IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	Civ. No. 1:23-1615 (CKK)

MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS BY SENS. AMY KLOBUCHAR, PETER WELCH, TAMMY BALDWIN, RICHARD BLUMENTHAL, SHERROD BROWN, CATHERINE CORTEZ MASTO, RICHARD J. DURBIN, JOHN FETTERMAN, JOHN HICKENLOOPER, JACKY ROSEN, JEANNE SHAHEEN, DEBBIE STABENOW, CHRIS VAN HOLLEN, AND ELIZABETH WARREN

Elizabeth J. Cabraser
ecabraser@lchb.com
Eric B. Fastiff (D.C. Bar No. 453854)
efastiff@lchb.com
Dean M. Harvey
dharvey@lchb.com
Ian R. Bensberg
ibensberg@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Tel.: (415) 956-1000
Fax: (415) 956-1008

Attorneys for Amici Curiae

MOTION

Amici curiae move the Court under Local Civil Rule 7(o)(1) for leave to file the attached proposed *amicus* brief in support of Defendants' motion for summary judgment and in opposition to Plaintiff's motion for summary judgment.

All parties have consented to the filing of the attached proposed *amicus* brief.

STATEMENT OF POINTS AND AUTHORITIES

The Court has "broad discretion" to permit the filing of amicus briefs. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 519 F. Supp. 2d 89, 93 (D.D.C. 2007). "Amicus participation is normally appropriate when ... the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide." *Hard Drive Prods., Inc. v. Does 1–1,495*, 892 F. Supp. 2d 334, 337 (D.D.C. 2012). "The filing of an *amicus* brief should be permitted if it will assist the judge by presenting ideas, arguments, theories, insights, facts or data that are not to be found in the parties' briefs." *Northern Mariana Islands v. United States*, No. 08-1572, 2009 WL 596986, *1 (D.D.C. 2009). As explained below, these standards are satisfied here.

I. Identity of *Amici*

Senator **Amy Klobuchar** has represented the State of Minnesota in the United States Senate since 2007. She is Chairwoman of the Senate Rules Committee and Democratic Steering Committee. She serves on the Judiciary Committee (where she is Chairwoman of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights), the Commerce, Science, and Transportation Committee, the Agriculture, Nutrition, and Forestry Committee, and the Joint Economic Committee. Sen. Klobuchar has been a leading advocate for reducing the cost of prescription drugs. For years until the passage of a Medicare drug price negotiation program,

Sen. Klobuchar sponsored a bill in the U.S. Senate to lift the ban on Medicare negotiating the price of prescription drugs.

Senator **Peter Welch** has represented the State of Vermont in the United States Senate since 2023. He serves on the Judiciary Committee; the Commerce, Science, and Transportation Committee; the Joint Economic Committee, and the Agriculture, Nutrition, and Forestry Committee, where he chairs the Subcommittee on Rural Development and Energy. Prior to serving as Vermont's junior Senator, he represented the Green Mountain State in the House of Representatives for eight terms. Senator Welch has been a longtime champion of policies to hold pharmaceutical companies accountable for skyrocketing drug costs and price-gouging, and he has worked across the aisle to lower the cost of health care for seniors, families, and patients.

Senator **Tammy Baldwin** has represented the State of Wisconsin in the United States Senate since 2013 and represented the 2nd Congressional District of Wisconsin in the House of Representatives from 1999 to 2012. She currently serves on the Senate Committee on Health, Education, Labor and Pensions (HELP), the Senate Committee on Commerce, Science and Transportation, and the Senate Appropriations Committee. Senator Baldwin has long championed efforts to provide quality health care for all Americans, including through policies to hold drug companies accountable and reduce out-of-pocket costs for families and taxpayers.

Senator **Richard Blumenthal** has represented the State of Connecticut in the United States Senate since 2011. He currently serves as a member of the Committee on the Judiciary, Committee on Homeland Security and Governmental Affairs, Committee on Armed Services, Committee on Veterans' Affairs, and Special Committee on Aging. Prior to becoming a United States Senator, he served an unprecedented five terms as Connecticut's Attorney General,

fighting for the people against large and powerful special interests. Senator Blumenthal has long been a champion for consumer rights and a staunch advocate for affordable health care.

Senator **Sherrod Brown** has represented the State of Ohio in the United States Senate since 2007. He serves as the Chair of the Senate Banking, Housing and Urban Affairs Committee and is a member of the Senate Finance, Agriculture, and Veterans' Affairs Committees. For decades, Brown has led efforts to allow Medicare to negotiate directly with pharmaceutical companies and take on Big Pharma to lower health care and prescription drug costs for Ohioans.

Senator **Catherine Cortez Masto** has represented the State of Nevada in the United States Senate since 2017. She currently serves on the Committee on Finance, the Committee on Banking, Housing, and Urban Affairs, the Committee on Energy and Natural Resources, and the Committee on Indian Affairs. Sen. Cortez Masto currently serves as the chair of the Energy and Natural Resources Committee's Public Lands, Forests, and Mining Subcommittee. Prior to serving in the Senate, she served two terms as Attorney General of Nevada. Sen. Cortez Masto has fought to lower drug costs for Nevada seniors, working hard to pass the Medicare drug price negotiation program, allowing Medicare to get the best deal for seniors.

