ORAL ARGUMENT NOT YET SCHEDULED
Nos. 25-5177, 25-5179, 25-5220, 25-5221, 25-5236

United States Court of Appeals for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, *et al.*,
Plaintiff-Appellants,
v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*,
Defendants-Appellees,

340B HEALTH, *et al.*,
Intervenors-Defendants-Appellees.

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 THE AMERICAN HOSPITAL ASSOCIATION, NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS, INC., D/B/A CHILDREN'S HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND AMERICA'S ESSENTIAL HOSPITALS, AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT PURSUANT TO CIRCUIT RULE 26.1

Amici Curiae the American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals are non-profit "trade associations" within the meaning of D.C. Circuit Rule 26.1(b). They have no parent corporations and do not issue stock.

The **American Hospital Association** represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations across the country. Its members are committed to improving the health of the communities they serve and to helping ensure that affordable care is available to all Americans.

The **National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association** is the national voice of more than 220 children's hospitals. It advances child health through innovation in the quality, cost, and delivery of care in children's hospitals.

The **Association of American Medical Colleges** is dedicated to improving the health of people everywhere through medical education, healthcare, medical research, and community collaborations. Its members include all 160 LCME-accredited medical schools; nearly 500 academic health systems and teaching hospitals; and more than seventy academic societies.

America's Essential Hospitals is dedicated to high-quality care for all people, including those who face social and financial barriers. Consistent with this mission, the association's more than 350 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of patients uninsured or covered by Medicare or Medicaid.

/s/
Chad Golder

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant To Circuit Rule 28(a)(1), undersigned counsel for *Amici* hereby certifies as follows:

A. Parties and Amici

Except for the following, all parties, intervenors and *amici* appearing before the district court and in this Court are listed in the Brief for Plaintiffs-Appellants:

ADAP Advocacy Association, Inc.;
Advocates for Compassionate Therapy Now;
America's Essential Hospitals;
American Hospital Association;
Arizona Hospital and Healthcare Association;
Arkansas Hospital Association;
Association of American Medical Colleges;
Biotechnology Innovation Organization;
California Hospital Association;
CF United;
Colorado Hospital Association;
Community Oncology Alliance, Inc.;
Connecticut Hospital Association;
Delaware Healthcare Association;
Florida Hospital Association;
Georgia Hospital Association;
Greater New York Hospital Association;
Healthcare Association of Hawaii;
Healthcare Association of New York State;
Hospital Association of Oregon;
Hospital and Healthsystem Association of Pennsylvania;
Idaho Hospital Association;
Illinois Health and Hospital Association;
Indiana Hospital Association;
Iowa Hospital Association;
Johnson & Johnson Health Care Systems Inc.;
Kentucky Hospital Association;

Louisiana Hospital Association;
Manufacturers of America;
Massachusetts Health & Hospital Association;
Michigan Health & Hospital Association;
Mississippi Hospital Association;
Missouri Hospital Association;
National Alliance for Healthcare Purchaser Coalitions;
National Association of Children's Hospitals, Inc.
d/b/a Children's Hospital Association;
New Jersey Hospital Association;
New Mexico Hospital Association;
North Carolina Healthcare Association;
North Dakota Hospital Association;
Ohio Hospital Association;
Oklahoma Hospital Association;
Pharmaceutical Research and California Hospital Association;
Pharmaceutical Research and Manufacturers of America;
Tennessee Hospital Association;
Texas Hospital Association;
Vermont Association of Hospitals and Health Systems;
Virginia Hospital & Healthcare Association;
Washington Legal Foundation;
Washington State Hospital Association;
West Virginia Hospital Association;
Wisconsin Hospital Association; and,
Wyoming Hospital Association.

B. Rulings Under Review.

Reference to the rulings at issue appear in the Brief for Defendants-Appellees.

C. Related Cases.

Reference to the related cases appear in the Brief for Defendants-Appellees.

/s/
Chad Golder

STATEMENTS PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29 AND CIRCUIT RULE 29

Pursuant to Federal Rule of Appellate Procedure 29, counsel states that all parties consented to the filing of this brief. No party's counsel authored any part of this brief, and no person other than *Amici* funded its preparation or submission.

Pursuant to Circuit Rule 29(d), *Amici* state that a separate brief is necessary because the American Hospital Association, the Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals have members that receive 340B discounts, and so *Amici* have extensive and unique knowledge of issues related to the 340B Program. The unlawful rebate policies at issue in this appeal will grievously harm those hospitals and the patients they care for. *Amici* therefore have a strong interest in preserving the Health Resources and Services Administration's lawful decision to reject those rebate policies, so that *Amici*'s members can continue to provide high-quality, affordable medical care to their vulnerable patients and communities.

TABLE OF AUTHORITIES

Cases

* Authorities upon which we chiefly rely are marked with an asterisk.

Statutes

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GLOSSARY

ADR	Administrative Dispute Resolution
AHA	American Hospital Association
CFTC	Commodity Futures Trading Commission
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IRA	Inflation Reduction Act
LCME	Liaison Committee on Medical Education

STATUTES AND REGULATIONS

Pursuant to Circuit Rule 28(a)(5), all relevant statutes and regulations are contained in the Brief for Plaintiffs-Appellants.

