

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

DAYTON AREA CHAMBER OF)	
COMMERCE, <i>et al.</i> ,)	
)	
<i>Plaintiffs,</i>)	No. 3:23-cv-00156-TMR-PBS
)	
v.)	Judge Thomas M. Rose
)	
XAVIER BECERRA, <i>et al.</i> ,)	Magistrate Judge Peter B. Silvain, Jr.
)	
<i>Defendants.</i>)	

**MOTION OF AARP AND AARP FOUNDATION FOR LEAVE TO FILE AMICUS
CURIAE MEMORANDUM IN SUPPORT OF DEFENDANTS’ OPPOSITION TO
PLAINTIFFS’ MOTION FOR A PRELIMINARY INJUNCTION**

AARP and AARP Foundation respectfully request leave to file a memorandum as *amicus curiae* in support of Defendants’ Opposition to Plaintiffs’ Motion for a Preliminary Injunction.

Proposed amici are national organizations that have a strong interest in ensuring that older adults have access to quality, affordable health care, including affordable prescription drugs. AARP is the nation’s largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older. AARP’s charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

The plaintiffs have asked this Court to preliminarily enjoin the U.S. Department of Health and Human Services from implementing the Inflation Reduction Act’s Medicare drug negotiation program. *See* 42 U.S.C. § 1320f(a) (establishing the “Negotiation Program”). That program allows Medicare to directly negotiate drug prices with manufacturers for the first time. Proposed amici have a strong interest in the outcome of this litigation because a ruling in favor of the plaintiffs would stop millions of older adults from accessing affordable prescription

drugs. Our memorandum would provide the Court with unique information and perspective on issues critical to the disposition of the plaintiffs' motion, including about how preliminarily enjoining the Medicare drug price negotiations would harm older adults and the financial sustainability of the Medicare program, and cost taxpayers billions of dollars in savings.

Proposed amici notified all parties timely of their intent to file an amicus curiae memorandum. The plaintiffs took no position on this motion. The defendants consented to the motion. The information in the amici curiae memorandum is timely as the proposed amici will file the memorandum within a week of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction.

A memorandum in support follows, and the proposed amicus curiae memorandum is attached to this submission.

August 18, 2023

Respectfully submitted,

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**MEMORANDUM IN SUPPORT OF MOTION OF AARP AND AARP FOUNDATION
FOR LEAVE TO FILE AMICUS CURIAE MEMORANDUM IN SUPPORT OF
DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY
INJUNCTION**

I. Statement of Interest

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With a nationwide presence, AARP strengthens communities and advocates for what matters most to the more than 100 million Americans 50 years old and older and their families: health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

Among other things, AARP and AARP Foundation advocate for access to affordable prescription drugs and health care, including through participation as amici curiae in state and federal courts. *See, e.g.,* Br. of AARP et al. as Amici Curiae in Support of Petitioners, *California v. Texas*, 593 U.S. __ (2021) (No. 19-840); Br. of AARP and AARP Foundation as Amici Curiae

in Support of Respondent, *Impax Labs., Inc. v. F.T.C.*, 994 F.3d 484 (5th Cir. 2021) (No. 19-60394).

II. Argument

Proposed amici's motion should be granted because their memorandum will provide unique information to assist the Court in deciding whether to grant the plaintiffs' motion for a preliminary injunction. The Local Rules of this Court contemplate the occasional submission of *amicus curiae* briefs, *see* Local Civil Rule 7.1.1 (disclosure requirements extend "to entities appearing as *amici curiae*"), and leave to appear as an amicus is "a matter of privilege committed to 'the sound discretion of the court.'... Grant of leave to appear as *amici* is appropriate where such parties have 'an important interest and a valuable perspective on the issues presented ...,'" *United States v. City of Columbus*, No. 2:99-cv-1097, 2000 WL 1745293, at *1 (S.D. Oh. 2000).