Senator **Richard J. Durbin** has represented the State of Illinois in the United States Senate since 1997. He is the Senate Majority Whip and Chair of the Senate Judiciary Committee. He also serves on the Senate Committee on Agriculture, Nutrition, and Forestry and the Senate Committee on Appropriations. Sen. Durbin has been a leading advocate for lowering the cost of prescription drugs borne by patients and lowering overall Medicare spending. Senator Durbin previously has introduced legislation to recoup certain amounts of reimbursements to manufacturers for excess medication in single-use vials that is discarded, create a public Part D

plan option, and empower patients by enhancing transparency in advertisements about the cost of prescription drugs covered by Medicare.

Senator **John Fetterman** has represented the State of Pennsylvania in the United States Senate since 2023. He serves on the Committee on Banking, Housing, and Urban Affairs; the Agriculture, Nutrition, and Forestry Committee, where he chairs the Subcommittee on Food and Nutrition; the Environment and Public Works Committee; the Joint Economic Committee; and the Committee on Aging. Prior to serving as Pennsylvania's junior Senator, he served as Pennsylvania's Lieutenant Governor and as Mayor of Braddock. Senator Fetterman believes that every Pennsylvanian must have affordable access to the medicines they need to maintain and restore their health.

Senator **John Hickenlooper** has represented the State of Colorado in the United States Senate since 2021. Sen. Hickenlooper took an unconventional path to public office. After starting out as a geologist, John took a chance by opening the first brewpub in Colorado. As a small business owner, he gained a deep understanding of the local community and the value of collaboration. John entered public service because he knew he could listen to the diverse array of Colorado voices and get things done. As Colorado's U.S. Senator, John is committed to bringing people together to solve our country's toughest problems. Senator Hickenlooper is focused on bringing costs down for patients and lowering prescription drug prices as part of his work on the HELP Committee.

Senator **Jacky Rosen** has represented the State of Nevada in the United States Senate since 2019. She serves in the Senate Armed Services Committee; the Homeland Security and Governmental Affairs Committee; the Commerce, Science, and Transportation Committee; and the Small Businesses Committee. Sen. Rosen has been a champion for lowering prescription

drug prices for Nevada's seniors, including through legislation to allow Medicare to negotiate the costs of prescription drugs. Throughout her time in the Senate, she has also introduced bipartisan legislation to lower drug prices by advancing medicine produced by nonprofit companies.

Senator **Jeanne Shaheen** has represented the State of New Hampshire in the United States Senate since 2009. She serves on the Senate Appropriations Committee; Armed Services Committee; Foreign Relations Committee; and the Small Business and Entrepreneurship Committee. Prior to her time in the Senate, Senator Shaheen served as Governor of New Hampshire from 1997 to 2003, as well as two terms in the New Hampshire State Senate. Senator Shaheen is a tireless champion for access to pharmaceuticals, including spearheading legislation to comprehensively lower the cost of insulin and supporting several pieces of legislation to address the skyrocketing costs of prescription drugs.

Senator **Debbie Stabenow** has represented the State of Michigan in the United States Senate since 2001.

Senator **Chris Van Hollen** has represented the State of Maryland in the United States Senate since 2017 and represented the 8th Congressional District of Maryland in the House of Representatives from 2003 to 2016. He currently serves on the Senate Budget Committee and Senate Appropriations Committee, and in the House of Representatives he was Ranking Member of the House Budget Committee and served on the House Committee on Ways and Means. Senator Van Hollen has supported a number of bills to allow Medicare price negotiation and has introduced legislation to address the high cost of prescription drugs developed using taxpayer-funded medical research and clinical trials.

Senator **Elizabeth Warren** has represented the State of Massachusetts in the United States Senate since 2013. She currently serves on the Committee on Finance, the Committee on

Banking, Housing, and Urban Affairs, the Committee on Armed Services, and the Special Committee on Aging. Senator Warren has consistently defended Medicare's constitutional right to negotiate prescription drug prices with pharmaceutical companies, who have engaged in a litany of anti-competitive tactics to stifle competition and keep prescription drug costs sky-high.

II. Interest of *Amici*

Amici curiae are United States Senators who have spearheaded legislative efforts to reduce drug prices. *Amici* have a unique interest in the constitutionality of laws enacted by Congress to permit Medicare price negotiations, and *amici* have relied on Congress's right under the Constitution to carefully review current laws and make improvements in order to bring down drug prices in federal programs.

III. Contribution of *Amici*

The attached proposed *amicus* brief provides relevant history of Medicare's prescription drug benefit, and a summary of how Congress carefully considered the competing interests at stake and struck an appropriate legislative balance. As members of the United States Senate who worked and voted on the legislation at issue in this case, *amici* are uniquely positioned to comment on its enactment. The proposed *amicus* brief also explains how Plaintiff misrepresents the challenged legislation, as well as the unsustainable status quo it reformed.

CONCLUSION

The Court should grant the motion of *amici curiae* and grant them leave to file the attached *amicus* brief.

Dated: September 19, 2023

/s/ Eric B. Fastiff

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

Elizabeth J. Cabraser
ecabraser@lchb.com
Eric B. Fastiff (D.C. Bar No. 453854)
efastiff@lchb.com
Dean M. Harvey
dharvey@lchb.com
Ian R. Bensberg
ibensberg@lchb.com
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Tel.: (415) 956-1000
Fax: (415) 956-1008

Attorneys for Amici Curiae

2849581.3

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,

Plaintiff,

v.

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

Defendants.

