No. 25-50661

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services, In his Official Capacity; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, Administrator of the Centers for Medicare and Medicaid Services, In his Official Capacity; CENTERS FOR MEDICARE AND MEDICAID SERVICES,
Defendants-Appellees,

On Appeal from the United States District Court
for the Western District of Texas
Case No. 1:23-cv-707 (Hon. David Alan Ezra)

BRIEF OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

In addition to the persons and entities listed in the Plaintiffs-Appellants' Certificate of Interested Persons, undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae

Stuart Altman, PhD

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INTEREST OF *AMICI CURIAE*[1]

The following *Amici* are eight 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

[1] Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for *Amici* certify that: no party's counsel authored this *amicus* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief; and no person or entity, other than *Amici* or their counsel, contributed money intended to fund the preparation or submission of this *amicus* brief. Defendants-Appellees consent and Plaintiffs-Appellants do not object to the filing of this *amicus* brief in this litigation. This brief represents the views of the individual *Amici* and not necessarily of their organizations.

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.

- **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 2023, the Centers for Medicare & Medicaid Services (CMS) paid $1.03 trillion to provide healthcare services to the elderly and disabled through the federal Medicare program.[2] 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, Plaintiffs-Appellants join the drug industry's frontal attack on the Government's ability to run the Medicare program through 10 lawsuits filed in six federal courts. In these cases, the drug industry challenges the

[2] CMS, *NHE Fact Sheet* (last updated June 24, 2025), https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

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; and finally, that no court has ever found that an entity's voluntary participation in Medicare creates a property interest, which would be necessary for Plaintiffs to prevail in arguing that the DPNP violates the Fifth Amendment's Due Process Clause.

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.[3] Today, more than 65

[3] *See* Meena Seshamani, Elizabeth Fowler, & Chiquita Brooks-LaSure, *Building on the CMS Strategic Vision: Working Together for a Stronger Medicare*, CMS (Jan. 11, 2022), https://www.cms.gov/blog/building-cms-strategic-vision-working-together-stronger-

million elderly or disabled Americans rely on Medicare for government-funded health insurance, which covers both healthcare services and prescription drugs for eligible beneficiaries.[4] *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.[5] Under Part B, Medicare enrollees are often saddled with significant drug costs. Once beneficiaries reach their deductible ($257 in 2025), they pay 20% coinsurance on Part B drugs.[6]

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medicare#:~:text=As%20the%20largest%20single%20purchaser,force%20in%20the%20United%20States.

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

[5] *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 May 29, 2025), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.

[6] 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 supplemental insurance to defray the costs of coinsurance or are covered by Medicaid or retiree

CMS contracts with insurance plans to offer Medicare participants Part A and B benefits under Part C.[7] 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%).[8]

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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plans, three 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. (Sept. 23, 2024), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/.

[7] *See Health Plans – General Information*, CMS (Sept. 10, 2024), https://www.cms.gov/medicare/health-plans/healthplansgeninfo#:~:text=The%20Balanced%20Budget%20Act%20of,)%20program%2C%20effective%20January%201999.

[8] *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.[9] 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.[10] Unsurprisingly, in the same year, 23% of seniors reported difficulty affording their prescription drugs.[11] Beginning in 2025,

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[9] *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.

[10] *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.

[11] *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 is capped at $2,000 per year under the Inflation Reduction Act (IRA).[12]

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.[13] 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.[14] 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.[15]

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[12] 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.

[13] *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.

[14] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 9, 16.

[15] *NHE Fact Sheet*, CMS (last modified Sept. 10, 2024), 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).[16] *See* §§ 1320f-1(b)–(d). From October 1, 2023 through August 1, 2024, CMS and manufacturers of the selected drugs that chose to participate negotiated a price for each drug, *id.* § 1320f(b)–(d), and each 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 Defendants-Appellees' Brief at 9–10, 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; withdraw from Medicare Parts B and D and Medicaid (which is similar to the only option currently

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

[16] *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.

available to many providers who choose not to accept Medicare rates); or pay an excise tax.

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.[17]

ARGUMENT

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

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

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). Plaintiffs do 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 Plaintiffs-Appellants' argument that the DPNP violates their 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.[18]

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

[18] For the reasons set forth in Defendants-Appellees' Brief, Plaintiffs-Appellants' arguments that the DPNP violates the nondelegation doctrine and the Excessive Fines Clause also fail. *See* Defs.-Appellees' Br. at 18–41.

and other medical services.[19] But it soon became clear that without additional regulatory limits, Medicare's original "reasonable cost" system was unsustainable.[20] 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).[21]

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.[22] In 1983, the Government began using the inpatient prospective payment system (IPPS) to set reimbursement rates for hospitals treating Medicare

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

[20] *Id.*

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

[22] 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.

beneficiaries in acute inpatient settings, based on diagnosis-related groups (DRGs).[23] 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.[24]

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.[25] Using a coding 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.[26]

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[23] *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.

[24] *Id.*

[25] *See Outpatient Hospital Services Payment System*, Medicare Payment Advisory Comm'n (Oct. 2022), https://www.medpac.gov/wp-content/uploads/2022/10/MedPAC_Payment_Basics_22_OPD_FINAL_SEC_v3.pdf.