STATEMENT OF INTEREST

Amici are hospital associations whose members receive 340B discounts. Appellants'[1] rebate policies will harm those hospitals and the patients they care for. *Amici* therefore have a strong interest in preserving the Health Resources and Services Administration's lawful decision to reject those rebate policies, so that *Amici*'s members can continue to provide high-quality, affordable care to their patients and communities.

The **American Hospital Association** represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations across the country. Its members are committed to improving the health of the communities they serve and to helping ensure that affordable care is available to all Americans.

The **Children's Hospital Association** is the national voice of more than 220 children's hospitals. It advances child health through innovation in the quality, cost, and delivery of care in children's hospitals.

The **Association of American Medical Colleges** is dedicated to improving the health of people everywhere through medical education, healthcare, medical research, and community collaborations. Its members include all 160 LCME-

[1] *Amici* understand that this Court prefers the use of party names and disfavors the use of "Appellants." In this consolidated five-appellant appeal, we hope that the use of "Appellants" provides sufficient clarity.

accredited medical schools; nearly 500 academic health systems and teaching hospitals; and more than seventy academic societies.

America's Essential Hospitals is dedicated to high-quality care for all, including those who face social and financial barriers. Consistent with this mission, the association's more than 350 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of patients uninsured or covered by Medicare or Medicaid.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is about an undisguised power grab. Appellants make no secret of their belief—hyperbolic as it is—that there is abuse in the 340B program. They make no secret of their belief that the Health Resources and Services Administration has not taken sufficient action to address this alleged abuse. They make no secret of their belief that the Centers for Medicare & Medicaid Services has not given the guidance they prefer for how to reconcile the 340B Program and the Inflation Reduction Act. And most important, they make no secret of their belief that they must now take the law into their own hands to fix all of this with their rebate policies. Appellants' motives and intentions do not "come before the Court clad, so to speak, in sheep's clothing." *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting). "[T]his wolf comes as a wolf." *Id*.

Amici appreciate that Appellants do not hide why they seek to engage in this self-help.[2] Appellants are far less frank about the consequences of their rebate policies. As these companies seek to boost their profits, these policies will devastate safety-net hospitals, vulnerable patients, and the struggling rural and urban communities they serve. In that respect, this case is not just about a power grab—it's also about a money grab.

But regardless of Appellants' motives, one thing is pellucidly clear: their rebate policies are "incompatible" with the 340B statute. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). The district courts correctly held that Appellants may not implement rebate models without HRSA's approval. But the 340B statute also makes plain that Appellants may not engage in "private enforcement" through their proposed rebate models. *Id*. at 119 n.4 (quotation marks omitted). As explained below (at 8-9), the Court can and should decide this case on this independent legal ground.

The text, structure, history, and purpose of the 340B statute reveal a carefully calibrated regime in which "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned *no auxiliary enforcement role* to" program

[2] *E.g.*, JA 204, 213, 220, 226 (Novartis Compl. ¶¶ 2, 34, 51, 52, 66); JA 132, 136, 143, 146 (BMS Compl. ¶¶ 5, 23, 45, 53); JA 89, 91, 104 (Lilly Compl. ¶¶ 1, 8, 10, 65); JA 160-61, 170, 173, 178 (Kalderos Amended Compl. ¶¶ 3, 4, 41, 49, 61); JA 1083, 1085, 1086, 1099, 1112 (J&J Compl. ¶¶ 1, 8, 11, 45, 48, 83, 84). Appellants' Br. 2, 4, 16 (arguing that the 340B Program is "plagued by massive levels of acknowledged fraud and abuse" and that their rebate models are intended to "tackle these" "program-integrity problems").

participants. *Id.* at 117 (emphasis added). Congress also did not permit drug companies to demand what are, effectively, *ex ante* audits in exchange for providing discounts that are owed under the 340B statute. And, ultimately, Congress did not permit drug companies to refuse 340B pricing, in their sole discretion, based on their subjective determination of program compliance.

For good reason. These rebate policies will be ruinous for 340B hospitals. As much as Appellants try to malign these "financially strapped, public and nonprofit safety-net hospitals," 340B hospitals treat America's most "vulnerable populations." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 840 (D.C. Cir. 2020) (Pillard, J., dissenting). They care for a significant share of the nation's children, cancer patients, and those living in rural and other underserved communities. For much of this care, 340B hospitals *never get paid*. That is why these hospitals "[o]ften operat[e] at substantial losses." *Id*. As this Court has recognized: "A congressionally mandated study of how eligible providers use [their] income from the 340B program found that [340B income] help[s] safety-net providers fund the uncompensated care they supply and expand the services they offer." *Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir. 2019) (cleaned up).