Proposed amici have an important interest and a valuable perspective on the issues presented in this case because it affects the ability of millions of older adults to access affordable prescription drugs and the integrity of the Medicare program. Proposed amici's memorandum is desirable and relevant to the disposition of this case because it addresses important preliminary injunction considerations about how enjoining the law is not in the public interest and will substantially harm older adults, the Medicare program, and American taxpayers. The memorandum will provide pertinent information regarding the challenges that millions of older adults face because they cannot afford prescription drugs and why proceeding with the statutorily-mandated schedule is crucial to their health and financial stability. Proposed amici will also explain how a delay in implementing the negotiations program will threaten the financial sustainability of the Medicare program and deprive taxpayers of billions of dollars in savings.

For these reasons, Movants respectfully request leave to file the attached amici curiae memorandum to facilitate the full consideration by the Court of the important legal and public policy issues presented in this case.

August 18, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2023, the foregoing was filed with the Clerk via the CM/ECF system, which shall serve notice hereof on all parties of record.

/s/Jeffrey P. Vardaro
Jeffrey P. Vardaro

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**MEMORANDUM OF AMICI CURIAE AARP AND AARP FOUNDATION
SUPPORTING DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A
PRELIMINARY INJUNCTION**

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CORPORATE DISCLOSURE STATEMENT

AARP and AARP Foundation

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act.

Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

STATEMENT OF INTEREST¹

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With a nationwide presence, AARP strengthens communities and advocates for what matters most to the more than 100 million Americans who are 50 and over and their families: health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

Among other things, AARP and AARP Foundation advocate for access to affordable prescription drugs and health care, including through participation as amici curiae in state and federal courts. *See, e.g.*, Br. of AARP et al. as Amici Curiae in Support of Petitioners, *California v. Texas*, 593 U.S. __ (2021) (No. 19-840); Br. of AARP and AARP Foundation as Amici Curiae in Support of Respondent, *Impax Labs., Inc. v. F.T.C.*, 994 F.3d 484 (5th Cir. 2021) (No. 19-60394).

INTRODUCTION AND SUMMARY OF ARGUMENT

The Inflation Reduction Act of 2022 ("IRA") is a landmark law that includes historic measures to lower the skyrocketing prices of prescription drugs. One key provision authorizes Medicare to directly negotiate drug prices with manufacturers for the first time, thereby halting the runaway prices that Medicare and its beneficiaries have been forced to pay. This change will bring much-needed relief to millions of older people who will finally be able to afford their prescription drugs and will save the Medicare program and American taxpayers billions of dollars.

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. Amici curiae also certify that only Amici Curiae provided funds to prepare and submit this brief.

Steep increases in drug prices have hit older people particularly hard, forcing millions of them to make devastating decisions because they cannot afford the medication they need. More than 50 million people are enrolled in Medicare Part D, the federal government's voluntary prescription drug benefit program for Medicare beneficiaries. On average, they take between four and five prescriptions per month and have a median annual income of just under \$30,000. Many older people simply do not have the resources to pay for rapidly escalating drug prices. As a result, many are forced to choose between paying for their medication or paying for basic life essentials such as food, housing, or heat. Some older people skip doses, split doses, or forego filling their prescriptions altogether to make ends meet. Other people sell everything they own and drain their resources because the price of their medication is beyond their reach.

For example, Kitty R. from New York often goes without her prescribed medications because she cannot afford them on her fixed income.² Ken O. from Pennsylvania sold his car, took out loans, and cut back on basic life necessities to afford his medication.³ And Therese B. from Indiana was forced to stop taking her life-changing medication because she could no longer afford it.⁴

Not only do high drug prices take a terrible toll on older people's finances, but they also impact their overall health. Millions of older people do not consistently adhere to their

² Dena Bunis, *AARP 'People's Hearing' Highlights Rx Struggles*, AARP (May 18, 2022), <https://www.aarp.org/politics-society/advocacy/info-2022/peoples-hearing-prescription-drug-prices.html> (displaying video of Kitty R.'s testimony at 13:48).

