IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY, *Plaintiff*, v. XAVIER BECERRA, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*, et al., *Defendants*.	Case No. 3:23-cv-03335-ZNQ-JBD Judge Zahid N. Quraishi Magistrate Judge J. Brendan Day

AMICUS CURIAE BRIEF OF THE ALLIANCE FOR AGING RESEARCH IN SUPPORT OF NEITHER PARTY

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The Alliance for Aging Research (the "Alliance") hereby submits this amicus curiae brief in support of neither party.

STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Alliance is the leading nonprofit organization dedicated to achieving healthy aging and equitable access to care. To support this aim, the Alliance ensures that the perspectives of older adults are represented and prioritized in health policy decision-making and clinical care. For more than thirty years, the Alliance has provided research resources to the federal government, patient and provider advocacy communities, and the healthcare industry. It is well-respected for its objective, data- and fact-driven work.

The Alliance has for many years been an active participant in policy discussions related to drug pricing and has consistently supported policies it believes will improve patient affordability and ensure access to care.[1] We have supported legislative solutions aimed at reducing older adults' actual costs for prescription drugs, such as lower out-of-pocket spending caps, broader eligibility for low-income

[1] The Alliance recognizes that the rising out-of-pocket costs for drugs threatens care, such as by leading to lower drug adherence and higher mortality. For instance, in 2020 the Alliance started Project LOOP (Lowering Out-of-Pocket) Costs, an ad hoc coalition effort that coordinates dozens of national patient and provider organizations that support creating an annual out-of-pocket (OOP) cap in the Medicare Part D program and implementing a smoothing mechanism to spread beneficiaries' financial liability over a longer timeframe-e to promote affordability. *See Project LOOP (Lowering Out-of-Pocket) Costs*, ALL. FOR AGING RSCH., https://www.agingresearch.org/project-loop/ (last visited Mar. 5, 2024).

subsidies, and other measures to modernize the Part D drug benefit. We have also supported proposals to help moderate the growth of drug prices, such as laws requiring manufacturers to pay inflationary rebates if the price of a Part D drug rises faster than the rate of inflation without justification. Policies like these can promote affordability, predictability, and accessibility while also generating savings to the Medicare program that can be reinvested to create additional benefits for services like dental, vision, and hearing care.

We have also steadfastly *opposed* proposed programs that would allow unelected government workers to make value judgments on critically important therapies, because we believe such efforts would have significant and adverse effects on older patients and undermine the judgment of treating clinicians, thereby conflicting with the Medicare statute's prohibition on federal interference with the practice of medicine and the administration of medical services.[2] Consistent with that stance, since 2019, the Alliance has urged federal policymakers to reject any prescription drug price-fixing measures, including international reference pricing, most favored nation pricing, and direct government negotiation, that would authorize the Medicare program's use of cost-effectiveness standards that have discriminatory

[2] *See* 42 U.S.C. § 1395.

effects against older and disabled patients when used in healthcare decision-making.[3]

We opposed the Inflation Reduction Act's Drug Price Negotiation Program ("the Program") for many of the same reasons that we opposed other price-fixing proposals, and we are additionally concerned about the lack of comment opportunities for patients that will be affected by the Program. The Program specifically targets drugs covered by the Medicare Part B and D programs, on which most people over age 65 rely,[4] and allows for an across-the-board, government price-setting structure under the guise of direct negotiation.

Contrary to the views expressed by some other advocacy organizations, the Alliance believes that the Program threatens access to life-sustaining therapies in both the Part B and Part D programs and will result in discrimination against older adults, people with disabilities, and historically underserved populations. The Alliance and those for whom it speaks therefore have a deep interest in the outcome

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[3] *See, e.g.*, *Alliance for Aging Research Sends Letter to Congress Regarding its Drug Pricing Efforts*, ALL. FOR AGING RSCH. (DEC. 12, 2019), https://www.agingresearch.org/news/alliance-for-aging-research-sends-letter-to-congress-regarding-its-drug-pricing-efforts/.

[4] *See Disability Organizations & Coalitions*, CTRS. FOR MEDICARE & MEDICAID SERVS. ("CMS"), https://www.cms.gov/training-education/partner-outreach-resources/partner-with-cms/disability-organizations-coalitions (last updated Oct. 17, 2023); *see also Part B Drugs and Biologicals*, CMS, https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs (last modified Sept. 6, 2023).

of this matter. We submit this brief to offer what we believe will be a useful perspective on why the law will be detrimental to patients and to rebut specific points made by *amici* regarding patient interests. We take no position on the constitutional questions before the Court.

INTRODUCTION

The Drug Price Negotiation Program established under the Inflation Reduction Act ("IRA") seeks to reduce the burden of Medicare prescription drugs on the federal fisc[5] by capping payments for certain drugs at a percentage of their actual price. It empowers unelected officials in the Centers for Medicare & Medicaid Services[6] to demand steep discounts on those drugs based on a long list of open-ended considerations, and to extract a substantial excise tax from those that do not accede to CMS's demands. *See* 42 U.S.C. §§ 1320f-3(c)(1)(C), 1320f-3(b)(2)(F).

[5] The Congressional Budget Office ("CBO") estimated that these price control measures will reduce the budget deficit by $25 billion over 10 years. CBO, SUMMARY, ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, TO PROVIDE FOR RECONCILIATION PURSUANT TO TITLE II OF S. CON. RES. ("CBO Cost Estimate") 14 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

[6] CMS is an agency within the Department of Health and Human Services ("HHS") that has been delegated by the HHS Secretary to administer the Program. Throughout this brief, we reference CMS as the decision-making agency, though the HHS Secretary also retains ultimate responsibility for the Program's administration.

