IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRISTOL MYERS SQUIBB, INC., *Plaintiff*, v. DOROTHY FINK, in her official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants.*	Case No. 1:24-cv-03337 (DLF)

BRIEF OF CF UNITED AND ADAP ADVOCACY AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, CF United 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.

IDENTITY AND INTEREST OF *AMICI CURIAE*[2]

CF United ("CF United") and ADAP Advocacy Association, Inc. ("ADAP Advocacy") are not-for-profit patient advocacy groups. CF United is a grassroots advocacy organization led by rare disease patients and caregivers. As an independent patient voice, it is dedicated to ensuring continued, affordable access to life-saving medications. Through advocacy, education, and community engagement, it amplifies patient voices to drive meaningful policy change and protect the rights of those living with rare diseases and complex medical conditions. ADAP Advocacy's mission is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP Advocacy works with a range of stakeholders to foster greater community collaboration for the benefit of patients.

Both organizations strongly support the 340B program as a potential means to make health care for the patients that they serve more affordable. Under the program, 340B covered entities receive billions in subsidies that should enable them, in turn, to support a reasonable level of charity care to the uninsured and underinsured, including at the pharmacy counter. Unfortunately, despite the explosive growth of the 340B program, which now generates approximately $58 billion in profits to covered entities annually, many 340B covered entities provide an abysmally low level of charity care, including to patients in need at the pharmacy counter. Sadly, too many covered entities, particularly 340B disproportionate share hospitals, have aggressively committed themselves to abusing the 340B program by maximizing their profits while reducing their charity care ratios. Amici Curiae serve those patients, hear from them about their struggles to access

[2] 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). Plaintiff has consented to this brief and the Federal Defendants take no position.

charity care at these covered entities, and try to help those patients not lose access to the drug therapies on which their health depends as a consequence.

Amici Curiae are committed to ensuring that pharmaceutical patients in need, including chronic and rare disease patients, receive a direct benefit[3] from the massive subsidies provided by the program, as intended by Congress. Despite the billions that are made available to 340B covered entities,[4] there is disappointedly little evidence that those billions actually benefit pharmaceutical patients in the form of charity care, including assistance at the pharmacy counter. Indeed, there is substantial evidence that billions in subsidies are diverted to third parties, like large, for-profit retail pharmacy chains and "administrators," many of whom are affiliated with massive entities called pharmacy benefit managers that control much of health care.[5]

Amici Curiae write in support of Plaintiff Bristol Myers Squibb, Inc.'s ("Plaintiff") motion for summary judgment because they believe that the rebate model is the only way to change this unacceptable situation. The 340B program, mired in opaqueness for years, must be made transparent. The rebate model would do exactly that.

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[3] *See* Nicole Longo, *340B Program Remains Second Largest Federal Drug Program, Yet Little Solid Evidence of Benefits to Patients*, PhRMA (June 30, 2022), https://phrma.org/Blog/340b-program-remains-second-largest-federal-drug-program-yet-little-solid-evidence-of-benefits-to-patient.

[4] Covered entities have "a financial incentive to catalog as many prescriptions as possible as eligible for [a 340B] discount", *Novartis Pharms. Corp. v Johnson,* 102 F.4th 452, 457-58 (D.C. Cir. 2024), because they generate "revenue from serving insured patients" by "turn[ing] a profit" when "the insurance companies reimburse them at full price for drugs that they bought at the 340B discount", *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

[5] Adam 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 of such sprawling for-profit pharmacy chains and PBMs, as CVS Health, Walgreens, Cigna, Express Scripts, UnitedHealth Group, OptumRx, and Walmart).

The rebate model can provide the platforms and the data to understand, clearly and without obfuscation or manipulation, what the connection is (or isn't) between a 340B covered entity and the person that receives the drug[6] and whether bona fide 340B patients in need receive assistance at the pharmacy counter. To justify the billions in subsidies generated off of the drug therapies of 340B patients, many of whom pay substantial sums out of their own pockets to help fund those massive subsidies, 340B must operate as a means to enable patients in need to secure the benefit of drug discounts at the pharmacy counter.

In opposing the transparency that the program and patients so desperately need, the Health Services and Resources Administration ("HRSA"), sadly, has put the interests of 340B entities that do not share their discounts with their patients above the needs of vulnerable patients.[7] Further, HRSA's position that it and only it can "approve" a transparent model for the operation of the 340B program is completely inconsistent with the text, structure, and purpose of the statute. HRSA is seeking an unworthy end through unlawful means.

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[6] Even some 340B advocates acknowledge excesses in the manner that some covered entities "claim" a patient for purposes of 340B purchases—and the profits that can be generated by doing so. *See* 340B Insider, Cloudmed, *Legal Considerations and Compliance for 340B Program Optimization*, https://www.cloudmed.com/resource/340b-insider-december-2022/ (various covered entities take the extreme position that "everybody we have ever treated at any point is our patient") (last visited Feb. 7, 2025).

