Case No. 26-2165

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA AB; ASTRAZENECA UK LTD,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; MEHMET C. OZ, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Maryland (Maddox, J.), No. 1:25-cv-4212

AMICUS BRIEF OF PATIENTS FOR AFFORDABLE DRUGS IN SUPPORT OF DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Patients For Affordable Drugs is a 501(c)(3) non-profit corporation. No other entity has any ownership interest in it.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF AUTHORITIES iii

STATEMENT OF INTEREST 1

INTRODUCTION AND SUMMARY OF ARGUMENT 1

ARGUMENT 4

I. The Negotiation Program Ends A Handout to Drug Companies Secured by Industry Lobbyists 20 Years Ago. 4

II. The Negotiation Program Will Help Millions of Americans Afford Their Prescription Drugs and Maintain Access to Life-Saving Treatments. 9

III. AstraZeneca's Statutory Arguments Fail. 14

CONCLUSION 21

CERTIFICATE OF COMPLIANCE i

CERTIFICATE OF SERVICE ii

TABLE OF AUTHORITIES

Cases

Biden v. Nebraska,
600 U.S. 477 (2023) 19

King v. Burwell,
576 U.S. 473 (2015) 19

Loper Bright Enters. v. Raimondo,
603 U.S. 369 (2024) 15, 16

Palmyra Park Hosp., Inc. v. Phoebe Putney Mem'l Hosp.,
604 F.3d 1291 (11th Cir. 2010).....20

Sekhar v. United States,
570 U.S. 729 (2013) 18

Summers v. Earth Island Inst.,
555 U.S. 488 (2009) 15

Teva Pharm. USA, Inc. v. Kennedy,
187 F.4th 587 (D.C. Cir. 2026).....15, 17, 19

United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs.,
484 U.S. 365 (1988) 15

Vanda Pharms. Inc. v. Ctrs. for Medicare & Medicaid Servs.,
98 F.4th 483 (4th Cir. 2024) 18

Statutes

42 U.S.C. § 1320f-1(d) 19

42 U.S.C. § 1320f-1(d)(3)(B) 3, 15, 18, 19, 20

42 U.S.C. § 1320f-5(a)(2).....15

42 U.S.C. § 1396r-8(c)(2)(C) 20

42 U.S.C. §1320f-3(e)(2)(D) 18

42 U.S.C. §1395w-111(i) (2003) 5

Other Authorities

60 Minutes: Under The Influence (CBS television broadcast Mar. 9, 2007).....6, 7, 20

Cong. Budget Off., *Cost Estimate* (Sep. 7, 2022) 5, 9

Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* (Feb. 2023).....11

Memorandum from Meena Seshamani to Interested Parties, *Medicare Drug Price Negotiation Program: Revised Guidance* (Jun. 30, 2023).....21

Robert Pear, *Medicare Debate Turns To Pricing Of Drug Benefits*, N.Y. Times, Nov. 24, 2003 7

Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network (May 18, 2023).....11

Xcenda, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, (Sept. 21, 2020).....14

STATEMENT OF INTEREST

Patients For Affordable Drugs (P4AD) is the only national patient advocacy organization focused exclusively on achieving policy changes to lower the price of prescription drugs. P4AD is bipartisan, independent, and does not accept funding from any organization that profits from the development or distribution of prescription drugs. Since its founding, P4AD has advocated to empower Medicare to negotiate prices directly with pharmaceutical companies for a better deal for both patients and taxpayers in the United States. P4AD is pleased to file this amicus brief to defend the Inflation Reduction Act's drug price negotiation program—a historic measure that will strengthen the health, well-being, and financial security of individuals and families across the country while ensuring innovation in new drug development.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

For too many years, pharmaceutical companies treated Medicare Part D as if it was enacted for their benefit—as if it is a government handout for them, allowing them to line their pockets at the expense of taxpayers and patients. The Inflation Reduction Act ("IRA") delivered a long-needed rebuttal. The IRA includes multiple,

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

groundbreaking reforms designed to lower the high cost of prescription drugs and make them more accessible to patients, particularly seniors enrolled in Medicare. Most important here, the IRA granted Medicare—for the first time—the authority to negotiate with drug manufacturers regarding the prices Medicare pays for some of the highest-cost brand-name drugs. This authority, and the Negotiation Program that implements it, drastically reduces government spending and makes life-saving treatments more accessible to seniors enrolled in Medicare. Medicare negotiation is projected to save nearly $99 billion and prevent more than 650,000 premature deaths over the next decade.

