ORAL ARGUMENT NOT YET SCHEDULED

Nos. 21-5299, 21-5304

United States Court of Appeals for the District of Columbia Circuit

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NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ET AL.,
Defendants-Appellants.

UNITED THERAPEUTICS CORPORATION,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ET AL.,
Defendants-Appellants.

On Appeals from the United States District Court for the District of Columbia
Case Nos. 1:21-cv-1479, 1:21-cv-1686 (Hon. Dabney L. Friedrich)

BRIEF FOR PLAINTIFF-APPELLEE UNITED THERAPEUTICS CORPORATION

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June 8, 2022

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies the following:

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 U.S. Health Resources and Services Administration ("HRSA")'s Opening Brief. As of the date of this filing, the following amici have filed amicus briefs before this Court: Connecticut, Arkansas, Colorado, Delaware, District of Columbia, Hawaii, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Utah, and Vermont, American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a/ Children's Hospital Association, American Society of Health-System Pharmacists, National Association of Community Health Centers, and Ryan White Clinics for 340B Access.

B. Rulings Under Review

Reference to the ruling under review appears in HRSA's Opening Brief.

C. Related Cases

These cases have not previously been before this Court or any other court, save the District Court where they originated. In the District Court, this case was consolidated with *Novartis Pharmaceuticals Corporation v. Espinosa*, No. 21-cv-1479 (D.D.C.). The appeal in that case was docketed in this Court as *Novartis Pharmaceuticals Corporation v. Carole Johnson*, No. 21-5299 (D.C. Cir.), and was consolidated with this appeal. Appeals involving other violation determinations issued by HRSA have been docketed in the Third and Seventh Circuits. *See Sanofi-Aventis US LLC v. U.S. Dep't of Health & Hum. Servs.*, Nos. 21-3167, 21-3379 (3d Cir.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Hum. Servs.*, Nos. 21-3168, 21-3380 (3d Cir.); *AstraZeneca Pharmaceuticals LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, No. 22-1676 (3d Cir.); *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.). Two cases involving similar legal issues are currently pending in the U.S. District Court for the District of Columbia, one stayed and one placed in abeyance for the outcome in this case. *See Kalderos, Inc. v. United States*, No. 21-cv-2608 (D.D.C.); *Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 21-cv-2826 (D.D.C.).

APPELLEE'S CORPORATE DISCLOSURE STATEMENT

As required by Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Appellee United Therapeutics Corporation ("UT") submits the following corporate disclosure statement:

UT is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular diseases and cancer. UT is a Delaware public benefit corporation with a place of business in Silver Spring, Maryland. UT has no parent corporation, and BlackRock Inc., collectively through different BlackRock entities, may own 10% or more of its stock.

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GLOSSARY

340B Program or Program	The statutory drug discount program established under Section 340B of the Public Health Service Act and codified as 42 U.S.C. § 256b
GAO	Government Accountability Office
HHS	U.S. Department of Health and Human Services
HHS OIG	U.S. Department of Health and Human Services Office of Inspector General
HRSA	U.S. Health Resources and Services Administration
UT	United Therapeutics Corporation

INTRODUCTION

The agency's interpretation in this case contravenes "[t]he plain language, purpose, and structure of the statute." JA410. The statutory text here imposes a straightforward, limited obligation: pharmaceutical manufacturers are obligated to "offer" 15 specified types of statutorily defined "covered entities"—healthcare facilities intended to serve indigent, underinsured, and vulnerable patient populations—the opportunity to "purchase[]" certain outpatient drugs at a discounted rate. 42 U.S.C. § 256b(a)(1). The statute does not require manufacturers to provide discounted drugs to anyone other than covered entities, nor does it limit manufacturers' historic rights (as sellers) to set the other commercial terms of sale beyond the price. Accordingly, and as the District Court properly held, the statute does not bar all commercial terms set by manufacturers as the agency asserted here. JA410.

At its core, this case is about a federal program that has become unmoored from its enabling statute. In 1992, Congress enacted the 340B Drug Pricing Program (the Program, or the 340B Program) as a reaction to the passage of the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Program inadvertently disincentivized manufacturers from voluntarily providing comparable discounts to safety-net providers so that those providers could pass on those savings to their patients. Congress enacted the 340B Program to reinstate those limited discounts

that were previously provided voluntarily. And in doing so, Congress anticipated that these "covered entities" would serve their specific vulnerable patient populations by passing on savings to their patients or reinvesting the money they saved in providing additional care to those populations. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992). But in recent years, the Program has gone off the rails.

Through serial and inconsistent informal "guidance," the federal agency charged with its administration—the U.S. Health Resources and Services Administration ("HRSA")—has opened the door for private parties, not included in the statutory scheme, to reap the benefits of the Program. Current HRSA guidance permits arrangements between a covered entity and an unlimited number of contract pharmacies for the sale of 340B-discounted drugs. A "contract pharmacy" is not part of any "covered entity" entitled to 340B drug discounts. It is a separate commercial entity that dispenses drugs to all patients who walk in the door, regardless of whether those patients are linked to covered entities. Indeed, the 340B statute does not identify any role in the 340B Program for contract pharmacies at all.

Now, rather than providing deeply discounted drugs to select, statutorily specified healthcare providers and their patients, the 340B Program has been leveraged as a tool to enhance the profitability of commercial pharmacies, third-party administrators, and other commercial actors Congress never intended to benefit from it. *See infra* 16-18. The nation's two largest pharmacy chains, CVS

and Walgreens, have publicly reported that their profits from the 340B Program are material to their finances. *See infra id.* Indeed, the number of 340B discount claims nationwide has *tripled* over recent years, with no evidence that charity care rates are keeping pace. Both the Government Accountability Office ("GAO") and the Department of Health and Human Services ("HHS") Office of Inspector General ("HHS OIG") have identified a number of significant concerns with Program abuse.

Appellee United Therapeutics Corporation ("UT") manufactures drugs for treatment of pulmonary arterial hypertension, a frequently fatal condition affecting the pulmonary vasculature. These drugs are dispensed almost exclusively by specific pharmacies that provide the appropriate patient training for safety and deliver the drugs to patients by mail. *See* JA540, 542-44.

UT is one of several pharmaceutical manufacturers that have instituted measures to try to stem 340B Program abuses. Almost all covered entities that purchase UT's drugs for their patients have been doing so for multiple years; under UT's policy, they can continue doing so. Other covered entities will be allowed to utilize one of the mail-order pharmacies trained to dispense UT's drugs, if they do not already have an in-house pharmacy. To make use of a contract pharmacy, including in that circumstance, covered entities must simply submit basic claims data to UT with their 340B orders. This provides UT with the information necessary to begin to evaluate whether the 340B discounts are indeed appropriate under the

Program.[1] Unrebutted information in the record indicates that these submissions generally require only a few minutes to make every month. JA577-78.

In May of 2021, HRSA issued violation determinations to UT and six other drug manufacturers, taking the position that manufacturers could not put any limitations at all on 340B discounts when contract pharmacies are involved, and must ship to any contract pharmacy designated by any covered entity—without restriction. UT filed suit.

Ultimately, the dispute centered on two sentences in 42 U.S.C. § 256b(a)(1). The first of those sentences sets a maximum "ceiling" price that manufacturers can charge "covered entities," which cannot "exceed" the "average manufacturer price . . . reduced by [a] rebate percentage" specified by statute. 42 U.S.C. § 256b(a)(1). The second sentence obligates drug manufacturers to "offer" drugs for sale to the "covered entities" at that price. *Id.* The District Court correctly concluded that HRSA, in an effort to justify its violation determinations, erroneously read into that plain text other obligations on drug manufacturers that do not exist either in that provision or elsewhere in the statute. JA408 ("HRSA makes no attempt to explain why Section 340B's structure prohibits *any* additional conditions, no matter how minor, and for the reasons stated above, it cannot."). And the District

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[1] *See infra* 51-52 (discussing HRSA guidance requiring a threshold showing before HRSA will authorize a manufacturer to conduct a statutory audit of any covered entity).

