No. 24-2968

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL.*,

Defendants-Appellees.

On appeal from the United States District Court
for the District of New Jersey
No. 3:23-cv-14221-ZNQ-JBD,
Judge Zahid N. Quraishi

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

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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 Executive Officer of the Institute for Healthcare Improvement, a non-profit organization.

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[1] No party's counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. The parties do not object to the filing of this brief.

- **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 2022, the Centers for Medicare & Medicaid Services (CMS) paid $944 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, Novartis Pharmaceuticals Corp. (Novartis) joins 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; and, finally, that the courts have uniformly rejected challenges to the federal authority to limit prices for drugs and services paid by federal healthcare programs.

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.[2] Today, more than 65 million elderly or disabled Americans rely on Medicare for government-funded

[2] *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-medicare#:~:text=As%20the%20largest%20single%20purchaser,force%20in%20the%20United%20States.

health insurance, which covers both healthcare services and prescription drugs for eligible beneficiaries.[3] *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.[4] 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.[5]

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

[4] *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 June 13, 2024), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.

[5] 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 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),

CMS contracts with insurance plans to offer Medicare participants Part A and B benefits under Part C.[6] 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%).[7]

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 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

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https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/.

[6] *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.

[7] *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.

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.[8] 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.[9] Unsurprisingly, in the same year, 23% of seniors reported difficulty affording their prescription drugs.[10] Beginning in 2025, out-of-pocket spending by beneficiaries for Part D will be capped at $2,000 per year under the Inflation Reduction Act (IRA).[11]

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[8] *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.

[9] *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.

[10] *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/.

[11] Bisma A. Sayed, Kenneth Finegold, *et al.*, *Inflation Reduction Act Research Series: Medicare Part D Enrollee Out-of-Pocket Spending: Recent Trends and*

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.[12] 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.[13] 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.[14]

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.

[12] *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.

[13] *Prescription Drugs: Spending, Use, and Prices*, *supra* note 8, 16.

[14] *NHE Fact Sheet*, CMS (last modified Sept. 10, 2024), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet#:~:text=NHE%20grew%202.7%25%20to%20%244.3,17%.

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).[15] *See* §§ 1320f-1(b)–(d). From October 1, 2023 until 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 Appellees' Brief at 10–11, 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 available to many providers who choose not to accept Medicare rates); or pay an excise tax.

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[15] *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.

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 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

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

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). Novartis 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 Novartis's argument that the DPNP affects a taking under the Fifth Amendment. 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.[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

[17] For the reasons set forth in Appellees' Brief, Novartis's arguments that the DPNP violates the First Amendment and Eighth Amendment also fail. *See* Appellees' Br. at 21–38, 53–64.

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]

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

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[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).

[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.

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 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]

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

[25] *Id.*

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 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

[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.

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

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

[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. (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,[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 wholesaler, retailer, or provider, excluding certain government programs, such as

[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 (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.[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).

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

[34] *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").[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]

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

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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* 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.

[36] *Id.*

[37] *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, *supra* note 34).

[38] 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.[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 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.

[39] *Id.*

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

C. Courts Have Consistently Rejected Takings Clause Challenges to Federal Healthcare Programs That Limit Prices.

As Appellees have explained, *see* Appellees' Opening Br. at 38–46, Novartis's Takings Clause argument has no support in existing case law. Three district courts have rejected analogous claims in challenges to the DPNP. *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024), *appeal docketed*, No. 24-1819 (3d Cir. May 2, 2024); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d. 440 (S.D. Ohio 2023) (*Chamber*), *appeal docketed*, No. 24-3868 (6th Cir. Oct. 8, 2024); *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 3:23-cv-01103(MPS), 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal docketed*, No. 24-2092 (2d Cir. Aug. 8, 2024). In fact, although numerous regulated parties have brought Fifth Amendment Takings Clause challenges against federal healthcare programs over the past 40 years, to our knowledge not one of those claims has succeeded. To the contrary, "a long line of cases instructs that no taking occurs where a person or entity voluntarily participates in a regulated program or activity." *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *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), *cert. denied*, 479 U.S. 813 (1986); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984).

