IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	)	Case No. 23-931-CFC

MOTION OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Movants Stuart Altman, PhD; Robert A. Berenson, MD; Donald Berwick, MD; David Blumenthal, MD; Francis J. Crosson, MD; Paul Ginsburg, PhD; Marilyn Moon, PhD; Robert D. Reischauer, PhD; and Bruce Vladeck, PhD respectfully move the Court for leave to file a brief as *amici curiae* in support of Defendants. Defendants consent to the filing of this *amicus* brief. Plaintiffs AstraZeneca

Pharmaceuticals LLP and AstraZeneca AB take no position on the filing of this *amicus* brief.

I. INTEREST OF MOVANTS

Movants are nationally recognized experts in healthcare, healthcare finance, and Medicare, who have led federal agencies and non-profit organizations dedicated to the effective administration of the Centers for Medicare & Medicaid Services (CMS). As experts in healthcare, movants place a high value on the financial stability of the Medicare program, and on the federal government's ability to manage costs for healthcare services provided to beneficiaries.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF THIS APPEAL.

As experts in healthcare, healthcare finance, and Medicare, movants have valuable insight to inform the Court's consideration of Plaintiffs' Motion for Summary Judgment and Defendants' Cross-Motion for Summary Judgment. Movants are uniquely positioned to explain: that ensuring prescription drug price affordability is essential to the financial stability of the Medicare program; that the authority conferred on CMS by the DPNP to negotiate drug prices for the Medicare program is consistent with the authority that Congress has given CMS to limit excessive prices of other Medicare services; that this authority is also consistent with that given to other agencies to limit drug prices in other federal government programs; that there is no legal support for AstraZeneca's argument that the DPNP

violates the Fifth Amendment's Due Process Clause; and, finally, that courts regularly apply provisions precluding judicial review of features of the Medicare program similar to the provision in the DPNP.

III. CONCLUSION

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Defendants and accept for filing the *amicus curiae* brief submitted contemporaneously with this motion. A proposed order is submitted with this motion.

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Dated: November 8, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	)	Case No. 23-931-CFC

[PROPOSED] ORDER GRANTING MOTION OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on the Motion of Nationally Recognized Healthcare and Medicare Experts for Leave to File Brief as *Amici Curiae* in Support of Defendants' Motion for Summary Judgment and in Opposition to Plaintiffs'

Motion for Summary Judgment. For good cause shown, the Motion is **GRANTED**.

The attached proposed *amicus* brief shall be docketed.

Judge Colm F. Connolly
UNITED STATES DISTRICT JUDGE

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	)	Case No. 23-931-CFC

BRIEF OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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Dated: November 8, 2023

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INTEREST OF *AMICI CURIAE*

The following *Amici* are nine nationally recognized experts in healthcare, healthcare finance, and Medicare, who place a high value on the financial stability of the Medicare program which is administered by the U.S. Department of Health and Human Services. As experts in healthcare and Medicare, *Amici* are qualified to explain how the recently enacted Drug Price Negotiation Program is consistent with the Government's well-established power to leverage its purchasing authority to constrain excessive fees charged to federal healthcare programs.

- **Stuart Altman, PhD** is the former Chairman of the Prospective Payment Assessment Commission (now the Congressional Medicare Payment Advisory Commission or MedPAC). Mr. Altman also served as Deputy Assistant Secretary for Planning and Evaluation/Health at the U.S. Department of Health Education and Welfare and as a member of the National Bipartisan Commission on the Future of Medicare.
- **Robert A. Berenson, MD** is the former Director of Health Plans and Providers, Health Care Financing Administration (the predecessor to Centers for Medicare & Medicaid Services). Dr. Berenson also served as Vice Chair of MedPAC.
- **Donald Berwick, MD** is a former Administrator of the Centers for Medicare & Medicaid Services. Dr. Berwick also served as the President and Chief Executive Officer of the Institute for Healthcare Improvement, a non-profit organization.
- **David Blumenthal, MD** is the former National Coordinator for Health Information Technology. Dr. Blumenthal is also the former President of the Commonwealth Fund.

- **Francis J. Crosson, MD** is the former Chairman of MedPAC. Dr. Crosson also served on the National Advisory Committee of the Agency for Healthcare Research and Quality.

