ORAL ARGUMENT NOT YET SCHEDULED
Nos. 25-5177, 25-5179, 25-5220, 25-5221, 25-5223, 25-5224, 25-5226

IN THE

United States Court of Appeals for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, *et al.*,

Plaintiffs-Appellants-Cross-Appellees,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary, United States Department of Health and Human Services, *et al.*,

Defendants-Appellees-Cross-Appellees,

340B HEALTH, *et al.*,

Intervenors-Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court for the District of Columbia
Nos. 21-cv-2608, 24-cv-3220, 24-cv-3337, 25-cv-117
District Judge Dabney L. Friedrich

BRIEF OF *AMICI CURIAE* CF UNITED, ACT NOW, AND ADAP ADVOCACAY IN SUPPORT OF PLAINTFFS-APPELLANTS

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June 24, 2025

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. PARTIES

1. The following are parties in this Court:

a. Plaintiffs-Appellants-Cross-Appellees: Bristol Myers Squibb Company (BMS); Novartis Pharmaceuticals Corporation (Novartis); Eli Lilly and Company (Lilly); Lilly USA, LLC; and Kalderos, Inc. (Kalderos).

b. Defendants-Appellees-Cross-Appellees: Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; Thomas J. Engels, in his official capacity as Administrator of Health Resources and Services Administration; the United States of America; the U.S. Department of Health and Human Services; and the U.S. Health Resources and Services Administration.

c. Intervenors-Defendants-Appellees-Cross-Appellants: 340B Health, University of Massachusetts Memorial Medical Center, and Genesis Healthcare System (collectively, Intervenors).

B. CORPORATE DISCLOSURE STATEMENT

CF United, ACT Now, and ADAP Advocacy state that they have no parent companies or subsidiaries, are not publicly held corporations, and that no part of their ownership is held by any publicly held corporation.

C. RULING UNDER REVIEW

BMS, Novartis, Lilly, and Kalderos appeal the District Court's May 15, 2025 order denying their motions for summary judgment and granting Defendants' and Intervenors' cross-motions for summary judgment. JA371-404; *Eli Lilly & Co. v. Kennedy*, No. 24-cv-03220-DLF, 2025 WL 1423630 (D.D.C. May 15, 2025) (Friedrich, J.) (Mem. Op.). Intervenors have filed a cross-appeal.

D. RELATED CASES

Johnson & Johnson Healthcare Systems Inc. v. Kennedy, 1:24-cv-03188-RC (D.D.C.) is a related case within the meaning of Circuit Rule 28(a)(1)(C).

/s/
William A. Sarraille

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IDENTITY AND INTEREST OF AMICI AND SOURCE OF AUTHORITY[1]

CF United, Advocates for Compassionate Therapy Now (ACT Now), and ADAP Advocacy Association (ADAP Advocacy) are patient advocacy groups. CF United is led by rare disease patients and caregivers, focuses on the cystic fibrosis disease, and is an independent patient voice dedicated to affordable access to medications. ACT Now works to connect chronic and rare disease patients and families and ensure access to treatment. ADAP Advocacy improves access to care for HIV/AIDS patients and promotes and enhances AIDS Drug Assistance Programs (ADAPs), where rebates are already used to effectuate 340B prices.

Amici all strongly support 340B as a way to make healthcare more affordable for needy patients. Under 340B, covered entities receive billions in subsidies that should enable them to support a reasonable level of charity care to the uninsured and underinsured. Unfortunately, despite the explosive growth of 340B, which now generates $80 billion in profits to covered entities annually, many covered entities

[1] No party's counsel authored this brief in whole or in part, and no party, its counsel, or any other person—other than Amici Curiae or its counsel—contributed money intended to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). Counsel for Amici was formerly counsel for Appellant Kalderos before his retirement from Sidley Austin, LLP in 2023. He currently serves as a board member at Kalderos. The content of this Brief and the points made in it have not been discussed with Kalderos or its counsel. Amici have solely directed and controlled the content of this Brief. Appellants, Intervenors, and the Federal Defendants have consented to the filing of this Brief.

provide an abysmally low level of charity care and do not share 340B pricing with patients when they are required to pay out-of-pocket for some or all of the cost of their drugs. Sadly, too many covered entities, particularly 340B hospitals, abuse the program by maximizing their profits while reducing their charity care. The needs of patients for financial assistance are ignored as billions in subsidies are generated. Amici serve those patients who, despite these massive 340B profits, do not receive charity care and see no benefit from 340B pricing at the pharmacy counter. We hear from these patients how they struggle to access their medications as a consequence.

Amici write in support of Plaintiffs-Appellants because the rebate model is the only way to change this unacceptable situation and because the plain language of the statute specifically permits rebates, without any agency "pre-approval" authority. The 340B program, mired in opacity for decades, must be made transparent. Rebates will provide the platforms and the data necessary to understand, without obfuscation or manipulation, whether needy 340B drug patients receive the benefit of the 340B price. To justify the billions in subsidies generated from 340B patients, many of whom pay substantial sums out of their own pockets to help fund those massive subsidies, the program should allow patients to understand whether their provider is sharing any of its heavily reduced prices with them. The source of authority for the filing of this Amicus Brief is Fed. R. App. 29(a)(3).