[7] Amici Curiae feel compelled, as patient advocates, to comment on HRSA's threat to remove a drug manufacturer from the 340B program and Plaintiff's view that this "nuclear" option was designed as a message to it and other manufacturers. Unfortunately, that fear is well-founded, and Amici share it. HRSA is effectively threatening to cut off drug therapy coverage for hundreds of thousands, or even millions, of Medicare and Medicaid patients dependent for their health and well-being on any of the many medications a drug maker manufacturers if it adopts a rebate model. Though Amici Curiae take no pleasure in saying this, that threat, with its disturbing implications for vulnerable patients with rare and chronic diseases, is recklessly anti-patient as it is so clearly detrimental to the interests of patients.

Amici Curiae, with their patient advocacy focus and mission, seek to assist the Court by providing additional information on the 340B statute, its history, and how the 340B program is failing patients. In debating the 340B program, HRSA and others often fail to consider the perspective and needs of the patient. We urge this Court, in addressing the important issue presented here, to consider that perspective and those needs. Amici submit this brief in support of Plaintiff because the rebate model is a vehicle to bring transparency to the program, will benefit patients, and is clearly permitted by the plain language, structure, and purpose of the statute.

SUMMARY OF ARGUMENT

Designed to help the uninsured and the underinsured by focusing on providers devoted to their "direct care",[8] the 340B program, now more than thirty years in, has utterly lost its way. Even as the 340B program dramatically expanded, in particular over the course of the last fifteen years, all too many covered entities have cut their charity care ratios, adversely affecting the very patients who are struggling to afford their medications at the pharmacy counter.[9] Despite the fact that it is their prescriptions that generate, collectively, billions in subsidies to covered entities, patients are left to pay out-of-pocket amounts for their drugs that they cannot afford. All too often patients who qualify for charity care are not offered that assistance. Typically, patients of covered entities paying out-of-pocket for the medications on which their health depends are not even told that they are not sharing—at all—in the steeply reduced prices that their providers receive.

Amici Curiae urge this Court to grant Plaintiff's Motion for Summary Judgment for the following reasons. *First*, patients are in desperate need for the transparency that only the rebate

[8] *See* House Report 102-384, Pt. 2, at 10-12 (1983); *see also* 106 Stat. at 4962 (codified at 42 U.S.C. § 1396r-8(c)(1)(C)).

[9] *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 30 (2019).

model can provide into what, to this point, has been a hopelessly opaque program. This Court should grant Plaintiff's motion because rebate models can 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 each stakeholders' legitimate interests. For patients, rebate models offer a means, finally, to understand when 340B concessions are being shared with them and when, even though it is their therapy that is generating profits for the covered entity, the patient is receiving no benefit at the pharmacy counter.

Second, the *Novartis*, 102 F.4th at 462-63, bona fide offer test is clearly satisfied here. Plaintiff's proposed rebate model only initially involves one drug and requires payment in "no more than seven to ten days" (faster than normally required for other rebate customers and faster even than the expedited payment window that the Secretary has established under the Inflation Reduction Act, *see, infra*, at 14). It is far from the "onerous" conditions necessary to establish that an offer is not bona fide. Complaint at ¶ 57, 59. But what to patient advocates is most exciting about this proposal is that it promises "even faster" payment if covered entities do the right thing and simply "agree[] to share the 340B price directly with the patient". *Id.* Amici commend Plaintiff for this thoughtful, patient-centric rebate design that may, finally, encourage some covered entities to share 340B pricing with patients at the pharmacy counter.

Third, the text, structure, and purpose of the 340B statute demonstrates that rebates are specifically authorized as a means to effectuate the 340B price, and HRSA has absolutely no authority to prevent the use of those rebates—or the transparency they would bring to the program. HRSA's contention that it has a "pre-approval" power is atextual and ahistoric, arbitrary and capricious, and leads, inevitably, to absurd results.

BACKGROUND

A. The Origins of 340B

The 340B program was created by Congress in 1992 to address an "unintended consequence" resulting from the enactment of the Medicaid Drug Rebate Program in 1990.[10] Previously, manufacturers provided substantial price concessions, voluntarily, that directly benefited patients at the pharmacy counter.[11] But, because Congress did not anticipate that the creation of the Medicaid program would compel manufacturers to abandon those voluntary concessions, Congress inadvertently forced the prices of drugs to vulnerable patients to be raised, precipitously higher, which adversely affected patients at the pharmacy counter.

Some 340B advocates claim, rather cynically, that Congress, in correcting this Medicaid issue, only intended the program to benefit covered entities. That is untrue. The loss of the voluntary discounts quite clearly and directly affected uninsured and underinsured patients dependent on drug therapies, who were forced to pay more out of their pockets as a consequence. The contention that the development of the 340B program was only about the covered entities and not about the prices vulnerable patients were required to pay out of pocket is manifestly wrong—and a perversion of the program and its origins.

