UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*,

Plaintiff,

v.

XAVIER BECERRA, In his official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Defendant.

Case No. 3:23-cv-20814-ZNQ-DEA

[PROPOSED] BRIEF OF THE CENTER FOR AMERICAN PROGRESS, THE NAACP, THE CENTURY FOUNDATION, AND UNIDOSUS ACTION FUND AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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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 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 through civic engagement and issue-based campaigns. One important focus of UnidosUSAF's work is lowering prescription drug costs for the millions of Latinos in America who rely on medication to treat chronic disease like diabetes.

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 and to explain that the IRA's modest delegation of power is constitutional. 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.

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[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.

Additionally, this brief argues that Congress's delegation of power under the IRA falls well within the permissible scope of delegation to executive agencies as defined by the Supreme Court, and such delegations are commonplace and necessary to a functioning government in a complex economy.

I. INTRODUCTION

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

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

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[2] *Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing/health-equity (last visited Dec. 19, 2023).

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

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

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

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

these affordability challenges.[7] Further, as medication costs increase, prescription adherence drops: a 2020 study found prescription abandonment rates were less than five percent when a prescription carried no out-of-pocket expense but jumped to 45 percent when out-of-pocket costs were over $125.[8] Abandonment rates jumped further still—to 60 percent—when the out-of-pocket cost was over $500.[9] This is not a personal failing: people cannot buy and take drugs they cannot afford. And a lack of prescription adherence (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

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

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

[9] *Id.*

[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 57-58.

[12] *Id.*

disparity in health and deepen existing health inequities.

The plaintiffs in the instant action, Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (Novo Nordisk), manufacture NovoLog/Fiasp—a biological insulin product used to treat diabetes.[13] According to 2022 data, 28 percent of Medicare fee-for-service beneficiaries live with diabetes.[14] As a result, it is unsurprising that, in 2022, about 760 thousand Part D beneficiaries filled prescriptions for Novolog/Fiasp.[15] With respect to health equity, diabetes disproportionately affects racial and ethnic minorities and low-income people.[16]

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

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[13] *Fact Sheet: Inflation Reduction Act Research Series—NovoLog/Fiasp: Medicare Enrollee Use and Spending*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS. (Nov. 3, 2023), https://aspe.hhs.gov/sites/default/files/documents/c4d457ad98871aca301d20320aafe4fa/NovoLog-Fiasp.pdf.

[14] *Id.*

[15] *NovoLog/Fiasp: Medicare Enrollee Use and Spending*, *supra* note 13.

[16] Felicia Hill-Briggs et al., *Social Determinants of Health and Diabetes: A Scientific Review*, 44 DIABETES CARE 258, 260-61 (2021) ("Prevalence of diabetes increases on a gradient from highest to lowest income."); Office of Minority Health, *Racial and Ethnic Disparities in Diabetes Prevalence, Self-Management, and Health Outcomes among Medicare Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID 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).

redesign for Medicare Part D benefits, and inflation rebates for Medicare Part B and D prescription drugs—the new Medicare drug price negotiations will cut the cost of prescription drugs.[17] These price cuts will save the Medicare program billions, enabling it to divert resources towards improving health outcomes for those most in need.[18] Through this brief, amici seek 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 will also argue that the IRA's delegation of power to the Department of Health and Human Services ("HHS") is constitutional because it is modest and cabined, and aligns with delegations the Supreme Court has repeatedly blessed over the past century—such delegations are necessary for the functioning of government.

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 . . . ."[19] Racial wealth disparities between Black and Hispanic Medicare beneficiaries and white

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

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

[19] Nicole Rapfogel, *5 Facts to Know About Medicare Drug Price Negotiations*, CTR. FOR AM. PROGRESS (Aug. 30, 2023), https://www.americanprogress.org/article/5-facts-to-know-about-medicare-drug-price-negotiation/; *see* Gillian Tisdale & Nicole Rapfogel, *Medicare Drug Price Negotiations Will Help Millions of Seniors and Improve Health Equity*, CTR. FOR AM. PROGRESS (July 17, 2023), https://www.americanprogress.org/article/medicare-drug-price-negotiation-will-help-millions-of-seniors-and-improve-health-equity/; Wyatt Koma et al., *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic*, KAISER FAMILY FOUND. (Apr.