While some stakeholders, including some *amici* in this and related cases including, surprisingly, the American Association of Retired Persons (AARP),[7] have messaged the Program as driving a "better deal" for America's seniors, the Court

[7] The Court should not be confused by the AARP's support of the exact opposite position advocated by the *amicus* here. The Alliance has consistently represented the interests of America's seniors; while AARP has significant conflicts of interest in relation to how its policy positions benefit the *insurance industry*. Why? Because AARP has a significant financial contract with the largest Medicare Part D plan sponsor in the U.S. whereby insurance products are marketed under the AARP brand name (the "AARP Insurance Plan") in exchange for hundreds of millions of dollars of "royalty" payments to AARP per year. AARP has made billions of dollars as a result of this commercial arrangement. In 2017 alone, for example, these payments amounted to about $627,000,000 according to AARP's own financial statements. *See* AARP, CONSOLIDATED FINANCIAL STATEMENTS TOGETHER WITH REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS. DEC. 31, 2017 AND 2016 (2018), https://www.aarp.org/content/dam/aarp/about_aarp/about_us/2018/aarp-2017-audited-financial-statement.pdf. AARP's interests have been previously exposed in Congressional investigations and media reports, *e.g.*, Press Release, H. Ways & Means Comm., Congressional Report Details AARP's Financial Gain From Health Care Law: Organization Stands to Make One Billion Dollars in Insurance Royalties Over the Next Ten Years (Mar. 30 2011), https://waysandmeans.house.gov/congressional-report-details-aarps-financial-gain-from-health-care-law/; H. WAYS & MEANS COMM., BEHIND THE VEIL: THE AARP AMERICA DOESN'T KNOW (2011), https://seniorsavingsnetwork.org/wp-content/uploads/2019/01/AARP_REPORT_FINAL_PDF_3_29_11.pdf; Tom Greene, *Is AARP representing seniors or insurers on drug costs?*, DES MOINES REG. (June 27, 2019, 11:09 a.m.), https://www.desmoinesregister.com/story/opinion/columnists/2019/06/27/aarp-policy-being-influenced-financial-partners/1569815001/. AARP has filed *amicus* briefs in several other cases in support of the IRA, including in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 23-cv-931 (D. Del. Nov. 16, 2023), ECF No. 55, and in *Merck & Co., Inc. v. Becerra*, No. 23-cv-1615 (D.D.C. Sept. 19, 2023), ECF No. 46, yet none of its pro-insurance position or billions of dollars of financial interests are disclosed whatsoever in its Statement of Interest.

should recognize that the Program is not designed to drive out-of-pocket savings.[8] First, the Program's only guarantee is savings to the federal government. It does not guarantee that the drugs subject to price controls will remain available to Medicare beneficiaries, or that they will be available at lower prices at the pharmacy counter. We acknowledge that a second-level effect may be slower growth of premiums and lesser coinsurance amounts. However, these effects are dependent on payer behavior and benefit design.

Second, the Program does not control drug formulary design, including amounts for deductibles, co-insurance, and co-pays, all of which determine the actual out-of-pocket cost for an individual patient. Rather, the Program is, by design, a governmental budget measure, intended to save[9] the federal government billions

[8] At least one study found that less than 10% of Medicare beneficiaries will see lower drug spending as a result of the Inflation Reduction Act, and for those that do benefit, savings are modest, with most seniors saving less than $300. Douglas Holtz-Eakin, *The 10-percent Solution: Who Gets IRA Drug Price Savings?*, AM. ACTION F. (Mar. 21, 2023), https://www.americanactionforum.org/research/the-10-percent-solution-who-gets-ira-drug-price-savings/.

[9] Some of these savings may flow from decreased utilization, as seen in previous attempts at producing savings for the government. See, for example, the Most Favored Nation ("MFN") Model and the Lower Drug Costs Now Act, which counted significant reductions in access and utilization to medications as part of the budgeted savings. *See* CMS, MFN Model, 85 Fed. Reg. 76,180, 76,244 (Nov. 27, 2020); H.R. 3, 117th Cong. (2021).

of dollars each year[10] without regard to the effects on patients' actual costs or their health.

Third, the Program does not target drugs that cost patients the most, but rather those drugs that cost the most to the government in the aggregate—those that are the most widely used among Medicare beneficiaries, including diabetes drugs and oral anticoagulants.[11] Eliquis, for instance, is one of the first ten drugs subject to government price fixing. Eliquis is a widely prescribed oral anticoagulant medication that reduces the risk of stroke and blood clots in patients with non-valvular atrial fibrillation and treats blood clots in the legs or lungs to reduce the risk of them recurring in patients with deep vein thrombosis and pulmonary embolism. It is a relatively inexpensive brand drug, costing Medicare beneficiaries on average less than $40 per month.[12] While we acknowledge that $40 a month still represents

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[10] Indeed, the Defendants themselves acknowledge the Program for what it is—a "budget measure" created to "reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries." *See, e.g.*, Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction ("Defendants' Opposition") at 4, 9, *Dayton Area Chamber of Com. v. Becerra*, No. 23-cv-156 (S.D. Ohio Aug. 11, 2023), ECF No. 34. According to the Defendants, the Program is designed to alleviate the "financial burden" of drug costs "to the Medicare program" and achieve savings for the "American people" and the "American taxpayer." *Id*. at 4–5, 19. Notably absent from this defense is any suggestion that the Program will somehow advance the interests of the Medicare beneficiaries.

[11] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(b)(1), 136 Stat. 1818, 1836.

[12] ASPE, FACT SHEET, INFLATION REDUCTION ACT RESEARCH SERIES—ELIQUIS: MEDICARE ENROLLEE USE AND SPENDING (Oct. 30, 2023),

a financial burden for some beneficiaries, this context illustrates the drug was selected due to the large number of Medicare patients who benefit from the medicine,[13] not its price.

Fourth, the Program does not protect patients' access to medication. The private insurers that administer drug benefits for Medicare enrollees are free to impose formulary restrictions and other utilization management techniques to steer patients toward drugs based on their own financial interests. For instance, while drugs selected for inclusion in the Program are required to be covered by all Part D plans,[14] incentives like rebates will continue to influence formulary design, and the insurer may give preferred treatment to the non-negotiated drug and move the presumably less expensive Price Negotiated drug to a specialty tier with higher co-insurance.[15] In this instance, a patient could end up paying more for the negotiated

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https://aspe.hhs.gov/sites/default/files/documents/d1e51e1f27136349e9a48677d14c5198/Eliquis.pdf.

[13] Over 3.7 million Medicare beneficiaries were taking Eliquis in 2022. CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 (Aug. 2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

[14] *See* 42 U.S.C. § 1395w-104(b)(3)(I).

[15] *See, e.g.*, JORDAN CATES, ET AL., MEDICARE PRICE NEGOTIATION: A PARADIGM SHIFT IN PART D ACCESS AND COST (Sept. 12, 2023), https://www.milliman.com/en/insight/medicare-price-negotiation-paradigm-shift-part-d-access-cost ("[T]here could be situations where a competing drug is able to offer a rebate that makes it more favorable to a plan sponsor than the selected drug. If a competing drug is placed on a preferred tier and the selected drug is placed on a

drug than for its non-negotiated counterpart. Alternatively, insurers could make other non-negotiated drugs more difficult to access as payers encourage use of these negotiated price medications and discourage others.[16] Congress did nothing to protect patients against new barriers to access that the Program incentivizes.

