ORAL ARGUMENT NOT YET SCHEDULED

Nos. 21-5299 & 21-5304

IN THE

United States Court of Appeals for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORPORATION and UNITED THERAPEUTICS CORPORATION,

Plaintiffs-Appellees,

v.

CAROLE JOHNSON, in her official capacity as Administrator, Health Resources and Service Administration, et al.,

Defendants-Appellants.

On Appeals from the United States District Court for the District of Columbia

BRIEF FOR APPELLEE NOVARTIS PHARMACEUTICALS CORPORATION

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties And Amici

Except for the Amici States, all parties, intervenors, and amici appearing before the District Court and in this Court are listed in the Government's Brief.

B. Rulings Under Review

References to the rulings at issue appear in the Government's Brief.

C. Related Cases

A complete list of related cases appears in the Government's Brief.

CORPORATE DISCLOSURE STATEMENT

Novartis Pharmaceuticals Corporation, a private non-governmental party, develops, manufactures, and markets pharmaceutical products. Its corporate parent is Novartis Finance Corporation. Novartis Pharmaceuticals Corporation is an indirect, wholly-owned subsidiary of Novartis AG.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

Page(s)

CASES:

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

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

STATUTES:

TABLE OF AUTHORITIES—Continued

Page(s)

REGULATIONS:

TABLE OF AUTHORITIES—Continued

Page(s)

OTHER AUTHORITIES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

GLOSSARY

AHA	American Hospital Association
GAO	Government Accountability Office
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
OIG	U.S. Department of Health and Human Services, Office of Inspector General
340B	Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b

INTRODUCTION

Like so many cases, this one comes down to a question of interpretation. Does a statute that is silent on whether certain limitations are *permitted* clearly *prohibit* the imposition of such limitations? No. A silent statute is precisely that—silent.

The statute at issue here is Section 340B of the Public Health Service Act. Under it, drug manufacturers wishing to enable federal reimbursements for their drugs under Medicaid and Medicare Part B must offer deep discounts to specified hospitals and clinics serving needy patient populations. To protect against abuse, the 340B statute carefully circumscribes the type of "covered entities" that may participate in the program.

In the last decade, many covered entities have entered into so-called "contract pharmacy" arrangements with third-party pharmacies—typically, branches of large, national for-profit pharmacy chains—some of which are located hundreds of miles from the covered entity itself. Under such arrangements, covered entities instruct a manufacturer participating in the 340B Program to ship its deeply discounted drugs directly to the contract pharmacy—wherever in the country that may be. Because many contract pharmacies are located nowhere near the covered entities they serve, and because of the nature of their drug replenishment processes, this system is ripe for abuse.

As a result, what began as a carefully calibrated program designed to benefit the most needy has become an easily abused system for profit-maximizing pharmacy chains and other commercial middlemen. Over the past decade, the number of contract-pharmacy arrangements has increased 4,228%; there has been a corresponding increase in the amount of drugs subject to the 340B discount. Each year, hospitals and big-chain contract pharmacies reap billions in profits from these arrangements. Neither has any duty to reinvest those dollars into the communities they purport to serve. And there is ample confirmation that the system is being abused.

The Health Resources and Services Administration (HRSA), the agency of the U.S. Department of Health and Human Services (HHS) responsible for administering the 340B Program, is well aware of these concerns. For years, the Government Accountability Office and HHS's own Inspector General have warned that HRSA's procedures for monitoring the 340B Program and curbing its related abuse are insufficient. And for years, HRSA has proclaimed that it would be too hard, too expensive, or too complicated to do something itself. As a result, manufacturers were left to right these wrongs. When they tried to do so, however, HRSA created a new roadblock.

In 2020, concerned about the potential for increased abuse due to the exponential growth of contract-pharmacy arrangements, Novartis announced a new

340B drug policy. It voluntarily recognizes (1) all contract-pharmacy arrangements within a 40-mile radius of the covered entity, and (2) all contract-pharmacy arrangements of federal grantee entities, regardless of location. Novartis's policy also provides an exemption to the 40-mile radius limitation when the facts and circumstances require. Novartis's contract-pharmacy policy does not affect whether or where patients can fill their prescriptions. Nor does it affect whether a patient can access needed medications or the patient's copay. The policy merely seeks to curtail the rampant exploitation of 340B discounts by hospitals and contract pharmacies.

HRSA responded by notifying Novartis that its contract-pharmacy policy purportedly violates the plain text of the 340B statute. Ignoring its own longstanding position that the statute is silent on whether manufacturers must deliver 340B drugs to contract pharmacies, HRSA concluded that the statute *unambiguously requires* manufacturers to deliver 340B drugs to every contract pharmacy, whenever and wherever located—even, according to HRSA, "the lunar surface." JA266.

That is wrong. The 340B statute speaks to the purchase of covered outpatient drugs by covered entities. It says nothing about deliveries of covered outpatient drugs to non-covered entities. The District Court correctly rejected the Government's attempt to parlay statutory silence into a statutory mandate that

manufacturers comply with covered entities' unilaterally-dictated delivery arrangements. As the District Court explained, "[t]he 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." JA410-411.

The District Court correctly set aside HRSA's Violation Letter. The judgment should be affirmed.

ISSUE PRESENTED

Section 340B, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer discounted drugs to covered entities for purchase. It is silent as to whether manufacturers must deliver those drugs to contract pharmacies. The issue presented in this appeal is whether HHS exceeded its statutory authority or otherwise violated the Administrative Procedure Act by concluding that Section 340B prohibits Novartis from adopting conditions on sales to covered entities that use contract pharmacies as delivery points.

STATUTES AND REGULATIONS

Pertinent statutes are reprinted in the addendum.

STATEMENT

A. Background

1. The 340B Program

Congress created the 340B Drug Pricing Program in 1992. The program requires participating pharmaceutical manufacturers to provide deep discounts on certain drugs to specified types of healthcare providers—known as "covered entities"—as a condition of the availability of federal payments for such drugs under Medicaid and Medicare Part B. *See* 42 U.S.C. § 256b. Under Section 340B, a participating pharmaceutical 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." *Id.* § 256b(a)(1).

"Covered outpatient drugs" means the more than 1.2 million drugs reported by manufacturers under the Medicaid Drug Rebate program. *See id.* § 256b(b)(1); 42 U.S.C. § 1396r–8(k); *Drug Products in the Medicaid Drug Rebate Program*, Data.Medicaid.gov, https://data.medicaid.gov/dataset/0ad65fe5-3ad3-5d79-a3f9-7893ded7963a (updated May 17, 2022). The "applicable ceiling price," or "340B price," is a steeply discounted rate—as low as one penny—calculated under a prescribed statutory formula. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1214-15 (Jan. 5, 2017); 42 U.S.C. § 256b(a)(2).

