Nos. 24-1820, 24-1821

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRISTOL MYERS SQUIBB CO.,
Plaintiff-Appellant.

v.

XAVIER BECERRA, ET AL.
Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant.

v.

XAVIER BECERRA, ET AL.
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey, Nos. 23-cv-03335 & 23-cv-03818

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1.1, *Amicus Curiae* the Alliance for Aging Research states that it is a section 501(c)(3) nonprofit organization, it has no corporate parent, no publicly held corporation owns 10 percent or more of any of its stock, and no publicly owned corporation not a party to the appeal has a financial interest in the outcome of the litigation.

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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*[1]

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 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.

We have also steadfastly *opposed* proposed programs that would have significant and adverse effects on older patients and undermine the judgment of treating clinicians.

[1] All parties have consented to the filing of this brief. No party's counsel authored this brief in whole or in part. No one other than the Alliance for Aging Research, its members, or its counsel contributed any money to fund its preparation or submission.

We are particularly concerned about the Inflation Reduction Act's Drug Price Negotiation Program ("the Program"), which specifically targets drugs covered by the Medicare Part B and D programs, on which most people over age 65 rely,[2] and allows for an across-the-board, government price-setting structure, implemented by unelected government officials, 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.

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 other *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

[2] *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).

on the federal fisc by capping payments for certain drugs at a percentage of their actual price. It empowers unelected officials in the Centers for Medicare & Medicaid Services ("CMS") to demand steep discounts on those drugs based on a long list of open-ended considerations. *See* 42 U.S.C. §§ 1320f-3(c)(1)(C), 1320f-3(b)(2)(F).

While some stakeholders, including, surprisingly, the American Association of Retired Persons ("AARP"),[3] have messaged the Program as driving a "better

[3] 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. AARP has made billions of dollars in royalties as a result of this commercial arrangement. In 2022 alone, these payments amounted to about $1.1 billion according to AARP's own financial statements. *See* AARP, IRS Form 990 (2022), at 11, "Other Revenue", line 5 "Royalties", (Oct. 31, 2023), *available at* https://www.aarp.org/content/dam/aarp/about_aarp/annual_reports/2023/2022-aarp-form-990-public-disclosure.pdf. AARP lobbied heavily for the passage of the IRA including the drug price control provisions at issue in this matter. *See* Open Secrets, 2022 report on AARP, https://www.opensecrets.org/orgs/aarp/lobbying?id=D000023726&lobbillscycle=2021 (last visited July 18, 2024), and Kimberley A. Strassel, *Whom Dies AARP Serve?*, WALL ST. J., Aug. 4, 2022, https://www.wsj.com/articles/whom-does-aarp-serve-conflict-of-interest-retirees-tax-spend-deal-joe-manchin-chuck-schumer-medicare-drug-_prices-11659650860?mod=article_inline. 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 (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

deal" for America's seniors, the Court should recognize that the Program is not designed to drive out-of-pocket savings for patients.[4] First, the Program's only guarantee is savings to the federal government. Second, the Program does not control drug formulary design, including amounts for deductibles, co-insurance, and co-pays, all of which determine the out-of-pocket cost for an individual patient and whether a drug is accessible at all. Rather, the Program is only intended to save the federal government billions of dollars each year without regard to the effects on patients' health or their out-of-pocket costs.

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—which are the most widely used among Medicare beneficiaries, including diabetes drugs and oral

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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.

[4] 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/.

anticoagulants.[5] Eliquis, for instance, is one of the first ten drugs subject to government price fixing, yet only costs Medicare beneficiaries on average less than $40 per month.[6] It was selected because of the large number of Medicare patients who use it,[7] and thus the potential federal budget savings, not because of its cost to patients.

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. Although drugs in the Program must be covered by Part D plans,[8] rebates will continue to influence formulary design, and the insurer may give preferred placement to a non-negotiated drug.[9] Alternatively, insurers could make non-negotiated drugs more difficult to

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

[6] ASPE, FACT SHEET, INFLATION REDUCTION ACT RESEARCH SERIES—ELIQUIS: MEDICARE ENROLLEE USE AND SPENDING (Oct. 30, 2023), https://aspe.hhs.gov/sites/default/files/documents/d1e51e1f27136349e9a48677d14c5198/Eliquis.pdf.

[7] 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.

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

[9] *See, e.g.*, JORDAN CATES, ET AL., MEDICARE PRICE NEGOTIATION: A PARADIGM SHIFT IN PART D ACCESS AND COST (Sept. 12, 2023),

access, as payers may encourage use of negotiated price medications and discourage appropriate non-negotiated price medications.[10] Congress did nothing to protect patients against new barriers to access that the Program incentivizes.

Contrary to misleading or incomplete narratives commonly espoused,[11] the Program is, on balance, a bad deal for America's older adults. The Program will

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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 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/.