beneficiaries are particularly staggering. As of 2019, the median savings of white Medicare beneficiaries was *over eight times higher* than that of Black beneficiaries and *twelve times higher* than that of Hispanic beneficiaries.[20] These disparities reflect, in part, "fewer opportunities among Black and Hispanic adults to accumulate wealth and transfer wealth from one generation to the next."[21] Such disparities mean that high medication costs hit Black and Hispanic Medicare enrollees harder—turning the underlying financial inequity into a health inequity.[22]

The same is true of women, the LGBTQI+ community, and disabled people, who are also more likely to have lower incomes, creating barriers to prescription access.[23] The median savings of women enrolled in Medicare was only 72 percent of their male counterparts.[24] And women who are Medicare beneficiaries spend 13 percent more on out-of-pocket costs for medical care.[25] Additionally, 19 percent of LGBT adults over 65 live under the federal poverty

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24, 2020), https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/; Bianca D.M. Wilson, *LGBT Poverty in the United States: Trends at the Onset of COVID-19*, WILLIAMS INST. (Feb. 2023); Rebecca Vallas, *Economic Justice Is Disability Justice*, THE CENTURY FOUND. (April 21, 2022), https://tcf.org/content/report/economic-justice-disability-justice/; Robin Bleiweis, Jocelyn Frye, & Rose Khattar, *Women of Color and the Wage Gap*, CTR. FOR AM. PROGRESS (Nov. 17, 2021), https://www.americanprogress.org/article/women-of-color-and-the-wage-gap/.

[20] 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/ ("Median per capita savings among White beneficiaries ($117,803) was more than eight times higher than savings among Black beneficiaries ($14,523) and about twelve times higher than savings among Hispanic beneficiaries ($9,634). Median per capita home equity was more than five times higher among White beneficiaries ($95,001) than among Black beneficiaries ($18,454) or Hispanic beneficiaries ($16,494).").

[21] *Id.*

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

[23] *Id.*

[24] *Id.*

[25] *Id.*

line compared to 15 percent of straight and cisgender adults over 65.[26] For disabled Medicare enrollees under the age of 65 in 2016, the median income was $17,950—lower than the median income for Medicare beneficiaries ($26,200).[27]

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

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[26] 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).

[27] Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries 2016-2035*, KAISER FAMILY FOUND. (Apr. 21, 2017), https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/.

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

[29] APA Working Group Report, *supra* note 28, at 1; Aric A. Prather, *Stress Is A Key To Understanding Many Social Determinants of Health*, HEALTH AFFAIRS (Feb. 24, 2020), https://www.healthaffairs.org/content/forefront/stress-key-understanding-many-social-determinants-health.

[30] *See* Prather, *supra* note 29; Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFFAIRS (Oct. 4, 2018), https://www.healthaffairs.org/do/10.1377/hpb20180817.901935/; Bruce S. McEwen, *Protective and Damaging Effects of Stress Mediators*, 338 NEW ENG. J. MED. 171, 172 (1998) ("[S]urges in blood pressure can trigger myocardial infarction in susceptible persons, 17 and in primates repeated elevations of blood pressure over periods of weeks and months accelerate atherosclerosis, 18 thereby increasing the risk of myocardial infarction.").

[31] Prather, *supra* note 29.

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

Discrimination and a lack of access to culturally responsive care also deters some populations from obtaining needed medical treatment. For racial and ethnic minorities, 32 percent of Black patients, 23 percent of Native American patients, and 20 percent of Latino patients report experiencing racial discrimination while receiving medical care.[35] As a result of concern about discrimination or poor treatment due to race, 22 percent of Black Americans, 17 percent of Latinos, and 15 percent of Native Americans have avoided seeking medical care for themselves or a member of their family, compared to nine percent of Asian Americans and only three percent of whites.[36] LGBTQ people similarly lack access to culturally responsive care. For example, eight percent of LGBTQ people reported avoiding or postponing "needed medical care because of disrespect or discrimination from health care staff," with the number rising to 22 percent for transgender respondents.[37] Inability to obtain responsive care affects

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

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

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

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

[36] *Id.*

[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-

detection and treatment of disease, which, in turn, increases health inequity.[38] In short, racism and other forms of discrimination drive poor health outcomes and prevent their treatment, trapping individuals in a vicious cycle of deteriorating health.