The 340B statute defines "covered entity" narrowly, to ensure that the program's steep discounts benefit only qualified safety-net providers and the neediest patient populations. 42 U.S.C. § 256b(a)(4). Covered entities include entities operating under federal grants as well as particular types of hospitals, such as certain children's hospitals and freestanding cancer hospitals. *Id.* Contract pharmacies are not on the list.[1] As a result, manufacturers need not "offer" contract pharmacies—and contract pharmacies are not eligible to purchase—340B drugs.

The 340B statute contains two other important limitations designed to protect against abuse. First, it prohibits "duplicate discounts": Manufacturers are not required to both pay a Medicaid rebate and provide a 340B discount on the same unit of drug. *See* 42 U.S.C. § 256b(a)(5)(A)(i). Second, the statute prohibits "diversion": Covered entities may not "resell or otherwise transfer" 340B drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). HRSA and manufacturers can audit individual covered entities in certain circumstances if they suspect duplicate discounts or diversion. *See id.* § 246b(a)(5)(C).

[1] By contrast, an adjacent provision of the same authorizing legislation requires manufacturers to "make" covered drugs "available for procurement" by certain federal agencies, including when purchased though a "commercial entity operating under contract with [the] agency." Veteran's Health Care Act of 1992, Pub. L. No. 102-585, sec. 603(a)(1), § 8216(a)(1), (h)(3)(A)(ii), 106 Stat. 4,943, 4,971, 4,974 (codified at 38 U.S.C. § 8126(a)(1), (h)(3)(A)).

2. HRSA's Evolving Guidance on Contract Pharmacies

At first, covered entities dispensed 340B-purchased drugs through their own in-house pharmacies. But shortly after the 340B statute was enacted, some covered entities without in-house pharmacies lobbied HRSA for permission to enter into contract-pharmacy arrangements to dispense 340B drugs.

Because HHS has only limited rulemaking authority over the 340B Program, it " 'lacks the authority to issue a legislative rule' regarding contract pharmacies." Gov. Br. 38 (quoting JA409). Accordingly, HRSA in 1996 issued non-binding guidance stating that a covered entity without an in-house pharmacy may contract with "only one" outside pharmacy site to dispense 340B-purchased drugs to the covered entity's patients. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996); *see also* U.S. Gov't Accountability Off., GAO-18-480, 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. If the chosen "contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007) (summarizing 1996 guidance).

HRSA did not identify any statutory basis for its guidance. In fact, it recognized that "[t]he statute is silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,549. HRSA found "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself," so the agency postulated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy." *Id.* at 43,549-50. The 1996 guidance did not purport to require manufacturers to honor contract-pharmacy arrangements.

The agency changed course in 2010. Following a pilot program allowing the use of multiple contract-pharmacy sites on a case-by-case basis, HRSA issued another non-binding guidance purporting to authorize *all* covered entities to use an *unlimited* number of contract pharmacies *even if* they have an in-house pharmacy. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). The guidance instructs that a covered entity using contract-pharmacy arrangements must enter into a written agreement with the contract pharmacy and must itself "maintain title to the drug." *Id.* at 10,277. But the 2010 guidance, like its 1996 predecessor, did not identify any statutory basis for the agency's contract-pharmacy policy. Nor, also like its predecessor, did it claim that the statute requires manufacturers to honor contract-pharmacy arrangements.

3. Contract-Pharmacy Arrangements Explode in Popularity

Under the 1996 guidance, contract-pharmacy arrangements were rare—just 49 as of 2000, nearly all of which were between federal grantees and independent pharmacies located within ten miles. Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 4 (2020).

Following HRSA's 2010 guidance, contract-pharmacy arrangements exploded. Although "[t]he actual number of 340B contract pharmacy arrangements . . . is unknown," GAO-18-480, at 19-20, estimates indicate there are more than 100,000 contract-pharmacy arrangements today. Vandervelde et al., *supra*, at 7. More than 43,000 such arrangements are between hospitals and contract pharmacies—up from 193 in 2010. *Id.* The vast majority of contract pharmacies are retail pharmacies operated by national chains, many of which are located hundreds or even thousands of miles from the covered entity and the community it serves. *Id.* at 4-5. "The five biggest pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60 percent of 340B contract pharmacies." GAO-18-480, at 21.

The reason for this "enormous growth . . . boil[s] down to a single factor: outsized profit margins." Vandervelde et al., *supra*, at 4. Covered entities have an incentive to maximize 340B utilization because they profit off the "340B spread." Covered entities purchase drugs at the deeply discounted 340B price—as low as

one penny—and then seek reimbursement from insured patients' payors. *See* 82 Fed. Reg. at 1214-15. The covered entity captures the resulting "spread" between the 340B price and the higher reimbursement rate—often more than three times greater than the margin they would realize if the covered entity had paid the commercial price. *See* Vandervelde et al., *supra*, at 7 (estimating profit margin on 340B drugs dispensed through contract pharmacies at 72%). The more contract pharmacies, the more prescriptions filled with drugs purchased at the 340B price, and the more opportunities to capture the 340B spread.

There is no statutory obligation for hospitals to share any of that revenue with the needy patients the 340B Program is intended to serve. And studies show that hospitals have not passed these cost savings along to patients, whether in the form of drug discounts or improved care. *See, e.g.*, GAO-18-480, at 31 (most hospitals did not provide patient discounts on 340B drugs dispensed at contract pharmacies); Adam J. Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—as Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019), *available at* https://bit.ly/3NLuxxU (despite billions in 340B discounts, "hospitals' charity care has dropped").

As a result, the savings from the 340B Program—designed to benefit carefully selected parties—"are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies,

contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." Vandervelde et al., *supra*, at 7. The actual extent to which the 340B Program savings inure to the benefit of these commercial interlopers is unknown, but studies estimate that contract pharmacies retain *billions* in 340B discounts as profits each year. *See, e.g.*, Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy*, AJMC (May 4, 2022), https://www.ajmc.com/view/340b-biosimilars-and-more-in-the-future-of-specialty-pharmacy.

