19, 2022), <u>https://tinyurl.com/ya3fhu</u>69.

targeted at people over 65 who have Medicare's guaranteed coverage 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

ARGUMENT

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

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 crushingurden for many lowand moderatencome 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 outêomes.

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 PartD came into force) and 2023 hassive than doubled. These cost increases Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 16 of 43 PageID #: 957

These cosincreases 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 outlays¹¹ 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 pér **Weat**ably, these high per capita costs have persisted, despite 90 percent of Medicare Part D prescriptions being for lowcost generics, and despite the average price for generics*dropping* between 2009 and 2018.

These high levels of spending are driven in large part by the widespread and long term use of so-

2009-

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.

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.

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% In contrast, Farxiga's price

¹⁸ Juliette Cubanski & Tricia Neuman, *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 b

went up 81%¹ 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 treat²² 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 glob²fly.

²¹ @AARP, Twitter (Sept. 8, 2023, 5:56pm), <u>https://tinyurl.com/3m64</u>hu2x

²² ATI Advisory, *The First 10 Drugs to be Negotiated by Medicare* **7** (Aug. 30, 2023),<u>https://tinyurl.com/294sj4</u>4f

²³ Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026, Ctrs. for Medicare & Medicaid Servs.(Aug. 2023), https://tinyurl.com/mrys5br.6

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

The table below summarizes availablat a for the drugs chosen for

negotiation.

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

Drug	Year of FDA approval		Part D Gross	Global lifetime sales (2021) ²⁷	Total R&D costs (2021) ²⁸
Enbrel	1998	701%	\$2.8 bn	\$132.5 bn	unknowr ²⁹
Novolog ³⁰	2000	628%	\$2.6 bn	\$42.8 bn	unknown
Januvia	2006	275%	\$4.1 bn	\$54.1 bn	· · ·

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

Even though most of the cost of highieed medication is borne by Medicare, a significant portion is also borne by older Americans and individuals with disabilities, whose cost haring can include significant monthly premiums and other costs².¹ 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 approxyment (usually for medications on lower tiers) or a consurance (for higher tier or specialty medications), they reach the 'donut hole' or coverage gap and pay 25% of a drug's list price until appfout pocket maximum is reached.During the coverage gap phase, plan reimbursements are often reduced with the switch from flappagoments to 25% co-insurance, which means patient contributions often increase.

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), <u>https://tinyurl.com/2tby57u</u>For the standard framework for Medicare Part D plans after the Inflation Reduction Act, see Part D Payment SysteMedPAC, <u>https://tinyurl.com/37c8754</u>(Jast 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/yc4tm4v.v

³³ Fo

PartD amendments in the IRA, patients with extremely high drug ecgessiverally 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 or pocket spending in the catastrophic phase in 2017, with average annual conf-pocket costs exceeding \$3,20°0."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 ³de Doday, "catastrophic coverage" for ultrahigh cost enrollees accounts for nearly half of total Medicare Part D spending, up from 14% in 20°61n 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 drug S.More than a third of older people have had

³⁴ Juliette Cubanski et aQptions 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), <u>https://tinyurl.com/nbuckbb3</u>.

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 Med2019, at 825 (analyzing the effects of increasing prices of multiple sclerosis drugs).

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 24 of 43 PageID #: 965

CRNA is the widely reported phenomenon where patients stop taking prescription drugs because of rising prices, even where the drugs are "essential" to their health⁴⁴ 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 householdsith 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 aladults over 65 (a total of 3.5 million people) faced affordability problems due to prescription costs, and allon of these older adults did not take needed prescriptions due to ⁴⁶ o She 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

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 669, <u>https://tinyurl.com/2p9yt463</u>.

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. Deplealth & Human Servs. 3 (Jan. 19, 2022), <u>https://tinyurl.com/3uxmyfwr</u>

range.⁴⁷ In 2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare P2aff[®] By the summer of 2023, that figure had increased by 5 percentage pointshese figures would likely be higher still, except that some older people.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.

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

⁴⁷ Id. a./er (rol4r2MTd (ld)Tj /TT0 1 Tf -0.001 Tc 0 Tw [(. a)31 (ght)1 (i)1 9 (t)1.019.6.9 (s

older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the U**R**."