SUMMARY OF ARGUMENT

Designed to help the uninsured and the underinsured, the 340B program has utterly lost its way. Even as 340B has expanded dramatically, many covered entities have cut their charity care ratios,[2] hurting the patients 340B was supposed to help. Despite the fact that it is their prescriptions that generate 340B's massive profits, patients are left to pay out-of-pocket amounts for their drugs they cannot afford. Those needy patients are often not even told that they are not sharing—at all—in the steeply reduced prices that their providers receive.

Amici urge this Court to strike down the agency's assertion of any "pre-approval" power over rebates for three reasons. *First*, the agency's unlawful assertion of a "pre-approval" authority would deny patients in desperate need of transparency the only means to achieve it. This Court should reverse the District Court's judgment because a rebate model will benefit all stakeholders, including patients, by providing each stakeholder group with the information necessary to ensure that the program is being operated in a fashion that serves their legitimate interests. For patients, a rebate model offers a means, finally, to understand if 340B concessions are being shared with them.

[2] A charity care ratio is the amount spent by a healthcare provider to cover the cost of care to needy patients who cannot pay for those services divided by the total amount it spends.

Second, the agency's asserted position is contrary to the plain language of the statute. Like the agency before it, the District Court erred in failing to recognize that the 340B statute specifically authorizes rebates as a means to effectuate the 340B price. The Health Resources and Services Administration (HRSA), the agency with limited oversight over the 340B program, has no authority to prevent the use of those rebates. The "pre-approval" power HRSA now claims, but never asserted for 30 years, is both atextual and ahistoric.

Third, the need to overturn the agency's decision and the District Court's judgment upholding it is urgent, as they threaten the successful implementation of the Inflation Reduction Act, framing a series of negative clinical and financial impacts on patients and frustrating Congress' intent. This threat to patients is a function of the Secretary's arbitrary and capricious actions in simultaneously permitting a rebate model if it results in payment in 14 days (his Inflation Reduction Act position) and in refusing to permit it if it results in payment in 7 to 10 days (his 340B position).

BACKGROUND

A. The Origins of 340B

Some 340B advocates cynically claim that Congress, in creating the 340B program, only intended it to benefit providers, not patients. That's untrue. When Congress enacted 340B it specifically tied the program to federally-funded clinics

and public hospitals precisely because they "*serve* large numbers of *low-income and uninsured patients*".[3] Though Congress' legislative history also referenced "stretching … resources" in creating the program, it did so specifically in a context that stressed the underlying purpose of "reaching more *eligible* patients".[4] "Eligible" patients are, by definition, those who use 340B drugs. Congress absolutely intended that needy drug patients at the pharmacy counter would receive assistance from 340B covered entities.

B. 340B and the Affordable Care Act

In 2010, when the Affordable Care Act (ACA) was enacted, Congress also expanded 340B. Those legislative changes were meant to work together to bring more affordable healthcare to needy patients,[5] including those patients at the pharmacy counter.[6]

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[3] *See* H.R. Rep. No. 102-384(II), at 10–12 (1992) (emphasis added).

[4] *See* Hearing Before the Subcommittee on Oversight and Investigations, "Examining How Covered Entities Utilize the 340B Drug Pricing Program" (Oct. 11, 2017) (emphasis added).

[5] U.S. Department of Health and Human Services, "About the Affordable Care Act", available at https://www.hhs.gov/healthcare/about-the-aca/index.html.

[6] S. Thomas, "The Unintended Consequences of the 340B Safety Net Drug Discount Program", *Health Services Research* 2020 Mar. 1;55(2):153-156, https://pmc.ncbi.nlm.nih.gov/articles/PMC7080379/ (the "340B Drug Pricing Program was created", among other purposes, "to increase access to outpatient medications" for low-income and uninsured patients).

In 2010, 340B covered entities made less than $6 billion in 340B purchases.[7] Then, as now, a small fraction of the covered entities, 340B hospitals, were the recipients of almost 80% of the revenues 340B generates.[8] Despite their often massive size, resources, and 340B subsidies, most 340B hospitals had charity care rates at the time that the ACA was enacted that failed to even meet the national all hospital average.[9] In 2011, just after the ACA was enacted, 340B hospitals had an average charity care rate of 2.60%,[10] meaning that for every $100 they spent, they devoted just $2.60 to charity care.

But, under the ACA, the expectation was that, with the expansion of 340B, hospitals would (finally) expand their commitment to patients and provide meaningful charity care. The exact opposite happened.

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[7] *See* S. Wright, "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program", OEI -05-13-00431, HHS-OIG (Feb. 4, 2014).

[8] *See* A. Fein, "The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money", *Drug Channels* (Aug. 15, 2022), https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html.