Unsurprisingly, the exponential increase in contract-pharmacy arrangements has been accompanied by a corresponding increase in the amount of drug products subject to the 340B discount—and an upsurge in the potential for abuse. Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (Jun. 9, 2020), *available at* https://bit.ly/3wI1yVW. The 340B "replenishment" model only exacerbates this problem. Under it, the contract pharmacy maintains a single, common inventory of all drugs purchased at any price. At the time of dispensing, the contract pharmacy does not distinguish between the general public and patients of a covered entity; it dispenses all medications from the common supply. If, *after* dispensing a drug to a pharmacy customer, it is later determined that the individual was a patient of the covered entity, the covered entity will order a "replenishment" unit at the

discounted 340B price for direct shipment to the contract pharmacy. There is no transparency into whether or how this retrospective determination is made. The contract pharmacy then commingles the newly purchased 340B-priced unit with commercially purchased units in its common inventory. 75 Fed. Reg. at 10,277. The kicker: the 340B replenishment unit is treated as it if had been purchased at the commercial price—and is thus available for dispensing to anyone, including individuals who are not patients of the covered entity.

Where covered entities make arrangements with pharmacies far outside their communities, concerns about diversion are further amplified. Because there is no reasonable proximity between such pharmacies and the covered entity's local community—where patients actually obtain services—such pharmacies are unlikely to dispense drugs to patients of the covered entity. *See id.* at 10,273 (explaining that contract-pharmacy arrangements are designed to allow covered entities to enter into "arrangements in their communities"); JA20.

HHS has long recognized that "[c]ontract pharmacy arrangements create complications in preventing diversion . . . [and] duplicate discounts." U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 16 (Feb. 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf ("OIG Report"). A whopping *72%* of audited covered entities have been shown to have compliance

issues, and HRSA has identified hundreds of instances of diversion and duplicate discounts at contract pharmacies through its audit efforts. GAO-18-480, at 16, 37-38, 44; U.S. Gov't Accountability Off., GAO-21-107, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, at 14 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

HRSA's enforcement efforts in this area, however, are lacking, to put it gently. "[W]eaknesses in HRSA's audit process compromise its oversight of covered entities," and HRSA's processes fall far short of federal standards. GAO-18-480, at 25; *see id.* at 16, 40-43; GAO-21-107, at 25-26.

These problems are exacerbated by HRSA's lack of leadership on compliance. HRSA does not require covered entities to register all contract pharmacy relationships. GAO-18-480, at 36. Moreover, although HRSA "expect[s]" covered entities to conduct oversight activities, it does not require any particular type of monitoring. OIG Report, *supra*, at 7. As a result, some covered entities do not employ *any* method to prevent duplicate discounts or otherwise "monitor their contract pharmacy arrangements." *Id.* at 12-15. Others employ methods that appear to undermine the statute's goals—like refusing to offer the discounted 340B price to uninsured patients using contract pharmacies. *Id.* at 14. Still others conduct some monitoring but do not report problems. *Id.* at 15.

4. Novartis's Contract-Pharmacy Policy

Concerned about the potential for abuse of fast-multiplying contract-pharmacy arrangements, Novartis notified HRSA of its plans to update its 340B drug contract-pharmacy policy, effective November 2020. JA37. Under that policy, Novartis honors all federal grantee contract-pharmacy arrangements, regardless of location. *Id.* It also honors all hospital covered entity contract-pharmacy arrangements within a 40-mile radius of the covered entity—about 5,000 square miles—although hospitals can seek exemptions beyond that range as necessary based on special circumstances. *Id.*

Novartis's 40-mile-radius policy draws on the federal Medicare "provider-based" policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius. *See* 42 C.F.R. § 413.65(e)(3)(i). It is also consistent with HRSA's statements that covered entities may enter into "arrangements in their communities" to dispense needed drugs to their patients. *See* 75 Fed. Reg. at 10,273. The vast majority of contract pharmacies are located within 40 miles of the hospital they serve. GAO-18-480, at 22-23.

To be clear, Novartis's policy does not affect or limit whether and where a *patient* can obtain her drugs; patients are free to fill prescriptions at any pharmacy of their choosing. Regardless of where the patient fills the prescription, the copay remains the same, such that the patient's insurer covers the same amount. *See*

JA40; 61 Fed. Reg. 43,555. Nor does Novartis's policy prohibit any covered entity from purchasing Novartis's medicines at 340B prices. JA39-40. Hospital covered entities are merely offered a choice of where to ship drugs: to their own in-house pharmacy (if applicable) or to any and every contract pharmacy located within a 40-mile radius of the hospital. *Id.* And if there are no contract pharmacies within that 40-mile radius (a rare occurrence, according to GAO data, *see* GAO-18-480, at 23-24), covered entities can seek an exemption. JA39-40. What Novartis's policy *does* do is to prevent a far-flung Walgreens from improperly securing a replenishment drug at the 340B price—and dispensing that drug to the next person to walk into Walgreens with that prescription, whether or not they are a covered-entity patient.

5. The Now-Withdrawn Advisory Opinion

In late December 2020, HHS issued a non-binding Advisory Opinion claiming that Section 340B facially *requires* manufacturers to deliver 340B drugs to an *unlimited* number of contract pharmacies. In a sharp departure from HRSA's longstanding view, the Advisory Opinion maintained that "the core requirement of the 340B statute" is that "manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities"—no matter what. JA265. According to the Advisory Opinion, that statutory "shall offer" language *unambiguously* requires manufacturers to *deliver* discounted drugs anywhere a

covered entity sees fit. In HHS's words, "[i]t is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise." *Id.* Also in HHS's words, the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." JA266.

Shortly thereafter, a federal district court held that the Advisory Opinion was "legally flawed." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021) (*AstraZeneca I*). As the Delaware district court explained, the Advisory Opinion "wrongly determine[d] that purportedly unambiguous statutory language mandate[d] its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies." *Id.* Contrary to the Advisory Opinion's conclusion—but consistent with HRSA's historical view—the court concluded that Section 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Id.* at 59. In fact, the statute is silent as to pharmacies, period; they "are not mentioned anywhere in the statutory text." *Id.* That is "a strong indication that," contrary to the Government's claim, "the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.* The court also recognized that "the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has *not* remained constant but has, instead, materially shifted" by "dramatically expand[ing] how covered entities may

purchase 340B drugs," which had in turn expanded manufacturers' duties. *Id*. at 56-57.

HHS responded by withdrawing the Advisory Opinion. *See* U.S. Dep't of Health & Hum. Servs., Off. of Gen. Counsel, Notice of Withdrawal (June 18, 2021), *available at* https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf.

B. Procedural History

1. The Violation Letter

On May 17, 2021, while *AstraZeneca I* and several other challenges to the Advisory Opinion were pending, HRSA sent a series of near-identical letters to manufacturers—each with different contract-pharmacy policies—asserting that each manufacturer's policy violates the 340B statute. JA586-597.