Court went on to note that UT "convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and [administrative dispute resolution] procedures that Congress had established for manufacturers in Section 340B." *Id.*

HRSA's brief does not provide any real argument that the District Court's reading of the 340B statute's plain text was wrong. Indeed, HRSA barely offers any explanation for why its interpretation accords with the statutory text. Instead, it asserts that the statute "set[s] forth the manufacturer's obligation in broad terms," and that interpreting the statute to implicitly prohibit manufacturers from setting the commercial terms of their offers is necessary to render the 340B Program "effectual." Opening Br. 25-31. But the statute uses exceedingly *specific* terms and imposes a *narrow* obligation on manufacturers: Offer eligible drugs to covered entities at the 340B *price*. No more. Under fundamental principles of statutory construction, the logical inference to draw from that single directive—and from the statutory silence surrounding it—is that manufacturers remain free, as they have historically been, to set the other terms of their offers. Nor is HRSA's interpretation *necessary* to the operation of the 340B Program. Indeed, HRSA's own 1996 guidance for years imposed the same types of conditions on contract pharmacies that UT and other manufacturers employ today. At bottom, HRSA seeks to rewrite the statute to comport with *its* view of the statute's purpose—but that supposed purpose

(which, as the District Court correctly noted, Congress did not pursue at all costs, JA406-07) cannot overcome the statutory text.

The judgment of the District Court should be affirmed.

STATEMENT OF THE ISSUE

Whether the District Court correctly concluded the plain text of Section 340B requires only that pharmaceutical manufacturers "offer" discounted drugs to covered entities at or below the statutory ceiling price, and properly rejected HRSA's vastly broader interpretation of the statutory text.

PERTINENT STATUTES AND REGULATIONS

The relevant statute is included as an addendum to HRSA's Opening Brief.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background

Congress established the 340B Program in 1992 to improve access to medications for specific types of hospitals and federal grantees that serve vulnerable patient groups. *See* H.R. Rep. No. 102-384, pt. 2, at 11-13; Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992) (codified as amended at 42 U.S.C. § 256b). Prior to the passage of the Medicaid Drug Rebate Program in 1990, manufacturers had "regularly offered discounts to . . . hospitals and other safety-net providers" (a group that did not involve contract pharmacies) on a voluntary basis. 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, 29 (2019). The Medicaid Drug Rebate Program had the unintended effect of disincentivizing manufacturers from offering these discounts. Recognizing Congress had limited healthcare providers' ability to purchase discounted drugs, Congress sought to remedy that limited problem by enacting the 340B Program.

The 340B Program, like its predecessor, was intended to benefit patients through savings on prescriptions or by increasing levels of charity care. *See* 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). It seeks to accomplish that goal by allowing statutorily defined "covered entities" to purchase drugs from pharmaceutical manufacturers at steep discounts. The Program operates through a contractual mechanism: The statute directs HHS to "enter into an agreement" with manufacturers under which the amount a "covered entity" is "required" to pay for certain of the manufacturers' drugs "does not exceed" a ceiling price that is calculated by statutory formula. 42 U.S.C. § 256b(a)(1). Practically, manufacturers have no real choice about participating—they must participate in order for their drugs to be reimbursable under Medicare Part B and Medicaid. *Id.* § 1396r-8(a)(1), (5); *AstraZeneca Pharms. LP v. Becerra* ("*AstraZeneca I*"), 543 F. Supp. 3d 47, 50 (D. Del. 2021).

Congress included several provisions in the 340B statute to ensure the Program was not manipulated. Congress restricted who may participate in and

benefit from the Program's discounts by carefully defining the eligible "covered entit[ies]." *See* 42 U.S.C. § 256b(a)(4). These entities all "generally care for underserved populations." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020). The 340B statute prohibits covered entities from causing "duplicate discounts or rebates," which occurs when a manufacturer sells a 340B-discounted drug to a covered entity and is also invoiced for a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered entities are also forbidden from engaging in "diversion"—which occurs when an entity "resell[s] or otherwise transfer[s] [a 340B-discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). And covered entities must let HHS and manufacturers "audit" "the records of the entity that directly pertain to the entity's compliance with" those limitations, *id.* § 256b(a)(5)(C)—though HRSA allows manufacturers to conduct audits only if they have "documentation which indicates that there is reasonable cause" that a statutory violation has occurred, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Importantly, these obligations are imposed on covered entities rather than contract pharmacies, which are not referenced in the statute.

1. HRSA Issues Guidance On Contract Pharmacies

In 1996, HRSA issued guidance about covered entities' use of "contract pharmacy services" under the Program. *See* 61 Fed. Reg. at 43,549-56. HRSA concluded that covered entities were authorized to contract with one, *and only one*,

contract pharmacy to "facilitate program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." *Id.* at 43,551.[2] The agency recognized the one-pharmacy limit was necessary to minimize the risk of unlawful duplicate discounts and diversion. *See id.* at 43,550 (one-contract-pharmacy limit resulted from "[the] develop[ment] [of] a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential").[3] But despite the 1996 guidance's seemingly prescriptive language, it did not *obligate* manufacturers to sell or ship 340B drugs to contract pharmacies. HRSA stressed the guidance "create[d] no new law and create[d] no new rights or duties." *Id.* The agency explained that the guidance merely conveyed its non-binding interpretation of how covered entities could choose to do business under the 340B statute. *See id.* at 43,549-50. HRSA identified no statutory basis for its endorsement of contract pharmacies. The agency candidly admitted the statute "[wa]s silent as to permissible drug distribution systems," but also asserted without

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[2] *See also* 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007) (under 1996 guidance, "a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity" and, "if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location").

[3] The 1996 guidance also recognized that, to the extent contract pharmacies are permissible, they must be "agents" of covered entities. *See* 61 Fed. Reg. at 43,550 ("[E]ntities possess the right to hire retail pharmacies to act as their agents[.]").

elaboration that "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549.

HRSA's 1996 guidance provided a "model agreement format" and "[s]uggested [c]ontract [p]rovisions" to govern a covered entity's relationship with its contract pharmacy. *Id.* at 43,555-56. Covered entities were advised to "retain[] title" to the 340B drugs until they were sold to a patient because the covered entity "retain[ed] responsibility" for ensuring the drugs were not sold "to an individual who is not a patient of the covered entity." *Id.* at 43,553. Contract pharmacies were also instructed to "provide the covered entity with reports" and "establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity." *Id.* at 43,555. The suggested contract provisions instructed that the "covered entity [not the contract pharmacy or any other third party] will order covered drugs directly." *Id.* at 43,556. And they further specified that the contract pharmacy would dispense a 340B drug only (a) "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) after "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." *Id.* HRSA explained

these requirements were appropriate because "[t]he contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program[]" *at the time of the transaction*. *Id.* at 43,553.

In 2010, without any relevant intervening change in the statute, HRSA eliminated the one-contract-pharmacy limit and endorsed the use of an *unlimited* number of contract pharmacies. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA identified no statutory basis for its new view but again asserted its guidance "neither imposes additional burdens upon manufacturers[] nor creates any new rights for covered entities." *Id.*

At the same time, the 2010 guidance instructed covered entities to include certain "essential elements" in their contracts with contract pharmacies, namely that: (1) the covered entity "maintain title to the drug and assume responsibility for establishing [the] price"; (2) the contract pharmacy establish "a tracking system suitable to prevent diversion"; (3) the covered entity "establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities"; and (4) both parties "develop a system to verify patient eligibility." *Id.* at 10,277-78. But HRSA disclaimed any responsibility for enforcing these requirements, declaring "[c]overed entities may determine how

to best meet th[eir] responsibility" to "ensure against diversion and duplicate discounts." *Id.* at 10,274.

2. Contract Pharmacy Abuses Explode

Contract pharmacy arrangements—and abuses—ballooned in the wake of HRSA's 2010 guidance. Without any scope restriction, pharmacies and other commercial actors quickly recognized the opportunity for profit from 340B discounts. *See* JA504. In 2018, for example, GAO found that the use of contract pharmacies had "increased more than fifteen-fold, from about 1,300 to approximately 20,000." GAO, GAO-18-840, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at 10 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf ("2018 GAO Rep."). A 2020 study put the increase at *4,228%*, with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating as contract pharmacies. JA504. By 2020, hospital covered entities were using an average of 22 contract pharmacies. JA507. And the number of claims for 340B discounts nationwide tripled between 2014 and 2019. *See* JA514-18.[4] The distance between a hospital covered entity and its contract pharmacies also changed dramatically, from an average of 34 miles in 2010 to an average of *334* miles in 2020, JA507—

[4] UT has itself experienced a drastic increase in the number of claims for 340B discounts between 2018 and 2020 as a result of the flood of contract pharmacies. *See* JA541.

suggesting many contract pharmacies are dispensing 340B drugs to individuals "who [are] not . . . patient[s] of the [covered] entity," 42 U.S.C. § 256b(a)(5)(B).

