24-1821

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

Janssen Pharmaceuticals, *et al.,*

Plaintiff- Appellants,

---v.---

Xavier Becerra, *et al.,*

Defendant- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, No. 3:23-cv-03818

[PROPOSED] BRIEF OF CENTER FOR AMERICAN PROGRESS, NAACP, THE CENTURY FOUNDATION, UNIDOSUS ACTION FUND AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE

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IDENTITY AND INTERESTS OF PROPOSED AMICUS CURIAE[1]

Center for American Progress (CAP) is an independent, nonpartisan policy institute that focuses, in part, on developing and advocating for policies that strengthen health. The NAACP is the oldest and largest civil rights organization in the country, with a mission to achieve equity, political rights, and social inclusion by advancing policies and practices that expand human and civil rights, eliminate discrimination, and accelerate the well-being, health care, education, and economic security of Black people and all persons of color. The Century Foundation (TCF) is a progressive, independent think tank that conducts research, develops solutions, and drives policy change to make people's lives better with a focus, in part, on advancing health equity. UnidosUS Action Fund (UnidosUSAF) is a Latino advocacy organization that works to expand the influence and political power of the Latino community work is lowering prescription drug costs for the millions of Latinos in America who rely on medication to treat chronic disease.

Amici submit this brief to provide the Court with the policy context necessary to understand the impact of the Inflation Reduction Act's (IRA) Medicare prescription drug price negotiations on prescription drug affordability

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[1] No counsel for any party authored this brief in whole or in part. No entity or person, aside from amicus curiae, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The parties have consented to the filing of this brief.

and health equity. This brief aims to provide an understanding of how these drug price negotiations will improve the health of vulnerable Medicare beneficiaries—including racial and ethnic minorities, women, the elderly, the Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, plus (LGBTQI+) community, and disabled people.

I. INTRODUCTION

As a matter of health equity, all individuals must have "a fair and just opportunity to access their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."[2] But the reality of American health care falls far short of this goal. Socioeconomic status, historic and current discrimination and racism, disability status, and many other factors impede access to adequate health care.[3] In America, health care has never truly been equitable.[4]

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[2] *Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/pillar/health-equity (last visited Sept. 15, 2024).

[3] Nambi Ndugga & Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KAISER FAMILY FOUND. (Apr. 21, 2023), https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers.

[4] *See e.g.*, Ruqaiijah Yearby, Brietta Clark, & José F. Figueroa, *Structural Racism in Historical and Modern US Health Care Policy*, 41 HEALTH AFF. 187 (2022).

For decades, high drug prices have been a driver of such inequitable health care access.[5] Roughly three in ten American adults report not being able to afford to take their medications as prescribed,[6] and historically marginalized populations are among those most likely to face these affordability challenges.[7] Further, as medication costs increase, prescription adherence drops: a 2020 study found prescription abandonment rates were less than five percent when a prescription carried no out-of-pocket expense but jumped to 45 percent when out-of-pocket costs were over $125.[8] Abandonment rates jumped further still—to 60 percent—when the out-of-pocket cost was over $500.[9] This is not a personal failing: people cannot buy and take drugs they cannot afford. And a lack of prescription adherence

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[5] *See infra* Section II.A.

[6] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAMILY FOUND. (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

[7] *See* Tomi Fadeyi-Jones et al., *High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It.*, PATIENTS FOR AFFORDABLE DRUGS NOW (Dec. 14, 2020) https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism; *cf*. Jennifer Tolbert, Patrick Drake, & Anthony Damico, *Key Facts about the Uninsured Population*, KAISER FAMILY FOUND. (Dec 19, 2022), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/ ("Most of the 25.6 million nonelderly people who are uninsured are adults, in working low-income families, and are people of color.").

[8] *Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicines*, IQVIA (Aug. 4, 2020), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us.

[9] *Id.*

(predictably) hastens more serious, costly, and painful health outcomes. For example, non-adherence to blood thinner medication is associated with increased bleeding, stroke, and death.[10] Such outcomes worsen (or prematurely end) individual lives. Higher drug costs feed a vicious cycle of increased health care spending for avoidably poor health outcomes.[11] And those poor outcomes fall disproportionately on low-income people, people of color, women, LGBTQI+, and people with disabilities.[12] Simply put, higher drug prices transform a disparity in wealth into a disparity in health and deepen existing health inequities.

The plaintiff in the instant action, Janssen Pharmaceuticals Inc. (Janssen), manufactures Xarelto[13]—a drug used to treat and prevent blood clots.[14] According to Janssen, Xarelto has been prescribed over 80 million times in the United

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[10] *See e.g.* Frank Cools, et al., *Risks Associated with Discontinuation of Oral Anticoagulation in Newly Diagnosed Patients with Atrial Fibrillation: Results from the GARFIELD-AF Registry*, 21 J. THROMBOSIS & HAEMOSTASIS 2322, 2326–27 (2021).

