24-2968

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

NOVARTIS PHARMACEUTICALS CORP.

Plaintiff- Appellants,

---v.---

U.S. SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Defendant- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY, No. 3:23-cv-14221

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

Hannah W. Brennan
Sophia K. Weaver
Hagens Berman Sobol Shapiro LLP
One Faneuil Hall Sq., 5th Floor
Boston, MA 02109
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
hannahb@hbsslaw.com
sophiaw@hbsslaw.com

Counsel for Proposed Amicus Curiae Center for American Progress, The Century Foundation, Unidos US Action Fund

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IDENTITY AND INTERESTS OF PROPOSED *AMICI 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 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 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

[1] Amici and their counsel are the sole authors of this brief. No party or counsel for a party authored any piece of this brief or contributed any money intended to fund its preparation or submission. The parties have consented to the filing of this brief.

people.

I. INTRODUCTION

As a matter of health equity, all individuals must have "a fair and just opportunity to be as healthy as possible."[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]

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

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[2] *What is Health Equity?* ROBERT WOOD JOHNSON FOUNDATION (May 1, 2017), https://www.rwjf.org/en/insights/our-research/2017/05/what-is-health-equity-.html.

[3] Nambi Ndugga, Drishti Pillai, & Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KAISER FAMILY FOUND. (Aug. 14, 2024), 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).

[5] *See infra* Section III.A.2.

[6] Grace Sparks et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAMILY FOUND. (Oct. 4, 2024), 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*

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 (predictably) hastens more serious, costly, and painful health outcomes. For example, non-adherence to heart failure medication is associated with increased heart failure symptoms, such as shortness of breath, the progression of heart failure, hospitalization, and increased mortality.[10] Such outcomes worsen (or prematurely end) individual lives. Higher drug costs feed a vicious cycle of

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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 et al., *Key Facts about the Uninsured Population*, KAISER FAMILY FOUND. (Dec 18, 2024), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/ ("Most of the 25.3 million people ages 0-64 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.*

[10] Jia-Rong Wu & Debra Moser, *Medication Adherence Mediated the Relationship Between Heart Failure Symptoms and Cardiac Event-Free Survival in Patients with Heart Failure*, 33 J. CARDIOVASCULAR NURSING 40, 45-46 (2018).

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, Novartis Pharmaceuticals Corporation (Novartis), manufactures Entresto—a drug used to treat heart failure.[13] According to Novartis, Entresto is a first choice therapy for heart failure.[14] As of 2023, fifteen percent of Medicare beneficiaries have been diagnosed with heart failure.[15] As a result, it is unsurprising that, in 2023, more than 664,000 Part D beneficiaries filled

[11] *See infra* notes 56-57.

[12] *Id.*

[13] *Fact Sheet: Inflation Reduction Act Research Series—Entresto: Medicare Enrollee Use and Spending*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. (Nov. 1, 2023), https://aspe.hhs.gov/sites/default/files/documents/5bc9a571d6ece32ed3afae52f490d66b/Entresto.pdf.

[14] *Novartis Announces FDA Filing Acceptance of Entresto (sacubitril/valsartan) for Patients with Heart Failure with Preserved Ejection Fraction (HFpEF)*, NOVARTIS (June 24, 2020) https://www.novartis.com/us-en/news/media-releases/novartis-announces-fda-filing-acceptance-entresto-sacubitrilvalsartan-patients-heart-failure-preserved-ejection-fraction-hfpef#:~:text=More%20than%20646%2C000%20patients%20to,prescribed%20Entresto%20in%20the%20US.&text=To%20reimagine%20medicine%20for%20heart,the%20pharma%20industry%20to%20date.

[15] *Entresto: Medicare Enrollee Use and Spending*, *supra* note 13.

prescriptions for Entresto.[16] With respect to health equity, heart failure disproportionately affects some racial and ethnic minority Medicare beneficiaries and low-income people.[17]

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.[18] These price cuts will save the Medicare program billions, enabling it to divert resources towards improving health outcomes for those most in need.[19] Through this brief, amici seek

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[16] Center for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, 1 (Aug. 2024), https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[17] *See* Office of Minority Health, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Sept. 2020) ("[P]revalence of heart failure is highest among Black/African American beneficiaries (17%), followed by American Indian/Alaska Native (15%), White (14%), Hispanic (13%), and Asian/Pacific Islander (11%) beneficiaries."); Nathaniel M. Hawkins et al., *Heart Failure and Socioeconomic Status: Accumulating Evidence of Inequality*, 14 EUROPEAN J. HEART FAILURE 138, 139 (2012). There is no set definition for "low income" because it is dependent on the geographic area and median income in that area.

