24-1819

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

AstraZeneca Pharmaceuticals LP, *et al.*,

Plaintiff- Appellants,

---v.---

U.S. Secretary of Health & Human Services, *et al.*,

Defendant- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE, No. 1:23-cv-00931 (Connolly, J.)

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

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Other Authorities

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.

Amicus submits 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

[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 SERV., 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 exceeded $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

[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, the rationing of insulin medications is associated with more emergency room visits in the short term and a higher incidence of amputations, blindness, kidney failure, and death among diabetics in the long term.[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, 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, AstraZeneca Pharmaceuticals LP (AstraZeneca), manufactures Farxiga—a drug used to treat diabetes, heart failure, and chronic kidney disease.[13] Of Medicare enrollees, 28 percent have diabetes, 1 in

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[10] *See* Mary Caffrey, *Gathering Evidence on Insulin Rationing: Answers and Future Questions*, 25 AM. J. MANAGED CARE (Sep. 26, 2019), https://www.ajmc.com/view/gathering-evidence-on-insulin-rationing-answers-and-future-questions; Stephen R. Benoit et al., *Trends in Emergency Department Visits and Inpatient Admissions for Hyperglycemic Crises in Adults with Diabetes in the U.S., 2006–2015*, 43 DIABETES CARE 1057, 1061 (Mar. 11, 2020).

[11] *See infra* notes 67-68.

[12] *Id.*

[13] *Fact Sheet: Inflation Reduction Act Research Series—Farxiga: Medicare Enrollee Use and Spending*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERV. (Nov. 2, 2023),

4 have been diagnosed with chronic kidney disease, and 15 percent have heart failure.[14] As a result, it is unsurprising that, in 2023, about 994,000 Part D beneficiaries filled prescriptions for Farxiga.[15] With respect to health equity, diabetes, chronic kidney disease, and heart failure disproportionately affect racial and ethnic minorities and low-income people.[16]

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https://aspe.hhs.gov/sites/default/files/documents/3950eb2fe9aaa75c39adac742be3e90f/Farxiga.pdf.

[14] *Id.*

[15] *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.

[16] *See* Office of Minority Health, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERV. 1 (Jan. 2024) ("[P]revalence of heart failure is highest among Black/African American beneficiaries (15%), followed by American Indian/Alaska Native (14%), White (11%), Hispanic (11%), and Asian/Pacific Islander (9%) beneficiaries."); Felicia Hill-Briggs et al., *Social Determinants of Health and Diabetes: A Scientific Review*, 44 DIABETES CARE 258, 260-61 (2021) ("Prevalence of diabetes increases on a gradient from highest to lowest income."); Office of Minority Health, *Racial and Ethnic Disparities in Diabetes Prevalence, Self-Management, and Health Outcomes among Medicare Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERV. 11 (Mar. 2017) ("[D]iabetes prevalence, including both Type 1 and Type 2 diabetes, was higher among Black and Hispanic beneficiaries compared to White beneficiaries, with prevalence highest among Black beneficiaries (30.0 percent)."); Office of Minority Health, *Chronic Kidney Disease Disparities in Medicare Fee-for-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERV. 2 (Mar. 2022) https://www.cms.gov/files/document/data-snapshot-ckd-march-2022.pdf. 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

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.[17] These price cuts will save the Medicare program billions, enabling it to divert resources towards improving health outcomes for those most in need.[18]

While amici did not file an amicus brief in the lower court, the amici seek now to provide this Court with an understanding of how high drug prices and costs exacerbate existing health inequities. Amici argue that 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.

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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 Dec. 1, 2023).

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

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

II. ARGUMENT

A. Socioeconomic inequities drive worse health outcomes among 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 . . . ."[19] Racial wealth disparities between Black and Hispanic Medicare beneficiaries and white beneficiaries are particularly staggering. As of 2023, the median savings of white Medicare beneficiaries was *over seven times higher* than that of Black beneficiaries and *eight times higher* than that of Hispanic beneficiaries.[20] These disparities reflect, in part, "fewer opportunities among Black and Hispanic adults to accumulate wealth and transfer wealth from one generation

[19] 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/.

[20] 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).")

to the next."[21] Such disparities mean that high medication costs hit Black and Hispanic Medicare enrollees harder—turning the underlying financial inequity into a health inequity.[22]

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.[23] The median savings of women enrolled in Medicare was only 72 percent of their male counterparts.[24] And women who are Medicare beneficiaries spend 13 percent more on out-of-pocket costs for medical care.[25] Additionally, 19 percent of LGBT adults over 65 live under the federal poverty line compared to 15 percent of straight and cisgender adults over 65.[26] 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).[27]

Second, it is well-documented that stress, racism, and discrimination drive

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

[22] Tisdale & Rapfogel, *supra* note 19.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] 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/.

