ORAL ARGUMENT NOT YET SCHEDULED

Case No. 25-5425

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., *et al*.,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., *et al*.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia
Hon. Sparkle L. Sooknanan
No. 1:25-cv-00113-SLS

BRIEF OF AMICI CURIAE AARP, AARP FOUNDATION, JUSTICE IN AGING, THE CENTER FOR MEDICARE ADVOCACY, AND THE MEDICARE RIGHTS CENTER IN SUPPORT OF DEFENDANTS-APPELLEES AND URGING AFFIRMANCE

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March 17, 2026

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici: All parties, amici, and intervenors appearing in the lower court and this Court are listed in the Opening Brief for Plaintiffs-Appellees and the Brief for Defendants-Appellees.

B. Rulings Under Review: References to the ruling at issue appear in Opening Brief for Plaintiffs-Appellees.

C. Related Cases: References to related cases appear in the Opening Brief for Plaintiffs-Appellees.

CORPORATE DISCLOSURE STATEMENTS

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a), and D.C. Circuit Rule 26.1, amici curiae state as follows:

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., the AARP Trust, Wish of a Lifetime, Older Adults Technology Services, and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

The Center for Medicare Advocacy

The Internal Revenue Service has determined that the Center for Medicare Advocacy 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. The

Center is organized as a non-profit corporation under Connecticut law and also operates as a registered non-profit in Washington, D.C. The Center is not a subsidiary of any other corporation, has no affiliated entities, and has not issued shares or securities.

The Medicare Rights Center

The Internal Revenue Service has determined that Medicare Rights Center Inc. 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. The Center is organized as a non-profit corporation under New York law. The Center is not a subsidiary of any other corporation, has no affiliated entities, and has not issued shares or securities.

Justice In Aging

Justice in Aging is a non-profit, tax-exempt organization incorporated in the District of Columbia. The organization has no parent corporation, and no publicly held company has 10% or greater ownership. It has no affiliated entities and has not issued shares or securities.

Dated: March 17, 2026

/s/ Maame Gyamfi
Maame Gyamfi

Counsel for Amici Curiae

CERTIFICATE PURSUANT TO D.C. CIRCUIT RULE 29

Pursuant to D.C. Circuit Rule 29(b), undersigned counsel for amici curiae represents that all parties have consented to the filing of this brief.

Pursuant to Rule 29(d), undersigned counsel also certifies that this separate brief is necessary. Amici are national organizations that have a strong interest in ensuring that older adults have access to quality, affordable prescription drugs. This brief provides the Court with unique information and perspectives on issues critical to the disposition of this case, including how ending the Medicare Drug Price Negotiation Program would harm older adults and the financial sustainability of the Medicare program, and cost taxpayers billions of dollars in savings.

Dated: March 17, 2026

/s/ Maame Gyamfi
Maame Gyamfi

Counsel for Amici Curiae

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INTEREST OF AMICI CURIAE[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering people 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 125 million Americans 50-plus and their families: health and financial security, and personal fulfillment. AARP Foundation is the nation's leading organization serving the 39 million older adults living in poverty or one life event away from slipping into it. AARP Foundation strengthens financial resilience for and with older adults by creating pathways to quality employment, removing barriers to benefits, and promoting equitable access to essential goods and services. Among other things, AARP and AARP Foundation advocate for access to affordable prescription drugs and health care, including through participation as amici curiae in federal and state courts.

The Center for Medicare Advocacy is a national, nonprofit law organization that works to advance access to comprehensive Medicare coverage, health equity, and quality health care for older adults and people with disabilities. Founded in 1986,

[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 no person, other than themselves, their respective members, and their undersigned counsel, contributed money intended to prepare or submit this brief. All parties have consented to the filing of this brief. FED. R. APP. P. 29(a)(2).

the Center advocates on behalf of beneficiaries in administrative and legislative forums and serves as legal counsel in litigation of importance to Medicare beneficiaries and others seeking healthcare coverage. The Center has addressed prescription drug affordability issues on behalf of beneficiaries for decades. It advocates for Medicare coverage of necessary medications and other health care, with a particular focus on the needs of beneficiaries with longer-term and chronic conditions. The Center provides training regarding Medicare and healthcare rights throughout the country. Its systemic advocacy is based on the experiences of the real people who contact the Center every day.

The Medicare Rights Center is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and casework, educational programs, and legislative and administrative advocacy. Medicare Rights was founded in 1989 to provide information and support to beneficiaries, caregivers, advocates, and professionals. Its National Helpline receives thousands of calls each year from people struggling to afford their care, including the prescription medications they need to maintain their health and well-being.

Justice in Aging is a national non-profit legal advocacy organization that fights senior poverty through law. Justice in Aging was founded in 1972 (originally under the name "National Senior Citizens Law Center") and maintains offices in

Washington, D.C. and Los Angeles, California. Justice in Aging advocates for affordable health care and economic security for older adults with limited resources, focusing especially on populations that have traditionally lacked legal protection. Justice in Aging's work includes substantial advocacy on behalf of nursing facility residents, including federal administrative and legislative advocacy.

