IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	Civ. No. 1:23-cv-01615-CKK
v.	)	
	)	
XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*,	)	
	)	
	)	
Defendants.	)	

BRIEF OF AMICI CURIAE AARP AND AARP FOUNDATION SUPPORTING DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND SUPPORTING DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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STATEMENT OF INTEREST[1]

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

Among other things, AARP and AARP Foundation advocate for access to affordable prescription drugs and health care, including through participation as amici curiae in state and federal courts. *See, e.g.*, Br. of AARP et al. as Amici Curiae in Support of Plaintiffs, *Stewart v. Azar*, 313 F.Supp.3d 237 (D.D.C. 2018) (No. 18-152) (Medicaid work requirements); 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); Br. of AARP and AARP Foundation as Amici Curiae in Support of Respondent, *Impax Labs., Inc. v. F.T.C.*, 994 F.3d 484 (5th Cir. 2021) (No. 19-60394) (anticompetitive conduct involving prescription drugs).

Amici are organizations that represent the interests of older adults. We file this brief because a ruling in favor of Merck & Co. ("Merck") would stop millions of older adults from accessing affordable prescription drugs, threaten the financial integrity of the Medicare program ("Medicare"), and cost taxpayers billions of dollars in related savings.

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[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.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Inflation Reduction Act of 2022 ("IRA") is a landmark law that includes historic measures to lower the skyrocketing prices of prescription drugs. 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 the drug companies to determine the price that Medicare will pay for a select number of costly single-source, brand-name drugs. This change is a watershed moment that 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 of them to make devastating decisions because they cannot afford the medication they need. More than 50 million people are enrolled in Medicare Part D, the federal government's voluntary prescription drug benefit program for Medicare beneficiaries. On average, they take between four and five prescriptions per month and have a median annual income of just under $30,000. The vast majority have chronic conditions that require lifelong treatment.

Many older people simply do not have the resources to pay for 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. Others sell everything they own and drain their resources because the price of their medication is beyond their reach.

For example, Catherine B. of Maryland has been forced to choose between buying groceries and paying for her diabetes medication due to its high price. *Medicare Targets 10 Drugs for Price Cuts*, CBS News (Aug. 29, 2023) (describing the sacrifices she must make to

afford Januvia, a drug selected for negotiation). Stephen H. of North Carolina repeatedly foregoes or rations his prescribed medications because he cannot afford them despite working multiple jobs. Patients for Affordable Drugs, *Steven's Story* (Sept. 7, 2022) (describing the sacrifices he makes to afford Januvia and other medication). Finally, Ken O. from Pennsylvania took out loans, sold one of his cars, and cut back on basic life essentials to afford his medication. Patients for Affordable Drugs, *Eliquis and Xarelto: Lockstep Price Hikes and Patent Gaming Exploit Patients and Taxpayers*, 5 (Apr. 2022) (describing his efforts to afford Eliquis, another prescription drug selected for negotiation).

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. Not surprisingly, their inability to follow their prescribed treatment leads to worsening health conditions, higher health care expenses, hospitalizations, and even death.

It is not just older people suffocating under ever-escalating drug prices. High drug prices 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. Until the passage of the IRA, there was no predictable limit to how high drug prices could go. Medicare had been powerless to do anything about the spiraling prices because the law prohibited it from negotiating the price of drugs. As a result, Medicare had no choice but to pay drug prices that drug manufacturers continued to increase as much as ten times faster than the rate of inflation. *See* Leigh Purvis & Stephen W. Schondelmeyer, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, AARP Pub.

Pol'y Inst., 5 fig. 1 (June 2021). The increases occurred without any justification and with no foreseeable endpoint. *Id.*

Recognizing the growing catastrophe, Congress passed the prescription drug provisions in the IRA to reduce drug prices and bring essential relief to older people, Medicare, and the American taxpayers. The Medicare drug price negotiation program ("Negotiation Program") is the cornerstone of the law because it addresses the central problem – out-of-control prescription drug prices. Allowing HHS to negotiate Medicare drug prices is imperative because, without it, drug companies will continue to set prices at exorbitant levels. This, in turn, will ultimately deny older people access to critical medications, increase premiums, and jeopardize Medicare's sustainability.

