24-2510

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

Novo Nordisk, Inc., *et al.,*

Plaintiff- Appellants,

---v.---

Xavier Becerra, *et al.,*

Defendant- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY, No. 3:23-cv-20814

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

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

Jamie Crooks
Fairmark Partners, LLP
1001 G Street, NW, Ste. 400E
Washington, DC 20001
jamie@fairmarklaw.com

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

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IDENTITY AND INTERESTS OF PROPOSED *AMICI CURIAE*[1]

Center for American Progress (CAP) is an independent, nonpartisan policy institute that focuses, in part, on developing and advocating for policies that strengthen health. The 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)

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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.

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. 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

[2] *Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/pillar/health-equity (last visited Dec. 9, 2024).

factors impede access to adequate health care.[3] In America, health care has never truly been equitable.[4]

For decades, high drug prices have been a driver of such inequitable health care access.[5] Roughly three in ten American adults report not being able to afford to take their medications as prescribed,[6] and historically marginalized populations are among those most likely to face these affordability challenges.[7] Further, as 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

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[3] Nambi Ndugga et al., *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 et al., 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, 2023), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.

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

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[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 50–52.

[12] *See infra* notes 46–48.

transform a disparity in wealth into a 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 2023, about 785 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]

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

[16] 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).

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, 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, cabined, and aligns with delegations the Supreme Court has repeatedly blessed over the past century—such delegations are necessary for the functioning of government.

The amici request that this Court affirm the lower court's decision.

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

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

II. PROCEDURAL HISTORY

In September 2023, Novo filed a lawsuit against CMS for, among other things, violating the separations of power doctrine and establishing an unconstitutional price control.[19] Parties filed cross motions for summary judgment and on July 31, 2024, and the district court denied Novo's motion and granted CMS's.[20] In relevant part, the Court held that the IRA is voluntary and does not run afoul of the nondelegation doctrine.[21]

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 . . . ."[22] As of 2023, the median savings of white Medicare

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[19] Order re Summary Judgment, *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J.) ECF No. 93 at 8; *see e.g.*, Complaint, *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J.) ECF No. 1.

[20] *Id.* at 18.

[21] *Id.* at 9–10, 14.

[22] Nicole Rapfogel, *5 Facts to Know About Medicare Drug Price Negotiations*, CTR. FOR AM. PROGRESS (Aug. 30, 2023), https://www.americanprogress.org/article/5-facts-to-know-about-medicare-drug-price-negotiation/; *see* Gillian Tisdale & Nicole Rapfogel, *Medicare Drug Price Negotiations Will Help Millions of Seniors and Improve Health Equity*, CTR. FOR AM. PROGRESS (July 17,

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

The same is true of women, the LGBTQI+ community, and disabled people, who are also more likely to have lower incomes, creating barriers to prescription access.[26] The median savings of women enrolled in Medicare was only 72 percent

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2023), https://www.americanprogress.org/article/medicare-drug-price-negotiation-will-help-millions-of-seniors-and-improve-health-equity/; Wyatt Koma et al., *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic*, KAISER FAMILY FOUND. (Apr. 24, 2020), https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/; Bianca D.M. Wilson, *LGBT Poverty in the United States: Trends at the Onset of COVID-19*, WILLIAMS INST. (Feb. 2023); Rebecca Vallas, *Economic Justice Is Disability Justice*, THE CENTURY FOUND. (April 21, 2022), https://tcf.org/content/report/economic-justice-disability-justice/; Robin Bleiweis, Jocelyn Frye, & Rose Khattar, *Women of Color and the Wage Gap*, CTR. FOR AM. PROGRESS (Nov. 17, 2021), https://www.americanprogress.org/article/women-of-color-and-the-wage-gap/.

[23] Alex Cottrill et al., *Income and Assets of Medicare Beneficiaries in 2023*, KAISER FAMILY FOUND. (Fed. 5, 2024), https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-in-2023/.

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

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

[26] *Id*.

of their male counterparts.[27] 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.[28] 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).[29]

Second, it is well-documented that stress, racism, and discrimination drive poor health outcomes.[30] 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.[31] Stress negatively impacts the endocrine system—the malfunctioning of which

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[27] *Id.*

[28] 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).

[29] Cottrill, *supra* note 23.