But as a bipartisan group of nearly 200 lawmakers wrote after the first rebate proposal was announced: "This unapproved and unlawful change would have severe consequences for our nation's safety net providers and the patients they serve.… A

rebate model would create significant financial challenges for safety-net hospitals." Congressional Letter to Secretary Becerra 1, 2 (Sept. 27, 2024), https://d12t4t5x3vyizu.cloudfront.net/spanberger.house.gov/uploads/2024/09/Quill-Letter-L20840-Letter-to-HHS-on-JJ-340B-Rebate-Model-Version-1-09-27-2024-@-03-08-PM.pdf. The letter further explained that the rebate model "would reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B." *Id*. at 1.

In particular, Appellants' rebate policies will dramatically erode the 340B discount that Congress intended for hospitals to receive. For starters, hospitals will be forced to advance millions of dollars to drug companies. "This approach is to the manufacturer's financial benefit because the company retains those sums for a longer time and creates hurdles for covered entities to claim the discount." *Id*. Already "operating under much lower operating margins than non-340B hospitals," *id*. at 2, 340B hospitals cannot afford to make zero-interest loans without any guarantee of when—or whether—they will be paid the discounts they are owed by law. In fact, *hundreds of hospitals* reported to *Amici* that these rebate policies could cause them to violate their bond covenants, which would lead to catastrophic financial distress and, for some, permanent closure. *See infra* at 22-23.

340B hospitals also will have to spend enormous amounts to comply with the rebate policies. These policies have no precedent in the three decades since the start

of the 340B Program. Hospitals therefore have no existing infrastructure to comply with them—let alone the many different variations and requirements across the hundreds of drug companies that could adopt them. 340B hospitals will be forced to hire new full-time employees to meet Appellants' demands, and they will have to buy new technologies to provide the required purchase data and to track the rebates they are owed. In a world of finite resources, 340B hospitals will have no choice but to divert funds away from patient services and towards burdensome compliance. All of these consequences "frustrate" the goal of the 340B statute. *NextEra Energy Res., LLC v. FERC*, 118 F.4th 361, 371 (2024).

Ultimately, this Court should bear in mind what Justice Kavanaugh wrote for a unanimous Supreme Court a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). The rebate policies shrink that already-limited funding even further, endangering the care that 340B hospitals provide for their patients and communities. But perhaps worse than anything, Appellants do so in flagrant disregard of the 340B statute. They may be dissatisfied with that law or how the Executive Branch is enforcing it, but that does not permit them to try to enforce the law themselves. Nor does it permit them to co-opt this Court in their vigilante efforts.

Objective HHS data proves that Appellants' overheated assertions about program abuse are wrong.[3] But even if they were correct, if Appellants are dissatisfied with 340B law or its enforcement, they can seek change in the political branches. But they cannot take the law into their own hands—in open defiance of the 340B statute—and seek judicial permission for their extra-legal actions.

ARGUMENT

I. The Structure, History, And Purpose Of The 340B Statute Precludes Appellants' Rebate Policies.

As the courts below correctly held, the textual arguments here are straightforward. The 340B statute, using the unambiguous phrase "as provided by the Secretary," gives HRSA the authority to approve any rebate model. 42 U.S.C. § 256b(a)(1).[4] The Pharmaceutical Pricing Agreements between HRSA and the drug companies "set[] out terms identical to those contained in the statute," and thus confer the same rebate-approval authority. *Astra*, 563 U.S. at 114.

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[3] *Compare Hospitals are complying with 340B rules, but drug companies are not* (June 16, 2025), https://www.aha.org/news/headline/2025-06-16-aha-report-hospitals-are-complying-340b-rules-drug-companies-are-not ("Duplicate discount and diversion findings in 340B hospital audits have declined significantly, reflecting very high rates of compliance in recent years."), *with* Appellants' Br. 14 (relying on outdated audit data).

[4] The legislative history reinforces this plain text. *E.g.*, H.R. Rep. No 102-384, pt. 2, at 16 (1992) ("The Committee bill does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'").

Amici focus on the structure, history, and purpose of the 340B statute because they, too, prove that Congress never intended for drug companies to take the law into their own hands to pursue their own vision of program integrity. These traditional tools of statutory construction also demonstrate that whatever comparisons the drug companies try to make with hospitals' "replenishment system" or a previous HRSA-approved rebate model for AIDS Drug Assistance Programs, the sweeping, surveillant nature of *these* rebate models is "incompatible" with "the statute Congress enacted." *Id*. at 113, 121. Put differently, the 340B statute does not bar all rebate models. It does, however, bar the models Appellants seek to impose here.

Amici offer these arguments because this Court can "affirm the District Court on any valid ground, and need not follow the same mode of analysis." *Baird v. Gotbaum*, 792 F.3d 166, 171 (D.C. Cir. 2015). And despite HRSA's current litigation position that it has not yet rejected Appellants' rebate proposals, the administrative record reveals otherwise. In its September 17, 2024 letter to Johnson & Johnson, the prior Administration offered a second basis for rejecting the rebate models, separate from the need for pre-approval. JA 455 ("This, *too,* violates Section 340B(a)(1) of the PHS Act." (emphasis added)). Specifically, in a separate paragraph of the letter, it explained that Section 340B(a)(1) bars a drug company

from deciding in its "sole discretion" whether to issue a rebate. JA 455 & n.2.[5] And contrary to the Government's present contentions (Appellees' Br. 47-48), the word "unilaterally" in *that* paragraph and footnote was not about Secretarial approval—it was about a model where rebates are "conditioned on J&J's prior approval at J&J's sole discretion." JA 455 & n.2.

