

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM)
 PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
 v.)
)
 DEPARTMENT of Health & Human)
 Services, *et al.*,)
)
Defendants.)

Civil Action No. 3:23-cv-01103

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

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STATEMENTS OF INTEREST¹

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With a nationwide presence, AARP strengthens communities and advocates for what matters most to the more than 100 million Americans 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 Amicus Curiae in Support of Defendants, *AstraZeneca Pharmaceuticals LP v. Becerra et al*, No. 1:23-cv-00931-CFC; 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 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).

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.

The Center for Medicare Advocacy (“the Center”) is a national, nonprofit law organization advancing access to comprehensive Medicare coverage, health equity, and quality health care for older people and people with disabilities. The Center was founded in 1986 and is headquartered in Connecticut and Washington, D.C. The Center advocates on behalf of beneficiaries in administrative and legislative forums and serves as counsel in litigation impacting 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 healthcare, with a particular focus on the needs of beneficiaries with longer-term and chronic conditions. The Center provides direct legal assistance to Medicare beneficiaries from Connecticut, and it provides training regarding Medicare and health care rights throughout the country. Its systemic advocacy is based on the experiences of real beneficiaries who contact the Center daily.

Justice in Aging is a national, non-profit law organization fighting senior poverty. 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 people with limited resources, focusing especially on populations traditionally lacking 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 (“Medicare Rights”) is a national, nonprofit organization bolstering access to affordable and equitable health care for older people 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.

Amici are organizations representing the interests of older people. We file this brief because a ruling in favor of Plaintiffs would prevent millions of older people from accessing affordable prescription drugs, threaten the financial integrity of the Medicare program (“Medicare”), and cost taxpayers billions.

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 gain access to affordable prescription drugs, protect the financial integrity of Medicare, and save American taxpayers billions of dollars.

Ever-escalating drug prices have especially impacted older people, forcing millions to make devastating decisions because they cannot afford their medications. 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 costing hundreds of dollars a 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 medications or for essentials like food, housing, or heat. Some skip doses, split doses, or forego filling their prescriptions altogether due to the strain high drug prices place on their finances.

I have to cut back elsewhere to afford my COPD medicine, and I can only afford around four months' worth per year instead of 12 months. I skip a lot of doses and don't pick it up because of the price. I cut back on groceries, cable TV, and I can't afford internet.

J.R., 81, Stamford, CT (Dec. 7, 2023).²

High drug prices also adversely impact people's health. Millions of older people do not consistently adhere to their prescription drug treatment because they cannot afford their medication. Their inability to afford their prescribed treatment leads to non-adherence to their prescribed treatment, worsening health conditions, higher health care expenses, unnecessary hospitalizations, and even death.

During open enrollment this year I helped a disabled woman with many chronic conditions try to find a Part D plan that covers all of her drugs. I worked with other experts and we used all the knowledge we have to explore the options. After hours of on-line searches and even calling her doctor to switch medications, the best plan we could find will cost her around \$12,000 for the year in cost-sharing -- \$1,000 per month. She does not have that money in her budget and will not pick up all of her drugs and or take them as prescribed.

K.G., Counselor for Connecticut's State Health Insurance Program, Ridgefield, CT (Dec. 6, 2023).

Ever-escalating prescription drug prices for Medicare beneficiaries also threaten the financial sustainability of Medicare and cost taxpayers billions of dollars annually. Every year, Medicare pays more than \$130 billion for prescription drugs. Before the IRA, there was no

² Amicus Center for Medicare Advocacy provides legal services to Connecticut Medicare beneficiaries. The Center recently collected stories from Connecticut residents about prescription drugs; answers received by email and telephone are included in this brief (using initials to maintain privacy).

mechanism to control how much pharmaceutical companies could increase drug prices. Prior to the enactment of the IRA, Medicare was powerless to address ever-increasing prescription drug costs because Medicare was explicitly precluded by federal law 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).*³

Recognizing the catastrophic impact of this growing crisis, Congress included in the IRA the prescription drug negotiation and other remedial provisions 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 beneficiaries face in accessing prescription drugs—the drug companies’ out-of-control prices. Allowing HHS to negotiate what Medicare will pay for certain drugs is imperative to limit the exorbitant prices and arbitrary price increases plaguing the American health system. Without the Negotiation Program, many older people will have limited or be denied access to essential medications. The continuation of the program is essential for the sustainability of the Medicare program to address the longstanding burden placed on the American taxpayers as a result of the unyielding increasing in the costs of medications that Medicare beneficiaries need.