[30] 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).

[31] *See* Aric A. Prather, *Stress is a Key to Understanding Many Social Determinants of Health*, HEALTH AFFAIRS (Feb. 24, 2020), https://www.healthaffairs.org/content/forefront/stress-key-understanding-many-social-determinants-health; Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFFAIRS (Oct. 4, 2018), https://www.healthaffairs.org/do/10.1377/hpb20180817.901935/; Bruce S. McEwen, *Protective and Damaging Effects of Stress Mediators*, 338 NEW ENG. J. MED. 171, 172 (1998).

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. 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 . . . ."[33]

Discrimination and a lack of access to culturally responsive care also deters some populations from obtaining needed medical treatment. As a result of concern about discrimination, 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 only three percent of white people.[34] 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," rising to 22

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[32] *See* McEwen, *supra* note 31, 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%20 known%20as,6.5%25%20of%20the%20U.S.%20population (last visited Dec. 10, 2024) (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] *Id.*

percent for transgender respondents.[35] Inability to obtain responsive and non-discriminatory care affects detection and treatment of disease, which, in turn, increases health inequity.[36]

Third, where individuals live plays a critical role in health care and prescription drug access.[37] 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.[38] 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

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[35] 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/.

[36] 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).

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

[38] Yearby, *supra* note 4, at 192; Ochieng, *supra* note 24, at 17.

prescriptions.[39] Black and Hispanic Medicare beneficiaries are also more likely to live in areas with low quality hospitals.[40]

For diabetes care, the geographic regions with the highest prevalence of diabetes are also characterized by the lowest rates of endocrinologists.[41] 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.[42] Black and Hispanic Medicare beneficiaries are diagnosed with diabetes at younger ages and have higher rates of diabetes-related complications than white beneficiaries.[43] The rate of diabetes among Asian American Medicare beneficiaries sits at 35 percent

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[39] '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/.

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

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

[42] *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 22.

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

compared 24 percent for white enrollees, with Asian Indian beneficiaries 70 percent more likely to be diagnosed with diabetes than white beneficiaries.[44] American Indian and Alaskan Native adults are also almost three times more likely to have diabetes and 2.5 times more likely to die from diabetes than white adults.[45]

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.[46] 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.[47] Finally, individuals with lower incomes are more likely to develop diabetes, with people with family incomes

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[44] *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).

[45] 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/.

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

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

below the federal poverty level being two times more likely *to die of Type 2 diabetes* than those with incomes above it.[48]

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—drives poor health outcomes within the same populations predisposed to worse health outcomes. The CDC 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."[49] These cost-saving strategies can result in more serious illnesses, more expensive treatments, and even death.[50] For example, 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

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

[49] 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).

[50] *Id.*; Nicole Rapfogel et al., *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/.

higher mortality compared to other patients with greater coverage.[51] That same study found that patients who had the greatest need for treatment were more likely to interrupt their prescription regimen due to cost.[52] 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.

For diabetes, which Novo Nordisk's drug treats, the consequences of poor medication adherence are especially stark.[53] In 2017, seven percent of adults over 65 with diabetes did not take their diabetes medication as prescribed because of cost.[54] Skipped medications results in worse glycemic control (i.e., control of blood sugar levels),[55] which is associated with more emergency room visits, hospitalization, and complications, such as hypertension, kidney disease,

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

[52] *Id*.

[53] 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).

[54] 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).

[55] Polonsky, *supra* note 55, at 1301.

amputation, and even death.[56] One study found that cost-related medication non-adherence in diabetes patients was associated with an 18 percent greater risk of death.[57] 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 complications compared to white patients.[58] 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 prescription drug affordability problems and 2.3 million seniors did not get needed prescriptions due to cost.[59] Female Medicare beneficiaries over 65 are more likely to experience

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

[57] 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).

[58] Yongkang Zhang et al., Chronic Medication Nonadherence and Potentially Preventable Healthcare Utilization and Spending Among Medicare Patients, 37 J. GEN INTERNAL MED. 3645, 3648 (2022).