[9] AIR340B, "Charity Care at 340B Hospitals is on a Downward Trend 2", at 6 (Oct. 2023), available at https://bit.ly/4eicWep.

[10] *See* Pioneer Institute, Hospital Charity Care (2022), available at https://pioneerinstitute.org/340babuse/hospital-charity-care/.

C. 340B Profits Burgeon and Charity Care Falls

Now, fifteen years after the ACA was enacted, hospitals have driven 340B profits far higher, without any corresponding benefit in the level of charity care. Indeed, 340B hospitals' disappointing charity care levels worsened.

By 2023, the $6 billion in 2010 340B purchases had become $66 billion, an increase of an astonishing 1,000%, with an average annual increase over that period of 71%. Even as 340B had grown 10 times over, charity care by 340B hospitals fell, by 2022, to 2.15%,[11] an 18% drop. The "spread" between the low 340B acquisition prices ($66 billion)[12] and the reimbursement value of those drugs ($124 billion as measured by list price value) [13] totaled nearly $58 billion in profits in 2023. With the list value of the program having reached $146 billion in 2024, the profit spread

[11] *See* Pioneer Institute, *supra*. Many hospitals have charity care ratios substantially below even the low averages discussed above, however. UMass Medical Center, an Intervenor in this case, had a 2022 charity care ratio of just 0.95%.

[12] A. Fein, "The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions", *Drug Channels* (Oct. 22, 2024), available at https://bit.ly/4fhCnwP.

[13] W. Sarraille, "Beyond the Sloganeering—A Data-Driven Analysis of Recent 340B Growth", *American Journal of Managed Care*, at 3 (June 3, 2025), available at https://www.ajmc.com/view/contributor-beyond-the-sloganeering-a-data-driven-analysis-of-recent-340b-growth.

increased a further 38% just last year, again, with no corresponding charity care increase.[14]

Amicus ADAP Advocacy has a "340B Map" that drills down on this disturbing problem.[15] The map shows the growth in 340B revenues and charity care. Sutter Valley Hospitals, one of the largest hospital systems in the country, for instance, has seen a 259% increase in 340B revenues, while its charity care has fallen 72% and its chief executive compensation has increased 1,133%.

Worse yet, contract pharmacies – typically large for-profit retail pharmacy chains and their affiliates that covered entities leverage to generate many billions more in 340B profits – do a particularly poor job providing needy patients affordable access to drugs.[16] 340B contract pharmacies, which now number in excess of 30,000

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[14] *See* S. Zeng, "What Is Driving 340B Growth: Utilization or Price?", *Health Affairs Scholar*, at 4 (May 21, 2025), available at https://doi.org/10.1093/haschl/qxaf104 ("when disproportionate share hospitals … begin participating in the program, total community benefit spending (including charity care) does not change") (citing S. Nikpay, "Relationship between Initiation of 340B Participation and Hospital Safety Net Engagement", *Health Serv. Rev.* 55(2), 157-169 (2020)).

[15] 340B Map, *ADAP Advocacy*, available at https://340bmap.org/mapster-wp-map/340b-map/.

[16] R. Martin, "Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program", *IQVIA* (Aug. 30, 2024); *see also* S. Zeng, *Health Affairs*, at 4.

locations, only provide assistance to patients on 1.4% of branded prescriptions,[17] a figure below even the abysmally low 340B hospital charity care rates.[18] To put this rate of assistance into even greater relief, more than 40% of the U.S. population are uninsured, underinsured, or experience a gap in coverage each year.[19]

The New York Times recently reported on a patient example that, rather shockingly, illustrates the problem.[20] Virginia King, a cancer patient, sought drug therapy from 340B hospital Christus St. Vincent (CSV). The manufacturer list price for the drug, before the 340B discount, was $2,700, but the hospital billed Ms. King's insurer $22,700, 8.4 times that amount. Ms. King's insurer paid $10,000, but CSV still billed her an additional $2,500 out of pocket, never offering her charity care.

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[17] R. Martin, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?", *IQVIA*, available at https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf.

[18] Pioneer Institute, Hospital Charity Care, available at https://pioneerinstitute.org/340babuse/hospital-charity-care/.

[19] *See* "The State of Health Insurance Coverage in the U.S.", *Commonwealth Fund* (2024) ("9 percent of adults were uninsured, 12 percent had a gap in coverage over the past year, and 23 percent were underinsured, meaning they had coverage for a full year that didn't provide them with affordable access to health care"), available at .https://www.commonwealthfund.org/publications/surveys/2024/nov/state-health-insurance-coverage-us-2024-biennial-survey#.

[20] E. Graber, "How a Company Makes Millions Off a Hospital Program Meant to Help Patients", *New York Times* (Jan. 15, 2025).