While it comes as no surprise that the pharmaceutical industry is trying to stop the government from implementing the law, the needs of the American people must be paramount in this Court's consideration of the present motions. Skyrocketing drug prices have caused a nationwide crisis that is wreaking havoc on millions of older people and federal spending. The Negotiation Program reins in this crisis by ending the pharmaceutical industry's special exemption and empowering HHS to negotiate the prices that Medicare will pay for the most expensive drugs. Thus, Merck's 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 reinforce the harm that the law is meant to prevent. Merck seeks to protect the pharmaceutical industry's ability to charge

unreasonable and astronomical prices at the expense of what people with chronic conditions need to survive. Its efforts threaten the financial health of Medicare. Its motion must be denied. 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 affordable medications they need to survive and thrive. The Negotiation Program culminates from years of Congressional investigations, hearings, and testimonies about the devastating effect that 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 (Dec. 10, 2021) (summarizing results of Congressional drug price investigation and recommendations for Medicare drug price negotiation); *Negotiating A Better Deal: Legislation to Lower the Cost of Prescription Drugs Before H. Comm. On Energy & Commerce*, 117th Cong. (May 4, 2021) (testimony of patient Therese B. describing how her health deteriorated after she was forced to stop taking her prescription drug due to its cost); *Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare Before S. Comm. On Fin.*, 117th Cong. (Mar. 16, 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)).

One of the IRA's primary objectives is to make prescription drugs more affordable. Inflation Reduction Act (IRA), 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. Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Current*

Empirical Estimates and Comparisons with Previous Studies, Rand Corp., at xii fig. S.1. (July 2022) (finding that U.S. prices were 256% higher than 32 comparison countries combined).

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 that pharmaceutical companies increased the prices of the top 25 drugs that Medicare Part D pays for by an average of 226% from the time that the drugs first entered the market. Leigh Purvis, *Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market*, AARP Pub. Pol'y Inst., 1 (Aug. 10, 2023) [hereinafter *2023 AARP Medicare Part D Drug Report*]. Some of these products' prices are more than eight times higher 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 (Consumer Price Index All Urban Consumers for All Items; CPI-U) since each product has been on the market (i.e., product launch date until May 2023). *Id.*

What is more, in 2022, while the country was in the midst of the pandemic and a financial crisis, the pharmaceutical industry raised prices on over 800 prescription medications – including 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); Leigh Purvis, *Prices for Most Top Medicare Part D Drugs Have Already Increased in 2022*, AARP Pub. Pol'y Inst. (Mar. 3, 2022) (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., *Issue Brief, Price Increases for Prescription Drugs, 2016-2022*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., 1 (Sept. 30, 2022).

Not only are the drug prices increasing, but the manufacturers are also launching new drugs at higher prices. *2023 AARP Medicare Part D Drug Report*, at 4; Deena Beasley, *U.S. New Drug Price Exceeds $200,000 Median in 2022*, Reuters (Jan. 5, 2023). The median price of a new brand-name prescription drug is now about $200,000 per year, meaning even a nominal price hike could increase a drug's price by 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 10 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. (Aug. 29, 2023). It found that the 10 selected drugs alone represented more than $180 billion in total Medicare Part D spending between 2017 and May 2023. *Id.* Januvia, a drug at issue here, accounted for $21.6 billion. *Id.* The product has been on the market since 2006, meaning Merck has benefited from an additional 11 years of Medicare Part D sales that were not included in the analysis. *2023 AARP Medicare Part D Drug Report* (showing that Januvia entered the market in 2006).

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. For example, 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). More than one in ten Medicare beneficiaries (12%) has no savings

at all or is in debt. Wyatt Koma et al., *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic* (Apr. 24, 2020). For this population, any financial setback can lead to financial ruin. They not only have few resources, but they also have less time to recover from their financial losses. *See e.g.*, Erika Beras, *Seniors are still struggling to recover after the financial crisis*, Marketplace (Dec. 19. 2018) (explaining that people who were close to retirement during the Great Recession are still having trouble recovering their financial losses a decade later).

In addition, more than 50 million Medicare beneficiaries depend on Medicare Part D for prescription drug coverage. Juliette Cubanski & Anthony Damico, *Key Facts About Medicare Part D Enrollment and Costs in 2023*, Kaiser Fam. Found. (July 26, 2023) [hereinafter *Key Facts about Part D*]. On average, they take four to five medications per month. Bunis, *supra*. Along with that, 80% of them have at least two chronic conditions, such as heart disease, cancer, and diabetes. Jane L. Tavares et al., *Chronic Inequities: Measuring Disease Cost Burden Among Older Adults in the U.S. A Health and Retirement Study Analysis,* Nat'l Council On Aging 5 (April 2022) (showing that about 80% of people age 60 and over have at least two chronic conditions). These health complications make it likely they will need to take prescription drugs for the rest of their lives.