Third, where individuals live plays a critical role in health care and prescription drug access.[39] For example, Black and Hispanic Medicare beneficiaries are more likely to live in medical deserts—areas with fewer primary care physicians and high-quality hospitals—making it harder for these individuals to access health care.[40] Ten percent of Black and 11 percent of Hispanic Medicare beneficiaries reported trouble accessing needed care, compared to six percent of white beneficiaries.[41] In large cities, where the majority of Black and Latino people live, Black and Latino people are more likely to live in pharmacy deserts—neighborhoods where the average distance to a pharmacy is one mile or more —which means they experience greater geographic barriers to filling their prescriptions.[42] Black and Hispanic Medicare beneficiaries are also more likely to live in areas with low quality hospitals.[43]

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[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).

[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 20, at 17.

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

[43] Ochieng, *supra* note 20, at 23.

For diabetes care, the geographic regions with the highest prevalence of diabetes are also characterized by the lowest rates of endocrinologists.[44] A general shortage of physicians, including a nationwide shortage of over 17,500 primary care doctors, will continue to exacerbate this trend.[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 NovoLog/Fiasp, diabetes disproportionately impacts racial and ethnic minorities, transgender people, disabled people, and people with low incomes.[46] 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.[47] The rate of diabetes among Asian American Medicare beneficiaries sits at 35 percent compared 24 percent for white enrollees.[48] Specifically, Asian Indian beneficiaries are 70 percent more likely to be diagnosed with diabetes than white beneficiaries.[49] American Indian and Alaskan Native adults are also almost three times more

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

[45] *See Healthcare Workforce Shortage Areas*, HEALTH RESOURCES & SERVS. ADMIN. https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited Dec. 19, 2023); Jacqueline Howard, *Concern Grows Around US Health-care Workforce Shortage: 'We don't have Enough Doctors,'* CNN (May 16, 2023, 11:00 AM), https://www.cnn.com/2023/05/16/health/health-care-worker-shortage/index.html.

[46] *Racial and Ethnic Disparities*, *supra* note 16, at 1 (Black (37 percent), Hispanic (38 percent) Medicare beneficiaries, and transgender (33 percent) had a higher prevalence of diabetes than White beneficiaries (25 percent)); Tisdale & Rapfogel, *supra* note 19.

[47] *Racial and Ethnic Disparities*, *supra* note 16, at 11.

[48] *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).

[49] *Id.*

likely to have diabetes than white adults,[50] 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.[51] American Indians and Native Alaskans are also *2.5 times more likely to die* from diabetes.[52]

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,[53] and people with cognitive limitations are up to five times more likely to have diabetes than those without.[54] 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.[55] Finally, individuals with lower incomes are more likely to develop diabetes, with people with family incomes below the federal poverty level being two times more likely *to die of*

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[50] 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/.

[51] 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/.

[52] Carratala & Maxwell, *supra* note 50.

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

[54] 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).

[55] *Diabetes Risk in the LGBTQ Community*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated July 11, 2023), https://www.cdc.gov/diabetes/library/features/diabetes_LGBTQ_community.html#:~:text=type %202%20 diabetes.-,If%20you're%20a%20member%20of%20the%20LGBTQ%20community%2C%20you, about%2098% 20million%20have%20prediabetes.

Type 2 diabetes than those with incomes above it.[56]

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."[57] These cost-saving strategies can result in more serious illnesses, more expensive treatments, and even death.[58] 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.[59] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[60] 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

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

[57] 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).

[58] *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/.

[59] 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%).").

[60] *Id.*

costs than patients at a lower risk of such conditions.[61]

For diabetes, which Novo Nordisk's drug treats, the consequences of poor medication adherence are especially stark.[62] In 2017, seven percent of adults over 65 with diabetes did not take their diabetes medication as prescribed because of cost.[63] Skipped medications results in worse glycemic control (i.e., control of blood sugar levels).[64] Deterioration in glycemic control, in turn, is associated with more emergency room visits, hospitalization, and complications from diabetes, such as hypertension, kidney disease, amputation, and even death.[65] One study found that cost-related medication non-adherence in diabetes patients was associated with an 18 percent greater risk of death.[66] Another study showed that for 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.[67] 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 have preventable medical

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[61] *Id.*

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

[63] 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).