- **Paul Ginsburg, PhD** is the former Executive Director at the Physician Payment Review Commission (the predecessor to MedPAC). Dr. Ginsburg also served as Vice Chair of MedPAC and Deputy Assistant Director of the Congressional Budget Office.

- **Marilyn Moon, PhD** is the former Public Trustee for the Social Security and Medicare Trust Funds. Dr. Moon also served as Chair of the Maryland Health Care Commission.

- **Robert D. Reischauer, PhD** is the President Emeritus of the Urban Institute. Mr. Reischauer also served as Director of the Congressional Budget Office, Public Trustee of the Social Security and Medicare Trust Funds, and Vice Chair of MedPAC.

- **Bruce Vladeck, PhD**. is the former Administrator of the Health Care Financing Administration (the predecessor to Centers for Medicare & Medicaid Services). Dr. Vladeck also served on the National Bipartisan Commission on the Future of Medicare.

INTRODUCTION

In 2022, the Centers for Medicare & Medicaid Services (CMS) paid $973 billion to provide healthcare services to the elderly and disabled through the federal Medicare program. Maintaining a program of this size is possible only because Congress has authorized CMS to manage costs. Over the past 50 years, federal legislation has empowered CMS to pay hospitals, physicians, and other providers much less for their services than they receive from commercial insurance and other private payors. In fact, prescription drugs are the only major component of Medicare that has not been subject to meaningful cost controls. Now, to address astronomical—and quickly growing—drug costs, Congress has enacted the Drug Price Negotiation Program (DPNP) to give the Department of Health and Human Services (HHS) limited authority to negotiate the prices Medicare pays for some of the highest-spending, covered drugs. With respect to these select few prescription drugs, the DPNP finally puts some drug manufacturers in a position similar to that of other Medicare-participating providers and physicians.

In challenging the DPNP, AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, AstraZeneca) join the drug industry's frontal attack on the Government's ability to run the Medicare program through nine lawsuits filed in six federal courts. In these cases, the drug industry challenges the Government's limitation of the prices that the Medicare program pays for prescription drugs, even

though the Government's authority to control costs paid by Medicare is long-standing and fundamental to the program. The *Amici*, nationally recognized experts in healthcare, healthcare finance, and Medicare, submit this brief to explain: that ensuring prescription drug price affordability is essential to the financial stability of the Medicare program; that the authority conferred on CMS by the DPNP to negotiate drug prices for the Medicare program is consistent with the authority that Congress has given CMS to limit excessive prices of other Medicare services; that this authority is also consistent with that given to other agencies to limit drug prices in other federal government programs; that no court has ever found that an entity's voluntary participation in Medicare creates a property interest, which would be necessary for AstraZeneca to prevail in arguing that the DPNP violates the Fifth Amendment's Due Process Clause; and, finally, that courts regularly apply provisions precluding judicial review of features of the Medicare program similar to the provision in the DPNP.

BACKGROUND

A. The Medicare Program

As the largest single purchaser of healthcare in the United States, the Medicare program pays one in every five healthcare dollars spent.[1] Today, more than 65

[1] *See* Meena Seshamani, Elizabeth Fowler, & Chiquita Brooks-LaSure, *Building on the CMS Strategic Vision: Working Together for a Stronger Medicare*,

million elderly or disabled Americans rely on Medicare for government-funded health insurance, which covers both healthcare services and prescription drugs for eligible beneficiaries.[2] *See generally* 42 U.S.C. § 1395 *et seq.* Traditional Medicare contains two parts: Part A covers services provided by hospitals and other institutional care providers, while Part B pays for outpatient services, including outpatient hospital services, physician visits, diagnostic tests and lab services, and drugs administered by physicians. Part B covers a relatively small number of drugs (617 in 2021), which are typically administered through infusion or injection.[3] Under Part B, Medicare enrollees are often saddled with significant drug costs. Once beneficiaries reach their deductible ($226 in 2023), they pay 20% coinsurance on Part B drugs.[4]

CMS (Jan. 11, 2022), https://www.cms.gov/blog/building-cms-strategic-vision-working-together-stronger-medicare#:~:text=As%20the%20largest%20single%20purchaser,force%20in%20the%20United%20States.

