| | |
|---|---|
| BOEHRINGER INGELHEIM PHARMACEUTICALS,<br>*Plaintiff,*<br>v.<br><br>UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,<br>*Defendants.* | Civil Action No. 3:23-CV-01103-RNC<br><br>Judge Robert N. Chatigny<br>Magistrate Judge Robert M. Spector |

MPROr*S584.16 Tm(, )408-BDC /TT3.3 T

Page

Leigh

## *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 ())3 ( D)2(e)4 (-1 (, publ)-2 (ieH)2)-2 (i P)-4 Tw 1a(l)-2 (l)1-2 (ow)2 (s)-1 ( t)-2 (h erices(()3 CR)(t)-2 ( n(e)4 (got)-2 (i)24 (a)4 (t)-2 (e)4 n dr)3 (ug pr)3 (i)-2 (c)-6 (e)4 (s)-1 (f)3 (or)3 (Ms)-11 (e) ug(c)4 (om)-2 paies ha eare doctorsand theraients ngot sorun trameeice incresesbyn drug mauf()-7 (a)4 octes. *ici*

to patients or to health insurance providers like the federal government, they no longer advance societal and individual health.

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

to gut the law, which would stop these vital reforms. The Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion for summary judgment.

---

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-

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."[9] Prescription drug expenditures per capita increased from $140 in 1980 to $1,073 in 2018 and $1,631 in 2020.[10]

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. In 2023, Part D benefits are estimated to total $120 billion, or 14% of net Medicare outlays.[11] 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.[12] Notably, these high per capita costs have persisted, despite 90 percent of Medicare Part D

https://tinyurl.com/4jaebbbc. After adjustment for differences in purchasing power, outpatient prescription drug spending among Organisation for Economic Co-operation and Development countries averaged $564 per person in 2017, with spending highest in the United States ($1,220), Switzerland ($963), and Japan ($838). *See* Am. Pub.

spending for Jardiance *every year*.[23] Jardiance has earned over $18.3 billion globally.[24] Recent additional indications for Jardiance are expected to increase profits even further.[25]

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

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

| | | [26] | [27] | [28] | [29] |
|---|---|---|---|---|---|
| Enbrel | 1998 | 701% | $2.8 bn | $132.5 bn | unknown[30] |
| Novolog[31] | 2000 | 628% | $2.6 bn | $42.8 bn | unknown |
| Januvia | 2006 | 275% | $4.1 bn | $54.1 bn | $5.3 bn |
| Stelara | 2009 | 184% | $2.6 bn | $54.8 bn | $2.1 bn |
| Xarelto | 2011 | 168% | $6.0 bn | $54.3 bn | $7.8 bn |
| Eliquis | 2012 | 124% | $16.5 bn | $57.1 bn | $4.3 bn |
| Imbruvica | 2013 | 108% | $2.7 bn | $36.8 bn | $1.4 bn |
| Jardiance | 2014 | 97% | $7.1 bn | $18.3 bn | $3.5 bn |
| Farxiga | 2014 | 81% | $3.3 bn | $15.8 bn | $5.2 bn |
| Entresto | 2015 | 78% | $2.9 bn | $14.3 bn | $4.8 bn |

[23] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, Ctrs. for Medicare & Medicaid Servs. 1 (Aug. 2023), https://tinyurl.com/mrys5br6.

[24] ATI Advisory, *supra* note 22, at 10.

[25] *See* Ludwig Burger & Patricia Weiss, *Boehringer's Profit Up as Jardiance Gains Offset Higher Costs*, Reuters (Mar. 29, 2023, 8:01 AM), https://tinyurl.com/2p8m5b5d.

[26] Purvis, *supra* note 19, at 2, fig. 1; @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinyurl.com/3m64hu2x.

[27] *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, *supra* note 23, at 1 (costs rounded). These costs do not necessarily incorporate data regarding rebates or other confidential price adjustments that are not available to the public.

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.[32] 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.[33] During the coverage gap phase, plan reimbursements are often reduced with the switch from flat co-payments to 25% co-insurance, which means patient contributions often increase.[34] Prior to the 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-pocket costs exceeding $3,200."[35] For context, the median annual income of Medicare beneficiaries was just below $30,000 and 12% of Americans over 65 have no savings or are in

---

[32] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5; 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).

[33] *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.

34

debt.[36] More than a third of older people have had medical debt recently.[37] Twenty-four percent of people over 65 with medical debt trace it to prescription drugs.[38]

The impact of an expensive prescription drug delivery system is most poignant when reviewing cost-related nonadherence (CRNA) to medications. 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.[45]

points.[50] 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.[51]

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.[52] Public health researchers have estimated that, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[53]

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.[54] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[55] Indeed, the

---

May 2023, at 3, https://tinyurl.com/4mccyu7x (estimating "20.2% [of older adults] reported any cost-related medication nonadherence").