[64] Polonsky, *supra* note 62, at 1301.

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

[66] 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).

[67] 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.

complications compared to white patients.[68] 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, 6.6 percent reported affordability problems with prescriptions, and 2.3 million seniors did not get needed prescriptions due to cost.[69] Female Medicare beneficiaries over 65 are more likely to experience prescription drug affordability problems than men.[70] 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.[71] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[72] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the general Medicare population.[73] 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.[74] High prescription drug costs lead to non-adherence and associated adverse health impacts, and those

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[68] 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).

[69] 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).

[70] Tisdale & Rapfogel, *supra* note 19; Tarazi, *supra* note 69, at 3.

[71] Tarazi, *supra* note 69, at 3.

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

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

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

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.[75]

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."[76] Medicare currently provides health insurance to 65 million Americans, with 53 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[77] 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).[78] In 2019, Medicare Part D enrollment rates were also higher among women (57 percent) than among men (43 percent).[79] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[80]

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

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[75] *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/.

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

[77] *Fact Sheet: Inflation Reduction Act Research Series—Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION 2 (Sep. 13, 2023).

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

[79] 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).

[80] *Id.* at 9.

still pay part of those costs and, historically, Part D patient out-of-pocket expenses have been significant. In 2019, the median income of Medicare beneficiaries 65 and older was around $31,000, and one in four beneficiaries had an income below $18,150.[81] Households in which all members are covered by Medicare also spend a greater percentage of their household spending on health care-related expenses; in 2021, one in three Medicare households spent 20 percent or more of their household spending on health-related expenses compared with one in 14 non-Medicare households.[82] 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.[83] Put simply, the high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[84]

As the government explained in its briefing,[85] 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.[86] Between June 2022 and May 2023, Medicare

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[81] Koma, *supra* note 19.

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

[83] 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.

[84] 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/.

[85] Defs. Combined Memo. of Law in Opp'n to Pl.'s Mot. For Summ. J. and in Support of Defs.' Cross-Mot. at 1, *Novo Nordisk, Inc. v. U.S. Dep't of Health & Human Servs.*, ECF No. 37 (D.N.J. 2024).

[86] Memorandum from Meena Seshamani, CMS Deputy Administrator and Director of the

spent $50.5 billion on the 10 drugs selected for negotiation, and nearly *$2.6 billion on NovoLog/Fiasp alone*.[87] Medicare's staggering spending on NovoLog/Fiasp is in part due to Novo Nordisk's relentless price hikes: since 2000, Novo Nordisk has raised the price of NovoLog by 628 percent—just under 9 times the rate of inflation.[88] Between just 2018 and 2022, the total annual Medicare Part D spending per enrollee taking NovoLog/Fiasp rose from $3,002 to $3,323, an 11 percent increase.[89]

By allowing the federal government to negotiate the purchase price of essential medicines for Medicare, the IRA's drug price negotiation program is projected to reduce the federal budget deficit by nearly *$100 billion by 2031*.[90] The CBO has further estimated that net prices for the drugs selected for negotiation will decrease by 50 percent on average.[91]

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, this year, CMS will implement IRA Section 11404, expanding the Medicare Part D low-income subsidy (LIS) program (also known

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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 77.

[87] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Aug. 2023).

[88] 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).

[89] *NovoLog/Fiasp: Medicare Enrollee Use and Spending*, *supra* note 13, at 1.

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

[91] *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.

as "Extra Help") for people with incomes up to 150 percent of the federal poverty level.[92] LIS generally limits out-of-pocket costs to $4.50 for generic drugs and $11.20 for brand drugs.[93] The expansion of LIS will cover 300,000 more low-income Medicare beneficiaries.[94] As of 2024, the IRA also eliminates the five percent coinsurance requirement in the catastrophic coverage phase from its Medicare Part D benefit design, and beginning in 2025, the IRA will 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.[95] 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.[96] 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.[97]

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[92] *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.

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

[94] *Fact Sheet: 2024 Medicare Advantage*, *supra* note 92.

[95] 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/.

[96] *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.