Amici are organizations that represent the interests of older adults. We file this brief because a ruling in favor of the Plaintiffs-Appellants reversing the lower court's decision would prevent millions of older adults from accessing affordable prescription drugs, threaten the financial integrity of the Medicare program ("Medicare"), and cost taxpayers billions of dollars.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Inflation Reduction Act of 2022 ("IRA") is a landmark law that, for the first time, authorizes the Secretary of the U.S. Department of Health and Human Services ("HHS") to negotiate directly with drug companies to determine the price that Medicare will pay for a select number of the most expensive brand-name drugs. This historic provision is already fulfilling its promise to lower drug prices, as the Medicare-negotiated prices for the first 25 drugs are 38% to 85% cheaper than the drugs' list prices. The negotiated prices are also lower than the prices that Medicare prescription drug plans pay. Overall, if the new negotiated prices had been in effect during 2023 and 2024, Medicare would have saved as much as $18 billion and

Medicare beneficiaries would have saved more than $2 billion in out-of-pocket costs. Simply put, this new law will allow millions of older people to access affordable prescription drugs, protect the financial integrity of Medicare, and save American taxpayers billions of dollars.

Ever-escalating drug prices have hit older people particularly hard, forcing millions to make devastating decisions because they cannot afford the medications they need. Nearly 55 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 prescription medications per month. They have a median annual income of just over $43,000, and one in four beneficiaries live on incomes below $24,000. The vast majority have chronic conditions requiring lifelong treatment.

Many older people lack the resources to pay exorbitant and continuously increasing drug prices. As a result, they are forced to make drastic choices such as choosing between paying for their medication or paying for basic life essentials such as food, housing, or heat. Some people skip doses, split doses, or forego filling their prescriptions altogether to make ends meet. Other older people sell a majority of their possessions or property and drain their resources because the price of their life-saving medication is out of reach.

Not only do high drug prices take a terrible toll on older people's finances, but they also adversely impact their health. Millions of older people do not consistently adhere to their prescribed drug treatment because they cannot afford their medication. Consequently, they can suffer from worsening health conditions, higher healthcare expenses, hospitalizations, and even death.

It is not only older people who suffer under ever-escalating drug prices. Spiraling drug prices also endanger the financial sustainability of Medicare and cost taxpayers billions of dollars in unnecessary spending. Every year, Medicare pays more than $145 billion for prescription drugs. Prior to the enactment of the IRA, there was no predictable limit to how high drug prices could go. Medicare was powerless to address out-of-control drug prices because the law prohibited the program from negotiating for better prices. As a result, Medicare had to pay whatever drug manufacturers charged, even when prices continued to increase as much as ten times faster than the rate of inflation. *See* Leigh Purvis & Stephen W. Schondelmeyer, AARP Pub. Pol'y Inst., *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2024*, 4 fig. 1 (Feb. 2026).[2] These increases have often occurred without any justification and with no foreseeable endpoint.

[2] https://www.aarp.org/content/dam/aarp/ppi/topics/health/prescription-drugs/prescription-drugstrends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans-2006-to-2024.doi.10.26419-2fppi.00397.001.pdf.

Recognizing the growing crisis, Congress included the prescription drug provisions in the IRA to reduce drug prices and bring essential relief to older people, Medicare, and American taxpayers. The Medicare drug price negotiation program ("Negotiation Program") is the cornerstone of the IRA's prescription drug provisions because it addresses the primary barrier to accessing prescription drugs: the drug companies' charging unjustifiable and out-of-control prices. Allowing the United States Department of Health and Human Services (HHS) to negotiate what Medicare will pay for certain drugs is imperative because, without it, drug companies will continue to set prices at exorbitant levels and many older people would be denied access to critical medications.

While it is no surprise that the pharmaceutical industry is attempting to stop the Negotiation Program, the needs of the American people must be paramount in this Court's consideration of this appeal. Skyrocketing drug prices are wreaking havoc on millions of older people and federal spending. The Negotiation Program addresses this crisis by allowing HHS to negotiate the Medicare prices of drugs. Consequently, the lower court's decision must be affirmed.

ARGUMENT

The IRA's Negotiation Program is a monumental step forward that will help millions of older people access affordable medications and protect the financial

security of Medicare. Any effort to end or weaken that program will only compound the harm the law is meant to prevent.

As the lower court and its sister courts have consistently ruled, the Medicare drug price negotiation provisions of the IRA are constitutional. *See, e.g., AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 119 (3d Cir. 2025) (concluding that the Negotiation Program does not violate the Due Process Clause and that the company lacked standing to pursue its APA claims); *Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76 (2d Cir. Aug. 7, 2025) (finding the Negotiation Program does not violate the First and Fifth Amendments, and does not violate the APA). The program should be upheld and be implemented as mandated.

I. The Medicare Price Drug Negotiation Program Will Help Millions of Older People Finally Be Able to Afford Life-Sustaining Prescription Drugs.