Civ. No. 1:23-1615 (CKK)

[PROPOSED] BRIEF OF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS BY SENS. AMY KLOBUCHAR, PETER WELCH, TAMMY BALDWIN, RICHARD BLUMENTHAL, SHERROD BROWN, CATHERINE CORTEZ MASTO, RICHARD J. DURBIN, JOHN FETTERMAN, JOHN HICKENLOOPER, JACKY ROSEN, JEANNE SHAHEEN, DEBBIE STABENOW, CHRIS VAN HOLLEN, AND ELIZABETH WARREN

Elizabeth J. Cabraser
ecabraser@lchb.com
Eric B. Fastiff (D.C. Bar No. 453854)
efastiff@lchb.com
Dean M. Harvey
dharvey@lchb.com
Ian R. Bensberg
ibensberg@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Tel.: (415) 956-1000
Fax: (415) 956-1008

Attorneys for Amici Curiae

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Statutes

Other Authorities

TABLE OF AUTHORITIES
(continued)

Page(s)

Constitutional Provisions

IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici curiae are United States Senators who have spearheaded legislative efforts to reduce drug prices. *Amici* have a unique interest in the constitutionality of laws enacted by Congress to permit Medicare price negotiations, and *amici* have relied on Congress's right under the Constitution to carefully review current laws and make improvements in order to bring down drug prices in federal programs.

Senator **Amy Klobuchar** has represented the State of Minnesota in the United States Senate since 2007. She is Chairwoman of the Senate Rules Committee and Democratic Steering Committee. She serves on the Judiciary Committee (where she is Chairwoman of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights), the Commerce, Science, and Transportation Committee, the Agriculture, Nutrition, and Forestry Committee, and the Joint Economic Committee. Sen. Klobuchar has been a leading advocate for reducing the cost of prescription drugs. For years until the passage of a Medicare drug price negotiation program, Sen. Klobuchar sponsored a bill in the U.S. Senate to lift the ban on Medicare negotiating the price of prescription drugs.

Senator **Peter Welch** has represented the State of Vermont in the United States Senate since 2023. He serves on the Judiciary Committee; the Commerce, Science, and Transportation Committee; the Joint Economic Committee, and the Agriculture, Nutrition, and Forestry Committee, where he chairs the Subcommittee on Rural Development and Energy. Prior to serving as Vermont's junior Senator, he represented the Green Mountain State in the House of Representatives for eight terms. Senator Welch has been a longtime champion of policies to hold pharmaceutical companies accountable for skyrocketing drug costs and price-gouging, and he has worked across the aisle to lower the cost of health care for seniors, families, and patients.

Senator **Tammy Baldwin** has represented the State of Wisconsin in the United States Senate since 2013 and represented the 2nd Congressional District of Wisconsin in the House of Representatives from 1999 to 2012. She currently serves on the Senate Committee on Health, Education, Labor and Pensions (HELP), the Senate Committee on Commerce, Science and Transportation, and the Senate Appropriations Committee. Senator Baldwin has long championed efforts to provide quality health care for all Americans, including through policies to hold drug companies accountable and reduce out-of-pocket costs for families and taxpayers.

Senator **Richard Blumenthal** has represented the State of Connecticut in the United States Senate since 2011. He currently serves as a member of the Committee on the Judiciary, Committee on Homeland Security and Governmental Affairs, Committee on Armed Services, Committee on Veterans' Affairs, and Special Committee on Aging. Prior to becoming a United States Senator, he served an unprecedented five terms as Connecticut's Attorney General, fighting for the people against large and powerful special interests. Senator Blumenthal has long been a champion for consumer rights and a staunch advocate for affordable health care.

Senator **Sherrod Brown** has represented the State of Ohio in the United States Senate since 2007. He serves as the Chair of the Senate Banking, Housing and Urban Affairs Committee and is a member of the Senate Finance, Agriculture, and Veterans' Affairs Committees. For decades, Brown has led efforts to allow Medicare to negotiate directly with pharmaceutical companies and take on Big Pharma to lower health care and prescription drug costs for Ohioans.

Senator **Catherine Cortez Masto** has represented the State of Nevada in the United States Senate since 2017. She currently serves on the Committee on Finance, the Committee on Banking, Housing, and Urban Affairs, the Committee on Energy and Natural Resources, and the Committee on Indian Affairs. Sen. Cortez Masto currently serves as the chair of the Energy and

Natural Resources Committee's Public Lands, Forests, and Mining Subcommittee. Prior to serving in the Senate, she served two terms as Attorney General of Nevada. Sen. Cortez Masto has fought to lower drug costs for Nevada seniors, working hard to pass the Medicare drug price negotiation program, allowing Medicare to get the best deal for seniors.

Senator **Richard J. Durbin** has represented the State of Illinois in the United States Senate since 1997. He is the Senate Majority Whip and Chair of the Senate Judiciary Committee. He also serves on the Senate Committee on Agriculture, Nutrition, and Forestry and the Senate Committee on Appropriations. Sen. Durbin has been a leading advocate for lowering the cost of prescription drugs borne by patients and lowering overall Medicare spending. Senator Durbin previously has introduced legislation to recoup certain amounts of reimbursements to manufacturers for excess medication in single-use vials that is discarded, create a public Part D plan option, and empower patients by enhancing transparency in advertisements about the cost of prescription drugs covered by Medicare.

Senator **John Fetterman** has represented the State of Pennsylvania in the United States Senate since 2023. He serves on the Committee on Banking, Housing, and Urban Affairs; the Agriculture, Nutrition, and Forestry Committee, where he chairs the Subcommittee on Food and Nutrition; the Environment and Public Works Committee; the Joint Economic Committee; and the Committee on Aging. Prior to serving as Pennsylvania's junior Senator, he served as Pennsylvania's Lieutenant Governor and as Mayor of Braddock. Senator Fetterman believes that every Pennsylvanian must have affordable access to the medicines they need to maintain and restore their health.