When she could not pay it, CSV sent her to collections. Ms. King then switched to a non-340B provider, with n*o* 340B subsidies, and she had no out-of-pocket costs at all there. CSV claimed its 340B profits "helped the hospital provide charity care", but its charity care ratio was just 1.95%, below even the embarrassingly low national average.[21]

The predatory charges Ms. King faced are, sadly, not an aberration. Because of aggressive 340B provider mark-ups, "the [340B] program has increased healthcare costs for employers, their workers, … payers, … state and local governments, …[and] Medicare and Medicaid".[22] "[T]he cost of outpatient oncology drugs", for example, "is significantly higher at 340B hospitals compared

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[21] Pioneer Institute, Hospital Charity Care, New Mexico (2022), available at https://pioneerinstitute.org/340babuse/hospital-charity-care/.

[22] S. Zeng, *Health Affairs*, at 4; *see also* R. Martin, "Are Discounts in the 340B Program Being Shared with Patients at Contract Pharmacies", *IQVIA* (2020), available at https://www.iqvia.com/locations/united-states/library/white-papers/are-discounts-in-the-340b-drug-discount-program (patients); C. Sun, "The Cost of the 340B Program: Part 1: Self-Insured Employers", *IQVIA* (Mar. 2024), available at https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-part-1-self-insured-employers; C. Sun, "The Cost of the 340B Program to States", *IQVIA* (Feb. 2025), available at https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-to-states; N. Masia, "The 340B Drug Purchasing Program and Per-Enrollee Medicaid Costs", *Health Capital Group* (May 2024), available at https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-to-states; W. Sarraille, *AJMC*, at 2.

to non-340B hospitals".[23] "Payers have struggled," as a consequence, "with the increasing costs associated with the growth of … 340B".[24] And higher costs to payers means higher out-of-pocket obligations for patients.[25]

It is true that non-hospital 340B covered entities that receive grants from HRSA have a limited obligation to provide assistance to some patients, including for pharmaceutical services. Specifically, these entities, which account for a small portion of the program's sales, are obligated under those grants to provide "sliding scale" assistance to patients at 200% of the federal poverty limit or below.[26] Only

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[23] S. Zeng, *Health Affairs, at 4* (citing J. Chang, "Association between New 340B Program Participation and Commercial Insurance Spending on Outpatient Biologic Oncology Drugs", *JAMA Health Forum* 4(6): e231485).

[24] W. Sarraille, *AJMC*, at 1.

[25] The adverse clinical and financial effects of out-of-pocket costs on needy patients are clear. *See, e.g.*, W. Shrank, "The Epidemiology to Prescriptions Abandoned at the Pharmacy", *Annals of Internal Medicine* (2010), available at https://www.researchgate.net/publication/47794551_The_Epidemiology_of_Prescriptions_Abandoned_at_the_Pharmacy (cost-sharing as low as "$40 to $50" leads many patients to forego treatment); J. Doshi, "Addressing Out-of-Pocket Specialty Drug Costs in Medicare Part D: The Good, The Bad, The Ugly, and the Ignored", *Health Affairs* (July 25, 2018), available at https://www.healthaffairs.org/do/10.1377/hblog20180724.734269/full/ (discussing the link between out of pocket costs and failure to access drug therapy in the Medicare program).

[26] U.S. Department of Health and Human Services, *HealthCare.Gov*, "Federal Poverty Limit", available at https://www.healthcare.gov/glossary/federal-poverty-level-fpl/.

28% of the US population is eligible to receive any assistance under this rather strict standard.

340B is broken, and the root cause is a lack of transparency about diversion, duplicate discounts, and whether patients are receiving any real charity care at the pharmacy counter. These are precisely the issues that a rebate model can address. All of this is not to say that there aren't many covered entities that do provide meaningful charity care to the vulnerable. But those covered entities that do the right thing, such as a number of ADAPs, are themselves harmed by the lack of transparency that protects those that don't.

ARGUMENT

I. A REBATE MODEL IS BADLY NEEDED AND WILL ENABLE PATIENTS TO UNDERSTAND IF THEY ARE SHARING IN 340B PRICING.

Before addressing the statute, Amici want to emphasize the importance of a rebate model from the patient perspective. The rebate model is the only mechanism that can bring transparency to a program mired in opacity. The need for transparency is acute because unsuspecting patients are losing what little access they have had to charity care even as 340B expands and expands, bringing additional billions to covered entities and for profit "middlemen".[27]

[27] *See* U.S. Senate, Health, Education, Pensions & Labor Majority Staff Report, "Congress Must Act to Bring Needed Reforms to the 340 Drug Pricing Program"

A rebate model can finally allow patients to understand whether they are receiving any part of the benefit of 340B pricing at the pharmacy counter. All too often paying cost sharing amounts based on provider charges that are wildly higher than their 340B providers' actual costs, the patients who generate billions in 340B profits for hospitals are excluded from any benefit of that pricing when it comes time to pay out-of-pocket at the pharmacy counter.