Stopping the IRA's Negotiation Program will prevent millions of older adults from affording the medications they need to survive. The program is already proving that it will provide substantial savings to older adults. The Centers for Medicare & Medicaid Services ("CMS") has announced the negotiated prices for the first 25 drugs that were selected by the program. Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price*

Applicability Year 2026 (Aug. 14, 2024)[3] and *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027 (Nov. 25, 2025)*[4] [hereinafter *CMS Negotiated Prices Fact Sheets*]. These drugs are prescribed to treat chronic conditions, such as cardiovascular disease, diabetes, and cancer. *Id.* The negotiated prices for the first 25 drugs are 38% to 85% cheaper than their list prices. *Id.* The negotiated prices for the first 10 selected drugs became available on January 1, 2026, and the negotiated prices for the next 15 selected drugs will become available on January 1, 2027.

The new prices are expected to save Medicare beneficiaries more than $2 billion in out-of-pocket costs in the first two years of the program alone. *Id.* For example, the negotiated price for Bristol Myers Squibb's formulations of Eliquis is 56% less expensive, bringing a 30-day supply of Eliquis from a list price of $521.00 in 2023 to a negotiated price of $231.00 in 2026. *Id.* Thus, ending the Negotiation Program would deny Medicare beneficiaries critical savings and reinforce the drug unaffordability crisis.

The Negotiation Program was passed as a result of decades of Congressional investigations, hearings, and testimonies about the devastating effect of escalating

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[3] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[4] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf.

prescription drug prices on the people who rely upon those drugs. *See, e.g.*, Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation, Majority Staff Report*, 162-63 (Comm. Print 2021) (summarizing Congressional drug price investigations and recommendations for Medicare drug price negotiation).[5]

A primary objective of the program is to make prescription drugs more affordable. Inflation Reduction Act, Pub. L. No. 117-169, §§ 11001-11003 (2022). This objective is essential 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 pay for the same medicines. *See* Andrew W. Mulcahy et al., Rand Corp., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, at xii fig. S.1. (Jan. 28, 2021)[6] (finding U.S. prices 256% higher than 32 comparison countries *combined*).

In the years preceding the implementation of the IRA, pharmaceutical companies raised drug prices at alarming rates. For example, in August 2023, AARP's Public Policy Institute released a report showing that pharmaceutical

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[5] https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

[6] https://www.rand.org/pubs/research_reports/RR2956.html.

companies increased the prices of the most expensive 25 drugs that Medicare Part D pays for by an average of 226% from the time the drugs first entered the market. Leigh Purvis, AARP Pub. Pol'y Inst., *Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market* 1 (Aug. 10, 2023).[7] Some of these products' prices were more than eight times higher in 2023 than when the company first launched the drug. *See id.* All but one of the top 25 drugs' lifetime price increases greatly exceeded the corresponding annual rate of general inflation since each product has been on the market. *Id.*

In 2022, amid a pandemic and a financial crisis, the pharmaceutical industry raised prices on over 800 prescription medications—including 75 of the top brand name drugs with the highest total Medicare Part D spending. Anna Wells, *Over 800 Prescription Medications Got More Expensive in January 2022*, Good Rx Health (Feb. 22, 2022)[8] (analyzing prescription drug list price increases from 2021 to 2022); Leigh Purvis, AARP Pub. Pol'y Inst., *Prices for Most Top Medicare Part D Drugs Have Already Increased in 2022* (Mar. 3, 2022) (analyzing list price changes for the 100 brand name drugs with the highest total Medicare Part D spending).[9]

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[7] https://www.aarp.org/content/dam/aarp/ppi/topics/health/prescription-drugs/prices-top-medicare-part-d-drugs-tripled-entering-market.doi.10.26419-2fppi.00202.001.pdf.

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

[9] https://www.aarp.org/pri/topics/health/prescription-drugs/prices-for-most-top-medicare-part-d-drugs-have-already-increased/.

Not only were drug prices increasing, but manufacturers are also launching new drugs at higher prices. Deena Beasley, *Prices for New US Drugs Doubled in 4 Years as Focus on Rare Disease Grows*, Reuters (May. 22, 2025).[10] The median price of a new brand-name prescription drug is approaching $400,000 per year, meaning even a nominal price hike equates to thousands of dollars. *Id.*

The first ten drugs selected for the Negotiation Program show the effect of high prescription drug prices on Medicare spending over time. AARP's Public Policy Institute, which has examined drug prices since 2004, analyzed total Medicare Part D spending between 2017 and May 2023 for the first ten drugs selected for negotiation. Leigh Purvis, AARP Pub. Pol'y Inst., *Medicare Part D Spending on Drugs Selected for Price Negotiation Exceeded $180 Billion between 2017 and 2023* (Aug. 29, 2023).[11] It found the ten selected drugs alone represented more than $180 billion in total Medicare Part D spending between 2017 and May 2023. *Id.* This number does not represent the full amount that drug companies gain from Part D sales because their products typically entered the market years earlier. Purvis, *supra* note3, at fig. 3.

