24-2092

United States Court Of Appeals
for the
Second Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare and Medicaid Services,

Defendant- Appellees.

On Appeal From The United States District Court
for the District Of Connecticut

Case No. 3:23-cv-01103

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

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TABLE OF CONTENTS

Page

I. IDENTITY AND INTERESTS OF PROPOSED *AMICI CURIAE* 1

II. INTRODUCTION 2

III. ARGUMENT 7

A. The federal government's ability to negotiate Medicare drug prices provides a critical tool for addressing health inequities. 7

1. Socioeconomic inequities drive worse health outcomes among some Medicare beneficiaries. 7

2. High prescription drug prices exacerbate existing health and financial burdens among these same groups of Medicare beneficiaries. 17

B. The IRA's Medicare drug price negotiations will advance health equity by lowering beneficiaries' medication costs and strengthening the Medicare program overall. 21

IV. CONCLUSION 28

CERTIFICATE OF COMPLIANCE 30

CERTIFICATE OF SERVICE 31

TABLE OF AUTHORITIES

Page(s)

OTHER AUTHORITIES

Abdul Mannan Khan Minhas et al., *Family Income and Cardiovascular Disease Risk in American Adults*, 13 SCI. REPS. 1, 5, 7 (2023) 16

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/ 8, 9, 22

Amitabh Chandra, Evan Flack, & Ziad Obermeyer, *The Health Costs of Cost-Sharing* 4 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28439, 2023) 18

Annika Constantino, *Here are the 3 most-used drugs on the Medicare Price Negotiation List*, CNBC (updated Aug. 29, 2023, 7:22 PM EDT), https://www.cnbc.com/2023/08/29/most-used-drugs-on-medicare-price-negotiation-list-see-the-top-three.html 24

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) 9, 10

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.....9, 10

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/ 23

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/ 7

Brad Sears & Kerith J. Conron, *LGBT People & Access to Prescription Medications*, THE WILLIAMS INSTITUTE, UCLA SCHOOL OF LAW 7 (Dec. 2018) 21

Bruce S. McEwen, *Protective and Damaging Effects of Stress Mediators*, 338 NEW ENG. J. MED. 171, 172 (1998).....10, 11

Center for Disease Control, *Disability Impacts All of Us* (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 16

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 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 5, 27, 28

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 22

CMS Framework for Health Equity 2022-2023, CTRS. FOR MEDICARE & MEDICAID SERVS. 13 (Apr. 2022) 12

Cost Estimate, CONG. BUDGET OFF. 5 (revised Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.....25

Courtney Harold Van Houtven et al, *Perceived Discrimination and Reported Delay of Pharmacy Prescriptions And Medical Tests*, 20 J. GEN. INTERNAL MED. 578 (2005).....12

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/.....14

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/ 10

Diabetes Risk in the LGBTQ Community, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated July 11, 2023), https://www.cdc.gov/diabetes/risk-factors/diabetes-risk-lgbtq.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/library/features/diabetes_LGBTQ_community.html 15

Disability & Diabetes Prevention, CTR. FOR DISEASE CONTROL (last visited Jan. 13, 2025), https://www.cdc.gov/disability-and-health/articles-documents/diabetes-prevention.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/disabilityandhealth/features/disability-and-diabetes-prevention.html.....15

Discrimination in America: Final Summary, Robert Wood Johnson Found., NPR & HARVARD T.H. CHAN SCH. PUB. HEALTH 13 (Jan. 2018) 11

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 10

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 25

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/ 21

Fact Sheet: Inflation Reduction Act Research Series-Jardiance: Medicare Enrollee Use and Spending, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. (Nov. 8, 2023), https://aspe.hhs.gov/sites/default/files/documents/b579122f216f5c3eb3f7ef6c6091b5c1/Jardiance.pdf 5, 24, 27, 28

Farrah Nekui et al., *Cost-Related Medication Nonadherence and its Risk Factors Among Medicare Beneficiaries*, 59 MED. CARE 13, 13 (2021) 20

Felicia Hill-Briggs et al., *Social Determinants of Health and Diabetes: A Scientific Review*, DIABETES CARE 258, 260-61 (2021) .5, 10, 13, 16