Contrary to misleading or incomplete narratives commonly espoused,[17] the Program is, on balance, a bad deal for America's older adults. It does not solve the

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non-preferred tier, then cost sharing for beneficiaries using the price-negotiated drug could actually increase."); Patrick Wingrove, *Launch of arthritis drug biosimilars ramps up US pressure on pricing 'middlemen'*, REUTERS (July 25, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/launch-arthritis-drug-biosimilars-ramps-up-us-pressure-pricing-middlemen-2023-07-25/.

[16] *See* CATES, *supra* note 13 ("If the [maximum fair price] of a selected drug does represent lower net plan sponsor liability relative to non-negotiated drugs, then plan sponsors may place the negotiated drug on a preferred tier to steer patients toward the lower net cost drug, while shifting the non-negotiated competing drug(s) to the non-preferred tier or removing them from coverage altogether.").

[17] Results from a Morning Consult poll commissioned by the Alliance in 2021 show a disconnect between what Congress is calling "negotiation" and the public's understanding of what negotiation means, and what, if any, benefits they will see. *See New Poll Highlights Seniors' Priorities and Concerns in Prescription Drug Pricing Legislation, Misalignment with Congress on Definition of Negotiation*, ALL. FOR AGING RSCH. (Sept. 22, 2021), https://www.agingresearch.org/news/new-poll-highlights-seniors-priorities-and-concerns-in-prescription-drug-pricing-legislation-misalignment-with-congress-on-definition-of-negotiation/. Nearly 6 in 10 (59%) seniors reported their understanding of government "direct negotiation" of Medicare prescription drug prices means "either the drug company or government proposes an initial price for a drug, then there is back-and-forth negotiation, and price ends somewhere in the middle." *Id*. Only 16% view "direct negotiation" as the government setting prices for prescription drugs and refusing to cover them if the company does not agree, which is how the IRA actually works. *Id.* After explaining how Congress planned to design the "negotiation" program, seniors were concerned that they would not see any benefits. *Id*.

affordability problem for prescription drugs. Further, and as described more fully below, the Program will cause harm to Medicare beneficiaries through diminished access to medication and lost investment in life-saving innovations, as well as through the deprivation of patients' rights to participate in the administrative process and protect themselves against unlawful agency action.

ARGUMENT

The IRA significantly alters prospects for pharmaceutical innovation in the U.S.—a market that has historically fostered robust research and development and new drug discoveries. While the Program may save the government money, the consequences for the people, especially America's seniors, are detrimental.

The broad authority to unilaterally set drug prices for Medicare that the Program conferred to the U.S. Department of Health and Human Services (and, by delegation, CMS) is unconstrained by any obligation to consider patient interests, or any other interests, and is insulated from any administrative or judicial review. The Program thus deprives Medicare beneficiaries—who are overwhelmingly older adults—along with other interested parties, including drug manufacturers, of any meaningful voice in CMS's price determinations. Because price directly affects supply and manufacturers may stop offering drugs through Medicare if CMS mandates a price they cannot accept, this Program jeopardizes older adults' continued access to drugs on which they depend, as well as disrupting and

disincentivizing future pharmaceutical innovation. The Program may in fact save the government money on prescription drug expenditures, but, ironically and cruelly, America's seniors will in effect be the ones to "pay the price" of those budget savings in the form of diminished and delayed access to the medications that are most appropriate for each individual's unique health and life circumstances. Delayed access will cause some individuals to suffer the consequences of untreated and undertreated serious medical conditions, negatively impacting their health, and in some cases, ultimately causing the loss of their lives.

I. THE IRA WILL CAUSE PATIENTS TO SUFFER IRREPARABLE HARM THROUGH PAYER ABUSE OF UTILIZATION MANAGEMENT AND LOSS OF FUTURE INNOVATIVE THERAPIES AND SOME CURRENT THERAPIES

The Medicare Part D program covers much-needed pharmaceutical products for the country's most vulnerable populations. Part D primarily covers people over the age of 65, but also covers medications for people with certain disabilities, kidney failure, amyotrophic lateral sclerosis ("ALS," also known as "Lou Gehrig's disease"), and other diseases and conditions.[18] Medicare Part B covers physician-administered drugs[19] including cancer treatments, immunosuppressive drugs in connection with organ transplants, and drugs to treat severe osteoporosis,

[18] *See Who's Eligible for Medicare?*, HHS (Dec. 8, 2022), https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html.

[19] *See Part B Drugs and Biologicals*, *supra* note 4.

Alzheimer's disease, and rheumatological diseases[20], all of which are serious conditions for which older Americans need effective and reliable treatments. Patients who rely on drugs covered by Part B and Part D will suffer irreparable harm. The Program puts patients at risk of losing access to existing and future therapies, including sudden loss of access to drugs they are currently prescribed, and this risk is particularly high for older, medically vulnerable patient populations. Moreover, the law will materially harm senior patients by creating disincentives for research for diseases affecting older adults.

a. Patients could lose access to existing treatments.

There is a significant risk that some currently prescribed drugs will simply cease to be available to Medicare beneficiaries if the Program is implemented. Defendants expressly acknowledge that as a direct result of the Program, some drugs may no longer be offered to Medicare beneficiaries.[21] Under the Program, manufacturers of selected drugs must participate in negotiations and must enter into an agreement, or be subject to an excise tax of up to 95% of a drug's U.S. sales, which could result in an excise tax rate of up to *1,900% of daily sales revenue* from

[20] *See Part B Drugs and Biologicals*, *supra* note 4; *Prescription drugs (outpatient)*, MEDICARE, https://www.medicare.gov/coverage/prescription-drugs-outpatient (last visited Mar. 5, 2024).