Pharmaceutical companies are doing everything they can to reverse this progress. Shortly after the IRA's passage, multiple pharmaceutical companies—including AstraZeneca—sued to dismantle the Negotiation Program, claiming it violated the First, Fifth and/or Eighth Amendments. Every court to address those arguments rejected them, and the Supreme Court denied every petition for certiorari that was filed (including one by AstraZeneca).[2]

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[2] *See Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *aff'd* 150 F.4th 76 (2d Cir. 2025), *cert. denied*, 146 S. Ct. 2658 (2026); *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024), *aff'd*, 137 F.4th 116 (3d Cir. 2025), *cert. denied*, 146 S.Ct. 2648 (2026); *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-3335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *aff'd*, 155 F.4th 245 (3d Cir. 2025), *cert. denied*, 146 S. Ct. 2647 (2026); *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *aff'd*, 155 F.4th 245 (3d Cir. 2025), *cert. denied*, 146 S. Ct. 2656 (2026); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL

AstraZeneca has now returned to court claiming to have found another problem with the Negotiation Program. AstraZeneca contends that when CMS calculates which drugs Medicare spends the most money on, it is required to treat these as two separate drugs, because one is a capsule and one is a tablet:



Calquence 100mg capsules *(left)* and Calquence 100mg tablets *(right)*

But Congress said exactly the opposite. The IRA states that when CMS calculates whether a drug is eligible for the Negotiation Program, "***the Secretary shall use data that is aggregated across dosage forms and strengths***." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). AstraZeneca's 62 pages of interpretative gymnastics cannot erase this plain statutory text.

3594413 (D.N.J. July 31, 2024), *aff'd* 154 F.4th 105 (3d Cir. 2025), *cert. denied*, 146 S.Ct. 2656 (2026); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), *aff'd* 155 F.4th 223 (3d Cir. 2025), *cert. denied* 146 S.Ct. 2653 (2026); *Nat'l Infusion Ctr. Ass'n v. Kennedy*, 798 F. Supp. 3d 748 (W.D. Tex. 2025), *aff'd*, -- F.4th -- (5th Cir. Aug. 26, 2026); *Teva Pharm., USA, Inc. v. Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), *aff'd in relevant part*, 187 F.4th 587 (D.C. Cir. 2026).

This brief proceeds in three parts. First, it provides historical context for the Negotiation Program, showing that the previous system—one that barred the government from using its purchasing power to save money only on prescription drugs—was the product of an intense, overnight industry lobbying campaign, not anyone's belief that it was actually good policy. Second, it highlights the IRA's extraordinary benefits to patients and taxpayers. Third, it addresses AstraZeneca's statutory argument and why it cannot be squared with the IRA's text or purpose.

ARGUMENT

I. The Negotiation Program Ends A Handout to Drug Companies Secured by Industry Lobbyists 20 Years Ago.

Medicare has historically set or negotiated prices for every good or service it buys, including hospital care, medical devices, diagnostics, and physician visits—every good or service, that is, except prescription drugs. With the Negotiation Program, Congress finally granted the Secretary of Health and Human Services the authority to also negotiate the prices Medicare pays for some of the most expensive prescription drugs it covers. In the pre-IRA world, the Secretary was prohibited from using the government's purchasing power to negotiate more favorable prices for prescription drugs; instead, Medicare was required to pay whatever prices were agreed to by each patient's private plan sponsor. As detailed below, allowing the Secretary to use the government's purchasing power to negotiate lower prices will make prescription drugs more affordable for millions of Medicare beneficiaries.