[27] Cottrill, *supra* note 20.

poor health outcomes.[28] Black and Hispanic people, as well as lower-income individuals, report higher levels of stress than their white and more affluent counterparts.[29] Numerous studies demonstrate that repeated exposure to stress leads to greater allostatic load—accumulated wear and tear on the body, such as elevated blood pressure that can lead to adverse cardiovascular outcomes and chronic kidney disease progression.[30] The link between stress and cardiovascular disease, in particular, is "fairly robust."[31] Stress also negatively impacts the endocrine system—the malfunctioning of which causes diabetes and other

[28] 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).

[29] APA Working Group Report, *supra* note 28, 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.

[30] *See* Prather, *supra* note 29; 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) ("[S]urges in blood pressure can trigger myocardial infarction in susceptible persons, 17 and in primates repeated elevations of blood pressure over periods of weeks and months accelerate atherosclerosis, 18 thereby increasing the risk of myocardial infarction."); Marino A. Bruce, et al., *Stress and the Kidney*, ADV. CHRONIC KIDNEY DISEASE 46 (2015).

[31] Prather, *supra* note 29.

disorders.[32] As an example of this link, one study found that Black women "in the highest quartile of exposure to everyday racism had a 31% increased risk of diabetes, and women with the highest exposure to lifetime racism had a 16% increased risk . . . ."[33] Finally, stress suppresses the immune system, leaving individuals more susceptible to disease.[34]

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.[35] As a result of concern about discrimination or poor treatment due to race, 22 percent of Black Americans, 17

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[32] *See* McEwen, *supra* note 30, at 172, 176; *Endocrine and Metabolic Disorders*, WASHINGTON UNIV. SCH. MED., https://endocrinology.wustl.edu/patient-care/patient-education/endocrine-and-metabolic-disorders/#:~:text=Diabetes%20mellitus%2C%20otherwise%20known%20as,6.5%25%20of%20the%20U.S.%20population (last visited Dec. 13, 2023) (explaining the link between diabetes and the endocrine system).

[33] Hill-Briggs, *supra* note 16, at 263, 271 (citing K.L. Bacon et al., *Perceived racism and incident diabetes in the Black Women's Health Study*, 60 DIABETOLOGIA 2221 (2017)).

[34] McEwen, *supra* note 30, at 176.

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

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 whites.[36] 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.[37] Inability to obtain responsive care affects detection and treatment of disease, which, in turn, increases health inequity.[38] In short, racism and other forms of discrimination drive poor health outcomes and prevent their treatment, trapping individuals in a vicious cycle of deteriorating health.

Third, where individuals live plays a critical role in health care and

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[36] *Discrimination in America: Final Summary,* Robert Wood Johnson Found., NPR & Harvard T.H. Chan Sch. Pub. Health 13 (Jan. 2018).

[37] 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/.

[38] 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).

prescription drug access.[39] 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.[40] Ten percent of Black and 11 percent of Hispanic Medicare beneficiaries reported trouble accessing needed care, compared to six percent of white beneficiaries.[41] 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.[42] Black and Hispanic Medicare beneficiaries are also more likely to live in areas with low quality hospitals.[43]

For diabetes care, the geographic regions with the highest prevalence of

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

[40] 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.").

[41] Ochieng, *supra* note 21, at 17.

[42] *'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/.

[43] Ochieng, *supra* note 21, at 23.

diabetes are also characterized by the lowest rates of endocrinologists.[44] For heart 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.[45] A general shortage of physicians, including a shortage of primary care doctors, will continue to exacerbate this trend.[46] 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 Farxiga, diabetes disproportionately impacts racial and ethnic minorities, transgender people, disabled people, and people with low incomes.[47] Black and Hispanic Medicare beneficiaries are diagnosed with diabetes at younger ages and have higher rates of diabetes-related complications, such as high blood pressure, than

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[44] Hill-Briggs, *supra* note 16, at 269.

[45] 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.