A rebate model affords a path for needy patients because, as Appellant BMS has committed, it will pay covered entities on an "even faster" schedule than the "seven to ten days" it otherwise commits to, if a covered entity simply "share[s] the 340B price directly with the patient".[28] That payment mechanism, which leaves covered entities still free to make billions from the program and use those funds

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(Apr. 2025), at 17-29, available at https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf (highlighting the large 340B related payments made to for profit "third party administrators", contract pharmacies, and others affiliated with the nation's largest insurers, pharmacy benefit managers, and national pharmacy chains); *see also* A. Fein, "EXCLUSIVE: For 2023, Five For-Profit Retailers and Dominate an Evolving 340B Contract Pharmacy Market", *Drug Channels* (July 11, 2023), https://bit.ly/3ZH23yG (discussing the "dominate[]" positions in 34B of such sprawling for-profit health giants as CVS Health, Walgreens, Cigna, Express Scripts, UnitedHealth Group, OptumRx, and Walmart).

[28] Letter from Bristol Myers Squibb to the U.S. Department of Health and Human Services (Oct. 22, 2024), JA702.

largely as they choose, will at least show which providers share a portion of the discounted price with patients—and which refuse to do so.

But a rebate model will provide transparency for other stakeholders, too. Covered entities will have transparency into manufacturer concessions, ensuring that covered entities know that they are receiving the 340B price they should. It will allow manufacturers to be confident they are not paying duplicate discounts or being targeted by diversion schemes. For the states, the rebate model will guard against improper Medicaid payments.

Nor is a rebate model infeasible, expensive, cumbersome, or costly. Amicus ADAP Advocacy views State Drug Assistance Programs, which currently operate under a rebate model, as the gold standard for 340B rebates. That 340B rebate model works—for everyone. Using a rebate model, ADAPs have been able to dramatically grow their drug and non-drug services for HIV/AIDS patients, while providing financial assistance to patients and funding for non-drug HIV/AIDS programs. Significantly, 340B ADAP drug rebates provided just 5% of ADAP funding for HIV/AIDS patients in 1997, but those rebates successfully and efficiently funded 47% of programs in 2022, an increase of more than 800%, including direct financial assistance to drug patients in need.[29] 340B rebates, which now are estimated to fund

[29] M. Hopkins, "NASTAD Releases 2024 Monitoring Project Annual Report", *The ADAP Blog* (May 2024), available

a full 55% of these programs, work.[30] And much larger, better-resourced 340B hospitals are in an even better position to operate effectively under a rebate model.

The rebate model will help patients share meaningfully in 340B pricing, and still allow covered entities to receive tens of billions of dollars in subsidies and spend it how they chose. But the rebate model is essential to the effort to bring transparency to 340B.

II. THE STATUTE'S PLAIN LANGUAGE SPECIFICALLY AUTHORIZES REBATES, WITHOUT ANY AGENCY "PRE-APPROVAL".

The agency and the District Court have misread the statute. Its plain language demonstrates that rebates are specifically authorized and that the Secretary has no "pre-approval" authority. Any contrary reading of the statute is atextual and ahistorical.

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at https://adapadvocacyassociation.blogspot.com/2024/05/nastad-releases-2024-monitoring-project.html.

[30] B. Macsata, "Is the 340B Drug Rebate Program the Next 'Too Big to Fail'?", *ADAP Advocacy* (Feb. 2025), available at https://www.adapadvocacy.org/pdf-docs/2025_ADAP_Project_RW_340B_Asset_16_Too_Big_To_Fail_03-07-25.pdf.

A. The Statute Is Important for What It Says and Doesn't Say.

Starting, as we must, with the text, *see Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009), it is important to stress both what the plain language of the statute says and what it does not say.

First, the plain language states that, in determining "the *amount* required to be paid", it is necessary for the Secretary to "*tak[e*] into *account any rebate* or discount". 42 U.S.C. § 256b(a)(1) (emphases added). The plain language of the statute, thus, specifically authorizes both "rebates" and "discounts". Indeed, the statute refers *first* to "rebate" and only second to "discount", indicating, if anything, that the "rebate" mechanism was the one *primarily* invoked by Congress.

The plain language then authorizes the Secretary to "account" for "the amount" required to be paid. The entire parenthetical "(taking into any rebate or discount, as provided by the Secretary)" modifies the phrase "amount to be paid". Thus, the Secretary is authorized to review and "account" for "the amount" of payments, whether in the form of a "rebate" or a "discount", in order to ensure that the correct amount is, in fact, "paid".

Equally important is what the statute does not say. The text does not include any reference to an "approval" power, let alone a "pre-approval" power, over the mechanism a drug maker chooses to use. The word "approve"—or any variation

of it—is wholly absent from the statute. The Secretary, in pressing for a "pre-approval" power, is quite literally attempting to insert words into the statute that are not there.

If Congress had intended to create an "approval" power, it would have clearly said so. Consistent with the Secretary's position that it need not have pre-approved a discount, but does need to preapprove a rebate, Congress could have said that "discounts are permissible, but rebates may only be used if the Secretary approves such rebate". But that is not what Congress said.

Significantly, the Secretary never asserted such a "pre-approval" power for three decades.[31] That's not surprising—because no such power exists.