When Congress enacted the 340B program, it referenced federally-funded clinics and public hospitals precisely because they "*serve* large numbers of *low-income and uninsured patients*."[12] Similarly, Congress spoke explicitly to the fact that, in permitting covered entities to access discounts, it was motivated to do so because those entities "provide *direct clinical care* to

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[10] *See* Nicholas C. Fisher, 22 J. Health Care L. & Pol'y at 30.

[11] *See id.* at 29.

[12] House Report, at 10–12 (1992) (emphasis added).

large numbers of *uninsured* Americans."[13] Indeed, the single line from the legislative history that 340B advocates cite as reflecting Congress' original intent says the same thing, when fully quoted. Though Congress referenced "stretching … resources", it did so specifically in a context that stressed the underlying purpose of "better *serv[ing] underinsured and underinsured patients*".[14] Those vulnerable patients are most directly impacted at the pharmacy counter and that specific context was the one most directly affected by the Medicaid rebate program's unintended effect of decreasingly the cost of pharmaceuticals used by vulnerable patients.

In other words, Congress did not see a distinction between the covered entities and the needy patients they were expected to serve; one (the entities) were referred to because the needs of the other (the patient) were embedded in the first; they were viewed as two sides of the same coin.

B. The 340B Program and the Affordable Care Act

In 2010, when the Affordable Care Act[15] ('the ACA") was enacted, Congress also expanded the 340B program. Those two steps were meant to work hand in glove to bring affordable health care to patients in need,[16] including patients dependent on drug therapies who

[13] *See* House Report at 12 (emphasis added).

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

[15] Public Law 111-148 (2010).

[16] U.S. Department of Health and Human Services, "About the Affordable Care Act", https://www.hhs.gov/healthcare/about-the-aca/index.html (ACA designed to "[m]ake affordable health insurance available to more people").

need assistance at the pharmacy counter.[17] At that time, 340B covered entities made less than $6 billion in purchases under the program.[18]

Then, as now, a small fraction of the covered entities, 340B disproportionate hospitals, were the recipients of almost 80% of the subsidies generated by the program.[19] Despite their often massive size, resources, and 340B subsidies, most disproportionate share hospitals had charity care rates that failed to even meet the national average.[20] The picture was not any better for all 340B hospital types, whose charity care ratios was a disappointingly low 2.60%.[21]

For those who advocated for the ACA, including patient advocates, the hope and expectation was that, with the expansion of the program, covered entities, particularly 340B hospitals, would significantly expand their commitment to patients in need, including those at the pharmacy counter. That was a central part of Congress' plan to bring more affordable health care to the uninsured and the underinsured.

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[17] S. Thomas, *et al.,* Health Services Research, "The Unintended Consequences of the 340B Safety Net Drug Discount Program", 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).

[18] S. Wright, "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program", OEI -05-13-00431, U.S. Department of Health and Human Services, Office of the Inspector General (Feb. 4, 2014) (finding a bit more than $7 billion in 340B sales in 2013, after the program had begun to expand following the passage of the ACA).

[19] *See* Adam J. 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.

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

[21] Pioneer Institute, Hospital Charity Care, available at https://pioneerinstitute.org/340babuse/hospital-charity-care/ (last visited Feb. 7, 2025) (2011 figures).

C. As 340B Profits Burgeoned, Charity Care Ratios Fall

Fast forward to now, fifteen years after the ACA was enacted, and the intervening years tell a very sad tale of a program that has exploded, without any demonstration of any corresponding benefit in the level of charity care the uninsured and underinsured receive.

There can be no legitimate dispute that the 340B program's growth has been dramatic. By HRSA's own calculation, the program now involves $66 billion in heavily discounted purchases on an annual basis.[22] That is at least 11 times the size of the estimate program in 2010. Those heavily discounted drugs now have a list price value of $124 billion, [23] a figure that likely understates, quite significantly, the true reimbursement value of the drugs.[24] In other words, the 340B program provides now on the order of $58 billion[25] (or more) in yearly subsidies.

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[22] Adam 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), https://bit.ly/4fhCnwP.

[23] R. Martin, et al., IQVIA, *The 340B Drug Discount Program Grew to $124B in 2023* (May 10, 2024), available at https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-grew-to-$124b-in-2023 (last visited Feb. 7, 2025).

[24] That is the case, in no small measure, because 340B hospitals mark up their drugs enormously in selling to commercial, employer, and Medicare payors. *See* Aimed Alliance, "Study Finds 340B Hospitals Significantly Markup Infusion Drugs", available at https://aimedalliance.org/study-finds-340b-hospitals-significantly-markup-infusion-drugs/ (last visited Feb. 7, 2025) ("Specifically, markups for some commonly administered infusion drugs were 6.59 higher at 340B hospitals than at independent doctor practices, and 4.34 times higher than at non-340B hospitals."); *see also* J. Robinson, *et al.,* "Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance", N Engl J Med 2024;390:338-345, DOI: 10.1056/NEJMsa2306609 (January 24, 2024) (cited in the Aimed Alliance article).