The business arrangements between contract pharmacies and covered entities have also fundamentally changed. Under the 1996 guidance, contract pharmacies were a mere conduit: The covered entity purchased the drugs and specified the drugs would be shipped to the contract pharmacy for dispensing only to the covered entities' patients. *See* 61 Fed. Reg. at 43,552; *see also id.* at 43,550 ("This situation is akin to a covered entity having its own pharmacy."). But under the now-prevalent "replenishment model," contract pharmacies literally dispense drugs from one common inventory to whoever walks in the door—340B and non-340B patients alike. *See AstraZeneca I*, 543 F. Supp. 3d at 61 n.19 (under replenishment model, "pharmaceutical manufacturers ship prescription [340B] drugs to pharmacies for dispensing to all patients"); Decl. of Krista M. Pedley ("Pedley Decl.") ¶¶ 9, 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), Dkt. No. 93-2 (HRSA's former Director of Office of Pharmacy Affairs stating, under the replenishment model, contract pharmacies use 340B drugs as "neutral inventory" that "may be dispensed to any subsequent patient"); *Examining Oversight Reports on the 340B Drug Pricing Program, Hearing of the S. Comm. on Health, Educ., Labor, and Pensions*, 115th Cong. 11 (May 15, 2018), https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/

pdf/CHRG-115shrg30195.pdf (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections, OIG) ("HHS OIG Test.") ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory."); JA854 (many "covered entities use administrators that determine 340B eligibility *after* drugs are *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible" (first emphasis added)). That means the covered entity does not take or retain the title to any particular drug shipment to the contract pharmacy. *See AstraZeneca I*, 543 F. Supp. 3d at 61 n.19.

HRSA appears to lack detailed knowledge of how the replenishment model works in many contexts, including for the covered entities who use the two specialty contract pharmacies that deliver UT's 340B drugs. Nothing in HRSA's administrative record provides this information, but what *is* clear is that, *after* a drug is dispensed (maybe to a 340B patient, maybe not), contract pharmacies or a "third-party administrator" will generally use some kind of black-box "algorithm" to conclude whether that transaction can trigger a 340B discount. *See id.*; *see also* Pedley Decl. ¶ 6 ("Various 340B-tailored software programs exist" to perform this function.); 2018 GAO Rep. 2 (explaining some "covered entities hire and pay a private company, referred to as a third-party administrator [ ], to help determine patient eligibility"). The contract pharmacies or other third-party administrators (not

the covered entities) then use this determination to order stocks nominally in the name of a covered entity at the 340B price to "replenish[]" those that were dispensed. Pedley Decl. ¶ 10. The analysis does not rely on the type of contemporaneous records identified in HRSA's 1996 guidance, which would establish that a particular prescription was dispensed to a patient of a covered entity. Instead, these algorithms likely stretch the concept of who is and who is not a 340B patient beyond any legally justifiable definition. *See* JA856 ("[T]here is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible."); Pedley Decl. ¶ 3 (conceding that "contract-pharmacy arrangements vary, and [HRSA] cannot speak to the exact details of every existing relationship").

HHS OIG has acknowledged this problem. It presented the following hypothetical: A physician practices part time at a 340B provider but also has a private practice. *See* HHS OIG Test. at 11. The physician first sees a patient at the 340B provider, and then sees the patient in private practice and writes the patient a prescription. *Id.* In this hypothetical, the prescription likely would not qualify for a 340B discount. *See* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015). Yet one contract pharmacy said it would claim a 340B discount because it simply matches the name of the prescriber with physicians who work at the 340B provider (even if part time). HHS OIG Test. at 11. That approach would drastically increase claimed 340B discounts and could partially explain why the number of patients treated in 340B

facilities has remained stable in recent years while claims for discounts have grown tremendously.

Contract pharmacies are now able to derive substantial profits from their relationships with covered entities. Typically, a contract pharmacy will bill a patient's third-party insurer at full price (or charge the patient out of pocket) for a 340B drug that the pharmacy obtained at a fraction of that price. *See* JA504. Sometimes, the contract pharmacy and covered entity agree to a percentage-based arrangement, where the contract pharmacy receives "a fee based on a percentage of revenue generated for each 340B prescription," and other times, the contract pharmacy collects a flat fee per prescription. Both fee schemes tend to be lucrative for pharmacies and allow them to skim off benefits Congress intended for covered entities and their patients. *See* 2018 GAO Rep. 26-27 (GAO finding that percentage-based fees range from 12% to 20% of revenue and that some flat fees for brand drugs are as high as $1,750); JA503 ("The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent . . . ."); *see also* Hospitals' *Amicus* Br. 6 & n.17 (acknowledging "[t]he pharmacy receives a fee" on a "per prescription" basis). In 2018 alone, covered entities and their contract pharmacies generated an estimated $13 billion in gross profits from 340B prescriptions. JA503. But all too often, none of these profits are shared with the patients that Congress intended to benefit. *See* 2018 GAO Rep. 30 (only 54% of

responding covered entities reported offering some discount on 340B drugs to low-income, uninsured patients).

The dramatic growth in contract pharmacies has mainly been among highly profitable chain pharmacies: *75%* of contract pharmacies are chain pharmacies, and just five chains account for almost 60% of all contract pharmacies. *Id.* at 20-21. Indeed, more than 80% of all Walgreens locations and more than 66% of all CVS locations are now 340B contract pharmacies. *See* Adam J. Fein, *Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021), https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html. Both chains have also publicly disclosed that 340B profits are material to their finances. *Compare* CVS Health Corporation, Annual Report (Form 10-K) at 22-23 (Feb. 9, 2022), https://bit.ly/3HVWvn5; Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 22 (Oct. 14, 2021), https://bit.ly/38b2ybF, *and* JA520-21, *with* JA524 (letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens, explaining the 340B Program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit").

Third-party administrators and pharmacies thus have substantial financial incentives to view as many individuals as possible as covered entity patients. *See* 2018 GAO Rep. 26 (describing findings regarding third-party administrator fees, with a smaller fee typically charged when the prescription may not be eligible for a

340B discount). HRSA has repeatedly been confronted with the fact that "[t]he expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts." *Id.* at 45. Indeed, notwithstanding its very limited oversight, HRSA has identified hundreds of instances of diversion. *Id.* at 37; *see also* GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement* at 28 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in house pharmacies."). And Congress has recognized that the number of audits finding violations is "staggering"—with over 80% of audited covered entities showing noncompliance in certain years. *See Examining HRSA's Oversight of the 340B Drug Pricing Program; Hearing Before the H. Subcomm. on Oversight & Investigations of the Comm. on Energy and Commerce*, 115th Cong. 68-69 (July 18, 2017) (July 18, 2017, H. Subcomm. Hr'g).

HRSA thus knows that 340B discounts are now being siphoned by for-profit entities that Congress never intended to benefit, but the agency does not seem to believe it can do anything about it. *See id.* at 79 (HRSA former Director of Office of Pharmacy Affairs testifying contract pharmacy arrangements are "a business matter between the parties and their contract" and conceding HRSA does not prohibit contract pharmacies from sharing the spread between the 340B discount and

the reimbursement). Indeed, HRSA has consistently failed to remedy the abuses. *See* JA842; JA856 ("[M]ost covered entities in our study do not conduct all of the oversight activities recommended by HRSA."). HRSA evidently does not police the contractual relationships between covered entities, third-party administrators, and contract pharmacies. The agency also lacks statutory authority to audit contract pharmacies or other third parties or compel them to submit to an audit by manufacturers. *See* 42 U.S.C. § 256b(a)(5)(C) (requiring only that a *covered entity* permit the government or the drug manufacturer to audit *the covered entity's* records directly pertaining to compliance with the diversion and duplicate discount prohibitions). And HRSA has explained that it does not issue audit findings against covered entities "for a failure to oversee 340B Program compliance *at contract pharmacies* through internal audits and other measures as set forth in guidance *because the 340B statute does not address contract pharmacy use*." GAO, GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 15-16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf ("2020 GAO 340B Rep.") (emphasis added).

Even when HRSA does audit covered entities, it does not require proof of corrective action to close an audit. *See* July 18, 2017, H. Subcomm. Hr'g at 54-55; *id.* at 55 (in few instances of re-audits, HRSA found repeated instances of similar

noncompliance). And HRSA almost never terminates a covered entity's participation in the Program for noncompliance. *See id.* at 63 (one covered entity terminated as of 2017).

B. Pharmaceutical Manufacturers Attempt To Mitigate The Abuses

In response to HRSA's persistent refusal or inability to address these abuses of the 340B Program—and because there is no requirement pharmaceutical manufacturers sell or ship 340B drugs to contract pharmacies—UT and other manufacturers adopted policies to try getting the Program back on track.

