EXHIBIT A

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

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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

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IDENTITY AND INTERESTS OF *AMICI CURIAE*[1]

Amici

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.*,

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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]

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 pt ofc(oc)4 2*378423T1y oma]TJ.e bn

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-*

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, Fe(r)-2 Che plDC 0u.4 515.58 TJ/TT

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.f[1

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

coverage phase when Medicare beneficiaries pay either a co-

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

[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.,

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

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 ou02 Tw 98.22Tw 11.[()

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

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,

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

[65] Analytics & Evaluation Div., Def. Health Agency, *The Evaluation of the TRICARE Program: Fiscal Year 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*

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

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

[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 aAauddd21714 t(e)0w1 (o)61r1 (o-5.5 (oTv ET8(a)r1 (o-5.a-5j8)0gT8(a)cEMC ETBTv eal(21)-6t2 ( )6T-1.4 car1 (o-

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* , *M A K 6 (e) 3*

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.

Dated: December 19, 2023

Respectfully submitted,

Democracy Forward Foundation

Ananda V. Burra*

[redacted]

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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.

Dated: December 19, 2023

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