[21] *See, e.g.*, Defendants' Opposition, *Dayton Area Chamber of Com.*, No. 23-cv-156, *supra* note 10, at 17–20.

that drug.[22] The penalty was set so high that even Congress did not expect any manufacturer to pay it,[23] making it clear that the Program's penalties are in effect an "extremely large stick" to coerce manufacturers to participate in the Program. HHS has maintained that if a manufacturer does not want to submit to price controls and wishes to avoid the penalties, it can "simply withdraw" from the Medicare and Medicaid programs or "stop selling the drug" subject to the price controls.[24] But

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[22] 26 U.S.C. § 5000D; *see also* MOLLY F. SHERLOCK, ET AL., CONG. RSCH. SERV., R47202, TAX PROVISIONS IN THE INFLATION REDUCTION ACT OF 2022 (H.R. 5376) 4 (2022), https://crsreports.congress.gov/product/pdf/R/R47202 ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance."); CBO, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* ("CBO Budget Presentation") 9 (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf ("The combination of [the] excise tax and corporate income taxes could exceed a manufacturer's profits from that product.").

[23] CBO Budget Presentation, *supra* note 22, at 10 ("CBO expects that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices.").

[24] Defendants' Opposition, *Dayton Area Chamber of Com.*, No. 23-cv-156, *supra* note 10, at 17, 19 n.4. In that respect, the Program follows the same savings model as earlier price control models like the MFN Medicare Model and H.R. 3, the Lower Drug Costs Now Act, which counted significant reductions in access and utilization to medications as part of the budgeted savings. *See supra* note 9, MFN Model, 85 Fed. Reg. at 76,244 ("[B]eneficiaries may . . . receiv[e] an alternative therapy that may have lower efficacy or greater risks, or postpon[e] or forg[o] treatment."); *id*. at 76,236 ("[P]roviders and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs."); *id.* at 76,237–38 (conceding that nearly 10% of Medicare beneficiaries may have no access to their Part B drugs through Medicare next year and that 20% of beneficiaries may have no access to drugs covered by MFN within three years of implementation);

according to the government, to "simply withdraw" means to withdraw *every product a manufacturer sells* from Medicare and Medicaid, not just the drug that is subject to negotiation.[25]

To a patient, the loss of access to a particular drug could be unexpected, sudden, and in some cases life-threatening. A manufacturer wishing to withdraw from the Medicare program and avoid penalties would need to act quickly after CMS

Letter from Phillip L. Swagel, CBO Dir., to Frank Pallone Jr., Chairman, Comm. on Energy & Com., *Re: Effects of Drug Price Negotiation Stemming from Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare* 2 (Oct. 11, 2019), https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf ("In addition to the effects on the federal budget, CBO anticipates, the bill would affect the use and availability of drugs over time. . . . In the longer term, CBO estimates that the reduction in manufacturers' revenues from title I would result in lower spending on research and development and thus reduce the introduction of new drugs."). Notably, the MFN Model was not implemented following a nationwide preliminary injunction, granted in part based on the high risk of irreparable financial harm. *See Cal. Life Scis. Ass'n v. Ctr. for Medicare & Medicaid Servs*., No. 20-cv-08603, 2020 WL 7696050 (N.D. Cal. Dec. 28, 2020).

[25] *See* Memorandum from Meena Seshamani, CMS Deputy Admin. & Dir., Ctr. for Medicare to Interested Parties, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* ("CMS Revised IRA Guidance") 129 (Jun. 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("Alternatively, the Primary Manufacturer may opt out of the Negotiation Program and avoid the excise tax on sales of the selected drug during the period for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act."); *see also* CBO Budget Presentation, *supra* note 22, at 9 ("Manufacturers that do not comply with the negotiation process must either[] [w]ithdraw all their drug products from the Medicare and Medicaid programs, or [p]ay an excise tax . . . .").

selects one of its drugs for the Program. For instance, the statute requires CMS to publish the list of drugs selected for negotiation on February 1 of each year, and to begin the negotiation process just weeks later, on February 28.[26] In other words, a manufacturer that decides to withdraw must, as soon as possible, submit a notice to CMS requesting termination of its participation with Medicare. Under this timeline, patients and their doctors may have very little time to learn of a withdrawal and switch to alternative treatments, if any are available.

Moreover, while the IRA guarantees formulary *inclusion* for all 10 drugs, it does not guarantee formulary *placement* for any. Due to misaligned incentives for pharmacy benefit managers (PBMs) and insurers, some plans may opt to give preferred formulary placement to drugs not selected for price negotiation for which PBMs can negotiate a greater rebate—as seen with the launch of rheumatoid arthritis biosimilars last year.[27]

Starting in 2026, Medicare beneficiaries and family caregivers will need to check their Part D plan's formulary during Open Enrollment to ensure their prescribed medications are still on the preferred tier. If their plan has switched formulary tier placement for a medication, beneficiaries may pay more out-of-pocket to stay on the medication, switch to a preferred drug in the same class, or switch to

[26] 42 U.S.C.§ 1320f(b).

[27] *See* Wingrove, *supra* note 15.

a new plan. Due to other provisions of the IRA that shift financial responsibility in the catastrophic phase of the Part D benefit to payers—plans were responsible for 15% of spending in this phase of the benefit in 2023, but will be charged with 60% starting in 2025—and limit the growth of the base beneficiary premiums to six percent a year through 2029, Part D plans are also likely to restrict access to selected drugs through increased use of utilization management practices such as prior authorization and step therapy. Currently, CMS has only pledged to "monitor" utilization management by Part D plans, but they have not promised to create guardrails to protect patient access.[28]

Additionally, if plans narrow access to certain medicines due to dynamics introduced by government price-setting, older patients who are stable on a given medication may lose access and be forced to switch to an alternative medicine that is not optimal for their unique circumstances. This is because CMS allows Part D plans to switch a beneficiary's medication—called "non-medical switching" since the practice excludes the beneficiary's healthcare provider—in order to save costs. Non-medical switching is confusing to patients at best and may result in life-threatening adverse outcomes for patients at worst.