[97] *See, e.g.*, Jonathan Cohn, *This is the Most Unprecedented Part of the Democratic Prescription Drug Bill*, HUFFINGTON POST (Aug. 6, 2022), https://www.huffpost.com/entry/prescription-drug-medicare-part-d-cap_n_62ed95cde4b09fecea4e24d4; Richard Eisenberg, *Medicare Will Negotiate Drug Prices with Big Pharma for the First Time. Here's How Your Prescription Costs Might Change*, FORTUNE WELL (Oct. 25, 2023, 4:07 PM) https://fortune.com/well/2023/10/25/medicare-drug-price-negotiation-affect-prescription-

Finally, as to NovoLog/Fiasp specifically, the Medicare drug price negotiations should bring down Medicare beneficiary out-of-pocket spending on that medication. While the exact decline in price for NovoLog/Fiasp cannot be predicted, the CBO estimates a reduction of $7 billion in out-of-pocket costs for Medicare beneficiaries by 2031 based on the overall lower prices and premium decreases.[98] Indeed, the Medicare drug price negotiations could potentially even lower prices such that Part D plans may be able to offer a fixed, low co-pay for the negotiated drugs rather than requiring patients to pay coinsurance.[99]

C. Plaintiffs' Non-Delegation Argument Ignores a Century of Precedent and Would Threaten Much of Government.

1. From 1935 Through Today, the Supreme Court Has Rejected Every Non-Delegation Challenge—With Good Reason

Plaintiffs' argument that the IRA amounts to an "unlawful delegation [by Congress] of legislative power,"[100] is antithetical to the way America's government has functioned since the Founding. Plaintiffs' argument also runs afoul of a century of jurisprudence considering congressional delegation to executive agencies, in which courts have consistently refused to

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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/.

[98] *How CBO Estimated the Budgetary Impact*, *supra* note 91, at 36.

[99] 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/.

[100] Plfs. Memo. of Law in Support of Pl.'s Mot. For Summ. J. at 39-42, *Novo Nordisk, Inc. v. U.S. Dep't of Health & Human Servs.*, ECF No. 28 (D.N.J. 2024) (hereinafter "MSJ").

cabin Congress's broad authority to delegate administrative power. Indeed, the Supreme Court understood as early as 1825 that Congress "may commit something to the discretion of the other departments, and the precise boundary of this power is a subject of delicate and difficult inquiry, into which a court will not enter unnecessarily."[101] In the instant case, the IRA's modest delegation (which is cabined by several congressionally dictated requirements) sits comfortably within a century of Supreme Court law blessing such arrangements.

The Supreme Court has long recognized Congress's authority to delegate power to executive agencies as "Congress after Congress delegated vast powers without even a whiff of constitutional protest."[102] Congressional delegations to administrative agencies became even more important to the good functioning of government after the Industrial Revolution, which brought an "increasingly complex society, replete with ever changing and more technical problems" that require Congress to have the "necessary resources of flexibility and practicality, which will enable it to perform its function."[103] Thus, as early as 1935, Justice Cardozo noted that "[i]n the complex life of today, the business of government could not go on without the delegation, in greater or less degree, of the power to adapt the rule to the swiftly moving facts."[104]

The Supreme Court has only twice invoked the non-delegation doctrine to strike down governmental actions, both times in 1935.[105] In the intervening nine decades, the Court has

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[101] *Wayman v. Southard*, 23 U.S. 1, 46 (1825), 23 U.S. 1, 46 (1825).

[102] Julian Davis Mortenson & Nicholas Bagley, *Delegation at the Founding*, 121 COLUM. L. REV. 277, 332 (2021) (hereinafter *Delegation at the Founding*).

[103] *Mistretta*, 488 U.S. at 372 (quoting *Panama Refining Co. v. Ryan*, 293 U.S. 388, 421 (1935)).

[104] *Panama Refining Co.*, 293 U.S. at 441 (Cardozo, J., dissenting).