The prices that Medicare pays for prescription drugs directly impact these beneficiaries because they often pay cost-sharing that is 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). Depending on their plan, they can incur out-of-pocket costs from premiums, copayments, deductibles, and coinsurance. *Id.* In fact, Medicare Part D plans are increasingly relying on coinsurance, which is

a percentage of the drug's price. *Key Facts about Part* D, *supra.* 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 whether or not they are taking one themselves because Medicare Part D premiums are calculated to cover a set share of costs for standard coverage. *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) [hereinafter *CBO Estimated Budgetary Effects*] ("Part D premiums are determined in part by a policy benchmark known as the base beneficiary premium, which is based on expected average benefit costs for all Part D enrollees.") Thus, high drug prices financially impact all Medicare Part D beneficiaries in some way.

Medicare Part B beneficiaries are also impacted 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., *Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage*, Kaiser Fam. Found. (Mar. 15, 2022). Like 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 beneficiaries in traditional Medicare who used Part B drugs faced an average annual cost-sharing liability of at least $1,000. *Id.* About 400,000—or about 1 in 10 of those who used Part B drugs—incurred at least $5,000 in cost-sharing. *Id.* In another parallel to Medicare Part D, Part B premiums cover a specific share of expected costs, meaning everyone in the program is paying for high-priced prescription drugs.

The first 10 drugs selected for negotiation underscore the financial toll that 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. 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, 5 (Aug. 9, 2023) [hereinafter *Medicare Enrollee's Expenditures*]. 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 tbl. 2 (Imbruvica).

Unfortunately, prescription drug prices are so high that millions of beneficiaries simply cannot afford their medication. As a result, they are either foregoing taking their medication altogether or making desperate choices to ration their care. A 2022 JAMA Network national panel study found that 20% of Medicare beneficiaries surveyed did not adhere to their treatment protocols as prescribed because their drugs were too expensive. Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network (May 18, 2023). About 8.5% made the devastating choice to go without basic life essentials, such as food and 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 that more than 5 million Medicare beneficiaries struggle to afford their prescription drugs. Wafa Tarazi et al., *Prescription Drug Affordability among Medicare Beneficiaries*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., 1 (Jan. 19, 2022).

Beneficiaries' not adhering to their prescribed treatment can worsen their health conditions, resulting in hospitalization, declining health, higher health care costs, and even death. The Centers for Disease Control and Prevention ("CDC") estimates that medication non-adherence causes 30% to 50% of chronic disease treatment failures and 125,000 deaths per year.

U.S. Food & Drug Admin., *Why You Need to Take Your Medications as Prescribed or Instructed* (Feb. 16, 2016) (citing CDC study). Similarly, a 2020 study released by the Council for Informed Drug Spending Analysis estimated that 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).

Given the dire consequences, it is no wonder that the American public has repeatedly called for HHS to directly negotiate Medicare drug prices with drug manufacturers. Poll after poll shows overwhelming nonpartisan public support for allowing Medicare to negotiate prices. For instance, a 2021 Kaiser Family Foundation public opinion survey found that 83% of Americans favored allowing Medicare to negotiate drug prices, including majorities of all political parties. Ashley Kirzinger et al., *The Public Weighs In On Medicare Drug Negotiations*, Kaiser Fam. Found. (Oct. 12, 2021) (finding that 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 became law, a West Health-Gallup poll again showed that 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*, West Health (Aug. 28, 2023).

In the end, skyrocketing drug prices have stretched the budgets of older adults to the point where they are forced to make impossible, life-altering choices that can worsen their health and financial situations. The goal of the Negotiation Program is to end this public crisis and interject long-overdue fairness, transparency, and predictability into the drug pricing process.

While prescription drugs are intended to treat illnesses and improve the quality of life, these benefits are meaningless if beneficiaries cannot afford them.

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

As described above, older adults will be harmed if the Negotiation Program is struck down. Ending the Negotiation Program will also harm the financial sustainability of Medicare and cost American taxpayers billions of dollars.