The pharmaceutical industry wants to stop the government from implementing the Negotiation Program, but the needs of the American people must be paramount in the Court’s

³ <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>.

consideration of the Plaintiff's pending motion. Skyrocketing drug prices are wreaking havoc on the health and financial stability of millions of older people and on federal spending. While prescription drugs are intended to treat illnesses and improve quality of life, these potential benefits are illusory if Medicare beneficiaries cannot afford to buy the drugs they need. The Negotiation Program quells this escalating crisis by ending the pharmaceutical industry's special exemption from limits on prices they may charge Medicare by enabling HHS to negotiate the maximum prices Medicare will pay for the costliest drugs. Plaintiff's motion must be denied.

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 the Negotiation Program will only compound the harm the law is meant to prevent. Plaintiff seeks 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 serious chronic conditions. Plaintiff's legal challenge threatens the financial sustainability of Medicare. Amici urge this Court to deny Plaintiff's Motion for Summary Judgment, grant Defendants' Cross-Motion for Summary Judgment, and uphold the validity of the Negotiation Program so that it can be implemented.

I. The Negotiation Program Will Help Millions of Older People To 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) (summarizing results of Congressional drug price investigation and recommendations for Medicare drug price negotiation);⁴ *Negotiating A Better Deal: 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);⁵ *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 Prof. Rena M. Conti, Ph.D., Boston University, explaining that lowering drug prices is pro-innovation and pro-consumer, starting at 2:30:00).⁶

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 to protect consumers, taxpayers and the Medicare program because, for decades, people in the U.S. have paid the highest prices in the world for brand name 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. S.1. (July 2022).⁷ (“U.S. prices were 344 percent of prices in all non-U.S. countries for [brand name] drugs”).

Despite already charging U.S. residents the highest prices in the world, pharmaceutical companies have been raising brand name drug prices at alarming rates for many years, which are

⁴ <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>.

⁵ <https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-negotiating-a-better-deal-legislation-to-lower-the-cost-of>.

⁶ <https://www.finance.senate.gov/hearings/prescription-drug-price-inflation-an-urgent-need-to-lower-drug-prices-in-medicare>.

⁷ <https://aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbe28b/international-prescription-drug-price-comparisons.pdf>.

often ultimately paid by Medicare, taxpayers, and older consumers who cannot afford these increases on their fixed incomes. 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, *Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market*, 1, AARP Pub. Pol’y Inst. (Aug. 10, 2023).⁸ Some of these products’ prices are more than eight times higher in 2023 than when the company launched the drug. *Id.* All but one of the top 25 drugs’ lifetime price increases greatly exceeded the corresponding annual rate of inflation since each product has been on the market. *Id.*

In 2022, amid a pandemic and 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) (analyzing prescription drug list price increases from 2021 to 2022);⁹ Leigh Purvis, *Prices for Most Top Medicare Part D Drugs Have Already Increased in 2022*, AARP Pub. Pol’y Inst. (Mar. 3, 2022, 9:59 a.m.) (analyzing list price changes for the 100 brand name drugs with the highest total Medicare Part D spending).¹⁰ 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-*

⁸ <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>.

⁹ <https://www.goodrx.com/healthcare-access/research/january-2022-drug-increases-recap>.

¹⁰ <https://blog.aarp.org/thinking-policy/prices-for-most-top-medicare-part-d-drugs-have-already-increased-in-2022>.

2022, 1 (Sept. 30, 2022).¹¹

Not only are drug prices increasing, but manufacturers are also launching new drugs at exorbitant prices. Deena Beasley, *U.S. New Drug Price Exceeds \$200,000 Median in 2022*, Reuters (Jan. 5, 2023).¹² 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.*

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).¹³ It found the ten selected drugs alone represented more than \$180 billion in total Medicare Part D spending between 2017 and May 2023, with Boehringer Ingelheim's ("BI's) drug Jardiance accounting for \$15.6 billion. *Id.* This enormous price tag does not even represent a full picture of the benefits BI has gained from Part D sales, since Jardiance entered the market years earlier. *See* Drugs.com, *Jardiance FDA Approval History* (last updated by Judith Stewart, BPharm, Aug., 1, 2014).¹⁴ Between June 2022

¹¹ <https://aspe.hhs.gov/sites/default/files/documents/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf>.