On November 13, 2020, UT notified HRSA that UT was implementing a narrowly tailored policy for shipments to contract pharmacies (but not to covered entities themselves) with the goal of stemming abuses going forward without upsetting the status quo or creating hardship. *See* JA803-10. UT's policy applies to its drugs which—because of their unique features—are dispensed either by covered entities' in-house pharmacies or by two specialty pharmacies that deliver the drugs directly to patients. *See* JA540, 544-45. Under UT's policy, UT will continue to accept orders destined for contract pharmacies if the contract pharmacy was used by the covered entity to place a valid 340B order during the first three quarters of 2020 (January 1 through September 30, 2020).[5] UT allows any covered entity that does not meet this requirement and does not have an in-house pharmacy to designate a

[5] UT chose this date range to maintain the status quo.

single contract pharmacy for purposes of this requirement. This requirement accords with HRSA's 1996 guidance, which envisioned that covered entities would contract with a single third-party pharmacy—a limitation that HRSA viewed as consistent with the 340B statute. *See* 61 Fed. Reg. at 43,554-55.

UT also established a second "claims data" requirement that would apply to contract pharmacy orders after December 2021 (postponed from May 2021). *See* JA550. Covered entities using a contract pharmacy for 340B orders after that date would be required to provide certain de-identified claims data to UT via a third-party platform: prescription number, prescribed date, fill date, National Drug Code, quantity, pharmacy ID, prescriber ID, wholesaler invoice number, and 340B covered entity ID. JA546. Unrebutted evidence in the record indicates that the burden of providing this information to UT is minimal. *See* JA577-78. This data allows UT to confirm that the orders are *bona fide* and eligible for 340B discounts.

As GAO has observed, "manufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries," frustrating manufacturers' ability to detect duplicate discounts. GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* at 32 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf. UT's policy aims to fill this informational gap by collecting the limited amount of de-identified claims data

described above. JA546. This is the same type of information HRSA's own 1996 guidance anticipated that every contract pharmacy would gather when dispensing 340B drugs. *See* 61 Fed. Reg. at 43,556. This data "does not include any protected health information" and "cannot be used to identify a patient." JA547. This limited information, however, should allow UT to identify concerns necessitating an audit of a covered entity, based upon potential diversion *or* duplicate discounts. *See* JA546-47. HRSA requires exactly this type of information before it will approve any manufacturer audit of a covered entity. *See* 61 Fed. Reg. at 65,409.

And, of course, neither of UT's requirements has any effect on a covered entity's ability to directly place a 340B order with UT for delivery to the covered entity.

C. HHS And HRSA Respond

On December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" on contract pharmacies. JA729-36. Although HRSA previously stated the 340B statute was silent as to permissible drug distribution systems, the Advisory Opinion asserted that the statute unambiguously "obligate[s]" manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. JA729. It based that conclusion on two assumptions: that contract pharmacies were agents of covered entities and that covered entities at all times retain title to the drugs. JA730-31. Based on those assumptions, the Advisory Opinion declared that the place of

delivery was irrelevant: "[B]e it the lunar surface, low-earth orbit, or a neighborhood pharmacy." JA731.

HHS's Advisory Opinion was promptly challenged in lawsuits brought by numerous manufacturers. On June 16, 2021, a court concluded that the Advisory Opinion "wrongly determines that purportedly unambiguous statutory language mandates its conclusion," and was thus "legally flawed" and unlawful. *AstraZeneca I*, 543 F. Supp. 3d at 58-59. HHS responded by withdrawing the Advisory Opinion, *see* JA399, but the court still "vacated and set aside the Opinion," *AstraZeneca Pharms. LP v. Becerra* ("*AstraZeneca II*"), No. 21-27, 2022 WL 484587, at *2 (D. Del. Feb. 16, 2022).

Before the Advisory Opinion's withdrawal, HRSA notified UT that the agency had determined that UT's policy violated the 340B statute. *See* JA596-97. HRSA's two-page Violation Determination asserted that the "Shall Offer" language in 42 U.S.C. § 256b(a)(1) imposed a "requirement" that "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." JA596. And HRSA declared that nothing in the statute "grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing" to covered entities, and insisted that the agency had made this requirement "plain, consistently since the issuance of its 1996 contract pharmacy guidance." *Id.* The Violation Determination also stated that HRSA "has determined

that [UT's] actions have resulted in overcharges," threatened UT with assessment of civil monetary penalties, and demanded that UT withdraw its policy. JA596-97.

D. The District Court Grants Summary Judgment To UT

In June 2021, UT filed this case against HRSA, HHS, and the heads of that agency and department. JA415. UT alleged that HRSA's Violation Determination was unlawful both because it (1) contravened the plain statutory language, and (2) was arbitrary and capricious and thus invalid under the Administrative Procedure Act. JA460-70. UT maintained those arguments at summary judgment. *See generally* UT's Mem. in Supp. of Summ. J., Dkt. 14-1.

In November 2021, the District Court agreed that the Violation Determination contravened "the plain language, purpose, and structure" of the 340B statute and was thus unlawful. JA410; *see also* JA406. The District Court analyzed the "Shall Offer" provision and explained that UT "continue[s] to present [its] drugs to covered entities, as the 'Shall Offer' provision requires." JA403-04. Even under its new policy, UT still extended "meaningful, *bona fide* offers" that gave "covered entities . . . far more opportunities to purchase drugs at 340B prices than they" had under HRSA's 1996 guidance. JA404. And HRSA failed to show why manufacturers were prohibited from putting some conditions on their offers but not others. JA405. The District Court thus determined that HRSA's Violation Determination was legally invalid and factually baseless. *See* JA410. The District

Court considered and rejected HRSA's arguments to the contrary, recognizing that, although one of the statute's purposes was to "provide[] discounts on drugs to certain kinds of healthcare facilities," the statute had other goals like preventing drug diversion and duplicative discounting and these dual purposes indicated Congress would not have pursued one at all costs. JA406-07.

The District Court thus declared that UT's policy "do[es] not violate Section 340B under the positions advanced in the Violation [Determination]" and vacated the Violation Determination. JA410. HRSA appealed.

SUMMARY OF THE ARGUMENT

The District Court correctly concluded that Section 340B does not "*prohibit* manufacturers from placing *any* conditions on covered entities." JA404-05. The Violation Determination states that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." JA552. But under ordinary background principles, manufacturers are entitled to set the terms of an offer for their goods. As a result, HRSA, which has no rulemaking authority in this area, could only conclude that UT violated the 340B statute if the statute itself modified that background rule and prohibited manufacturers from refusing or limiting shipments to non-purchasers like contract pharmacies. The District Court correctly determined that it does not.

The statute requires only that manufacturers "offer" covered entities the opportunity to "purchase" their outpatient prescription drugs at a discounted price. Contract pharmacies categorically *do not* qualify as covered entities under the statute. And the only term of the offer set by Congress is the price. Here, as the District Court recognized, UT's policy provides "covered entities . . . far more opportunities to purchase drugs at 340B prices than they" had for years under HRSA's 1996 guidance, and UT still makes "meaningful, *bona fide* offers" as required under the statute. JA404. UT is required to do no more.

HRSA contends that the 340B statute must be interpreted broadly to render the 340B Program effective. But HRSA's sweeping interpretation is unmoored from the text and not necessary to the Program's viability or the statute's operation. Indeed, HRSA's interpretation is only necessary to make the statute work in the way that HRSA *wishes* it worked. And HRSA's arguments on this point ignore Supreme Court and D.C. Circuit precedent, which establish that a court should not expand a statute "by implication" in these circumstances.

Finally, HRSA's reliance on a purported "conflict" between UT's policy and the statutory audit mechanism and legislative history cannot overcome the plain statutory text. HRSA cannot root a substantive obligation on the part of manufacturers in a *procedural* provision requiring covered entities to submit to audits. In any event, the statute does not provide for audits of contract pharmacies,

and HRSA has disclaimed any authority to audit contract pharmacies. UT's policy, which only concerns 340B drugs dispensed by contract pharmacies, accordingly cannot "conflict" with a nonexistent statutory power. And HRSA's resort to legislative history warrants skepticism here, not just because it cannot overcome the text but also because the import from the legislative history is far from clear: one court has already concluded that the legislative history favors manufacturers, not HRSA.