[25] *Compare id.* (list value of 340B purchases equaling $124 billion), *with* HRSA, *2023 340B Covered Entity Purchases* ($66 billion in acquisition costs in 2023, creating a "spread" estimate of $58 billion), available at https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases (last visited Feb. 7, 2025); *see also* Eleanor Blalock, BRG, *Measuring the Relative Size of the 340B Program; 2020 Update*, at 7 (June 2022), https://media.thinkbrg.com/wp-

Cruelly, even as vulnerable patients' need for drug therapies permitted covered entities, particularly 340B hospitals, to increase their 340B profits by billions and billions of dollars, those 340B hospitals not only failed to increase their percentage commitments to charity care, they dramatically *decreased* their charity care ratios. Even as the 340B program expanded and expanded and expanded, providing billions more in subsidies, 340B hospitals' charity care ratios plummeted. By 2022, the last year for which those charity care data are available, 340B hospital charity care had fallen from 2.60%, in 2011, to 2.15%. That is almost a 20% drop, even as 340B program purchases increased by 1,000%.[26] Those increased purchases brought massive new opportunities to profit on the "spread" between the low acquisition prices and the reimbursement value of those drugs, but with no corresponding increase in charity care, including at the pharmacy counter.

One of the Amici Curiae here, ADAP Advocacy, has produced a "340B Map" that drills down on this disturbing problem.[27] The map shows, for a wide cross-section of covered entities, including a number of 340B hospitals, growth in 340B revenues and, in many cases, a simultaneous fall in charity care ratios. Johns Hopkins University Hospital, for example, has seen a 329% increase in its 340B revenues, taking its total revenues over a billion dollars, while its charity care ratio has fallen by 21% in the same period. Sutter Valley Hospitals, one of the largest hospital

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content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf. (analyzing the delta in list to acquisition price for 2020).

[26] Many hospitals have charity care ratios way below even these low averages, however. UMass Medical Center, for instance, according to Pioneer Institute, had a charity care ratio of just 0.95% in 2022. *See* Pioneer Institute, Hospital Charity Care, Massachusetts (2022), available at https://pioneerinstitute.org/340babuse/hospital-charity-care/ (last visited Feb. 7, 2025).

[27] ADAP Advocacy, 340B Map, available at https://340bmap.org/mapster-wp-map/340b-map/ (last visited Feb. 7, 2025).

systems in the country, has seen a 259% increase in 340B revenues, part of its total revenues that now exceed $16 billion annually, while its charity care ratio has fallen by 72%. Sutter's chief executive officer compensation has increased 1,133%.

The *New York Times* recently reported on a patient example that, rather shockingly, illustrates the problem.[28] Virginia King, a metastatic breast cancer patient, sought drug therapy from Christus St. Vincent, a 340B hospital. The manufacturer list price for the drug, before the 340B discount to the hospital, was $2,700.[29] The hospital billed Mrs. King's insurer $22,700, 8.4 times the list price of the drug, even without considering the 340B discount.[30] Although Mrs. King's insurer paid $10,000 on the claim, almost 4 times the list price of the drug, Christus St. Vincent billed her, in addition, for $2,500, itself almost the entire list price of the drug. It did so without offering her any charity care.[31] To add insult to injury, Christus St. Vincent subsequently sent her to collections. When Mrs. King switched to a non-340B provider with *no* 340B subsidies, her patient "responsibility was nothing". Christus St. Vincent defended itself by claiming, in part, that the 340B program "helped the hospital provide charity care", but a review of its charity care reveals that its ratio was just 1.95%, below even the embarrassingly low national average.[32]

The history of the 340B program is, unfortunately, a story of a well-intentioned program that has lost its way. Clearly designed to bring affordable health care to patients in need, including

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

[29] *Id*.

[30] *See id.*

[31] *Id.*

[32] Pioneer Institute, Hospital Charity Care, New Mexico (2022), available at https://pioneerinstitute.org/340babuse/hospital-charity-care/ (last visited Feb. 7, 2025).

by virtue of its expansion at the time of the enactment of the ACA, the 340B program has grown at a break-neck pace without any corresponding benefit to patients in charity care, including assistance at the pharmacy counter.

D. 340B Growth Drivers

What drove the dramatic expansion of the program? Contract pharmacies were certainly a significant part of that story. 340B contract pharmacy relationships have increased exponentially from roughly 1,300 in 2010 to more than 33,000,[33] an increase of 2,200%. Disappointedly, many of those contract pharmacies are located in affluent neighborhoods.[34] Of the more than 33,000 340B contract pharmacy relationships used by covered entities, only 35% are located within a medically underserved location.[35] The all too clear message is that too many 340B covered entities care much more about creating new opportunities to make more money from the program than to address access issues for the needy who so often live in pharmacy desserts.