The sudden loss of access to drugs can have devastating effects on patients. These effects have been studied extensively in the context of drug shortages. Studies

[28] CMS Revised IRA Guidance, *supra* note 25, at 84.

have found that sudden lack of availability of drugs causes serious harms, including significant rates of delayed and cancelled treatment and surgical intervention,[29] increased medication errors[30], and serious adverse patient outcomes—including death.[31] These harms are especially severe in older adults, who are more vulnerable

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[29] *See, e.g.*, Jonathan Minh Phuong et al., *The Impacts of Medication Shortages on Patient Outcomes: A Scoping Review*, PLOS ONE, at 6–8 (May 3, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6499468/; Ali McBride et al., *National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey*, 18 JCO ONCOLOGY PRAC. e1289, e1291 (2022), https://ascopubs.org/doi/full/10.1200/OP.21.00883; Kenneth L. Kehl et al., *Oncologists' Experiences With Drug Shortages*, 11 J. ONCOLOGY PRAC. e154, e157 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4371121/; Keerthi Gogineni & Katherine L. Shuman, *Correspondence: Survey of Oncologists about Shortages of Cancer Drugs*, 360 NEW ENG. J. MED. 2463, 2464 (2013), https://www.nejm.org/doi/full/10.1056/nejmc1307379; Amy E. McKeever et al., *Drug Shortages and the Burden of Access to Care: A Critical Issue Affecting Patients With Cancer*, 17 CLINICAL J. ONCOLOGY NURSING 490, 490–93 (2013), https://store.ons.org/cjon/17/5/drug-shortages-and-burden-access-care-critical-issue-affecting-patients-cancer; Milena McLaughlin et al., *Effects on Patient Care Caused by Drug Shortages: A Survey*, 19 J. MANAGED CARE PHARMACY 740, 786 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10437927/; Am. Hosp. Ass'n, *AHA Survey on Drug Shortages* (July 12, 2011), https://www.aha.org/system/files/content/11/drugshortagesurvey.pdf.

[30] *See, e.g.*, Phuong, *supra* note 29, at 6, 12 (citing a study's finding that in 54% of drug shortages, "clinicians may be unfamiliar with the alternative product regarding its mechanism of action, adverse effects, or interactions" (footnote omitted)); McBride, *supra* note 29, at e1291; McKeever, *supra* note 29, at 491; McLaughlin, *supra* note 29, at 785.

[31] *See, e.g.*, Phuong, *supra* note 29, at 5–10 (citing eight studies linking drug shortages to patient deaths); Kehl, *supra* note 29, at e157; McKeever, *supra* note 26, at 491 (citing studies linking patient deaths to delays or cancellations in oncology treatment or drug substitutions); McLaughlin, *supra* note 29, at 785 (noting 41.4% of directors of pharmacy reported possible or probable adverse events from drug

to adverse events. Older adults are at greater risk of harm due to, among other factors, increased likelihood of dangerous drug-to-drug interactions. This risk is heightened when a provider is forced to switch a patient to an alternative medication, which will be the case if sale of a drug suddenly stopped, or the drug's manufacturer withdraws from Medicare and Medicaid.

The prescription medicines covered by both Medicare Part B and D are widely used by and are critical for the health and well-being of older Americans in particular. The HHS appears to be satisfied with the result where a drug is no longer available through Medicare, since it will have the effect of significant governmental budget savings (which is, broadly, the purpose of the IRA). Meanwhile, the government has offered no plan for addressing the needs of actual patients who will no longer receive treatment for their serious medical conditions.

b. Patients will lose access to future therapies

Moreover, the Program will materially harm patients by creating disincentives for research into treatments and cures for a number of diseases, including those affecting older adults. The Program will undoubtedly affect whether and how

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shortages); Am. Hosp. Ass'n, *supra* note 29, at 8; *see also* Timothy P. Hanna et al., *Mortality due to Cancer Treatment Delay: Systematic Review and Meta-analysis*, BMJ, at 1–11 (2020), https://www.bmj.com/content/371/bmj.m4087 (finding significant association between treatment delay and increased mortality).

pharmaceutical manufacturers invest in research and development.[32] Even the Congressional Budget Office ("CBO") expects that the statutory price controls will cause research and development investment to decline and that fewer drugs will be brought to market.[33] Independent analysts have predicted that the anticipated cut in R&D activity will mean 135 fewer new drugs, and a loss of 331.5 million life years in the U.S.[34] Experts predict that the decreases in revenue under IRA's price control

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[32] *See generally* Compl. ¶¶ 29–44, ECF No. 1; *see also* Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market* (Apr. 13, 2023), https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market/ ("Lowering pharmaceutical revenues leads to less R&D investment and fewer drug discoveries over time." (first citing Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q. J. ECON. 1049, 1049–90 (2004), https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=72e30175e2750ebb585db709a54010dfab0571ea; then citing Pierre Dubois et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. ECON. 844, 844–71 (2015), https://onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12113; and then citing Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327–36 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711884/)).

[33] CBO Cost Estimate, *supra* note 5, at 15 ("CBO estimates that under P.L. 117-169, the number of drugs that would be introduced to the U.S. market would be reduced by about 1 over the 2023-2032 period, about 5 over the subsequent decade, and about 7 over the decade after that.").

[34] Tomas J. Philipson & Troy Durie, *Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health*, U. CHI., at 7–9 (2021), https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf. A November–December 2022 survey of 25 of

provisions will "reduce financial incentives to develop drugs against diseases that disproportionately impact the elderly, such as Alzheimer's disease, cancer and heart failure."[35] In other words, it is undisputed that fewer products will be developed to treat and potentially cure diseases.

There is significant concern that the Program will disincentivize therapeutics for conditions that disproportionately affect the aging population. The causes for this are two-fold: (1) The disproportionate market size and power of the Medicare program will make it more attractive to instead focus on conditions that primarily affect non-Medicare populations; and (2) the potential application of measures such as the equal-value of life years (evLY) gained would have similar effects as the

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33 PhRMA member companies found that "78% expect to cancel early-state pipeline projects[,]" "63% said they expect to shift R&D investment focus away from small molecule medicines[,]" and "82% or more of companies with pipeline projects in cardiovascular, mental health, neurology, infectious disease, cancers and rare diseases expect 'substantial impacts' on R&D decisions in these areas." Nicole Longo, *WTAS: Inflation Reduction Act already impacting R&D decisions*, PHRMA (Jan. 17, 2023), https://phrma.org/en/Blog/WTAS-Inflation-Reduction-Act-already-impacting-RD-decisions.

[35] Goldman, *supra* note 32. This prediction is based in part on the premise that reduction in revenues "is likely to decrease innovation for both novel, groundbreaking drugs as well as those that are less novel but have large consumer markets, such as the elderly population, which accounts for a significant portion of overall healthcare and pharmaceutical drug utilization in this country." *Id*. (citing David Dranove et al., *Does consumer demand pull scientifically novel drug innovation?*, 53 RAND J. ECON. 590, 590–638 (2022), https://onlinelibrary.wiley.com/doi/abs/10.1111/1756-2171.12422).

prohibited "quality-adjusted life year" ("QALY") measures, as well as fail to account for value of symptomatic treatments.