[10] *See* CATES, *supra* note 9 ("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.").

[11] 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

cause harm to Medicare beneficiaries through diminished access to medication, decreased incentives for continued 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— of any meaningful voice in CMS's price determinations. Because the government has clearly stated in this case, and in other cases challenging the IRA, that it is perfectly content with drug companies removing all of their products from the Medicare program if they do not want any one drug to be price-controlled, the

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how Congress planned to design the "negotiation" program, seniors were concerned that they would not see any benefits. *Id*.

court below found the Program "voluntary,"[12] and therefore dismissed the Plaintiff's claims. That is a rather odd outcome for a law which Congress intended to *increase* patients' access to medication.. The Program may save the government money on prescription drug expenditures, in part by having drugs excluded from the Medicare program altogether, 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. Seniors will suffer the consequences of untreated 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

The Medicare Part D program covers much-needed pharmaceutical products for the country's most vulnerable populations, primarily covering people over the age of 65.[13] Medicare Part B covers physician-administered drugs[14] including cancer treatments, immunosuppressive drugs in connection with organ transplants, and drugs to treat severe osteoporosis, Alzheimer's disease, and rheumatological

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[12] Brief for the Defendant, *Novo Nordisk Inc. et al., v. Xavier Becerra, et al*., at 34-53, No. 3:23-CV-20814 (D.N.J. Jan. 26, 2024).

[13] *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.

[14] *See Part B Drugs and Biologicals*, *supra* note 2.

diseases[15], 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 who will lose access to existing and future therapies, and the sudden loss of access to drugs they are currently prescribed. 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.

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.[16] HHS has maintained that if a manufacturer does not want to submit to price controls and wishes to avoid the IRA's penalties for not offering drugs at the required price, it can "simply withdraw" from the Medicare and Medicaid programs or "stop selling the drug" subject to the price controls.[17] But according to the government, to "simply withdraw" means to withdraw *every*

[15] *See Part B Drugs and Biologicals*, *supra* note 2; *Prescription drugs (outpatient)*, MEDICARE, https://www.medicare.gov/coverage/prescription-drugs-outpatient (last visited July 18, 2024).

[16] *See, e.g.*, Defendants' Opposition, *Dayton Area Chamber of Com.*, No. 23-cv-156, *supra* note 3, at 17–20.

[17] Defendants' Opposition, *Dayton Area Chamber of Com.*, No. 23-cv-156, *supra* note 3, at 17, 19 n.4.

product a manufacturer sells from Medicare and Medicaid, not just the drug that is subject to negotiation.[18]

Loss of access to a particular drug could be unexpected, sudden, and in some cases life-threatening. Under the IRA, it would not just be loss of access to one drug, but loss of access to *all other drugs made by that same manufacturer*. Patients and their doctors may have very little time to learn of a withdrawal and switch to alternative treatments, if any are available.

Even where a manufacturer chooses to keep its drugs in the Medicare program and be price-controlled under the Program, access by patients is still not certain. While the IRA guarantees formulary *inclusion* for all price-negotiated drugs, it does not guarantee formulary *placement* for any. Due to misaligned incentives for

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[18] *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, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* 9 (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf ("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 . . . .").

pharmacy benefit managers (PBMs) and insurers, plans are free to give preferred formulary placement to higher priced drugs, for example if PBMs can negotiate a greater rebate—as seen with the launch of rheumatoid arthritis biosimilars last year.[19] Part D plans also restrict access to drugs through utilization management practices such as prior authorization and step therapy. Currently, CMS has only pledged to "monitor" utilization management by Part D plans, but CMS has not taken action to create guardrails to protect patient access.[20]

Additionally, if plans narrow access to certain medicines in response 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 particular 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 have found that sudden lack of availability of drugs causes serious harms, including

[19] *See* Wingrove, *supra* note 9.

[20] CMS Revised IRA Guidance, *supra* note 18, at 84.

significant rates of delayed and cancelled treatment and surgical intervention,[21] increased medication errors,[22] and serious adverse patient outcomes—including death.[23] These harms are especially severe in older adults, who are more vulnerable to adverse events and dangerous drug-to-drug interactions.

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[21] *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.

[22] *See, e.g.*, Phuong, *supra* note 21, 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 21, at e1291; McKeever, *supra* note 21, at 491; McLaughlin, *supra* note 21, at 785.

[23] *See, e.g.*, Phuong, *supra* note 21, at 5–10 (citing eight studies linking drug shortages to patient deaths); Kehl, *supra* note 21, at 157; McKeever, *supra* note 21, at 491 (citing studies linking patient deaths to delays or cancellations in oncology treatment or drug substitutions); McLaughlin, *supra* note 21, at 785 (noting 41.4% of directors of pharmacy reported possible or probable adverse events from drug

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 these drugsare 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.