[2] *See Medicare Monthly Enrollment*, CMS (May 2023), https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.

[3] *Drug Coverage Under Different Parts of Medicare* at 1, CMS (Mar. 2023), https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf; *see Medicare Part B Spending by Drug*, CMS (last modified Mar. 6, 2023), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.

[4] This copay will decrease under a provision of the Inflation Reduction Act which limits beneficiaries' coinsurance responsibility when a drug's price increases have outpaced inflation. Although many of Medicare's enrollees purchase

CMS contracts with insurance plans to offer Medicare participants Part A and B benefits under Part C.[5] Under Part C, Medicare beneficiaries can obtain benefits covered under Part A and Part B, plus additional benefits, typically including the Part D prescription drug benefit. Medicare payments to Part C plans are based on a percent of average per capita spending in traditional Medicare (which ranges from 95% to 115%).[6]

In 2003, Congress established Medicare Part D, a prescription drug benefit available to all Medicare recipients. Under Part D, Medicare subsidizes the cost of drugs administered outside of hospitals and outpatient facilities. 42 U.S.C. § 1395w-101 *et seq.* In Part D, Congress barred the federal government from participating in price negotiations between drug manufacturers or pharmacies and prescription drug plan sponsors through the "noninterference" clause. 42 U.S.C. § 1395w-111(i). In

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supplemental insurance to defray the costs of coinsurance or are covered by Medicaid or retiree plans, nearly five million individuals are left to cover these costs on their own. *See* Gabrielle Clerveau, Nancy Ochieng, *et al.*, *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, Kaiser Fam. Found. (Aug. 14, 2023), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/.

[5] *See Health Plans – General Information*, CMS (May 9, 2023), https://www.cms.gov/medicare/health-plans/healthplansgeninfo#:~:text=The%20Balanced%20Budget%20Act%20of,)%20program%2C%20effective%20January%201999.

[6] *See Medicare Advantage Program Payment System*, Medicare Payment Advisory Comm'n (revised Oct. 2021), https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_ma_final_sec.pdf.

the years since the passage of Part D, however, it has become increasingly evident that although competition within the market for prescription drugs has largely succeeded at moderating the growth of costs for prescription drugs that face competition from generics or medications treating the same condition, market forces cannot curb prescription drug prices in the absence of competition.[7] This left Medicare with no leverage over excessive drug prices, which must be borne by Medicare's beneficiaries and taxpayers.

Under Part D, beneficiaries' financial responsibility for drugs depends on how much they spend on prescription drugs in a given plan year, and some beneficiaries spend thousands of dollars out-of-pocket before they hit the catastrophic coverage phase in which copays and coinsurance for drugs are significantly reduced. In 2019, beneficiaries paid more than $16.1 billion out-of-pocket for Part D drugs, an increase of 27% over the previous five years.[8] Unsurprisingly, in the same year, 23% of seniors reported difficulty affording their prescription drugs.[9] Beginning in 2025,

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[7] *Prescription Drugs: Spending, Use, and Prices* at 16, Cong. Budget Off. (Jan. 2022), https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.

[8] *Frequently Asked Questions About Prescription Drug Pricing and Policy* at 8–9, Cong. Rsch. Serv. (updated May 6, 2021), https://crsreports.congress.gov/product/pdf/R/R44832/7.

[9] *See* Ashley Kirzinger *et al.*, *KFF Health Tracking Poll—February 2019: Prescription Drugs*, Kaiser Fam. Found. (Mar. 1, 2019), https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.

out-of-pocket spending by beneficiaries for Part D will be capped at $2,000 per year under the Inflation Reduction Act (IRA).[10]

Skyrocketing drug costs have also plagued the program. In 2022, Medicare spent $118 billion on Part D drugs—an increase of $36 billion from 2018.[11] These increases are largely driven by brand-name, single-source drugs without generic competition, the average net price of which more than doubled from 2009 to 2018.[12] By 2019, these drugs "accounted for almost three quarters (72 percent) of total Part D spending." H.R. Rep. No. 116-324, pt. 1 at 38 (2019). Moreover, Medicare's spending on prescription drugs is not expected to slow down. During the next decade, CMS projects that Medicare will spend between 4% and 12% more on prescription drugs (not including drugs administered in hospitals or physician's offices) each year.[13]

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[10] Bisma A. Sayed, Kenneth Finegold, *et al.*, *Inflation Reduction Act Research Series: Medicare Part D Enrollee Out-of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act*, Assistant Sec. for Planning & Evaluation (July 7, 2023), https://aspe.hhs.gov/sites/default/files/documents/93a68f3c5ca949dcf331aa0ec24dd046/aspe-part-d-oop.pdf.