The Violation Letter HRSA directed to Novartis asserted that Novartis's policy is "in direct violation of the 340B statute" because the statute "requires . . . manufacturers" to provide discounted drugs to covered entities, without conditions or restrictions. JA65. In HRSA's view, because the "shall . . . offer" "requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," the statute unambiguously prohibits the imposition of "conditions on covered entities' access to 340B pricing." *Id.* The Violation Letter also claimed—incorrectly—that Novartis's

policy "places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform." *Id.*[2]

HRSA contended that, under its reading of the statute, Novartis is required to honor any and every contract-pharmacy arrangement—not just those within a 40-mile radius of a covered-entity hospital. JA66. HRSA maintained that its interpretation had remained "consistent[ ] since the issuance of its 1996 contract pharmacy guidance," JA65—the very guidance that previously had limited covered entities to just one contract pharmacy location. HRSA also waved off Novartis's concerns about duplicate discounts and diversion, without acknowledging the drastic increase of contract-pharmacy arrangements in recent years, the documented rise in abuse, or the many recognized shortcomings in the existing compliance-monitoring processes. JA66.

Faced with a Hobson's choice between submitting to HRSA's demand that it continue to provide steep discounts benefiting large pharmacy chains despite documented abuses or face stiff penalties and reputational harms from an unwarranted and unlawful enforcement proceeding, Novartis filed suit.

[2] The Government later acknowledged that this was a "misstatement." Defs.' Combined Mem. of Points and Authorities in Opp. to Pl's. Mot for Prelim. Inj. and in Supp. of Defs.' Mot. for Summ. J., Dkt. 13-1, at 10 n.2 ("Gov. Opp.").

2. The District Court's Decision

The District Court vacated HRSA's decision. As the court explained, HRSA's enforcement letter rested on the contention that the manufacturers' policies were "in direct violation of the 340B statute." JA402 (quoting JA65). Thus, HRSA could prevail only if, as it claimed, the 340B statute "*prohibit[s]* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies." JA410-411.

The 340B statute does no such thing. As the District Court explained, "[t]he plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." JA410. "To be sure, Section 340B does not expressly grant manufacturers the authority 'to place conditions on [their] fulfillment of [their] statutory obligations.' " JA404 (quoting JA65). But as HRSA itself had long recognized, nothing in the statute "*prohibit*[s] manufacturers from placing *any* conditions on covered entities" through a "meaningful, *bona fide* offer[ ]." JA404-405. "[E]ven with the added conditions," Novartis's policy satisfies that requirement. JA403-404.

The District Court likewise rejected the Government's remaining arguments. The Government argued that, because Section 340B aims to "provide[ ] discounts on drugs to certain kinds of healthcare facilities," the statute must therefore

prohibit anything that might even slightly frustrate that purpose. *See* JA406-407. The District Court rejected that claim as both an improper basis on which to affirm the Violation Letter and wrong on the merits. JA406-408. The District Court also rejected HRSA's claim that its position reflected "the agency's 'longstanding interpretation of the statute,' " explaining that, by "changing its position on 'what *covered entities may* do' " in 2010 with respect to contract-pharmacy arrangements, "the agency necessarily changed its position on 'what *drug manufacturers must* do.' " JA408-409 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 57) (emphases altered). Likewise, the court made short work of HRSA's invocation of legislative history, observing that "the absence of specific language that Congress considered in the final statute d[oes] not speak to whether Congress rejected that scheme." JA409 n.7.

The District Court concluded that the Violation Letter "rests upon an erroneous reading of Section 340B," "declare[d] that [Novartis's] policies do not violate Section 340B" on this record, and vacated HRSA's May 17 Violation Letter. JA410. Although the court decided against injunctive relief "at this time," it made clear that "any future [administrative] enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here." JA410-411.

SUMMARY OF ARGUMENT

I. Section 340B does not prohibit manufacturers from adopting conditions on the sales of covered drugs to covered entities that use contract pharmacies as delivery points. The Violation Letter maintains that Section 340B "requires" manufacturers to deliver drugs purchased at the 340B discounted rate to an unlimited number of contract pharmacies. Thus, the Government cannot prevail unless the statute plainly *prohibits* manufacturers from imposing conditions on sales to covered entities using contract pharmacies as delivery points. But, as the Government concedes, "nothing in the 340B statute . . . explicitly prohibits" such a policy. Gov. Br. 30. That silence resolves this case. By nevertheless insisting that "the fact that Congress did not directly bar" Novartis's contract-pharmacy policy "does not mean that Congress *permitted* it," *id.*, the Government gets it backwards.

Section 340B's context and structure confirm that it does not prohibit manufacturers from adopting limitations on deliveries to contract pharmacies. Congress knew how to mandate recognition of contract-pharmacy arrangements in this statute if it desired—it did so in the very next section of the legislation enacting Section 340B—but it did not mention contract pharmacies anywhere in Section 340B itself. The Government's own near-15-year position limiting covered entities to a single contract pharmacy further supports Novartis's reading. The Government fails to acknowledge, let alone explain, that statutory switcheroo.

Hitting a dead end on the text, the Government deploys a motley collection of policy concerns. Those concerns are neither as dire as the Government predicts nor relevant to the task at hand: interpreting the statute as written. Nor can the post-hoc arguments offered by the Government's amici save the Violation Letter's (or the Government's) faulty analysis.

II. In addition to resting on an erroneous reading of the statute, the Violation Letter is arbitrary and capricious. It misstated and did not differentiate Novartis's policy, failed to acknowledge (let alone explain) HRSA's change in position over time, and did not account for the serious risks of diversion and duplicate discounts created by the explosion of contract pharmacies. The District Court did not need to reach this argument, but HRSA's haphazard, half-baked rationale provides yet another reason to affirm the judgment.

III. Finally, the Government urges this Court to reach for the first time on appeal whether Novartis's policy satisfies the statute. This Court should not reach out to decide that belated argument. But if it does, the answer is plainly yes: by "offer[ing]" to sell drugs to covered entities at the 340B price, Novartis satisfies the statutory "shall offer" requirement, and it may impose reasonable delivery limitations designed to further Section 340B's goals of preventing diversion.

The District Court's judgment should be affirmed.

STANDARD OF REVIEW

This Court reviews the District Court's grant of summary judgment de novo, "applying the familiar [Administrative Procedure Act] standard, which requires [the Court] to set aside agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.' " *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1118 (D.C. Cir. 2010) (quoting 5 U.S.C. § 706(2)(A)).