[18] *See infra* Section III.B.

[19] *See infra* Section III.B.

to provide the Court with an understanding of how high drug prices and costs exacerbate existing health inequities. Amici then 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. Amici respectfully request that the Court affirm the District Court's decision.

II. ARGUMENT

A. The federal government's ability to negotiate Medicare drug prices provides a critical tool for addressing health inequities.

1. 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 . . . ."[20] Racial wealth disparities between Black and Hispanic

[20] 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,

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.[21] These disparities reflect, in part, "fewer opportunities among Black and Hispanic adults to accumulate wealth and transfer wealth from one generation to the next."[22] Such disparities mean that high medication costs hit Black and Hispanic Medicare enrollees harder—turning the underlying financial inequity into a health inequity.[23]

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.[24] The median savings of women enrolled in Medicare was only 72 percent

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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/.

[21] 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).").

[22] Nancy Ochieng et al., *Racial and Ethnic Health Inequities and Medicare*, KAISER FAMILY FOUND. 10 (Feb. 2021), https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.

[23] Tisdale & Rapfogel, *supra* note 20.

[24] *Id.*

of their male counterparts.[25] And women who are Medicare beneficiaries spend 13 percent more on out-of-pocket costs for medical care.[26] 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.[27] 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).[28]

Second, it is well-documented that stress, racism, and discrimination drive poor health outcomes.[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.[30] The

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[25] *Id.*

[26] *Id.*

[27] Lauren Bouton, Amanda Brush & Ilan Meyer, *LGBT Adults Aged 50 and Older in the US During the COVID-19 Pandemic*, WILLIAMS INST. 3 (Jan. 2023).

[28] Cottrill, *supra* note 21.

[29] 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).

[30] *See* 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; 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.

link between stress and cardiovascular disease, in particular, is "fairly robust."[31] Black and Hispanic people, as well as lower-income individuals, report higher levels of stress than their white and more affluent counterparts.[32] For example, one study found that self-reported interpersonal racism in employment, housing, and interactions with the police was associated with a 26 percent higher risk of heart disease for Black women.[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, and 15 percent of Latino patients report experiencing racial discrimination while

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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.").

[31] Prather, *supra* note **Error! Bookmark not defined.**.

[32] APA Working Group Report, *supra* note 29, at 1; Prather, *supra* note **Error! Bookmark not defined.**.

[33] Abstract, *Higher Levels of Perceived Racism Linked to Increased Risk of Heart Disease in Black Women,* AMERICAN HEART ASSOCIATION EPIDEMIOLOGY, PREVENTION, LIFESTYLE & CARDIOMETABOLIC HEALTH SCIENTIFIC SESSIONS 2023 (Mar. 1, 2023) https://newsroom.heart.org/news/higher-levels-of-perceived-racism-linked-to-increased-risk-of-heart-disease-in-black-women.

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

receiving medical care.[35] As a result of concern about 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 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 and non-discriminatory care affects detection and treatment of disease, which, in turn, increases health inequity.[38] In

[35] Samantha Artiga, et al., *Survey on Racism, Discrimination and Health: Experiences and Impacts Across Racial and Ethnic Groups*, KAISER FAMILY FOUND. (Dec. 5, 2023), https://www.kff.org/report-section/survey-on-racism-discrimination-and-health-findings/.

[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 Harold Van Houtven et al, *Perceived Discrimination and Reported Delay of Pharmacy Prescriptions And Medical Tests*, 20 J. GEN. INTERNAL MED. 578 (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).

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 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

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[39] *CMS Framework for Health Equity 2022-2023*, CTRS. FOR MEDICARE & MEDICAID SERVS. 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 22, at 17.

[42] '*Pharmacy Deserts' Disproportionately Affect Black and Latino Residents in Largest U.S. Cities*, USC Schaeffer Center (May 3, 2021),

live in areas with low quality hospitals.[43] A general shortage of physicians, including a nationwide shortage of over 13,000 primary care doctors, will continue to exacerbate this trend.[44] For heart failure treatment, 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] 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 Entresto, heart disease disproportionately impacts some racial and ethnic minorities, LGBTQ+ people, disabled people, and people with low incomes.[46] Among

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https://healthpolicy.usc.edu/article/pharmacy-deserts-disproportionately-affect-black-and-latino-residents-in-largest-u-s-cities/.