Worse yet, contract pharmacy arrangements do a very poor job of providing needy patients meaningful access to affordable drugs, underscoring why the Amici Curiae are so concerned that patients are not sharing adequately in the dramatically reduced prices at which covered entities are

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[33] Adam Fein, *Hospitals Are Relying More on PBMs to Manage Manufacturers' 340B Contract Pharmacy Restrictions*, Drug Channels (Oct 2, 2024), available at https://www.drugchannels.net/2024/10/hospitals-are-relying-more-on-pbms-to.html (last visited Feb. 7, 2025).

[34] R. Conti, *et al.*, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 Health Affs. 1786 (2014), https://bit.ly/3ZFC9uP

[35] AIR340B, *340B – A Missed Opportunity To Address Those That Are Medically Underserved: 2023 Update* (2023), https://bit.ly/4eDzyG1 (65% of covered entities themselves not located in medical underserved areas).

able to purchase drugs under the program.[36] Despite the massive growth in the 340B program, only 1.4% of contract pharmacy patients can be shown to have received any assistance at the contract pharmacy counter.[37] That is even below the abysmally low 340B hospital charity care rate of 2.15% in 2022.[38] But 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.[39] A 1.4% level of assistance at the pharmacy counter seems indefensible in light of the billions and billions generated by the 340B program and this level of need.

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 in connection with pharmaceutical items and services. Specifically, these entities, which account for no more than 20% of the program, are obligated under those grants to provide "sliding scale" assistance to patients at 200% of the federal poverty limit or below.[40] That, coupled with the low rate of

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[36] R. Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* (Aug. 30, 2024), available at https://bit.ly/3XFDWh8.

[37] R. Martin, *et al.,*IQVIA, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, 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 (last visited Feb. 7, 2025).

[38] Pioneer Institute, Hospital Charity Care, available at https://pioneerinstitute.org/340babuse/hospital-charity-care/ (last visited Feb. 7, 2025).

[39] Commonwealth Fund, "The State of Health Insurance Coverage in the U.S." (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# (last visited Feb. 7, 2025).

[40] U.S. Department of Health and Human Services, HealthCare.Gov, "Federal Poverty Limit", available at https://www.healthcare.gov/glossary/federal-poverty-level-fpl/ (last visited Feb. 8, 2025). Only 28% of the US population was ineligible to receive any assistance under this

identified assistance at contract pharmacies, goes a long way towards showing why so many patients continue to struggle with coinsurance and other out of pocket costs for their drug therapy.

The 340B program is broken, and the root cause is a lack of transparency about what persons 340B entities are claiming as their patients and whether they are receiving charity care at the pharmacy counter. These are issues that a rebate model can address. All of this is not to say that there aren't many covered entities that do, in fact, provide meaningful charity care and assistance to the vulnerable at the pharmacy counter. But those covered entities that do the right thing are themselves harmed by the lack of transparency that mars the program at present and protects those that fail to do right by patients.

E. Plaintiff's Proposed Model

As patient advocates, Amici Curiae appreciate that Plaintiff's plan is to move forward in a patient-centric, targeted manner. Although its proposal would apply to all entity types, it is, at least initially, limiting its program to a single drug that is subject to Inflation Reduction Act ("the IRA") mandated pricing. Complaint at ¶ 57, 59. Clearly, there needs to be a functional means to ensure that IRA/340B duplicate discounts do not complicate an already disturbing level of duplicates and defeat IRA implementation, and the rebate model is that means.[41] Further, Plaintiff

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standard. Kaiser Family Foundation, "Distribution of the Total Population by Fed3eral Poverty Level", available at https://www.kff.org/other/state-indicator/population-up-to-200-fpl/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Feb. 7, 2025).

[41] Because of the differences between 340B hospitals and some other covered entities, like clinics serving HIV and AIDS patients, Amici Curiae appreciate that, in deploying rebate mechanisms, manufacturers have taken such steps as designing rapid payment turn-arounds, considering even faster payments where a covered entity commits to share 340B pricing with patients, carving out some entity types, or limiting the drugs involved. Given their overwhelming dominance of the 340B program, *see* HRSA, *2022 340B Covered Entity Purchases*, available at https://bit.ly/3Y1GQ17, the conduct of 340B disproportionate hospitals is a particular source of concern.

commits to providing payment under its rebate model in "no more than seven to days" and, most importantly, will make payment "even faster" if covered entities agree[] to share the 340B price with the patient". *Id*. This important design feature begins to open the door to the rebate model's potential to make drug therapy more affordable for needy patients—exactly what the program was intended to do. Finally, under a rebate model, HRSA would, of course, retain its enforcement mechanisms and could appropriately pursue rebate systems should they be structured effectively to provide no "bona fide offer" of 340B pricing.[42]

ARGUMENT

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

In a program that has lost its way, the rebate model is a mechanism to ensure fair and equitable transparency in all directions, including for patients who seem to be losing access to charity care, both at the pharmacy counter and elsewhere, even as the program expands and expands, bringing additional billions to both covered entities and to "middlemen" who are absolutely not the intended beneficiaries of the program.