¹² <https://www.reuters.com/business/healthcare-pharmaceuticals/us-new-drug-price-exceeds-200000-median-2022-2023-01-05/>.

¹³ <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.>

¹⁴ <https://www.drugs.com/history/jardiance.html> (showing the U.S. Food and Drug Administration first approved Jardiance to treat Type 2 diabetes on August 1, 2014); *see also* U.S. Food & Drug Administration, *Drug Approval Package, Jardiance* (showing same approval date), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000TOC.cfm.

and May 2023, the number of Medicare Part D beneficiaries taking Jardiance (for diabetes, and/or heart failure) totaled 1,573,000. Ctrs. for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, 1 (Aug. 2023)¹⁵ [hereinafter CMS, *Medicare Drug Price Negotiation Program Selected Drugs*]. In calendar year 2020, Medicare spent \$2,376,166,292 on Jardiance, of which more than \$383 million likely represented out-of-pocket costs for beneficiaries. Dickson, S., and Hernandez, I., *Drugs Likely Subject to Medicare Negotiation, 2026-2028*, 29 *Journal of Managed Care & Specialty Pharmacy* 3, Table 1 (predicting Jardiance would be designated for negotiation in 2028),¹⁶; see also 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 (Aug. 20, 2023, rev'd Sept. 13, 2023)¹⁷ [hereinafter *Medicare Enrollee's Expenditures*]. Average overall costs to Medicare for Jardiance users in calendar year 2022 was \$4,430; average out-of-pocket costs for non-low-income-supplement enrollees was \$290. Ass't Sec'y for Plan. & Evaluation, *Inflation Reduction Act Research Series—Jardiance: Medicare Enrollee Use and Spending*, 1, table 1 (November 8, 2023).¹⁸

¹⁵ <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>.

¹⁶ <https://www.jmcp.org/doi/full/10.18553/jmcp.2023.29.3.229>.

¹⁷ <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 Jardiance users (1,321,000) amounted to \$383,346,000). Describing Jardiance's overall market performance, the agency found that "The German drugmaker reported a 9.7% jump in overall sales over the first half of 2023, largely thanks to growth in Eli Lilly-partnered SGLT2 inhibitor Jardiance." Zoey Becker, *Boehringer Ingelheim posts more Jardiance growth as potential US kidney disease approval nears*, <https://www.fiercepharma.com/pharma/boehringer-ingelheim-sees-jardiance-growth-ahead-potential-us-chronic-kidney-disease-nod>.

¹⁸ <https://aspe.hhs.gov/sites/default/files/documents/b579122f216f5c3eb3f7ef6c6091b5c1/Jardiance.pdf>.

The high price of prescription drugs can be especially burdensome 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. One woman who takes 16 medications, including Jardiance, said:

My drug costs are so high that we are just making our monthly bills, and we can never do something like go out for dinner, even at McDonald's.

L.W., 71, Norwich, CT (Dec. 13, 2023).

A couple on a fixed income found themselves grappling with high costs after the husband was prescribed Xarelto and the wife was prescribed Eliquis. Both drugs have been selected for the first cycle of price negotiation.

My Xarelto increased our costs by over \$100 a month and the Eliquis costs us about double out of pocket compared to the drug she used to take. We're paying more for two drugs than we paid monthly for most of our cars.

E.S., 77, Woodstock, CT (Dec. 13, 2023).

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).¹⁹ More than one in ten Medicare beneficiaries (12%) have no savings at all or are in debt. Wyatt Koma et al., Kaiser Fam. Found, *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic*, (Apr. 24, 2020).²⁰ For this population, any financial setback can lead to financial ruin, because they not only have few resources, but they also have less time in the workforce before retirement to recover from financial losses. *See e.g.*, Erika Beras, *Seniors are still struggling to recover after the financial crisis*, Marketplace (Dec. 19, 2018) (explaining

¹⁹ <https://www.aarp.org/politics-society/advocacy/info-2022/medicareprescription-drug-costs.html>.