[11] *See infra* notes 55–56.

[12] *Id.*

[13] Janssen also manufactures the drug Stelara, which is in the Medicare price negotiation program, but it is not the subject of this appeal. Appellant Opening Br. at 12 n.10.

[14] *Fact Sheet: Inflation Reduction Act Research Series—Xarelto: Medicare Enrollee Use and Spending*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. (Nov. 13, 2023), https://aspe.hhs.gov/sites/default/files/documents/5bc9a571d6ece32ed3afae52f490d66b/Entresto.pdf.

States.[15] Medicare enrollees are at a high risk for blood clots due to age and other comorbidities, for example, over seven hundred thousand Medicare beneficiaries were hospitalized with deep vein thrombosis (DVT) between 1999 and 2010.[16] As a result, it is unsurprising that, in 2023, more than 1.3 million Part D beneficiaries filled prescriptions for Xarelto.[17] With respect to health equity, cardiovascular conditions that occur from blood clots, like strokes and pulmonary embolisms,[18] disproportionately affect some racial and ethnic minority Medicare beneficiaries and low-income people.[19]

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[15] *Xarelto Official Patient Website*, Janssen Pharm. Inc. (accessed Aug. 27, 2024) https://www.xarelto-us.com/.

[16] *Xarelto: Medicare Enrollee Use and Spending*, *supra* note 14; Karl Minges, et al., National and Regional Trends in Deep Vein Thrombosis Hospitalization Rates, Discharge Disposition, and Outcomes for Medicare Beneficiaries, 131 AM. J. MED. 1200, 1202 (2018).

[17] *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, CTR. FOR MEDICARE & MEDICAID SERVS. (Aug. 2024) https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[18] *What is Cardiovascular Disease?*, AM. HEART ASSOC. (Jan. 10, 2024) https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease.

[19] *See* Office of Minority Health, *Stroke Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (July 2021), https://www.cms.gov/files/document/omhdatasnapshot-strokepdf.pdf (6 percent of Black beneficiaries, 4 percent of white beneficiaries, 4 percent of Hispanic beneficiaries, 4 percent of American Indian and Alaska Natives, and 3 percent of Asian/Pacific Islander beneficiaries suffered from strokes in 2019.); Richard White & Craig Keenan, *Effects of Race and Ethnicity on the Incidence of Venous*

The Inflation Reduction Act of 2022 has provided the federal government with a powerful tool to improve health outcomes. Combined with other critical IRA elements—including an insulin cost cap of $35 per month for Medicare beneficiaries, a cost-sharing redesign for Medicare Part D benefits, and inflation rebates for Medicare Part B and D prescription drugs—the new Medicare drug price negotiations will cut the cost of prescription drugs.[20] These price cuts will save the Medicare program billions, enabling it to divert resources towards improving health outcomes for those most in need.[21] While the amici did not file a brief in the lower court, amici seek to provide this Court with an understanding of how high drug prices and costs exacerbate existing health inequities. Amici then

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Thromboembolism, 123 THROMBOSIS RES. S11, S12, S14 (2009); Abdul Mannan Khan Minhas et al., *Family Income and Cardiovascular Disease Risk in American Adults*, 13 SCI. REPS. 1, 5 (2023). There is no set definition for "low income" because it is dependent on the geographic area and median income in that area. The federal government uses several different measurements. HUD calculates "low income" as families earning 50-80 percent of the "area median income," HUD also maintains a database of "state median income," where low income families earn 50-80 percent below the state's median income. The U.S. government calculates eligibility for federal aid based on the "federal poverty level" determined by the U.S. Department of Health and Human Services' poverty guidelines for household size. Office of State and Community Energy Programs, *Low-Income Community Energy Solutions*, ENERGY.GOV, https://www.energy.gov/scep/slsc/low-income-community-energy-solutions (last visited Sept. 16, 2024).

[20] *See infra* Section II.C.

[21] *See infra* Section II.C.

explain how the IRA's Medicare drug price negotiations will help to alleviate that unfairness, bringing the United States closer to the goal of achieving health equity.