[43] Ochieng, *supra* note 22, at 23.

[44] *See Healthcare Workforce Shortage Areas*, HEALTH RESOURCES & SERVS. ADMIN. https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited Jan. 13, 2025); 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.

[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] Office of Minority Health, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Sept. 2020) (Black (17 percent) and American Indian and Native Alaskan (15) Medicare beneficiaries had higher prevalence of heart failure than white beneficiaries (14

Medicare beneficiaries, the prevalence of heart failure is higher among Black (17 percent) and American Indian and Native Alaskan (15 percent) beneficiaries than white beneficiaries (14 percent), and is higher for Latino beneficiaries (13 percent) than Asian/Pacific Islander beneficiaries (11 percent).[47] Black and Hispanic people on average also have younger ages of heart failure onset.[48] For Medicare beneficiaries, emergency room visits were two times higher for Black beneficiaries, 1.2 times higher for Hispanic beneficiaries, and 1.4 times higher for American Indian and Native Alaskan beneficiaries than white beneficiaries.[49] Black people more generally are nearly 2.5 times more likely to be hospitalized for heart failure than white people,[50] and are more likely to die prematurely from heart

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percent); and the prevalence of heart failure is higher for Latino beneficiaries (13 percent) than Asian/Pacific Islander beneficiaries (11 percent)); *Health, United States Spotlight: Racial and Ethnic Disparities in Heart Disease*, CTR. FOR DISEASE CONTROL 1 (Apr. 2019) (In 2017, Black people (208) had the highest deaths per 100,000 persons from heart disease, followed by white people (168.9), Hispanic people (114.1), and Asian or Pacific Islander persons (85.5)); Tisdale & Rapfogel, *supra* note 20.

[47] Office of Minority Health, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Sept. 2020).

[48] Sabra Lewsey & Khadijah Breathett, *Racial and Ethnic Disparities in Heart Failure: Current state and Future Directions*, 36 CURRENT OP. CARDIOLOGY 320, 322-323 (2022).

[49] Ochieng, *supra* note 22.

[50] Ileana L. Piña et al., Race and Ethnicity in Heart Failure, 78 J. AM. COLL. CARDIOLOGY 2589, 2589 (2021).

failure than white people.[51] 9.6 percent of adults with disabilities have heart disease compared with 3.4 percent of adults without a disability.[52] Studies have also found elevated rates of risk factors for heart disease in the LGBTQ+ community, including higher rates of smoking, alcohol consumption, and poor mental health.[53] Low-income people also have a higher risk of heart failure[54] and a greater risk of hospitalization and a higher rate of one-year mortality from heart failure.[55]

2. 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

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[51] Lewsey, *supra* note 49, at 322.

[52] *Disability Impacts All of Us*, CTR. FOR DISEASE CONTROL (July 15, 2024), https://www.cdc.gov/disability-and-health/articles-documents/disability-impacts-all-of-us-infographic.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html.

[53] 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., *Assessing 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).

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

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

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."[56] These cost-saving strategies can result in more serious illnesses, more expensive treatments, and even death.[57] 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.[58] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[59] For example,

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[56] 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).

[57] *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/.

[58] 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%).").

[59] *Id.*

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.[60] For heart failure, which Novartis's Entresto treats, medication non-adherence due to cost can lead to increased hospitalization rates and mortality because heart failure drugs need to be taken consistently to achieve their benefits.[61] 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. Of 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.[62] In 2019, 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.[63] Women over 65 with Medicare

[60] *Id.*

[61] Emily F. Lowe et al., *Contributors and Solutions to High Out-of-Pocket Costs for Heart Failure Medications*, 85 JACC 365, 369 (2025).

[62] 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).

[63] *Id.*

are more likely to experience prescription drug affordability problems than men.[64] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[65] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the general Medicare population.[66] A 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.[67] 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.

B. The IRA's Medicare drug price negotiations will advance health equity by lowering beneficiaries' 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

[64] Tisdale & Rapfogel, *supra* note 20; Tarazi, *supra* note 62, at 3.

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

[66] Tisdale & Rapfogel, *supra* note 20.

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

as a whole.[68]

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."[69] Medicare currently provides health insurance to 67 million Americans, with 54 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[70] 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).[71] In 2019, Medicare Part D enrollment rates were also higher among women (57 percent) than among men (43 percent).[72] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[73]

While Medicare Part D helps cover the costs of prescription drugs,

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[68] *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/.

[69] Ochieng, *supra* note 22, at 1.