1. Medicare

In *Garelick v. Sullivan*, the Second Circuit rejected the plaintiff anesthesiologists' challenge to a federal statute limiting reimbursement rates for services provided under Medicare Part B. 987 F.2d at 914–15. Although no provision of federal law mandated the anesthesiologists' participation in Medicare, the plaintiffs argued that they were compelled to participate in the program because New York state law effectively required hospitals to treat all Medicare patients, and it would not be "economically viable" for the anesthesiologists to practice outside of hospitals, where most of the procedures requiring their services are performed. *Id.* at 917. But the court explained, "economic hardship is not equivalent to legal compulsion," which is required for a regulation to give rise to a taking under the Fifth Amendment. *Id.*; *see also St. Francis v. Heckler*, 714 F.2d at 875 (The "fact

that practicalities may in some cases dictate participation does not make participation involuntary.").

2. The Emergency Medical Treatment and Active Labor Act

Courts have also rejected takings challenges to the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires Medicare-participating hospitals to provide medical care (screening and stabilization services) to all patients who present with an emergency medical condition, regardless of their ability to pay for care. 42 U.S.C. §§ 1395dd(a), (b)(1)(A), (h). Hospitals that violate EMTALA are subject to exclusion from Medicare and state healthcare programs as well as penalties of up to $119,942 (adjusted for inflation) per violation and civil damages available under the relevant state personal injury laws from suits brought by individuals harmed by such violation. *Id.* §§ 1395dd(d)(1)(A), (2)(A). Recently, in *Virginia Hospital & Healthcare Association v. Roberts*, the Eastern District of Virginia rejected the plaintiffs' claim that the federal government effected a *per se* taking through EMTALA's mandatory emergency care requirement. 671 F. Supp. 3d 633 (E.D. Va. 2023). The plaintiffs argued that they were "virtually compelled" to provide emergency services without just compensation under EMTALA because Virginia's "certificate of public need" program required participating hospitals to treat Medicare and Medicaid patients, and Medicare participants are required to participate in EMTALA. *Id.* at 644. The court disagreed, ruling that the takings claim

turned on whether the plaintiffs' "participation in Medicaid and Medicare are voluntary as a matter of *federal* law."[40] *Id.* at 666.

3. 340B Drug Program

Courts have also dismissed takings challenges brought in the context of federal and state laws related to the 340B Drug Program, where as a condition to participating in Medicaid and Medicare Part B, drug companies are required to provide significant discounts on outpatient prescription drugs purchased by public and not-for-profit hospitals and federally funded clinics serving low-income patients to provide to their patients. *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), *appeal docketed*, No. 21-3128 (7th Cir. Nov. 15, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, 570 F. Supp. 3d 129 (D.N.J. 2021), *reversed on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024).

[40] The Eastern District of Virginia also rejected the plaintiffs' comparison to *Horne v. Dep't of Agric.*, 576 U.S. 350 (2015), which Novartis relies on extensively. The court explained that "*Horne* is distinguishable because it involved a regulatory scheme in which plaintiffs were forced to yield part of their property, their crop of raisins, to the Government without receiving *any benefit whatsoever*." *Va. Hosp. & Healthcare Ass'n*, 671 F. Supp.3d at 667 (emphasis added).

Since the beginning of the 340B program, drug companies provided 340B discounts for drugs dispensed through both in-house and outside (*i.e.*, contract) pharmacies. *See e.g.*, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–56 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272-10279 (Mar. 5, 2010). Beginning in 2020, various drug companies challenged the requirement that they provide discounted drugs to covered entities via an unlimited number of contract pharmacies, and in two cases, plaintiffs claimed that the requirement constituted a taking. But these takings claims were both wholly rejected. *Eli Lilly*, 2021 WL 5039566, at *21; *Sanofi-Aventis*, 570 F. Supp. 3d at 207–10.[41]

In the Southern District of Indiana, Eli Lilly argued that a contract pharmacy requirement effected a taking "by forcing Lilly to transfer its drugs to contract pharmacies solely to serve those entities' private interests, and that, by requiring Lilly to succumb to a private taking of property to obtain coverage of its drugs under federal health-insurance programs," the program imposed "an unconstitutional condition on a valuable government benefit." *Eli Lilly*, 2021 WL 5039566, at *21. The court disagreed, explaining that the plaintiff's voluntary participation in the

[41] Although the *Sanofi-Aventis* case was reversed on other grounds, the Third Circuit did not rule on the appellant drug companies' takings claim. *See generally* 58 F.4th 696.