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

[51] 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; *see also* Karthik W. Rohatgi et al., *Medication Adherence and Characteristics of Patients Who Spend Less on Basic Needs to Afford Medications*, J. Am. Bd. Fam. Med., June 2021, https://tinyurl.com/ybzbf9nf.

[52] Morgan & Lee, *supra* note 39, at 4.

[53] *Id.* at 1.

[54] *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).

[55] Goldman, Joyce, & Zheng, *supra* note 45, at 7.

initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[56] 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 an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[57]

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 Delaware: "Patients consistently resist trying to get us to change them from Lisinopril to Entresto despite what the data shows when it comes to readmissions and quality of life. It is the same issue with Jardiance. If we convince them, it often means they are giving up something else in their life given many are on a limited income."

- A doctor in Maryland: "I find it increasingly difficult to help patients maintain stable adherence to their medications for controlling diabetes because insurance companies frequently make changes in whether they will cover high-cost medications like Jardiance. Treatment is disrupted whenever an insurance company insists on changing the patient from one brand to another brand of that class of medication."

- A doctor in Florida: "I have patients who are stable on their oral anticoagulant like Xarelto or Eliquis and then they hit the doughnut hole [gap in coverage in Medicare] and have to stop their medications. 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

[56] 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.

[57] *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost,*

> afford gas to the appointment, he had reduced how often he took his medication so it would last longer."

---

The drug price negotiation program in the Inflation Reduction Act is a measured attempt to bolster public health and to ensure care for all of us as we age by permitting the federal government, which foots the bill for 45% of nationwide spending on retail prescription drugs, to negotiate prices for the drugs it will pay for.[58] Allowing Medicare to negotiate the price of drugs in the Part D program has 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.[59] Indeed, the federal government negotiates rates in several other areas of Medicare. The benefit of drug price

---

[58] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9; Erin Trish, Jianhui Xu, & Geoffrey Joyce, *Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase*, 35 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").

[59] 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.

negotiation to the public will be substantial: KFF has estimated that many older Americans would save over 60% of their out-of-pocket costs under the new standards set by the IRA.[60] Plaintiff's dramatic characterization of drug price negotiation as "price controls," Pl.'s Mot. for Summ. J., ECF No. 28-1 at 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 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.[61] In 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.[62]

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

---

[60] 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.

[61] 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.

[62] *Id*. at 7.

drug prices independent of government authority.[67] Studies show that drug prices in the US are between 2 and 2.5 times more expensive than in other comparable countries.[68] Medicare's inability to negotiate drug prices, as compared to the ability of other large public health systems, is a key reason for higher US drug prices.[69]

---

Plaintiff 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.[70] The Brookings Institute has similarly found that the Program is unlikely to substantially change the future development of medications, based on

[67] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*

drug manufacturers' public market activity.[71] This is unsurprising, in part, because the Program

contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[75] 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 tar

60% of research and development spending is post-approval research into additional indications for approved drugs, rather than into new drugs.[79]

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.[80] Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[81] 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.

*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 governments 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.[82] 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

[79] ATI Advisory, *supra* note 22. 0.006 Tc -0.0032f. (e)-6 Dy, lug d.5/TT1 1 Tf-00 (p)-10ities. 4-2 1032 (i) (d. .0r)-2 1032 (i) (d. .0r)g

private companies, generating enormous revenues for drug companies.[83] 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.[84] From 2010 through 2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[85]

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.[86] 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

research was sponsored by the NIH.[88]

Pls.' Mot. for Prelim. Inj., ECF No. 54, *Dayton Area Chamber of Com. v. Becerra*, No. 23-cv-00156 (S.D. Ohio, argued Sept. 15, 2023). *Amici* wish to make it clear that they do support this Program and do not support the manufacturers' efforts to gut drug price negotiation.

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

Dated: December 22, 2023

Respectfully submitted,

*/s/ Michael W. Brown*

Michael W. Brown (CT30820)

Ananda V. Burra*
Ben Seel*
Robin Thurston*
P.O. Box 34553
Washington, DC
(202) 448-9090
aburra@democracyforward.org
bseel@democracyforward.org
rthurston@democracyforward.org

* *pro hac vice* forthcoming

I hereby certify that this brief complies with the type-volume limitation set forth in the Court's local rules and court procedures because it does not exceed the page requirements mandated by local rules.

Dated: December 22, 2023

/s/ Michael W. Brown

Koch, Garg & Brown, LLP
8 W. Main St., Suite 2-10
Niantic, CT 06357
Office: (860) 452-6860
mike@kgb-law.com