[105] *See Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495 (1935).

upheld *every* congressional delegation of power it has considered, finding that so long as Congress gives agencies an "intelligible principle" to follow, the delegation is valid.[106] To hold otherwise would render "most of Government [] unconstitutional."[107]

Plaintiffs' reliance on the two 1935 cases in which the Supreme Court struck down two provisions of the Depression-era National Industrial Recovery Act ("Recovery Act")[108] is inapposite to the century of jurisprudence that preceded and followed them. Unlike the IRA, which explicitly circumscribes HHS authorities, the Recovery Act granted the President "virtually unfettered" discretion to regulate or prohibit entire categories of commerce.[109] This lack of any "intelligible principle" from Congress to guide agency decision making was key to the result in both *Panama Refining* and *A.L.A. Schecther Poultry*.[110]

Conversely, the IRA cabins HHS's discretion far more stringently than the Recovery Act limited the various agencies it empowered. The IRA falls well within the scope of the wide berth the Court has afforded to Congress to delegate the authority by which executive agencies may effectuate the law.[111]

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[106] *See, e.g., Mistretta v. U.S.*, 481 U.S. 361, 372 (1989) ("[I]n our increasingly complex society ... Congress simply cannot do its job absent an ability to delegate under broad general directives.") *see also Opp Cotton Mills v. Administrator, Wage and Hour Div. Dept. of Labor*, 312 U.S. 126, 145 (1941) (same).

[107] *Gundy v. U.S.*, 588 U.S. ___, 139 S.Ct. 2116, 2120 (2019).

[108] MSJ at 53-54 (discussing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, (1935) and *Panama Refining Co.*, 293 U.S. 388).

[109] *A.L.A. Schechter Poultry*, 295 U.S. at 42; *see also Panama Refining Co.*, 293 U.S. at 431.

[110] *Panama Refining Co.*, 293 U.S. at 430 ("As to the transportation of oil production in excess of state permission, the Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited."); *A.L.A. Schechter Poultry*, 295 U.S. at 541 (delegation at issue "supplie[d] no standards for any trade, industry, or activity").

[111] *See, e.g., Whitman v. Am. Trucking Assoc.*, 531 U.S. 457, 465, 473-75 (2001) (quoting 42 U.S.C. § 7409(b)(1)) (upholding delegation to EPA of authority to set nationwide air quality

Plaintiffs' refusal to acknowledge this robust post-1935 case law permitting delegation far more expansive than that set forth under the IRA is an implicit recognition of the weakness of their reliance on the only two cases that affirmatively assert the non-delegation in American jurisprudential history. *See* MSJ at 50-53 (purporting to apply the Supreme Court's "non-delegation and separation-of-powers principles" but failing to cite a single non-delegation case after 1935 in which the Supreme Court struck down a delegation as unconstitutional).[112]

2. Compared to Previously Approved Delegations, the IRA Provides HHS a Far More Comprehensive Set of Guidance

Looking more closely at the delegations the Supreme Court has blessed—both in terms of the authority given and the guidance from Congress to the relevant agency—it becomes clear that the IRA's limited delegation to HHS is lawful.

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standards for air pollutants to standards "requisite to protect the public health"); *Mistretta v. United States*, 488 U.S. 361, 374 (1989) (quoting 28 U.S.C. § 991(b)(1)) (granting U.S. Sentencing Commission authority to promulgate sentencing guidelines to "provide certainty and fairness" in criminal sentencing, with all of its constitutional implications.); *Touby v. United States*, 500 U.S. 160, 166 (quoting 21 U.S.C. § 811(h)(1) (upholding grant to Attorney General of broad discretion to categorize illegal drugs—the possession or distribution of which could result in multidecade criminal sentences—if he believes it is "necessary to avoid an imminent hazard to public safety"); *Yakus v. United States*, 321 U.S. 414, 420 (1944) (approving of grant of power to executive commission to create and enforce price controls that would ensure prices would be "generally fair and equitable and [would] effectuate the purposes of [the statute]"); *Nat'l Broadcasting Co. v. United States*, 319 U.S. 190, 225-26 (1943) (quoting 47 U.S.C. § 303(g) (affirming grant of authority to FCC to regulate the country's airwaves "in the public interest.").

[112] The only Supreme Court cases Plaintiffs rely on from this century dealt with an issue not relevant here—whether Congress can insulate executive officers from at-will removal by the President. *See* MSJ at 51 (discussing *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183 (2020), and *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477 (2010)). Notably, Plaintiffs fail to note that the HHS Secretary is removable by the President at will. Plaintiffs also fail to mention that *Seila Law* and *Free Enterprise Fund* take it as given that Congress can do exactly what it did here: delegate to an administrative "body of experts" the power to "perform[] legislative and judicial functions," so long as the experts are accountable through at-will removal. *See, e.g.*, *Seila Law*, 140 S. Ct. at 2199 (*citing Humphrey's Executor v. United States*, 295 U.S. 602 (1935)).

