IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *et al.*, Plaintiffs, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-00931-CMC

BRIEF OF AMICI CURIAE AARP, AARP FOUNDATION, CENTER FOR MEDICARE ADVOCACY, JUSTICE IN AGING, AND THE MEDICARE RIGHTS CENTER SUPPORTING DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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STATEMENTS OF INTEREST[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans age 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 and over and their families: health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works for and with vulnerable people 50 and over to end senior poverty and reduce financial hardship by building economic opportunity.

A major priority for AARP and AARP Foundation is advocating for access to affordable prescription drugs and health care, including participating as amici curiae in federal and state courts. *See, e.g.* Br. of AARP and AARP Foundation as Amici Curiae in Support of Defendants, *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-03818-ZNQ, and *Bristol Myers Squibb, Co. v. Becerra*, No. 23-cv-03335-ZNQ (D.N.J. Oct. 23, 2023); Br. of AARP and AARP Foundation as Amici Curiae in Support of Defendants, *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023); Br. of AARP and

[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.

AARP Foundation as Amici Curiae in Support of Defendants, *Merck & Co. v. Becerra*, No. 1:23-cv-01615 (D.D.C. Sept. 18, 2023); Br. of AARP et al. as Amici Curiae in Support of Petitioners, *California v. Texas*, 593 U.S. _ (2021) (No. 19-840) (Affordable Care Act).

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, 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 health care 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 health care rights throughout the country. Its systemic advocacy is based on the experiences of the real people who contact the Center every day.

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.

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. Our 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.

Amici are organizations that represent the interests of older adults. We file this brief because a ruling in favor of the Plaintiffs 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 will lower the skyrocketing prices of prescription drugs. A key provision in the law

authorizes the Secretary of the U.S. Department of Health and Human Services ("HHS")—for the first time—to negotiate directly with drug companies to determine the price Medicare will pay for a select number of costly single-source, brand-name drugs. This watershed change will allow millions of older people to gain access to 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. More than 50 million people are enrolled in Medicare Part D, the federal government's voluntary prescription drug benefit program for Medicare beneficiaries. Beneficiaries take, on average, between four and five prescription medications per month and have a median annual income of just under $30,000. The vast majority have chronic conditions requiring lifelong treatment.

Many older people lack the resources to pay exorbitant and escalating drug prices. As a result, they are forced to choose between paying for their prescribed 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.

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 prescription drug treatment because they cannot afford their medication. Their inability to follow their prescribed treatment leads to worse health conditions, higher health care expenses, hospitalizations, and even death.

Ever-escalating drug prices do far more harm than just to individual Medicare beneficiaries: they also place the financial sustainability of Medicare at risk and cost taxpayers billions of dollars in unnecessary spending. Every year, Medicare pays more than $130 billion for prescription drugs. Before the IRA, there was no basis for a predictable limit to how high drug prices could go. Medicare was powerless when it came to the spiraling costs of drugs because the law prohibited the program from negotiating for better prices. As a result, Medicare had no choice but to pay what 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 2020*, 5 fig. 1 (June 2021).[2] These increases have often occurred without any justification and with no foreseeable endpoint. *Id.*

Recognizing the growing catastrophe, Congress included the prescription drug provisions in the IRA to reduce drug prices and bring essential relief to older

[2] https://www.aarp.org/content/dam/aarp/ppi/topics/health/prescription-drugs/trends-retail-prices-of-generic-prescription-drugs-widely-used-older-americans-2006-2020.doi.10.26419-2fppi.00198.001.pdf.

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' out-of-control prices. Allowing 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. This, in turn, will deny many older people access to critical medications, increase premiums, and jeopardize Medicare's sustainability.

