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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. 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] , Am. Pub. Health Ass'n,

amended the Medicare statute to create Part D pharmacy benefits.

, 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. 42 U.S.C. §§ 1395w-111(i). Drug prices—especially for drugs

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[3] Reshma Ramachandran, Tianna Zhou, & Joseph S. Ross, (Jan. 7, 2022), .

[4] .

[5] Kaiser Fam. Found., (Oct. 19, 2022), https://tinyurl.com/ya3fhu69.

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. 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

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 between 2009 and 2018.[13]

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.[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, , Kaiser Fam. Found. (July 12, 2023), https://tinyurl.com/ycytf6wm. The Office of Health Policy with the Department of b

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 .[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, 7 (Aug. 30, 2023), https://tinyurl.com/294sj44f.

[23] , Ctrs. for Medicare & Medicaid Servs. (Aug. 2023), https://tinyurl.com/mrys5br6.

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

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

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	

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] , note 5; Juliette Cubanski & Anthony Damico, , Kaiser Fam. Found. (July 26, 2023), https://tinyurl.com/2tby57ue. For the standard framework for Medicare Part D plans after the Inflation Reduction Act, , MedPAC, https://tinyurl.com/37c87548 (last revised Oct. 2022).

[32] , Council for Informed Drug Spending Analysis (Nov. 18, 2020), https://tinyurl.com/yc4tm4vv.

[33] Fo

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

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[34] Juliette Cubanski et al., , Kaiser Fam. Found. 4 (Dec. 8, 2020), https://tinyurl.com/52n7hj82.

[35] Dena Bunis, , AARP (March 8, 2022), https://tinyurl.com/nbuckbb3.

[36] , note 5.

[37] Hilary Daniel & Sue S. Bornstein, , Annals Internal Med. 2019, at 825 (analyzing the effects of increasing prices of multiple sclerosis drugs).

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, , JAMA Network, July 2007, at 669, https://tinyurl.com/2p9yt463.

[45] Montero et al., note 41.

[46] Wafa Tarazi et al., , 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—18.5% 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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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

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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] , note 9; Erin Trish, Jianhui Xu, & Geoffrey Joyce, , 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. advocated for the repeal of Medicare's "non-interference" provisions specifically because of that provision's negative effects on public and patient health.

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 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 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. 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, , 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 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]

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., 15 (2021), https://tinyurl.com/mpr7edhz; Marc-André Gagnon & Sidney Wolfe,

countries.[67]

proportion of pharmaceutical costs are for direct-to-consumer marketing and lobbying, rather than research and development.[72]

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.

: 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

[75] Abby Alpert, Darius Lakdawalla, & Neeraj Sood,

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

: Drug manufacturers’ claims about private innovation and market

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. Oral Argument on Plaintiffs' Motion for a Preliminary Injunction, D.N. 54, , No. 23-cv-00156 (S.D. Ohio, argued Sept. 15, 2023). 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.

Dated: November 8, 2023

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 contains 7,476 words, exclusive of the matters designated for omission, according to the word count function of Microsoft Word 365.

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