³ Patients for Afford. Drugs, *Eliquis and Xarelto: Lockstep Price Hikes and Patent Gaming Exploit Patients and Taxpayers*, 5 (Apr. 2022), <https://patientsforaffordabledrugs.org/wp-content/uploads/2022/04/Eliquis-and-Xarelto-report.pdf>.

⁴ *Negotiating A Better Deal: Legislation to Lower the Cost of Prescription Drugs*, 117th Cong. (May 4, 2021), <https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Witness%20TestimonyBallHE2021.05.04.pdf> (Statement of Therese B.)

prescription drug treatment because they cannot afford their medication. Not surprisingly, their inability to follow their prescribed treatment leads to worsening health conditions, hospitalizations, and even death.

It is not just older Americans suffocating under ever-escalating drug prices. The financial sustainability of Medicare and billions in savings for taxpayers are also at stake. Every year, Medicare pays more than \$130 billion for prescription drugs. Until the passage of the IRA, there was no predictable limit to how high drug prices could go. Medicare was powerless to do anything about the spiraling prices because the law prohibited it from negotiating the price of drugs. As a result, the Medicare program had no choice but to pay drug prices that increased as much as ten times faster than the rate of inflation, without any justification for the continuous rise and with no foreseeable end.⁵

Recognizing the growing catastrophe, Congress passed the prescription drug provisions in the IRA to reduce the prices of prescription drugs and bring necessary relief to older people, the Medicare program, and taxpayers. The Medicare drug price negotiation program is the cornerstone of the law because it addresses the central problem – out-of-control prescription drug prices. The IRA allows the Medicare program to use its buying power to negotiate the price of drugs. These negotiations are imperative because without them, drug companies will continue to set prices at exorbitant levels which will ultimately undermine the other Medicare beneficiary protections in the law.

Now, at the 11th hour, the plaintiffs bring this action to stop the negotiations before they even begin. This attempt must fail. While it comes as no surprise that the pharmaceutical

⁵ See 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. 5 (Figure 1) (June 2021), <https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.doi.10.26419-2Fppi.00143.001.pdf>.

industry and its allies are trying to stop the law in its tracks, the needs of the public must be paramount in the Court's consideration of whether a preliminary injunction is warranted. Under the IRA, millions of older people already have to wait until 2026 to start benefiting from the first set of Medicare-negotiated drug prices. A preliminary injunction would make them wait even longer. Older people cannot afford to wait. Many have chronic conditions that require ongoing treatment. They need access to affordable prescription drugs and they need the access now. The negotiation process should go forward as mandated.

Preliminarily enjoining the implementation of the law will harm millions of older people, the Medicare program, and American taxpayers. Enjoining negotiations is not in the public's interest. The plaintiffs' motion should be denied.

ARGUMENT

The plaintiffs have not met their burden of showing that they are entitled to a preliminary injunction. A preliminary injunction is an "extraordinary remedy" that is "never awarded as of right." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008). To obtain a preliminary injunction, a plaintiff must establish that: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) the preliminary injunction is in the public interest. *Id.* at 20. If a plaintiff fails to meet its burden on any of these four requirements, its request for a preliminary injunction must be denied. *Id.* at 20-23.

Stopping the drug price negotiation program before it even begins is not in the public interest. On the contrary, it will only reinforce the substantial harm that the IRA is meant to prevent. It would protect the pharmaceutical industry's unreasonable and astronomical profits at the expense of what people with chronic conditions need to survive. What is in the public interest

is for the negotiations to proceed as scheduled so that millions of older people have no delay in affording their life-saving medication. It is also in the public interest for negotiations to proceed to stop Medicare and taxpayers from losing billions of dollars from unjustified prescription drug prices. The health and economic needs of the American people should not be pushed aside in favor of more unfettered price increases. The plaintiffs' motion for a preliminary injunction should be denied.

I. Stopping The Medicare Drug Price Negotiations Is Not In The Public Interest Because It Will Delay Older People's Access To Affordable Prescription Drugs.