While it comes as no surprise that the pharmaceutical industry wants to stop the government from implementing the Negotiation Program, the needs of the American people must be paramount in this Court's consideration of the present motions. Skyrocketing drug prices are wreaking havoc on millions of older people and on federal spending. While prescription drugs are intended to treat illnesses and improve the quality of life, these potential benefits are illusory if Medicare beneficiaries cannot afford to use the drugs they need. The Negotiation Program reins in this crisis by ending the pharmaceutical industry's special exemption from limits on prices they may charge Medicare and, instead, empowers HHS to negotiate the prices Medicare will pay for the costliest drugs. Plaintiffs' motion must be denied, and the government's cross-motion must be granted.

ARGUMENT

The IRA's Negotiation Program is a monumental step forward that will help millions of older people access affordable medication and protect the financial security of Medicare. Any effort to end or weaken the Negotiation Program will only compound the harm the law is meant to prevent. Plaintiffs seek to protect the pharmaceutical industry's ability to charge unlimited prices regardless of the harm that imposes to the health and, in some cases, the survival of older people with chronic conditions. Plaintiffs' legal challenge threatens the financial health of Medicare. It is essential that the Negotiation Program be upheld and implemented.

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

Stopping the Negotiation Program will prevent millions of older adults from accessing the medications they need to survive and thrive. The Negotiation Program is the culmination of decades of Congressional investigations, hearings, and testimonies about the devastating effect escalating prescription drug prices have on the people who need them. *See e.g.*, H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation, Majority Staff Report*, 162-63 (2021)[3] (summarizing results of Congressional drug price investigation and recommendations for Medicare drug price negotiation); *Negotiating A Better Deal:*

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

Legislation to Lower the Cost of Prescription Drugs Before H. Comm. On Energy & Commerce, 117th Cong. (2021) (testimony of Therese B. describing how her health deteriorated after she was forced to stop taking her prescription drug due to its cost)[4]; *Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare Before S. Comm. On Fin.*, 117th Cong. (2022) (testimony of health care expert Professor Rena M. Conti, Ph.D., Boston University, explaining that lowering drug prices is pro-innovation and pro-consumer, starting at 2:30:00).[5]

One of the IRA's primary objectives 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 for the same medicines. Andrew W. Mulcahy et al., Rand Corp., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, at xii fig.

[4] https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-negotiating-a-better-deal-legislation-to-lower-the-cost-of.
[5] https://www.finance.senate.gov/hearings/prescription-drug-price-inflation-an-urgent-need-to-lower-drug-prices-in-medicare.

S.1. (July 2022)[6] (finding U.S. prices 256% higher than 32 comparison countries *combined*) (emphasis added).

Despite this fact, pharmaceutical companies continue to raise drug prices at alarming rates. For example, in August 2023, AARP's Public Policy Institute released a report showing pharmaceutical companies increased the prices of the top 25 drugs 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] [hereinafter *2023 AARP Medicare Part D Drug Report*]. Some of these products' prices are more than eight times higher in 2023 than when the company 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.*

What is more, 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

[6] https://www.aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbecf28b/international-prescription-drug-price-comparisons.pdf?_ga=2.90776860.706627665.1697548340-86060493.1695758914.
[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.

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, *Prices for Most Top Medicare Part D Drugs Have Already Increased in 2022*, AARP Pub. Pol'y Inst.: Thinking Policy, (Mar. 3, 2022, 9:59 a.m.)[9] (analyzing list price changes for the 100 brand name drugs with the highest total Medicare Part D spending). 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., Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., *Issue Brief, Price Increases for Prescription Drugs, 2016-2022*, 1 (Sept. 30, 2022).[10]

Not only are drug prices increasing, but manufacturers are also launching new drugs at higher prices. 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 now about $200,000 per year, meaning even a nominal price hike equals thousands of dollars. *Id.*

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[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/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf.
[11] https://www.reuters.com/business/healthcare-pharmaceuticals/us-new-drug-price-exceeds-200000-median-2022-2023-01-05/.