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/ 7, 8, 9, 20, 21

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) 15

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/ 3

Health Equity, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/pillar/health-equity#:~:text=To%20CMS%2C%20health%20equity%20means,preferred%20language%2C%20or%20other%20factors (last visited Jan. 10, 2025) 2

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

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 25

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/ 28

Ileana L. Piña et al., *Race and Ethnicity in Heart Failure*, 78 J. AM. COLL. CARDIOLOGY 2589, 2589 (2021).....16

Inflation Reduction Act Series-Projected Impact for Asian Medicare Enrollees, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. 3 (Sept. 2023) 14

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.....13

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/ 3

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 26

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/ 26

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/ 26

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/ 27

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) 17

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) 9

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) 24

Manage Blood Sugar, CTR. FOR DISEASE CONTROL (last updated Sep. 30, 2022), https://www.cdc.gov/diabetes/treatment/?CDC_AAref_Val=https://www.cdc.gov/diabetes/managing/manage-blood-sugar.html 19

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 4

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.....3, 4

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.....24

Mohamad Taha et al., *Cost-Related Medication Nonadherence in Adults with Diabetes in the United States: The National Health Interview Survey 2013-2018*, 45 DIABETES CARE 594, 598 (2022).....19

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.....2

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/.....8, 13, 22

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/.....23

Nathaniel Hawkins et al., *Heart Failure and Socioeconomic Status: Accumulating Evidence of Inequality*, 14 EUR. J. HEART FAILURE 138, 141 (2012).....17

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/ 7, 24

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/.....17

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 23

Office of Minority Health, *Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Sept. 2020) 5

Office of Minority Health, *Racial and Ethnic Disparities in Diabetes Prevalence, Self-Management, and Health Outcomes among Medicare Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS. 11 (Mar. 2017) 6, 14

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).....6

'*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/ 13

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 26

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/ 27

Robin Bleiweis, Jocelyn Frye, & Rose Khattar, *Women of Color and the Wage Gap*, CTR. FOR AM. PROGRESS (Nov. 17, 2021), https://www.americanprogress.org/article/women-of-color-and-the-wage-gap/ 8

Robin Cohen & Amy Cha, *Strategies Used by Adults with Diagnosed Diabetes to Reduce their Prescription Drug Costs, 2017-2018*, CTRS. FOR MEDICARE & MEDICAID SERVS., NAT'L CTR. FOR HEALTH STATS., Data Brief 349, at 2 (Aug. 2019) 18

Ruqaiijah Yearby, Brietta Clark, & José F. Figueroa, *Structural Racism in Historical and Modern US Health Care Policy*, 41 HEALTH AFF. 187 (2022) 3, 12

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/ 11

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 1, 4 (Dec. 3, 2020) 19

Sasha Santhakumar, *What Conditions May Occur Alongside Type 2 Diabetes?*, MEDICAL NEWS TODAY (June 21, 2022), https://www.medicalnewstoday.com/articles/comorbidities-of-diabetes-type-2 19

Saving Money with the Prescription Drug Law, MEDICARE.GOV, https://www.medicare.gov/about-us/prescription-drug-law (last visited Dec. 20, 2023) 25

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/ 11

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/ 14, 15

Statement by Boehringer Ingelheim on selection of Jardiance (empagliflozin) by the Centers for Medicare and Medicaid Services (CMS) Drug Price Negotiation Program, BOEHRINGER INGELHEIM (Aug. 28, 2023, 7:45AM), https://www.boehringer-ingelheim.com/us/statement-boehringer-ingelheim-selection-jardiance-empagliflozin-centers-medicare-medicaid 5

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 27

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) 4

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 3

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) 20

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) 22

William Polonsky & Robert Henry, *Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and its Key Contributors*, 10 PATIENT PREFERENCE & ADHERENCE 1299, 1301 (2016) 18, 19

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/ 7, 22

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) 9

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) 20

I. 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 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.

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

[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 do not object 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.

II. 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

[2] *Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/pillar/health-equity#:~:text=To%20CMS%2C%20health%20equity%20means,preferred%20language%2C%20or%20other%20factors (last visited Jan. 10, 2025).