[11] *Compare Baseline Projections: Medicare*, Cong. Budget Off. (May 2023), https://www.cbo.gov/system/files/2023-05/51302-2023-05-medicare.pdf, *with Baseline Projections: Medicare*, Cong. Budget Off. (May 2019), https://www.cbo.gov/system/files?file=2019-05/51302-2019-05-medicare.pdf.

[12] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 7, 16.

[13] *NHE Fact Sheet*, CMS (last modified July 31, 2023), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-

B. The Drug Price Negotiation Program

Through the creation of the DPNP, Congress has begun the process of stemming the high costs and rapidly increasing prices of drugs for Medicare and its beneficiaries by allowing the Secretary of HHS to negotiate prices of a select number of the highest-spending drugs in Part D, and later, Part B. *See* Inflation Reduction Act, Pub. L. 117-169, 42 U.S.C. § 1320f *et seq.* On August 29, 2023, HHS selected 10 of the highest-spending, single-source, brand-name drugs that have been on the market for at least seven years (or 11 years for biologics).[14] *See* §§ 1320f-1(b)–(d). From October 1, 2023 until August 1, 2024, CMS and manufacturers of the selected drugs that choose to participate will negotiate a price for each drug. *Id.* § 1320f(b)–(d). If CMS and the manufacturer agree on a price during this period, the drug will become available to Part D at that price in 2026. 42 U.S.C.§ 1320f-1(c)(2).

As outlined in more detail in the Government's brief, Mem. of Law in Support of Defs. Opp'n to Pls. Mot. Summ. J. and Cross-Mot. ("Defs. Cross-Mot.") at 8, ECF No. 21-1, drug manufacturers that do not wish to participate in negotiations or enter an agreement may transfer their interest in the selected drug to another entity;

Reports/NationalHealthExpendData/NHE-Fact-Sheet#:~:text=NHE%20grew%202.7%25%20to%20%244.3,17%.

[14] *See HHS Selects the First Drugs for Medicare Price Negotiation*, HHS (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

withdraw from Medicare Parts B and D and Medicaid (which is similar to the only option currently available to many providers who choose not to accept Medicare rates); or pay an excise tax.[15]

The DPNP is tailored to address the issues with Part D's original, fragmented model of price negotiations, where the program is administered by regional plan sponsors that separately negotiate with individual drug companies. CMS is only empowered to select a drug for negotiation where that drug has had an unchallenged market position for at least seven years and is one of the highest spending drugs paid for by taxpayers and beneficiaries. For these drugs, Congress has designed a cautious negotiation process, which starts off with a small set of covered drugs under Part D and increases slowly to include some covered drugs under Part B. The Congressional Budget Office projects that the DPNP will save nearly $100 billion in Medicare spending from 2026 to 2031—a significant savings, but a small percentage of what the program will spend on prescription drugs during that time.[16]

ARGUMENT

The DPNP is consistent with the federal government's well-established ability

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[15] For the reasons set forth in the Government's brief, *see* Defs. Cross-Mot. at 11–12, 46–47, AstraZeneca is incorrect that drug manufacturers will not be permitted to withdraw from the Medicare program at will.

[16] *See Cost Estimate*, Cong. Budget Off. (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

to regulate the prices that the Medicare program pays for services by physicians, hospitals, and other providers. Congress has also extended this cost-controlling authority to Medicaid, the Department of Veterans Affairs (VA), the Coast Guard, the Department of Defense (DoD), and the Vaccines for Children Program, which are all entitled to significant discounts or rebates from drug companies when they purchase prescription drugs. Likewise, in the 340B Drug Program, Congress has required substantial discounts for drugs used by certain providers serving low-income populations. Congress has also limited prices for Part D drugs in certain circumstances through the Affordable Care Act (ACA). AstraZeneca does not and cannot distinguish these long-standing statutory authorities to establish prices from HHS's ability to likewise negotiate prescription drug prices paid by Medicare through the DPNP.