B. The District Court Misread the Statute by Failing to Apply Its Own Reasoning to Its Logical Conclusion.

The District Court begins, correctly enough, by noting that the language at issue—both textually and as a matter of structure—"sets forth a *formula* for *calculating* the maximum [340B] price" and the "*amount* to be paid". Mem. Op., at 19 (emphases added). Thus, the District Court begins by observing that the

[31] The ADAP model and the replenishment model are both "retrospective" systems, like the rebate model. But HRSA has never conditioned those models on a "pre-approval". *See, e.g.,* 62 Fed. Reg. 45,823 (Aug. 29, 1997) (discussing ADAPs). Indeed, it has never conditioned the use of any "discount" on a pre-approval.

language the government hangs its hat on—the parenthetical "(taking into any rebate or discount, as provided by the Secretary)"-- must be read in the context of the phrase that it modifies, "the *amount* to be paid" and the "calculation" of or "accounting" for that amount.

A bit later, the District Court recognizes the natural conclusion that follows—that the provision at issue only addresses "*how* any rebate or discount is *accounted* for" in what "ultimately [is] paid". *Id.* at 20. How a payment is to be "accounted" for in an "amount paid" is manifestly different than "if" or "whether" a particular payment mechanism may be used at all. They are two entirely different things.

But having laid the tracks that should lead to the correct plain language reading of the statute, the District Court reverses course on its own analysis. It gives the agency unlimited authority to negate the choice of the *means* used to effectuate a payment, whether rebates or discounts or any other mechanism, instead of merely being able to address the appropriate "accounting" for the "amount paid", regardless of the form taken. The District Court twists the statutory language to permit a veto over any *form* of payment, even when it results in the correct "amount" being "paid".

As set out in the brief of Amici below in the District Court, at 20-23, there clearly is a role for the agency to play where, whatever the form of payment

chosen by a drug maker, the "amount to be paid" is not, in fact, paid to the covered entity. Of course, payments not actually transferred to a covered entity need not be "accounted" for in the "amount to be paid" to the covered entity. But rather than recognize this common sense authority—and its limits— the District Court fundamentally misreads the statute.

Where Congress told the agency to "provide" for the "account[ing]" of the "amount to be paid" for "any rebate or discount", the District Court rewrites the statute to instead give the agency broad authority to categorically prohibit either or both rebates and discounts, *regardless* of how accurately they deliver the "amount to be paid". In the District Court's misreading of the statute, the obligation to ensure appropriate calculation or "accounting" of "any rebate or discount" becomes the wholly distinct power to determine "if" a particular form of payment can be used at all. For the District Court that is true even if, as a mathematical matter, the rebate or discount clearly yields an "amount to be paid" that is fully in accord with the statutory "maximum price".

The District Court's decision simply cannot be squared with the plain language of the words chosen by Congress.

C. The District Court Repeatedly Compounds Its Error in Misreading the Statute.

The District Court compounds its failure to give effect to the plain language of the statute by making multiple other errors. It (1) misstates the relevant

regulatory history, failing to appreciate the entirely ahistorical nature of the agency's position, (2) recognizes, but gives no effect, to the fact that the agency has never asserted a "pre-approval" authority, (3) relies on "evidence" that was not part of the administrative record, and (4) uses a misreading of the legislative history to support its negation of the statute's plain language.

First, the District Court incorrectly asserts that the "approval" authority HRSA claims "has previously [been] exercised" by the agency. Mem. Op., at 20. The District Court states that the HRSA has used the "as provided by the Secretary" provision previously in two prior guidances. *Id*. (citing the 340B "penny" pricing and the initial "interim price" guidance for new drugs). But the non-binding guidances that the court cites never mentioned this clause; those guidances were premised on *different* provisions of the statute, *see* 42 U.S.C. §256b(d)(1)(B)(i)(1), not implicated here.[32]

Second, though conceding that the agency has "not preapprove[d]" any "other price reduction model" in 340B's thirty year history, Mem. Op., at 30-31, the District Court gave no effect to that important fact. As the courts have repeatedly held, belated, "novel" assertions of statutory positions, like the "pre-approval" authority HRSA now claims thirty years too late, are inherently

[32] *See, e.g.*, HRSA, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation", 82 Fed. Reg. 1210, 1210-11 (Jan. 5, 2017)

suspect.[33] But the District Court brushes right by this rule of statutory construction.

Third, the District Court adds to its error by relying on purported "evidence" that was not a part of the administrative record at the time the agency finalized the letters at issue here. *See* Mem. Op., at 15 (conceding that, "[i]n an APA case, summary judgment serves as a mechanism for deciding … whether the agency action is *supported by the administrative record* … ") (emphasis added). The Testoni Declaration, repeatedly cited by the District Court, is but one example. Created only after this litigation had begun, it makes a series of sweeping and unsupported statements about how the replenishment model supposedly works in an effort to cast the rebate model as a fundamental departure from the status quo. It contends that, under the current replenishment system, covered entities supposedly "only" have to buy product at a non-discounted price "once". *See* Mem. Op., at 6, citing Testoni Dec, at ¶ 9.