For instance, in *Yakus*, the Supreme Court considered a challenge to Congress's delegation of the power to impose price controls under the 1942 Inflation Control Act ("ICA").[113] The ICA delegated to the newly created Office of Price Administration the authority to determine whether commodity prices had "risen or threaten to rise in a manner inconsistent with the" ICA's purposes.[114] If the Administrator determined that prices had risen too sharply, the ICA gave him the power to fix prices at the level that "in his judgment w[ould] be fair and equitable."[115] The seven factors the statute directed the Administrator to consider were extremely broad: for instance, the Administrator was empowered to decide whether price increases were "speculative, unwarranted, and abnormal," and given complete discretion to fix prices at a level that would "eliminate and prevent profiteering" and "to protect persons with relatively fixed and limited incomes."[116] Notably, a violation of the prices set by the Administrator could result in a criminal conviction (Yakus himself was prosecuted).[117] Yet despite this sweeping delegation, the majority could not have been clearer: "The standards prescribed by the present Act, with the aid of the 'statement of the considerations' required to be made by the Administrator, are sufficiently definite and precise to enable Congress, the courts and the public to ascertain whether the Administrator, in fixing the designated prices, has conformed to those standards."[118]

Comparing these broad mandates to what Congress prescribed in the IRA—which is replete with specific, concrete directions that HHS must consider when implementing the

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[113] 321 U.S. at 420.

[114] *Id.* at 426.

[115] *Id.* at 427.

[116] *Id.* at 449-50 (Roberts, J., dissenting) (citations to statutory provisions omitted).

[117] *Id.* at 427-31 (maj. op.).

[118] *Id.* at 426.

statute—reveals how far Plaintiffs fall short of establishing a constitutional violation. The IRA tells HHS *which* types of drugs to select for negotiation: the costliest, single-source drugs that have been on the market for several years with no competing generic or biosimilar on the market.[119] The statute also tells HHS *how* to determine if a drug is "single-source": by looking to "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation."[120] The same is true for the prices HHS can set for negotiation: The IRA dictates what factors HHS must consider in determining a maximum fair price,[121] the manner in which HHS must negotiate with drug manufacturers,[122] and the "[c]eiling for maximum fair price" that HHS cannot exceed.[123]

Never before has the Supreme Court considered the validity of a delegation so precise as what Congress has laid out in the IRA. To assert that the specific choices of the drugs to be included in the drug price negotiations must be designated by Congress evidences either ignorance or willful blindness of the functional capacities and expertise maintained by executive agencies and Congress respectively. HHS employs numerous career civil servants whose primary work function is tracking and understanding the highly complex and technical issues related to the pharmaceutical industry and prescription drug financing relationships.[124]

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[119] *See* 42 U.S.C.A. § 1320f-1(b)(1)-(3).

[120] *Id.* § 1320f-1(d)(3)(B).

[121] *Id.* § 1320f-2(e) (listing R&D costs, current unit costs, and market data and sales volume data for each drug).

[122] *Id.* § 1320f-(b) ("Negotiation process requirements"), *id.* § 1320f-(b)(2) ("Specific elements of the negotiation process")

[123] *Id.* § 1320f-3(c).

[124] *See* Sam Hughes and Nicole Rapfogel, *Following the Money: Untangling U.S. Prescription Drug Financing*, CTR. FOR AM. PROGRESS (Oct. 12, 2023) https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/ (explaining financial flows between drug manufacturers, production costs, insurers, pharmacies, wholesalers, and PBMs).

Conversely, the congressional committees with jurisdiction over HHS (the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions) combined, and between the Majority and Minority parties, employ likely less than twenty health staffers in total (meaning this total is divided between four distinct entities) whose focus cannot consist solely of fulfilling the edicts of the IRA lest they abandon the remaining scope of their work.[125]

American governance has functioned since the Founding with the precept that Congress creates statutory frameworks under which agencies are delegated the authority to operate and execute the law. Indeed, Plaintiffs concede that even under their view of the non-delegation doctrine, Congress has the power to pass a statute that delegates authority to an agency so long as there is an "intelligible principle" in the statute.[126] This is exactly what Congress did in the IRA—it told HHS how to choose the drugs to regulate, what data to look to in selecting them and deciding on a price, and the procedures to follow when negotiating with drug manufacturers.