II. ARGUMENT

A. Socioeconomic inequities drive worse health outcomes among some Medicare beneficiaries.

First, Medicare enrollees who are Black, Latino, women, disabled, and/or LGBTQI+ are "more likely to have less money saved, lower incomes, and a greater likelihood of poverty . . . ."[22] Racial wealth disparities between Black and Hispanic Medicare beneficiaries and white beneficiaries are particularly staggering. As of 2019, the median savings of white Medicare beneficiaries was *over seven times*

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[22] Nicole Rapfogel, *5 Facts to Know About Medicare Drug Price Negotiations*, CTR. FOR AM. PROGRESS (Aug. 30, 2023), https://www.americanprogress.org/article/5-facts-to-know-about-medicare-drug-price-negotiation/; *see* Gillian Tisdale & Nicole Rapfogel, *Medicare Drug Price Negotiations Will Help Millions of Seniors and Improve Health Equity*, CTR. FOR AM. PROGRESS (July 17, 2023), https://www.americanprogress.org/article/medicare-drug-price-negotiation-will-help-millions-of-seniors-and-improve-health-equity/; Wyatt Koma et al., *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic*, KAISER FAMILY FOUND. (Apr. 24, 2020), https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/; Bianca D.M. Wilson, *LGBT Poverty in the United States: Trends at the Onset of COVID-19*, WILLIAMS INST. (Feb. 2023); Rebecca Vallas, *Economic Justice Is Disability Justice*, THE CENTURY FOUND. (April 21, 2022), https://tcf.org/content/report/economic-justice-disability-justice/; Robin Bleiweis, Jocelyn Frye, & Rose Khattar, *Women of Color and the Wage Gap*, CTR. FOR AM. PROGRESS (Nov. 17, 2021), https://www.americanprogress.org/article/women-of-color-and-the-wage-gap/.

higher than that of Black beneficiaries and *eight times higher* than that of Hispanic beneficiaries.[23] These disparities reflect, in part, "fewer opportunities among Black and Hispanic adults to accumulate wealth and transfer wealth from one generation to the next."[24] Such disparities mean that high medication costs hit Black and Hispanic Medicare enrollees harder—turning the underlying financial inequity into a health inequity.[25]

The same is true of women, the LGBTQI+ community, and disabled people, who are also more likely to have lower incomes, creating barriers to prescription access.[26] The median savings of women enrolled in Medicare was only 72 percent of their male counterparts.[27] And women who are Medicare beneficiaries spend 13 percent more on out-of-pocket costs for medical care.[28] Additionally, 19 percent of LGBT adults over 65 live under the federal poverty line compared to 15 percent of

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[23] Alex Cottrill et al., *Income and Assets of Medicare Beneficiaries in 2023*, KAISER FAMILY FOUND. (Fed. 5, 2024), https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-in-2023/ ("Median savings among White beneficiaries ($158,950 per person) was more than seven times higher than among Black beneficiaries ($22,100), and more than eight times higher than among Hispanic beneficiaries ($20,050).").

[24] Nancy Ochieng et al., *Racial and Ethnic Health Inequities and Medicare*, KAISER FAMILY FOUND. 10 (Feb. 2021).

[25] Tisdale & Rapfogel, *supra* note 22.

[26] *Id*.

[27] *Id.*

[28] *Id*.

straight and cisgender adults over 65.[29] For disabled Medicare enrollees under the age of 65 in 2023, the median income was $23,900—lower than the median income for Medicare beneficiaries ($36,000).[30]

Second, it is well-documented that stress, racism, and discrimination drive poor health outcomes.[31] Black and Hispanic people, as well as lower-income individuals, report higher levels of stress than their white and more affluent counterparts.[32] Numerous studies demonstrate that repeated exposure to stress, such as racial and ethnic discrimination, leads to greater allostatic load—accumulated wear and tear on the body, which can increase risk for obesity, hypertension, high cholesterol, and cigarette smoking that can lead to adverse cardiovascular outcomes, such as blood clotting.[33] The link between stress and

[29] Lauren Bouton et al., *LGBT Adults Aged 50 and Older in the US During the COVID-19 Pandemic*, WILLIAMS INST. 3 (Jan. 2023), https://williamsinstitute.law.ucla.edu/publications/older-lgbt-adults-us/.

[30] Cottrill, *supra* note 23.

[31] Yin Paradies et al., *Racism as a Determinant of Health: A Systematic Review and Meta-Analysis*, 10 PLOS ONE 1, 24-27 (Sept. 23, 2015); APA Working Group Report on Stress and Health Disparities, *Stress and Health Disparities: Contexts, Mechanisms, and Interventions Among Racial/Ethnic Minority and Low Socioeconomic Status Populations*, AM. PSYCH. ASS'N 5 (2017).

[32] APA Working Group Report, *supra* note 31, at 1; Aric A. Prather, *Stress Is a Key To Understanding Many Social Determinants of Health*, HEALTH AFFAIRS (Feb. 24, 2020), https://www.healthaffairs.org/content/forefront/stress-key-understanding-many-social-determinants-health.

