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

NOVARTIS PHARMACEUTICALS CORP., , v XAVIER BECERRA, U.S. Secretary of Health & Human Services, ,	Civil Action No. 23-14221 (ZNQ)(DEA)

CONSENT MOTION OF THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL MEDICINE, THE AMERICAN GERIATRICS SOCIETY, AND THE AMERICAN SOCIETY OF HEMATOLOGY FOR LEAVE TO FILE AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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Amici Curiae

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issues so that the court may reach a proper decision, or where an issue of general public interest is at stake.” , 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005) (cleaned up). Proposed are some of the preeminent professional organizations in the country that focus on public health and patient outcomes. This case, relating to one of the nation’s largest public health programs, with implications for the long

approvingly by the Supreme Court.[6] APHA has publicly supported the government program at issue in this case.[7]

patients.[10] Organization members of the ACP have addressed issues related to coverage and cost of care, Medicare and Medicaid policy changes, healthcare payment systems, and more. The ACP has submitted comments on the government program at issue in this case.[11]

Society of General Internal Medicine

The Society of General Internal Medicine (SGIM) is a member-based association of more than 3,300 of the world's leading academic general internal medicine physicians, who are dedicated to delivering comprehensive, coordinated, and cost-effective care to ad

Sustainable Rx Pricing (CSRxP) in 2016,

American Society of Hematology

The American Society of Hematology (ASH) represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders as well as classical (non-malignant) conditions. ASH believes that all individuals should have access to and be able to afford high-quality, clinically appropriate care. High drug prices continue to be a major issue facing patients with hematologic diseases and disorders, and ASH continues to identify and advocate for ways to limit patient out-of-pocket expenses.

RELEVANCE TO THE COURT

Plaintiff Novartis alleges that the drug price negotiation program ("Program") of the Inflation Reduction Act (IRA), that allows the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices for Medicare, 42 U.S.C.

may support drug manufacturers' efforts to gut the Program. Oral Arg. on Pls.' Mot. for Prelim. Inj., ECF No. 54,

., No. 23-cv-00156 (S.D. Ohio, argued Sept. 15, 2023). Defendants have responded to Plaintiff's constitutional arguments but do not devote substantial time to Plaintiff's public health representations. ECF No. 24;

, , 293 F.3d 128, 132 (3d Cir. 2002) ("Even when a party is very well represented, an amicus may provide important assistance to the court.") (Alito, J.). The attached brief by proposed provides the Court a detailed analysis of research on the effects of high prescription drug prices on public health, justifying the substantial public policy need for the Program. Proposed also explain why drug manufacturers' warnings regarding the negative effects of these new rules on public health are exaggerated, considering longstanding concerns about the nature and scope of drug manufacturers' investment04 Tc -0.0.004 Tn3.1 (t)s2 -2.291gesyidc helest2 (or)12.4.2 (i)-8.J.00

CONCLUSION

For these reasons, the Court should enter the attached Proposed Order granting leave to proposed to file the attached brief.

Dated: January 192 (a)-46 heoh249.24

CERTIFICATE OF SERVICE

I hereby certify that the foregoing motion has been served upon all counsel of record via ECF.

Date: January 19, 2024

_____
Madeline Gitomer

EXHIBIT A

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

NOVARTIS PHARMACEUTICALS CORP., *Plaintiff*, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*, *Defendants.*	Civil Action No. 23-14221 (ZNQ)(DEA)

PROPOSED BRIEF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL MEDICINE, THE AMERICAN GERIATRICS SOCIETY, AND THE AMERICAN SOCIETY OF HEMATOLOGY AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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Juliette Cubanski & Anthony Damico,

IDENTITY AND INTERESTS OF *AMICI CURIAE*[1]

Amici the American Public Health Association, the American College of Physicians, the Society of General Internal Medicine, the American Geriatrics Society, and the American Society of Hematology are some of the world's leading public health organizations, representing hundreds of thousands of doctors, public health officials, and health professional trainees (including medical students) who have treated and managed care for millions of Americans. They have been active for decades in tracking the effects of high prescription drug prices on public health and patient outcomes. They explain below why the Inflation Reduction Act's (IRA) Drug Price Negotiation Program, which allows the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices for Medicare, 42 U.S.C. §1320f(a) (the "Program"), is vital to maintaining and strengthening patient care and the Medicare program. Contrary to what drug companies have argued, doctors and their patients do not support untrammeled price increases by drug manufacturers. *Amici* also explain why Plaintiff Novartis's assertions regarding the negative effects of these new rules on public health are exaggerated.