[10] https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22/.
[11] https://blog.aarp.org/thinking-policy/medicare-part-d-spending-on-drugs-selected-for-price-negotiation-exceeded-180-billion-between-2017-and-2023.

Meanwhile, prices have continued to grow for medications not yet selected for the Negotiation Program. Over the past two years, AARP's Public Policy Institute has released reports showing that list prices for brand-name drugs with the highest total Medicare Part D spending in 2022 and 2023 that were not yet selected for negotiation have grown significantly from the time they first entered the market. Leigh Purvis, AARP Pub. Pol'y Inst., *Prices for Top Medicare Part D Drugs Have Nearly Doubled Since Entering the Market* 1 (Jan. 9, 2025);[12] Leigh Purvis, AARP Pub. Pol'y Inst., *Prices for Top Medicare Drugs Have Increased Substantially Since Entering the Market* (Jan. 22, 2026).[13]

The high price of prescription drugs is particularly crushing for older people because they generally live on fixed incomes, have higher rates of chronic health conditions, and have higher rates of prescription drug use. In fact, the median annual income of Medicare beneficiaries is $43,200. Alex Cotrill et al., Kaiser Fam. Found., *Income and Assets of Medicare Beneficiaries in 2024*, Figure 2 (Aug. 25, 2025).[14] One in ten Medicare beneficiaries (6.6 million) has no savings or is in debt. *Id.* For this population, any financial setback can lead to financial ruin. They not only have

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[12] https://www.aarp.org/content/dam/aarp/ppi/topics/health/prescription-drugs/prices-top-medicare-part-d-drugs-nearly-doubled-since-entering-market.doi.10.26419-2fppi.00352.001.pdf.

[13] https://www.aarp.org/pri/topics/health/prescription-drugs/top-medicare-drug-prices-increased-entering-market/.

[14] https://www.kff.org/medicare/income-and-assets-of-medicare-beneficiaries/.

few resources, but they also have less time to recover from financial losses. *See, e.g.*, Erika Beras, *Seniors Are Still Struggling to Recover After the Financial Crisis*, Marketplace (Dec. 19, 2018)[15] (explaining that people close to retirement during the Great Recession still had trouble recovering their financial losses a decade later).

Nearly 55 million Medicare beneficiaries depend on Medicare Part D for prescription drug coverage. Medicare Payment Advisory Comm'n, *July 2025 Databook: Health Care Spending and the Medicare Program*, 161, Chart 10-10 (2025).[16] On average, they take four to five medications per month. *Id.* at 173, Chart 10-20. Many of these prescribed drugs are used to treat chronic conditions. Nearly eighty percent of older adults have at least two chronic conditions, such as diabetes, heart disease, and chronic kidney disease. Ctrs. for Disease Cont'l and Prevention, *Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013–2023* (April 17, 2025).[17] They often need to take prescription drugs for the rest of their lives to survive.

The prices Medicare pays for prescription drugs directly impact these beneficiaries because what they pay in cost sharing is often directly linked to their drug's price. Medicare Part D beneficiaries enroll in private stand-alone drug plans

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[15] https://www.marketplace.org/2018/12/19/seniors-still-affected-financial-crash/.
[16] https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_Sec10_SEC.pdf.
[17] https://www.cdc.gov/pcd/issues/2025/24_0539.htm.

or Medicare Advantage drug plans. Kimberly Lankford, *What Are the Costs of Medicare Part D?* AARP (Jun. 3, 2022).[18] Depending on their plan, Medicare beneficiaries incur out-of-pocket costs from premiums, copayments, deductibles, and coinsurance. *Id.* Medicare Part D plans are increasingly reliant on beneficiaries paying coinsurance, which is a percentage of the drug's price. Juliette Cubanski & Anthony Damico, Kaiser Fam. Found, *Key Facts About Medicare Part D Enrollment and Costs in 2023* (July 26, 2023).[19]

Beneficiaries share the financial burden of high-priced prescription drugs even if they are not taking one themselves because Medicare Part D premiums are calculated to cover a set share of costs for standard coverage. *See, e.g.*, Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, 25 (Feb. 2023)[20] [hereinafter *CBO Methods*] (stating "Part D premiums are determined in part by a policy benchmark known as the base beneficiary premium, which is based on expected average benefit costs for all Part D enrollees"). Thus, to some degree, high drug prices impose financial strain on *all* Medicare Part D beneficiaries.

[18] https://www.aarp.org/medicare/faq/what-are-costs-for-part-d//.
[19] https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/.
[20] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

Medicare Part B beneficiaries are also adversely affected by ever-increasing drug prices. Part B beneficiaries are responsible for 20% of their prescription drug costs with no annual out-of-pocket limit. Juliette Cubanski et al., Kaiser Fam. Found., *Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage* (Mar. 15, 2022).[21] As it does for Medicare Part D beneficiaries, Part B cost-sharing can represent a significant financial burden for people who are prescribed expensive prescription drugs. *Id.* In 2019, one in four traditional Medicare beneficiaries 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 had Part B drug costs—incurred at least $5,000 in cost-sharing. *Id.* In another parallel to Medicare Part D, Part B premiums cover a specific share of overall expected costs, meaning *everyone* in the program is paying more due to high-priced prescription drugs.