Stopping the Medicare drug negotiation process from proceeding as mandated will improperly delay or prevent millions of older adults from accessing affordable medication. A key objective of the IRA's Medicare drug price negotiations is to make drugs affordable for the people who need them. This objective is needed because, for decades, people in the U.S. have paid among the highest prices in the world for prescription drugs – often two to three times higher than people in other countries. Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, Rand Corp. act xii fig. S.1. (July 2022) (finding that U.S. prices were 256 percent higher than 32 comparison countries combined).⁶

Despite this fact, pharmaceutical companies continue to raise drug prices at alarming rates and have done so for years. For example, in August 2023, AARP's Public Policy Institute released a report showing that pharmaceutical companies had increased the prices of the top 25 drugs that Medicare Part D pays for by an average of 226 percent – more than triple – since the drugs first entered the market. Leigh Purvis, *Prices for Top Medicare Part D Drugs Have More*

⁶ <https://www.rand.org/pubs/researchreports/RR2956.html>.

Than Tripled Since Entering the Market, AARP Pub. Pol’y Inst. (Aug. 10, 2023) [2023 AARP Medicare Part D Drug Report].⁷ Some of these products’ prices are more than eight times higher than when the company launched the drug product. *See id.* All but one of the top 25 drugs’ lifetime price increases greatly exceeded the corresponding annual rate of general inflation (Consumer Price Index All Urban Consumers for All Items; CPI-U) while each product has been on the market (i.e., product launch date until May 2023). *Id.*

What is more, in 2022, while the country was in the midst of the pandemic and a financial crisis, the pharmaceutical industry raised prices on over 800 prescription medications – including the top 75 Medicare Part D drugs. Anna Wells, *Over 800 Prescription Medications Got More Expensive in January 2022*, Good Rx Health (Feb. 22, 2022) (analyzing prescription drug list price increases from 2021 to 2022);⁸ Leigh Purvis, *Prices for Most Top Medicare Part D Drugs Have Already Increased in 2022*, AARP Pub. Pol’y Inst. (March 3, 2022) (analyzing list price changes for the 100 brand name drugs with the highest total Medicare Part D spending).⁹ That same year, several manufacturers increased their drugs’ list prices by more than \$20,000 or by more than 500 percent. Arielle Bosworth et al., *Issue Brief, Price Increases for Prescription Drugs, 2016-2022*, Ass’t Sec’y for Plan. & Evaluation, U.S. Dep’t of Health & Human Servs. 1 (Sept. 30, 2022).¹⁰

⁷ <https://www.aarp.org/politics-society/advocacy/info-2023/medicare-drug-prices-triple.html>.

⁸ <https://www.goodrx.com/healthcare-access/research/january-2022-drug-increases-recap>.

⁹ <https://blog.aarp.org/thinking-policy/prices-for-most-top-medicare-part-d-drugs-have-already-increased-in-2022>.

¹⁰ <https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf>.

Not only are the drug prices increasing, but the manufacturers are launching new drugs at higher prices. *AARP Medicare Part D Drug Report*, at 4; Deena Beasley, *U.S. New Drug Price Exceeds \$200,000 Median in 2022*, Reuters (Jan. 5, 2023).¹¹ The median price of a new brand-name prescription drug is approximately \$200,000, meaning even a nominal price change could increase a drug's price by thousands of dollars. *Id.*

The high price of prescription drugs is particularly crushing for older people because they have higher rates of prescription drug use and higher rates of chronic health conditions. For example, around 50 million Medicare beneficiaries depend on Medicare Part D for prescription drug coverage. Juliette Cubanski & Anthony Damico, *Key Facts About Medicare Part D Enrollment and Costs in 2023*, Kaiser Fam. Found. (July 26, 2023) [*"Key Facts about Part D"*].¹² On average, they take four to five medications per month. Dena Bunis, *AARP Research: Prescription Drugs That Cost Medicare the Most*, AARP (March 8, 2022).¹³ In addition, about 80% of people age 60 and over have at least two multiple chronic conditions, such as heart disease, cancer, and lung disease. Jane L. Tavares et al., *Chronic Inequities: Measuring Disease Cost Burden Among Older Adults in the U.S. A Health and Retirement Study Analysis*, Nat'l Coun. On Aging 5 (April 2022).¹⁴

¹¹ <https://www.reuters.com/business/healthcare-pharmaceuticals/us-new-drug-price-exceeds-200000-median-2022-2023-01-05/>.