[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.

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 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—

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[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 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.

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, 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, Boehringer Ingelheim Pharmaceuticals Inc. (Boehringer), manufactures Jardiance—a drug used to treat diabetes and heart

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[9] *Id.*

[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 63–64.

[12] *Id* notes 47, 58–61.

failure.[13] According to Boehringer, Jardiance is the number one prescribed drug of its class (SGLT2 inhibitors) with 59 million prescriptions.[14] Of Medicare enrollees, 28 percent live with diabetes and 15 percent have heart failure.[15] As a result, it is unsurprising that, in 2023, about 1.8 million Part D beneficiaries filled prescriptions for Jardiance.[16] With respect to health equity, diabetes and heart failure disproportionately affect racial and ethnic minorities and low-income people.[17]

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[13] *Fact Sheet: Inflation Reduction Act Research Series—Jardiance: Medicare Enrollee Use and Spending*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. (Nov. 8, 2023), https://aspe.hhs.gov/sites/default/files/documents/b579122f216f5c3eb3f7ef6c6091b5c1/Jardiance.pdf.

[14] *Statement by Boehringer Ingelheim on selection of Jardiance (empagliflozin) by the Centers for Medicare and Medicaid Services (CMS) Drug Price Negotiation Program*, BOEHRINGER INGELHEIM (Aug. 28, 2023, 7:45AM), https://www.boehringer-ingelheim.com/us/statement-boehringer-ingelheim-selection-jardiance-empagliflozin-centers-medicare-medicaid.

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

[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."); Felicia Hill-Briggs et al., *Social Determinants of Health and Diabetes: A Scientific*

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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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 SERVS. 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)."). There is no set definition for "low income" because it is dependent on the geographic area and median income in that area. The federal government uses several different measurements. HUD calculates "low income" as families earning 50-80 percent of the "area median income," HUD also maintains a database of "state median income," where low income families earn 50-80 percent below the state's median income. The U.S. government calculates eligibility for federal aid based on the "federal poverty level" determined by the U.S. Department of Health and Human Services' poverty guidelines for household size. Office of State and Community Energy Programs, *Low-Income Community Energy Solutions*, ENERGY.GOV, https://www.energy.gov/scep/slsc/low-income-community-energy-solutions (last visited Dec. 1, 2023).

[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.

III. 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*

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

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Disability Justice, THE CENTURY FOUND. (April 21, 2022), https://tcf.org/content/report/economic-justice-disability-justice/; Robin Bleiweis, Jocelyn Frye, & Rose Khattar, *Women of Color and the Wage Gap*, CTR. FOR AM. PROGRESS (Nov. 17, 2021), https://www.americanprogress.org/article/women-of-color-and-the-wage-gap/.

[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.

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

[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),

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 disorders.[32] Black and Hispanic people, as well as lower income individuals, report higher levels of stress than their white and more affluent counterparts.[33] For example, 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 . . . ."[34] Finally, stress suppresses the immune system, leaving individuals more

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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. 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] *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 Jan. 13., 2025) (explaining the link between diabetes and the endocrine system).

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

[34] Hill-Briggs, *supra* note 17, 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)).

susceptible to disease.[35]

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.[36] 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.[37] 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.[38] Inability to obtain responsive and non-discriminatory

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

[36] 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/.

[37] *Discrimination in America: Final Summary, Robert Wood Johnson Found.*, NPR & HARVARD T.H. CHAN SCH. PUB. HEALTH 13 (Jan. 2018).

[38] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ*

care affects detection and treatment of disease, which, in turn, increases health inequity.[39] 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 prescription drug access.[40] 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.[41] Ten percent of Black and eleven percent of Hispanic Medicare beneficiaries reported trouble accessing needed care, compared to six

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People from Accessing Health Care, CTR. FOR AM. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/.

[39] 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).