The District Court's judgment should be affirmed.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE VIOLATION DETERMINATION IS UNLAWFUL

Unlike some statutory schemes where an agency claims that Congress has either explicitly or implicitly authorized the agency to speak with the force of law and the agency's efforts to fill a gap in the statute should be accorded judicial deference, *United States v. Mead Corp.*, 533 U.S. 218, 222 (2001), HRSA and HHS lack general rulemaking authority under the 340B statute, *see Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 41, 45 (D.D.C. 2014); Opening Br. 38. HRSA has also disclaimed any entitlement to *Chevron* deference and has not requested *Skidmore* deference. Opening Br. 38-39. As a result, the sole issue in this case is whether the 340B statute itself, interpreted using the ordinary tools of statutory interpretation, forecloses UT's policy. It does not.

A. The 340B Statute Does Not Bar Manufacturers From Setting The Commercial Terms Of Their Offers Of 340B Prices

The Violation Determination issued to UT stated that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." JA552. But, as the District Court concluded, that determination has the inquiry backwards. After all, absent constraints imposed by law, a manufacturer is generally free to sell its goods to whomever it wants on whatever terms it wants. *See, e.g.*, *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 448 (2009) ("As a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing."); *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984) ("A manufacturer of course generally has a right to deal, or refuse to deal, with whomever it likes . . . ."). That includes placing limitations on the circumstances in which it is willing to deliver to someone other than the purchaser and the information it requires to complete the purchase. *See Pac. Bell*, 555 U.S. at 448; *Gen. Motors Corp. v. Darling's*, 444 F.3d 98, 109 (1st Cir. 2006) ("Absent a clear mandate from the legislature, we are disinclined to unnecessarily interfere with the bargains that have been struck between the manufacturers and their distributors."). Neither the "Shall Offer" provision in § 256b(a)(1) "nor any other language in Section 340B *prohibit*[*s*] manufacturers from placing *any* conditions on covered entities." JA404-05.

1. The Statutory Text Does Not Bar Manufacturers From Setting Commercial Terms

"In addressing a question of statutory interpretation, [the Court] begin[s] with the text," presuming that the "legislature says in a statute what it means and means in a statute what it says there." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020) (citations omitted). Where the text is clear, the analysis "ends there as well." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018) (citation omitted).

The 340B statute contains two plain and unambiguous provisions that are relevant here. *First*, the statute imposes an obligation on the Secretary to enter into agreements with manufacturers requiring them to "offer" certain drugs for "purchase[] by a covered entity" at a discounted price:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the discounted price] . . . . Each such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

42 U.S.C. § 256b(a)(1).[6] *Second*, the statute carefully defines who qualifies as a "covered entity" eligible to receive an offer at the 340B price, listing 15 specific types of providers. *Id.* § 256b(a)(4).

The statute makes clear that manufacturers are not required to provide contract pharmacies 340B pricing. Congress defined "covered entity" at a fine level of granularity. *See, e.g.*, *id.* § 256b(a)(4)(G) (one type of "covered entity" is a "comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act"). And "[i]t is axiomatic that the statutory definition of [a] term excludes unstated meanings of that term." *Meese v. Keene*, 481 U.S. 465, 484 (1987); *see Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979); *AstraZeneca I*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."). HRSA has accordingly long conceded that that the statute does not require manufacturers to offer 340B-pricing to contract pharmacies themselves. *See* JA796 ("Contract pharmacies . . . [are] not independent covered entities.").

Since the statute imposes no obligation on manufacturers to provide 340B-discounted drugs to contract pharmacies, the question is whether the statute's

[6] The agreement—known as a Pharmaceutical Pricing Agreement—parrots the statutory language in relevant respects. *See* JA633-44.

requirement to "offer" discounted drugs to "covered entities" somehow *prohibits* manufacturers from setting the terms of the offer to a covered entity when it involves shipment to a third-party contract pharmacy. The District Court correctly concluded that neither the "Shall Offer" provision nor any other part of the statute imposes such a prohibition. JA410-11 ("The statute's plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies.").

The statute's plain language compels that conclusion. As the District Court explained, because the term "offer" is not defined, we look to its plain meaning. *See* JA403; *see also HollyFrontier Cheyenne Refin., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2176 (2021) ("Where Congress does not furnish a definition of its own, we generally seek to afford a statutory term 'its ordinary or natural meaning.'" (quoting *FDIC v. Meyer*, 510 U.S. 471, 476 (1994))); *Ass'n of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 443 (D.C. Cir. 2012) (same). And nothing about the ordinary meaning of "offer" *prohibits* an offeror from setting the commercial terms of an offer. *See* JA403; *see also Concise Oxford American Dictionary* 614 (2006) (defining "offer" as "present or proffer (something) for (someone) to accept or reject as so desired"); *American Heritage College Dictionary* 964 (4th ed. 2004) (defining "offer" as "1. To present for acceptance or rejection"). That conclusion is reinforced by the common law and standard commercial practice, under which

"offers" are routinely subject to terms and limitations. *See Comcast Corp. v. Nat'l Ass'n of Afr. American-Owned Media*, 140 S. Ct. 1009, 1016 (2020) ("[W]e generally presume that Congress legislates against the backdrop of the common law.").

Statutory structure further supports this conclusion. Congress explicitly restricted manufacturers' ability to set the terms of the offer in only one respect—the price. *See* 42 U.S.C. § 256b(a)(1) ("[T]he manufacturer [shall] offer each covered entity covered outpatient drugs for *purchase at or below the applicable ceiling price* if such drug is made available to any other purchaser at any price." (emphasis added)). Congress chose not to impose any other limitations on manufacturers. "[C]ommon sense, reflected in the canon *expressio unius est exclusio alterius*, suggests that the specification of [one requirement] implies the exclusion of others." *United States v. Jumaev*, 20 F.4th 518, 551 (10th Cir. 2021) (second alteration in original) (citation omitted); *EchoStar Satellite, LLC v. FCC*, 704 F.3d 992, 999 & n.5 (D.C. Cir. 2013). Congress is therefore presumed to have intended no other limitations. *See Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

Moreover, manufacturers must necessarily be able to impose at least *some* terms on the sale of 340B drugs—like requiring that the purchasing entity *be* 340B eligible, that orders be submitted using the manufacturer's established ordering system, and that payment for the drugs be made within a certain amount of time. Unsurprisingly, HRSA has itself long recognized that the statute allows manufacturers to impose terms and conditions on 340B sales. Since 1994, HRSA has recognized that manufacturers can impose terms including "customary business practice[s]," to "request standard information," and to utilize "appropriate contract provisions." 59 Fed. Reg. 25,110, 25,114 (May 13, 1994). So even HRSA agrees that the "Shall Offer" provision does not prohibit *all* terms and conditions. And HRSA explicitly recognized in its Pharmaceutical Pricing Agreement with manufacturers that ordinary background principles apply—and that other commercial terms are not governed by the Program. *See* JA108 ("Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the [agency] . . . .").

In its response briefing below and now before this Court, HRSA relies on a different sentence in the provision (the "purchase[] by" sentence) as textual grounding for its interpretation. HRSA's late-in-the-day resort to that sentence fares no better. For starters, that is not the statutory language that the agency identified

and relied on in its Violation Determination. *See* JA596-97 (relying on the "Shall Offer" text); *see also SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency.").

In any event, it does not provide a textual hook for HRSA's interpretation. The "purchase[] by" clause states: "The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . the manufacturer for covered outpatient drugs . . . *purchased by a covered entity* . . . does not exceed [the discounted price]." 42 U.S.C. § 256b(a)(1) (emphasis added). The phrase "purchased by" in that sentence merely indicates that covered outpatient drugs must be purchased by a covered entity for the discounted rate requirement to apply, *i.e.*, it is simply specifying to whom the offer must be made. *See Grecian Magnesite Mining, Indus. & Shipping Co., SA v. Commissioner*, 926 F.3d 819, 824 (D.C. Cir. 2019) (applying the nearest-reasonable-referent canon: "ordinarily, and within reason, modifiers and qualifying phrases attach to the terms that are nearest"). The provision says nothing about any obligation to provide 340B-discounted drugs to contract pharmacies (or entities other than covered entities), nor about the terms or conditions that may be imposed by the seller concerning where it

will ship the drugs.[7] The District Court thus properly held that the statute does not prohibit terms related to delivery or the provision of basic information that a manufacturer may impose as part of its offer of 340B-discounted drugs to covered entities who seek to direct shipments to contract pharmacies.[8]

2. Statutory Context Confirms That Congress Did Not Implicitly Prohibit Manufacturers From Setting The Delivery Terms Of An Offer

Statutory context further reinforces that Congress did not implicitly prohibit manufacturers from setting the delivery terms of an offer.