[33] *See Stroke*, JOHNS HOPKINS MEDICINE,

cardiovascular disease, in particular, is "fairly robust."[34] As an example of this link, one study found that self-reported interpersonal racism in employment, housing, and interactions with the police was associated with a 38 percent higher risk of stroke for Black women.[35] Finally, stress suppresses the immune system, leaving individuals more susceptible to disease.[36]

Discrimination and a lack of access to culturally responsive care also deters some populations from obtaining needed medical treatment For racial and ethnic minorities, 24 percent of Black patients, 19 percent of Native American patients, 15 percent of Latino patients, and 11 percent of Asian patients report experiencing racial discrimination while receiving medical care.[37] As a result of concern about

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https://www.hopkinsmedicine.org/health/conditions-and-diseases/stroke (accessed Sept. 9, 2024); *Risk Factors for Venous Thromboembolism*, AM. HEAR ASSOC. (Nov. 13, 2023), https://www.heart.org/en/health-topics/venous-thromboembolism/risk-factors-for-venous-thromboembolism-vte; Prather, *supra* note 32; Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFFAIRS (Oct. 4, 2018), https://www.healthaffairs.org/do/10.1377/hpb20180817.901935/; Bruce S. McEwen, *Protective and Damaging Effects of Stress Mediators*, 338 NEW ENG. J. MED. 171, 172 (1998); Office of Minority Health, *Stroke and African Americans*, DEPT. OF HEALTH & HUMAN SERV. (accessed Aug. 27, 2024) https://minorityhealth.hhs.gov/stroke-and-african-americans.

[34] Prather, *supra* note 32.

[35] Shanshan Sheehy, Perceived Interpersonal Racism and Incident Stroke Among US Black Women, 6 JAMA NET. OPEN 1, 4 (2023).

[36] McEwen, *supra* note 33, at 176.

[37] Samantha Artiga, et al., *Survey on Racism, Discrimination and Health:*

discrimination or poor treatment due to race, 22 percent of Black Americans, 17 percent of Latinos, and 15 percent of Native Americans have avoided seeking medical care for themselves or a member of their family, compared to nine percent of Asian Americans and only three percent of white people.[38] LGBTQ people similarly lack access to culturally responsive care. For example, eight percent of LGBTQ people reported avoiding or postponing "needed medical care because of disrespect or discrimination from health care staff," with the number rising to 22 percent for transgender respondents.[39] Inability to obtain responsive care affects detection and treatment of disease, which, in turn, increases health inequity.[40] In short, racism and other forms of discrimination drive poor health outcomes and

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Experiences and Impacts Across Racial and Ethnic Groups, KAISER FAMILY FOUNDATION (Dec. 5, 2023) https://www.kff.org/report-section/survey-on-racism-discrimination-and-health-findings/.

[38] *Discrimination in America: Final Summary*, ROBERT WOOD JOHNSON FOUND., NPR & HARVARD T.H. CHAN SCH. PUB. HEALTH 13 (Jan. 2018).

[39] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/.

[40] Courtney H. Van Houtven et al, *Perceived Discrimination and Reported Delay of Pharmacy Prescriptions and Medical Tests*, 20 J. GEN. INTERNAL MED. 578, 580 (2005) (finding that the odds of delaying filling prescriptions were significantly for persons who perceived unfair treatment and the odds of delaying tests or treatments were significantly higher for persons who thought racism was a problem in health care locally).

prevent their treatment, trapping individuals in a vicious cycle of deteriorating health.

Third, where individuals live plays a critical role in health care and prescription drug access.[41] For example, Black and Hispanic Medicare beneficiaries are more likely to live in medical deserts—areas with fewer primary care physicians and high-quality hospitals—making it harder for these individuals to access health care.[42] Ten percent of Black and 11 percent of Hispanic Medicare beneficiaries reported trouble accessing needed care, compared to six percent of white beneficiaries.[43] In large cities, where the majority of Black and Latino people live, Black and Latino people are more likely to live in pharmacy deserts—neighborhoods where the average distance to a pharmacy is one mile or more — which means they experience greater geographic barriers to filling their prescriptions.[44] Black and Hispanic Medicare beneficiaries are also more likely to

[41] *CMS Framework for Health Equity 2022-2023*, CTRS. FOR MEDICARE & MEDICAID SERVS. 13 (Apr. 2022).

[42] Yearby, Clark, & Figueroa, *supra* note 4, at 192 ("One reason racial and ethnic minority communities are underserved is that they have been drained of vital health resources through public hospital closures and the flight of nonprofit hospitals from minority communities to predominantly White communities.").

[43] Ochieng, *supra* note 24, at 17.

[44] *Pharmacy Deserts' Disproportionately Affect Black and Latino Residents in Largest U.S. Cities,* USC SCHAEFFER CENTER (May 3, 2021), https://healthpolicy.usc.edu/article/pharmacy-deserts-disproportionately-affect-black-and-latino-residents-in-largest-u-s-cities/.

live in areas with low quality hospitals.[45] A general shortage of physicians, including a nationwide shortage of over 13,000 primary care doctors, will continue to exacerbate this trend.[46] For cardiovascular disease, 16.8 million Black Americans live in areas with limited or no access to a cardiologist, and nearly 2.5 million Black Americans live in a county with no cardiologist.[47] Quality medical care is something that people tend to have only when they also have a lot of other things.