[70] Center for Medicare & Medicare Servs, *Medicare Monthly Enrollment* (May 2024) https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.

[71] Ochieng, *supra* note 22, at 16.

[72] 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).

[73] *Id.* at 9.

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.[74] Households in which all members are covered by Medicare also spend a greater percentage of their household spending on health care-related expenses; in 2022, three in ten Medicare households spent 20 percent or more of their household spending on health-related expenses compared with seven percent non-Medicare households.[75] A 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.[76] Put simply, the high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[77]

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[74] Cottrill, *supra* note 21.

[75] Nancy Ochieng, Juliette Cubanski, & Anthony Damico, *Medicare Households Spend More on Health Care than Other Households*, KAISER FAMILY FOUND. (Mar. 14, 2024), https://www.kff.org/medicare/issue-brief/medicare-households-spend-more-on-health-care-than-other-households/.

[76] 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.

[77] 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/.

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.[78] In 20233, Medicare spent $56.2 billion on the 10 drugs selected for negotiation, and about *$3.4 billion on Entresto alone*.[79] Medicare's staggering spending on Entresto is in part due to Novartis's relentless price hikes: since 2015, Novartis has raised the price of Entresto by 78 percent—just under 3 times the rate of inflation.[80] Between just 2018 and 2022, the total annual Medicare Part D spending per enrollee taking Entresto rose from $3,126 to $4,780, a 51 percent increase.[81]

By allowing the federal government to negotiate the purchase price of essential medicines for Medicare, the IRA's drug price negotiation program is

[78] 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; *Medicare Enrollees' Use and Out-of-Pocket Expenditures*, *supra* note 78.

[79] *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

[80] 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).

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

projected to reduce the federal budget deficit by nearly *$100 billion by 2031*.[82] In 2023, the CBO further estimated that by 2031 net prices for the drugs selected for negotiation will decrease by 50 percent on average.[83]

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 2024, CMS implemented 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.[84] LIS generally limits out-of-pocket costs to $4.50 for generic drugs and $11.20 for brand drugs.[85] As of 2024, the IRA also eliminated the five percent coinsurance requirement in the

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

[83] *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.

[84] *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.

[85] *Saving Money with the Prescription Drug Law*, MEDICARE.GOV, https://www.medicare.gov/about-us/prescription-drug-law (last visited Dec. 20, 2023).

catastrophic coverage phase from its Medicare Part D benefit design, and beginning this year, the IRA will also 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 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]

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[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/; Juliette Cubanski, *A Current Snapshot of the Medicare Part D Prescription Drug Benefit*, KAISER FAMILY FOUND. (Oct. 9, 2024), https://www.kff.org/medicare/issue-brief/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/.

[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)

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 administration estimated that had the negotiated prices been in effect in 2023, the Medicare program would have saved $6 billion (in other words, Medicare would have benefitted from a 22 percent reduction in those drug costs).[91] Combined across the ten drugs, these 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] The Biden-Harris administration secured a 53 percent discount from Entresto's 2023 list price, bringing the cost down from $628 to $295 for a 30-

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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 15 at 1.

[90] *Id.*

[91] *Id.* at 4.

[92] *Id.* at 2.

day supply.[93] In 2022, Medicare beneficiaries paid $375 on average in out-of-pocket costs for Entresto.[94] Cost-savings from the drug negotiation program is likely to result in savings to beneficiaries in the form of premium decreases over time and 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 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

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[93] *Id.*

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

[95] *How CBO Estimated the Budgetary Impact*, *supra* note 93, at 36; Mariana Socal, *How the Drug Price Negotiation Program Could Affect Medicare Part D Beneficiaries*, STAT (Sep. 8, 2023), https://www.statnews.com/2023/09/08/medicare-part-d-drug-price-negotiations/.

making its decision.

Date: February 25, 2025

Respectfully submitted,

/s/ *Hannah W. Brennan*
Hannah W. Brennan
Sophia K. Weaver
Hagens Berman Sobol Shapiro LLP
One Faneuil Hall Sq., 5th Floor
Boston, MA 02109
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
hannahb@hbsslaw.com
sophiaw@hbsslaw.com

Counsel for Proposed Amicus Curiae Center for American Progress, The Century Foundation, UnidosUS Action Fund

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

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Date: February 25, 2025

/s/ Hannah W. Brennan
Hannah W. Brennan

CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on this 25th day of February, 2025, 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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/s/ *Hannah W. Brennan*
Hannah W. Brennan