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, **pr**entative medications" that would save them from death or serious injury^{5,3} Collectively, that leads to greater use of inpatient and emergency medical services by those patie^{fft}sIndeed, the initiation of Medicare Part-D which reduced CRNA-was itself associated with a drop in hospitalization rates for several condition^{§5}. Some analysts have estimated that "highod**ut**ocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare

⁵² *Id.* yur.1 (iuse)4 (2.3 Td [1 (re)4/di)1y(l)1.yn1 (s fo88hn)4.1 (s.)]TJ EMC /Span 3(t)1.1⁻ 3 Tw [(SoM)2.6 (e)3.9 (m)3.2 (a)3f sene (t)s 2.3 Td [1 (r.8 (o)4)6 (ao (c)4 Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 28 of 43 PageID #: 969

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 longe

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. <u>The Program Is A Vital First Step In Ensuring The Health Of</u> <u>Americans And The Medicare Program</u>.

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 OuOf-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. Andrico cated for the repeal of Medicare's "noninterference" 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 pu**ses** from private companies; it routinely does so for a wide variety of other products for which it is the monopson(a)4 (ths (i)1 (nc) (7b)3.9 (t:o)1.1 (c(m)3.2 s1utc)3.9Tj 2Tj EMg1s.5 (e)41 (hi1 of-pocket costs under the new standards set by the RestraZeneca's dramatic characterization of drug price negotiation as "governineptsed 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. *Sec*38 U.S.C. §§126(a)(h). The Veterans Health Administration (VHA) provides care to veterans, covering several million people. It purchases drugsdirectly from manufacturers and has a national formulary, u**Mitte**icare 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. 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.

⁵⁹ Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023),

Another example is the Department of Defense (DoD) uniform drug formulary (TRICARE formulary), which provides prescription drug coverage for roughly 9.5 million activeduty 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 In its most recent report from 2022, the Defense Health Agency estimated \$1 billion annual savings in retail pharmacy refunds on most brandame retail drugs and reported a very low rate of annual growth in costs in recent yeafts. CBO has estimated that the average price of tolenging brandhame drugs in Medicare Part D is almost three times higher than in Medfe aid.

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 theroember 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 authorityStudiesshowthat 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), <u>https://tinyurl.com/mpr7ed</u>bzee 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

countries⁶⁷

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 35 of 43 PageID #: 976

proportion of pharmaceutical costs are for diffectustomer marketing and lobbying, rather than research and development.

insurance⁷⁵ 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 alter⁷fatives. 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 thatould reduce morbidity and mortality. Recent studies suggest that

⁷⁵ Abby Alpert, Darius Lakdawalla, & Neeraj Sodd; escription Drug Advertising and Drug Utilization: The Role of Medicare Part D 17-18 (Nat'l Bur1 (8 (Od[(t)-4.E1 Tc -[(t

more than 60% of research and development spending isposstval research into additional indications for approved drugs, rather than into new drugs.

Fourth: Drug manufacturers' claims about private innovation and market

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 40 of 43 PageID #: 981

Case 1:23-cv-00931-CFC Document 41-2 Filed 11/08/23 Page 41 of 43 PageID #: 982

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, DNo. 54, *Dayton Area Chamber of Commerce v. Becerra*, No. 23cv-00156 (S.D. Ohio, argued Sept. 15, 2023). *Amiwish to make it clear that thelo* 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' crosenotion for summary judgment.

Dated: November 8, 2023

Democracy Forward Foundation

Block & Leviton LLP

Respectfully submitted,

<u>/s/ Kimberly A. Evans</u> Kimberly A. ElÖ#588BDC /8)ID 53 >>BDC 0 s

Ananda V. Burra* Ben Seel* Robin Thurston* P.O. Box 34553 Washington, DC (202) 4489090 aburra@democracyforward.org bseel@democracyforward.org rthurston@democracyforward.org

* pro hac vice forthcoming

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the typedume limitation set

forth in the Court's local rules and court procedures because it contains 7,4

words, exclusive of the matters designated for omission, according to the word

count function of Microsoft Word 365.

Dated: November 8, 2023

<u>/s/ Kimberly A. Evans</u> Kimberly A. Evans (#5888) 3801 Kennett Pike, Suite-**3**05 Wilmington, DE 19807 (302) 4993600 kim@blockleviton.com