There is no support for AstraZeneca's argument that the DPNP violates its Fifth Amendment procedural due process rights. To the contrary, to our knowledge, every court to consider the issue has held that the decision to participate in Medicare is voluntary, and such participation does not create a constitutional property interest. Lastly, the DPNP's provision precluding judicial review is consistent with Congress's long-recognized authority to shield the Medicare program from judicial

review.[17]

A. Congress Has Provided HHS Broad Authority to Regulate the Prices Medicare Will Pay for Healthcare Services Other than Drugs.

Initially, there were limited cost controls in Medicare. Under both Part A and Part B, healthcare providers were entitled to "reasonable costs" for hospital and institutional services or "usual, customary and reasonable charges" for physicians and other medical services.[18] But it soon became clear that without additional regulatory limits, Medicare's original "reasonable cost" system was unsustainable.[19] To protect taxpayers from having to pay excessive rates for Medicare services, Congress has amended these payment structures numerous times over the past 50 years, giving HHS increasing authority to curb costs. Thus, in 1972, six years after the Government first began paying Medicare providers, Congress limited reasonable costs and charges to the Medical Economic Index, which tracks the physician's cost of doing business (as opposed to what the physician charges patients).[20]

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[17] For the reasons set forth in the Government's Cross-Motion, AstraZeneca's argument that the DPNP violates the Administrative Procedure Act also fails. *See* Defs. Cross-Mot. at 14–44.

[18] *Medicare Primer* at 3, Cong. Rsch. Serv. (May 21, 2020), https://crsreports.congress.gov/product/pdf/R/R40425/55.

[19] *Id.*

[20] *See* Benson L. Dutton, Jr. & Peter McMenamin, *The Medicare Economic Index: Its Background and Beginnings*, Health Care Finance Rev. (Sept. 1981).

In subsequent years, Congress began setting rates for reimbursement by adopting prospective payment systems for hospitals and fee schedules for physicians and other providers, which are updated annually and establish the payment rates for the following year.[21] In 1983, the Government began using the inpatient prospective payment system (IPPS) to set reimbursement rates for hospitals treating Medicare beneficiaries in acute inpatient settings, based on diagnosis-related groups (DRGs).[22] Under this methodology, the Medicare program establishes a fee schedule for the following year adjusted annually for inflation that pays hospitals a base payment amount (based on data from hospitals in the program), which includes payments for operating costs and capital expenses, subject to adjustments for geographic location and other factors.[23]

Similarly, for services provided in hospital outpatient departments under Part B, in 2000 CMS implemented the outpatient prospective payment system (OPPS) annually to set reimbursement rates for the subsequent year.[24] Using a coding

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[21] Critical access hospitals (CAHs) represent a small statutory exception. *See Critical Access Hospitals Payment System*, Medicare Payment Advisory Comm'n (Oct. 2022), https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_ CAH_FINAL_SEC.pdf.

[22] *See Medicare Hospital Payments: Adjusting for Variation in Geographic Area Wages*, Cong. Rsch. Serv. (Mar. 3, 2021), https://crsreports.congress.gov/product/pdf/R/R46702.

[23] *Id.*

[24] *See Outpatient Hospital Services Payment System*, Medicare Payment Advisory Comm'n (Oct. 2022), https://www.medpac.gov/wp-

system that classifies services based on their clinical attributes and cost, the OPPS sets payment rates by multiplying the average cost of services in the relevant classification by a wage-adjusted conversion factor.[25]

Today, Medicare also regulates the prices it pays physicians under Part B pursuant to the Medicare fee schedule (MFS).[26] Relying on the same coding system used by the OPPS, the MFS generally sets payment rates by service—including everything from discrete services like injections to bundles of services for more complex procedures like surgeries.[27] The MFS provides for far lower prices than what commercial insurers pay, with commercial insurers paying an average of 129% of MFS prices for physician services.[28] Medicare also regulates prices for services administered to beneficiaries of private plans under Part C, where plans are paid based on bids under a formula-based payment system, using benchmarks tied to the

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content/uploads/2022/10/MedPAC_Payment_Basics_22_OPD_FINAL_SEC_v3.pdf.