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

[41] 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.").

percent of white beneficiaries.[42] 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.[43] Black and Hispanic Medicare beneficiaries are also more likely to live in areas with low quality hospitals.[44]

For diabetes care, the geographic regions with the highest prevalence of diabetes are also characterized by the lowest rates of endocrinologists.[45] A general shortage of physicians, including a nationwide shortage of over 13,000 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 Jardiance,

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[42] Ochieng, *supra* note 22, at 17.

[43] '*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/.

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

[45] Hill-Briggs, *supra* note 17, at 269.

[46] *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.

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 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

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[47] *Racial and Ethnic Disparities*, *supra* note 17, 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 20.

[48] *Racial and Ethnic Disparities*, *supra* note 17, 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 SERVS. 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*

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 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

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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.

[54] *Disability & Diabetes Prevention*, CTR. FOR DISEASE CONTROL (last visited Jan. 13, 2025), https://www.cdc.gov/disability-and-health/articles-documents/diabetes-prevention.html?CDC_AAref_Val=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 Risk in the LGBTQ Community*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated July 11, 2023), https://www.cdc.gov/diabetes/risk-factors/diabetes-risk-lgbtq.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/library/features/diabetes_LGBTQ_community.html.

likely *to die of Type 2 diabetes* than those with incomes above it.[57]

Heart failure is also more prominent 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 Alaskan (14 percent) beneficiaries than white beneficiaries (11 percent).[58] Black people are 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-

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[57] Hill-Briggs, *supra* note 17, at 260-61.

[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) ("The age-adjusted death rate for HF is highest in Black men (118.2 per 100,000), followed by non-Hispanic White men (111.3 per 100,000), Black women (86.0 per 100,000), and White women (80.4 per 100,000).").

[60] Center for Disease Control, *Disability Impacts All of Us* (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.

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

year mortality from heart failure.[62]

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 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."[63] These cost-saving strategies can result in more serious illnesses, more expensive treatments, and even death.[64] 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

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

[63] 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).

[64] *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/.

in 13.9 percent higher mortality compared to other patients with greater coverage.[65] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[66] 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.[67]

For diabetes, which Boehringer's drug treats, the consequences of poor medication adherence are especially stark.[68] In 2017, seven percent of adults over 65 with diabetes did not take their diabetes medication as prescribed because of cost.[69] Skipping medications results in worse glycemic control (i.e., control of

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[65] 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%).").

[66] *Id*.

[67] *Id.*

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

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

blood sugar levels),[70] which is associated with more emergency room visits, hospitalization, and complications from diabetes, such as hypertension, kidney disease, amputation, and even death.[71] One study found that cost-related medication non-adherence in diabetes patients was associated with an 18 percent greater risk of death.[72] Another study showed that among diabetics over 65 who did not take medication as directed due to cost, 84 percent had hypertension and 75 percent had high cholesterol—both comorbidities of diabetes.[73] 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

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[70] Polonsky, *supra* note 63, at 1301.

[71] *Id.*; *Manage Blood Sugar*, CTR. FOR DISEASE CONTROL (last updated Sep. 30, 2022), https://www.cdc.gov/diabetes/treatment/?CDC_AAref_Val=https://www.cdc.gov/diabetes/managing/manage-blood-sugar.html.

[72] 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 1, 4 (Dec. 3, 2020).

[73] Mohamad Taha et al., *Cost-Related Medication Nonadherence in Adults with Diabetes in the United States: The National Health Interview Survey 2013-2018*, 45 DIABETES CARE 594, 598 (2022); Sasha Santhakumar, *What Conditions May Occur Alongside Type 2 Diabetes?*, MEDICAL NEWS TODAY (June 21, 2022), https://www.medicalnewstoday.com/articles/comorbidities-of-diabetes-type-2.

white patients.[74] 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. 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.[75] 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.[76] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[77] Women over 65 with Medicare are more likely to experience prescription drug affordability problems than men.[78] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the

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[74] 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).

[75] 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).

[76] *Id.*

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

[78] Tisdale & Rapfogel, *supra* note 20; Tarazi, *supra* note 75, at 3.

general Medicare population.[79] 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.[80] 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 as a whole.[81]

Historically, Medicare "has helped to mitigate racial and ethnic inequities in health care in its role as both a regulator and the largest single purchaser of

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

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

[81] *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/.

personal health care in the U.S."[82] Medicare currently provides health insurance to 67 million Americans, with 54 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[83] 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).[84] In 2019, Medicare Part D enrollment rates were also higher among women (57 percent) than among men (43 percent).[85] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[86]

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.[87] Households in which all members are covered by

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

[83] 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.