Fourth, and especially relevant in a case concerning the cost of Xarelto, strokes and pulmonary embolisms disproportionately impact some racial and ethnic minorities, LGBTQ+ people, disabled people, and people with low incomes.[48] Among Medicare beneficiaries, the prevalence of stroke is highest among Black beneficiaries (6 percent), followed by American Indian and Native

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[45] Ochieng, *supra* note 24, at 23.

[46] *See Healthcare Workforce Shortage Areas*, HEALTH RESOURCES & SERVS. ADMIN. https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited Sept. 16, 2024); Jacqueline Howard, *Concern Grows Around US Health-care Workforce Shortage: 'We don't have Enough Doctors*,' CNN (May 16, 2023, 11:00 AM), https://www.cnn.com/2023/05/16/health/health-care-worker-shortage/index.html.

[47] Trinidad Cisneros, *More than 16 Million Black Americans Live In Counties with Limited or No Access to Cardiologists*, GOODRX HEALTH (May 2, 2023) https://www.goodrx.com/healthcare-access/research/black-americans-cardiology-deserts.

[48] Tisdale & Rapfogel, *supra* note 22.

Alaskan, Hispanic, and White (4 percent) beneficiaries, and then Asian/Pacific Islander beneficiaries (3 percent).[49] One study found pulmonary embolism among Black men was 47 percent higher compared to white people, and 62 percent higher among Black women.[50] Black patients on average also have higher stroke and pulmonary embolism mortality than other races and ethnicities.[51] Studies have also found elevated rates of risk factors for stroke in the LGBTQ+ community, including higher rates of smoking, alcohol consumption, and poor mental health.[52] People with lower incomes also have a higher risk of stroke, experience more

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[49] Office of Minority Health, *Stroke Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (July 2021); *Age-Adjusted Total Stroke Mortality Rates by Race/Ethnicity*, AM. HEART ASSOC. (NOV. 11, 2020) https://www.heart.org/en/about-us/2024-health-equity-impact-goal/age-adjusted-total-stroke-mortality-rates-by-raceethnicity ("Black adults are 45 percent are likely to die from stroke.").

[50] Dona Schneider et al., *The Epidemiology of Pulmonary Embolism: Racial Contrasts in Incidence and In-Hospital Case Fatality*, 98 J. NAT'L MED. ASSOC. 1967, 1970 (2006).

[51] Amanda R. Phillips, et al., *Association Between Black Race, Clinical Severity, and Management of Acute Pulmonary Embolism: A Retrospective Cohort Study*, 10 J. Am. Heart Assoc. 1, 4 (2021); Mohamed Zghouzi, et al., *Sex, Racial, and Geographic Disparities in Pulmonary Embolism-Related Mortality Nationwide*, 20 AN. AM. THORACIC SOC. 1571, 1574 (2023).

[52] Billy Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities*, 107 AM. J. PUBLIC HEALTH e13, e18 (2017); Carl Streed et al., A*ssessing and Addressing Cardiovascular Health in People who are Transgender and Gender Diverse: A Scientific Statement from the American Heart Association*, 144 CIRCULATION e136, e139-e140, e144 (2021); Risk Factors for Stroke, CTR FOR DISEASE CONTROL (May 15, 2024), https://www.cdc.gov/stroke/risk-factors/index.html.

severe strokes, have adverse outcomes after stroke, and have reduced access to treatment.[53] Older adults living in poverty who are hospitalized for pulmonary embolism have higher 1-year mortality rates compared to older adults not living in poverty.[54]

B. High prescription drug prices exacerbate existing health and financial burdens among these same groups of Medicare beneficiaries.

Placing a high price tag on medications—and preventing the federal government from negotiating down that price for the Medicare population—drives poor health outcomes within the same populations predisposed to worse health outcomes. The Centers for Disease Control and Prevention has shown that people that do not fill their prescriptions because of cost employ strategies like "skipping doses, taking less than the prescribed dose, or delaying filling a prescription."[55]

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[53] Minhas, supra note 18, at 5; Juliet Addo, et al., *Socioeconomic Status and Stroke: An Updated Review*, 43 STROKE 1186, 1189 (2012).

[54] Rishi Wadhera, et al., *Association of Socioeconomic Disadvantage with Mortality and Readmission Among Older Adults Hospitalized for Pulmonary Embolism in the United States*, 10, J. AM. HEART ASSOC. 1, 5 (2021); Ioannis Farmakis, et al., *Social Determinants of Health in Pulmonary Embolism Management and Outcome in Hospitals: Insights from the United States Nationwide Inpatient Sample*, 7 RES. PRACTICE THROMBOSIS & HAEMOSTASIS 1, 3 (2022).