[25] *Id.*

[26] *See* Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), Pub. L. 101-239.

[27] *See Physician and Other Health Professional Payment System*, Medicare Payment Advisory Comm'n (Oct. 2022), https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.

[28] Michael Cohen, Jared Maeda, & Daria Pelech, *The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services*, Cong. Budget Off. (Jan. 2022), https://www.cbo.gov/publication/57778.

average spending under traditional Medicare per beneficiary under Parts A and B.[29] In addition to all these programs, throughout Medicare's history, Congress has repeatedly imposed additional limits on increases to hospital and physician payment rates.[30]

None of these payment systems is subject to negotiation. To the contrary, providers other than physicians who do not agree to these terms must totally opt out of the Medicare program. Physicians who do not contract with Medicare must accept a lower payment from the program.[31]

B. Congress Has Empowered Federal Healthcare Programs Other than Medicare to Regulate Drug Prices.

For more than 30 years, Congress has attempted to address the rapidly rising costs of drugs for patients and federal healthcare programs by placing significant restrictions on drug prices paid by Medicaid; all direct federal purchasers of drugs; federal healthcare programs administered by the VA, the DoD, the Coast Guard, and the Public Health Service (PHS); and the Vaccines for Children (VFC) program administered by HHS. Through section 340B of the Public Health Service Act,

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29 *See Medicare Advantage Program Payment System*, *supra* note 6.

30 *See, e.g.*, Balanced Budget Act of 1997, Pub. L. No. 105-33 (1997); Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (2010).

31 *See* Nancy Ochieng & Gabrielle Clerveau, *How Many Physicians Have Opted Out of the Medicare Program?*, Kaiser Fam. Found. (Sept. 11, 2023), https://www.kff.org/medicare/issue-brief/how-many-physicians-have-opted-out-of-the-medicare-program/.

Congress has restricted prices for certain drugs used by nonprofit hospitals and federally funded health centers. In recent years, Congress has also imposed some modest regulation of prescription drug prices in Part D.

1. *Medicaid*

In response to rising drug prices and projected increased Medicaid spending, Congress enacted the Medicaid Prescription Drug Rebate Program (MDRP), requiring drug companies participating in the Medicaid program to enter into rebate agreements with HHS to refund specified portions of Medicaid payments to the States. 42 U.S.C. § 1396r-8. In exchange, Medicaid will cover nearly all the manufacturer's FDA-approved drugs. *Id.* Though the pharmacy benefit is optional, all States cover prescription drugs,[32] and approximately 780 drug manufacturers participate in the MDRP.[33]

For brand-name drugs, the rebate is 23.1% of Average Manufacturer Price (AMP) or the difference between AMP and "best price," whichever is greater. 42 U.S.C. § 1396r-8(c). Best price is defined as the lowest available price to any

[32] *Prescription Drugs*, CMS, https://www.medicaid.gov/medicaid/prescription-drugs/index.html#:~:text=Although%20pharmacy%20coverage%20is%20an,within%20their%20state%20Medicaid%20programs.

[33] *See Medicaid Drug Rebate Program*, CMS, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html#:~:text=Approximately%20780%20drug%20manufacturers%20currently,of%20the%20Social%20Security%20Act.

wholesaler, retailer, or provider, excluding certain government programs, such as the health program for veterans. *Id.* § 1396r-8(c)(1)(C). AMP is defined as the average price paid to drug manufacturers by wholesalers and retail pharmacies. *Id.* § 1396r-8(k)(1)(A). For generic drugs, the rebate amount is 13% of AMP, and there is no "best price" provision. There is also an inflationary penalty if the drug's price rises faster than the rate of inflation. *Id.* § 1396r-8(c)(2).

2. *Direct Federal Purchasers*

The Federal Supply Schedule (FSS) establishes prices available to all direct federal purchasers, including the VA, DoD, PHS, and the Coast Guard. 38 U.S.C. § 8126(a)–(b). The FSS is intended to allow direct federal purchasers to buy brand-name drugs at prices equal to or below the lowest prices negotiated between manufacturers and their most-favored commercial customers, defined as the customers that receive the best discount or price agreement.[34] If a drug company fails to comply with this provision, it may not receive payments from Medicaid, DoD, PHS, the Coast Guard, or any entity that receives funding under the Public Health Service Act. 38 U.S.C. § 8126(a).