Thus, for the reasons below, this Court should rely on this independent basis and hold that the 340B statute prohibits Appellants' rebate models—with or without pre-approval:

1) a decision on this separate legal ground will definitively resolve ongoing questions surrounding "rebate models," especially with HRSA having recently announced a "Rebate Model Pilot Program," *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program*, 60 Fed. Reg. 36,163 (Aug. 1, 2025);

2) Appellants may persuade this Court that a decision is ripe for review, *see* Appellants' Br. 49-54;

3) this complete legal bar to Appellants' rebate proposals necessarily resolves *all* of Appellants' APA claims; and

4) a decision on this separate legal ground is "supported by the record," *Chambers v. Burwell*, 824 F.3d 141, 143 (D.C. Cir. 2017), and the current Administration's "post hoc" abandonment of that ground during this litigation "will not suffice," *Williams Gas Processing - Gulf Coast Co., L.P. v. FERC*, 373 F.3d 1335, 1345 (D.C. Cir. 2004).

[5] J&J and Judge Contreras identified this independent basis for HHS's decision. *See* Brief for Pl., *Johnson & Johnson Health Care Sys., Inc. v. Becerra*, No. 24-cv-3188 (Dkt. 55) at 13 (D.D.C. Filed May 29, 2025) *Johnson & Johnson Health Care Sys., Inc. v. Becerra*, No. 24-cv-3188, 2025 WL 1783901, at *8 n. 8 (D.D.C. June 27, 2025).

A. Appellants' rebate policies are incompatible with the 340B statute's structure.

A statute's structure can inform its meaning. So when courts are "called on to resolve a dispute over a statute's meaning," the parties "are entitled … to have independent judges exhaust all the textual *and structural* clues bearing on that meaning." *Niz-Chavez v. Garland*, 593 U.S. 155, 160 (2021) (quotation marks omitted and emphasis added). Here, the structure and design of the 340B statute provide dispositive "clues." Specifically, the statute contains several provisions addressing audits, compliance, and dispute resolution that are incompatible with Appellants' rebate models.

These provisions send two unmistakable messages about Congress' intent for the 340B Program. *First*, Congress did not intend for participants in the 340B Program to engage in self-enforcement. Quite the contrary. The 340B statute contemplates that HHS will always have a role in enforcing program integrity requirements. Consider the following provisions:

- 42 U.S.C. § 256b(a)(5)(C) provides for audits to enforce the statute's prohibitions on diversion and duplicate discounts. It gives audit responsibility to the "Secretary and the manufacturer of a covered outpatient drug"—not the manufacturer alone. *Id.* It also gives the Secretary—and not the manufacturer—the authority to develop procedures "relating to the number, duration, and scope of audits." *Id.*

- 42 U.S.C. § 256b(a)(5)(D) relatedly provides for "[a]dditional sanction for noncompliance" with the diversion and duplicate discount provisions, but only *after* an audit is completed and only *after* the covered entity is given an opportunity for "notice and hearing." *Id.* This subsection also specifies that

the sanction will be "an amount equal to the reduction in the price of the drug," *i.e.*, *exactly what Appellants will refuse to pay up-front (without any audit, notice, or hearing) under their rebate policies*. *Id.*

- 42 U.S.C. § 256b(d)(2) directs the Secretary to "provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount." *Id.* It also specifies certain compliance improvements, including the "imposition of sanctions, in appropriate cases *as determined by the Secretary*." *Id*. (emphasis added).

- 42 U.S.C. § 256b(d)(3) formalizes a statutory ADR process with HHS playing a central role. Not only does the statute require the Secretary to "promulgate regulations to establish and implement" the ADR process, but it requires that these regulations "designate or establish a decision-making official or decision-making body *within the Department of Health and Human Services* to be responsible for reviewing and finally resolving claims." *Id*. (emphasis added).

These structural features make clear that Congress did not want drug companies to enforce 340B requirements in their sole discretion.

Critically, the Supreme Court has recognized this statutory design. As the Court held in *Astra*, Congress "centralized" 340B "enforcement in the "government," creating a "unitary administrative and enforcement scheme." 563 U.S. at 119-120 (quotation marks and citations omitted). Congress did *not* give an "auxiliary enforcement role" to participants in the 340B program. *Id*. at 117.

Appellants know this. They made this exact point in opposing 340B Health's Motion to Intervene in this case, arguing that "*Astra* forbids[] the *private* enforcement of 340B program requirements *in all forms*." Pls.' Joint Opp'n to Mot. to Intervene (Dkt. 22) at 10, *Novartis Pharm. Corp. v. Becerra*, No. 25-cv-117

(D.D.C. Filed Feb. 19, 2025) (second emphasis added and quotation marks omitted); *see id*. at 9 (quoting *Astra* twice for same proposition).