[55] Laryssa Mykyta & Robin Cohen, *Characteristics of Adults Aged 18-64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, CTRS. FOR MEDICARE & MEDICAID SERVS., NAT'L CTR. FOR HEALTH STATS., Data Brief No. 470, at 5 (June 2023).

These cost-saving strategies can result in more serious illnesses, more expensive treatments, and even death.[56] For example, a 2021 working paper from the National Bureau of Economic Research found that an increase in Medicare Part D recipients' out-of-pocket liability for prescription drugs of $100 per month resulted in 13.9 percent higher mortality compared to other patients with greater coverage.[57] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[58] For example, patients at greatest risk of stroke and heart attack were four times more likely to interrupt their cardiovascular drugs after an increase in costs than patients at a lower risk of such conditions.[59] Simply put, when the sickest patients are among the least-resourced, high drug prices can be dangerous.

Some populations within Medicare are more likely to experience affordability problems and forgo their prescribed medications due to cost. Among

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[56] *Id.*; Nicole Rapfogel, Maura Calsyn, & Colin Seeberger, *7 Ways Drug Pricing Legislative Proposals Would Lower Costs for Consumers and Business*, CTR. FOR AM. PROGRESS (July 26, 2021), https://www.americanprogress.org/article/7-ways-drug-pricing-legislative-proposals-lower-costs-consumers-businesses/.

[57] Amitabh Chandra, Evan Flack, & Ziad Obermeyer, *The Health Costs of Cost-Sharing* 4 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28439, 2023) ("For each $100/month decrease in the pre-donut budget caused by enrollment month (on average, a 24.4% change in our sample), mortality increases by 0.0164 p.p. per month (13.9%).").

[58] *Id.*

[59] *Id.*

Medicare beneficiaries older than 65 in 2019, 6.6 percent reported affordability problems with prescriptions, and 2.3 million older adults did not get needed prescriptions due to cost.[60] Latino and Black adults over 65 were 1.5 times more likely to have affordability problems and two times more likely not to get a prescription due to cost as white adults over 65.[61] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[62] Women over 65 with Medicare are more likely to experience prescription drug affordability problems than men.[63] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the general Medicare population.[64] A 2018 study of California adults over 60 showed that over 21 percent of lesbian, gay, and bisexual adults over 60 delayed or did not fill prescriptions because of cost compared to 9.8 percent of straight adults over 60.[65] High prescription drug costs lead to non-adherence and associated adverse

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[60] Wafa Tarazi et al., *Data Point: Prescription Drug Affordability among Medicare Beneficiaries*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. 3 (Jan. 19, 2022).

[61] *Id.* at 3.

[62] Farrah Nekui et al., *Cost-Related Medication Nonadherence and its Risk Factors Among Medicare Beneficiaries*, 59 MED. CARE 13, 13 (2021).

[63] Tisdale & Rapfogel, *supra* note 22; Tarazi, *supra* note 60, at 3.

[64] Tisdale & Rapfogel, *supra* note 22.

[65] Brad Sears & Kerith J. Conron, *LGBT People & Access to Prescription Medications*, THE WILLIAMS INSTITUTE, UCLA SCHOOL OF LAW 7 (Dec. 2018).

health impacts, and those outcomes are disproportionately felt and borne by historically marginalized communities.

C. The IRA's Medicare drug price negotiations will advance health equity by lowering beneficiaries' out-of-pocket medication costs and strengthening the Medicare program overall.

Access to more affordable medication is necessary to reduce the health and wealth disparities outlined above. Medicare's new drug price negotiation authority makes significant inroads toward this goal by lowering drug costs for the program as a whole.[66]

Historically, Medicare has "has helped to mitigate racial and ethnic inequities in health care in its role as both a regulator and the largest single purchaser of personal health care in the U.S."[67] Medicare currently provides health insurance to 67 million Americans, with 54 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[68] In 2018, Medicare Part D enrollment rates were higher among Black beneficiaries (72 percent) and

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[66] *See FACT SHEET: How Medicare's New Drug Price Negotiation Power Will Advance Health Equity*, PROTECT OUR CARE (Sept. 27, 2023), https://www.protectourcare.org/fact-sheet-how-medicares-new-drug-price-negotiation-power-will-advance-health-equity/.

[67] Ochieng, *supra* note 24, at 1.

[68] *Medicare Monthly Enrollment*, CTR. FOR MEDICARE & MEDICARE SERVS (May 2024) https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.