More broadly, the Negotiation Program is projected to reduce Medicare spending by $99 billion by 2031 and by untold billions in years beyond.[3]

These obvious benefits raise an obvious question: Why wasn't the Secretary already allowed to negotiate the prices the government pays for prescription drugs, which Medicare has long been able to do for every other purchase it makes? The answer is a so-called "non-interference" provision that was slipped into the Medicare Modernization Act of 2003. That Act created Medicare Part D, which for the first time provided prescription-drug coverage to millions of Medicare-eligible Americans. But one provision of the Act undermined the rest—it prohibited the Secretary from "interfer[ing] with the negotiations between drug manufacturers and [private insurance plans]" and from "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. §1395w-111(i) (2003). This meant that the federal government, despite being the largest purchaser of prescription drugs in the United States, was forbidden from using its bargaining power to secure lower prices for itself and for Medicare recipients, and instead had to pay whatever prices prevailed in the rest of the market.

This, of course, raises only more questions. Allowing the federal government to negotiate lower prices for itself seems like a no-brainer, and yet Congress

[3] Cong. Budget Off., *Cost Estimate* ("CBO Estimate") (Sep. 7, 2022) at 5, https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

expressly prohibited it despite granting similar authority for other Medicare purchases. Was there some drug-specific fiscal or policy benefit that explains the prohibition on using the government's bargaining power to trim billions from the deficit and help millions of Americans better afford their prescription drugs? Was there some doubt, as Appellant might suggest, about the constitutionality of the government negotiating drug prices with manufacturers?

No and no. The answer, as Rep. Walter Jones (R–NC) succinctly explained, is that "[t]he pharmaceutical lobbyists wrote the bill."[4] Pharmaceutical lobbyists insisted on adding the so-called "non-interference" provision at the last minute because, as Rep. Dan Burton (R–IN) put it, "the drug companies … wanted to make as much money as possible, and if there's negotiation, like there is in other countries around the world, then they're going to have their profit margin reduced."[5] After discovering the "non-interference" provision, Medicare's chief actuary revised the cost estimate for the bill upwards by $140 billion, but he was coerced into withholding that revision from Congress—specifically, he was directed by the then-Administrator of CMS to "withhold the [updated] numbers from Congress if he

[4] *60 Minutes: Under The Influence* (CBS television broadcast Mar. 9, 2007) ("60 Minutes"), at 1:12, https://www.youtube.com/watch?v=RikKAelRX1w.

[5] *Id.* at 7:00.

wanted to keep his job."[6] Then, after an all-night session of "arm-twisting"[7] by congressmen and staffers and an "extraordinary three-hour roll call"[8]—all part of what Rep. Jones described as "the ugliest night I have ever seen [in Congress]"[9]—House leaders secured enough votes to get the bill through by a margin of 220 to 215.[10]

Those most instrumental to the bill's passage went almost immediately to work for the pharmaceutical companies their efforts benefited. The representative who led efforts to shepherd the bill through the House promptly left to become the head of industry trade group PhRMA.[11] The Staff Director for the Health Subcommittee of the House Ways and Means Committee soon became a lobbyist for PhRMA, Pfizer, Lilly, and Merck.[12] The Chief of Staff for the House Committee on Energy and Commerce took a job lobbying for Novartis and Hoffmann-LaRoche.[13] The administrator of CMS—the person who forced Medicare's chief actuary to

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[6] *Id.* at 7:35.

[7] *Id.* at 2:45.

[8] Robert Pear, *Medicare Debate Turns To Pricing Of Drug Benefits*, N.Y. Times, Nov. 24, 2003.

[9] 60 Minutes, *supra n.*4, at 1:35.

[10] Pear, *supra* n.8.

[11] Representative turned drug industry lobbyist Billy Tauzin, 60 Minutes, *supra* n.4, at 9:33.

[12] Staffer turned drug industry lobbyist John McManus, *Id.* at 11:47.

[13] Staffer turned drug company lobbyist Patrick Morrisey, *Id.* at 12:10.

withhold the revised cost estimates—became a lobbyist for the pharmaceutical industry just ten days after the President signed the bill.[14] In all, at least 15 congressmen, staffers, and federal officials who were instrumental to the bill's passage left government to work for the pharmaceutical industry.[15]

In subsequent years, legislators introduced multiple proposals to eliminate the "non-interference" provision, but each time, drug company lobbyists convinced enough members to oppose it or vote it down. In 2007, for example, the House approved the Medicare Prescription Drug Price Negotiation Act of 2007, which would have repealed part of the noninterference provision to allow negotiation of Part D prices. After aggressive industry opposition and a presidential veto threat, however, the Act was never put to a vote in the Senate. In 2019, the House passed the Elijah E. Cummings Lower Drug Costs Now Act, but that bill, too, languished in the Senate amid intense industry opposition.

