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AMICI CURIAE

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 assertions by Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together, "Novo Nordisk") regarding the negative effects of these new rules on public health are exaggerated.

[1] *Amici Curiae* certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission.

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 so. However, if prescription drugs are so expensive that they are unaffordable to patients or to health insurance providers like the federal government, they no longer advance societal and individual health. *Amici* have long advocated for evidence-based and value-oriented public policy regarding drug pricing.[2]

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-

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. Medicare's inability to negotiate prices, paired with a lack of price and cost transparency in the industry, was an anomaly, both domestically and compared to equivalent programs in countries like Denmark, Novo Nordisk's corporate home. It is one of the reasons US consumers pay far more for prescription drugs than do consumers in Denmark.

With passage of the Inflation Reduction Act, Congress empowered CMS

Medicare, no matter how vital it may be to a business model, is a completely voluntary choice”). Plaintiffs

than doubled.[7] These cost increases have been greater for a small group of ultra-expensive drugs

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]

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 for their manufacturers.

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

Prescription Drugs Chosen for Negotiation: Price Hikes, Revenue, and Research

		[19]	[20]	[21]	[22]
Enbrel	1998	701%	$2.8 bn	$132.5 bn	unknown [23]
Novolog/Fiasp	2000	628%			

anticipated to cover part of the additional federal spending.[32] Members of *Amici* have already encountered patients for whom these caps

health.[36] In 2022, "[a]bout a quarter of [US] adults [said] they or [a] family member in their household have not filled a prescription, cut pills in half, or skipped doses of medicine in the last year because of the cost, with larger shares of those in households with lower incomes, Black and Hispanic adults, and women reporting this."[37]

Although Americans covered by Medicare are insulated from some of the challenges faced by uninsured Americans under 65, they are not immune. A recent analysis by the Office of Health Policy using the National Health Interview Survey found that 6.6% of all adults over 65 (a total of 3.5 million people) faced affordability problems due to prescription costs, and 2.3 million of these older adults did not take needed prescriptions due to cost.[38] The same survey found that "Black and Latino beneficiaries were 1.5 to 2 times as likely to experience medication-related affordability challenges as White beneficiaries in this age range," evidencing a persistent lack of pharmacoequity in US healthcare.[39] In

[36] Dana P. Goldman, Geoffrey F. Joyce, & Yuhui Zheng, *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, JU.1 (n8.2 (w)-3.7 (i)0.5 (t)-8.1 (h)-8.2 ( ) l)3h aeoalit laed 30n (e)-5.145 TD1 (i)0.5 (c

2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[40] By the summer of 2023, that figure had increased by 5 percentage points.[41] 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.[42] 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.[43] Public health researchers have estimated that, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and

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[40] Montero et al., *supra* note 33; *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").

[41] Ashley Kirzinger et al., "

older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[44]

an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[48]

Members of *Amici* have observed and treated patients who ration their use of critical medications because of the high costs passed on to them. For instance:

- A doctor in Maryland: "I had a patient with a history of recurrent

of-pocket costs under the new standards set by the IRA.[51] Plaintiffs' dramatic characterization of drug price negotiation as an "extreme and unprecedented" "price-control regime," Compl., ECF No. 1 10, 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.[52] In

[51] Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023), https://tinyurl.com/3adurnbk.

[52] U.S. Gov't Accountability Off., *GAO-21-111, Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, at 1 (2020), https://tinyurl.com/bdusnnrt.

more than half the 399 drugs the GAO analyzed, the VHA paid less than half the price per unit Medicare paid; for 106 drugs, the VHA paid less than 25% of what Medicare paid.[53]

Another example is the Department of Defense (DoD) uniform drug formulary (TRICARE formulary), which provides prescription drug coverage for roughly 9.5 million active-duty and retired military personnel, their dependents, and others. Within two years of being implemented in 2005, the DoD drug formulary led to roughly $1 billion in cost savings, representing approximately a 13% reduction in drug expenditures.[54] In its most recent report from 2022, the Defense Health Agency estimated $1 billion annual savings in retail pharmacy refunds on most brand-name retail drugs and reported a very low rate of annual growth in costs in recent years.[55]