Senator **John Hickenlooper** has represented the State of Colorado in the United States Senate since 2021. Sen. Hickenlooper took an unconventional path to public office. After starting

out as a geologist, John took a chance by opening the first brewpub in Colorado. As a small business owner, he gained a deep understanding of the local community and the value of collaboration. John entered public service because he knew he could listen to the diverse array of Colorado voices and get things done. As Colorado's U.S. Senator, John is committed to bringing people together to solve our country's toughest problems. Senator Hickenlooper is focused on bringing costs down for patients and lowering prescription drug prices as part of his work on the HELP Committee.

Senator **Jacky Rosen** has represented the State of Nevada in the United States Senate since 2019. She serves in the Senate Armed Services Committee; the Homeland Security and Governmental Affairs Committee; the Commerce, Science, and Transportation Committee; and the Small Businesses Committee. Sen. Rosen has been a champion for lowering prescription drug prices for Nevada's seniors, including through legislation to allow Medicare to negotiate the costs of prescription drugs. Throughout her time in the Senate, she has also introduced bipartisan legislation to lower drug prices by advancing medicine produced by nonprofit companies.

Senator **Jeanne Shaheen** has represented the State of New Hampshire in the United States Senate since 2009. She serves on the Senate Appropriations Committee; Armed Services Committee; Foreign Relations Committee; and the Small Business and Entrepreneurship Committee. Prior to her time in the Senate, Senator Shaheen served as Governor of New Hampshire from 1997 to 2003, as well as two terms in the New Hampshire State Senate. Senator Shaheen is a tireless champion for access to pharmaceuticals, including spearheading legislation to comprehensively lower the cost of insulin and supporting several pieces of legislation to address the skyrocketing costs of prescription drugs.

Senator **Debbie Stabenow** has represented the State of Michigan in the United States Senate since 2001.

Senator **Chris Van Hollen** has represented the State of Maryland in the United States Senate since 2017 and represented the 8th Congressional District of Maryland in the House of Representatives from 2003 to 2016. He currently serves on the Senate Budget Committee and Senate Appropriations Committee, and in the House of Representatives he was Ranking Member of the House Budget Committee and served on the House Committee on Ways and Means. Senator Van Hollen has supported a number of bills to allow Medicare price negotiation and has introduced legislation to address the high cost of prescription drugs developed using taxpayer-funded medical research and clinical trials.

Senator **Elizabeth Warren** has represented the State of Massachusetts in the United States Senate since 2013. She currently serves on the Committee on Finance, the Committee on Banking, Housing, and Urban Affairs, the Committee on Armed Services, and the Special Committee on Aging. Senator Warren has consistently defended Medicare's constitutional right to negotiate prescription drug prices with pharmaceutical companies, who have engaged in a litany of anti-competitive tactics to stifle competition and keep prescription drug costs sky-high.

This *amicus* brief is filed with the parties' consent.

FED. R. APP. P. 29(a)(4)(E) STATEMENT

As required by Local Civil Rule 7(o)(5) and Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* state as follows: No party's counsel authored this *amicus* brief in whole or part. No party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief. No person other than *amici*'s counsel contributed money that was intended to fund preparing or submitting this *amicus* brief.

INTRODUCTION

Plaintiff Merck & Co., Inc., complains of legislation that resulted from a policy debate in which industry participants have been afforded, and availed themselves of, a full and fair opportunity to be heard.[1] Congress weighed the competing interests at stake carefully. The Court should respect the policy decisions Congress made here and turn away Merck's meritless efforts to nullify them.

Drug prices in the United States are the highest in the developed world.[2] In an effort to lower these prices, the Inflation Reduction Act of 2022 (IRA), Pub. L. 117–169, authorizes Defendant Centers for Medicare & Medicaid Services (CMS) to do what it does with doctors and other providers as a matter of course—as well as what other federal payers such as the Department of Veterans Affairs and the Department of Defense do—but which CMS has been prohibited from doing since 2003: negotiate the prices of certain costly drugs directly with drug manufacturers (the "Medicare Drug Price Negotiation Program" or "Program").

Merck and its allies in the pharmaceutical industry tried to prevent this legislative result. Merck now attempts to accomplish through judicial action what it could not through the

---

[1] Notably, Plaintiff's complaints relate to a drug, Januvia, that it does not even manufacture. This threshold deficiency dooms its case, as the government explains. *See* Cross-Mot. & Opp. Br. 8–9, ECF Nos. 24-1, 25.

[2] Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons* vii (2021), tps://aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbecf28b/international-prescription-drug-price-comparisons.pdf ("U.S. prices for drugs in 2018 were 256 percent of those in the 32 OECD comparison countries combined."). Unsurprisingly, pharmaceutical profits have followed suit. *See* Bob Herman, *The U.S. is the drug industry's gold mine*, Axios (Sept. 30, 2021), https://www.axios.com/2021/09/30/drug-prices-pharma-revenue-usa-international; Fred D. Ledly, M.D. et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323(9) JAMA 834-43 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054843/ ("[T]he profitability of a set of large, fully integrated pharmaceutical companies, which generate revenue primarily from the sale of pharmaceutical products, was shown to be significantly greater than that of other large, nonpharmaceutical companies in the S&P 500 Index from 2000 to 2018.").

legislative process. Merck's position in this litigation boils down to the argument that the United States Constitution somehow prohibits the federal government from negotiating the prices of the products it purchases. Merck seeks to prevent reform of a purchasing process that Congress itself made, but now, according to Merck, cannot unmake, or even amend for the benefit of the American public and the American taxpayer. As a matter of constitutional law, that position is baseless, as the government's opposition and cross-motion for summary judgment ably explain. *See* ECF Nos. 24-1, 25 (memorandum in support of cross-motion and in opposition). Congress improves laws all the time, and it has the right and indeed the duty to do so. The Program takes nothing from Merck: not its drugs and not its patents. And the Program likewise does not coerce Merck to do or say anything: like every other market participant, it may sell its products at a price the buyer thinks is fair, or it may not.