The first ten drugs selected for the Negotiation Program show the effect of high prescription drug prices on Medicare spending. AARP's Public Policy Institute, which has been examining drug prices since 2004, examined total Medicare Part D spending between 2017 and May 2023 for the first ten drugs selected for negotiation. Leigh Purvis, *Medicare Part D Spending on Drugs Selected for Price Negotiation Exceeded $180 Billion between 2017 and 2023*, AARP Pub. Pol'y Inst., Thinking Policy, (Aug. 29, 2023).[12] It found the ten selected drugs alone represented more than $180 billion in total Medicare Part D spending between 2017 and May 2023, with AstraZeneca's drug Farxiga accounting for $6.5 billion. *Id.* This enormous number does not even represent a full picture of the benefits AstraZeneca has gained from Part D sales, since Farxiga entered the market years earlier. *See* Drugs.com, *Farxiga FDA Approval History* (last updated by Judith Stewart, BPharm, May 17, 2023).[13] Between June 2022 and May 2023, the number of Medicare Part D beneficiaries taking Farxiga (for diabetes, and/or heart failure and/or chronic kidney disease) totaled 799,000. Ctrs.

[12] https://blog.aarp.org/thinking-policy/medicare-part-d-spending-on-drugs-selected-for-price-negotiation-exceeded-180-billion-between-2017-and-2023#:~:text=On%20average%2C%20total%20Part%20D,between%202017%20and%20May%202023.

[13] https://www.drugs.com/history/farxiga.html (showing the U.S. Food and Drug Administration first approved Faxriga to treat Type 2 diabetes on January 8, 2014); see also U.S. Food & Drug Administration, *Drug Approval Package, Farxiga* (showing same approval date), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000TOC.cfm.

for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 202*6, 1 (August 2023)[14] [hereinafter CMS, *Medicare Drug Price Negotiation Program*]. In calendar year 2020, Medicare spent $736,787,564 on Farxiga. Dickson, S., and Hernandez, I., *Drugs Likely Subject to Medicare Negotiation*, *2026-2028*, 29 Journal of Managed Care & Specialty Pharmacy 3, Table 1 (predicting Farxiga would be designated for negotiation in 2028),[15] of which close to $200 million likely represented out-of-pocket costs for beneficiaries, 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 Negotiation Program,* 6-7, tables 1 & 2 (August 20, 2023, rev'd Sept. 13, 2023)[16] [hereinafter *Medicare Enrollee's Expenditures*]. Average overall costs to Medicare for Farxiga users in calendar year 2022 was $4,046; average out-of-pocket costs for non-low-income-supplement enrollees was

[14] https://www.cms.gov/files/document/fact-sheet-medicare-slected-drug-negotiation-list-ipay-2026.pdf.
[15] https://www.jmcp.org/doi/full/10.18553/jmcp.2023.29.3.229.
[16] https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf (2022 out-of-pocket costs for 20% fewer Farxiga users (639,000) amounted to $166,026,000). As for Farxiga's overall market performance, "[af]ter delivering revenue growth of 67% year-over-year, Farxiga reached $1 billion in quarterly sales for the first time during the first three months of 2022 … handily beat[ing] Wall Street's expectations by 20%, according to SVB Securities." Angus Liu, *AstraZeneca's Farxiga hits $1B* quarterly mark, but flagship oncology and Chinese units lag, https://www.fiercepharma.com/pharma/astrazenecas-farxiga-hits-1b-quarterly-mark-flagship-oncology-china-businesses-pull-back.

$448. Ass't Sec'y for Plan. & Evaluation, *Inflation Reduction Act Research Series—Farxiga: Medicare Enrollee Use and Spending*, 1, table 1 (November 2, 2023).[17]

The high price of prescription drugs is particularly crushing for older people because they generally live on fixed incomes, have higher rates of prescription drug use, and have higher rates of chronic health conditions. The median annual income of Medicare beneficiaries is just below $30,000. Dena Bunis, *AARP Research: Prescription Drugs That Cost Medicare the Most*, AARP (Mar. 8, 2022).[18] More than one in ten Medicare beneficiaries (12%) has no savings at all or is in debt. Wyatt Koma et al., Kaiser Fam. Found, *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic*, (Apr. 24, 2020).[19] For this population, any financial setback can lead to financial ruin, because they not only have 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)[20] (explaining people close to retirement during the Great Recession are still having trouble recovering their financial losses a

[17] https://aspe.hhs.gov/sites/default/files/documents/3950eb2fe9aaa75c39adac742be3e90f/Farxiga.pdf.
[18] https://www.aarp.org/politics-society/advocacy/info-2022/medicare-prescription-drug-costs.html.
[19] https://www.kff.org/report-section/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic-tables/.
[20] https://www.marketplace.org/2018/12/19/seniors-still-affected-financial-crash/.

decade later).