First, Congress explicitly limited manufacturers' ability to set the terms in another part of the statute, indicating that it did not wish to do so here by implication. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) (Where "Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and

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[7] Nor does the Pharmaceutical Pricing Agreement, which simply reflects the statutory requirements. *See* JA633-44.

[8] There is a potential limiting principle, as the District Court acknowledged: The offer must be *bona fide*. JA404. At some point, a manufacturer's terms may become so onerous that it cannot truly be said to be "offering" a 340B drug to a covered entity. UT's policy does not prevent any covered entity from purchasing covered outpatient drugs, and HRSA has no record evidence to establish that it does. JA404 n.2 (stating HRSA was incorrect to assert "that the record contains evidence of 340B violations"). And HRSA has failed to conduct any individualized assessment of the manufacturers' policies, instead taking the blanket position that *any* policy concerning contract pharmacies is barred by the statute.

purposely in the disparate inclusion or exclusion." (citation omitted)). In the very next provision of the statute that enacted Section 340B, Congress provided that manufacturers could not charge certain federal agencies more than a specified amount for covered drugs, including drugs that were "purchased under depot contracting systems." *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603(a), 106 Stat. 4943, 4971 (codified at 38 U.S.C. § 8126(a)). Congress defined "depot" to mean a system through which drugs "procured by an agency of the Federal Government are . . . received, stored, and delivered through . . . a federally owned and operated warehouse system, *or* . . . *a commercial entity operating under contract with such agency*." *Id.* at 4974 (emphasis added). So Congress (1) recognized a difference between entities operating on their own versus entities operating through commercial arrangements with third parties, and (2) expressly approved the latter relationship in a different provision of the statute but not the one at issue here.[9] *See Russello v. United States*, 464 U.S. 16, 23 (1983) (where provisions are enacted in the same statute, the "presum[ption] that Congress acts intentionally and purposely in the disparate inclusion or exclusion" of language is at its strongest (citation omitted)).

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[9] The same is true of 42 U.S.C. § 1320a-7b(b)(3)(C), which permits "vendor[s] of goods or services" to pay "a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if . . . the person has a written contract, with each such individual or entity."

Second, another provision of the 340B statute confirms that Congress did not silently displace the background rule that manufacturers may set the terms (other than price) of their offers. The statute explicitly prohibits covered entities from transferring a drug purchased at the 340B price to anyone other than their patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell *or otherwise transfer* the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). It would be odd, to say the least, for Congress to have included such an express prohibition while simultaneously intending to silently allow covered entities to direct manufacturers to deliver 340B-discounted drugs to non-patients entities (such as contract pharmacies) who in turn dispense to non-patients. *See supra* 13-14 (discussing replenishment model).

B. UT's Policy Is Lawful And Appropriate

The 340B statute lays out one relevant requirement: That manufacturers offer 340B drugs for purchase by covered entities at a discounted rate. UT's policy complies with that requirement, as all covered entities (regardless of whether they have an in-house pharmacy) are able to purchase 340B drugs at the specified price. JA544-47.

Under UT's policy, covered entities are not limited in any way when they purchase drugs for dispensing themselves. *See supra* 20-22. That is all the statute

requires. To the extent a covered entity was already using a contract pharmacy or does not have an in-house pharmacy, UT's policy goes further than required by ensuring that those covered entities maintain access to 340B-discounted drugs.

And, while UT's policy does impose limited terms on sales shipped to non-covered entities, those terms are similar to those that HRSA previously asserted were mandated by law. As the District Court recognized, under UT's policy, "covered entities now have far more opportunities to purchase drugs at 340B prices than they did when HRSA limited covered entities to one contract pharmacy." JA404. Indeed, although UT's policy imposes some conditions on some offers involving contract pharmacies, "they are still meaningful, *bona fide* offers." *Id.*

The claims-data requirement of UT's policy also tracks the information that HRSA has long recognized can be lawfully gathered under the statute. UT's claims-data submission process only requires a 15-minute, one-time investment of time to set up, and thereafter facilitates the efficient delivery of basic data on each of the prescriptions for which 340B discounts are applied. *See* JA577-78. This data is no more than what HRSA itself has recommended covered entities require contract pharmacies to identify before dispensing 340B drugs. *Compare* JA546 (UT would require input of Rx Number, prescribed date, fill date, drug identifier, quantity, pharmacy ID, prescriber ID, wholesaler invoice number, and 340B covered entity ID), *with* 61 Fed. Reg. at 43,556 (covered entities should tell contract pharmacies to

dispense drugs only "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or a telephone call to the same effect). It in no way limits the ability of covered entities to obtain drugs—it simply requires that information be provided in connection with contract pharmacy orders. HRSA fails to reconcile HRSA's previous position that such information should be collected under the statute with its argument that UT's policy violates the statute for requesting the same information.

It is little wonder then that the record is devoid of any evidence that UT has actually "overcharged" any covered entity. JA404 n.2. None of the evidence in the record establishes that covered entities were refused 340B pricing by UT, which "is what HRSA would need to show for the record to establish a 340B violation." *Id.*[10] Instead of offering any serious attack on UT's policy, HRSA takes aim at *other* manufacturers' policies. Opening Br. 36. But the only policy at issue here is UT's.

[10] There are only three complaints about UT in the entire administrative record. One of those complaints is generic, lists multiple "manufacturers" without specifying anything about UT, and does not even identify any UT drug that was supposedly unavailable for purchase. *See* JA704. And the other two complaints were *preemptive* complaints about UT's claims-data requirement, which had not even gone into effect when the complaints were filed. *See* JA707-12.

And nothing about that policy, including the claims-data requirement, renders UT's "offers" not *bona fide*.

II. HRSA'S ARGUMENTS TO THE CONTRARY ARE UNPERSUASIVE

HRSA offers a number of reasons why, notwithstanding the absence of an express prohibition in the statutory text, the statute must be read to prohibit UT's policy. But its arguments contravene the statutory text and are otherwise wrong.

A. HRSA's Interpretation Is Not Necessary To Render The Statute Effectual

HRSA's main argument is that "manufacturers cannot add provisos to th[e] straightforward statutory requirement" that they "sell their drugs to covered entities at a discounted price" because the "statutory scheme must be construed to ensure that 'everything necessary to make it effectual, or requisite to attaining the end, is implied.'" Opening Br. 26-27 (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012) ("*Reading Law*")). That argument fails.

1. Reading A Prohibition On Commercial Terms Into The Statute Is Not Necessary To Make It Effectual

First, HRSA fails to put forward *any* argument regarding the ordinary meaning of "offer" or "purchase." HRSA's failure to grapple with the statutory text severely undercuts its argument. *See Allegheny Def. Project v. FERC*, 964 F.3d 1, 14 (D.C. Cir. 2020) (en banc) (concluding that agency's interpretation of statutory

term was incorrect and noting that agency failed to argue that its interpretation "f[e]ll[] within the ordinary meaning" of the statutory term).

Second, HRSA's reliance on the predicate-act canon, which provides that "[i]n the context of legislation, it has long been held that 'whenever a power is given by a statute, everything necessary to make it effectual or requisite to attaining the end is implied,'" *Reading Law* 192-93 (citation omitted), is misplaced. HRSA's expansive interpretation—that manufacturers are categorically barred from setting any terms of an offer, including delivery terms—is not required to render the statute effectual. *See Reading Law* 123 ("The implication under this rule . . . must be a necessary, not a conjectural or argumentative one." (quoting *Field v. People ex rel. McClernand*, 3 Ill. 79, 83 (1839))). Instead, it is only required to make the statute work in the way that the agency wishes it did: that manufacturers must provide 340B drugs in any manner, to any third-party entity, and to any place a covered entity wants.[11] But that is not how Congress wrote the law. And the very source on which

[11] The States rely on the same preferred read of the statute in their amicus brief. For example, they appear to argue (at 19) that manufacturers must be prohibited from setting the delivery terms of their 340B offers because unrestrained contract pharmacy use is necessary to providing 340B drugs "beyond the traditional workday hours and at geographically convenient locations." But the 340B statute only speaks to the *lower price* that covered entities must be offered; it does not direct manufacturers to fill 340B orders in compliance with whatever demand a covered entity makes, like shipping the drugs wherever the entity might want. Nor does a policy like UT's prevent covered entities from continuing to serve their patients at convenient hours and locations.

HRSA relies explains that this canon "must be applied with caution, lest the tail of what is implied wag the dog of what is expressly conferred." *Reading Law* 193.