ARGUMENT

I. SECTION 340B DOES NOT PROHIBIT MANUFACTURERS FROM IMPOSING CONDITIONS ON SALES TO COVERED ENTITIES THAT DISPENSE DRUGS THROUGH CONTRACT PHARMACIES.

The question in this case is whether HRSA unlawfully determined that Novartis was "in direct violation of the 340B statute." JA65, JA402. In its Violation Letter, HRSA concluded that Section 340B categorically prohibits a manufacturer from "plac[ing] conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." JA65. In other words, according to HRSA, Section 340B "requires manufacturers to honor" covered entities' "purchases regardless of the dispensing mechanism." *Id.* HRSA therefore concluded that "Novartis must . . . offer[ ] its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." JA66. This unequivocal position echoed

HRSA's view in the since-withdrawn Advisory Opinion that the statute is unambiguous, "and no amount of linguistic gymnastics can ordain otherwise." JA265.

Courts judge "the validity of" an administrative decision solely on "the grounds upon which the [agency] itself based its action." *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943). Where an agency contends that its statutory "interpretation is the only permissible [one]," this Court asks whether the statute "in fact compels [that] interpretation." *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021) (per curiam) (internal quotation marks omitted), *cert. granted sub nom. N. Am. Coal Corp. v. EPA*, 142 S. Ct. 417 (2021) (No. 20-1531). If the agency's "assumption that it was Congress' judgment that such [action] is . . . required" proves "unjustified," the agency action "must be declared invalid"—*even if* the agency might have been able to take the same action on some other basis. *Id.* (quoting *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985)).

That is doubly true where, as here, the agency has disclaimed any entitlement to *Chevron* deference. Gov. Br. 2, 38-39. To be sure, in many agency-review cases, if the statute does not "unambiguously require" the agency's reading, the Court asks at *Chevron* step two whether the agency's interpretation is "permissible." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (internal quotation marks omitted). But the Violation Letter never claimed

that Congress left this question open for *HRSA* to resolve. On the contrary, HRSA asserted in no uncertain terms that *Congress* had decided this issue. JA65-66. HRSA's position is understandable; as the Government acknowledges, HRSA "has no rulemaking authority with respect to contract-pharmacy arrangements." Gov. Br. 38. *Chevron* deference is thus unwarranted here. *See* JA402; *Smith v. City of Jackson*, 544 U.S. 228, 267 (2005) ("[N]o deference is due to agency interpretations at odds with the plain language of the statute itself." (internal quotation marks omitted)).

To prevail, HRSA therefore must demonstrate that the statute unambiguously requires manufacturers to honor *all* contract-pharmacy arrangements, wherever and whatever they are. It cannot.

A. The Statute Does Not Prohibit Manufacturers From Imposing Delivery Conditions On Sales To Covered Entities Using Contract Pharmacies.

As the District Court explained, "[t]he 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." JA410-411. Because nothing in the statute prohibits manufacturers from imposing delivery limitations on drugs purchased at the 340B price, the statute does not unambiguously require manufacturers to honor covered entities' unilateral fiat that the manufacturer must deliver those drugs to a contract pharmacy, rather than the covered entity. The

Violation Letter's contrary conclusion that Novartis's policy is "in direct violation of the 340B statute" is thus unlawful. JA65; *see* JA402.

1. Start with the text. Section 340B requires a participating manufacturer to "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). As the Government has acknowledged for nearly two decades, the statute "is silent as to permissible drug distribution systems." Gov. Opp. 4 (quoting 61 Fed. Reg. at 43,549). It has maintained that position throughout this litigation, explaining to the District Court that "340B 'is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs.' " *Id.* at 39 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 59); *see also id.* at 21 ("[t]he 340B statute is (unsurprisingly) silent as to delivery location"). Every court to consider the issue has reached the same conclusion.[3] Even the Government's amici concede as much. *See* Am. Hosp.

[3] *AstraZeneca Pharms. LP v. Becerra*, No. 21-27-LPS, 2022 WL 484587, at *6 (D. Del. Feb. 16, 2022) (*AstraZeneca II*), *appeal docketed*, No. 22-1676 (3d Cir. Apr. 15, 2022); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *14, *17, *19 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 21-00634 (FLW), 2021 WL 5150464, at *35 (D.N.J. Nov. 5, 2021), *appeal docketed*, No. 21-3167 (3d Cir. Nov. 26, 2021).

Ass'n et al. (AHA) Br. 8-9; States' Br. 9 & n.14; Nat'l Ass'n Cmty. Health Ctrs. et al. Br. 3, 12, 16-17.

That resolves this case. Because the statute is silent on this issue, it does not prohibit manufacturers from adopting limitations on sales to covered entities that dispense 340B-purchased drugs through contract pharmacies. "[S]ilence . . . is not tantamount to proscription." *People of State of N.Y. v. O'Neill*, 359 U.S. 1, 8 (1959); *see Fisher v. Pension Benefit Guar. Corp.*, 994 F.3d 664, 671 (D.C. Cir. 2021) ("Silence, in other words, may signal permission rather than proscription." (internal quotation marks omitted)). As the Supreme Court recently put it, " 'a matter not covered is to be treated as not covered'—a principle 'so obvious that it seems absurd to recite it.' " *GE Energy Power Conversion France SAS, Corp. v. Outokumpu Stainless USA, LLC*, 140 S. Ct. 1637, 1645 (2020) (quoting Antonin Scalia & Bryan J. Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012)). And because Section 340B does not prohibit the imposition of such a limitation, it does not unambiguously require that manufacturers honor all contract-pharmacy arrangements.

Perhaps recognizing this obstacle, the Violation Letter and the Government's brief on appeal instead focus on whether the 340B statute expressly *permits* manufacturers "to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered

entities." JA65; *see* Gov. Br. 30. The Government concludes that, because the statute is silent on whether such conditions are *permitted*, they must necessarily be prohibited—and therefore Section 340B "requires" a manufacturer to honor a covered entity's demand that the manufacturer deliver drugs to contract pharmacies. JA65; *see* Gov. Br. 30.

As the Supreme Court has explained, however, that gets the question "exactly backwards." *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). *Christensen* involved the Fair Labor Standards Act, which provides that "an employer must honor an employee's" reasonable "request to use compensatory time." *Id.* at 580. But the Act is "silent" on whether an employer can "*require* employees to use" accrued compensatory time. *Id.* at 585. Because the statute does not expressly "*permit* an employer" to adopt such a policy, the Department of Labor concluded that the employer's policy violated the law. *Id.* at 588 (internal quotation marks omitted). The Supreme Court disagreed, explaining that the key question was not whether the statute *permitted* the policy, but whether it *prohibited* it. *Id.* Because the statute was silent on this issue, the Supreme Court answered "no," and upheld the employer's policy.