In addition to reducing new drug development, the IRA would disincentivize pharmaceutical manufacturers from further developing approved drugs for additional and new uses (indications) to address other diseases and medical conditions. The loss of these approvals for unmet needs would be significant. Nearly 10% of people in the U.S. have a rare disease, but 95% of rare diseases lack an FDA approved treatment.[36] FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition.[37] FDA approved approximately one-quarter of orphan drugs for at least one follow-on indication between 2003 and 2022, and the majority of these indications were considered in expedited review programs.[38] However, lowered revenues under the IRA "may lead to less research, especially for follow-on drug

[36] *See Delivering Hope for Rare Diseases*, NAT'L INSTS. OF HEALTH ("NIH") (Jan. 2023), https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf.

[37] *See Designating an Orphan Product: Drugs and Biological Products*, FDA (July 8, 2022), https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products.

[38] *See* James D. Chambers et al., *Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act*, 6 JAMA NETWORK OPEN, at 1–2 (Aug. 15, 2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808362.

innovation."[39] Manufacturers have confirmed that the IRA would have deterred them from investigating further uses of important drugs.[40]

The detrimental effects of the Program on future innovation are of grave concern, and, in fact, these effects are already being seen in the marketplace. Recent analysis found that R&D investment is already shifting away from development of small molecule medicines, with experts attributing this shift to the requirement to subject small molecules to price negotiations after only nine years of approval.[41] This incentive materially harms drug development for certain conditions that more typically impact the aging population. For example, therapeutic development for dementia and other diseases affecting the central nervous system should be incentivized to favor rather than penalize small molecules, as they are more likely to

[39] Goldman, *supra* note 30.

[40] *See* Complaint ¶¶ 10–11, *AstraZeneca*, No. 23-cv-00931 (Aug. 25, 2023), ECF No. 1 (explaining that the IRA would have created significant disincentives with regards to seeking approval for Lynparza, a cancer medicine initially approved for late-line ovarian cancer patients in 2014 and approved for prostate cancer patients in 2023, and continuing to expand the indications for Soliris, initially approved to treat paroxysmal nocturnal haemoglobinuria in 2007 and approved over a decade later for neuromyletis optica spectrum disorder after continued research to support further innovation).

[41] Isabel Cameron, *Inflation law drives biologic drugs to outpace small molecules in US venture financing*, BIOPHARMA REP. (July 6, 2023), https://www.biopharma-reporter.com/Article/2023/07/06/inflation-law-drives-biologic-drugs-to-outpace-small-molecules-in-us-venture-financing.

be able to traverse the blood-brain barrier.[42] In addition, small molecules, which are typically administered in pill form, are often preferred by older adults based on cost and lessened need to travel outside the home for administration. Creating disincentives for the development of one category of drugs over another without any medical or scientific rationale does not make sense. Most troublingly, a number of manufacturers have cited the IRA as the basis for decisions not to pursue new drug development or to stop current development efforts.[43] This trend is certain to continue unless and until the design of the Program is enjoined or modified.

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[42] John L. Mikitsh & Ann-Marie Chacko, *Pathways for Small Molecule Delivery to the Central Nervous System Across the Blood-Brain Barrier*, PERSPECT MEDICIN CHEM (June 16, 2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064947/.

[43] *See, e.g.*, *Alnylam Pharmaceuticals Reports Third Quarter 2022 Financial Results and Highlights Recent Period Activity*, BUS. WIRE (Oct. 27, 2022), https://www.businesswire.com/news/home/20221027005172/en/Alnylam-Pharmaceuticals-Reports-Third-Quarter-2022-Financial-Results-and-Highlights-Recent-Period-Activity ("The Company also announces today that it is considering options for the best path toward advancing an RNAi therapeutic for the treatment of Stargardt Disease. At this time, it will not initiate a Phase 3 study of vutrisiran in Stargardt Disease in late 2022, as previously guided, as it continues to evaluate the impact of the Inflation Reduction Act."); Max Gelman, *Updated: Eli Lilly blames Biden's IRA for cancer drug discontinuation as the new pharma playbook takes shape*, ENDPOINTS NEWS (Nov. 1, 2022), https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun/ ("As part of its third quarter update . . . [Eli Lilly] revealed it had removed a Phase I drug licensed from Fosun Pharma, a BCL2 inhibitor that had been undergoing studies for a variety of blood cancers. Though the reasoning had been initially unclear, an Eli Lilly spokesperson told Endpoints News in an email that 'in light of the Inflation Reduction Act, this program no longer met our threshold for continued investment.'"); James Waldron, *Bristol Myers CEO already reassessing*

c. The law gives CMS limitless discretion, with insufficient guardrails to protect against age- and disability-based discrimination that could lead to loss of access to therapies

Based on initial guidance from CMS, the price-setting process required by the IRA will employ inherently discriminatory measures that will disproportionately harm individuals with disabilities and chronic illnesses (and thus disproportionately harm older adult populations). So long as CMS merely considers a list of vaguely worded statutory factors, the law gives unelected government officials virtually free rein in setting what they believe is a "fair price" for a drug.[44] There is no floor on how low CMS can price a drug. The only outer limit Congress placed on CMS is a prohibition on using evidence of comparative effectiveness in a manner that discriminates against the elderly, disabled, or terminally ill individual.[45] This amounts to a broad grant of discretion with very narrow limitation.

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portfolio in wake of US pricing law: report, FIERCE BIOTECH (Nov. 21, 2022), https://www.fiercebiotech.com/biotech/bristol-myers-already-reassessing-portfolio-wake-ira-ceo-tells-ft (quoting Bristol Myers Squibb CEO Giovanni Caforio as stating that, because of the IRA, "I do expect that we will cancel some programs, whether that is, you know, a full-on indication for an existing medicine or a new medicine. We are undergoing a review of our portfolio now . . . ."); Reuters, *Roche: Have Abandoned Some Trials Due to U.S. Drug Pricing Plans*, U.S. NEWS & WORLD REP. (June 27, 2023), https://www.usnews.com/news/us/articles/2023-07-27/roche-have-abandoned-some-trials-due-to-u-s-drug-pricing-plans (quoting Roche Holding AG CEO Thomas Schinecker as explaining that, because of the IRA, "[w]e have decided that we are not going to do certain trials, or that we are not going to do a merger or acquisition or licensing (deal) because it is becoming financially not viable").

[44] 42 U.S.C. § 1320f-3(e).