It made no difference, moreover, to the *Astra* Court that there had been various "reports of inadequate HRSA enforcement." 563 U.S. at 121. Appellants point to similar reports in this case. But in *Astra*, the Court explained that Congress was aware of those kinds of reports when it amended the 340B statute, and yet it still did not unleash program participants to go out and fend for themselves. Rather, Congress chose to reinforce the ADR process and to "strengthen and formalize HRSA's enforcement authority." *Id*. at 121-122. Thus, *Astra* holds that participants in the 340B Program—be they covered entities in that case or drug companies in this one—cannot seek to unilaterally enforce the statute themselves.[6]

Second, the 340B statute does not contemplate audits or other enforcement *before* payment at discounted pricing. The 340B statute contemplates: 1) some awareness of a past violation, which then kicks off 2) a review of completed transaction records, followed by 3) a determination and remedy by HHS, either under the ADR process, *see* 42 U.S.C. § 256b(d)(3)(B)(i), or through agency-imposed sanctions and civil monetary penalties, *see id*. §§ 256b(a)(5)(D),

[6] Congress also carefully crafted the IRA's compliance mechanisms to foreclose unilateral manufacturer enforcement. Sections 1193(a)(5), 1196, and 1197 of the IRA contain a detailed regime, empowering *the Secretary* to conduct compliance monitoring and other enforcement. As Novartis explained below, "the IRA does not provide manufacturers the right to audit covered entities to ensure they are not creating illegal MFP-340B duplicates." Pl.'s Mem. in Supp. of Mot. Sum. J. (Dkt. 12-1) at 15, *Novartis*, No. 25-cv-117 (D.D.C. Filed Feb. 3, 2025).

256b(d)(2)(B)(v). *See Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process."). Neither the audit nor the ADR process contemplates a regime where drug companies can conduct their own free-wheeling self-enforcement *before* providing 340B discounts, with the authority to refuse such pricing based on a drug company's unilateral belief that violations of the statute are occurring.

"[C]onsidered and consistent" HHS practice "buttresses" this interpretation of the statute. *Kennedy v. Braidwood Mgmt., Inc*., No. 24-316, 2025 WL 1773628, at *19 (U.S. June 27, 2025). In 1996, acting under its statutory discretion to establish audit procedures, *see* 42 U.S.C. § 256b(a)(5)(C), the Secretary responded to public comments insisting that "[m]anufacturers should not be required to continue to sell to a covered entity at the mandated price once an audit has been initiated, particularly since reasonable cause has already been demonstrated." Manufacturer Audit Guidelines and Dispute Resolution Processes, 61 Fed. Reg. 65,406, 65,408 (Dec. 12, 1996). HHS rejected that proposal:

> Manufacturers must continue to sell at the statutory price during the audit process. Once the audit has been completed and the manufacturer believes that there is sufficient evidence to indicate prohibited entity activity, then the manufacturer may bring the claim to the Department through the informal dispute process. Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from

> the covered entity list, will the manufacturers no longer be required to extend the discount.

Id.; *see Oregon Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630, at *3 (D.D.C. June 17, 2025). By denying 340B hospitals the statutory price long before the audit process has even begun, Appellants' rebate models "flout[] [several] decades of consistent [agency] understanding of" the 340B statute. *Fin. Plan. Ass'n v. SEC*, 482 F.3d 481, 490 (D.C. Cir. 2007).

Plainly, the Secretary did not want drug companies to unilaterally deny 340B discounts in advance based on generalized suspicion of prohibited activity—precisely what Appellants are now seeking to do with their rebate policies. That is what the agency reaffirmed in Footnote 2 of its September 17, 2024 letter to J&J. *See* JA 455 n.2; *Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 372-373 (D.C. Cir. 2013) ("So long as CFTC provided a reasoned explanation for its regulation, and the reviewing court can reasonably ... discern[ ] the agency's path, we must uphold the regulation, even if the agency's decision has less than ideal clarity.… CFTC's regulation clears this *low bar*." (emphasis added)). And that is why HRSA correctly determined that Appellants' proposed rebate models are inconsistent with Section 340B(a)(1).

Statutory structure matters. *E.g.*, *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014) (rejecting an interpretation that would be "inconsistent with—in fact, would overthrow—the Act's structure and design"). Here, the many structural features discussed above are incompatible with Appellants' rebate policies. Contrary

to those policies, the statute does not permit drug companies to engage in unilateral enforcement outside the statutory audit and ADR processes. Congress granted *HHS* the authority to "superintend" and "control" the 340B Program. *Astra*, 563 U.S. at 113-14. "That control could not be maintained were" hundreds of drug companies permitted to impose their own individual rebate policies. *Id*. at 114. Nor could it be maintained if *every* drug company were permitted to pre-condition payment on the surrender of *different* data depending on what *any given* company demands at *any given* time. Instead, the 340B statute and time-honored HHS guidelines set forth procedures where subjective manufacturer suspicions about diversion and duplicate discounts do not permit them to withhold discounts until purchase data is turned over or program compliance is verified. Anything else—including and especially Appellants' rebate policies—"runs contrary to how the [340B] Program is supposed to work." *Ams. for Clean Energy v. EPA*, 864 F.3d 691, 710 (D.C. Cir. 2017).