In addition, more than 50 million Medicare beneficiaries depend on Medicare Part D for prescription drug coverage. Juliette Cubanski & Anthony Damico, Kaiser Fam. Found, *Key Facts About Medicare Part D Enrollment and Costs in 2023*, (July 26, 2023)[21] [hereinafter *Key Facts about Part D*]. On average, they take four to five medications per month. Bunis, *supra* p. 9. Many of these prescribed drugs are used to treat chronic conditions: 80% of older adults have at least two chronic conditions, such as diabetes, heart disease and chronic kidney disease, the conditions treated by Farxiga. Jane L. Tavares et al., Nat'l Council On Aging, *Chronic Inequities: Measuring Disease Cost Burden Among Older Adults in the U.S. A Health and Retirement Study Analysis*, 5 (April 2022)[22]. These health complications make it likely they will need to take prescription drugs for the rest of their lives. And of the four most common chronic conditions, at an annual cost of $165 billion, diabetes—condition for which Farxiga was first approved and for which it is still prescribed—far outstrips the rest in related treatment spending for Medicare beneficiaries. *Id.* (2018 data showing diabetes trailed only cancer in annual treatment costs).

[21] https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/.
[22] https://assets-us-01.kc-usercontent.com/ffacfe7d-10b6-0083-2632-604077fd4eca/de93d9f3-fa31-497f-adeb-2e1220431fd1/2022-Research_Chronic%20Inequities_Measuring%20Burden_3-4.pdf.

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. 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).[23] Depending on their plan, they incur out-of-pocket costs from premiums, copayments, deductibles, and coinsurance. *Id.* In particular, Medicare Part D plans are increasingly reliant on beneficiaries paying coinsurance, which is a percentage of the drug's price. *Key Facts about Part D*, *supra* [p. 14]. Coinsurance directly exposes Medicare beneficiaries to high prescription drug prices and price increases. In addition, beneficiaries share the financial burden of high-priced prescription drugs regardless of whether they are 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)[24] [hereinafter *CBO Estimated Budgetary Effects*] (stating "Part D premiums are determined in part by a policy benchmark known as the base beneficiary premium, which is based on expected average

[23] https://www.aarp.org/health/medicare-qa-tool/what-are-costs-for-part-d/.
[24] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

benefit costs for all Part D enrollees"). Thus, to some degree, high drug prices impose financial strain on *all* Medicare Part D beneficiaries.

Medicare Part B beneficiaries also are adversely affected by the 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).[25] As under Medicare 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 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 high drug prices have on older adults. In 2022, about 9 million Medicare Part D beneficiaries took at least one of the 10 drugs selected for negotiation. *Medicare*

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

Enrollees' Expenditures, supra [p.12], at 5.[26] 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 tbl. 2 (Imbruvica).

The prices of prescription drugs are so high that millions of beneficiaries cannot afford their medication, and as a result must make impossible choices, including foregoing their prescribed medication altogether or rationing its use. 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. Stacie B. Dusetzina et al., JAMA Network, *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, (May 18, 2023).[27] About 8.5% made the devastating choice to go without basic life essentials, such as food and/or housing, to pay for their medication. *Id.* Twelve percent of respondents delayed filling prescriptions, 11.1% did not fill a prescription at all, and 7.9% took less medication or skipped doses. *Id.* A separate 2022 study found more than 5 million Medicare

[26] https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf.
[27] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012#:~:text=Conclusion-,In%202022%2C%20approximately% 201%20in%205%20older% 20adults%20reported%20cost,are%20enthusiastic%20about%20their%20use.