[45] *Id.*

Indeed, CMS has read the non-discrimination clause in a way that renders it virtually meaningless. CMS has, for instance, said it will consider comparative effectiveness studies that employ a QALY measure to determine the value of a particular drug. A QALY is a measure used by some comparative effectiveness analyses to place a dollar value on particular kinds of medical treatments (including drugs), and measures "how well all different kinds of medical treatments lengthen and/or improve patients' lives."[46] In the case of older adults, health status is usually worse and life expectancy is shorter than for younger people, and a QALY measure as applied to a treatment for this population will be valued lower than a treatment for a younger, healthier population. Yet according to CMS, the statutory non-discrimination clause allows it to review and consider studies using QALYs as long as it does not use QALYs in the Negotiation Program.[47] If CMS's interpretation is

[46] The Institute for Clinical and Economic Review ("ICER") describes the QALY as "the academic standard for measuring how well all different kinds of medical treatments lengthen and/or improve patients' lives, and therefore the metric has served as a fundamental component of cost-effectiveness analyses in the US and around the world for more than 30 years." *Cost-Effectiveness, the QALY, and the evLYG*, ICER, https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/ (last visited Mar. 5, 2024).

[47] *See* CMS Revised IRA Guidance, *supra* note 25, at 47–48 (noting that CMS "will consider studies that use QALYs" if they "contain other content that is relevant" and that CMS "may review the underlying data, results, or other content in studies that employ QALYs" to "glean important insights into the outcomes associated with the drug under consideration"). CMS has also indicated it may use the Equal Value of Life Years Gained ("evLYG") measure as an alternative to inform comparative effectiveness of a drug subject to negotiation. *See id.* at 46. But

correct, then the singular limitation on CMS's discretion is really no limit at all, as it will be impossible for anyone outside the agency to ascertain whether and to what extent the QALY-based research influenced the determination of a maximum fair price.

The use of the QALY and similar metrics such as the evLYG demonstrate the very real threat the Program poses to older Americans. The QALY devalues the lives of older adults, people with disabilities and chronic conditions, and communities of color.[48] The National Council on Disability, an independent federal

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this measure is also problematic, as it (i) results in denial of coverage "even where a drug would provide significant clinical benefit, including life extension"; (ii) "relies on health utility weights to measure quality of life improvements, despite the fact that such measures are typically derived from survey data and do not account for the complexity of the preferences and experiences of people with disabilities"; and (iii) "affords no opportunity to account for clinical knowledge not reflected in the research literature . . . ." *Quality-Adjusted Life Years and the Devaluation of Life with Disability* 62, NAT'L COUNCIL ON DISABILITY ("NCD QALY Report") (Nov. 6, 2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf. As such, use of the evLYG measure for establishing price would be in direct conflict with the statutory nondiscrimination clause at 42 U.S.C. § 1320f-3(e).

[48] *See* Press Release, Comm. on Energy & Com., Chairs Rodgers, Smith and Reps. Burgess, Wenstrup Introduce Legislation to Ban QALYs (Jan. 31, 2023), https://energycommerce.house.gov/posts/chairs-rodgers-smith-and-reps-burgess-wenstrup-introduce-legislation-to-ban-qal-ys; *accord* NCD QALY Report, *supra* note 47 ("QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities. In this report, NCD found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used. In addition, QALY-based programs have been found to

agency, has repeatedly warned that the use of the QALY in healthcare decision-making may run afoul of federal statutes, including the Rehabilitation Act and the Americans with Disabilities Act.[49] Congress' failure to include meaningful limits on CMS's consideration of QALY-based valuations of drugs places seniors and disabled individuals at risk.

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violate the Americans with Disabilities Act."); Letter from Andrés J. Gallegos, NCD Chairman, to Phillip Swagel, CBO Dir., *Congressional Budget Office's Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act* (Apr. 7, 2021), https://ncd.gov/publications/2022/ncd-letter-cbo-reliance-qaly-estimate-budgetary-scoring ("[C]ountries that rely on the QALY to set drug prices have restricted or denied patients with disabilities access to effective drugs used to treat chronic conditions and to breakthrough medications."); William S. Smith, Pioneer Institute, *Quality Adjusted Life Years (QALY): The Threat to Older Americans* (Mar. 2020), https://pioneerinstitute.org/wp-content/uploads/dlm_uploads/QALYcovid-PB.pdf; Paul Schneider, *The QALY is ableist: on the unethical implications of health states worse than dead*, 31 QUAL. LIFE RSCH. 1545 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9023412/; Kirsten Axelsen & Rajini Jayasuriya, *Assessing the value of medicine for diverse patients: Implications of a QALY approach for health disparities: A study for the Alliance for Aging Research* (Nov. 11, 2021), https://media.crai.com/wp-content/uploads/2021/11/15184733/CRA-Implications-of-a-QALY-approach-for-health-disparities-1.pdf.

[49] *See, e.g.*, NCD QALY Report, *supra* note 47, at 45–46 (noting that the Bush administration rejected Oregon's Medicaid plan, which utilized QALYs, based on a finding that it violated the ADA because the plan "in substantial part values the life of a person with a disability less than the life of a person without a disability" (footnote omitted)).

II. THE IRA PROVIDES PERFUNCTORY PUBLIC PARTICIPATION, NO TRANSPARENCY, AND NO PROTECTION FROM ARBITRARY DECISION-MAKING

As discussed above, the Program risks significantly limiting patients' access to prescription drugs that they need to treat serious health conditions such as leukemia, diabetes, rheumatoid arthritis, and cardiac conditions, including atrial fibrillation and heart failure. Patients could suddenly lose access to existing therapies, including therapies they are currently prescribed and relying on for their therapy, and will also suffer from the loss of innovation. Changing an ongoing therapy can cause adverse reactions, harmful side effects, and diminished response to treatment. These changes can lead to disease progression, reduced functional capabilities, and a lower quality of life for patients. Yet Congress set up a Program where a federal agency can make decisions affecting patient care without any input from patients, and without transparency or accountability.

a. The Program absolves CMS from notice and comment rulemaking procedures and insulates its decisions from judicial scrutiny

When it gave virtually limitless discretion to CMS to implement some of the most consequential changes to the Medicare program since the prescription drug benefit's inception in 2003, Congress should have left in place the normal procedures that promote transparency and guard against agency overreach and arbitrary decision-making. Instead, Congress opted to strip *all* of the procedural

protections that typically apply to agency action – leaving patients without a voice, and without recourse.