[84] Cottrill, *supra* note 21.

[85] 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).

[86] *Id.* at 9.

[87] Koma, *supra* note 20.

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 of non-Medicare households.[88] 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.[89] Put simply, the high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[90]

As the government explained in its briefing,[91] 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

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[88] 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/.

[89] 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.

[90] 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/.

[91] Memo. of Law in Opp'n to Pl.'s Mot. For Summ. J. and in Support of Def.'s Cross-Mot. at 5-6, *Boehringer Ingelheim Pharm., Inc. v. U.S. Dep't of Health & Human Servs.*, Civ. A. No. 3:23-cv-1103-RNC (D. Conn. Dec. 20, 2023), ECF No. 48-1.

aggregate Medicare spending and do not have a generic or biosimilar competitor.[92] Between June 2022 and May 2023, Medicare spent $50.5 billion on the 10 drugs selected for negotiation, and about *$7 billion on Jardiance alone*.[93] Medicare's staggering spending on Jardiance is in part due to Boehringer's relentless price hikes: since 2014, Boehringer Ingelheim has raised the price of Jardiance by 97 percent—just under 3.5 times the rate of inflation.[94] Between just 2018 and 2022, the total annual Medicare Part D spending per enrollee taking Jardiance rose from $3,063 to $4,430, a 45 percent increase.[95] In fact, Medicare spent more, in aggregate, on Jardiance and two blood thinner medications (Xarelto and Eliquis) than the other seven drugs slated to have their prices negotiated combined.[96]

By allowing the federal government to negotiate the purchase price of

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[92] 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.

[93] *5 Facts to Know*, *supra* note 20 (citing *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Aug. 2023)); Annika Constantino, *Here are the 3 most-used drugs on the Medicare Price Negotiation List*, CNBC (updated Aug. 29, 2023, 7:22 PM EDT), https://www.cnbc.com/2023/08/29/most-used-drugs-on-medicare-price-negotiation-list-see-the-top-three.html.

[94] 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).

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

[96] Constantino, *supra* note 94.

essential medicines for Medicare, the IRA's drug price negotiation program is projected to reduce the federal budget deficit by nearly *$100 billion by 2031*.[97] In 2023, the CBO further estimated that by 2031 net prices for the drugs selected for negotiation will decrease by 50 percent on average.[98]

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, which expanded 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.[99] LIS generally limits out-of-pocket costs to $4.50 for generic drugs and $11.20 for brand drugs.[100] In 2024, the IRA also removed the five percent coinsurance

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

[98] *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.

[99] *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.

[100] *Saving Money with the Prescription Drug Law*, MEDICARE.GOV,

requirement in the 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.[101] 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.[102] 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.[103]

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https://www.medicare.gov/about-us/prescription-drug-law (last visited Dec. 20, 2023).

[101] 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/.

[102] *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.

[103] *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-

On August 15, 2024, HHS announced negotiated drug prices for the first ten drugs to undergo negotiations.[104] These prices will take effect in 2026.[105] 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 benefitted from a 22 percent reduction in those drug costs).[106] 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.[107] HHS

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

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

[105] *Id.*

[106] *Id.* at 4.

[107] *Id.* at 2.

secured a 66 percent discount from the drug's 2023 list price, bringing the cost down from $573 to $197 for a 30-day supply.[108] In 2022, Medicare beneficiaries paid $290 on average in out-of-pocket costs for Jardiance.[109] 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.[110]

IV. 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

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[108] *Id.*

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

[110] *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/.

respectfully request that the Court take health equity into consideration and affirm the District Court's decision.

Date: January 28, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(5) and 32(a)(7)(B)(ii) because this brief contains 6,286 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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Date: January 28, 2025

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CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on January 28, 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 six paper copies of the foregoing brief will be sent to the Clerk's office.

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