A rebate model can, and should, give covered entities transparency into manufacturer concessions, ensuring that covered entities know that they are, in fact, receiving the price they should. It should, similarly, allow manufacturers a means of having confidence, when they make the 340B price available, that they are not paying duplicate discounts or being targeted by diversion schemes. For the states, the rebate model can be a means to guard against improper Medicaid

[42] *See Novartis,* 102 F.4th at 455.

payments, conserving badly needed Medicaid resources meant to provide medical care to the indigent and disabled.

Finally, a rebate model can, and should, allow patients to understand whether they are receiving any part of the benefit of 340B pricing at the pharmacy counter. That is tangibly the case here because Plaintiff promises to pay rebates to covered entities "even faster" than "seven to ten days" if a covered entity simply agrees to "share the 340B price directly with the patient".[43] This is exactly how the 340B program was intended to serve the interests of the underinsured and the uninsured. Working in collaboration with all stakeholders, we can improve the ability of patients to share meaningfully in 340B discounts, but still allow covered entities to receive very substantial subsidies beyond that patient sharing.

The rebate model lies at the absolute heart of that effort, and HRSA should not be permitted to stand in the way of that step forward.

II. PLAINTIFF'S MODEL IS A BONA FIDE OFFER COMPLETELY CONSISTENT WITH THE STATUTE.

In *Novartis*, 102 F.4th at 455, HRSA asserted an authority (the ability to forestall any contract pharmacy limitations) based on a statutory power it does not have. The US. Court of Appeals for the District of Columbia Circuit struck down HRSA's "atextual and ahistorical position" because the manufacturer offers there were "bona fide". *See id.* That holding is controlling here, where HRSA's "pre-approval" authority is yet another "atextual and ahistorical" deviation from the statute designed to override another "bona fide" offer.

[43] Complaint at ¶ 57.

It is a high bar for HRSA to demonstrate that an offer is not bona fide. That standard is met where a manufacturer asserts "conditions … onerous enough to effectively increase the contract 'price'" so as to set it "above the statutory ceiling". *Id.* at 46. That is clearly not the case here.

Whether Plaintiff effectuates the correct price by a "rebate or discount", Plaintiff's model, as presented, quite clearly effectuates the correct price, and there are no "unreasonable conditions" present. *Id*. The proposed rebate model initially applies to only one drug, which is subject to the Inflation Reduction Act and, as such, requires some functional means of avoiding a circumstance where the manufacturer is unlawfully asked to provide duplicate IRA-negotiated pricing and 340B pricing on the same drug at the same time.

Beyond that, Plaintiff's rebate model is contingent on rapid payment in "no more than seven to ten days". The "carrying costs" for any drug over so short a period would be a sliver of the lucrative financial opportunity covered entities have under the program. As the Minnesota 340B Report shows, 340B revenue above covered entity acquisition costs is at least 42%. *See* Minnesota Department of Health, 340B Covered Entity Report (Nov. 15, 2024). But, even more fundamentally, covered entities will often incur no carrying costs at all because, in many cases, they will receive payment from Plaintiff before the covered entities themselves are obligated to pay their wholesalers for their drugs.

In addition, the data that would be requested under the rebate model is not burdensome because that information is already collected by 340B entities in the normal course of their operations as 340B entities and in their health care billing operations. Indeed, covered entities cannot lawfully participate in the 340B program without collecting the data at issue, which they routinely send to their "own third party administrators" to develop a basis for "cataloging"

patients in order to capture the reimbursement spread. *See Novartis*, 102 F.4th at 457-58. Those "administrators", which include affiliates of some of the largest and most sophisticated entities in health care, are able to efficiently transmit all the necessary data to manufacturers.

On these facts, it would be the height of "arbitrary and capricious" conduct for the Secretary to refuse to recognize bona fide rebate offers actually "paid" within just "seven to ten days" (or even less) of the triggering "purchase". This is particularly true because that speed in the payment of rebates is much faster than the 30 to 90 days that usually applies for rebates paid to other customers.[44] Thus, HRSA rather absurdly rejects *preferential* treatment for covered entities *vis-à-vis* other rebate customers.

In this regard, Plaintiff is right to hammer away at the point that it is setting a faster standard than the Centers for Medicare and Medicaid Services, a sister agency to HRSA, set even in the unusually expedited Medicare negotiated price context under the IRA (14 days). HRSA's refusal to recognize payments made within "no more than seven to ten days" simply cannot be squared with either *Novartis*' "bona fide offer" test or with the recently (government) formulated IRA standard.[45]

Accordingly, this court should grant Plaintiff's Motion for Summary Judgment, as the rebate model is a bona fide offer, the only thing that the statute requires.