It is this system of removing drugs from Medicare altogether and thus blocking access by seniors to the drugs they need that makes the Program "voluntary" in the eyes of the District Court. The harms of this outcome on America's seniors could not be more clear, or more cruel.

b. Patients will lose access to future therapies due to IRA's disincentives for research

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

shortages); Am. Hosp. Ass'n, *supra* note 21, 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.[24] 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.[25] 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.[26] Experts predict that the decreases in revenue under IRA's price control provisions will "reduce financial incentives to develop drugs against diseases that disproportionately impact the elderly, such as Alzheimer's disease, cancer and heart

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[24] *See* 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."

[25] CBO, SUMMARY ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, TO PROVIDE FOR RECONCILIATION PURSUANT TO TITLE II OF S. CON. RES. 15 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf ("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.").

[26] 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 33 PhRMA member companies found that "78% expect to cancel early-state pipeline projects[,]" 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.

failure."[27] In other words, there is broad agreement that fewer products will be developed to treat and potentially cure diseases.

The Alliance is concerned that the Program will disincentivize therapeutics for conditions that disproportionately affect the aging population, in part because the disproportionate market size and power of the Medicare program will make it more attractive for pharmaceutical manufacturers to instead focus on development of drugs for conditions that primarily affect non-Medicare populations. 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. Lowered revenues under the IRA "may lead to less research, especially for follow-on drug innovation." [28] Manufacturers have confirmed that the IRA would have deterred them from investigating further uses of important drugs.[29]

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[27] Goldman, *supra* note 26. .

[28] Goldman, *supra* note 26.

[29] *See, e.g.*, 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).

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 the medicines' approval.[30] 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 be able to traverse the blood-brain barrier.[31] 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. 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

[30] 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.

[31] 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/.

efforts.[32] This trend is certain to continue unless and until the design of the Program is enjoined or modified.

[32] *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 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").

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. The Program unfortunately has been designed so that unelected officials in 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 purportedly insulates its decisions from judicial scrutiny

The IRA purportedly allows HHS to proceed with implementing the Program without notice-and-comment rulemaking.[33] 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."[34]

[33] 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).

[34] IRA § 11001(c).

HHS has interpreted this provision to mean that notice-and-comment rulemaking procedures are unnecessary.[35]

The IRA also purportedly 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 [the Act]," or "[t]he determination of renegotiation-eligible drugs."[36] 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.[37] In other words, the government's own position is that the statutory review preclusion is all-encompassing.

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[35] *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.

[36] 42 U.S.C. § 1320f-7(2)–(4).

[37] 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.

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."[38] CMS has, on its own accord, invited public comments on draft guidance, which explains how the agency intends to implement the Program.[39] These measures, however laudable, fall short of achieving the level of transparency and 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.[40] 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

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

[39] *See* Initial Guidance, *supra* note 35, at 2.

[40] Initial Guidance, *supra* note 35, at 5.

negotiation process,[41] 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, 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. CMS's most recent guidance indicates that future listening sessions may not even be live-streamed to the public, but only summarized in writing by CMS.[42] With nothing

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[41] *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 May 3, 2024).

[42] *See* Memorandum from Meena Seshamani, CMS Deputy Admin. & Dir., Ctr. for Medicare to Interested Parties, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the*

requiring CMS to respond to significant points raised by stakeholders, "the opportunity to comment is meaningless . . . ."[43]

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.[44] For the proposed rule that included these hospital price transparency provisions, CMS received 3,777 timely pieces of correspondence, and reviewed and addressed them in the final rule.[45] CMS undertakes this exercise on an annual basis for several of its programs,[46] and

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Maximum Fair Price (MFP) in 2026 and 2027 at 89 (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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

[44] 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).

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

[46] CMS conducts annual rulemaking for several of its programs, including Medicare Part D, the inpatient prospective payment system, the physician fee

typically conducts the same practice for programs outside the scope of its routine rulemaking schedule.[47] 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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Respectfully submitted,

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schedule, the End-Stage Renal Disease prospective payment system, and the prospective payment system and consolidated billing for skilled nursing facilities, among others.

[47] *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 BAR MEMBERSHIP

Pursuant to Local Appellate Rule 28.3(d), I hereby certify that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

s/Craig B. Bleifer
Craig B. Bleifer

July 19, 2024

CERTIFICATE OF COMPLIANCE

The foregoing brief is in 14-point Times New Roman proportional font and contains 5,687 words, and thus complies with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

I further certify that the text of this electronic brief is identical to the text of paper copies of this brief that will be filed with the Court, and that a virus detection program (CylancePROTECT Agent version 1340) has been run on this file and no virus was detected.

s/Craig B. Bleifer
Craig B. Bleifer

July 19, 2024

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, I served the foregoing brief upon all counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system.

/s/ Craig B. Bleifer
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