The point here is not to indict past members of Congress. The point is that the non-interference provision was an artificial constraint that departed from both normal market practices and standard government procurement methods—every other major government health program routinely negotiates drug prices, as do private insurers and pharmacy benefit managers. The Negotiation Program does not

[14] CMS Administrator turned drug company lobbyist Thomas Scully, *Id.* at 8:08.

[15] *Id.* at 12:36.

give the Executive Branch some unprecedented power to override natural market mechanisms, but rather restores to Medicare the same negotiating authority that other government purchasers have always possessed and that the Constitution has never been thought to prohibit. Through the Negotiation Program and the IRA's other reforms, Medicare will finally be structured in a way that puts the needs of patients above the profits and political power of drug companies.

II. The Negotiation Program Will Help Millions of Americans Afford Their Prescription Drugs and Maintain Access to Life-Saving Treatments.

With the Negotiation Program and associated enactments, Congress addressed exorbitant drug prices and ensured that patients can continue to obtain—or afford for the first time—the medications they need. These prescription drug provisions are projected to lower drug costs by approximately $237 billion through 2031, with about $100 billion of those savings coming from the Negotiation Program.[16] And those numbers substantially understate the long-term impact, as even greater savings to taxpayers will come in years after 2031. As to Calquence, AstraZeneca and CMS agreed to a negotiated price that is 40% lower than the previous list price. *See* Br. for Appellees at 15. For Medicare patients, the price for a 30-day supply will drop from $14,228 to $8,600. *Id.*

[16] CBO Estimate, *supra* n.3, at 5.

Much of these savings will be passed through to the individual patients who rely on these drugs. While Medicare pays most of the cost of prescription drugs, Part D beneficiaries remain responsible for out-of-pocket payments, including deductibles, copays, and coinsurance. The prices Medicare negotiates for the selected drugs directly impact patients' out-of-pocket responsibility. For example, three of the ten drugs selected in the first round of negotiations—Enbrel, Imbruvica, and Stelara—are "on the specialty tier in virtually all Part D plans that cover these drugs, with median coinsurance of 30-33%." Accordingly, the price reductions that Medicare negotiated for those drugs—overall savings of $4,751 for a 30-day supply of Enbrel; $5,615 for a 30-day supply of Imbruvica, and $9,141 for a 30-day supply of Stelara—are being enjoyed proportionally by patients because their out-of-pocket costs will now be based on the much lower negotiated price. The same is true for every drug that has been or will be selected for negotiation. For example, patient out-of-pocket costs for Entresto will be reduced by 53%; for many beneficiaries, this will lower the out-of-pocket cost of a 30-day supply from $157 to $74.

Furthermore, all Part D beneficiaries share the financial burden of high-priced prescription drugs regardless of whether they take any of those drugs themselves. This is because Medicare Part D premiums are calculated based on overall programmatic costs—*i.e.*, the more Medicare spends on prescription drugs overall,

the more each Part D beneficiary is required to pay in premiums.[17] The Negotiation Program will cut spending by billions of dollars each year and everyone's Part D premiums will decrease accordingly.

While the financial savings are substantial, the Negotiation Program's impact goes far beyond money in pockets. Prescription drugs, and especially the brand-name drugs likely to be chosen for the Negotiation Program, are so expensive that Medicare beneficiaries are not always able to fill their prescriptions. A 2022 study found that more than ***one in five*** Medicare beneficiaries aged 65 or older did not adhere to their medications as prescribed because doing so would have been too expensive.[18] These patients reported skipping or delaying prescription refills, skipping doses, or taking smaller doses than their doctors prescribed.[19] More than half of all respondents in the study used one of several cost-coping strategies, with nearly one in ten reporting that they made the impossible choice to go without basic life essentials, such as food and/or housing, to pay for their medication.[20]

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[17] Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* (Feb. 2023), at 25.

[18] Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network (May 18, 2023).