This Court applied the same logic in *Serono Laboratories, Inc.*, in deciding whether a statute prohibited drug manufacturers from relying on certain types of evidence to prove that a proposed generic had the "same" active ingredient as the

pioneer drug. 158 F.3d at 1319. "[T]he statute says nothing at all about the type of information an applicant must submit to demonstrate 'sameness,' " the Court explained. *Id.* So although "nothing in the statute *permits* the use of" a particular type of evidence, "the important point is that nothing in the statute *prohibits*" the use of that evidence. *Id.* Thus, "the statute does not unambiguously require the term 'same as' to be defined" in a manner that excluded the manufacturer's evidence. *Id.* at 1320.

The same is true here. The Government concedes "the important point," *id.*—that "nothing in the 340B statute . . . explicitly prohibits" manufacturers from imposing conditions on sales to covered entities using contract pharmacies. Gov. Br. 30. Because nothing in the statute prohibits such a policy, the Violation Letter's conclusion that Novartis's policy is "in direct violation of the 340B statute" is unlawful. JA65; *see* JA404-405.

Where, as here, an agency erroneously claims that the statute "compels [its] interpretation" and the text indicates otherwise, that ends the matter. *Am. Lung Ass'n*, 985 F.3d at 944. That is true even if the agency could show (unlike here) that its interpretation "is but one of several permissible interpretations of the statutory language." *Id.* Because the Violation Letter "rises and falls with its legally flawed interpretation of the statute," the District Court correctly declared it unlawful. *Id.* at 958.

2. Even if this Court chooses to "look[] beyond the text," *id.* at 951, Section 340B's context and structure confirm that the statute does not prohibit manufacturers from imposing conditions on sales to covered entities using contract pharmacies as delivery points.

To start, contract pharmacies "are not mentioned anywhere in the statutory text." *AstraZeneca I*, 543 F. Supp. 3d at 59. "[T]he term 'covered entity' means . . . one of" 15 types of safety-net institutions. 42 U.S.C. § 256b(a)(4). That list is exhaustive, and it does not include contract pharmacies. *See id.*; *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1114-15 (D.C. Cir. 2009) (per curiam) ("means" signals an exhaustive list). As the *AstraZeneca I* court explained, "[i]t 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." 543 F. Supp. 3d at 60.

Nor does the definition of "covered entity" mention agents, even though Congress knows how to reference contractors and other agents and to distinguish among covered entities, distributors, and manufacturers. *See* 42 U.S.C. § 256b(d)(3)(B)(vi) ("associations or organizations" that can assert overcharge claims on a covered entity's behalf); *id.* § 256b(d)(2)(B)(iv) ("manufacturers, distributors, [and] covered entities"); *id.* § 256b(d)(1)(B)(v) ("manufacturers and wholesalers"). In fact, in the very next section of the legislation that created the

340B Program, Congress mandated that manufacturers "make available" discounted drugs for purchase by federal agencies that are "received, stored, and delivered through . . . a commercial entity operating under contract with" the federal agency. Sec. 603(a)(1), § 8216(a)(1), (h)(3)(A), 106 Stat. at 4971, 4974. "Had Congress intended to" mandate recognition of similar arrangements in Section 340B, "it presumably would have done so expressly." *Russello v. United States*, 464 U.S. 16, 23 (1983).

Moreover, although the statute says nothing about how a *manufacturer* must deliver 340B drugs, it does restrict how a *covered entity* may transfer those drugs. The statute expressly prohibits a covered entity from "resell[ing] or otherwise transfer[ring]" a covered drug to a non-patient. 42 U.S.C. § 256b(a)(5)(B). "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 purposely in the disparate inclusion or exclusion." *Russello*, 464 U.S. at 23 (internal quotation marks and brackets omitted).

3. HRSA's prior readings of Section 340B further support the conclusion that Congress did not prohibit manufacturers from imposing delivery restrictions on sales to covered entities using contract pharmacies.

In its 1996 guidance, HRSA explained that, although Section 340B "requires manufacturers to sell to covered entities at or below a ceiling price determined by a

statutory formula," "[t]he statute is silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,549. HRSA explained what this meant in practice: "[I]f a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug* [to the covered entity] at the discounted price." *Id.* (emphasis added). But "[i]f the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B *precludes* this type of transaction." *Id.* (emphasis added). In other words, HRSA concluded that, although the statute requires manufacturers to sell drugs to covered entities at the 340B price, it does not preclude manufacturers from agreeing to ship the drugs to a contract pharmacy. But if the statute does not "preclude th[at] type of transaction," it perforce does not mandate that type of transaction, either.

Moreover, HRSA's 1996 guidance set a "limitation of one" contract-pharmacy location "per entity," if the covered entity lacked an in-house pharmacy. *Id.* at 43,555; *see* 72 Fed. Reg. at 1540. But the guidance did not purport to require that manufacturers recognize such arrangements; indeed, the guidance explained that it "create[d] no new rights or duties." 61 Fed. Reg. at 43,550.

Even when HRSA later backtracked its one-contract-pharmacy limit, the agency continued to maintain that it was not "impos[ing] additional burdens upon

manufacturers." 75 Fed. Reg. at 10,273. During the first five years of its pilot program allowing covered entities to seek approval to use multiple contract pharmacies, HRSA authorized only 0.01% of covered entities to deviate from the 1996 guidance. 72 Fed. Reg. at 1540; *see* 75 Fed. Reg. at 10,273. It was not until 2010—nearly two decades after Congress created the 340B Program—that HRSA granted covered entities blanket permission to contract with an unlimited number of contract pharmacies. But although the 2010 guidance changed *covered entities'* ability to enter into contract-pharmacy arrangements, as in 1994 and 1996, the 2010 guidance did not claim to limit *manufacturers'* ability to impose conditions on deliveries to contract pharmacies—let alone suggest that Section 340B unambiguously prohibits such conditions. *See* 75 Fed. Reg. at 10,278; *AstraZeneca I*, 543 F. Supp. 3d at 56; *AstraZeneca II*, 2022 WL 484587, at *8-9 (discussing Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994)). The first time HRSA articulated that interpretation was in 2020.