²⁰ <https://www.kff.org/report-section/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic-tables/>.

people close to retirement during the Great Recession are still having trouble recovering their financial losses a decade later).²¹

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)²² [hereinafter *Key Facts about Part D*]. On average, they take four to five medications per month. Bunis, *supra*, at 10. 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).²³ These health complications make it likely that someone 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—the condition for which Jardiance was first approved and for which it is still prescribed—far outpaces the rest in related treatment spending for Medicare beneficiaries. *Id.* (2018 data showing diabetes trailed only cancer in annual treatment costs).

The prices Medicare pays for prescription drugs directly impact older beneficiaries because the amount that 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

²¹ <https://www.marketplace.org/2018/12/19/seniors-still-affected-financial-crash/>.

²² <https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/>.

²³ 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.

Advantage drug plans. AARP, *What are the costs of Medicare Part D?* (Updated Nov. 17, 2023).²⁴ 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*, at 11. 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) (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”) [hereinafter *CBO Feb. Estimated Budgetary Effects*].²⁵ Thus, to some degree, high drug prices impose financial burdens 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).²⁶ 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

²⁴ <https://www.aarp.org/health/medicare-qa-tool/what-are-costs-for-part-d/>.

²⁵ <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf>.

²⁶ <https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/>.

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 Enrollees' Expenditures, supra*, at 5.²⁷ 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 (Jardiance).

The prices of prescription drugs are so high that millions of beneficiaries cannot afford their medication, and as a result must make devastating decisions, 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 treatment as prescribed because their drugs 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).²⁸ About 8.5% made the unimaginable decision 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, more than 11%

²⁷ <https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf>.

²⁸ <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.>

did not fill a prescription at all, and nearly 8% of older people took less medication or skipped doses. *Id.* A separate 2022 study found more than 5 million Medicare 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).²⁹

Beneficiaries not adhering to their prescribed treatment can worsen their health which can result in expensive hospitalizations, 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) (citing CDC study).³⁰ 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).³¹

Given the dire consequences caused by high drug costs, the 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

²⁹ <https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efec9c6f96f0/prescription-drug-affordability.pdf>.

³⁰ <https://www.fda.gov/drugs/special-features/why-you-need-to-take-your-medications-prescribed-or-instructed#:~:text=Taking%20your%20medicine%20as%20prescribed%20or%20medication%20adherence%20is%20important,important%20part%20of%20medication%20adherence.>

³¹ https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

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) (finding 95% of Democrats, 82% of Independents, and 71% of Republicans support Medicare drug price negotiation).³² 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).³³

Skyrocketing drug prices have stretched the budgets of older adults to the point where they are forced to make wrenching, life-altering decisions that disrupt their health and financial well-being. The explicit goal of the Negotiation Program is to end this public crisis and interject long-overdue fairness, transparency, and predictability 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, deciding the in favor of Plaintiff and ending the Negotiation Program will also harm the financial sustainability of Medicare and cost American taxpayers billions of dollars.

A. Skyrocketing Drug Prices Destabilizes 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.

³² <https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations/>.

³³ <https://www.westhealth.org/press-release/regardless-of-political-party-americans-overwhelmingly-support-medicare-drug-price-negotiations/>.

Found., *What to Know About Medicare Spending and Financing*, (Jan. 19, 2023).³⁴ 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, 2008-2021*, 2 (June 2023).³⁵ HHS also did not have data necessary to assess whether pharmaceutical companies could justify the prices they were demanding Medicare pay.

Medicare's historic 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

³⁴ <https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/>.

³⁵ https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b_61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.

than \$135 billion on drugs every year. Nguyen et al., *supra*, at 2 (explaining in 2021, spending by Medicare Part D was \$105 billion and Medicare Fee-for-Service Part B was \$33 billion). Notably, Medicare pays higher net prices for top-selling brand-name drugs than the Department of Veterans Affairs, the Department of Defense, and Medicaid. *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, 1-3 (CBO Feb. 2021).³⁶ 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);³⁷ *see also*, Gov't Acct. Off., *Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, 5 *GAO-21-111* (Dec. 15, 2020) (finding the Department of Veterans Affairs paid an average of 54% less per unit of medication than Medicare, even after considering rebates and discounts).³⁸ Prior to the IRA, Medicare had no such authority.