The first 10 drugs selected for negotiation underscore the financial toll of high drug prices on older adults. In 2022, about 9 million Medicare Part D beneficiaries were prescribed and took at least one of the 10 drugs selected for negotiation. Ass't Sec'y for Plan. & Evaluation, *Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price*

[21] https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/.

Negotiation Program 5 table 1 (Aug. 9, 2023).[22] In that year alone, they paid more than $3.4 billion in out-of-pocket costs for just these 10 drugs. *Id.* at 6. For beneficiaries without additional financial assistance, average annual out-of-pocket costs for these drugs were as high as $6,497 per beneficiary. *Id.* at 6, table 2.

The prices of prescription drugs are so high that millions of beneficiaries cannot afford their medication. Many are forced to make impossible choices, including forgoing their prescribed medication altogether or rationing its use. A 2024 AARP Research survey found that nearly four in ten (38%) Medicare-eligible adults either personally skipped filling a prescription due to its cost or knew someone who did not fill a prescription due to its cost. Teresa A. Keenan, AARP Research, *Affording Prescription Medications Continues to be a Challenge for Adults Ages 50 and Older* (Aug. 28, 2024).[23]

Similarly, a 2022 JAMA Network national panel study found 20% of Medicare beneficiaries surveyed did not adhere to their drugs as prescribed because they were too expensive; 12.9% of respondents delayed filling prescriptions, 11.1% did not fill a prescription, and 7.9% took less medication or skipped doses. Stacie B. Dusetzina et al., JAMA Network Open, *Cost-Related Medication Nonadherence and*

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[22] https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf.

[23] https://www.aarp.org/pri/topics/health/prescription-drugs/prescription-medication-costs-medicare/.

Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022 (May 18, 2023).[24] About 8.5% went without basic life essentials, such as food and heat, to pay for their medication. *Id*.

Older people who do not adhere to their prescribed treatments experience worsened health outcomes, resulting in expensive hospitalizations and higher future healthcare costs; they can even experience death. The Centers for Disease Control and Prevention ("CDC") estimates that medication non-adherence causes 30% to 50% of chronic disease treatment failures and 125,000 deaths per year. U.S. Food & Drug Admin., *Why You Need to Take Your Medications as Prescribed or Instructed* (Feb. 16, 2016)(citing CDC study). Similarly, a 2020 study released by the Council for Informed Drug Spending Analysis estimated unaffordable prescription drug prices would cause 1.1 million people to die prematurely between 2020 and 2030. Council for Informed Drug Spending Analysis, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, 3 (Sept. 21, 2020).[25]

Given the dire consequences of exorbitant drug costs, it is no wonder the American public has consistently called for HHS to directly negotiate Medicare drug

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[24] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012 #:~:text= Conclusion,In%202022%2C%20approximately%201%20in%205%20 older%20adults %20reported%20cost,are%20enthusiastic%20about%20their %20use.

[25] https://cdn.prod.website-files.com/5e5972d438ab930a0612707f/5f9788d653d2 da5f728509b0_Xcenda_NonAdherence%20Population%20ModelReportFinal.pdf.

prices with manufacturers. Poll after poll shows overwhelming bipartisan public support for authorizing Medicare to negotiate prescription drug prices. For instance, in August 2023, almost exactly a year after the IRA was enacted, a West Health-Gallup poll showed 83% of the U.S. population favors Medicare being allowed to negotiate with drug companies. West Health-Gallup, *Regardless of Political Party, Americans Overwhelmingly Support Medicare Drug Price Negotiations* (Aug. 28, 2023).[26]

Skyrocketing drug prices force older adults to make life-altering choices that risk their health and financial well-being. The reduced prices and estimated savings from the Negotiation Program will provide them with much needed relief. The prospect of lower drug prices should not be ripped away from them when they are on the cusp of receiving the long-awaited benefits of these negotiations.

II. The Negotiation Program Will Protect the Financial Integrity of Medicare and Save Taxpayers Billions of Dollars.

Together with harming older adults, ending the Negotiation Program would also harm the financial sustainability of Medicare and cost American taxpayers billions of dollars.

[26] https://www.westhealth.org/press-release/regardless-of-political-party-americans-overwhelmingly-support-medicare-drug-price-negotiations/.

A. Skyrocketing Drug Prices Hurt Medicare.

Medicare is a cornerstone of health and financial security for 68 million people who are either at least 65 years old or have disabilities. Juliette Cubanski et al., Kaiser Fam. Found., *Medicare 101* (Oct. 8, 2025).[27] It also accounts for 21.2% of national health spending and 13.5% of the federal budget. *Id.* (citing figures from 2023 and 2024).

Prior to the passage of the IRA, a non-interference clause in the Social Security Act prohibited HHS from negotiating the price Medicare pays for drugs directly 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 accounted for almost one-quarter of all U.S. prescription drug spending. Nguyen X. Nguyen et al., Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., *Medicare Part B Drugs: Trends in Spending and Utilization*, *2008-2021,* 2 (June 2023).[28] Before the IRA, HHS had authority to assess whether pharmaceutical companies could justify the prices they were demanding that Medicare pay.