HRSA's changing positions undermine any claim of statutory clarity. If the statute mandates recognition of an unlimited number of contract-pharmacy arrangements, as the Government now claims, the one-contract-pharmacy limit and pilot program were unlawful from the outset. *See Loan Syndications & Trading Ass'n v. SEC*, 882 F.3d 220, 222 (D.C. Cir. 2018) ("[I]f Congress has directly

spoken to an issue then any agency interpretation contradicting what Congress has said would be unreasonable." (internal quotation marks omitted)). Nor can HRSA claim it has consistently prohibited manufacturers from imposing delivery limitations on 340B-discounted drugs. *See* 59 Fed. Reg. at 25,113-14 (authorizing manufacturers to craft "appropriate contract provisions" in their dealings with covered entities).

In short, the Government's longstanding position confirms what the text, context, and structure of Section 340B make plain: Contrary to the Violation Letter, the statute does not prohibit manufacturers from imposing limitations on sales to covered entities using contract pharmacies as delivery points.

4. That conclusion likewise comports with Congress's aims in establishing the 340B Program. The program's purpose is to "provide[ ] discounts on drugs to certain kinds of healthcare facilities." JA406. But "no legislation pursues its purposes at all costs." *Id.* (quoting *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014)). The 340B Program rests on a careful balance between Congress's desire to make discounted drugs available to covered entities, the need to ensure those discounts are carefully monitored and appropriately circumscribed, and the importance of continued pharmaceutical innovation. *See* 42 U.S.C. § 256b(e) (excluding "orphan drugs" from 340B pricing caps in certain circumstances). Yet under the Government's reading, covered entities can unilaterally mandate that

manufacturers deliver drugs anytime, any way, and literally anywhere the covered entity demands. *See* JA266. The Government has since (predictably) backtracked from its "lunar surface" rhetoric, but under the Government's reading, a covered entity could also mandate that a manufacturer deliver drugs in color-coded boxes to ease processing; or only use 100% compostable packaging; or deliver drugs only between 2 AM and 3 AM, when hospitals are least busy. It would be unreasonable to expect that Congress implicitly required manufacturers to offer drugs to covered entities at the 340B price without any ability to protect themselves against such outlandish requirements.

At minimum, Section 340B does not prohibit manufacturers from refusing to honor onerous delivery demands such as these. Nor does it prevent them from imposing reasonable limitations on deliveries of 340B-purchased drugs to contract pharmacies.

Indeed, declining to accede to covered entities' unilateral demands that manufacturers deliver 340B drugs to contract pharmacies serves the statute's goal of preventing duplicate discounts and diversion. *See* 42 U.S.C. § 256b(a)(5)(B); *Nat'l Corn Growers Ass'n v. EPA*, 613 F.3d 266, 272 (D.C. Cir. 2010) (statute must be interpreted to give effect to all provisions).[4] Contract-pharmacy

[4] Before the District Court, the Government argued that manufacturers can impose only those conditions that comport with the statute's goals—meaning, in its view,

arrangements inherently "create complications in preventing diversion" and "duplicate discounts." OIG Report, *supra*, at 16. As the contract pharmacy industry has grown, the need for effective monitoring has only increased.

Yet HRSA's audit process is incapable of effectively identifying or remedying these issues. *E.g.*, GAO-18-480, at 16, 40-43. Covered entities are not themselves providing sufficient oversight. *Id.* at 16, 43 (*e.g.*, covered entity serving 21,000 patients conducted independent audit of just five claims). And a manufacturer's right to audit an individual covered entity has proved insufficient in the face of a rapidly expanding number of contract-pharmacy arrangements. *See* Vandervelde et al., *supra*, at 4 (noting that the number of contract-pharmacy arrangements has increased 4,228% since 2010); *infra*, at 52-53. Manufacturers need not facilitate "the well-documented, long-standing, and significant program integrity risks occasioned by the contract pharmacy program in its current form," JA39, by acceding to covered entities' unilateral delivery demands.

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those that facilitate, as opposed to restrict, access. Gov. Opp. 23-24. As explained, "access" is not the statute's sole aim. The Government does not revive that claim on appeal. *See Al-Tamimi v. Adelson*, 916 F.3d 1, 6 (D.C. Cir. 2019) (arguments missing from opening brief are forfeit). So instead amicus AHA takes up the mantle (at 15). This Court does not "entertain" arguments "only raised in [an] amicus brief." *FG Hemisphere Assocs., LLC v. Democratic Republic of Congo*, 637 F.3d 373, 379 (D.C. Cir. 2011). In any event, this argument points in favor of recognizing only those conditions that comport with the statutory scheme. By imposing reasonable restrictions to limit diversion, Novartis's policy satisfies that requirement.

B. The Government's Arguments Do Not Demonstrate That Section 340B Prohibits Manufacturers From Imposing Delivery Limitations On Sales To Covered Entities Using Contract Pharmacies.

Despite twice disclaiming *Chevron* deference, Gov. Br. 2, 38-39, the Government's argument reads like a classic *Chevron*-step-two argument. It spends a scant two pages on the text of Section 340B before pivoting to a lengthy discourse on statutory purpose, legislative history, and policy. But the Government has boxed itself in; it cannot prevail unless the Violation Letter was correct that the statute plainly prohibits manufacturers from adopting limitations on deliveries to contract pharmacies. And the statute plainly does not.

1. The Government's purported textual and contextual arguments are unpersuasive.

1. The Government's affirmative textual case spans only three paragraphs. Paragraph one quotes the statutory text, which requires that a manufacturer "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the" 340B price. Gov. Br. 26 (quoting 42 U.S.C. § 256b(a)(1)). From this—with no intermediate analysis—the Government infers that Section 340B implicitly requires drug manufacturers to "sell their drugs to covered entities at a discounted price," with no conditions or limitations. *Id*.

That is not what the statute says. It requires only that manufacturers "*offer*" their drugs for sale, which "is defined as '[t]he act or instance of presenting

something for acceptance,' " at the 340B price. JA403 (quoting *Offer* (def. 1), Black's Law Dictionary (11th ed. 2019)). Nothing in the text prevents manufacturers from imposing delivery conditions on sales to covered entities using contract pharmacies.

Having exhausted any arguments keyed to the actual text, the Government pivots in paragraph two to the "canon of donut holes" point. Catchy, but not compelling. The question is not whether Congress "create[d] a tacit exception" to Section 340B to allow manufacturers to impose delivery restrictions. Gov. Br. 26 (quoting *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020)). As the Government admits, the statute is simply silent on this issue. *Supra*, at 26-32.