Unchecked drug prices also inflate 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*, at 3. According to the 2020 Council for Informed Drug Spending Analysis, medication nonadherence leads to an additional \$177.4 billion in avoidable Medicare medical costs. *Id.* Conversely, a study published in 2022 found that by eliminating cost-related medication

³⁶ <https://www.cbo.gov/publication/57007>.

³⁷ <https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices>.

³⁸ <https://www.gao.gov/assets/gao-21-111.pdf>.

nonadherence both medication uptake and overall health improved, and patient deaths and overall medical spending decreased. Zhang et al., *Chronic Medication Nonadherence and Potentially Preventable Healthcare Utilization and Spending Among Medicare Patients*, 3 J. Gen. Intern. Med. (Nov. 2022).³⁹

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

The IRA is essential to 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., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023) [hereinafter *Explaining the Prescription Drug Provisions*].⁴⁰

HHS has already announced the first ten Medicare Part D drugs that will be subject to the Negotiation Program. Press Release, *Medicare Drug Price Negotiation Program Selected Drugs*, *supra*, at 1. 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 Jardiance, will go into effect in 2026; for drugs covered under Medicare Part B, negotiated prices will go into effect in 2028. *Id.*

³⁹ https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

⁴⁰ <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>.

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 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 Selected Drugs*, *supra*, at 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 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 alone. *CBO Feb. Estimated Budgetary Effects*, *supra*, at 4. This reduction will result from reduced Medicare Part D and Part B spending of \$14 billion and \$9

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.

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*, 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 Feb. Estimated Budgetary Effects, supra*, 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 a dollar 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., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, Kaiser Fam. Found. (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) (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

⁴³ <https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/>.

generally increase in line with drug spending trends[.]”).⁴⁴

The Negotiation Program protects the financial integrity of Medicare because it allows HHS to ensure it is paying justified and 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 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, Plaintiff seeks 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

⁴⁴ https://www.healthaffairs.org/doi/10.1377/hpb20171008.000172/full/health_policybrief_172-1525353500165.pdf.

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) (explaining that “participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.”).

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. 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).⁴⁵ 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*. 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*, at 3. In other words, reducing out-of-pocket costs is not a sustainable solution without also addressing high drug prices because high drug prices drive high out-of-pocket costs.

Similarly, the expansion of the Medicare Part D Low-Income Subsidy ("LIS") benefit will

⁴⁵ <https://aspe.hhs.gov/sites/default/files/documents/93a68f3c5ca949dcf331aa0ec24dd046/aspe-part-d-oop.pdf>.

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.* 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)⁴⁶ (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*. But unlike the Medicare drug price negotiation program, the rebates do not address whether the underlying drug prices are justified, leaving beneficiaries and taxpayers exposed to paying unchecked and arbitrary prices 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 addresses insurmountably 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

⁴⁶ <https://www.cms.gov/files/document/2023medicarepartdlowincomesubsidyisincomeandresourcestandardsg.pdf>.

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 injure the health and finances of millions of older Americans, undermine sustainability of Medicare Parts B and D, and defy the interests of American taxpayers in the efficient operation and long-term viability of Medicare. The Negotiation Program promises long-overdue relief from excessive drug prices. Accordingly, Plaintiff's motion for summary judgment should be denied and Defendants' cross-motion for summary judgment should be granted.

December 26, 2023

Respectfully submitted,

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** Pro hac vice Admission Pending.*

CERTIFICATE OF SERVICE

On the 26th day of December, 2023, this Brief of Amici Curiae AARP, AARP Foundation, Center for Medicare Advocacy, Justice in Aging, and the Medicare Rights Center Supporting Defendants' Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion for Summary Judgment and accompanying Motion for Leave to File Brief of Amici Curie were filed electronically on all parties of record with the Clerk of Court using the Court's CM/ECF system.

December 26, 2023

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