Hispanic beneficiaries (75 percent) than among white beneficiaries (70 percent).[69] In 2019, Medicare Part D enrollment rates were also higher among women (57 percent) than among men (43 percent).[70] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[71]

While Medicare Part D helps cover the costs of prescription drugs, beneficiaries must still pay part of those costs and, historically, Part D patient out-of-pocket expenses have been significant. In 2019, the median income of Medicare beneficiaries 65 and older was around $36,000, and one in four beneficiaries had an income below $21,000.[72] Households in which all members are covered by Medicare also spend a greater percentage of their household spending on health care-related expenses; in 2021, one in three Medicare households spent 20 percent or more of their household spending on health-related expenses compared with one in 14 non-Medicare households.[73] A 2021 poll conducted by Gallup found that one

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[69] Ochieng, *supra* note 24, at 16.

[70] Wafa Tarazi et al., *Issue Brief: Medicare Beneficiary Enrollment Trends and Demographic Characteristics*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. 10 (Mar. 2, 2022).

[71] *Id.* at 9.

[72] Cottrill, *supra* note 23.

[73] Nancy Ochieng, Juliette Cubanski, & Anthony Damico, *Medicare Households Spend More on Health Care than Other Households*, KAISER FAMILY FOUND. (July 19, 2023), https://www.kff.org/medicare/issue-brief/medicare-households-spend-more-on-health-care-than-other-households/.

in four adults 65 and older cut back on necessities like medication, food, utilities, and clothing due to health care costs.[74] Put simply, the high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[75]

As the government explained in its briefing,[76] the IRA empowers the Secretary of Health and Human Services, on behalf of the Medicare program, to directly negotiate lower prices for certain medications that are responsible for high aggregate Medicare spending and do not have a generic or biosimilar competitor.[77] In 2023, Medicare spent $56.2 billion on the 10 drugs selected for negotiation, and about *$6.3 billion on Xarelto alone*.[78] Medicare's staggering spending on Xarelto is

[74] Nicole Willcoxon, *Older Adults Sacrificing Basic Needs Due to Healthcare Costs,* GALLUP (June 15, 2022), https://news.gallup.com/poll/393494/older-adults-sacrificing-basic-needs-due-healthcare-costs.aspx.

[75] More than half of adults 65 and older report taking four or more prescription drugs. Ashley Kirzinger et al., *Data Note: Prescription Drugs and Older Adults*, KAISER FAMILY FOUND. (Aug. 9, 2019), https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

[76] Defs.' Memo. of Law in Support of Defs.' Opp'n to Pl.'s Mot. For Summ. J. and Cross-Mot. at 1, ECF No. 33 (D.N.J. Oct. 16, 2023).

[77] *Memorandum from Meena Seshamani, CMS Deputy Administrator and Director of the Center for Medicare*, CTRS. FOR MEDICARE AND MEDICAID SERVS. 104 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[78] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1-2 (Aug. 2024).

in part due to Janssen's relentless price hikes: since 2011, Janssen has raised the price of Xarelto by 168 percent—just under 6 times the rate of inflation.[79] Between just 2018 and 2022, the total annual Medicare Part D spending per enrollee taking Xarelto rose from $3,197 to $4,402 a 38 percent increase.[80]

By allowing the federal government to negotiate the purchase price of essential medicines for Medicare, the IRA's drug price negotiation program is projected to reduce the federal budget deficit by nearly *$100 billion by 2031*.[81] In 2023, the CBO has further estimated that by 2031 net prices for the drugs selected for negotiation will decrease by 50 percent on average.[82]

These savings buy the federal government room to drastically improve Medicare affordability and access. The IRA's Medicare drug price negotiations will directly enable the Medicare program to both expand subsidized care and lower beneficiary out-of-pocket drug costs, thereby reducing health inequities. For example, in January 2024, CMS began implementing IRA Section 11404,

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[79] Leigh Purvis, *Prices for Top Medicare Part D Drugs Have More than Tripled Since Entering the Market*, AARP PUBLIC POLICY INSTITUTE 2 (Aug. 10, 2023).

[80] Xarelto: Medicare Enrollee Use and Spending, supra note 14, at 1.

[81] *Cost Estimate*, CONG. BUDGET OFF. 5 (revised Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

[82] *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, CONG. BUDGET OFF. 10 (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

expanding the Medicare Part D low-income subsidy (LIS) program (also known as "Extra Help") for people with incomes up to 150 percent of the federal poverty level.[83] LIS generally limits out-of-pocket costs to $4.50 for generic drugs and $11.20 for brand drugs.[84] The expansion of LIS is estimated to cover 300,000 more low-income Medicare beneficiaries.[85] This year, the IRA also eliminates the five percent coinsurance requirement in the catastrophic coverage phase from its Medicare Part D benefit design, and beginning in 2025, the IRA will cap Part D out-of-pocket expenses at $2,000 for all Medicare beneficiaries, a major improvement over the current Part D benefit design.[86] Finally, the IRA includes a provision that institutes a $35 out-of-pocket cap for a month's supply of Medicare-covered insulin products, which was made effective January 2023 for Part D

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[83] *Fact Sheet: 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 5, 2023), https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f.