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[27] https://www.kff.org/medicare/health-policy-101-medicare/?entry=table-of-contents-what-is-medicare .

[28] https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.

Medicare's inability to negotiate drug prices provided drug companies with a special exemption that other Medicare healthcare providers do not have. For decades, hospitals, nursing facilities, and physicians participating in Medicare have faced limits on payments for their services to ensure the program is affordable for beneficiaries and taxpayers. *See, e.g.*, 42 C.F.R. § 412.1(a) (describing prospective payment systems for inpatient hospital systems). Drug companies, in contrast, received a special carve-out from payment negotiation with Medicare.

The drug companies' special exemption and lack of transparency have led to unsustainable and unjustifiable increases in Medicare drug spending. For example, Medicare currently spends more than $145 billion on drugs every year. Bd. Of Trustees, *2025 Annual Rpt. of the Bds. Of Trustees of the Fed'l Hosp. Insur. And Fed'l Supplementary Medical Insur. Trust Funds*, 10 (June 18, 2025).[29] 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).[30] Medicare spending is higher because the other federal health care programs have had the statutory authority to negotiate with drug companies or otherwise obtain lower drug prices. The Commonwealth Fund, *Allowing Medicare*

[29] https://www.cms.gov/oact/tr/2025.

[30] https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf.

to Negotiate Drug Prices (May 5, 2021);[31] *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*, 5 (Dec. 15, 2020)[32] (finding the Department of Veterans Affairs paid an average of 54% less per unit of medication than Medicare in 2017, even after considering rebates and discounts). Prior to the IRA, Medicare did not have that same authority, forcing it to pay more.

Spiraling drug prices also increase Medicare spending by contributing to the healthcare costs the program must absorb when Medicare beneficiaries suffer bad outcomes when they cannot afford to take their medications as prescribed. Council for Informed Drug Spending Analysis, *supra* note 29, at 3. A 2020 study released by the Council for Informed Drug Spending Analysis found medication nonadherence leads to an additional $177.4 billion in avoidable Medicare medical costs. *Id.* Conversely, a study published in 2022 found that eliminating cost-related medication nonadherence improved both medication uptake and overall health, and decreased patient deaths and overall medical spending. Zhang et al., *Chronic Medication Nonadherence and Potentially Preventable Healthcare Utilization and Spending Among Medicare Patients*, J. Gen. Intern. Med., 3647-48 (Nov. 2022).[33]

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[31] https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices.

[32] https://www.gao.gov/assets/gao-21-111.pdf.

[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9585123/pdf/11606_2021_Article_7334.pdf.

B. The Negotiation Program Protects the Financial Health of Medicare and Generates Savings for Taxpayers.

The IRA was designed to curb price gouging that is passed on to Medicare beneficiaries and taxpayers. The Constitution does not guarantee that the government must pay what amounts to monopoly prices without negotiating a fair price. HHS has already announced the first 40 Medicare drugs subject to the Negotiation Program. *See* Press Release, U.S. Dep't of Health & Human Servs., *CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs* (Jan. 27, 2026) (listing the 15 Medicare Part B and Part D drugs selected for the third round of negotiation).[34] The number of drugs with negotiated prices will increase every year and could include as many as 60 drugs by 2029. 42 U.S.C. §§ 1320f-1(a)-(b).

As noted above, CMS has already announced the negotiated prices for the first 10 drugs that went into effect in 2026 and another 15 drugs whose negotiated prices will go into effect in 2027. Fifteen more drugs were selected in early 2026 for negotiated prices that will go into effect in 2028. *CMS Negotiated Prices Fact Sheets*, *supra.* Medicare will save as much as $18 billion in 2026 and 2027 based on the negotiated prices of the first 25 drugs alone. *Id.*

[34] https://www.cms.gov/newsroom/press-releases/cms-announces-selection-drugs-third-cycle-medicare-drug-price-negotiation-program-including-first.

So, while HHS is only negotiating prices for a subset of the costliest single-source brand name drugs, the benefits of the Negotiation Program are substantial. First, it will save Medicare and taxpayers billions of dollars. Second, it will bring program payments for prescription drugs in line with how HHS pays for other Medicare items and services and how other federal healthcare programs pay for prescription drugs. Finally, it will support continued innovation while lowering drug prices.

1. The Negotiation Program Will Save Medicare and Taxpayers Billions of Dollars.

Medicare will save billions of dollars as a result of the Negotiation Program because the drugs that are subject to negotiation are by definition the ones that result in the highest Medicare spending. For example, between November 2023 and October 2024, Medicare Part D spent roughly $100 billion on the first 25 drugs selected for negotiation alone. Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027*, 1 (Jan. 2025).[35] That number represents 36% of all Medicare Part D spending during that period. *Id.*

In fact, the Congressional Budget Office ("CBO") originally estimated the Negotiation Program would save Medicare and the American taxpayers nearly $98.5

[35] https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf.