B. Appellants' rebate policies are incompatible with the 340B statute's history.

In keeping with this statutory structure and design, HHS has long and consistently interpreted the 340B statute to preclude Appellants' rebate proposals. This "agency guidance" is relevant to the analysis, and it "supports" HRSA's independent legal determination that the rebate proposals violate Section 340B(a)(1). *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024).

In 1993, HRSA sought public comment to inform its superintendence of the 340B Program, particularly with regard to the statutory bars on diversion and duplicate discounts. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68,922 (Dec. 29, 1993). Five months later, the agency issued a Final Notice stating: "A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).[7] HRSA also specifically stated that drug companies may not require hospitals to submit information about "drug acquisition" and "purchase" as a condition for 340B discounts. *Id*. at 25,113-114.[8]

[7] The only time in thirty years that HRSA exercised its statutory authority to approve a rebate model, in the narrow and distinguishable context of State AIDS Drug Assistance Programs, it reemphasized this limitation on drug company behavior. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option*, 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) ("In addition, manufacturers and covered entities are referred to 59 FR 25113 for a reminder that 'a manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions.'").

[8] Although that guidance allowed manufacturers to request "standard information," *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. at 25,113-114, there is nothing "standard" about the current demands. The term "standard information" must be understood in light of the rest of HRSA's guidance. By explicitly barring demands for "drug acquisition" and "purchase" information, "standard information" cannot include the kind of data that the drug companies now demand under their rebate policy. And if that were not enough, another portion of the Final Notice seems to equate "standard information" with "routine information necessary to set up and maintain an account." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,112. Not only did *Novartis* not consider the full text of HRSA's guidance—especially its statements regarding "drug acquisition" and "purchase" information—but unlike the policies at issue in *Novartis*, the

HHS's analysis is precisely the type of agency interpretation that can assist this Court in construing the 340B statute. "[T]he contemporary and consistent views of a coordinate branch of government can provide evidence of the law's meaning." *Bondi v. VanDerStok*, 145 S. Ct. 857, 874 (2025). Here, HHS' interpretation has remained steadfast since the earliest days of the 340B Program—including and importantly in Footnote 2 of its September 17, 2024 letter to J&J. Accordingly, as this Court "exercise[s] independent judgment in determining the meaning of statutory provisions," *id*. (quotation marks omitted), HRSA's position that drug companies cannot unilaterally condition or withhold 340B discounts on the handover of drug acquisition or purchase data should be given "great weight," *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 388 (2024) (quotation marks omitted).

Novartis Pharmaceuticals Corp. v. Johnson does not undermine HHS's interpretation of the 340B statute. Nor does it authorize the drug companies' rebate policy. *See Novartis*, 102 F.4th at 464 ("We do not foreclose the possibility that other, more onerous conditions might violate the statute."). That decision upheld a United Therapeutics policy requiring "covered entities to provide claims data associated with all 340B contract pharmacy orders to a third-party platform, to facilitate efforts to police diversion and duplicate discounts." *Id*. at 458. But United

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burden and administrative cost of *these* rebate policies are much more than "minimal." *Novartis*, 102 F.4th at 463.

Therapeutics' policy was *meaningfully different* from the current rebate policies. It dealt only with contract pharmacies and drug companies' "contractual limits on distribution." *Id*. at 462; *see also* JA 392 (distinguishing this case from *Novartis*).

The differences between these contexts are determinative. In the contract pharmacy context, *Novartis* found the statute to be silent as to distribution. *Novartis*, 102 F.4th at 460. Here, the statute includes "carefully calibrated" compliance, audit, and dispute resolution procedures that do not permit unilateral drug company enforcement. *Id*. at 462. In the contract pharmacy context, drug companies and HRSA could *not* audit those pharmacies because the 340B statute does not provide for audits of third parties. Here, drug companies *can* audit 340B hospitals, provided they follow the appropriate processes. These distinctions are dispositive, as they directly implicate the textual and structural features discussed above that are incompatible with the rebate model.

More fundamentally, the scope of the rebate policies at issue here, and the consequences to hospitals for violating them, are even more drastic than anything at issue in *Novartis*. United Therapeutics' policy did not deny 340B discounts to hospitals altogether. It refused to sell *only to contract pharmacies* if data was not provided. *See* Pl.'s Compl. (Dkt. 1) Ex. 3 at 6, *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686 (D.D.C. Filed June 23, 2021). A hospital still could obtain 340B pricing if it distributed a drug from its in-house pharmacy. Here, the rebate

policies would *completely deny* hospitals their 340B discounts if those covered entities refuse to surrender important purchase data or assure program compliance.