[59] 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).

prescription drug affordability problems than men.[60] In 2019, Latino and Black adults over 65 were 1.5 times more likely to have prescription drug affordability problems and two times more likely not to get a prescription due to cost as white adults over 65.[61] In 2016, 14 percent of adults with disabilities over 65 did not take their medications due to cost.[62] Younger Medicare beneficiaries with disabilities are 3.5 times more likely to report medication affordability issues compared with the general Medicare population.[63] 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 heterosexual adults over 60.[64] 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.

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[60] Tisdale & Rapfogel, *supra* note 22; Tarazi, *supra* note 61, at 3.

[61] Tarazi, *supra* note 61, at 3.

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

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

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

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.[65]

Medicare currently provides health insurance to 67 million Americans, with 54 million Americans enrolled in Medicare Part D, which covers outpatient prescription drugs.[66] 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).[67] In 2019, Medicare Part D enrollment

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[65] *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/.

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

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

rates were also higher among women (57 percent) than among men (43 percent).[68] Also in 2019, roughly 14 percent of Medicare Part D enrollees were disabled.[69]

While Medicare Part D helps cover the costs of prescription drugs, 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.[70] In 2021, one in three Medicare households spent 20 percent or more of their household spending on health-related expenses compared with seven percent of non-Medicare households.[71] 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

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[68] 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).

[69] *Id.* at 9.

[70] Cottrill, *supra* note 23.

[71] 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/.

health care costs.[72] The high costs of prescription medications harm individual beneficiaries, especially when they take more than one medication.[73]

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.[74] In 2023, Medicare spent $56.2 billion on the 10 drugs selected for negotiation, and nearly *$2.6 billion on NovoLog/Fiasp alone*.[75] 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.[76] Between just

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[72] 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.

[73] 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/.

[74] Memorandum from Meena Seshamani, 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.

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

[76] 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).

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.[77]

The IRA's drug price negotiation program is projected to reduce the federal budget deficit by nearly *$100 billion by 2031*.[78] The CBO has further estimated that by 2031 net prices for the drugs selected for negotiation will decrease by 50 percent on average.[79]

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, the IRA eliminated the five percent coinsurance requirement in the catastrophic coverage phase from its Medicare Part D benefit design, and beginning in 2025, the IRA will cap Part D out-of-pocket expenses at $2,000 for all Medicare beneficiaries.[80] The IRA also includes a provision that institutes a $35 out-of-

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

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

[79] 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.

[80] Juliette Cubanski et al., *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/.

pocket cap for a month's supply of Medicare-covered insulin products.[81] 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.[82]

On August 15, 2024, HHS announced negotiated drug prices for the first ten drugs to undergo negotiations.[83] These prices will take effect in 2026.[84] The Biden-Harris administration estimates that had the negotiated prices been in effect in 2023, the Medicare program would have saved $6 billion (in other words, Medicare would have benefited from a 22 percent reduction in those drug costs).[85]

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[81] 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.

[82] *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-costs/; 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.

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

[84] *Id.* at 2.

[85] *Id.* at 4.

As of 2024, 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.[86] HHS secured a 76 percent discount from NovoLog/Fiasp's 2023 list price, bringing the cost down from $495 to $119 for a 30-day supply.[87] Cost-savings from the drug negotiation program are likely to result in savings to beneficiaries in the form of premium decreases over time, along with lower copays or coinsurance.[88]

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,"[89] 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 historically and consistently refused to cabin Congress's broad

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[86] Medicare Drug Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, supra note 15, at 4.

[87] *Id*. at 2.

[88] See, e.g., Eisenberg, supra note 84; Sy, supra note 84; NovoLog/Fiasp: Medicare Enrollee Use and Spending, supra note 13, at 1.

[89] 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").

authority to delegate administrative power.[90] 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 only twice invoked the non-delegation doctrine to strike down governmental actions, both times in 1935.[91] In the intervening nine decades, the Court has 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.[92] The intelligible principle test requires only that Congress specify "broad general directives" for agencies to follow.[93] To hold otherwise would render "most of Government [] unconstitutional."[94]

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")[95] is inapposite to the century of jurisprudence that preceded and

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

[91] *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).

[92] *See*, *e.g.*, *Mistretta v. U.S.*, 481 U.S. 361, 372 (1989); *see also Opp Cotton Mills v. Administrator, Wage and Hour Div. Dept. of Labor*, 312 U.S. 126, 145 (1941).