[84] *Saving Money with the Prescription Drug Law*, MEDICARE.GOV, https://www.medicare.gov/about-us/prescription-drug-law (last visited Sept. 16, 2024).

[85] *Fact Sheet: 2024 Medicare Advantage*, *supra* note 83.

[86] Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAMILY FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

beneficiaries and July 2023 for Part B beneficiaries.[87] Experts have concluded that the IRA's drug price negotiation program, as well as the IRA's inflation rebates, are what make these affordability measures possible.[88]

On August 15, 2024, HHS announced negotiated drug prices for the first ten drugs to undergo negotiations.[89] These prices will take effect in 2026.[90] The Biden-

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[87] *Research Report: Inflation Reduction Act Research Series—Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. 4 (Dec. 14, 2023), https://aspe.hhs.gov/sites/default/files/documents/4bf549a55308c3aadc74b34abcb7a1d1/ira-drug-negotiation-report.pdf.

[88] *See, e.g.*, Jonathan Cohn, *This is the Most Unprecedented Part of the Democratic Prescription Drug Bill,* HUFFINGTON POST (Aug. 6, 202), https://www.huffpost.com/entry/prescription-drug-medicare-part-d-cap_n_62ed95cde4b09fecea4e24d4; Richard Eisenberg, *Medicare Will Negotiate Drug Prices with Big Pharma for the First Time. Here's How Your Prescription Costs Might Change*, FORTUNE WELL (Oct. 25, 2023, 4:07 PM) https://fortune.com/well/2023/10/25/medicare-drug-price-negotiation-affect-prescription-costs/ ("Kesselheim says the cap on catastrophic prescription prices made it into the Inflation Reduction Act *because* Medicare will save so much money through drug price negotiations."); Stephanie Sy, Dorothy Hastings, & Laura Santhanam, *Medicare Drug Price Negotiations Could Save Government Billions*, PBS NEWS HOUR (Aug. 29, 2023, 6:45 PM), https://www.pbs.org/newshour/show/medicare-drug-price-negotiations-could-save-government-billions; Juliette Cubanski, Tricia Neuman, Meredith Freed, & Anthony Damico, *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, KAISER FAMILY FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.

[89] *Medicare Drug Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, supra note 17 at 1.

[90] *Id.* at 2.

Harris administration estimates that had the negotiated prices been in effect in 2023, the Medicare program would have saved $6 billion (in other words, Medicare would have benefited from a 22 percent reduction in those drug costs).[91] The administration estimates that combined across the ten drugs, negotiated prices will result in Medicare beneficiaries saving an estimated $1.5 billion in out-of-pocket costs when the prices go into effect in 2026.[92] While the exact beneficiary savings for Xarelto specifically is not yet known, HHS secured a 62 percent discount from the drug's 2023 list price, bringing the cost down from $517 to $197 for a 30-day supply.[93] In 2022, Medicare beneficiaries paid $451 on average in out-of-pocket costs for Xarelto.[94] Cost-savings from the drug negotiation program are likely to result in savings to beneficiaries in the form of premium decreases over time, along with lower copays or coinsurance.[95]

III. CONCLUSION

Lowering Medicare drug prices will work to ameliorate some of the systematic and persistent inequities that have prevented many Americans from

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[91] *Id.* at 4.

[92] *Id.* at 2.

[93] *Id.*

[94] *Xarelto: Medicare Enrollee Use and Spending*, *supra* note 14, at 1.

[95] See, e.g., Eisenberg, *supra* note 88; Sy, *supra* note 88; *Xarelto: Medicare Enrollee Use and Spending*, *supra* note 14, at 1.

obtaining the care needed to achieve good health outcomes. By enabling the expansion of subsidized care for low-income and historically marginalized communities and reducing Medicare beneficiaries' out-of-pocket costs, the IRA's drug price negotiation program will improve health equity. Lower out-of-pocket costs and improved subsidized coverage will increase patient prescription drug adherence, leading to reduced complications and better health outcomes. More affordable prescription drugs will also serve to close the treatment gap, helping to reduce inequity in the American health care system. For these reasons, amici respectfully request that the Court take health equity into consideration when making its decision.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this brief:

(i) Complies with the type-volume limitation of Rule 32(a)(7) because it contains 5,639 words, excluding the parts of the brief exempted by Rule 32(f); and

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Pursuant to Third Circuit Local Appellate Rules 28.3(d) and 46.1(e), I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Date: September 16, 2024

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CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on September 16, 2024, I electronically filed this Amicus Curiae Brief with the Court to all counsel of record via the CM/ECF system. I further certify that seven paper copies of the foregoing brief will be sent to the Clerk's office.

Date: September 16, 2024

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