It is not too much to say that Appellants' rebate policies, unlike United Therapeutics' policy, strike at the heart of the 340B Program. Not merely addressing where 340B drugs can be sold, the rebate policies touch on the core function of the Program—whether 340B discounts are provided at all. This runs headlong into HRSA's three-decade-old ban on drug companies conditioning 340B discounts on their own satisfaction about a covered entity's compliance or the handover of purchase data. Because *Novartis* adjudicated a far narrower set of drug company conditions, it has no bearing on the rebate policies at issue here.

C. Appellants' rebate policies are incompatible with the 340B statute's purpose.

Purpose also can be relevant to statutory interpretation—particularly where, as here, it aligns with the statute's text, structure, and history. *See United States v. Griffin*, 119 F.4th 1001, 1025 (D.C. Cir. 2024) ("We reject Griffin's reading, which is so squarely at odds with that clear purpose."); *Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014). Of course, "even the most formidable argument concerning the statute's purposes could not overcome the clarity ... in the statute's text," *Kloeckner v. Solis*, 568 U.S. 41, 55 n.4 (2012), and "no legislation pursues it purposes at all costs." *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014). But if purpose is considered

at all—and it should be here—it is important to understand what the 340B statute's purpose *actually is* and how the rebate policies bulldoze it.

The purpose of the 340B Program is indisputable and well-recognized. Drawing on language from a congressional report, courts have held that the "program was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp.3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)); *see Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020), *rev'd sub nom.*, *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022) (quoting same language from the House Report). Thus, while the statute's provisions regarding diversion and duplicate discounts indicate that Congress did not want covered entities to obtain 340B discounts fraudulently (*i.e.*, "at all costs"), those provisions must be considered in light of this purpose. In fact, the same congressional report states that "in developing [audit] procedures, the Secretary will make every effort to *minimize* the administrative and financial burdens that these audits impose on 'covered entities.'" H.R. Rep. No. 102–384, pt. 2, at 17 (1992) (emphasis added). Putting all of this together, these statements make clear that Congress wanted any anti-fraud efforts to interfere *as little as possible* with the statute's true purpose of allowing 340B hospitals to stretch their limited financial resources as far as possible to better serve patients.

Appellants' rebate policies make a mockery of this statutory purpose. Far from helping 340B hospitals to stretch financial resources, they squeeze them. The key function of the 340B Program is to allow "covered entities (including eligible hospitals) to purchase drugs from manufacturers at heavily discounted rates." *Azar*, 967 F.3d at 822. But the rebate policies eat away at those intended discounts in two ways.

First, the rebate policies will require hospitals to float significant sums to drug companies. *Amicus* AHA surveyed its membership during the district court proceedings, and it learned that 340B hospitals anticipate, on average, *multi-million-dollar* annual losses as a result of just the announced policies. *Hundreds* of 340B hospitals have reported that they, in turn, will have to restrict or close healthcare service lines, thus directly harming the patients that the 340B program is supposed to help.

For example, Baptist Hospital in Pensacola, Florida reports that if forced to comply with just the announced rebate policies, it would have to advance *$33 million* per year to the drug companies. Not only would it be handing the drug companies any interest it could earn on that sum, but Baptist fears that it will not be reimbursed for 100% of the rebates they are rightly owed under the law. What's more, Baptist reports that, due to these upfront costs, it likely would not be able to keep certain drugs in stock. In particular, it would have to pay more than $9 million a year in

upfront costs for *just five* oncology medications; Baptist Hospital would need to take a hard look whether they could continue to offer these costly medications to its cancer patients. More generally, Baptist Hospital uses its 340B savings to further its charitable mission of delivering health care services to all individuals within the Pensacola and Northwest Florida communities. One service in particular that has benefited from 340B savings is oncology care for underinsured patients. That program would be in real jeopardy. As Baptist Hospital explained, the "rebate program would severely curtail our ability to provide nonessential community services and our ability to remain in certain service lines with high drug expenses."

Stories like these abound. But another way to measure the financial impact of the rebate policies is to look at hospitals' cash-on-hand. According to a report from the independent agency S&P Global, median days cash-on hand have plummeted to a 10-year low. *See* Laura Dyrda, *Hospital average days cash on hand hit 10-year low: S&P*, Becker's Hospital CFO Report (Aug. 9, 2024), at https://www.beckershospitalreview.com/finance/hospital-average-days-cash-on-hand-hit-10-year-low-s-p.html. Indeed, a second independent report confirms that, from February 2022 to February 2024, the number of days cash-on-hand for hospitals has declined by 25.4%. *See* Jay Asser, *Hospitals' Cash Reserves Diminished in Recent Years*, Health Leaders (Apr. 4, 2024), *at* https://www.healthleadersmedia.com/finance/hospitals-cash-reserves-diminished-

recent-years. As that report describes, "[t]he steep decrease … means hospitals are less prepared for unexpected emergencies or sudden market changes." *Id*. The imposition of a rebate policy in which hospitals must advance millions from their cash reserves to drug companies easily qualifies as a "sudden market change" that many 340B hospitals are not financially prepared for.