Third, HRSA's reliance on *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), does not overcome its statutory text problem. In *Bostock*, the Supreme Court rooted the imposed "broad[]" obligation in the statutory text. *Id.* at 1739. It noted that Title VII's text barred discrimination "'because of' . . . sex." *Id.* The Court gave the phrase "because of" its "ordinary meaning": "but-for causation." *Id.* Based on the "ordinary public meaning of the statute's language at the time of the law's adoption, a straightforward rule emerge[d]: An employer violates Title VII when it intentionally fires an individual employee based in part on sex." *Id.* at 1741.

To be sure, *Bostock* states that "when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Id.* at 1747. But a party needs a broad rule, supported by the "ordinary meaning" of the statutory text, before that principle can apply. And here, HRSA makes no attempt to demonstrate that the "ordinary meaning" of the statutory terms imposes a broad rule. As discussed *supra* 28-35, the statute imposes a narrow rule specifying only that manufacturers offer drugs at a specific price to specific entities. Indeed, HRSA told Congress just last year that "manufacturers only have one core statutory obligation in the 340B Program - to offer the 340B ceiling price pursuant to section 340B(a)(1) of the Public Health Service Act." HHS/HRSA, *Fiscal Year 2022: Justification*

of Estimates for Appropriations Committees at 418 (2021), https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2022.pdf.

Finally, HRSA's prior interpretations do not square with its position today. In 1994, HRSA issued guidance that permitted covered entities to use purchasing agents but mandated that all 340B drugs must still be "distribut[ed] *to the* [*covered*] *entity*" *itself* before they could be dispensed to patients. 59 Fed. Reg. at 25,113 (emphasis added). In 1996, HRSA said that it could not obligate manufacturers to deliver to contract pharmacies but that covered entities could, under the statute, use one contract pharmacy as their *agent*. 61 Fed. Reg. at 43,550, 43,555. That remained HRSA's interpretation for almost two decades.[12] HRSA cannot square its view that the statute *has always* required manufacturers to deal with contract pharmacies and barred manufacturers from setting commercial terms, including a delivery term, with HRSA's longstanding position that covered entities could only use *one* contract pharmacy.

[12] In 2010, HRSA expanded its guidance to allow use of multiple contract pharmacies, but still insisted that this was not obligatory, and, as late as December 2020, HRSA justified contract pharmacies using the principal-agent rationale. 75 Fed. Reg. at 10,272-73; *see* JA734.

2. *HRSA's Construction Is Not Necessary To Avoid Rendering The Statute A Dead Letter Or To Avoid A Parade Of Horribles*

Contrary to HRSA's assertion, following the statute's plain text does not render it a dead letter. HRSA argues that approximately 5% of covered entities had in-house pharmacies when the 340B statute was enacted and that most covered entities would therefore not have been able to participate in the 340 Program without contract pharmacies. Opening Br. 27-28.[13] But the limited nature of the Program at its inception is no surprise. As discussed, *supra* 6-7, the Program was intended to restore the pre-Medicaid Drug Rebate Program status quo. *See* H.R. Rep. No. 102-384, pt. 2, at 12. Under that prior framework, manufacturers voluntarily offered discounted drugs for use by safety-net providers for "direct care," not for "resale" or "transfer" to for-profit entities such as chain retail pharmacies. *Id.* at 9-10. That limited scope was the product of Congress's limited purpose.

In any event, the relatively small number of covered entities with in-house pharmacies at the time of the statute's enactment does not establish that covered entities could not or would not create their own in-house pharmacies in the absence of HRSA's illegal contract pharmacy policy, or enlist a specific single pharmacy as an agent or instrumentality of the covered entity to perform this specific role (as was

[13] It is black letter law that "no amount of policy-talk can overcome a plain statutory command." *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (2021); *see also Eagle Pharms.*, 952 F.3d at 335.

contemplated by HRSA's own 1996 guidance). Indeed, the statute operated in precisely that way (which HRSA then thought was reasonable and lawful, and evidently did not render the statute a dead letter) for 14 years.[14]

And this argument says nothing about UT's policy. HRSA has conducted *no* analysis of whether *UT's* policy would render the 340B Program ineffective. *See* JA596-97. UT's policy permits covered entities to continue to use contract pharmacies if the covered entity used them previously or to designate a contract pharmacy for use if the entity does not have an in-house pharmacy. JA545. Accordingly, under UT's policy, all covered entities, including those without an in-house pharmacy, are able to obtain 340B-discounted drugs.

HRSA also argues that, under the District Court's interpretation of the statute, a manufacturer could require a covered entity to purchase the manufacturer's drugs whenever possible and never a competitor's because "[t]here is nothing in the 340B statute that explicitly prohibits such a unilateral condition." Opening Br. 30. It is unclear how this rhetorical flourish relates at all to whether a manufacturer can impose conditions on contract pharmacy orders. And the District Court recognized

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[14] Even after HRSA started allowing covered entities to use unlimited contract pharmacies in 2010, a vast majority of them did not as of 2014 (82%) and 2018 (73%). HRSA, Contract Pharmacy Oversight, *Office of Pharmacy Affairs Update* (Feb. 6, 2014), https://tinyurl.com/323ynmx7; July 18, 2018, H. Subcomm Hr'g at 12.

that the statute requires manufacturers to extend "meaningful, *bona fide* offers." JA404. In the hypothetical HRSA offers, the agency would be required to assess, taking into account the surrounding factual circumstances as well as the unique characteristics of the policy, whether the offer amounted to a *bona fide* one.[15] *See, e.g.*, *Black's Law Dictionary* (11th ed. 2019) (defining "*bona fide*" as "[m]ade in good faith" and defining "good faith" as "[a] state of mind consisting in . . . observance of reasonable commercial standards of fair dealing" or "absence of intent to . . . seek unconscionable advantage"). UT's policy in no way resembles HRSA's inapplicable hypothetical, as UT has allowed, and continues to allow, covered entities to order UT's covered outpatient drugs, without any anti-competitive limitation. HRSA cannot justify its position—that no conditions are permissible, or at least not the ones imposed by UT's policy—by conjuring a nonexistent condition that might not be permissible.

Nor does HRSA grapple with the implications of its own interpretation. In its view, manufacturers must provide 340B drugs to covered entities *no matter what conditions a covered entity demands of them*. Even if this Court were to accept HRSA's arguments (1) that these contract pharmacy orders are genuinely sales to covered entities (they are not) and (2) that contract pharmacy arrangements do not

[15] Of course, the agency failed to undertake any evaluation of UT's policy in this case.

violate the diversion prohibition (they do), the bottom-line of *HRSA's* interpretation is that manufacturers must provide 340B drugs to covered entities in any manner the covered entity wishes—even if that is delivery to the moon. JA731. And, in HRSA's telling, if manufacturers do not, they fail to offer the covered entity 340B drugs and violate the statute. That is an absurd proposition, and one sensibly nowhere to be found in the statute.

3. Reading Prohibitions Into The 340B Statute By Implication Contravenes Precedent

Finally, HRSA's approach—which seeks to read a prohibition into the statute by implication—does not comport with Supreme Court or this Court's precedent.

The Supreme Court's decision in *Christensen v. Harris County*, 529 U.S. 576 (2000), is on all fours. There, the government conceded that nothing in the statute "expressly prohibit[ed]" an employer's policy regarding the utilization of accrued compensatory time but nonetheless contended that the statute "implicitly prohibit[ed]" it. *Id.* at 582, 588. Rejecting that contention, the Court held that the approach was "exactly backwards." *Id.* at 588. For the employer to be barred from adopting the policy, the statute had to *prohibit* it. *Id.*; *see also Julmice v. Garland*, 29 F. 4th 206, 208 (4th Cir. 2022) (explaining that "silence" in that case meant that Congress "chose not to include such a requirement").

This principle has been recognized since at least the 1920s. *See Iselin v. United States*, 270 U.S. 245, 251 (1926). In *Iselin*, a statute established a

comprehensive scheme for taxing theater and opera tickets. *Id.* at 249-50. Presented with a ticket not clearly covered by the statute, the government argued that the general purpose of Congress was to tax all tickets, that there was no indication of an intent to exempt any tickets, and that the act should therefore be extended to cover the tickets at issue. *Id.* at 250. The Supreme Court disagreed, holding that "[t]he statute was evidently drawn with care," and "[t]he particularization and detail with which the scope of each provision" was drawn "preclude[d] an extension of any provision by implication to any other subject." *Id.*

So too here. The 340B statute requires only that manufacturers offer drugs at a certain price to 15 specific covered entities; the statute's "particularization and detail" on certain subject matters "preclude[s] an extension" to others. *Id.* *Iselin* remains good law, and this Court continues to reject arguments like the one offered by HRSA here. *See Nat'l R.R. Passenger Corp. v. United States*, 431 F.3d 374, 377 (D.C. Cir. 2005) (rejecting agency's argument that its interpretation of the statute should be adopted because the "intent of the statute would be frustrated" otherwise (citation omitted)). This principle has even more significance in this context. Statutes are the product of legislative compromise, trying to appease multiple "highly interested parties." *Barnhart*, 534 U.S. at 461. And only Congress can make that compromise. *Allegheny Def. Project*, 964 F.3d at 17.