340B Drug Program "forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Id.* (quoting *S.E. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016)). Although withdrawing from 340B—and necessarily, Medicaid and Medicare Part B—would "result in a significant financial impact for" the plaintiff, such realities were insufficient to find legal compulsion for the purposes of the court's takings analysis. *Id.*

Likewise, the Southern District of Mississippi has also rejected takings claims in a case brought by another pharmaceutical company challenging a state law requiring it to provide 340B discounts to drugs dispensed at contract pharmacies, citing the fundamental principle that "[g]overnmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *AbbVie v. Fitch*, 2024 WL 3503965, at *17 (internal quotation marks omitted) (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)).

4. Reimbursement Rates for Detainees in Federal Facilities

The Eleventh Circuit likewise upheld 18 U.S.C. § 4006(b)(1), a federal statute setting maximum reimbursement rates for emergency services provided to detainees in federal jails and prisons at Medicare reimbursement rates. *Baker Cnty. Med. Servs.*, 763 F.3d at 1280. Although § 4006 was not cross-referenced in the Medicare

statute and § 4006 did not require the provision of emergency services for federal detainees, the plaintiff hospital argued that the statute effected an unconstitutional taking because, under both EMTALA and Florida state law, the plaintiff was required to provide emergency care for all patients, including detainees. *See id.* at 1279–80. Even leaving aside the state law that essentially required participation in EMTALA, the plaintiff hospital argued that it could not practically withdraw from Medicare because such withdrawal would result in a "grave financial setback" and leave Medicare participants in the plaintiff's rural county with no other place to receive care. *Id.* at 1280. The court was unpersuaded, finding that the plaintiff nonetheless voluntarily participated in Medicare (and, accordingly, voluntarily provided care to federal detainees), and therefore that the limits to reimbursement rates for such care under § 4006 was not a taking under the Fifth Amendment. *Id.* at 1278 (citing *Bowles v. Willingham*, 321 U.S. 503 (1944)).

5. State Legislation

According to the Eighth Circuit, a Minnesota state statute requiring nursing homes participating in Medicaid to accept limits on rates charged to certain residents did not constitute a *per se* taking under the Fifth Amendment. *See Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446. The court explained that despite "the strong financial inducement to participate in Medicaid . . . a nursing home's decision to do so is nonetheless voluntary[,]" which "forecloses the possibility that the statute could

result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Id.* To support its analysis, the court contrasted participation in federal healthcare programs with participation in public utilities because, unlike public utility providers, nursing homes "have freedom to decide whether to remain in business and thus subject themselves voluntarily to the limits imposed by [the state] on the return they obtain from investment of their assets in nursing home operation." *Id.*

* * * *

Like the plaintiffs in *Garelick*, *Virginia Hospital & Healthcare Association*, *Burditt*, *Eli Lilly*, *Baker County Medical Services*, and *Minnesota Association of Health Care Facilities*, Novartis has not suffered an unconstitutional taking. In fact, Novartis's arguments are weaker than the claims brought by the plaintiff anesthesiologists in *Garelick*. Unlike drug companies, which market their drugs outside of Medicare and Medicaid, virtually the only place of anesthesiologists' practice is hospitals. But as the Second Circuit pointed out, economic *pressure* to participate in a federal program does not constitute a taking. *Garelick*, 987 F.2d at 917. Further, unlike in *Baker County Medical Services*, Novartis does not argue that it is somehow *legally* compelled to participate in Medicare.

Rather, Novartis essentially contends that its desire to continue reaping profits from its relationships with Medicare and Medicaid leaves it without a choice not to

participate. But according to the courts that have evaluated this issue, it does not matter that a significant portion of Novartis's business is selling drugs to Medicare because it does so voluntarily. As a result of that choice, Novartis must abide by the Medicare program's requirements, including the requirements of the DPNP. Even if Novartis's withdrawal from Medicare would cause significant financial loss, its economic hardship does not support a Fifth Amendment claim.

CONCLUSION

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

Date: February 26, 2025

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Local Appellate Rule 28.3(d), I hereby certify that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

Date: February 26, 2025

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CERTIFICATE OF COMPLIANCE

The foregoing brief is in 14-point Times New Roman proportional font and contains 5,826 words, and thus complies with the type-volume limitation set forth in Rules 29(a)(5) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

I further certify that the text of this electronic brief is identical to the text of paper copies of this brief that will be filed with the Court, and that a virus detection program (CylancePROTECT Agent version 1340) has been run on this file and no virus was detected.

Date: February 26, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2025, I served the foregoing brief upon all counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system.

Date: February 26, 2025

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