To put an even finer point on it, Appellants' rebate policies put hospitals at risk of violating their bond covenants. 340B hospitals rely on bond financing to raise money for new projects that enhance patient care. Those bonds typically include covenants requiring hospitals to maintain a certain number of days cash-on-hand. *See* Steven Shill, *Healthcare providers face a growing risk of violating debt covenants*, Healthcare Financial Management Magazine (Feb. 2022), https://www.bdo.com/getmedia/bdd99fa0-6f39-4f70-b28d-accf0ba66ea2/0222_HFM_Debt-Covenants.pdf. Following the announcement of these rebate policies, *more than 200 hospitals* reported to the AHA that their cash-on-hand would drop low enough to risk violating their bond covenants. This would have calamitous effects on 340B hospitals, including downgrades in credit ratings, increased borrowing costs, lack of access to state-of-the-art medical equipment, and more. Worst of all, "[v]iolating a debt covenant can have a downward spiral effect on an organization's ability to continue *as a going concern*." *Id*. (emphasis added).

That consequence—closing a hospital's doors—is obviously antithetical to the 340B statute's purpose.

Second, the rebate policies will further gobble up the intended 340B discounts by raising administrative costs. Those policies require a 340B hospital to do two things: provide data to drug companies and track whether it received the discount. At both ends, hospitals will be required to spend considerable resources, all to obtain a discount that they are entitled to under law. *Amici's* members report that, among other things, they will need to hire new full-time employees, develop or purchase new software, and incur the costs of filing disputes to challenge inevitable unjustified denials of the 340B discounts. And not every drug company will impose the *same* requirements, use the *same* data fields or feeds, accept the *same* electronic or manual formatting, rely on the *same* vendors, have the *same* contractual language, or provide rebates on the *same* timetables. So when thinking about these new costs and burdens, the Court—like *Amici*'s members—must think about them exponentially.

For example, Dallas County Medical Center is a small Critical Access Hospital in Fordyce, Arkansas. It uses its 340B savings to provide uncompensated care to the rural population of South-Central Arkansas. Complying with the rebate policies will inflict substantial administrative costs on its 25-bed facility—on top of the costs of having to float its cash reserves to the drug companies while hoping that

all of its claims are actually rebated. Already thinly-staffed, it will have to hire expensive outside contractors, along with new full-time employees, to assist with the compliance and operations of the rebate policies. Over time, these contractors, FTEs, and other administrative expenses are likely to cost more than the 340B discounts bring in. If all the discounts are doing is allowing Dallas County Medical Center to break even (or worse) on compliance and administrative costs and not allowing it to help its patients, it will have to weigh the benefit of participating in the 340B Program at all—something Congress certainly did not intend when enacting the 340B statute.

Finally, it is worth underscoring that "[e]very statute proposes, not only to achieve certain ends, but also to achieve them by particular means—and there is often a considerable legislative battle over what those means ought to be." *Dir., OWCP v. Newport News Shipbuilding & Dry Dock Co*., 514 U.S. 122, 136 (1995); *see MCI Telecommunications Corp. v. American Tel. & Tel. Co.,* 512 U.S. 218, 231 n. 4 (1994) (courts "are bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."). As explained above, Congress had a precise intention about what "means" should be used to enforce the statute's program integrity prohibitions—the carefully calibrated audit and ADR processes. Appellants' rebate

policies are incompatible with those "means," thereby clashing with statutory purpose in a second (but equally consequential) way.

For all of these reasons, Appellants' rebate policies are incompatible with Congress' purpose in enacting the 340B statute. *Amici* recognize that "it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987). But what if the rebate policies are doing the "frustrating"—here, by dramatically draining the discount Congress intended to provide and supplanting the program integrity measures Congress specifically prescribed? At some point, even if Congress did not intend to pursue its purpose at *all* costs, the costs to that purpose will be *great enough* to shed light on a statute's meaning. *See NextEra Energy Res., LLC*, 118 F.4th at 371 ("[C]ourts should prefer textually permissible readings that would advance statutory or regulatory goals over ones that would frustrate them. These are bedrock principles of statutory construction." (internal citations omitted)); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 63 (2012) ("A textually permissible interpretation that furthers rather than obstructs a document's purpose should be favored.").

This is one of those cases. When combined with text, structure, and history, the consequences of Appellants' rebate policies cannot be squared with Congress' intent in enacting the 340B statute.

CONCLUSION

This Court should affirm on separate legal grounds.

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Respectfully submitted,

/s/

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(5), 32(a)5, 32(a)6, 32(a)(7), and 32(g)(1), the undersigned certifies that this brief complies with the applicable typeface, type-style, and type-volume limitation. This brief was prepared using a proportionally spaced type (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e), this brief contains 6,496 words. This certificate was prepared in reliance on the word-count function of the word-processing system used to prepare this brief.

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CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2025, the foregoing Brief of *Amici Curiae* was filed electronically using this Court's CM/ECF system, which will cause notice of filing to all attorneys of record who are registered users with this Court's CM/ECF system.

/s/
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