Perhaps more than other statutory programs, the 340B Program requires careful balancing. On one hand, Congress sought to restore the pre-Medicaid Drug Rebate Program status quo and establish a limited program that benefited needy patients through discounts or increased charity care. *See* H.R. Rep. No. 102-384, pt. 2, at 12; *see also* 61 Fed. Reg. at 43,551. On the other hand, Congress was also incentivized to ensure that the Program did not become so onerous that manufacturers ceased participating. The statute thus reflects Congress's careful and considered balance, and the Court should be wary of reading into its text requirements by implication. *Allegheny Def. Project*, 964 F.3d at 17 (Congress, not the agency, "is both qualified and constitutionally entitled to weigh the costs and benefits of different approaches and make the necessary policy judgment." (citation omitted)).[16]

[16] State *amici* suggest that UT's policy "undermine[s]" the 340B Program as well as "state laws that allow for the use of contract pharmacy services" and "[u]pset[s] the role of the States in the 340B Program." States' *Amicus* Br. 22, 25. But this Court is reviewing whether the Violation Determination accords with federal statutory requirements, not state laws involving contract pharmacies. And there is no "partnership" between the 340B Program and the States here, unlike Medicaid where Congress chose to establish such relationships. Rather, Congress simply recognized that States regulate prescription practices, as they regulate the practice of medicine generally, in their traditional state role. That does not mean state policy interests can expand a federal program or alter congressional language in a federal statute.

B. The Statutory Audit Mechanism Does Not Suggest Manufacturers Are Barred From Setting Commercial Terms

HRSA also argues that the way in which the 340B Program deals with diversion and duplicate discounts shows that UT must deliver to contract pharmacies and cannot require covered entities to submit claims data when using contract pharmacies. *See* Opening Br. 31-37. Specifically, the statute provides that covered entities cannot "resell or otherwise transfer" their covered outpatient drugs to non-patients, nor can they request a Medicaid rebate for an already discounted drug. 42 U.S.C. § 256b(a)(5)(A)-(B). The statute also provides that HHS and drug manufacturers can audit a covered entity's records to ensure compliance with these requirements. *Id.* § 256b(a)(5)(C). Only after an audit can manufacturers initiate an administrative dispute resolution process to perhaps recuperate some of the money they lost. *See id.* § 256b(a)(5)(D), (d)(3). HRSA contends that, because the statute provides manufacturers the ability to audit covered entities, manufacturers may not take any other measures to prevent or detect statutory violations. Opening Br. 33-35. HRSA's arguments are flawed for multiple reasons.

HRSA yet again tries to find a statutory obligation or prohibition where there is none. Nothing in the audit provision says that it precludes straightforward commercial self-help measures or displaces manufacturers' rights to set the commercial terms of their offers. *Cf. Pac. Bell*, 555 U.S. at 448. HRSA's statutory argument—which seeks to impose a *substantive* obligation on manufacturers—is

even more dubious here because it is rooted in a *procedural* enforcement provision that gives manufacturers the ability to audit covered entities. *Cf. James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 280-81 (D.C. Cir. 2000) (explaining the difference between substantive and procedural provisions). This enforcement provision says *nothing* about what *UT* must or cannot do; it only requires that *covered entities* comply with audit requests. 42 U.S.C. § 256b(a)(5)(C). And it cannot be read to impose delivery obligations on UT or prohibit UT from including a claims-data requirement in its offers.

Even if HRSA could locate a substantive requirement in a procedural provision, there is no conflict because the audit provision, as HRSA has long stated, does not extend to contract pharmacies. *See id.* (requiring only that a *covered entity* permit auditing of *the covered entity's* records); *see also* 2020 GAO 340B Rep. 15-16 (HRSA does not issue audit findings against covered entities "for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use."). UT's policy only covers drugs dispensed by contract pharmacies, so there is no conflict with the audit provisions of the statute.

Moreover, UT's claims-data requirement helps UT comply with HRSA's guidelines. *Cf.* JA408 ("United Therapeutics convincingly argues that the claims data conditions . . . will enable it to better utilize the anti-fraud audit and ADR

procedures that Congress established for manufacturers in Section 340B."). HRSA's guidelines require manufacturers to have "documentation which indicates that there is reasonable cause" that a statutory violation has occurred before conducting an audit. 61 Fed. Reg. at 65,409. Specifically, HRSA mandates that a manufacturer provide "sufficient facts and evidence." *Id.* Otherwise, the agency "will not intervene." *Id.* at 65,409-10.

UT has established a low-cost business practice that will help it detect diversion and duplicate discounting and demonstrate "reasonable cause" to conduct an audit. Congress has clearly expressed its desire to avoid diversion and duplicative discounting, and it strains credulity to think Congress would bar manufacturers from imposing a low-cost method of detecting and preventing such violations in the context of contract pharmacy ordering.

C. Legislative History Does Not Support HRSA

HRSA points to a draft bill that would have required discounts for drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with," covered entities. Opening Br. 28-29 (emphasis omitted). HRSA argues that in omitting the "dispensed by" language in the final bill, Congress intended to allow covered entities to use off-site contract pharmacies to dispense 340B drugs.

Because the statutory text here is clear, this Court should "not resort to legislative history." *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994). And the Court should be especially hesitant to rely on the type of the legislative history proffered by HRSA. A "failed legislative proposal," is "'a particularly dangerous ground on which to rest an interpretation of a . . . statute'" because "'several equally tenable inferences may be drawn.'" *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (citations omitted). HRSA has provided *no* explanation from the legislative history for *why* this proposal was eliminated. *See Bridgestone/Firestone, Inc. v. Pension Benefit Guar. Corp.*, 892 F.2d 105, 110 (D.C. Cir. 1989).

It is also far from clear that the choice not to include this language favors HRSA. Indeed, Judge Stark in *AstraZeneca I* concluded that the bill is best read to support manufacturers' positions because it shows that Congress considered and rejected language that would have expressly required distribution to contract pharmacies. 543 F. Supp. 3d at 60; *AstraZeneca II*, 2022 WL 484587, at *6 & n.9.

III. THE DISTRICT COURT DID NOT ERR IN SETTING ASIDE THE VIOLATION DETERMINATION

Finally, HRSA faults the District Court for "refusing to decide whether plaintiffs' policies violate Section 340B." Opening Br. 37. But the court had no cause to decide that question given its conclusion that the Violation Determination was legally flawed and should be vacated. *See* JA408-11. In any event, the District

Court correctly found that the record is devoid of any evidence that UT violated its statutory obligation. *See* JA404 n.2.

It is black letter law that "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 615 (D.C. Cir. 2017) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983)). Here, HRSA's rationale for the Violation Determination was that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities" and that UT's policy is "in direct violation of the 340B statute." JA552. But that was "an erroneous reading of Section 340B"—"[t]he plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers," and thus at least some conditions are permitted. JA410-11. So the Violation Determination was properly vacated. *See Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999).

Even if this Court were to disagree with the District Court's interpretation, the Violation Determination still cannot stand. The agency also asserted that "United Therapeutics' actions *have resulted in overcharges* and are in direct violation of the 340B statute." JA552 (emphasis added). But there is *nothing* in the administrative record to support that conclusion. *See supra* n.10; *see also* UT's Mem. in Supp. of

Summ. J. 24-25, 34-35, Dkt. No. 14-1. That means the Violation Determination is arbitrary and capricious in any event, *see Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 997 F.3d 1247, 1254-57 (D.C. Cir. 2021)—and that there is no basis for addressing UT's policy regardless. Finally, UT raised several other bases for why the Violation Determination was arbitrary and capricious that the District Court did not reach and should be allowed to address in the first instance on remand before any finding the Violation Determination is lawful. *See Cobell v. Jewell*, 802 F.3d 12, 26 (D.C. Cir. 2015).

CONCLUSION

The judgment of the District Court should be affirmed.

Date: June 8, 2022

Respectfully submitted,

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