In this brief, *amici* respectfully offer the Court some relevant historical and legislative background against which to evaluate the parties' respective arguments.

ARGUMENT

I. Merck's Opposition to the Program Should Be Considered in Light of the History of Medicare's Prescription Drug Benefit.

Today, Medicare is the largest payer for pharmaceuticals in the United States, measured by total spending.[3] But when Medicare was originally enacted in 1965, it did not provide an outpatient prescription drug benefit.[4] The journey from 1965 to the current prescription drug

[3] MedPAC, *Chapter 3: Medicare Payment Strategies to Improve Price Competition and Value for Part B Drugs*, in Report to the Congress: Medicare and the Health Care Delivery System (2019), *available at* https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf.

[4] Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 Milbank Q. 283, 291 (2004).

benefit provided by Medicare Part D, enacted as part of the Medicare Modernization Act of 2003, is characterized by the competing pressures of ensuring adequate coverage for Medicare beneficiaries' most expensive and potentially catastrophic outlays, on the one hand, and the fiscal necessity of lowering the program's costs, on the other.

As originally enacted, Medicare covered the cost of prescription drugs dispensed in a physician's office, primarily to disincentivize physicians from recommending hospitalization—which costs were frequently unpredictable—simply to ensure coverage.[5] A universal outpatient benefit was rejected in 1965 "on the grounds of unpredictable and potentially high costs."[6]

Over the next four decades, Congress continued to expand outpatient prescription drug coverage piecemeal, without enacting a comprehensive solution. President Johnson convened a Task Force on Prescription Drugs in 1967, which reported to President Nixon in 1969 that "a drug insurance program under Medicare is needed . . . and would be both economically and medically feasible."[7] The urgency for such coverage was heightened by drug costs that had begun spiraling out of control beginning in the 1950s, and by the limitations imposed by private insurers on outpatient prescription coverage.[8] But the Task Force's recommendation was not adopted.

A major barrier to the enactment of full outpatient coverage was the resistance of the pharmaceutical industry to any form of price regulations, first instituted across the national

[5] *Id.* at 292.

[6] *Id.* at 291.

[7] *Id.* at 294.

[8] *Id.* at 293.

economy in peacetime by President Nixon in 1971.[9] From Nixon's New Economic Policy, the pharmaceutical industry (whose political power was still largely nascent) "drew . . . the lesson that price controls would likely accompany any federal sponsorship of prescription drug coverage."[10] In 1988, Congress enacted the Medicare Catastrophic Coverage Act (MCAA), which, as its name suggests, covered outpatient prescriptions only in "catastrophic" situations.[11] The MCAA was deeply unpopular. Its defenders "alleged, but never proved conclusively, that the pharmaceutical industry helped organize and fund the campaign for repeal."[12] Whatever its funding sources, the campaign was successful, and the MCAA—the first major Medicare expansion in two decades—was largely repealed a year after its passage.[13]

In 1994, the next opportunity for extending prescription drug coverage met a swift end under "withering attack" from the pharmaceutical industry, which argued that proposals to require drug manufacturers to sign rebate agreements with the federal government, to authorize the government to negotiate rebates for new drugs, and to encourage the use of generics, would impose unnecessary layers of complex bureaucracy and would lead to rationing.[14] In the late 1990s, by contrast, when Congress showed greater interest in subsidizing private health insurance than it had previously, the pharmaceutical industry softened its stance on expansion of Medicare prescription drug benefits.[15] The industry believed it would have "stronger negotiating

---

[9] Burton A. Abrams et al., *The Political Economy of Wage and Price Controls: Evidence from the Nixon Tapes*, 170 Pub. Choice 63, 63 (2017).

[10] Oliver, *A Political History of Medicare and Prescription Drug Coverage*, *supra*, at 296.

[11] *Id.* at 300.

[12] *Id.*

[13] *Id.* at 301.

[14] *Id.* at 302; *see also id.* at 331.

[15] *Id.* at 306.

power vis-à-vis private organizations" such as private insurers and pharmacy benefit managers "than it would if it had to deal directly with the federal government."[16]

This conditional support for expanded prescription drug benefits (conditioned, in other words, on the proposition that federal money would be paid without a centralized federal role) bore fruit for the pharmaceutical industry in 2003 with the passage of the Medicare Modernization Act (MMA). Known today as Medicare Part D, as relevant here, the Medicare expansion implemented by the MMA greatly expanded prescription drug coverage, but at a steep cost: the government was prohibited from directly negotiating the prices it paid to drug manufacturers.[17] In this respect (together with the MMA's maintenance of a ban on reimporting prescription drugs from other countries), the pharmaceutical industry came out a "clear winner[]": it had prevailed on its "priority issue[]" of avoiding "direct administration of benefits by the federal government."[18]

II. Congress Carefully Considered the Competing Interests at Stake in the Program and Struck an Appropriate Balance.

Over the next two decades, it became clear (if it had not been so before) that the status quo created by the MMA was unsustainable. In 2019, the Congressional Research Service observed that "the Medicare Trustees indicate that Part D spending is growing rapidly."[19] In 2021, Medicare accounted for 10 percent of the nearly $7 trillion national budget, more than one fifth (21 percent) of all national health expenditures, and nearly one third (32 percent) of all retail

[16] *Id.* at 339–40.