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INTRODUCTION

New pharmaceutical interventions for chronic or acute illnesses can save millions of lives. They can also save patients and insurance plans money by treating illnesses before patients must undergo more expensive, invasive treatments. *Amici* believe private sector drug manufacturers play a vital role in inventing, testing, and supplying these drugs, and they should be encouraged to do

rel. Spay v. CVS Caremark Corp., 875 F.3d 746, 749 & 749 n.2 (3d Cir. 2017). "At the time, more than 14 million seniors in America had no access to drug coverage and more than one-third reported not taking their medicines as prescribed due to cost."[3] Starting in 2006, older adults and people with certain disabilities could enroll in plans run by private companies that contracted with Medicare. These plans generally charge enrollees a premium and, for each prescription filled, enrollees pay co-insurance or make a co-payment. Part D benefits have allowed older adults, especially low-income people, to access critical care: "annual out-of-pocket drug costs dropped an average of 49% among those who previously did not have drug coverage."[4] Part D was very successful and, in 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[5] As a result, Medicare has become one of the single largest underwriters of drug therapy in the United States.

The federal government now pays for roughly 45% of nationwide drug spending through Medicare, Medicaid, and other smaller programs. Despite its

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key role in the market, and unlike private health insurance providers, Medicare was not allowed to negotiate directly with drug manufacturers for the prices of the drugs it paid for. *See* 42 U.S.C. §§ 1395w-111(i). Drug prices—especially for drugs targeted at people over 65 who have Medicare's guaranteed coverage—have ballooned over the last two decades. They have put the system at peril, have bankrupted older Americans, and have undercut the core public health mission Congress was advancing through its 2003 revisions.

With passage of the Inflation Reduction Act, Congress empowered CMS to

[redacted].5

ARGUMENT

I. America's High Prescription Drug Pricing Regime Has Substantial and Escalating Negative Effects on Public Health and Patient Outcomes.

The 2003 reforms to Medicare sought to address a key gap in the social safety net: until the creation of Medicare Part D, Medicare beneficiaries had to pay out of pocket for prescription drugs taken outside a doctor's office. These costs were a crushing burden for many low- and moderate-income people. By covering prescription drugs for them, Medicare Part D allowed beneficiaries to afford lifesaving medications and avoid even more ex.3 (d Tw22Hg12.1 3r3.6 (c)3 Pv.3 (e)3.6 (n 8.3

A. Medicare prescription drug costs have become unsustainable.

Prescription drug costs, driven in part by per unit drug price hikes, have increased at rates far above inflation in recent years. According to a report published by the Congressional Budget Office (CBO) in 2022, "nationwide spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018."[8] The same report found that prescription drug expenditures per capita increased from $140 in 1980 to $1,073 in 2018 and $1,631 in 2020.

These cost increases are particularly burdensome for Medicare Part D as it is one of the largest single underwriters of drug therapy in the United States. The CBO estimated that Part D benefits would total $120 billion in 2023, or 14% of net Medicare outlays.[9] By 2018, per enrollee spending on Medicare Part D averaged about $2,700 per year.[10] Notably, these high per capita costs have persisted, despite 90 percent of Medicare Part D prescriptions being for low-cost generics, and despite the average price for generics *dropping* between 2009 and 2018.[11]

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[8] *Id.* (these numbers (t004 Tc -0.006 Tw 0.248)3.7 (grd( )T.7lnn ₱BDC5)8.3 (d)8.3 B Tc - 0.6

These high levels of spending are driven in large part by the widespread and long-term use of so-called “blockbuster” or specialty drugs that account for billions of dollars in revenue to their manufacturers. The CBO estimates that, “[o]ver the 2009–2018 period, the average price of a prescription for a brand-name drug more than doubled in the Medicare Part D program and increased by 50 percent in Medicaid.”[12] The American Association for Retired Persons (AARP) has calculated that between 2007 and 2017, the average annual cost of chronic therapy increased by more than $51,000 per specialty drug.[13]

chosen for negotiation under the Program increased far above inflation.[16] Novartis's Entresto is a case in point. Its price has gone up by 78% since its introduction in 2015, more than twice the level of cumulative retail inflation.[17] Today, Entresto costs more than double in the US than in the most expensive comparable overseas market.[18] It cost roughly $3.5 billion to develop Entresto; after it was already on the market, Entresto's manufacturers spent another $2.3 billion to identify other conditions it may be able to treat.[19] Gross Medicare costs for Entresto for just the period June 2022 to May 2023 were almost $2.9 billion, roughly half of the drug's lifetime research and development spending.[20]

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[16] Leigh Purvis, *Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market* 1, AARP Pub. Pol'y Inst. (Aug. 2023), https://tinyurl.com/388becj2.

[17] *Id.* at 2, fig. 1; *CPI Inflation Calculator*, U.S. Bureau Lab. & Stat., https://tinyurl.com/4xdtjs4j (retail inflation from 2015 to 2023 was 31%).