[19] *Id.*

[20] *Id.*

Consider Trevor Watts, a retired glazier living in Roseburg, Oregon who now dedicates his time to volunteering with Habitat for Humanity. He was diagnosed with Type 2 Diabetes at the age of 62. Farxiga—another drug manufactured by AstraZeneca—is vital for managing his condition. Before the Negotiation Program, his coinsurance responsibility for Farxiga was as high as $161 per thirty-day prescription. Paying those costs means forgoing other necessities. He has been forced to delay trips to visit family members, visits to the dentist, and repairs on a three-year-old leak in his roof that would drip water into his entryway but for a tarp covering the hole. Some months, he has to choose between buying presents for his grandchildren and filling his prescriptions. Trevor believes that access to affordable medication is crucial so that he and everyone else can afford groceries and other everyday essentials without worrying about whether they can also afford their life-saving medications.

Or consider Aly Elbaga, a retired chemist living in Old Bridge, New Jersey. He has been on Eliquis—another drug that was part of the first round of Medicare Negotiation—for nearly a decade. Aly has long struggled to afford the costs of his prescription drugs, which eat up nearly half of his monthly income. Instead of enjoying his well-earned retirement, Aly has been unable to afford vacations or other leisure activities, and he struggles even to buy himself new clothing, shoes, or other basic necessities. He sometimes has no choice but to skip doses of his medication

to ensure that he has enough money to pay for rent, food, and car insurance. Aly understands that pharmaceutical companies are entitled to make a profit on the life-saving drugs they make, but is frustrated that Eliquis and other drugs are so much cheaper in other countries. Given that the companies still make profits from their sales in other countries, Aly does not understand why they should get to make even more money in the United States. As Aly put it: "How greedy can you be?"

Finally, consider Lynn Scarfuto, a retired nurse in Herkimer, New York who spent her career working with cancer patients to ensure they received the best treatment possible. After retirement, in a cruel twist of fate, she was diagnosed with chronic lymphocytic leukemia, and later, lung cancer. She has taken Imbruvica for more than ten years, during which time the price has more than doubled. Lynn has been fortunate enough to obtain grants from the PAN Foundation to assist with her out-of-pocket costs for Imbruvica, but without those grants, Lynn would not have been able to afford housing because of the crippling cost of her prescription drugs. Lynn believes that patients like her should not be forced to choose between being homeless and being healthy, or to rely on grants that are unpredictable and can come and go, especially when pharmaceutical companies are making billions in profits each year.

The Negotiation Program will dramatically improve the lives of millions of people like Trevor, Aly, and Lynn. Because of the Negotiation Program, the prices

of their prescriptions will be substantially lower—68% lower for Farxiga, 56% lower for Eliquis, and 38% lower for Imbruvica—delivering meaningful relief that will allow them to afford the medicines they need, take vacations, pay their rent, and allay some of the daily concern about making ends meet. For many Medicare patients, the IRA's prescription-drug provisions will make a literal life-or-death difference: One study estimates that Medicare negotiation, by lowering out-of-pocket costs, will result in "656,967 fewer deaths over 7 years (an average of 93,852 lives saved annually) due to the effects of improved adherence."[21]

III. AstraZeneca's Statutory Arguments Fail.

A. If the Court reaches the merits of AstraZeneca's statutory claim, *but see* Br. for Appellees at 20-36, it should reject AstraZeneca's argument. At its core, the Negotiation Program's design is simple: CMS (1) identifies the drugs on which Medicare spends the most money; and (2) tries to negotiate a lower price for those drugs. The question here is how CMS determines which drugs Medicare spends the most money on—and specifically, whether every dosage and formulation of a drug should be counted separately or whether those dosages and formulations should be aggregated and counted together.

[21] Xcenda, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, (Sept. 21, 2020), at 15.

Fortunately for the task at hand, Congress spoke directly to that question: the IRA states that when CMS ranks drugs by total Medicare expenditures, it "shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and *not based on the specific formulation or package size or package type of the drug*." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). Likewise, the IRA instructs that after CMS negotiates a new price for a drug, that new price applies "across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." 42 U.S.C. § 1320f-5(a)(2). That answers that. When CMS determines how much Medicare spends on Calquence, Calquence (tablet) and Calquence (capsule) both count as Calquence. *See Teva Pharm. USA, Inc. v. Kennedy*, 187 F.4th 587 (D.C. Cir. 2026) (holding that IRA requires aggregating "Austedo and its extended-release formulation, Austedo XR").