[26] *Id.*

Today, Medicare also regulates the prices it pays physicians under Part B pursuant to the Medicare fee schedule (MFS).[27] 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.[28] 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.[29] 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 average spending under traditional Medicare per beneficiary under Parts A and B.[30] In addition to all these programs, throughout Medicare's history, Congress has

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

[28] *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.

[29] 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.

[30] *See Medicare Advantage Program Payment System*, *supra* note 7.

repeatedly imposed additional limits on increases to hospital and physician payment rates.[31]

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.[32]

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, Congress has restricted prices for certain drugs used by nonprofit hospitals and

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[31] *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).

[32] *See* Nancy Ochieng & Gabrielle Clerveau, *How Many Physicians Have Opted Out of the Medicare Program?*, Kaiser Fam. Found. (Jan. 17, 2025), https://www.kff.org/medicare/issue-brief/how-many-physicians-have-opted-out-of-the-medicare-program/.

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,[33] and approximately 780 drug manufacturers participate in the MDRP.[34]

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 wholesaler, retailer, or provider, excluding certain government programs, such as

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

[34] *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 (last updated Nov. 8, 2024).

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.[35] 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).

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

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

the Coast Guard (collectively referred to as the "Big Four").[36] 38 U.S.C. § 8126(b). The federal ceiling price (FCP) established by the 1992 Act is 76% of the non-Federal Average Manufacturer Price ("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.[37]

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.[38]

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.[39] The VFC

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[36] 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* Cong. Budget Off., *Prices for Brand Name Drugs Under Selected Federal Programs* 8 (June 2005), https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-16-prescriptdrug.pdf.

[37] *Id.*

[38] *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, *supra* note 35).

[39] Ctrs. for Disease Control & Prevention, *Vaccines for Children Program (VFC): About VFC*, Ctrs. for Disease Control & Prevention (June 16, 2024),

Program authorizes HHS to negotiate the price of vaccines and purchase doses directly from manufacturers at discounted prices.[40]

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 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 this year with another mandatory discount of 20% that will apply after a beneficiary hits the annual out-of-pocket $2,000 threshold, per

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https://www.cdc.gov/vaccines-for-children/about/?CDC_AAref_Val=https://www.cdc.gov/vaccines/programs/vfc/about/index.html

[40] *Id.*

a provision of the IRA not challenged by Plaintiffs in this litigation. *See id.* § 1395w-114c(g)(4)(ii).

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

As the Government has explained, *see* Defs.' Br. at 41–50, Plaintiffs-Appellants' Due Process Clause argument has no support in existing case law. Other courts have consistently rejected analogous due process claims against the DPNP. *Boehringer Ingelheim Pharms, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 24-2092, --- F.4th ----, 2025 WL 2248727, at *8 (2d Cir. Aug. 7, 2025) ("Boehringer's claim fails because the Negotiation Program does not deprive it of any protected property interest. . . . A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program."); *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814-ZNQ-JBD, 2024 WL 3594413, at *6 (D.N.J. July 31, 2024) ("The Court can dispose of Plaintiffs' Due Process Clause claim quickly because the Due Process Clause is not implicated here."); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d. 440, 456 (S.D. Ohio 2023) (*Chamber*) ("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).

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 Burditt v. U.S. Dep't of Health & Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *AbbVie Inc. v. Fitch*, No. 24-60375, 2025 WL 2630900, at *16–20 (5th Cir. Sept. 12, 2025); *Novartis Pharms. Corp. v. Sec., U.S. Dep't of Health & Hum. Servs.*, No. 24-2968, --- F.4th ----, 2025 WL 2619133, at *7 (3d Cir. Sept. 11, 2025); *Bristol Myers Squibb Co. v. Sec., U.S. Dep't of Health & Hum. Servs.*, Nos. 24-1820, 24-1821, --- F.4th ----, 2025 WL 2537005, at *3–9 (3d Cir. Sept. 4, 2025); *Baker Cnty. Med. Servs. Inc. v. U.S. Atty. Gen.*, 763 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); *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); *PhRMA v. Murrill*, No. 6:23-cv-01042-RRS-CBW, 2024 WL 4361597, at *13–15 (W.D. La. Sept. 30, 2024). 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*, 696 F. Supp. 3d at 456 (internal citations omitted). 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.* at 457 (citing *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991)).

Drug manufacturers voluntarily participate in Medicare, so the consequences of their 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 the manufacturers' business is selling drugs to Medicare because they do so voluntarily. The drug companies' voluntary participation in the Medicare program is not a basis for a valid constitutional claim, even if their withdrawal from Medicare would cause significant financial loss.

CONCLUSION

For the foregoing reasons and those set forth in Defendants-Appellees' Brief, this Court should affirm the decision below.

Date: September 22, 2025

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I certify that on September 22, 2025, the foregoing Brief of Nationally Recognized Healthcare and Medicare Experts as *Amici Curiae* in Support of Defendants-Appellees was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,599 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

I further certify that (1) any required privacy redactions have been made, 5th Cir. R. 25.2.13; and (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1.

/s/ William B. Schultz
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United States Court of Appeals

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September 24, 2025

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No. 25-50661 Natl Infusion Center v. Kennedy
USDC No. 1:23-CV-707

Dear Mr. Schultz,

You must submit the 6 paper copies of your brief required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1.

Sincerely,

LYLE W. CAYCE, Clerk

Lisa E. Ferrara

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