¹² <https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/>.

¹³ <https://www.aarp.org/politics-society/advocacy/info-2022/medicare-prescription-drug-costs.html>.

¹⁴ https://assets-us-01.kc-usercontent.com/ffacfe7d-10b6-0083-2632-604077fd4eca/de93d9f3-fa31-497f-adeb-2e1220431fd1/2022-ResearchChronic%20InequitiesMeasuring%20Burden_3-4.pdf.

The price that Medicare pays for prescription drugs directly impacts Medicare beneficiaries. People who participate in Medicare Part D enroll in private stand-alone drug plans or Medicare Advantage drug plans. AARP, *What are the costs of Medicare Part D?* (Jan. 5, 2023).¹⁵ Depending on their plan, they may incur out-of-pocket costs from premiums, copayments, deductibles, and coinsurance. *Id.* In fact, Medicare Part D plans are increasingly relying on coinsurance, which is a percentage of the drug's price. *Key Facts about Part D, supra* note 12. Coinsurance directly exposes Medicare beneficiaries to prescription drug prices and price increases. Moreover, beneficiaries share the burden of high-priced prescription drugs whether or not they are taking one themselves because Medicare Part D premiums are calculated to cover a set share of costs for standard coverage.

Likewise, Medicare Part B beneficiaries are also impacted by the ever-increasing price of drugs. Part B beneficiaries are responsible for 20% of their prescription drug costs with no annual out-of-pocket limit. Juliette Cubanski et al., *Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage*, Kaiser Fam. Found. (Mar. 15, 2022).¹⁶ Like Part D, this cost-sharing can represent a significant financial burden for people who are prescribed expensive prescription drugs. *Id.* In 2019, one in four beneficiaries in traditional Medicare who used Part B drugs faced an average annual cost-sharing liability of at least \$1,000. *Id.* About 400,000—or about 1 in 10 of those who used Part B drugs—faced at least \$5,000 in cost-sharing. *Id.* In another parallel to Part D, Part B premiums cover a specific share of expected costs, meaning everyone in the program must pay more for high-priced prescription drugs.

¹⁵ <https://www.aarp.org/health/medicare-qa-tool/what-are-costs-for-part-d/>.

¹⁶ <https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/>.

Unfortunately, many drug prices are so high that beneficiaries simply cannot afford their medication. The median annual income of Medicare beneficiaries is just below \$30,000. Bunis, *supra* note 13.¹⁷ More than one in ten Medicare beneficiaries (12%) has no savings at all or is in debt. Wyatt Koma et al., *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic* (Apr. 24, 2020).¹⁸

When beneficiaries cannot afford to pay for their medication, they either forego taking it altogether or end up making desperate choices to ration their care. A 2022 JAMA Network national panel study of Medicare beneficiaries found that 20% did not adhere to their prescription treatment because their drugs were too expensive. 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 18, 2023).¹⁹ About 8.5% made the impossible choice of going without basic life essentials, such as food and housing, to pay for their medication. *Id.* Another 4.8% went into debt. *Id.*

A separate 2022 study found that more than 5 million Medicare beneficiaries struggle to afford their prescription drugs. Wafa Tarazi et al., *Prescription Drug Affordability among Medicare Beneficiaries*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 1 (Jan. 19, 2022).²⁰ Medicare beneficiaries with lower incomes and those under age 65

¹⁷ <https://www.aarp.org/politics-society/advocacy/info-2022/medicare-prescription-drug-costs.html>.

¹⁸ <https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>.

¹⁹ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>.