beneficiaries struggle to afford their prescription drugs. Wafa Tarazi et al., Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. *Prescription Drug Affordability among Medicare Beneficiaries*, 1 (Jan. 19, 2022).[28]

Beneficiaries not adhering to their prescribed treatment can worsen their health: this may result in expensive hospitalization, declining health, higher future health care costs, and even death. The Centers for Disease Control and Prevention ("CDC") estimates 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)[29] (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 premature deaths of Medicare beneficiaries over the next 10 years. Council for Informed Drug Spending Analysis, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, 3 (Sept. 21, 2020).[30]

Given the dire consequences of high drug costs, it is no wonder the

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[28] https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf.

[29] https://www.fda.gov/drugs/special-features/why-you-need-take-your-medications-prescribed-or-instructed#:~:text=Taking%20your%20medicine%20as%20prescribed%20or%20medication%20adherence%20is%20important,important%20part%20of%20medication%20adherence.

[30] https://global-uploads.webflow.com/5e5972d438ab930a0612707f/.5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

American public has consistently and repeatedly called for HHS to directly negotiate Medicare drug prices with drug manufacturers. Poll after poll shows overwhelming bipartisan public support for allowing Medicare to negotiate prices. For instance, a 2021 Kaiser Family Foundation public opinion survey found 83% of Americans favored allowing Medicare to negotiate drug prices, including large majorities of members of all political parties. Ashley Kirzinger et al., Kaiser Fam. Found., *The Public Weighs In On Medicare Drug Negotiations*, (Oct. 12, 2021)[31] (finding 95% of Democrats, 82% of Independents, and 71% of Republicans support Medicare drug price negotiation). More recently, in August 2023, almost exactly a year after the IRA was enacted, a West Health-Gallup poll again 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).[32]

Skyrocketing drug prices have stretched the budgets of older adults to the point where they are forced to make wrenching, life-altering choices risking their health and financial well-being. The goal of the Negotiation Program is to end this public crisis and interject long-overdue fairness, transparency, and predictability

[31] https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations/.
[32] https://www.westhealth.org/press-release/regardless-of-political-party-americans-overwhelmingly-support-medicare-drug-price-negotiations/.

into the drug pricing process.

II. The Negotiation Program Will Protect The Financial Integrity Of Medicare And Save Taxpayers Billions Of Dollars.

In addition to harming older adults, ending the Negotiation Program will also harm the financial sustainability of Medicare and cost American taxpayers billions of dollars.

A. Skyrocketing Drug Prices Hurt Medicare.

Medicare is a bedrock of health and financial security for 65 million people who are either at least 65 years old or have disabilities. Juliette Cubanski & Tricia Neuman, Kaiser Fam. Found., *What to Know About Medicare Spending and Financing,* (Jan. 19, 2023).[33] It also accounts for 21% of national health spending and 10% of the federal budget. *Id.* (citing figures from 2021).

Prior to 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 despite accounting 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-*

[33] https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/.

2021, 2 (June 2023).[34] HHS also did not have data necessary to assess whether pharmaceutical companies could justify the prices they were demanding Medicare pay.

Medicare's inability to negotiate drug prices provided drug companies with a special exemption other entities and individuals providing items and services to Medicare do not have. Hospitals, nursing facilities, and physicians participating in Medicare all face 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). Many of these payment structures have been in place for decades. Drug companies, in contrast, received a special carve-out from payment negotiation.

The drug companies' special exemption and lack of transparency led to unsustainable and unjustifiable increases in Medicare drug spending. For example, Medicare currently spends more than $135 billion on drugs every year. Nguyen, *supra* p. 14, at 2 (explaining in 2021, spending by Medicare Part D was $105 billion and Medicare Fee-for-Service Part B was $33 billion). It also 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*

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

Comparison of Brand-Name Drug Prices Among Selected Federal Programs, 1-3 (Feb. 2021).[35] Medicare spending is higher because the other federal health care programs have the statutory authority to negotiate with drug companies or otherwise obtain lower drug prices. The Commonwealth Fund, *Allowing Medicare to Negotiate Drug Prices* (May 5, 2021)[36]; *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)[37] (finding the Department of Veterans Affairs paid an average of 54% less per unit of medication than Medicare, even after considering rebates and discounts.) Prior to the IRA, Medicare did not.