[34] *See A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* at 10–13, Cong. Budget Off. (Feb. 2021), https://www.cbo.gov/publication/57007.

3. *VA, DoD, PHS, and the Coast Guard*

The 1992 Veterans Health Care Act created an additional mechanism for lowering drug prices for the four largest federal purchasers: the VA, DoD, PHS, and the Coast Guard (collectively referred to as the "Big Four").[35] 38 U.S.C. § 8126(b). The federal ceiling price (FCP) established by the 1992 Act is 76% of the non-FAMP or the average sales price to purchasers outside the federal government, with an adjustment if the non-FAMP grew more quickly than the rate of inflation during the previous one-year period.[36]

The combination of the FSS, this discount, and the fact that the VA is a single, integrated health system with a unified list of covered drugs strengthens the VA's bargaining position to negotiate drug prices. As a result, the VA generally receives the lowest drug prices of any federal program—paying around 55% of the average net price paid by Medicare Part D.[37]

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[35] The prices available to the Big Four for brand-name drugs are the lower of the FFS price and the cap set by this law. *See Prices for Brand Name Drugs Under Selected Federal Programs* at 8, Cong. Budget Off. (June 2005), https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-16-prescriptdrug.pdf.

[36] *Id.*

[37] *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, *supra* note 37).

4. *Vaccines for Children (VFC) Program*

In 1993, Congress created the VFC Program to expand access to childhood vaccines by providing free vaccines to children who are eligible for Medicaid, uninsured, underinsured, or are American Indian or Native Alaskan.[38] The VFC Program authorizes HHS to negotiate the price of vaccines and purchase doses directly from manufacturers at discounted prices.[39]

5. *340B*

In 1992, Congress created the 340B Program under section 340B of the Public Health Service Act to provide certain nonprofit hospitals and federally funded clinics servicing low-income patients (under the statute, "covered entities") with outpatient drug discounts comparable to those available to state Medicaid agencies. As a condition of having their outpatient drugs covered through Medicaid and Medicare Part B, drug manufacturers are required to offer 340B hospitals and clinics outpatient

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[38] *Vaccines for Children Program (VFC): VFC Childhood Vaccine Supply Policy*, Ctrs. for Disease Control & Prevention (last reviewed Feb. 18, 2016), https://www.cdc.gov/vaccines/programs/vfc/about/distribution.html; *Vaccines for Children Program (VFC): About VFC*, Ctrs. for Disease Control & Prevention (last reviewed Aug. 18, 2023), https://www.cdc.gov/vaccines/programs/vfc/about/index.html..

[39] *See Vaccines for Children Program (VFC): VFC Childhood Vaccine Supply Policy*, *supra* note 41.

drugs at or below a discount of 23.1% for brand drugs and 13% for generic drugs. 42 U.S.C. § 256b(a)(1).

6. *Medicare*

Through the ACA in 2010, Congress also created mandatory discounts for brand-name drugs in certain circumstances under Part D where beneficiaries are responsible for paying a portion of their drug's cost. *See* 42 U.S.C. § 1395w-114a. This requirement will be replaced in 2025 with another mandatory discount of 20% that will apply after a beneficiary hits the annual out-of-pocket $2,000 threshold, per a provision of the IRA not challenged by AstraZeneca in this litigation. *See id.* § 1395w-114c(g)(4)(ii).

C. AstraZeneca's Voluntary Participation in the Medicare Program Does Not Create a Property Interest Under the Fifth Amendment.

As the Government has explained, *see* Defs. Cross-Mot. at 44–48, AstraZeneca's Due Process Clause argument has no support in existing case law. Just last month, the Southern District of Ohio rejected an analogous due process claim in denying a motion for a preliminary injunction against the DPNP. *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d. ---, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (*Chamber*). Following consistent decisions of numerous other courts, the *Chamber* court held that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice,"

and does not create a property interest under the Due Process Clause. *Id.* at *11.