Setting aside that the IRA would leave 99.9 percent of drugs unaffected, Plaintiffs have another problem: the delegations the Supreme Court has approved regulated at similar (or much greater) scales. In full, Plaintiffs do not explain why the IRA's delegation to HHS is broader or more important than any of the delegations the Supreme Court has previously

[125] Cong. Research Serv., *House of Representatives Staff Levels, 1977-2023*, R43947 (2023); Cong. Research Serv., Senate Staff Levels, 1977-2022, R43946 (the Committees have a combined 182 employees split between the Majority and Minority parties, which includes administrative, communications, labor, employment, finance, commerce, energy, oversight and health staff).

[126] MSJ at 40.

approved, or even reference the economic benefits reaped by everyday Americans.[127] EPA's air quality regulations have generated more than *$2 trillion* in economic benefits;[128] FCC's management of spectrum auctions for *radio waves alone* has netted the federal government $230 billion;[129] and the federal government itself spends $3.3 billion incarcerating people for drug-related offenses (and loses $6 billion in tax revenue).[130] As already discussed, Congress has long given the agencies implementing these enormously important schemes *far* less guidance than the IRA gives HHS in negotiating drug prices.[131]

Finally, it is worth noting that, while Plaintiffs claim that the IRA violates separation-of-powers principles,[132] they utterly ignore that their own proposed remedy would raise profound concerns about the respective roles of the three federal branches of government. Plaintiffs ask the court to strike down a statutory regime implemented by the people's representatives to provide them with greater access to health care and health equity, because, in Plaintiffs' view, their industry is too important and HHS too unaccountable to be subject to this particular structure. But as the near-century of case law discussed above makes clear, in the non-delegation sphere the Supreme Court has acted with far more humility and practicality. The

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[127] *Id.*; *see also Whitman*, 531 U.S. at 465 (nationwide regulation of air pollutants); *Nat'l Broadcasting Co.*, 319 U.S. at 225-26 (FCC control of the nation's airwaves), *Touby*, 500 U.S. at 166 (the Attorney General's plenary authority to criminalize controlled substances).

[128] *Progress Cleaning the Air and Improving People's Health*, EPA (last updated May 1, 2023) https://www.epa.gov/clean-air-act-overview/progress-cleaning-air-and-improving-peoples-health.

[129] *See, e.g.*, Roslyn Layton, *Spectrum Auctions Have Raised $230 Billion; The FCC's Authority To Conduct Them Will Lapse Soon If Congress Doesn't Act*, FORBES (Apr. 29, 2022) https://www.forbes.com/sites/roslynlayton/2022/04/29/spectrum-auctions-have-raised-230-billion-the-fccs-authority-to-conduct-them-will-lapse-soon-if-congress-doesnt-act/.

[130] *See, e.g.*, *Ending the War on Drugs: By the Numbers*, Ctr. for Am. Progress (June 27, 2018), *available at* https://www.americanprogress.org/article/ending-war-drugs-numbers.

[131] *Supra* at II.C.1.

[132] MSJ at 39-42.

Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law."[133] To the contrary, "[i]t is wisdom and humility alike that this Court has always upheld such necessities of government."[134]

Overturning a century of precedent is not an act of judicial humility. Nor should the court "enter unnecessarily" into the "delicate and difficult inquiry" posed by congressional delegation of authority in this case.[135] The Court here should affirm these same principles and experience and reject Plaintiffs' non-delegation argument.

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. The IRA's delegation of power should also be upheld because it is limited by Congress, within the scope of delegation allowed by the Supreme Court, and necessary for a functional government and economy. For these reasons, amici respectfully request that the Court take health equity and the constitutionality of the IRA's delegation of

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[133] *Whitman*, 531 U.S. 474-75 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)).

[134] *Gundy*, 139 S. Ct. at 2130 (citations and internal quotations omitted).

[135] *See*, *Wayman*, 23 U.S. 1, at 46.

power into consideration when making its decision.

Date: February 2, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Donald A. Ecklund, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: February 2, 2024

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