Spiraling drug prices also increase Medicare spending by contributing to the costs the program must absorb when Medicare beneficiaries cannot afford to take their medications as prescribed. Beneficiaries who do not take their medicines because they cannot afford them can experience subsequent higher medical costs because of worsening health conditions that might have been avoided with appropriate treatment. Council for Informed Drug Spending Analysis, *supra* [p.18], at 3. A 2020 study released by the Council for Informed Drug Spending Analysis

[35] https://www.cbo.gov/publication/57007.
[36] https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices.
[37] https://www.gao.gov/assets/gao-21-111.pdf.

found medication nonadherence would lead to an additional $177.4 billion in avoidable Medicare medical costs. *Id.* In short, high drug costs can lead to even higher healthcare costs. Conversely, a study published in 2022 found that by eliminating cost-related medication nonadherence both medication uptake and overall health improved, and patient deaths and overall medical spending decreased. Zhang et al., J. Gen. Intern. Med., *Chronic Medication Nonadherence and Potentially Preventable Healthcare Utilization and Spending Among Medicare Patients*, 3 (Nov. 2022).[38]

B. The Negotiation Program Protects The Financial Health of Medicare And Generates Savings For Taxpayers.

The IRA will help reverse the harm caused by skyrocketing drug prices and protect the financial integrity of Medicare. The IRA partially amends Medicare's "non-interference" clause by authorizing HHS to directly negotiate prices with pharmaceutical companies for a limited number of single source, brand-name drugs or biologics covered under Medicare Part B or Part D. 42 U.S.C. § 1320f(a); *see* Juliette Cubanski et al., Kaiser Fam. Found, *Explaining the Prescription Drug*

[38] https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

Provisions in the Inflation Reduction Act (Jan. 24, 2023)[39] [hereinafter *Explaining the Prescription Drug Provisions*].

HHS has already announced the first ten Medicare Part D drugs that will be subject to the Negotiation Program. Press Release, U.S. Dep't of Health & Human Servs., *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023)[40] (listing the ten Medicare Part D drugs selected for negotiation). The number of drugs subject to negotiation will increase every year to include as many as 60 negotiated drugs by 2029. 42 U.S.C. § 1320f-1(a)-(b). The negotiated prices for the first set of Medicare Part D drugs, including Farxiga, will go into effect in 2026; for drugs covered under Medicare Part B, negotiated prices will go into effect in 2028. *Id.*

While HHS is only negotiating prices for a subset of the costliest drugs, the Negotiation Program will confer great benefits on Medicare and all beneficiaries. 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 health care programs pay for

[39] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
[40] https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

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 June 2022 and May 2023, Medicare Part D spent more than $50 billion on the first 10 drugs selected for negotiation alone. CMS, *Medicare Drug Price Negotiation Program*, 1.[41] That number represents nearly 20% of all Medicare Part D spending during that period. *Id.*

In fact, the Congressional Budget Office (CBO) estimates the 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*, 5 (Sept. 2022)[42] [hereinafter *Estimated Budgetary Effects of Public Law 117-169*]. Permitting HHS to negotiate drug prices will also reduce the federal deficit. The CBO estimates the program will reduce the budget deficit by $25 billion in 2031

[41] https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.
[42] https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

alone. *CBO Estimated Budgetary Effects*, *supra* p. 10, at 4. 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.*

Increased savings will also benefit Medicare beneficiaries, who last year spent $3.4 billion out-of-pocket on the first 10 drugs that will be subject to negotiation. *Medicare Enrollee's Expenditures*, *supra* [p. 12], at 6. The CBO estimates the program will save Medicare Part D enrollees more than twice this amount in 2031 due to lower out-of-pocket costs and premiums. *CBO Estimated Budgetary Effects*, *supra* [p.15-16], at 36.