[46] *See Healthcare Workforce Shortage Areas*, HEALTH RESOURCES & SERV. ADMIN. https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited Dec. 19, 2023); 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] *Racial and Ethnic Disparities in Diabetes Prevalence*, *supra* note 16, at 1 (Black (37 percent), Hispanic (38 percent) Medicare beneficiaries, and transgender (33 percent) had a higher prevalence of diabetes than White beneficiaries (25 percent)); Tisdale & Rapfogel, *supra* note 19.

white beneficiaries.[48] The rate of diabetes among Asian American Medicare beneficiaries sits at 35 percent compared 24 percent for white enrollees.[49] Specifically, Asian Indian beneficiaries are 70 percent more likely to be diagnosed with diabetes than white beneficiaries.[50] American Indian and Alaskan Native adults are also almost three times more likely to have diabetes than white adults,[51] and nearly a third of American Indians and Native Alaskans over 65 report having diabetes compared with 22 percent of the general population over 65.[52] American Indians and Native Alaskans are also *2.5 times more likely to die* from diabetes.[53]

In 2020, 16 percent of people with disabilities living in the United States had been diagnosed with diabetes compared to 7.5 percent of people without

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[48] *Racial and Ethnic Disparities in Diabetes Prevalence*, *supra* note 16, at 11.

[49] *Inflation Reduction Act Series—Projected Impact for Asian Medicare Enrollees*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERV. 3 (Sept. 2023).

[50] *Id*.

[51] Sofia Carratala & Connor Maxwell, *Health Disparities by Race and Ethnicity*, CTR. FOR AM. PROGRESS (May 7, 2020), https://www.americanprogress.org/article/health-disparities-race-ethnicity/.

[52] Cristina Boccuti, Christina Swoope, & Samantha Artiga, *The Role of Medicare and Indian Health Services for American Indians and Alaska Natives: Health, Access and Coverage*, KAISER FAMILY FOUND. (Dec. 18, 2014), https://www.kff.org/report-section/the-role-of-medicare-and-the-indian-health-service-for-american-indians-and-alaska-natives-health-access-and-coverage-report/.

[53] Carratala & Maxwell, *supra* note 51.

disabilities,[54] and people with cognitive limitations are up to five times more likely to have diabetes than those without.[55] LGTBQI+ people too are more likely to have diabetes: 25 percent of gay and bisexual men and 14 percent of lesbian and bisexual women have diabetes compared to 10 percent of the general population.[56] Finally, individuals with lower incomes are more likely to develop diabetes, with people with family incomes below the federal poverty level being two times more likely *to die of Type 2 diabetes* than those with incomes above it.[57]

Heart failure is also more prevalent among racial and ethnic minorities and people with disabilities. Among Medicare beneficiaries, the prevalence of heart failure is higher among Black (15 percent) and American Indian and Native

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[54] *Disability & Diabetes Prevention*, CTR. FOR DISEASE CONTROL (last updated Nov. 28, 2022), https://www.cdc.gov/ncbddd/disabilityandhealth/features/disability-and-diabetes-prevention.html.

[55] Gloria Krahn, Deborah Walker, & Rosaly Correa-De-Araujo, *Persons with Disabilities as an Unrecognized Health Disparity Population*, 105 AM. J. PUB. HEALTH 198, 201 (2015).

[56] *Diabetes the LGBTQ Community*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 15, 2024), https://www.cdc.gov/diabetes/risk-factors/diabetes-risk-lgbtq.html#:~:text=Lesbian%2C%20gay%2C%20bisexual%2C%20transgender,or%20bisexual%20women%20have%20it.

[57] Hill-Briggs, *supra* note 16, at 260-61.

Alaskan (14 percent) beneficiaries than white beneficiaries (11 percent).[58] Black people are also nearly 2.5 times more likely to be hospitalized for heart failure than white people and are more likely to die prematurely from heart failure than white people.[59] 10.4 percent of adults with disabilities have heart disease compared with 3.7 percent of adults without a disability.[60] Low-income people also have a higher risk of heart failure[61] and a greater risk of hospitalization and a higher rate of one-year mortality from heart failure.[62]

In 2020, 25 percent of Medicare beneficiaries had chronic kidney disease.[63] The prevalence of chronic kidney disease was highest among Black beneficiaries (36%) followed by American Indian/Alaska Native (32%), Hispanic (29%), and Asian/Pacific Islander beneficiaries, with white beneficiaries (24%) having the

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[58] Center for Medicare & Medicaid Services, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries* (Jan. 2024), https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Snapshot-Heart-Failure.pdf.

[59] Ileana L. Piña et al., *Race and Ethnicity in Heart Failure*, 78 J. Am. Coll. Cardiology 2589, 2589 (2021).

[60] *Disability Impacts All of Us*, CTR. FOR DISEASE CONTROL (July 2024), https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html.

[61] Abdul Mannan Khan Minhas et al., *Family Income and Cardiovascular Disease Risk in American Adults*, 13 SCI. REPS. 1, 5, 7 (2023).