Even Medicaid, which does not have the kind of direct negotiation and unified formulary system as TRICARE and the VHA, has been able to obtain substantially larger rebates than Medicare through statutory and State-run rebate

programs, and it has substantially lower net costs for brand name drugs.[56] 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.[57]

The importance of negotiation to reducing prices is also illustrated by the differences in drug prices between the US and other similarly situated countries. The United States is the only country in the 34-member Organisation for Economic Co-operation and Development (OECD) that lacks some degree of government oversight or regulation of prescription drug pricing, and it is one of only two developed countries that allows the drug industry to set its own drug prices independent of government authority.[58] Drug prices in the US are between 2 and 2.5 times higher than in other comparable countries and Medicare's inability to

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[56] Off. Inspector Gen., Dep't Health & Hum. Servs., *OEI-03-13-00650, Medicaid Rebates 8 (r)3.7 (i)5 (e)3.4 TF.3 (ntr)0.004 Tw -25.3t*

negotiate drug prices, as compared to the ability of other public health systems, is a key reason for higher prices [59]

The routine nature of such negotiation is illustrated by Denmark, which runs a fully nationalized public health system with a state body (Amgros) empowered to negotiate drug purchases for hospitals, taking clinical effectiveness of drugs into account.[60] The Danish government has entered into price reduction agreements with pharmaceutical groups and has started a process of setting external benchmarks for the amounts it will pay for prescription drugs, based on transparent international reference prices.[61] Even though drug companies can set prices for drugs people buy at pharmacies in Denmark, those prices are listed publicly, are compared to clinically equivalent drugs, and are embedded in a drug cost reimbursement system that reduces drug costs and drives down prices.[62] Denmark

[59] *See* Andrew W. Mulcahy et al., *U.S. Prescription Drug Prices Are 2.5 Times Those in Other OECD Countries*, Rand Corp. (2021); Kaiser Permanente Inst. for Health Pol'y, *Pharmaceutical Pricing: Lessons from Abroad* (2015), https://tinyurl.com/3nbaj9a6.

[60] *See* Karsten Vrangbæk, *Denmark*, *in* International Profiles of Health Care Systems, at 47, 55 (Roosa Tikkanen et al., eds., Dec. 2020), http://tinyurl.com/ytd2r4v3.

[61] *Id.* at 56.

[62] *See* Danish Meds. Agency, *Reimbursement and Prices* (last updated Sept. 23, 2019), http://tinyurl.com/2u77r5p4 (describing the drug cost reimbursement policy in Denmark).

has recently gone a step further by collaborating with other Nordic countries to negotiate drug prices collectively, to increase “price pressure” by leveraging a larger market share.[63] Drug price negotiation has not caused the sky to fall for Danish patients.

unlikely to substantially change the future development of medications, based on drug manufacturers' public market activity.[65] This is unsurprising, in part, because the Program does not apply to new drugs on the market and continues to grant drug companies almost unfettered discretion to price new drugs at exorbitant rates, which they may continue to do.[66]

Nevertheless, even without changing the price of new drugs, the public health benefits from lower drug prices for drugs that have been on the market for several years are likely to be orders of magnitude greater than the harm caused by this 1% reduction in new drugs. Making existing drugs more affordable will enable more patients—especially older people with fixed, and often limited, incomes—to take and maintain existing necessary medication.

Second: Drug manufacturers' claim that negotiated drug prices will automatically lead to less money available for research is difficult to substantiate considering their longstanding opposition to price and cost transparency, which limits public access to their research costs. The public must trust that drug manufacturers are unilaterally setting the correct price for their drugs, without

[65] Richard G. Frank & Ro W. Huang,

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.[67] 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.[68] 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.[69] 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

[67] Daniel, *supra* note 58, at 59; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 3 (Nov. 8, 2022).

[68] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 33 (Nat'l Bureau Econ. Rsch., Working Pa 0.002 od-4.5 (ri-4.5.4 Tc 0.07&Ad)-8.2 (l-8.2 (l5t-ug 0)8.7 (La))6.1 (Tg(l5t8ug 006

insurance.[70] Even if the Program results in lower prices for certain drugs, any difficulty bringing new viable products to market may just as likely be attributable to self-imposed marketing overhead.