[17] *Id.* at 318.

[18] *Id.*

[19] Cong. Research Serv., *Negotiation of Drug Prices in Medicare Part D* at 1 (2019), *available at* https://crsreports.congress.gov/product/pdf/IF/IF11318/2.

prescription drug sales.[20] In 2022, CMS estimated that from 2021 to 2030, Medicare would see the fastest cost growth rates among major federal payers.[21] Medicare spending alone was projected to exceed $1 trillion annually for the first time in 2023.[22] While prescription drug costs were not the sole factor driving this projected growth, they were a substantial driver of it, with an average growth rate of 5 percent from 2021 to 2030.[23] This growth in Medicare drug spending mirrors broader trends in the national economy that affect every American. For example, "[n]early 80 percent of Americans said prescription drug prices were unreasonable in 2019."[24] And almost *one third* of Americans have decided to take prescription drugs otherwise than as prescribed by their physicians due to cost concerns.[25]

The Inflation Reduction Act of 2022, and the Medicare Price Negotiation Program specifically, were carefully designed to give Defendant Health and Human Services Secretary negotiation authority, which will help contain these ballooning costs and preserve the health of the Medicare program for future generations of American seniors. Beginning in 2026, the first year of effective negotiated pricing under the Program, the non-partisan and independent Congressional Budget Office estimates that the Program will result in nearly $5 billion in federal

---

[20] Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, KFF (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/.

[21] Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Office of the Actuary Releases 2021-2030 Projections of National Health Expenditures (Mar. 28, 2022), https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2021-2030-projections-national-health-expenditures.

[22] *Id.*

[23] *Id.*

[24] Henry A. Waxman et al., *Getting to Lower Prescription Drug Prices* at 6 (2020), https://www.commonwealthfund.org/sites/default/files/2020-10/Waxman_GettingtoLowerRxPrices_report_v3.pdf.

[25] *Id.*

savings, nearly $10 billion the following year, and a total savings of more than *$1 trillion* between 2022 and 2031.[26] Nine million American seniors and Medicare beneficiaries use the first ten drugs selected by Defendant Secretary for price negotiation under the Program,[27] including the drug that Plaintiff markets (but does not manufacture),[28] Januvia. As Defendant Secretary adds drugs under the Program in coming years, more and more of America's *64 million* Medicare enrollees will benefit.[29] And because Medicare is the largest pharmaceuticals payer in the country,[30] reductions in the prices paid by Medicare are anticipated to lower prices across the economy.[31]

Like the IRA as a whole,[32] the Program is the result of careful congressional fact-finding, interest-balancing, and deliberation through a process in which the industry has been able to

---

[26] Cong. Budget Office, *Cost Estimate* (2022), https://www.cbo.gov/system/files/2022-08/hr5376_IR_Act_8-3-22.pdf.

[27] ASPE, *Fact Sheet* (2023), https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf.

[28] *See* Cross-Mot. & Opp. Br. 8–9.

[29] CMS, *CMS Program Statistics - Medicare Part D Enrollment* (2021), https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/cms-program-statistics-medicare-part-d-enrollment.

[30] *See Chapter 3: Medicare Payment Strategies to Improve Price Competition and Value for Part B Drugs*, *supra*.

[31] Cong. Budget Office, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 10–11 (2023), *available at* https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

[32] The IRA was passed according to the Senate's rules of reconciliation and after consideration by the Senate Parliamentarian (originally appointed by a Republican-majority Senate), who also reviewed and approved the Program. *See Parliamentarian weakens Democrats' drug plan in Inflation Reduction Act, as Senate prepares to vote*, CBS News (Aug. 6, 2022), https://www.cbsnews.com/news/inflation-reduction-act-senate-prepares-to-vote/. There is nothing remarkable about the IRA's passage through reconciliation; it is the process by which many other Medicare-related bills have been enacted, including without limitation Omnibus and Budget Reconciliation Acts enacted in 1986, 1987, 1990, and 1993; the Affordable Care Act of 2010; and the Tax Equity and Fiscal Responsibility Act of 1982. *See* OpEd Chart, N.Y. Times

participate fully and fairly. Following the introduction of the provisions that would become the IRA as part of H.R. 5376, 117th Cong. (2021), in September 2021, Congress heard from numerous experts and stakeholders who testified in favor of the negotiation principle embodied by the Program.

The Program was the culmination of ten years' work examining the Medicare Part D system and escalating drug costs across the national economy. In December 2009, the U.S. Government Accountability Office observed in a letter to Vice Chairman of the Joint Economic Committee Sen. Charles Schumer and Committee Member and *amicus* Sen. Amy Klobuchar, responding to the Senators' request for information, that, looking back to the year 2000, "the growing cost of brand name prescription drugs can be a burden on patients, payers, and providers of health care—particularly when price increases are large and occur suddenly."[33] In 2012, both the launch prices of medicines, as well as the annual cost increases of prescription drugs already on the market, started to grow. Medicare Part D reinsurance cost started to climb at a faster annual pace than before.[34]

Ten years after the Medicare Part D program had been enacted, committees in both legislative chambers began to hold hearings.[35] In 2016, at the direction of the Committee on

---

(Mar. 7, 2010), https://archive.nytimes.com/www.nytimes.com/imagepages/2010/03/07/opinion/07opedchart_graphic.html.