But that assertion is wrong. In a program that has grown in excess of 70% per year, on average, over a 15 year period, covered entities have routinely bought large quantities of non-discounted product to feed their program growth, as the inventory demands inherent in that kind of explosive expansion cannot possibly be

[33] *See Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 454 (D.C. Cir. 2017); *see also Loving v. IRS*, 742 F.3d 1013, 1021 (D.C. Cir. 2014).

satisfied by only retroactively "replenishing" inventory. Further, as the Declaration effectively concedes, covered entities regularly buy undiscounted product to dispense before a full package is accumulated, because they can only "replenish" a unit when a full package has been used first. Finally, 340B contract pharmacy units—a large proportion of the program—are, like ADAP rebate units, always initially subject to "commercial prices". *Id*. at ¶ 7. Despite all these—and other routine circumstances--in which non-340B prices are initially paid at commercial prices, those initial non-340B prices have not in any way impeded the incredible expansion of this program.

Similarly, the "survey" that the District Court relies upon from Intervenor 340B Health, which also was not a part of the agency administrative record, is deeply flawed. *See* Mem. Op., at 12, citing "Preliminary Results of 340B Health Survey", *340B Health* (Mar. 18, 2025), available at https://tinyurl.com/4jj3ukjf. Based on just "200 responses",[34] the survey's "preliminary results" state that some of those very small number of respondents "would be unable to maintain their

[34] The 200 respondents do not constitute a random sample and are just a tiny fraction of the more than 53,000 covered entities in the U.S.

current levels of community benefits and free services", without disclosing what those existing levels are or how much they would supposedly be affected. [35]

Among the many problems here is how the survey (mis)defines the "cost" of a rebate program in a manner that predetermines a negative response. It presupposes first that all purchases are currently at 340B prices, which is clearly inaccurate (*see, supra*, at 22). Next, disregarding that drug makers would pay rebates within 7 to 10 days, it takes the position that a covered entity occurs a "cost" even when it would be paid that rebate *before* the provider ever has to pay for the underlying drug. Significantly, providers routinely receive up to 30 days to pay a distributor for product that is shipped to them in advance of their making any payment, meaning payment from a drug maker in 7 to 10 days would regularly occur before the provider has to pay the distributor for the drug. [36] Similarly, the survey ignores that pharmacies and distributers use frequent drug orders and deliveries to enable pharmacies to carefully limit the days on hand they hold any

[35] The survey makes no effort to identify a minimum "impact" threshold such that even a single dollar of purported "impact" would generate a "negative" survey response.

[36] *See* McKesson, Terms and Conditions of Sale, https://sites.mckesson.com/mscs/images/MSCS_Terms_and_Conditions_102008.pdf (large distributor stating that standard "[p]ayment terms are net 30 [days]").

drug, maximizing their receipt of rebates and other price concessions before they ever pay their distributors.[37]

Finally, the District Court misreads a single line of legislative history and fails to consider multiple other pieces of that history that are contrary to its atextual conclusion. The single line the District Court references refers only to the "discretion" of the agency over "implement[ing]" the statute, whether by "a point-of service discount, a rebate, or other mechanisms".[38] That line just reflects Congress' expectation that, consistent with the plain language of the statute, multiple mechanisms would, in fact, be employed, but that the Secretary would have "discretion" over determining the "account[ing]" for the "amount to be paid", whichever mechanism was used. Other parts of the legislative history clearly contemplate the use of both rebates and discounts. *See* H.R. Rep. No. 102-384(II), at 12. At one point, for instance, the House Report refers to "price reductions" to be paid alternatively "whether through a discount, rebate, or other mechanism", with no reference to the agency being authorized to strike one or more means. *Id.* And, of course, legislative history cannot undermine the plain language of

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[37] *See* J. Rawlison, "How Pharmacies Get Medications from Distributors", *Return Customer* (Nov. 29, 2023) (describing the systems in place to allow even small pharmacies to achieve impressive efficiency in managing their inventories), available at https://returncustomer.com/pharmacies-get-medications/.

[38] Mem. Op., at 20 (citing H.R. Rep. No. 102-384(II)), at 8, 12, 16.

Congress' statutory text, which itself repeatedly references "rebates" or "discounts".[39]

Unfortunately, even beyond the District Court's misreading of the statute's plain language, that court's analysis suffers from numerous other errors.

III. THE INFLATION REDUCTION ACT OVERLAY UNDERSCORES THE URGENCY PRESENTED AND THE ARBITRARY NATURE OF THE SECRETARY'S INTERNALLY INCONSISTENT POSITIONS.

In opposing 340B rebates paid in 7 to 10 days or less, the Secretary adopts a position that is fundamentally at odds with the payment window he has set (and found entirely acceptable) in the Medicare negotiated price context under the Inflation Reduction Act (14 days). The Secretary's refusal to recognize faster 340B rebate payments cannot be squared with the Secretary's IRA standard for "prompt" payment.[40] That arbitrary and capricious inconsistency is a violation of the Administrative Procedure Act, 5 U.S.C. §555, *et. seq*., and all the more troubling

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[39] *See Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 339 (D.C. Cir. 2020).