[18] Evan D. Gumas, et al., *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*,

The table below summarizes available data for the drugs chosen for negotiation.

Prescription Drugs Chosen for Negotiation:

health.[39] In 2022, “[a]bout a quarter of [US] adults [said] they or [a] family

2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[43] By the summer of 2023, that figure had increased by 5 percentage points.[44] These figures would likely be higher still, except that some older people—8.5% according to one 2022 survey—choose the rock instead of the hard place and forego other basic needs, such as food, in order to afford their prescription drugs.[45] Other older Americans are only able to avoid this impossible choice thanks to assistance from non-profits and state pharmacy assistance programs that try to provide a safety net for the most needy.

Older adults in other countries do not struggle so mightily. Cost-related medication nonadherence in the United States is two to four times higher than in other developed countries.[46] Public health researchers have estimated that, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and

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[43] Montero et al., *supra* note 36; *see also* Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network, May 2023, at 3, https://tinyurl.com/4mccyu7x (estimating "20.2% [of older adults] reported any cost-related medication nonadherence").

[44] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, Kaiser Fam. Found. (Aug. 21, 2023), https://tinyurl.com/hun2y8bn.

[45] Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network, May 2023, at 1.

[46] Morgan & Lee, *supra* note 32, at 4.

older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[47]

Beyond these direct effects, cost-related medication nonadherence has downstream effects on healthcare costs and patient wellbeing because financial barriers may prevent people from filling prescriptions for drugs that can prevent serious medical complications that are life-threatening, permanently disabling, and/or extremely costly to treat.[48] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[49] Indeed, the initiation of Medicare Part D—which reduced cost-related medication nonadherence —was itself associated with a drop in hospitalization rates for several conditions.[50] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare program and will lead to

[47] *Id.* at 4.

[48] *Id.* at 5; *see also* Jessica Williams et al., *Cost-related Nonadherence by Medication Type Among Medicare Part D Beneficiaries with Diabetes*, Med. Care, Feb. 2013, at 1, https://tinyurl.com/ycynd88h (finding more frequent CRNA for cholesterol-lowering medication as compared to medications for symptom relief).

[49] Goldman, Joyce, & Zheng, *supra* note 39, at 7.

[50] Aaron S. Kesselheim et al., *Prescription Drug Insurance Coverage and Patient Health Outcomes: A Systematic Review*, Am. J. Pub. Health, Feb. 2015, at e19, https://tinyurl.com/3ts9cew5.

an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[51]

Members of *Amici*

They run the risk of blood clots and stroke but they can't afford [their medications]."

- A doctor in Georgia: A patient had "atrial fibrillation and his cardiologist and primary care physician agree[d] that Eliquis is safer for him than Warfarin. He cannot afford Eliquis under his Medicare plan. He shared with his primary care physician that if it were not for the samples sometimes made available to him through his doctors' offices, he wouldn't know what he would do to afford and receive the Eliquis as he is on a fixed income."
- A doctor in New Mexico: "I took care of a patient who didn't take his blood pressure medication on the day he was to see me because in order to be able to afford gas to the appointment, he had reduced how often he took his medication so it would last longer."

II. The Program Is A Vital First Step In Ensuring The Health Of

of-pocket costs under the new standards set by the IRA.[54] Plaintiff's dramatic characterization of drug price negotiation as "compelled below-market price controls," Compl., 93, notwithstanding, the Program will restore some semblance of freedom to a market that has, for many years, been shielded from market forces by the largest purchaser's inability to negotiate the prices it pays.

Two other federal government programs that provide prescription drug coverage and allow for direct negotiation illustrate the value of drug price negotiation between the government and drug manufacturers. *See* 38 U.S.C. §§ 8126(a)-(h). The Veterans Health Administration (VHA) operates as a closed system and provides care directly to veterans, covering several million people. It purchases drugs and other pharmaceuticals directly from manufacturers and has a national formulary that does not exist in Medicare or Medicaid. The Government Accountability Office (GAO) found that, in 2017, the VHA paid an average of 54% less per unit of medicine than Medicare, including for brand name drugs.[55] In more than half the 399 drugs the GAO analyzed, the VHA paid less than half the

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price per unit Medicare paid; for 106 drugs, the VHA paid less than 25% of what Medicare paid.

programs, and it has substantially lower net costs for brand name drugs.[59] The CBO has estimated that the average price of top-selling brand-name drugs in Medicare Part D is almost three times higher than in Medicaid.[60]

negotiate drug prices, as compared to the ability of other public health systems, is a key reason for higher prices [62]

III. Public Health Research Shows That The Program Is Unlikely To Have Substantial Negative Effects On Drug Availability Or Patient Outcomes.