[33] GAO, *Brand-Name Prescription Drug Pricing* at 1 (2009), https://www.gao.gov/assets/gao-10-201.pdf.

[34] Bds. of Trs. of Fed. Hosp. Ins. Tr. Fund & Fed. Supplementary Med. Ins. Tr. Fund, *2017 Annual Report* (2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf.

[35] *Ten Years Later: A Look at the Medicare Prescription Drug Program, Hearing Before the S. Special Comm. on Aging*, 113th Cong. (2013); *Examining Reforms to Improve the Medicare Part B Drug Program For Seniors, Hearing Before the H. Energy & Commerce Comm.*, 113th Cong. (2013).

Appropriations of the House of Representatives and the Senate, the Assistant Secretary for Planning and Evaluation at HHS issued a report to Congress explaining that growth in prescription drug spending was rising faster than overall health spending.[36] The 2016 presidential election saw the front runners debate proposals to lower the price of prescription drugs. Public and policymaker focus on prescription drug prices and the Medicare Part D program was clear.

Congress started passing a number of bills focused on fixing the prescription drug market, starting with the 21st Century Cures Act of 2016, which, among other measures, sought to reduce overpayments for infusion drugs.[37] In 2017, the Senate Committee on Health Education Labor and Pensions (HELP) held a two-part hearing on "The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay." In 2018, the House Energy and Commerce Committee, the Senate Judiciary Committee, Senate HELP, and the Senate Finance Committee all held hearings examining the pharmaceutical market and consumer costs. In 2019, the Senate Finance Committee held a three-part hearing on "Drug Pricing in America." This was followed by the House Oversight Committee, under Chairman Elijah Cummings, holding several hearings and conducting a years-long investigation on the behavior of pharmaceutical companies and the price of prescription drugs for consumers. In fact, between 2015 and 2022, over two dozen hearings were held in the Senate and the House on prescription drug pricing. And between 2018 and 2020, five pieces of enacted legislation addressed the problem.[38]

---

[36] ASPE, *Issue Brief: Observations and Trends in Prescription Drug Spending* (2016); ASPE, *Report to Congress: Prescription Drugs: Innovation, Spending, and Patient Access* (2016).

[37] *See* Cong. Research Serv., *The 21st Century Cures Act (Division A of P.L. 114-255)* (2016), https://sgp.fas.org/crs/misc/R44720.pdf.

[38] *See* Waxman, *Getting to Lower Prescription Drug Prices*, *supra*, at Appendix B, 38–39.

The Congressional Budget Office, the Government Accountability Office, and the Congressional Research Service all produced reports and analyses at Congress's request on the topics of prescription drug pricing generally and negotiation of prescription drug prices specifically. Committees, both those mentioned above and the Joint Economic Committee, also did their own investigations and released reports on prescription drug pricing. On December 12, 2019, the House passed the Elijah Cummings Lower Drug Costs Now Act by a vote of 230 to 192. This bill included a provision to allow Medicare to negotiate prescription drugs on seniors' behalf.

Moreover, outside the Medicare context, other federal payers have long had price negotiation authority—without appearing to harm the vitality and innovativeness of the pharmaceutical industry. The Veterans Health Care Act of 1992, P.L.102-585, established contractual pricing mechanisms (on which the Program's "Maximum Fair Price" was consciously modeled) that set price ceilings for certain federal agencies, including the Veterans Health Administration, which operates the nation's largest public direct health care system.[39] The Act requires drug manufacturers to sell covered drugs to four agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard—at no more than 76 percent of the nonfederal average manufacturer's price ("non-FAMP"). Noncompliant manufacturers are barred from accessing Medicaid and Medicare Part B funds. Notably, these pricing mechanisms are not limited to a certain set of drugs, and are available for new pharmaceuticals coming into the market, thus covering a far broader range of drugs than do the Program's narrowly tailored interventions.

[39] U.S. Dept. of Veterans Affairs, *FY2023 Congressional Submission, Medical Programs and Information Technology Programs* at VHA-21 (2022), *cited at* https://sgp.fas.org/crs/misc/R47423.pdf.

Unsurprisingly, the non-partisan and independent Congressional Budget Office, in a 2021 study of 176 brand-name drugs, found that the Department of Veterans Affairs and the Department of Defense pays lower prices than does Medicare Part D.[40]

With the benefit of this long history and experience, Congress was fully prepared in 2021 to weigh and debate the negotiation provisions that would eventually win passage as part of the IRA. For example, in March 2022, the Senate Finance Committee heard the testimony of Prof. Rena M. Conti, a health economist at Boston University, that the Program would help renew the "social compact between the American public and pharmaceutical companies": taxpayer investment to fund innovation in exchange for affordable drugs.[41] That compact, according to Prof. Conti, had been undermined by the industry's setting of prices "so high they impose financial toxicity on the American public."[42] And this result was eminently fair to the pharmaceutical companies: "Empirical evidence suggests even many of the most expensive drugs" recoup "the full costs of research and development within 5 years post-launch," and the Program targets only drugs that have been on the United States market for over five years.[43] This timeframe, Prof. Conti testified, obviated the industry's argument that "companies will refrain from launching their products in the U.S. if they are subject to negotiation."[44]

---

[40] Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (2021), https://www.cbo.gov/publication/56978.