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*, 5 Table 1 (Sept. 7, 2022)[36] [hereinafter *Estimated Budgetary Effects of Public Law 117-169*]. If HHS can negotiate drug prices as authorized by the IRA, it will reduce the federal deficit. The CBO estimated the program will reduce the budget deficit by $25 billion in 2031 alone. *CBO Methods*, *supra*, at 4. This reduction would 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.*

Taxpayers will also benefit from the program since they assume the burden of skyrocketing drug prices because Medicare is a public program funded by taxes. Each taxpayer dollar spent for prescription drugs with unjustifiably high prices is money that cannot be invested elsewhere. The savings obtained from the Negotiation Program will help fund other changes in the IRA designed to help reduce Medicare beneficiaries' costs. *Id.* at 2. For example, the savings generated from the negotiations will offset a $35 monthly insulin copayment cap, no co-payments for recommended adult vaccines, and a new annual out-of-pocket cap for Medicare Part D enrollees that started in 2025. Juliette Cubanski et al., Kaiser Fam. Found., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare*

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

Beneficiaries? (Jan. 24, 2023).[37] Indeed, the annual cap would not be feasible without the price limitations on prescription drugs, which would otherwise increase taxpayers' costs and force higher Medicare Part D premiums. *See* Mike McCaughan, *Medicare Part D*, Health Affairs (Aug. 10, 2017)[38] ("Beneficiaries' costs for stand-alone Part D plans are directly related to the expected prescription drug spending in the population, so annual premiums and cost sharing generally increase in line with drug spending trends.").

The Negotiation Program also protects the financial integrity of Medicare because it allows HHS to ensure it is paying more reasonable prices for prescription drugs. The IRA requires drug companies to provide information about their products that HHS would otherwise be unable to access easily. 42 U.S.C. § 1320f-3(e). Using this information, HHS can identify the appropriate drug price and negotiate accordingly. Thus, this program finally allows HHS to save billions for Medicare and its beneficiaries by giving HHS the tools and transparency needed to push back on indiscriminately escalating drug prices and ensure taxpayer funds are paying for value.

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[37] https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.

[38] https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/.

2. The Medicare Drug Price Negotiation Program Will Align Medicare Payments for the Selected Prescription Drugs with Medicare Payments for Other Medicare Items and Services and with How Other Federal Programs Pay for Prescription Drugs.

The Negotiation Program finally places drug companies on more equal footing with other healthcare providers by ending their special exemption. *See* 42 U.S.C. § 1320f(a). It also allows Medicare to be on similar footing with other federal health care programs like the Veterans' Administration, the Department of Defense, and Medicaid to use its bargaining power to obtain lower prices. By allowing HHS to negotiate the prices of certain drugs, the IRA corrects the imbalance of bargaining power enjoyed by drug manufacturers because of their exemption. Thus, by upholding the IRA, this Court will affirm what has long been true for other federal programs—that "[t]he Constitution does not guarantee the unrestricted privilege to engage in business or to conduct it as one pleases." *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440 (S.D. Ohio 2023) (denying plaintiffs' request for a preliminary injunction in a similar case and explaining "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice").

3. The Medicare Drug Price Negotiation Program Supports Innovation While Lowering Drug Prices.

Finally, the Negotiation Program allows for continued innovation while lowering drug prices. Plaintiffs-Appellants say it will harm innovation. App. Br. at

3. But that implies a false binary choice between innovation and lowered prices. They are not mutually exclusive.

First, American taxpayers fund nearly all the initial research that leads to new drugs. Virtually all of today's new drugs have roots stemming from and developed using government-funded research at the HHS National Institutes of Health ("NIH") or leading academic centers across the country. Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum 1, 2, 5, 14-15 (2023).[39] A study comparing research spending by the NIH and the pharmaceutical industry reveals funding from the NIH—totaling $187 billion—contributed to 354 of 356 drugs (99.4%) approved from 2010 to 2019. *Id.* at 4. As HHS and taxpayers are funding the initial research, they should not be priced out of the benefits of the resulting drugs when they enter the market.

In addition, the CBO found Medicare drug price negotiation will have little to no adverse impact on innovation. The CBO has estimated 13 out of 1,300 drugs, or a mere 1%, would not come to market over the next 30 years as a result of the drug provisions in the reconciliation legislation. *Estimated Budgetary Effects of Public Law 117-169*, *supra*, at 15. This minimal number contradicts claims from the pharmaceutical industry and its allies that the program harms innovation. These

[39] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378.

results do not provide evidence supporting the contention that the IRA reduced R&D activity and, if anything, they suggest the law may have increased R&D. Richard G. Frank and Ben Graham, *Research and Development Intensity and the Inflation Reduction Act's Prescription Drug Provisions*, Brookings, 9 (Sept. 2025).[40]

The bottom line is that the Negotiation Program protects the integrity of Medicare and ensures that its taxpayer-funded spending on the costliest prescription drugs is justified. The negotiations have already shown that they will yield billions of dollars in savings. For the good of the country, the Negotiation Program should remain.