[93] *Mistretta v. U.S.*, 481 U.S. 361, 372 (1989).

[94] *Gundy v. U.S.*, 588 U.S. 129, 139 S.Ct. 2116, 2120 (2019).

[95] 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).

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.[96] 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. Schechter Poultry*.[97]

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 wide berth the Court has afforded to Congress to delegate the authority by which executive agencies may effectuate the law.[98]

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.[99]

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

[97] *Panama Refining Co.*, 293 U.S. at 430; *A.L.A. Schechter Poultry*, 295 U.S. at 541.

[98] *See*, *e.g.*, *Whitman v. Am. Trucking Assoc.*, 531 U.S. 457, 465, 473-75 (2001); *Mistretta v. United States*, 488 U.S. 361, 374 (1989); *Yakus v. United States*, 321 U.S. 414, 420 (1944); *Nat'l Broadcasting Co. v. United States*, 319 U.S. 190, 225-26 (1943).

[99] *See* MSJ at 50-53.

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.

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).[100] 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. If the Administrator of the Office of Price Administration 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."[101] The seven factors the statute directed the Administrator to consider were extremely broad, including deciding whether the price increases were "speculative, unwarranted, and abnormal," and whether fixing prices at a given level would "eliminate and prevent profiteering" and "protect persons with relatively fixed and limited incomes."[102] Notably, a violation

[100] 321 U.S. at 420.

[101] *Id.* at 427.

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

of the prices set by the Administrator could result in a criminal conviction (Yakus himself was prosecuted).[103] Yet despite this sweeping delegation, the majority upheld the delegation.[104]

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 statute—reveals how far Plaintiffs fall short of establishing a constitutional violation. The IRA tells HHS *which* types of drugs to select for negotiation,[105] and *how* to determine if a drug is eligible.[106] 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,[107] the manner in which HHS must negotiate with drug manufacturers,[108] and the "[c]eiling for maximum fair price" that HHS cannot exceed.[109]

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

[104] *Id.* at 426.

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

[106] *Id.* § 1320f-1(d)(3)(B).

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

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

[109] *Id.* § 1320f-3(c).

The Congress' delegation in the IRA is precise. 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 understanding the highly complex and technical issues related to the pharmaceutical industry and prescription drug financing.[110] Conversely, the two congressional committees with jurisdiction over HHS 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.[111]

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.[112] Indeed, Plaintiffs concede that

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[110] *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/.

[111] Cong. Research Serv., *House of Representatives Staff Levels, 1977-2023,* R43947 (2023); Cong. Research Serv., Senate Staff Levels, 1977-2022, R43946.

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

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.[113] This is exactly what Congress did in the IRA.

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 approved, or even reference the economic benefits reaped by everyday Americans.[114] For example, EPA's air quality regulations have generated more than *$2 trillion* in economic benefits.[115] FCC's management of spectrum auctions for *radio waves alone* has netted the federal government $230 billion. 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.[116]

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[113] MSJ at 40.

[114] *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).

[115] *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.

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

Finally, it is worth noting that, while Plaintiffs claim that the IRA violates separation-of-powers principles,[117] 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, the 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."[118] To the contrary, "[i]t is wisdom and humility alike that this Court has always upheld such necessities of government."[119] The Court should not "enter unnecessarily" into the "delicate and difficult inquiry" posed by congressional delegation of authority in this case.[120] The Court here should affirm these same principles.

[117] MSJ at 39-42.

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

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

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

IV. CONCLUSION

For these reasons, amici respectfully request that the Court affirm the District Court's decision.

Date: December 13, 2024

Respectfully submitted,

/s/ *Hannah W. Brennan*

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

Jamie Crooks
Fairmark Partners, LLP
1001 G Street, NW, Ste. 400E
Washington, DC 20001
jamie@fairmarklaw.com

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

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

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Date: December 13, 2024

/s/ Hannah W. Brennan
Hannah W. Brennan

CERTIFICATE OF SERVICE

I, Hannah Brennan, hereby certify that on December 13, 2024, I electronically filed this Amicus Curiae Brief with the Court to all counsel of record via the CM/ECF system. I further certify that seven paper copies of the foregoing brief will be sent to the Clerk's office.

Date: December 13, 2024

/s/ *Hannah W. Brennan*
Hannah W. Brennan