²⁰ <https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efec9c6f96f0/prescription-drug-affordability.pdf>.

had above-average rates of foregoing medications because their medication was too expensive. *Id.*

A snapshot of the experiences of Medicare beneficiaries living with cancer underscores the dire consequences for beneficiaries who cannot afford their medication. *See Patients for Afford. Drugs, The Burden of Cancer Drug Prices on Patients. The Relief in the Inflation Reduction Act*, 6 (June 2023).²¹ For these people, the price of prescription medication plays a pivotal role in whether they can follow their prescribed medical treatment plan. *Id.* After all, the price growth of cancer drugs outpaces many other classes of medication. *Id.* For example, between 2009 and 2019, 74% of cancer drugs had price increases that outpaced inflation even though there was no change in clinical efficacy. *Id.*

People living with cancer who struggle to afford their prescriptions have two awful options. *Id.* at 3. On one hand, they can fill the prescription and risk significant financial hardship, including incurring immense debt and bankruptcy. *Id.* at 3. Sadly, more than 40% of people living with cancer spend their entire life savings in the first two years of treatment. *Id.* On the other hand, they forego filling their prescription and experience worsening health, cancer spreading in their body, or even death. *Id.* A study of Medicare beneficiaries living with cancer found that 30% did not fill a prescription because of its cost. *Id.* Other beneficiaries delay or skip doses. *Id.* at 2.

This snapshot is just one example of why millions of beneficiaries cannot afford any delay in Medicare negotiating the price of prescription drugs. While prescription drugs are intended to treat illnesses and improve the quality of life, these benefits are meaningless if beneficiaries cannot afford them. Allowing Medicare to proceed with negotiations will provide it

²¹ https://patientsforaffordabledrugs.org/wp-content/uploads/2023/06/P4AD-CancerReport_06092023-Final.pdf

with the bargaining power it needs to lower drug prices and help millions of older people afford life-saving medication.

II. Stopping The Medicare Drug Price Negotiations Is Not In The Public Interest Because It Will Further Deplete the Financial Integrity Of The Medicare Program At The Cost Of Billions Of Dollars To Taxpayers.

As described above, older adults will be harmed if Medicare drug price negotiations are stopped before they even begin. Stopping the negotiations will also harm the financial sustainability of the Medicare program and cost American taxpayers billions of dollars.

To begin with, Medicare is a bedrock of health and financial security for millions of people and represents a large portion of the national economy. It currently provides health care coverage for 65 million people who are either at least 65 years old or have disabilities. Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, Kaiser Fam. Found. (Jan. 19, 2023).²²

Prior to the IRA, a non-interference clause in the Social Security Act prohibited the Secretary of Health and Human Services (“HHS”) from negotiating the price of drugs with manufacturers. 42 U.S.C. § 1395w-111(i). As a result, HHS could not use Medicare’s considerable buying power to negotiate lower drug prices even though Medicare accounts for 24% of U.S. prescription drug spending. Nguyen X. Nguyen et al., *Medicare Part B Drugs: Trends in Spending and Utilization, 2008-2021*, Ass’t Sec’y for Plan. & Evaluation, U.S. Dep’t of Health & Human Servs. 2 (June 2023).²³ HHS and the Medicare program did not have the

²² <https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/>.

²³ <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

information necessary to assess whether pharmaceutical companies could justify the high drug prices that the program had to pay.

This lack of transparency has led to increases in Medicare drug spending that are difficult for the program to sustain and equally challenging for the program to justify. For example, Medicare spends more than \$135 billion on drugs every year. *Id.* (explaining that in 2021, spending by Medicare Part D was \$105 billion and Medicare Fee-for-Service Part B was \$33 billion). It pays higher net prices for top-selling brand-name drugs than the Department of Veterans Affairs, the Department of Defense, and Medicaid. Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, 1-3 (Feb. 2021).²⁴ In comparing the programs, the difference is that these other U.S. healthcare programs have the statutory authority to negotiate or otherwise lower drug prices. The Commonwealth Fund, *Allowing Medicare to Negotiate Drug Prices* (May 5, 2021);²⁵ see also, Gov't Acct. Off., *GAO-21-111, Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017* (Dec. 15, 2020) (finding that the Department of Veterans Affairs paid an average of 54% less per unit than Medicare, even after considering rebates and discounts.)²⁶ Prior to the IRA, Medicare did not have similar ways to protect beneficiaries and taxpayers from exorbitant drug prices. *Id.*

Another source of Medicare's increased spending is caused by beneficiaries foregoing taking their medicine which takes a severe toll on both the beneficiary's health and on the

²⁴ <https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>.