[62] Nathaniel Hawkins et al., *Heart Failure and Socioeconomic Status: Accumulating Evidence of Inequality*, 14 EUR. J. HEART FAILURE 138, 141 (2012).

[63] *Farxiga: Medicare Enrollee Use and Spending*, supra note 13, at 1.

lowest prevalence.[64] Prevalence of chronic kidney disease is higher in LGBT+ men than their heterosexual counterparts, and both LGBT+ men and LGBT+ women are more likely to report higher incidences of known risk factors for chronic kidney disease.[65] Chronic kidney disease is also more common in people with low incomes.[66]

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."[67]

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[64] *Chronic Kidney Disease Disparities in Medicare*, supra note 16, at 2.

[65] Meghana Chandra, et al., *Prevalence of Self-Reported Kidney Disease in Older Adults by Sexual Orientation: Behavioral Risk Factor Surveillance System Analysis (2014-2019)*, 34 J. AM. SOC. NEPHROLOGY 682, 682 (2023).

[66] Yun Han et al., *Mapping the Overlap of Poverty Level and Prevalence of Diagnosed Chronic Kidney Disease Among Medicare Beneficiaries in the United States*, 21 PREVENTING CHRONIC DISEASE 1, 2 (2024).

[67] Laryssa Mykyta & Robin Cohen, *Characteristics of Adults Aged 18-64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, CENTERS FOR MEDICARE & MEDICAID SERV., 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.[68] 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 patients with greater coverage.[69] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[70] 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.[71]

[68] *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/.

[69] 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%).").

[70] *Id.*

[71] *Id.*

For diabetes, which AstraZeneca's drug treats, the consequences of poor medication adherence are especially stark.[72] In 2017, seven percent of adults over 65 with diabetes did not take their diabetes medication as prescribed because of cost.[73] Skipping medications results in worse glycemic control (i.e., control of blood sugar levels).[74] Deterioration in glycemic control, in turn, is associated with more emergency room visits, hospitalization, and complications from diabetes, such as hypertension, kidney disease, amputation, and even death.[75] One study found that cost-related medication non-adherence in diabetes patients was associated with an 18 percent greater risk of death.[76] There may also be racial and ethnic non-adherence disparities among diabetics: one study found that Black diabetes patients who did not use diabetes medication because of costs were 3.4 percent more likely to have preventable medical complications compared to white

[72] Polonsky, *Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and its Key Contributors*, 10 PATIENT PREFERENCE & ADHERENCE 1299, 1301 (2016).

[73] Robin Cohen & Amy Cha, *Strategies Used by Adults with Diagnosed Diabetes to Reduce their Prescription Drug Costs, 2017-2018*, CTRS. FOR MEDICARE & MEDICAID SERV., NAT'L CTR. FOR HEALTH STATS., Data Brief 349, at 2 (Aug. 2019).

[74] Polonsky, *supra* note 72, at 1301.

[75] *Id.*; *Manage Blood Sugar*, CTR. FOR DISEASE CONTROL (last updated Sep. 30, 2022), https://www.cdc.gov/diabetes/treatment/index.html.

[76] Sarah Van Alsten & Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000-2014*, PREVENTING CHRONIC DISEASE, Dec. 3, 2020, at 1, 4.

patients.[77] Simply put, when the sickest patients are among the least-resourced, high drug prices are dangerous.

Some populations within Medicare are more likely to experience affordability problems and forgo their prescribed medications due to cost. Among 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.[78] 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.[79] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[80] Women over 65 with Medicare are more likely to experience prescription drug affordability problems than men.[81] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the

[77] Yongkang Zhang, James Flory, & Yuhua Bao, *Chronic Medication Nonadherence and Potentially Preventable Healthcare Utilization and Spending Among Medicare Patients*, 37 J. GEN INTERNAL MED. 3645, 3648 (2022).

[78] 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 SERV. 3 (Jan. 19, 2022).

[79] *Id.* at 3.

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

[81] Tisdale & Rapfogel, *supra* note 19; Tarazi, *supra* note 78, at 3.

general Medicare population.[82] 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.[83] High prescription drug costs lead to non-adherence and associated adverse 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.[84]

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

[82] Tisdale & Rapfogel, *supra* note 19.

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

[84] *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/.

purchaser of personal health care in the U.S."[85] Medicare currently provides health insurance to 67 million Americans, with 54 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[86] In 2018, Medicare Part D enrollment rates were higher among Black beneficiaries (72 percent) and Hispanic beneficiaries (75 percent) than among white beneficiaries (70 percent).[87] In 2019, Medicare Part D enrollment rates were also higher among women (57 percent) than among men (43 percent).[88] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[89]

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 2023, the median income of Medicare beneficiaries 65 and older was around $36,000, and one in four beneficiaries had an income below $21,000.[90] Households in which all members are covered by

[85] Ochieng, *supra* note 20, at 1.