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[44] D. Bell, "Rebates at the Point of Sale", *The Actuary* (May 2020), available at https://www.theactuarymagazine.org/rebates-at-the-point-of-sale/ (last visited Feb. 7, 2025).

[45] *Novartis*, 102 F.4th at 455.

III. THE PLAIN LANGUAGE OF THE STATUTE SPECIFICALLY AUTHORIZES REBATES, AND HRSA IS WITHOUT ANY AUTHORITY TO PRECLUDE THEM.

The plain language of the statute demonstrates that (1) rebates are specifically authorized and that the Secretary has no rebate "pre-approval" authority, (2) the Secretary's reading of the "as provided by the Secretary" language is completely at odds with the structure of the statute, and (3) the Secretary's interpretation is arbitrary and capricious and would result, inevitably, in absurd, counter-textual outcomes. We take each of these points in turn, appreciating that we must begin the statutory analysis "with the plain language of the statute.'" *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009).

A. The Plain Language of the Statute Clearly Demonstrates that Rebates Are Specifically Authorized, without any "Pre-Approval" by the Secretary.

Starting, as we must, with the text, it is important to stress two interrelated, critically important threshold points: (1) what the plain language of the statute says and (2) what it does not say.[46]

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) (emphasis added). The plain language of the statute, thus, states that there are two parts to assessing what a manufacturer has actually "paid": "rebates", on the one hand, and "discounts" on the other. *Id*. That clear textual signal that both "rebates" and "discounts" are specifically (and equally) authorized is reinforced by the broad framing of the word "any" that precedes both. Further, beyond that, the statute refers *first* to "rebate" and only second to

[46] After making these initial points, we will return, with the context established, to the ", as provided by the Secretary" language.

"discount", indicating, if anything, that the "rebate" mechanism was the one *primarily* invoked by Congress.[47]

Beyond what the statute says, it is equally important to observe that it quite emphatically does not say, as the Secretary seems to suggest, that a rebate must be "approved" before it is deployed. The word "approve"—or any variation of it—is wholly absent from the statute here. *See id.* The Secretary, in pressing for a "pre-approval" power, is quite literally attempting to insert a word into the statute that is not there, while simultaneously trying to eliminate words that are clearly there ("any rebate"). The Secretary's reading, as a consequence, is doubly wrong.

If Congress had intended to create an "approval" power, it would have clearly said so. It could quite easily have said, for instance, 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 more than three decades.[48] That's not surprising—because no such power exists.

B. The Structure of the Statute Is Formed by the Distinction between the "Ceiling Price" and the "Amount Required to Be Paid".

To understand what the phrase "as provided by the Secretary" means (and does not mean), it is important to focus on the structure of the statute, which addresses two different

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[47] Although it is unnecessary to consider legislative history here, because the plain language of the statute demonstrates that the Secretary's position must be rejected, the legislative history contemplates "reductions (*whether through a discount, rebate, or other mechanism*) to these 'covered entities' on covered outpatient drugs." H.R. Rep. No. at 12 (emphasis added).

[48] 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.

things: (1) the calculation of the "ceiling price" and (2), separately, the "account[ing]" for the "amount required to be paid". 42 U.S.C. § 256b(a)(1)-(2).

There is, first, as a temporal matter under the statute, the task of calculating the "ceiling price", the target that must be hit in order for the statutory requirement to be satisfied. The statute speaks to this part of the equation by stating that the "ceiling price", the target, is "equal to the average manufacturer price", a defined term under the Medicaid rebate program, "in the preceding calendar quarter, reduced by the rebate percentage", which is "described in paragraph (2)". *Id.* The targeted "ceiling price" is calculated, as a matter of timing, first and "furnish[ed]" to the Secretary in "reports". *Id.*

Second, after a ceiling price is calculated, reported, and the stakeholders have chosen the means they think best—"rebate or discount"—to effectuate that ceiling price, there must be an "accounting" of the "amounts … paid", as the drug flows through various entities in the distribution chain until it reaches the covered entity. *Id*. In other words, "any rebate or discount" that is paid must be subject to evaluation to determine that those "amounts" actually were "paid" such that the "ceiling price" target was satisfied. *Id*.

An example will illustrate. In our example, the 340B ceiling price, as calculated and reported to the Secretary for a drug, is $100. The manufacturer initially sells the drug at a $200 list price to a distributor, the first entity in the distribution chain. The drug maker offers $15 at that time to the distributor, thinking that $10 will be passed on to the subsequent purchaser, as a base discount, whether the purchaser is a 340B entity or not. Thereafter, in a case where the product is, in fact, purchased by a covered entity, the manufacturer extends a further $90

"rebate" to that entity, payable, like in Plaintiff's model, in "no more than seven to ten days" of the covered entity's triggering "purchase".