²⁵ <https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices#:~:text=Medicare%2C%20which%20does%20not%20have,negotiate%20prices%20or%20participate%20in.>

²⁶ <https://www.gao.gov/products/gao-21-111>.

financial sustainability of the Medicare program. For instance, a 2020 study released by the Council for Informed Drug Spending Analysis estimated that unaffordable prescription drug prices would cause 1.1 million premature deaths of Medicare beneficiaries over the next 10 years.²⁷ Council for Informed Drug Spend. Analysis, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, 3 (Sept. 21, 2020).²⁸ They also would lead to an additional \$177.4 billion in avoidable Medicare medical costs. *Id.*

The IRA is Congress's effort to change this unsustainable and unjustifiable situation and protect the integrity of the Medicare program. IRA, Pub. L. No. 117-169 (2022). The IRA amends the non-interference clause by authorizing HHS to negotiate prices with pharmaceutical companies for certain brand-name drugs or biologics that are covered under Medicare Part B or Part D. 42 U.S.C. § 1320f(a); see Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act* (Jan. 24, 2023) (explaining the Medicare drug price negotiations provisions) [*"Explaining the Prescription Drug Provisions"*].²⁹ HHS will publish the list of the first 10 Part D drugs subject to negotiation by September 1, 2023, and initiate the negotiations on October 1, 2023. 42 U.S.C. §§ 1320f(b)(4), (d). The negotiated prices will go into effect in 2026 for drugs covered under Medicare Part D and in 2028 for drugs covered under Medicare Part B. *Id.* The number of drugs subject to negotiation will increase in later years, reaching as many as 60 negotiated drugs by 2029. *Id.*

²⁷ <https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190WHPC-XcendaNonAdherence%20Population%20ModelReport22Oct2020r.pdf>.

²⁸ <https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190WHPC-XcendaNonAdherence%20Population%20ModelReport22Oct2020r.pdf>.

²⁹ <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/#bullet02>.

To protect the financial security of the Medicare program, the negotiation process must go forward as scheduled. The Medicare program stands to save billions of dollars as a result of these negotiations. The nonpartisan Congressional Budget Office (“CBO”) estimates that the Medicare drug price negotiation program will save Medicare and the American taxpayers nearly \$98.5 billion over 10 years. Cong. Budget Off., *Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14*, 4 (Sept. 2022).³⁰ It also estimates that Medicare drug price negotiation will reduce the budget deficit by \$25 billion in 2031. Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, 5 (Feb. 2023).³¹ This reduction will result from reduced Medicare Part D and Part B spending of \$14 billion and \$9 billion, respectively, as well as \$1 billion in other federal spending. *Id.* Medicare cannot afford to lose billions of dollars on unjustified drug prices when that money is needed to provide other important items and services to its beneficiaries.

These savings are also vital to American taxpayers. Taxpayers assume the burden of skyrocketing drug prices because Medicare is a public program funded by taxes. Every dollar that taxpayers pay in unjustified drug prices is money that is not being invested in other national priorities.

The bottom line is that the government must proceed with negotiations to protect the integrity of the Medicare program and ensure that its spending is justified. Current federal drug spending trends are unsustainable and unfair. The negotiations will yield billions of dollars in savings that will benefit the Medicare program and support public investment in national priorities. For the good of the country, the negotiations must begin.

³⁰ https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

³¹ <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf>.

III. Stopping The Medicare Drug Price Negotiations Is Not In The Public Interest Because It Will Erode Efforts To Address A Primary Driver of Escalating Drug Prices.