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 paid 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' out-of-pocket costs. *Id.* at 2. These benefits include a $35 monthly insulin copayment cap, no co-payments for recommended adult vaccines, and a new $2,000 annual out-of-pocket cap for Medicare Part D enrollees starting in 2025. Juliette Cubanski et al., Kaiser Fam. Found., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare*

Beneficiaries? (Jan. 24, 2023).[43] Indeed, the $2,000 annual cap would not be feasible without price limitations on drug manufacturers, because higher price drugs would dramatically increase taxpayers' costs, which in turn would increase Medicare Part D premiums. *See* Mike McCaughan, *Medicare Part D*, Health Affairs, 2 (Aug. 10, 2017)[44] (stating "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 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). For instance, drug companies will submit comprehensive information about their research and development costs, including any prior federal financial support. *Id.* They will also provide evidence on how their drug represents a therapeutic advance over existing alternatives. *Id.* In this way, HHS will have the data it needs to make an informed decision on the appropriate drug price and

[43] https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.
[44] https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/healthpolicybrief_172-1525353500165.pdf.

negotiate accordingly. This process finally allows HHS to save billions for Medicare and its beneficiaries by giving HHS tools to push back on indiscriminately escalating drug prices and ensure taxpayer funds are paying for value.

2. The Negotiation Program Will Align Medicare Payment For The Selected Prescription Drugs With How Medicare Pays for Other Items And Services And How Other Federal Programs Pay for Prescription Drugs.

By its motion and its lawsuit generally, Plaintiffs seek to maintain a special exemption for drug companies that no other health care provider group has, which would allow drug companies to continue charging Medicare and its beneficiaries whatever price they want for their products. This request should be denied. The Negotiation Program finally places drug companies on more equal footing with other health care providers by ending this special treatment, which has been harmful to beneficiaries and the Medicare program. *See* 42 U.S.C. § 1320f(a).

The Negotiation Program will finally allow Medicare to use its bargaining power to obtain lower prices, putting it on similar footing with other federal health care programs like the Veterans' Administration, the Department of Defense, and Medicaid. Prior to the IRA, HHS was barred from negotiating drug prices under Medicare Part D or otherwise intervening in the commercial arrangements between manufacturers and the private insurance plans that contract with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i). By allowing HHS to negotiate the

prices of certain drugs, the IRA finally starts to rebalance the bargaining power of Medicare and its beneficiaries with the power of drug manufacturers—affirming 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*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423 (S.D. Ohio Sept. 29, 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 Negotiation Program Supports Innovation While Lowering Drug Prices.

Finally, the Negotiation Program will allow for continued innovation while lowering drug prices. Plaintiffs argue that allowing the government to negotiate Medicare drug prices would come at a cost of stifling innovation. *See e.g.*, AstraZeneca Op. Br. at 3, 5, 12, 17, 18. But this argument sets up a false binary.

For starters, American taxpayers fund nearly all the initial research that leads to new drugs. Virtually all of today's new drugs, such as blockbuster immunotherapies for cancer, have roots in government-funded research at the National Institutes of Health ("NIH") or leading academic centers across the country. Ekaterina Galkina Cleary et al., JAMA Health Forum, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs*

the Pharmaceutical Industry, 2010-2019, 2, 5, 14-15 (Apr. 28, 2023).[45] 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 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 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* [p.25], at 15. This minimal number contradicts the pharmaceutical industry's claims.

The bottom line is that the Negotiation Program will protect the integrity of Medicare and ensure that its taxpayer-funded spending on the costliest prescription drugs is justified. Current federal drug spending trends are unsustainable and unfair to both beneficiaries and taxpayers. The negotiations will yield billions of dollars in savings, benefitting Medicare and permitting public investment in other national

[45] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378#:~:text=Spending %20and%20approval%20by%20NIH,003).

priorities. For the good of the country, the Negotiation Program must be implemented.