[86] *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.

[87] Ochieng, *supra* note 20, at 16.

[88] 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 SERV. 10 (Mar. 2, 2022).

[89] *Id.* at 9.

[90] Cottrill, *supra* note 20.

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.[91] A 2021 poll conducted by Gallup found that one in four adults 65 and older cut back on necessities like medication, food, utilities, and clothing due to health care costs.[92] Put simply, the high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[93]

As the government explained in its district court briefing,[94] 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

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[91] 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/.

[92] 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.

[93] 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/.

[94] Defs.' Memo. of Law in Support of Defs.' Opp'n to Pl.'s Mot. For Summ. J. and Cross-Mot. at 1, ECF No. 21 (D.N.J. Nov. 1, 2023).

biosimilar competitor.[95] In 2023, Medicare spent $56.2 billion on the 10 drugs selected for negotiation, and about *$4.3 billion on Farxiga alone*.[96] Medicare's staggering spending on Farxiga is in part due to AstraZeneca's relentless price hikes: since 2014, AstraZeneca has raised the price of Farxiga by 54 percent.[97] Between just 2018 and 2022, the total annual Medicare Part D spending per enrollee taking Farxiga rose from $3,093 to $4,046, a 31 percent increase.[98]

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 over *$100 billion by 2031*.[99] In

[95] *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.

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

[97] Protect Our Care, *Medicare Negotiations for Lower Drug Prices Explained: Farxiga*, https://www.protectourcare.org/wp-content/uploads/2024/01/MedicareNegotiationProfiles_Farxiga.pdf (accessed Aug. 26, 2024).

[98] *Farxiga: Medicare Enrollee Use and Spending*, *supra* note 13, at 1.

[99] *Cost Estimate*, CONG. BUDGET OFF. 5 (revised Aug. 5, 2022), https://www.cbo.gov/system/files/2022-08/hr5376_IR_Act_8-3-22.pdf.

2023, the CBO further estimated that by 2031 net prices for the drugs selected for negotiation will decrease by 50 percent on average.[100]

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, 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.[101] LIS generally limits out-of-pocket costs to $4.50 for generic drugs and $11.20 for brand drugs.[102] The expansion of LIS is estimated to cover 300,000 more low-income Medicare beneficiaries.[103] This year, the IRA also removed the five percent coinsurance requirement in the catastrophic coverage phase from its

[100] *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.

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

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

[103] *Fact Sheet: 2024 Medicare Advantage*, *supra* note 101.

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.[104] 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 beneficiaries and July 2023 for Part B beneficiaries.[105] 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.[106]

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[104] 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/.

[105] *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 SERV. 4 (Dec. 14, 2023), https://aspe.hhs.gov/sites/default/files/documents/4bf549a55308c3aadc74b34abcb7a1d1/ira-drug-negotiation-report.pdf.

[106] *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*

On August 15, 2024, HHS announced negotiated drug prices for the first ten drugs to undergo negotiations.[107] These prices will take effect in 2026.[108] The Biden-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).[109] 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.[110] While the exact beneficiary savings for Farxiga specifically is not yet known, HHS secured a 68 percent discount from the drug's 2023 list price, bringing the cost down from $556 to $178.50 for a 30-day supply.[111] In 2022, Medicare beneficiaries paid $260 on

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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/.

107 Medicare Drug Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, supra note 15 at 1.

108 *Id.* at 2.

109 *Id.* at 4.

110 *Id.* at 2.

111 *Id.*

average in out-of-pocket costs for Farxiga.[112] Cost-savings from the drug negotiation program is likely to result in savings to beneficiaries in the form of premium decreases over time, along with lower copays or coinsurance.[113]

III. CONCLUSION

Lowering Medicare drug prices will work to ameliorate some of the systematic and persistent inequities that have prevented many Americans from 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, amicus respectfully requests the Court take health equity into consideration when making its decision.

Date: September 18, 2024 Respectfully submitted,

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[112] *Farxiga: Medicare Enrollee Use and Spending*, *supra* note 13, at 1.

[113] *See, e.g.*, Eisenberg, *supra* note 106*;* Sy, *supra* note 106; *Farxiga: Medicare Enrollee Use and Spending*, *supra* note 13, at 1.

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Date: September 18, 2024

Respectfully submitted,

/s/ Hannah W. Brennan
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I, Hannah Brennan, hereby certify that on September 18, 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.

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