AstraZeneca's labored statutory analysis cannot erase this clear statutory text. Statutory interpretation is not "an ingenious academic exercise in the conceivable," *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009), but an exercise in which courts "determine the best reading of the statute," *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024); *see also United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988) (Scalia, J.) (if there are multiple "permissible meanings," courts should choose the one that "produces a substantive

effect that is compatible with the rest of the law"). The best reading of the statute is the one that honors Congress's express direction to aggregate "across dosage forms and strengths of the drug," without differentiating "based on the specific formulation or package size or package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). Thus, even if AstraZeneca had successfully back-solved from its desired result to a convoluted but coherent way around this explicit command, *but see infra*, that would by no means make it the "best reading." *Loper Bright*, 603 U.S. at 400. The Court's task is not to "declar[e] a particular party's reading 'permissible,'" but to "use every tool at [its] disposal to determine the best reading of the statute." *Id.* There is no prize for creative lawyering; statutory interpretation is not an exercise in making the obvious complicated.

In all events, AstraZeneca's statutory analysis fails on its own terms. AstraZeneca tries to avoid the IRA's command to "use data that is aggregated across dosage forms and strengths of the drug," 42 U.S.C. § 1320f-1(d)(3)(B), by arguing that this command applies only *after* a drug is identified as a "qualifying single source drug" ("QSSD") under 42 U.S.C. § 1320f-1(e)(1)(A). *See* AZ Br. at 16-17, 42-45. And according to AstraZeneca, a QSSD cannot encompass products with distinct NDAs, like Calquence (tablet) and Calquence (capsule). *Id.* at 27-32. This NDA-focused interpretation of QSSD is wrong, as the government's brief persuasively argues and as the D.C. Circuit has already held. *See* Br. for Appellees

at 36-54; *Teva*, 187 F.4th 587 ("Several IRA provisions undercut Teva's NDA-specific theory."). But even if it were right, it still would not get AstraZeneca where it needs to go: even under that incorrect reading, expenditures on Calquence (capsule) and Calquence (tablet) would still have to be aggregated, Calquence would still be selected, and the negotiated price would apply to all forms of Calquence.

As already discussed, CMS determines whether each QSSD is negotiation-eligible by calculating whether it is among the 50 highest-expenditure drugs. 42 U.S.C. § 1320f-1(d). When CMS does so, it must "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation." 42 U.S.C. § 1320f-1(d)(3)(B). Accordingly, even if the QSSD were just Calquence (capsule), when CMS calculates expenditures on that QSSD, it must aggregate expenditures on all other dosage forms and strengths of the drug, which includes Calquence (tablet). *Id.* Thus, regardless of whether the QSSD is Calquence writ large or one specific Calquence formulation, the total expenditures are the expenditures across all "dosage forms and strengths of the drug, *including new formulations of the drug*, such as an extended release formulation." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added).

Anticipating this problem, AstraZeneca asserts that the only "new formulations of the drug" that can be included in the aggregation are those that were "approved via the original NDA and any supplements to that NDA" rather than those

approved in separate NDAs. AZ Br. at 18. But this Court already rejected essentially the same argument regarding essentially the same text. *See Vanda Pharms. Inc. v. Ctrs. for Medicare & Medicaid Servs.*, 98 F.4th 483 (4th Cir. 2024). In *Vanda*, this Court addressed the Medicaid rebate statute, which uses the same phrase as the IRA's aggregation provision: "a new formulation of the drug, such as an extended release formulation." 42 U.S.C. § 1396r-8(c)(2)(C). The drug manufacturer in *Vanda*, like AstraZeneca here, argued that this phrase included only drugs approved under the same NDA. *See Vanda*, 98 F.4th at 495. This Court rejected that reading as "wholly unpersuasive," holding that "a new drug application is not the silver bullet Vanda imagines." *Id.*

When "a word is obviously transplanted from another legal source, whether the common law or other legislation, it brings the old soil with it." *Sekhar v. United States*, 570 U.S. 729, 733 (2013). Thus, when Congress used the same "new formulation of the drug, such as an extended release formulation" language in the IRA, that language carried the same meaning as in the Medicaid rebate statute—language this Court held in *Vanda* is *not* limited to formulations under the same NDA. *Vanda*, 98 F.4th at 495. Accordingly, Calquence (tablet) is a "new formulation[] of the drug" even though FDA approved it as a separate NDA, and Medicare's spending on it must be aggregated with its spending on Calquence (capsule).