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

Finally, the Negotiation Program is essential to achieve what Congress intended – making drugs more affordable and therefore more accessible to Medicare beneficiaries. *See e.g.*, *Explaining the Prescription Drug Provisions*, *supra* [p.23-24]. As noted above, aside from the negotiation provisions, the IRA has several other 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.; 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 on its own, they are designed to work together with the Negotiation Program in a coordinated manner to collectively reduce high out-of-pocket costs and high prescription drug prices.

In particular, the Negotiation Program addresses a well-known obstacle to reducing high prescription drug prices by allowing Medicare to negotiate directly with drug companies. If the program is eliminated or weakened, on top of the harms listed in Sections I and II above, drug prices and related Medicare spending will continue to increase because Medicare will still need to purchase these life-

saving drugs for its beneficiaries, despite the lack of justification for these extreme prices. The rest of the IRA prescription drug provisions, while critical, are designed to complement drug price negotiations, but cannot meaningfully bring down the cost of prescription drugs on their own, without the Negotiation Program. Thus, drug prices will continue to rise, escalating the affordability crisis. Three examples illustrate this point.

First, the IRA includes a provision capping 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 (July 7, 2023).[46] It also includes critical provisions that reduce Medicare beneficiaries' out-of-pocket costs for insulin and vaccines and allows beneficiaries to spread their cost-sharing over the full plan year. *Id*; *Explaining the Prescription Drug Provisions*, *supra* [p.23-24]. Yet, without the Negotiation Program, Medicare will still pay high and ever-escalating prices that will ultimately be passed back to the beneficiary in the form of higher premiums and cost-sharing and passed on to taxpayers to cover higher costs in Medicare Part D. *See* McCaughan, *supra* [p.27], at 3. In other words,

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

reducing out-of-pocket costs is not a sustainable solution without also addressing the high drug prices driving them.

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* [p.23-24]. Estimates indicate roughly 400,000 people would qualify for improved benefits based on the program's income and asset threshold. *Id.* So, although this improvement is critical, many beneficiaries with lower incomes still will 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., *2023 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards*, 2-7 (Feb. 9, 2023)[47] (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.

Finally, 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 Provisions*, *supra* p. 16. But unlike the Medicare drug price

[47] https://www.cms.gov/files/document/2023medicarepartdlowincomesubsidylisincomeandresourcestandardsg.pdf.

negotiation program, the rebates do not address whether the underlying drug prices are 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, though critical, cannot accomplish the goal of stopping unjustified escalation of drug costs without implementation of the Negotiation Program. Thus, the Negotiation Program should proceed as mandated to relieve Medicare and its beneficiaries of the most serious perils of out-of-control drug prices.

CONCLUSION

Striking down or otherwise restricting implementation of the Negotiation Program will harm the health and finances of millions of older Americans, undermine the integrity of Medicare Parts B and D, and defy the interests of American taxpayers in the efficient operation and long-term viability of Medicare. The program promises long-overdue relief from excessive drug prices and should be upheld. Plaintiffs' motion for summary judgment should be denied and the government's cross-motion for summary judgment should be granted.

November 8, 2023

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CERTIFICATE OF COMPLIANCE

In accordance with this Court's Standing Order Regarding Briefing In All Cases:

1. This brief has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point type with a New Times Roman font.

2. This brief contains 6,957 words (excluding parts of the brief exempted by the guidance provided by Fed. R. App. P. 32(a)(7)(B)(iii)).

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CERTIFICATE OF SERVICE

This is to certify that on the 8th day of November 2023, this Brief of Amici Curiae AARP, AARP Foundation, Center for Medicare Advocacy, Justice in Aging, and the Medicare Rights Center Supporting Defendants' Cross-Motion For Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment, accompanying Motion for Leave to File Brief of Amici Curie, Memorandum in Support of Motion for Leave to File, and Proposed Order were filed electronically on all parties of record with the Clerk of Court using the Court's CM/ECF system.

November 8, 2023

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