Third: New pharmaceutical development in the United States, and especially private corporate research priorities, does not always align with the goal of long-term effective increases in public health. In particular, the US regulatory system for pharmaceutical drugs does not require drug developers to routinely evaluate the

Driven by a wish for higher investment returns, pharmaceutical research and development often focuses on relatively low risk research into marginal changes to differentiate similar drugs, instead of higher risk research into new scientific paradigms that could reduce morbidity and mortality.[73] Recent studies suggest that more than 60% of research and development spending is post-approval research into additional indications for approved drugs, rather than into new drugs.[74] The current market thus incentivizes less breakthrough research, rather than more. Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[75] Even if the Program were to lead to less research funds for 'me-too' drugs, it may divert that funding towards more innovative drug development.

Medicare prices for 'me-too' drugs are significantly higher than older, equally effective versions, but that Medicare continues to pay higher prices and thereby incentivizes the continued production of such drugs with marginal value to patients); *see also* Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, J. L., Med. & Ethics, 2013, https://tinyurl.com/yckypnhf.

[73] *Ensuring Equitable Access to Affordable Prescription Medications, supra* note 69, at 10.

[74] ATI Advisory, *supra* note 21.

[75] *See* Ashish Arora, Sharon Belenzon, & Andrea Patacconi, *Killing the Golden Goose? The Decline of Science in Corporate R&D* (Nat'l Bureau Econ. Rsch., Working Paper No. 20902, 2015), https://tinyurl.com/bdeuzpt8.

Fourth: Drug manufacturers' claims about

through 2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[79]

Insulin is illustrative of the public health benefits of government-funded research. 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, and there is a wealth of research into the significant market failures associated with this market in the US.[81]

Novo Nordisk was founded after two Danish scientists travelled to Canada "to seek permission from the researchers to produce this life-saving medicine in Denmark."[82] It started producing insulin in 1923, based on these patents. It

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[79] 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.

[80] Hilary Daniel, Josh Serchen, & Thomas G. Cooney, *Policy Recommendations to Promote Prescription Drug Competition: A Position Paper from the American College of Physicians*, Annals Internal Med., Sept. 2020, at 1006, https://tinyurl.com/y56byn7y.

[81] *See*, *e.g.*, David Beran et al., *A Perspective on Global Access to Insulin: A Descriptive Study of the Market, Trade Flows and Price*, 36 Diabetic Med., no. 6, 2019, http://tinyurl.com/4m5nwpzb.

[82] *See* Novo Nordisk, *About Us* (last accessed Jan. 24, 2024), http://tinyurl.com/49c3t8r3.

describes itself as seeking to "drive change to defeat diabetes and other serious chronic diseases, such as obesity, and rare blood and rare endocrine diseases." Compl., ECF No. 1 27. By 2016, Novo Nordisk controlled 52% of the global market for insulin by volume, and 41% of market share by revenue.[83]

Amongst the most expensive insulin-based treatments are Novo Nordisk's Fiasp and Novolog products, part of a group of drugs known as insulin asparts. They are vital treatments for endocrinologic conditions, primarily diabetes, which in turn can lead to serious pulmonary, hematological, and cardiac complications. Combined, these insulin aspart products accounted 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.[84]

Under the current system, U.S. taxpayers end up paying twice for pharmaceutical products: by funding basic research and then by paying high prices

[83] *See* Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, 7 J. L & Biosciences, no. 1, 2020, at 4, http://tinyurl.com/ycy9xnpm (noting that the US insulin market is effectively an oligopoly, with only three major companies (including Novo Nordisk) supplying the country).

[84] Jeannie Baumann, Celine Castronuovo, & John ToTw -28ck7.9 (ar)0(n)8.3 (uo)8.3 (14.04 ott

through government health programs.[85] Where funding for research comes from public programs, there is little reason to believe reduction in prices charged by manufacturers will result in substantially reduced effective innovation.

There is thus no reason to credit Novo Nordisk's claim that the Program will cause the sky to fall. The federal government can use its purchasing power, like other market participants, to command a better price for the goods it purchases without threatening pharmaceutical innovation.

Recently, industry groups suing in parallel in the Southern District of Ohio argued that doctors and patients will be harmed by the Drug Negotiation Program and suggested that doctors supported efforts by the drug companies to gut the Program. *See* Oral Argument on Plaintiffs' Motion for a Preliminary Injunction, 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.

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

Dated: February 2, 2024 Respectfully submitted,