B. AstraZeneca's reading also cannot be squared with the statutory plan. *See King v. Burwell*, 576 U.S. 473, 498 (2015) ("A fair reading of legislation demands a fair understanding of the legislative plan."); *Biden v. Nebraska*, 600 U.S. 477, 513 (2023) (Barrett, J., concurring) ("A clerk who disregards context and stretches the words to their fullest will not have a job for long."). No one earnestly thinks that Congress wanted CMS to treat Calquence (tablet) and Calquence (capsule) as different drugs when determining how much Medicare spends on Calquence. While AstraZeneca claims that Congress would have had "good reasons" for doing so, AZ Br. at 32, its argument is a non sequitur. It says that "[p]atent protection and marketing-exclusivity laws" provide "key incentives for innovation," *id.* at 32-33, but Medicare Negotiation does not alter those laws. Medicare Negotiation simply allows the federal government, in its role as a buyer, to negotiate with AstraZeneca about how much it will pay for Calquence.

AstraZeneca claims that Medicare Negotiation would undermine its supposed entitlement to "a period of market pricing before generic competition is allowed" for new formulations of old drugs. *Id.* at 32. This argument is doubly flawed. First, the argument "assumes its answer." *Teva*, 187 F. 4th 587. AstraZeneca's premise is that it is entitled to a new seven-year period of pricing protection every time it reformulates a capsule as a tablet, but that is the very question in dispute.

Second, AstraZeneca's conception of "market pricing" is detached from reality. AstraZeneca uses the term "market pricing" to refer to the pre-IRA system, in which CMS was prohibited from using the government's purchasing power to negotiate more favorable prices for prescription drugs; instead, CMS was required to pay whatever prices each patient's private plan sponsor negotiated. That is not "market pricing"—it is a skewed system in which the buyer with the most purchasing power and the greatest ability to exert downward pressure on prices was artificially excluded from the market, resulting in a *non*-market-based windfall for pharmaceutical companies. As Rep. Burton said all those years ago, "if there's negotiation, … then [drug companies are] going to have their profit margin reduced."[22]

The actual fair market prices for prescription drugs are the prices that now result from the Negotiation Program—prices determined in actual negotiations between buyer and seller. In fact, to the extent that CMS's conduct deviates from free market forces, those deviations actually work *in the pharmaceutical companies' favor*. When private market participants negotiate prices, they "seek to maximize profits by … minimizing costs" to the greatest extent possible. *Palmyra Park Hosp., Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1300 (11th Cir. 2010). The

[22] 60 Minutes, *supra* n.4, at 7:00.

government's incentives are different. CMS must follow Congress's direction to consider several factors *other* than simply aiming for the lowest possible price. For example, CMS must consider "the extent to which the manufacturer has recouped research and development costs," 42 U.S.C. § 1320f-3(e)(1)(A), and whether a selected drug "address[es] unmet medical needs" for patients, *id*. § 1320f-3(e)(2)(D). If a drug is truly innovative or if a manufacturer has not recouped its R&D costs, CMS may offer more than a similarly situated private party would.[23]

More broadly, it could be catastrophic for the federal government if manufacturers withdrew their products from the Medicare and Medicaid markets. Accordingly, when CMS determines its offers under the Negotiation Program, it must consider not only dollars and cents like a market participant would, but also the public good, knowing that the public good will be best served if negotiations are successful, companies continue participating in Medicare, and incentives for innovation remain strong.

CONCLUSION

This Court should affirm the judgment below.

[23] Memorandum from Meena Seshamani to Interested Parties, *Medicare Drug Price Negotiation Program: Revised Guidance*, at 150-51 (Jun. 30, 2023).

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) because it contains 4,856 words, not counting portions of the brief listed in Federal Rule of Appellate Procedure 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2026, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in these cases are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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