[41] *Prescription Drug Price Inflation: Hearing on H.R. 5376 Before the S. Finance Comm.*, 117th Cong. (2022) (statement of Prof. Rena M. Conti), 2022 WL 3221004 (Mar. 16, 2022).

[42] *Id.*

[43] *Id.* While the IRA as enacted mandates a minimum of seven years on the market rather than ten for a drug to be eligible for negotiation, Prof. Conti's point stands. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 7 (2023).

[44] *Prescription Drug Price Inflation: Hearing on H.R. 5376 Before the S. Finance Comm.*, 2022 WL 3221004.

Naturally, Congress also heard from the Program's opponents—and found their evidence and arguments wanting. For example, Douglas Holtz-Eakin, the president of the American Action Forum, testified before the Finance Committee that the Program's "negotiations" were illusory; rather, the Program "would empower the HHS secretary to dictate prices to manufacturers who would have little to no leverage."[45] The same argument is central to both of Merck's constitutional challenges here. Dr. Holtz-Eakin also testified against the "unique and punitive" excise tax that the Program would impose on nonparticipating manufacturers.[46] Again, the same argument is central to Merck's claims here. And the same arguments have long been central to the pharmaceutical industry's categorical opposition, as explained above, to any meaningful attempts by Congress to control the explosion of federal health care spending.

In other words, the legislative record makes clear that Merck has simply repackaged the policy arguments it and its allies unsuccessfully advanced before Congress as constitutional arguments. This litigation is simply the continuation of a failed legislative campaign by other means. These arguments and policy questions belong in the political branches, not the Courts.

III. Merck Misrepresents the Program's Operation and the Unsustainable Status Quo It Reformed.

In its cross-motion and opposition brief, the government ably dispatches Merck's litany of mischaracterizations of the IRA's and the Program's operation. *Amici* offer one additional point on this score: Merck alleges that, "[h]istorically," and in purported contrast to the Program, Medicare relied on "market-based pricing." Pl.'s Mot. 4. That is misleading, as explained in part I above. There is nothing "market based" about *prohibiting* price negotiation between buyers and sellers. Simultaneously, Merck conveniently skips over the essential characteristics of the drugs

[45] *Id.*

[46] *Id.*

that CMS may subject to negotiation under the Program: certain exceptionally costly, "single source" drugs without generic or biosimilar competition that have been on the market for a period likely sufficient for the manufacturer to recoup (and more) its initial research and development outlays.[47] Januvia, the drug selected for initial negotiations at issue in this case,[48] cost Medicare more than $4 billion from May 2022 to June 2023, and was first approved by the FDA nearly twenty years ago in October 2006.

The upshot is that, since Januvia's inception, the American taxpayer has been held hostage to the sweetheart deal Merck has enjoyed at the expense of America's seniors and the American taxpayer. The negotiation bar has, until now, blocked the government from using its purchasing power to negotiate a better price for the Medicare program and consequently, the American public. In other words, Merck's real complaint is the introduction of genuine market principles. That introduction offends no provision of the Constitution.

IV. Adopting Merck's Position Would Disable Congress's Control of Medicare Prescription Drug Outlays.

Finally, as explained above, the fiscal bind in which the federal government found itself between 2003 and 2022 was in large part a result of Congress's own creation. And Congress—as is its proper constitutional role, *see* U.S. Const. Art. I, § 8, cl. 1—settled on an appropriate legislative solution to the legislative problem it helped create. That is just how the exercise of the "legislative Powers" with which Congress is exclusively invested is supposed to work. *Id.* § 1.

---

[47] *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (2023), *available at* https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

[48] Actually not *Plaintiff Merck's* drug, as the government points out, but a drug Plaintiff markets. *See* Cross-Mot. & Opp. Br. 8–9.

Adopting Merck's position would turn the constitutional scheme on its head. According to Merck, what Congress has done, it cannot undo, so long as it profits Merck. In other words, Merck asks this Court to forever freeze in place a legislative regime that the legislature has found to be detrimental to the "general Welfare" that it *and it alone* is entrusted with protecting. *Id.* § 8. Merck is wrong. *Cf. id.* § 8, cl. 18 (granting Congress power to make "all Laws which shall be necessary and proper for carrying into Execution" is previously vested authorities).

CONCLUSION

Merck's motion for summary judgment should be denied, and the government's motion for summary judgment should be granted, for the reasons stated above and in the government's brief.

Dated: September 19, 2023

/s/ Eric B. Fastiff

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

Elizabeth J. Cabraser
ecabraser@lchb.com
Eric B. Fastiff (D.C. Bar No. 453854)
efastiff@lchb.com
Dean M. Harvey
dharvey@lchb.com
Ian R. Bensberg
ibensberg@lchb.com
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Tel.: (415) 956-1000
Fax: (415) 956-1008

Attorneys for Amici Curiae

2849409.6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	Civ. No. 1:23-1615 (CKK)

[PROPOSED] ORDER

Having considered the Motion for Leave to File Brief of *Amici Curiae* in Support of Defendants by Sens. Amy Klobuchar, Peter Welch, Tammy Baldwin, Richard Blumenthal, Sherrod Brown, Catherine Cortez Masto, Richard J. Durbin, John Fetterman, John Hickenlooper, Jacky Rosen, Jeanne Shaheen, Debbie Stabenow, Chris Van Hollen, and Elizabeth Warren, and the full record before the Court,

It is hereby ORDERED that the motion is GRANTED.

Dated: _____

_____

HON. COLLEEN KOLLAR-KOTELLY
UNITED STATES DISTRICT JUDGE