EXHIBIT A

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, Kaiser Fam. Found. (July 12, 2023), https://tinyurl.com/ycytf6wm

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 largest 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 Bristol Myers Squibb ("BMS") and Plaintiff Janssen's[2] assertions regarding the negative effects of these new rules on public health are exaggerated.

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[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.

[2] BMS and Janssen have filed parallel lawsuits against the same set of Defendants and have sought summary judgment on almost identical grounds. Potential *amici*

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. Private sector drug manufacturers of course 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.[3]

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are providing the same information to the Court in both lawsuits and, for the sake of judicial efficiency, have submitted identical briefs in these cases.

[3] *See, e.g.*, Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), https://tinyurl.com/4v7c35j8; Am. Pub. Health Ass'n, *APHA Applauds Senate Passage of Inflation Reduction Act* (Aug. 8, 2022), https://tinyurl.com/3etz4e7d; Am. Pub. Health Ass'n, *Ensuring That Trade Agreements Promote Public Health* (Nov. 13, 2015), https://tinyurl.com/b2et6uvp; Am. Pub. Health Ass'n, *Creating the Healthiest Nation: Advancing Health Equity*, https://tinyurl.com/5xn4ue8n (last visited Oct. 23, 2023); Am. Pub. Health Ass'n, *Regulating Drugs for Effectiveness and Safety: A Public Health Perspective* (Nov. 8, 2006), https://tinyurl.com/5n7zv9bd; Am. Coll. Physicians, *ACP: Passage of Inflation Reduction Act Improves Access to Health Care Services, Treatments*, https://tinyurl.com/44wmn2b6 (last visited Oct. 23, 2023); William Fox, *ACP*

Controlling unsustainable drug prices and fixing the market failures that contribute to the astronomical cost of prescription drugs is necessary to preserve patient health and to ensure the longevity and sustainability of the social safety net.

For decades, Medicare did not cover prescription drug costs for older adults. Older adults had to find their own private plans to access care. Congress, in 2003, amended the Medicare statute to create Part D pharmacy benefits. *United States ex rel. Spay v. CVS Caremy v. temy v. temy v. temy ts.*

outlays.[12] Although the introduction of a number of generic drugs into the marketplace has worked to modulate some of these cost increases, by 2018 per enrollee spending on Medicare Part D averaged about $2,700 per year.[13] 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.[14]

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.[15] 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

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[12] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 6; Cong. Budget Off., *Medicare: Baseline Projections* 2 (2022), https://tinyurl.com/28fu8xzp.

[13] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10.

[14] *Id*. The Federal Trade Commission has investigated so-called "Pay for Delay" schemes, where branded drug manufacturers enter into settlements with manufacturers of generic medicines to keep generic alternatives off the market. *See* Fed. Trade Comm'n, *Pay-for-Delay: When Drug Companies Agree Not to Compete*, https://tinyurl.com/9u24eu2k (last visited Oct. 23, 2023).

[15] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 10; Juliette Cubanski et al., *No Limit: Medicare Part D Enrollees Exposed to High Out of-Pocket Drug Costs Without a Hard Cap on Spending*, Kaiser Fam. Found. 3-4 (Nov. 2017), https://tinyurl.com/2rypz7yr.

Medicaid."[16] 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.[17] Had specialty drug prices merely tracked general retail inflation, their average annual cost would have gone up by only about $2,000 during this period; a saving of almost $50,000 per drug.[18] This disproportionate growth has continued since the AARP's 2017 study: KFF, formerly known as the Kaiser Family Foundation, estimated that between 2018 and

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2021 gross Medicare spending for the top selling Part D drugs more than doubled.[19]

The Drug Negotiation Program intervenes in the unsustainable growth in prices of drugs already on the market. The AARP found that prices for drugs chosen for negotiation under the Program increased far above inflation,r

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

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

Drug	**Year of FDA approval**	**Percentage increase in price since approval**[29]	**Medicare Part D Gross Cost (June 2022-May 2023)**[30]	**Global lifetime sales (2021)**[31]	**Total R&D costs (2021)**[32]
Enbrel	1998	701%	$2.8 bn	$132.5 bn	unknown[33]
Novolog[34]	2000	628%	$2.6 bn	$42.8 bn	unknown

B. Americans, especially older adults, cannot sustain these high prices.

Even though most of the cost of high-priced medication is borne by Medicare, a significant portion is also borne by older Americans and individuals with disabilities, whose cost-sharing can include significant monthly premiums and other costs.[35] In addition to these premiums, many drug plans have annual deductibles that beneficiaries must pay. After the initial coverage phase when Medicare beneficiaries pay either a co-payment (usually for medications on lower tiers) or a co-insurance (for higher tier or specialty medications), they reach the 'donut hole' or coverage gap and pay 25% of a drug's list price until an out-of-pocket maximum is reached.[36] During the coverage gap phase, plan reimbursements are often reduced with the switch from flat co-payments to the 25% co-insurance, which means patient contributions often increase.[37] Prior to the

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[35] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 6; Juliette Cubanski & Anthony Damico, *Key Facts About Medicare Part D Enrollment and Costs in 2023*, Kaiser Fam. Found. (July 26, 2023), https://tinyurl.com/2tby57ue. For the standard framework for Medicare Part D plans after the Inflation Reduction Act, *see Part D Payment System*, MedPAC, https://tinyurl.com/37c87543 (last revised Oct. 2022).

[36] *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*, Council for Informed Drug Spending Analysis (Nov. 18, 2020), https://tinyurl.com/yc4tm4vv.

[37] Louise Norris, *How Did the Medicare Donut Hole Change for 2023?* (Jan. 10, 2023) https://tinyurl.com/4r92uedt.