Finally, the negotiations must go forward so all of the IRA's prescription drug provisions can achieve what Congress intended – making drugs more affordable. *Explaining the Prescription Drug Provisions*, *supra* note 28. Aside from the negotiation provisions, the IRA has provisions that reduce prescription drug-related cost-sharing for people enrolled in Medicare and require drug companies to pay rebates when they increase their prices faster than inflation. *Id.* While each of these provisions is critical and targets a specific problem, taken together, they address reducing high out-of-pocket costs and high prescription drug prices at the same time.

In particular, the Medicare drug price negotiations address a well-known obstacle to reducing high prescription drug prices by allowing Medicare to negotiate with drug companies. If this Court preliminarily enjoins negotiations, on top of the harms listed in Sections I and II above, drug prices will continue to increase because the Medicare program will still need to purchase these life-saving drugs for its beneficiaries, even though the government will have no way to justify the prices it pays. The rest of the IRA prescription drug provisions, while critical, are designed to complement drug price negotiations but cannot replace the negotiations. Three examples illustrate this point.

First, the IRA includes a provision capping out-of-pocket costs from Part D beneficiaries beginning in 2025. 42 U.S.C. § 1395w-102; Bisma Sayed et al., *Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 1 (July 7, 2023).³² It also includes provisions reducing Medicare beneficiaries' costs for insulin and vaccines and allowing

³² <https://aspe.hhs.gov/sites/default/files/documents/93a68f3c5ca949dcf331aa0ec24dd046/aspe-part-d-oop.pdf>.

them to spread their cost-sharing over the full plan year. *Id.* These changes are incredibly important. However, without the drug price negotiation provisions, Medicare will still pay prices that will ultimately be passed back to the beneficiary in the form of higher premiums and cost-sharing that could eventually make such coverage unaffordable. In other words, reducing out-of-pocket costs is not a sustainable solution unless it also addresses the underlying high drug prices.

Similarly, the expansion of the Medicare Part D Low-Income Subsidy (“LIS”) benefit will help qualifying beneficiaries cover their prescription drug costs. Juliette Cubanksi et al., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, Kaiser Fam. Found. (Jan. 24, 2023).³³ However, while this improvement is clearly important, estimates indicate that roughly 400,000 new beneficiaries would qualify for the improved benefit based on the program’s income and asset thresholds. *Id.* Many beneficiaries are not financially eligible for this benefit, so more needs to be done to protect them. *See* Jerry Mulcahy, *2023 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards*, U.S. Dep’t of Health & Human Servs., 2-7 (Feb. 9, 2023) (listing the income and asset standards to qualify for LIS).³⁴ Thus, these subsidies will not independently solve the problem of prescription drug affordability.

Finally, requiring drug companies to pay rebates when they increase their prices faster than inflation is an important step that will help discourage brand-name drug companies from engaging in relentless price hikes year after year. *Explaining the Prescription Drug Provisions*, *supra*. But unlike the Medicare drug price negotiation program, the rebates do not address

³³ <https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/>.

³⁴ <https://www.cms.gov/files/document/2023medicarepartdlowincomesubsidyisincomeandresourcestandards.pdf>.

whether underlying existing drug prices or the launch prices of new drugs are justified in the first place, leaving beneficiaries and taxpayers exposed to overpaying for prescription drugs.

Taken together, the IRA's prescription drug provisions are designed to address both high out-of-pocket costs and the high drug prices that are driving them. They will help ensure that beneficiaries and taxpayers are no longer subject to unjustifiably high prescription drug prices. The negotiations must proceed to obtain the benefit of the provisions and ensure that Medicare coverage remains affordable. Any delay in that process will run afoul of the law's goals to reduce federal spending and help millions of beneficiaries gain access to affordable drugs.

CONCLUSION

In the end, preliminarily enjoining the government from implementing the Medicare drug price negotiations is not in the public interest and will harm millions of older people, the Medicare program, and American taxpayers. Instead, the government should proceed with negotiations so that millions of older people can finally get access to affordable prescription drugs. Time is of the essence. The plaintiffs' motion for a preliminary injunction should be denied.

August 18, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2023, the foregoing was filed with the Clerk via the CM/ECF system, which shall serve notice hereof on all parties of record.

/s/Jeffrey P. Vardaro
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