III. The Negotiation Program Combats a Primary Driver of Escalating Drug Prices.

The Negotiation Program is essential to achieve what Congress intended: making prescription drugs more affordable and therefore more accessible to Medicare beneficiaries. *See, e.g.*, Juliette Cubanski et al., Kaiser Fam. Found, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act* (Jan. 24, 2023)[41] [hereinafter *Explaining the Prescription Drug Provisions*]. As noted above, aside from the negotiation provisions, the IRA has several other provisions that reduce prescription drug-related cost-sharing for Medicare beneficiaries and require

[40] https://www.brookings.edu/articles/research-and-development-intensity-and-the-inflation-reduction-acts-prescription-drug-provisions/

[41] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

drug companies to pay rebates when they increase their prices faster than inflation. *Id.*; *see* 42 U.S.C. § 1395w-3a(i) (rebates); 42 U.S.C. § 1395w-102 (vaccines, insulin copay caps, and out-of-pocket spending caps). While each of these provisions is critical and targets a specific problem, they are designed to work together with the Negotiation Program to collectively reduce high out-of-pocket costs and high prescription drug prices. The rest of the IRA prescription drug provisions cannot meaningfully bring down prescription drug prices without the implementation of the Negotiation Program. Thus, without the program, drug prices will continue to rise, escalating the affordability crisis. Three examples illustrate this point.

First, the IRA includes a provision that capped annual out-of-pocket costs for Medicare Part D enrollees beginning in 2025. 42 U.S.C. § 1395w-102; Bisma Sayed et al., Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., *Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act* 1 (2023).[42] It also includes critical provisions that reduce Medicare beneficiaries' out-of-pocket costs for insulin and vaccines and allow beneficiaries to spread their cost-sharing over the full plan year. *Id.*; *Explaining the Prescription Drug Provisions*, *supra*. But without the Negotiation Program, Medicare will still pay high and ever-escalating prices that will ultimately

[42] https://aspe.hhs.gov/sites/default/files/documents/93a68f3c5ca949dcf331aa0ec24dd046/aspe-part-d-oop.pdf.

be passed back to the beneficiary in the form of higher premiums and cost-sharing. The prices will also be passed on to taxpayers to cover higher costs in Medicare Part D. *See* McCaughan, *supra*, at 3. In other words, reducing out-of-pocket costs is not a sustainable solution unless the unjustified high drug prices are also addressed.

Similarly, the expansion of the Medicare Part D Low-Income Subsidy ("LIS") benefit will help qualifying beneficiaries cover their prescription drug costs. *Explaining the Prescription Drug Provisions*, *supra*. Estimates indicate roughly 400,000 people would qualify for improved benefits based on the program's income and asset threshold. *Id.* Yet while this improvement is critical, many beneficiaries with lower incomes will still be unable to qualify for this benefit and will continue to struggle to afford their prescription drugs. *See* Jerry Mulcahy, U.S. Dep't of Health & Human Servs., *2024 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards* 2-7 (Jan. 29, 2024)[43] (listing the income and asset standards to qualify for LIS). Thus, the Medicare Part D low-income subsidy expansion will not independently solve the problem of prescription drug affordability.

Requiring drug companies to pay rebates when they increase their prices faster than inflation is an important step that will help discourage drug companies from engaging in relentless price hikes each year. *Explaining the Prescription Drug*

[43] https://medicareadvocacy.org/wp-content/uploads/2024/02/2024-Medicare-Part-D-Low-Income-Subsidy-LIS-Income-and-Resource5082.pdf.

Provisions, *supra*. But unlike the Medicare drug price negotiation program, the rebates are designed to moderate price increases and do not address whether the underlying drug prices can be justified, leaving beneficiaries and taxpayers exposed to overcharging for prescription drugs.

Taken together, the IRA's prescription drug provisions are designed to address high out-of-pocket costs, high taxpayer costs, and high drug prices. The Negotiation Program uniquely addresses unreasonably high prescription drug prices by empowering HHS to directly negotiate Medicare prices for the costliest drugs. The other IRA provisions cannot accomplish the goal of stopping unjustified escalation of drug prices without the Negotiation Program.

CONCLUSION

Striking down or otherwise restricting the Negotiation Program will harm the health and finances of millions of older Americans, undermine the integrity of Medicare, and defy the interests of American taxpayers. The recently announced negotiated prices show that the program is delivering on its promise of financial relief. The lower court's decision should be affirmed.

Dated: March 17, 2026

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume requirements of Federal Rules of Appellate Procedure 29(a)(5) because it contains 6,423 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and DC Circuit Rule 32(e)(1).

2. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

Dated: March 17, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on March 17, 2026, the foregoing Brief of Amici Curiae AARP, AARP Foundation, Justice in Aging, the Center For Medicare Advocacy, and the Medicare Rights Center in Support of Defendants-Appellees was electronically filed with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system which will send notice of such filing to all registered CM/ECF users.

Dated: March 17, 2026

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