A. Skyrocketing drug prices harm 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, *What to Know About Medicare Spending and Financing,* Kaiser Fam. Found. (Jan. 19, 2023). 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 would pay for drugs directly with manufacturers. 42 U.S.C. § 1395w-111(i). As a result, HHS could not use Medicare's considerable buying power to negotiate lower drug prices even though Medicare accounts for almost one-quarter of all U.S. prescription drug spending. Nguyen X. Nguyen et al., *Medicare Part B Drugs: Trends in Spending and Utilization*, *2008-2021*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 2 (June 2023). HHS also did not have the information necessary to assess whether pharmaceutical companies could justify the prices that they were demanding that Medicare pay.

Medicare's inability to negotiate drug prices provided drug companies with a special exemption that other entities and individuals that provide 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 special exemption and lack of transparency led to increases in Medicare drug spending that were unsustainable and unjustifiable. For example, Medicare spends more than $135 billion on drugs every year. Nguyen, *supra*, at 2 (explaining that 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 Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, 1-3 (Feb. 2021). 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); *see also*, Gov't Acct. Off., *GAO-21-111, Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017* (Dec. 15, 2020) (finding that the Department of Veterans Affairs paid an average of 54% less per unit than Medicare, even after considering rebates and discounts.) Prior to the IRA, Medicare did not.

Spiraling drug prices also increase Medicare spending by contributing to the costs the program must endure 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. In short, high costs can compound into even higher costs. For instance, a 2020 study released by the Council for Informed Drug Spending Analysis found that medication nonadherence would lead to an additional $177.4 billion in avoidable Medicare medical costs. *Id.* The nonpartisan Congressional Budget Office ("CBO") also found that the lower prescription drug prices resulting from the Negotiation Program will increase the use of needed prescription drugs and subsequently reduce enrollees' use of other health care services. *CBO Estimated Budgetary Effects, supra*, at 11.

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 the non-interference clause by authorizing HHS to create the Negotiation Program to directly negotiate prices with pharmaceutical companies for a limited number of single source, brand-name drugs or biologics that are covered under Medicare Part B or Part D. 42 U.S.C. § 1320f(a); *see* Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Ac*t (Jan. 24, 2023) [hereinafter *Explaining the Prescription Drug Provisions*].

HHS has already announced the first 10 Medicare Part D drugs that will be subject to the Negotiation Program. U.S. Dep't of Health & Human Servs., *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023) (listing the 10 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 will go into effect in 2026 and for drugs covered under Medicare Part B in 2028. *Id.*

While HHS is only negotiating prices for a subset of the costliest drugs, the negotiations will greatly benefit Medicare and beneficiary spending and the integrity of the program. 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 program 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. Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, 1 (Aug. 2023). That number that represents nearly 20% of all Medicare Part D spending during that period. *Id.*

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

These 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 estimated that the Medicare drug price negotiation 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*, at 36.

Taxpayers will also benefit from the program. Taxpayers assume the burden of skyrocketing drug prices because Medicare is a public program funded by taxes. Every dollar that taxpayers pay for prescription drugs with unjustified prices is money that cannot be invested in other priorities. The savings obtained from the Negotiation Program will help fund other changes in IRA that will help reduce Medicare beneficiaries' out-of-pocket costs. *Id.* 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) [hereinafter *IRA's Prescription Drug Provisions*]. Indeed, the $2,000 annual cap would not be feasible without price limitations on drug manufacturers. Without such limitations, higher price drugs would dramatically increase costs to the taxpayers and over time dramatically increase the amount of premiums in Medicare Part D. *See e.g.*, Mike McCaughan, *Medicare Part D*, Health Affairs (Aug. 10, 2017) ("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 that it is paying justifiable 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. § 1320-f-3(e) (describing information HHS will consider, including manufacturer-submitted data). 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 will finally allow HHS to push back on indiscriminately escalating drug prices and ensure that taxpayer funds are paying for value – all while saving billions for Medicare and its beneficiaries.

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, Merck seeks for drug companies to once again obtain a special exemption which no other health care provider group has that would allow drug companies to charge Medicare and its beneficiaries whatever price they want for their products. This request should be denied. The Negotiation Program finally places drug companies on the same footing with other health care providers by ending their special treatment that caused substantial harm. *See* 42 U.S.C. § 1320f(a) (establishing the Negotiation Program).

Similarly, the Negotiation Program will also allow Medicare to use its bargaining power to obtain lower prices and put 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 intervene 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 rebalances the bargaining power of Medicare and its beneficiaries with the power of the industry.