Plaintiff Novartis and other drug companies opposed to the negotiation program are correct that the United States leads the world in bringing drugs to market. But their claim that the Program will make it uneconomical to continue this pace of innovation, and thereby irretrievably hurt public health, is insufficiently supported.

First: While it is true that developing new pharmaceuticals is an expensive and risky enterprise, it is not clear that the price reductions that result from the Program will lead to substantial reduction in the number of high-impact drugs brought to market. The CBO estimates that the Program will lead to only 13 fewer drugs being brought to market in the next 30 years, for an overall reduction of 1% in volume.[63] The Brookings Institute has similarly found that the Program is

[62] *See* Andrew W. Mducs2.Dt04 Tc 0.0r0 d-d-T.7 (be)3 0 r./ (a)3.6 (r)3.6 (l)8.5 (y f)12.8wew8.5

competition, negotiation, or transparency. For instance, an unknown but large proportion of pharmaceutical costs are for direct-to-customer marketing and lobbying, rather than research and development.[66] A 2015 study from the National Bureau of Economic Research estimated that nearly one third of the growth in drug spending is attributable to an increase in advertising.[67] Other estimates suggest that marketing and administration can contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[68] The US is one of the only countries that allows such a vast scale and scope of direct-to-consumer advertising. Research has shown that direct to consumer advertising increased substantially after the introduction of Medicare Part D and may have been targeted to reach older Americans who were newly covered by governmental prescription drug

[66] Daniel, *supra* note 61, at 59; Am. Pub. Health Ass'n, *Ensuring Equitable*

Driven by a wish for higher investment returns, p

Fourth: Drug manufacturers' claims about private innovation and market prices for drugs ignore the large share of research and development carried out or funded by the government and universities. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring new innovations and breakthroughs.[75] Major

of research funded by the NIH.[78] Clinical research into Novartis's Entresto has received hundreds of thousands of dollars of NIH funding.[79]

Insulin is illustrative of this kind of process. It was developed in a non-commercial laboratory in the early 20th century and its patent was sold to the University of Toronto for $3, which in turn allowed manufacturers to license it royalty-fee.[80] Despite being the product of public and academic research a century ago, insulin prices have skyrocketed in recent years. Amongst the most expensive of these insulin-based treatments are Fiasp and Novolog, both of which are on the list of drugs eligible for negotiation under the Program. Combined, they accounted

[78] Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 Proc. Nat'l Acad. Scis., no. 10, Mar. 2018, at 2329, https://tinyurl.com/bdhu39t9.

[79] *See, e.g.*, NIH Reporter, *Project Details: Diagnostic and Therapeutic Approach to Heart Failure with Preserved Ejection Fraction Based on Circulating Neprilysin* (last visited Jan. 9, 2023), http://tinyurl.com/5n6d26df. Other Novartis drugs like Tasigna (nilotinib) have received even more funding for clinical trials. *See, e.g.*, NIH Reporter, *Project Details: A randomized, double blind, placebo-controlled study to evaluate the impact of Nilotinib treatment on safety, tolerability, pharmacokinetics and biomarkers in Dementia with Lewy Bodies (DLB)* (last visited Jan. 9, 2023), http://tinyurl.com/yckrr6r5.

[80] Hilary Daniel, Josh Serchen, & Thomas G. Cooney, *Policy Recommendations to Promote Pre-s-81 (c)-4.4 conseootr oe( )87 (i)-81 0(e)-4.i(o)-83 ( )-8n: ( )87 A 4 (ol)0.52 ( )-81 0ions*

for $2.6 billion in total Medicare Part D spending between June 2022 and May 2023, despite being built on a base of publicly supported research.[81]

Under the current system, U.S. taxpayers end up paying twice for pharmaceutical products: by funding basic research and then by paying high prices through government health programs.[82] Where funding for research comes from phcJ84.1 (s)-4.1 (ii (l)8.7 (pr)12.2g (pr)12.(n a)3.6 (m))7.s[(,)6.1th (o)8. (ye)3.6 (r)12.6 (e)3.6i

ECF No. 54, *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-00156 (S.D. Ohio, argued Sept. 15, 2023). *Amici* wish to make it clear that they do support Medicare negotiating drug prices and do not support the manufacturers' efforts to hollow out this significant reform.

CONCLUSION

The Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion for summary judgment.

Dated: January 19, 2024

Respectfully submitted,

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Having considered the motion of the American Public Health Association, the American College of Physicians, the Society of General Internal Medicine, the American Geriatrics Society, and the American Society of Hematology for leave to file a brief as *amici curiae* in support of Defendants' motion for summary judgment and in opposition to Plaintiff's motions for summary judgment, the Court hereby **GRANTS** the motion filed in this case and directs the