First, the IRA purportedly allows HHS to proceed with implementing the Program without notice-and-comment rulemaking.[50] The section in the IRA creating the Program provides that the Secretary of HHS "shall implement this section…. for 2026, 2027, and 2028 by program instruction or other forms of program guidance."[51] HHS has interpreted this provision to mean that notice-and-comment rulemaking procedures are unnecessary.[52]

Second, the IRA bars administrative and judicial review of all of HHS's critical determinations in administering the Program, including: "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," "[t]he determination of a maximum fair price under

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[50] Only a very limited set of IRA provisions are reviewable administratively or judicially, none of which will significantly affect patients. *See, e.g.*, IRA § 1191(b) (defining the initial price applicability period and timeframe for negotiation); *id.* § 1191(c)(1) (defining "manufacturer"); *id.* § 1191(d) (setting forth timing for initial price applicability year 2026); *id.* § 1192(a) (outlining the number of negotiation-eligible drugs to be selected each year).

[51] IRA § 11001(c).

[52] *See* Memorandum from Meena Seshamani, CMS Deputy Admin. & Dir., Ctr. for Medicare to Interested Parties, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Section 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* ("Initial Guidance") 2 (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.

[the Act]," or "[t]he determination of renegotiation-eligible drugs."[53] The government reads this preclusion broadly, to shield from review not only individual determinations made with respect to individual products, but also "the manner in which the agency makes those individual" determinations.[54] In other words, the government's own position is that the statutory preclusion is all-encompassing, leaving the agency with unchecked freedom to give meaning to Congress' words.

b. CMS's efforts to solicit public comment on draft guidance are laudable, but insufficient to protect patient interests

The notice and comment requirements that normally attach to agency rulemaking are "intended to assist judicial review as well as to provide fair treatment for persons affected by a rule[,]" and to serve these functions "there must be an exchange of views, information, and criticism between interested persons and the agency."[55] CMS has, on its own accord, invited public comments on draft guidance, which explains how the agency intends to implement the Program.[56] These measures, however laudable, fall short of achieving the level of transparency and

[53] 42 U.S.C. § 1320f-7(2)–(4).

[54] Defendants' Opposition to Plaintiffs' Motion for Summary Judgment and Cross-Motion at 23–24, *AstraZeneca*, No. 23-cv-00931 (Nov. 1, 2023), ECF No. 21.

[55] *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977) (citations omitted).

[56] *See* Initial Guidance, *supra* note 52, at 2.

accountability that notice and comment rulemaking procedures are designed to achieve.

First, CMS's solicited comment on some, but not all aspects of the Program. For instance, CMS did not solicit comments regarding one of the elements of the law most critical for patients—CMS's plans for selecting the ten drugs subject to price negotiations in 2026.[57] In connection with its written guidance, CMS only solicited comments on a select few administrative aspects of the Program, such as on data that manufacturers must submit to facilitate negotiations, and on negotiation procedures. Further, while CMS conducted patient-focused listening sessions as part of the negotiation process,[58] these brief sessions exclude patient advocates who do not have the means or know-how to navigate the CMS process. Moreover, the subject and timing of the listening sessions are quite narrow in comparison to the entirety of the Program: Upon the announcement of the ten selected drugs, CMS opened a brief 30-day window for written public input, which closed on October 2, 2023. *Id.* The listening sessions themselves were limited to only 90 minutes per drug, and, while open to anyone from the public, CMS allowed up to 20 individuals the opportunity to speak, and only for 3 minutes per speaker. *Id.* Further, in the listening sessions,

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[57] Initial Guidance, *supra* note 52, at 5.

[58] *See Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions*, CMS, https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions (last updated Feb. 2, 2024).

CMS failed to indicate the scope and questions for which the agency desired input. This is hardly a robust comment solicitation process.

Second, CMS has not taken any steps to respond to the comments it received during the listening sessions in a manner consistent with typical notice-and-comment rulemaking or demonstrated that stakeholder feedback was considered. With nothing requiring CMS to respond to significant points raised by stakeholders, "the opportunity to comment is meaningless . . . ."[59]

In other CMS programs, by contrast, the agency routinely engages in thorough notice-and-comment rulemaking. For example, to implement policies related to hospital price transparency, CMS published a proposed rule on July 31, 2023, in which CMS solicited public comment, and published a final rule on November 22, 2023, in which CMS responded to commenters, and presented the final regulations that took these comments into consideration.[60] For the proposed rule that included these hospital price transparency provisions, CMS received 3,777 timely pieces of

[59] *Home Box Off., Inc.*, 567 F.2d at 35–36 (citation and footnote omitted).

[60] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; etc., 88 Fed. Reg. 49,552, 49,557 (proposed July 31, 2023) (to be codified at 42 C.F.R. pts. 405, 410, 416, 419, 424, 485, 488-80, 45 C.F.R. pt. 180); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; etc., 88 Fed. Reg. 81,540 (Nov. 22, 2023) (to be codified at 42 C.F.R. pts. 405, 410, 416, 419, 424, 485, 488–80; 45 C.F.R. pt. 180).

correspondence, and reviewed and addressed them in the final rule.[61] CMS undertakes this exercise on an annual basis for several of its programs,[62] and typically conducts the same practice for programs outside the scope of its routine rulemaking schedule.[63] And yet, CMS is not engaging in comparable interactive policymaking for the Program's dramatic change to the Medicare program that directly and potentially harmfully impacts patients, particularly older patients. Expediency is not a suitable reason to abrogate public engagement, comment, and response processes, which the agency regularly accomplishes in a timely manner for other significant and substantial initiatives.

CONCLUSION

Although the Alliance takes no position on the ultimate resolution of the legal questions before the Court, we respectfully request that the Court take into account the perspectives offered above when considering patient equities.

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[61] *Id.* at 81,549.

[62] CMS conducts annual rulemaking for several of its programs, including Medicare Part D, the inpatient prospective payment system, the physician fee schedule, the End-Stage Renal Disease prospective payment system, and the prospective payment system and consolidated billing for skilled nursing facilities, among others.

[63] *See, e.g.*, Medicare Program: Medicare Secondary Payer and Certain Civil Monetary Penalties, 88 Fed. Reg. 70,363 (Oct. 11, 2023) (to be codified at 42 C.F.R. pt. 402; 45 C.F.R. pt. 102); Medicare and Medicaid Programs; Policy and Technical Changes etc., 88 Fed. Reg. 6,643 (Feb. 1, 2023) (to be codified at 42 C.F.R. pt. 422).

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CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2024, I served the foregoing document upon all counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system.

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