Contrary to the manufacturer's intent, however, the distributor charges the covered entity $195, passing only $5 of the initial $15 to the covered entity, not $10. Thus, the covered entity has, unknown to the manufacturer, been charged a net price of $105 ($200-$5-$90), not the "ceiling price" of $100.

This is where the "as provided by the Secretary" language applies. If the covered entity complains to the agency that it did not actually receive the "amount required to be paid", the Secretary may determine that "amount" by "taking into account any rebate or discount" actually paid. *Id*. The Secretary "provide[s]" for "any rebate or discount" *actually* transferred to the covered entity, but she will not "provide[]" for any amount that is *not* actually passed to the covered entity. *Id*.

The language that the Secretary misreads to supposedly entitle her to read the word "rebate" entirely out of the statute only, in fact, addresses this potential "account[ing]" issue. It is no accident that the entire parenthetical "(taking into account any rebate or discount, as provided by the Secretary)" modifies the phrase "the amount required to be paid". *Id.* The "provided" language is about the "amount" of a "rebate or discount" for payment evaluation purposes, not the question whether either a "rebate or discount" may be used as a mechanism. *See id*.

Said another way, the statute directs the Secretary to "provide" for "any rebate or discount" in "account[ing]" for the "amounts" actually "paid". It gives the Secretary no power at all to foreclose rebates as an acceptable *means* of ensuring that the correct "amount" is "paid", no more than it could "pre-approval" discounts into oblivion. The statute specifically authorizes

stakeholders to select "any rebate or discount", without interference. But, if the "rebate or discount" does not actually make it to the covered entity, the statute permits the Secretary to address that "amount" question.

C. It Would be Arbitrary and Capricious for the Secretary to Disregard Rebates Actually Paid to Covered Entities.

Courts must seek a "sensible construction [of a statute] that avoids . . . an absurd conclusion." *United States v. Granderson*, 511 U.S. 39, 56 (1994) (internal quotations and citation omitted); the Secretary effectively urges this court to disregard that basic tenet of statutory interpretation in arguing that she can simply disregard "rebates" categorically when "offered" by a manufacturer. The Secretary's position is arbitrary and capricious for at least three reasons.

First, as *Novartis*, 102 F.4th at 455, made clear, all that a manufacturer is required to do under the statute is to make a "bona fide offer" at the ceiling price. If funds actually offered to a covered entity in the form of a rebate are categorically ignored by the Secretary, the Secretary has exceeded her authority by requiring not just a "bona fide offer", but by demanding an offer in a form dictated by the Secretary. That the Secretary cannot do, as she would be fundamentally rewriting the nature and scope of the statutory "offer" obligation. The *Novartis* decision was crystal clear that in the absence of truly "onerous" conditions any bona fide offer is completely sufficient to satisfy the statutory obligation. *Id.*, at 462.

Second, refusing, particularly on a categorical basis, to recognize "any rebate" would be fundamentally inconsistent with the Secretary's obligation to "provide" for "any rebate" that is, in fact, "paid" to the covered entity. 42 U.S.C. § 256b. In such a case, the Secretary would have stretched the words "taking into account", "paid", "any rebates or discounts", and the obligation

to "provide[]" for them beyond the text or the structure or the purpose of the statute. The Secretary at that point would be refusing to apply basic math to a set of transactions and then saying that the absurd result that follows is what Congress intended.

Third, pretending that rebates actually paid do not contribute to the "amount required to be paid" would lead to an absurd outcome that is specifically *not* authorized by statute. The statute is clear on its face that a manufacturer, though required to make an "offer" at the ceiling price, is in no way obligated to allow covered entities to purchase at any price *below* that figure. *See* 42 U.S.C. § 256b(a)(1). But if the Secretary can disregard rebates actually provided to covered entities, that is exactly what would follow. Returning to our example from above, if the $90 rebate actually paid can be disregarded simply because it is in the form of a "rebate", the Secretary could force an entirely duplicate $90 payment, and a manufacturer, contrary to the clear intent of the law, would be forced to pay a subceiling price that far exceeds the statutory obligation.

The Secretary's interpretation of the statute is triply arbitrary and capricious and leads, inevitably, to absurd results.

CONCLUSION

For these reasons, Plaintiff's motion for summary judgment should be granted. The time to permit transparency in the 340B program has come. It is not possible, without a transparent system, to separate those that put the patient first, from those that do not. Patients need a rebate model now, and HRSA has no authority to stop this badly needed step forward.

Dated: February 10, 2025

Respectfully submitted,

/s/

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Local Rule 7 and Federal Rule of Appellate Procedure 29(a)(4), because it does not exceed 25 pages and uses 12-point Times New Roman font.

Dated: February 10, 2025

/s/_____
William A. Sarraille

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing will be served this 10th day of February, 2025, electronically through the Court's CM/ECF system on all registered counsel.

/s/_____
William A. Sarraille