Part D amendments in the IRA, patients with extremely high drug costs—generally associated with taking one or more specialty drugs—entered the "catastrophic phase" of coverage. A December 2020 study by KFF reported that "over one million Part D enrollees had out-of-pocket spending in the catastrophic phase in 2017, with average annual out-of-

CRNA is the widely reported phenomenon where patients stop taking prescription drugs because of rising prices, even where the drugs are "essential" to their health.[48] 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."[49]

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.[50] The same survey found that

range."[51]

older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[56]

Beyond these direct effects, CRNA has downstream effects on healthcare costs and patient wellbeing because the same financial barriers that prevent people from filling prescriptions for "drugs taken for symptom relief" also "impede the use of essential, preventative medications" that would save them from death or serious injury.[57] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[58] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[59] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare

[56] *Id.* at 1.

[57] *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).

[58] Goldman, Joyce, & Zheng, *supra* note 48, at 7.

[59] 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.

program and will

offices, he wouldn't know what he would do to afford and receive the Eliquis as he is on a fixed income."

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been debated since the creation of Part D in 2003. *Amici* advocated for the repeal of Medicare's "non-interference" provisions specifically because of that provision's negative effects on public and patient health.

Amici are under no illusions that negotiation alone will rein in drug prices, but this approach at least allows the government to leverage its purchasing power to reduce Medicare program costs—as any market participant would—while also allowing plan sponsors to maintain the power to negotiate for the vast majority of drugs covered in the program. As the National Academies of Sciences, Engineering, and Medicine have noted, there is nothing unusual about the federal government negotiating prices on goods it purchases from private companies; it routinely does so for a wide variety of other products for which it is the monopsonist (the sole or primary purchaser), for instance, for purchasing defense equipment.[62] Indeed, the federal government negotiates rates in several other areas of Medicare. Here, the benefit to the public will be substantial: KFF has estimated that many older Americans would save over 60% of their out-of-pocket costs under

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Health Affs. no. 9, Sept. 2016, at 1569 ("the large price increases in specialty drugs observed [between 2008 and 2012] could have been partly a response by manufacturers to more generous coverage in the doughnut hole").

[62] Nat'l Acads. of Scis., Eng'g, & Med., *Making Medicines Affordable: A National Imperative* 52 (Norman R. Augustine et al. eds., 2018), https://tinyurl.com/2zjvmfk2.

the new standards set by the IRA.[63] Plaintiffs' dramatic characterization of drug price negotiation as "mandatory price controls and forced sales," Complaint, *BMS v. Becerra*, Case No. 3:23-cv-03335, ECF No. 1 6, 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 between the government and drug manufacturers illustrate the value of drug price negotiation. *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 drugsan Medicare

programs, and it has substantially lower net costs for brand name drugs.[68] The

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 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.[76] 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.[77] 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.[78] 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

[76] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 3 (Nov. 8, 2022).

[77] 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 Paper No. 21714, 2015), https://tinyurl.com/ytewscn3; *see also* Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*tewscn3

after the introduction of Medicare Part D and may have been targeted to reach older Americans who were newly covered by governmental prescription drug insurance.[79] 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 marginal benefit of new and expensive treatments over longstanding alternatives.[80] 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

[79] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 17-18 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3.

[80] Some studies have suggested that the lower average healthcare spending seen in other countries may stem in part by their more careful striction on the use of new drugs that have unproven marginal clinical advantages over longstanding generic alternatives. *See* Panos Kanavos, *Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*,

paradigms that could reduce morbidity and mortality.[81] 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.[82] The current market thus incentivizes less breakthrough research, rather than more. This is also evident in the number of so-called 'me-too' drugs—that is, drugs that are similar to products already on the market and provide little, if any, added benefit.[83] Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[84]

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[81] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 78, at 10.

[82] ATI Advisory, *supra* note 23.

[83]

Even if the Program were to lead to less research funds for 'me-too' drugs, it may divert that funding towards new and more innovative drug development.

Fourth: Drug manufacturers' claims about private innovation and market prices for drugs ignores the large share of research and development carried out or funded by the government or 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.[85] Major innovative drugs have been discovered in public universities funded through grants from the NIH, and patent rights have been purchased after drug discovery by private companies, generating enormous revenues for drug companies.[86] Between 1988 and 2005, federal research funding contributed to 45% of all drugs approved by the FDA and to 65% of drugs that received priority review.[87] From 2010 through

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[85] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11.

[86] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 78, at 2. Studies have suggested that between 6 and 10% of "new molecular entities" (new innovative drugs) were first patented by public sector or academic institutions and that up to 40% of new molecular entities were first synthesized or purified in academic institutions. *See* 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 2332.

[87] Daniel, *supra* note 85, at 11 (citing Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 Health Affs., no. 2, Feb. 2011, at 332-39).

2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[88] Insulin is a great example 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.[89] 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 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.[90]

Where funding for research and development comes from public programs, there is little reason to believe reduction in prices charged by manufacturers will

[88] 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.

[89] 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.

[90] Jeannie Baumann, Celine Castronuovo, & John Tozzi, *Insulin Makers Facing Price Talks Appear Poised to File Lawsuits*, Bloomberg Law (Aug. 31, 2023, 5:01 AM), https://tinyurl.com/2j44msz6.

result in substantially reduced effective and impactful innovation. 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.

For all of these reasons, there is no reason to credit BMS and Janssen'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, an industry group suing in parallel in the Southern District of Ohio argued that doctors and patients will be harmed by the Drug Negotiation Program in the IRA 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 clear that they do support this Program and do not support the manufacturers' efforts to gut drug price negotiation.

CONCLUSION

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

Dated: October 23, 2023

Respectfully submitted,

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