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

Finally, the Negotiation Program will allow for continued innovation while lowering drug prices. The pharmaceutical industry has intimated that allowing the government to negotiate Medicare drug prices would come at a cost of stifling innovation. *See e.g.*, Merck Br. 1, 10, and 31. But their argument sets up a false binary choice.

For starters, American taxpayers fund nearly all the initial research that leads to new drugs. For example, 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., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, JAMA Health Forum, 2, 5, 14-15 (Apr. 28, 2023). A study comparing research spending by the NIH and the pharmaceutical industry reveals that 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 that Medicare drug price negotiation will have little to no impact on innovation. The CBO has estimated that 13 out of 1,300 drugs, or 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,* at 15. This minimal number contradicts the pharmaceutical industry's claims.

Notably, public opinion has rejected the pharmaceutical industry's threat of reduced innovation. In a response that spanned party lines, a 2021 AARP survey found that 80% of survey respondents said the drug prices could be lowered without harming innovation. Dena Bunis, *COVID-19 Vaccines Show Government Negotiations Can Work to Lower Drug Prices*, AARP (July 8, 2021).

The bottom line is that the Negotiation Program protects the integrity of Medicare and ensures that its taxpayer-funded spending is justified. Current federal drug spending trends are unsustainable and unfair. The negotiations will yield billions of dollars in savings that will benefit Medicare and support public investment in other national 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 for all of the IRA's prescription drug provisions to achieve what Congress intended – making drugs more affordable. *See e.g.*, *Explaining the Prescription Drug Provisions*, *supra*. As noted above, aside from the negotiation provisions, the IRA has provisions that reduce prescription drug-related cost-sharing for people enrolled in Medicare and require drug companies to pay rebates when they increase their prices faster than inflation. *Id.; see* 42 U.S.C. § 1395w-3a(i) (rebates); 42 U.S.C. § 1395w-102 (vaccines, insulin caps, and out-of-pocket cost caps). While each of these provisions is critical and targets a specific problem on its own, they are designed to work in a coordinated way to reduce high out-of-pocket costs and high prescription drug prices at the same time.

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, even though the government will have no way to justify the prices it pays. The rest of the IRA prescription drug provisions, while critical, are designed to complement drug price negotiations but cannot replace the negotiations. 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., *Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs., 1 (July 7, 2023). It also includes critical provisions that reduce Medicare beneficiaries' out-of-pocket costs for insulin and vaccines and allows them 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 escalating prices that will ultimately be passed back to the beneficiary in the form of higher premiums and cost-sharing and passed to taxpayers to cover the higher costs in Medicare Part D. *See* McCaughan, *supra*. In other words, reducing out-of-pocket costs is not a sustainable solution unless it also addresses the underlying high drug prices that are 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.* While this improvement is critical, estimates indicate that roughly 400,000 new beneficiaries would qualify for the improved benefit based on the program's income and asset thresholds. *Id.* Consequently, many beneficiaries with lower incomes will still

be unable to qualify for this benefit and could continue to struggle to afford their prescription drugs. *See* Jerry Mulcahy, *2023 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards*, U.S. Dep't of Health & Human Servs., 2-7 (Feb. 9, 2023) (listing the income and asset standards to qualify for LIS.) 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 brand-name drug companies from engaging in relentless price hikes year after year. *Explaining the Prescription Drug Provisions*, *supra*. But unlike the Medicare drug price negotiation program, the rebates do not address whether the underlying drug prices are justified, leaving beneficiaries and taxpayers exposed to overpaying 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 attacks 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 escalating drug costs without the implementation of the Negotiation Program. Thus, the Negotiation Program should proceed as mandated to relieve Medicare and its beneficiaries of the perils of out-of-control drug prices.

CONCLUSION

Striking down the Negotiation Program will harm millions of older people, Medicare, and American taxpayers. The program provides long-overdue relief from excessive drug prices and should be upheld. Merck's motion for summary judgment should be denied and the government's cross-motion should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that on the 18th day of September, 2023, this Brief of Amici Curiae AARP and AARP Foundation Supporting Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Supporting Defendants' Cross-Motion For Summary Judgment, accompanying Motion for Leave to File An Amici Curiae Brief and Proposed Order were filed electronically on all parties of record with the Clerk of Court using the Court's CM/ECF system.

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