Significantly, in challenges brought against federal healthcare programs under the Fifth Amendment's Takings Clause, courts have consistently held that participation in Medicare is voluntary. *See Baker Cnty. Med. Servs. Inc. v. U.S. Atty. Gen.*, 763 U.S. F.3d 1274, 1276 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt v. U.S. Dep't of Health & Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963 (11th Cir. 1986); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983). Because "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases," the court in *Chamber* declined the plaintiffs' comparison between the DPNP and the imposition of conditions on public utility companies, which are required to serve the public. *See Chamber*, 2023 WL 6378423, at *11 (internal citations omitted); Defs. Cross-Mot. at 45–48. Instead, the court found that, "[a]s there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation." *Id.* (citing *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991)).

AstraZeneca voluntarily participates in Medicare, so the consequences of its participation cannot be the basis for finding a constitutional violation. According to

the courts that have evaluated this issue, it does not matter if a significant portion of AstraZeneca's business is selling drugs to Medicare because it does so voluntarily. AstraZeneca's voluntary participation in the Medicare program is not a basis for a valid constitutional claim, even if its withdrawal from Medicare would cause significant financial loss.

D. Where Congress Has Barred Judicial Review of Agency Action, Courts Have Evaluated Only Whether the Challenged Action Falls Within the Scope of the Preclusion Provision.

AstraZeneca is also incorrect in suggesting that the DPNP's provision precluding judicial review somehow infringes on its due process rights. *See* AstraZeneca Mot. Summ. J. at 31–32. As in other parts of the Medicare program, the DPNP establishes standards for CMS action while requiring the agency to engage with a wide range of stakeholders, including the pharmaceutical industry, to inform agency decision-making. As the Government described in its Cross-Motion, *see* Defs. Cross-Mot. at 21–26, the Supreme Court has repeatedly held that Congress has sole authority to determine the subject-matter jurisdiction of the lower federal courts. Further, where Congress bars judicial review of an agency action, the courts' only role is to determine "whether the challenged action falls 'within the preclusive scope' of the statute." *Id.* (quoting *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505–06 (D.C. Cir. 2019)).

In enacting the DPNP, Congress followed its common practice of precluding

administrative and judicial review of many administrative decisions made in implementing the Medicare program, and the phrase "no administrative or judicial review" appears more than 60 times in the Medicare statute. 21 U.S.C. § 1395. Administrative and judicial review prohibition appears ten times each in 42 U.S.C. § 1395w-4, Medicare's physician payment provision, and in 42 U.S.C. § 1395ww, a provision related to payments to hospitals for inpatient services. A half century ago, Medicare's first prospective payment system precluded judicial review, *see* Pub. L. 98-21, 96 Stat. 144, 601, and a judicial review prohibition has been added to new payment programs since. When agency actions within the scope of these provisions have been challenged, the courts have consistently upheld Congress's decision to preclude judicial review. *See Yale New Haven Hosp. v. Becerra*, 56 F.4th 9 (2d Cir. 2022); *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503 (D.C. Cir. 2019); *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125 (D.C. Cir 2017); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527 (5th Cir 2012).

In applying preclusion provisions, the courts recognize that tremendously complex Medicare payment programs cannot function if they are continually burdened by litigation at every step of implementation. Similarly, here the need to implement drug price negotiation in a timely fashion, focusing on drugs where the highest cost savings are possible, justifies preclusion of judicial review.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' Memorandum of Law in Support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion, this Court should grant Defendants' Cross-Motion and deny Plaintiff's Motion for Summary Judgment.

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Dated: November 8, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	)	Case No. 23-931-CFC

CERTIFICATE OF COMPLIANCE WITH TYPEFACE
REQUIREMENT AND TYPE-VOLUME LIMITATION

1. The Motion of Nationally Recognized Healthcare and Medicare Experts for Leave to File Brief as *Amici Curiae* in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion For Summary Judgment complies with the typeface requirement of the Standing Order Regarding Briefing in All Cases, dated November 10, 2022 (the "Standing Order") because all text, including footnotes, is in Times New Roman 14-point typeface.

2. The Motion of Nationally Recognized Healthcare and Medicare Experts for Leave to File Brief as *Amici Curiae* in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion For Summary Judgment complies with the word type-volume limitation of the Standing Order because the document contains 355 words.

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