[40] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program: Final Guidance" (Oct. 2, 2024), at 132 (discussing the 14 day "prompt" pay window under the IRA), available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

because the Secretary's position will undermine IRA implementation and harm patients.

A. The IRA Implementation Issue Is Urgent and Threatens Serious Patient Harms.

The urgency for this Court to invalidate HRSA's letters could not be clearer. If the letters are not invalidated and a 340B rebate permitted, an Inflation Reduction Act implementation disaster will follow. That is, admittedly, strong language, but we think that it is entirely justified.

Without a feasible mechanism to identify duplicate IRA negotiated prices and 340B concessions, IRA "true up" payments cannot occur in a timely fashion. With no effective system in place, prompt payments will not be made because drug makers, covered entities, contract pharmacies, and the government will be lost in a long, contorted debate about whether or not a duplicate 340B concession is present in millions of transactions. Concerned about this, pharmacies are already saying they will not stock IRA drugs. The need to permit 340B rebates to prevent this breakdown is urgent. It is a critically important issue that must be faced now, as there are effectively only five months to go before the IRA implementation deadline.

Though the District Court acknowledged the issue, it also downplayed it, suggesting it only "may" materialize. Mem. Op., at 9. The District Court was hoping against hope that the government, after years of refusing to implement an

IRA duplicate discount screening program, will in the few remaining months before the January 1, 2026 deadline reverse course and stand up a functioning program.

As patient advocates, we want to be clear. There are no alternatives to a rebate model at this point. It is impossible for the government to stand up an alternative to manufacturer rebates now. The contracting, payment, financial, operational, technical, data, system, and testing requirements would have been a challenge even if the decision to pursue an alternative had been taken when the IRA was passed in 2022. It is hopeless now. Manufacturers are, as the government itself has effectively conceded, the ones going to fix this fundamental challenge to the IRA--or implementation will inevitably suffer.

What are the consequences of an IRA implementation that does not address this fundamental problem? They are awful. Many of the patients that we represent will be switched from a lower priced IRA drug with a price set by the government -- and that has met their critically important health care needs -- to a higher cost drug that they have never used. The adverse consequences for patients are both clinical and financial, requiring patients to pay more out of pocket for a drug they have not used before and that may fail to address their health needs. Disruption in treatment is inevitable, as the link between higher out of pocket patient costs and

patients delaying or terminating needed treatment is beyond debate.[41] And the negative consequences are not limited to patients. The government, with patients being switched to higher cost drugs, will see the "savings" it hoped for under the IRA evaporate, frustrating Congressional intent.[42]

B. The IRA Overlay Demonstrates the Arbitrary and Capricious Nature of the Secretary's Simultaneous Maintenance of Inconsistent Positions.

As patient advocates, we are struck by the arbitrary and capricious nature of the government's simultaneous acceptance of a 14 day payment window, in the case of the IRA, and its refusal to accept a faster payment window of 7-10 in an overlapping 340B context. The maintenance of inconsistent positions with respect to overlapping, intricately intertwined programs, is a stark and indefensible

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[41] *See, e.g.*, A. Chandra, "The Health Costs of Cost-Sharing", *Nat'l Bureau of Economic Research* (Feb. 2021) (showing that monthly mortality increases with out-of-pocket costs); A. Chandra, "Health Consequences of Patient Cost-Sharing", *Law & Economic Symposium* (Apr. 28, 2021) (for every 3% increase in co-insurance obligation, there is a 1% increase in mortality); *see also, infra*, at fn 25.

[42] The District Court's failure to fully appreciate the IRA issue is only further underscored by the fact that it only considered the incorrect IRA provision. *See, e.g.*, Mem. Op., at 17. The District Court repeatedly addresses "the Medicaid inflation program [that] takes effect on January 1, 2026". But the IRA provision at issue in this case, the provision that allows the government to set Medicare drug prices, 42 U.S.C. § 1320f-2(a), is a *Medicare* program element and is not an *inflation* penalty at all. There is a *separate* Medicare inflation provision that is a part of the IRA, but that statutory requirement was implemented 3 years ago in 2022; the *Medicaid* inflation penalty provision was implemented in 1993, more than 30 years ago.

example of arbitrary and capricious conduct under the Administrative Procedure Act. *See* Mem. Op. at 27 (conceding the "intersection" of the IRA and 340B programs). It is the definition of arbitrary and capricious for two related agencies in a single Department to take two diametrically different positions at the same (critically important) time.

CONCLUSION

For all these reasons, the agency's letters should be invalidated, and the District Court's judgment should be reversed.

Dated: June 24, 2025

Respectfully submitted,

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/s/
William A. Sarraille

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I hereby certify that a copy of the foregoing will be served this 24th day of June, 2025, electronically through the Court's CM/ECF system on all registered counsel.

/s/
William A. Sarraille