In any event, the anti-donut-holes-canon only applies where the plain text necessarily includes the alleged exception. *Bostock* is one such example: "[D]iscrimination based on homosexuality or transgender status necessarily entails discrimination based on sex; the first cannot happen without the second." 140 S. Ct. at 1747; *see also White v. United Airlines, Inc.*, 987 F.3d 616, 620-621 (7th Cir. 2021) (cited at Gov. Br. 26-27) (declining to construe "rights and benefits" to tacitly exclude paid leave, where Congress defined that term to include all "terms, conditions, or privileges of employment, including any advantage, profit, privilege, [or] gain" (quoting 38 U.S.C. § 4303(2))). The requirement that a manufacturer offer drugs to covered entities at the 340B price does not "necessarily entail[ ]" the

requirement that the manufacturer must deliver 340B-purchased drugs on the covered entity's unilaterally dictated terms. *Cf.* Gov. Br. 26-27. On the contrary, the "shall offer" requirement simply means that the manufacturer must make a "meaningful, *bona fide* offer[ ]" to sell drugs to covered entities at the 340B price. JA404. Adopting reasonable delivery limitations on sales to covered entities using contract pharmacies is not a "tacit exception" to the "shall offer" requirement.

The Government has long recognized as much. Two years after Congress enacted Section 340B, HHS explained that manufacturers were free to "condition the offer of statutory discounts upon an entity's" agreement to "provisions that address customary business practice, request standard information, or . . . other appropriate contract provisions." 59 Fed. Reg. at 25,113-14. The Government does not explain "why the plain language of the statute allows manufacturers to impose only the conditions they previously imposed," and not also a reasonable delivery limitation. JA405.

Of course, manufacturers' offers must still be "meaningful" and "*bona fide*," as the District Court explained. JA404. Just as a manufacturer cannot require "minimum purchase amounts," 59 Fed. Reg. at 25,113, a manufacturer cannot condition its offer on a requirement that the covered entity preference the manufacturer's drugs over competing products, *cf.* Gov. Br. 30, or condition its offer on a requirement that someone named John accept delivery, *cf.* JA266.

Paragraph three of the Government's brief then concludes that, because "Congress created the 340B Program to ensure that covered entities could obtain discounted drugs under the conditions that Congress established," manufacturers may not impose conditions of their own. Gov. Br. 27. But there is no evidence that Congress prohibited manufacturers (or HRSA, as it did for over a decade) from imposing *other bona fide* conditions on deliveries of 340B drugs to contract pharmacies. The section of *Reading Law* that the Government quotes cautions against this precise error: The canon that "everything necessary to" make a statute "effectual . . . is implied" "must be applied with caution" because "[d]etermining what is *reasonably* implied takes some judgment." *Reading Law*, *supra*, at 193 (internal quotation marks omitted). The agency's judgment fell short here.[5]

2. "Lacking a clear textual hook for its interpretation of Section 340B," the Government again "invokes the statute's purpose to defend" the Violation Letter. JA406; *see* Gov. Br. 27-28. As the District Court explained, it is true that "the more opportunities that covered entities have to purchase discounted drugs, the

[5] In its District Court briefing, the Government also claimed that Novartis's policy violates the statutory "non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases"—an argument absent from the Violation Letter. Gov. Opp. 23. Although the Government criticizes the District Court for rejecting that claim, Gov. Br. 29-30, that "skeletal" mention is not sufficient to preserve the affirmative textual argument, *see Al-Tamimi*, 916 F.3d at 6 (internal quotation marks omitted). The Government's non-discrimination argument is also wrong, for the reasons the District Court explained. JA405-406.

more money they can save." JA406. But the text of the statute and the Government's prior guidance demonstrate "that Congress did not intend" that goal "to be pursued at all costs." JA407. For example, Section 340B "clearly prohibits covered entities from receiving duplicate discounts on drugs," "prohibits covered entities from reselling or transferring discounted drugs to anyone who is not a patient of the covered entity," allows for audits of covered entities, and creates sanctions for covered entities' non-compliance with the 340B Program's rules. JA406-407; *see* 42 U.S.C. § 256b(a)(5)(B)-(D). And for nearly 15 years, the Government *itself* limited covered entities' ability to use more than one contract pharmacy. *Supra*, at 7, 21, 32.

3. Out of textual options, the Government resorts to pseudo-textual jiu-jitsu, gesturing repeatedly at unenacted legislative history to reason (again, implicitly) that Congress must not have intended to allow manufacturers to adopt delivery conditions on sales of 340B-purchased drugs. Gov. Br. 1, 6-7, 22, 28-29. "In general, citation to legislative history is problematic." JA409 n.7. Here, it is even more problematic than usual. The Government's argument rises and falls on whether the plain text of Section 340B is unambiguous. "Legislative history, for those who take it into account, is meant to clear up ambiguity, not create it." *Bostock*, 140 S. Ct. at 1749 (quoting *Milner v. Dep't of Navy*, 562 U.S. 562, 574 (2011)). Even those "who believe that clear legislative history can illuminate

ambiguous text won't allow ambiguous legislative history to muddy clear statutory language." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814 (2019) (internal quotation marks omitted).

That the Government resorts to unenacted legislation that was not adopted for unknown reasons is even more telling. "[F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute," *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (internal quotation marks omitted), because a "bill can be proposed for any number of reasons, and it can be rejected for just as many others," *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001). And "mute intermediate legislative maneuvers are not reliable indicators of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (internal quotation marks omitted).

Nor does this unreliable legislative history demonstrate that Congress implicitly required that manufacturers accept covered entities' demands to deliver 340B-purchased drugs to any and all contract pharmacies. *See* Gov. Br. 29; AHA Br. 12-13. For years, HRSA said otherwise and restricted where covered entities could direct 340B drugs to be dispensed. 61 Fed. Reg. at 43,551; *see* 72 Fed. Reg. at 1540 (summarizing 1996 guidance). At most, this legislative history confirms that Congress knew how to draft terms related to drugs dispensed by contract

pharmacies—yet it chose to *omit* such references in the statute. *See AstraZeneca I*, 543 F. Supp. 3d at 61. That is hardly unimpeachable evidence that Congress intended to allow covered entities and contract pharmacies separated by thousands of miles to profit from these arrangements.

4. From these collected inferences, the Government concludes that the District Court erred in requiring an "explicit prohibition" against adopting delivery restrictions. Gov. Br. 29. But as the Government acknowledges, because the statute is silent on this point, the Government can only prevail if an inference drawn from that silence is "contrary to all other textual and contextual evidence of congressional intent." *Id.* (quoting *Burns v. United States*, 501 U.S. 129, 136 (1991)). It cannot make that showing. Just as in *Burns*, "[t]he Government's construction of congressional 'silence' would . . . render what Congress has expressly said absurd" by preventing manufacturers from attaching sensible delivery conditions to sales to covered entities using contract pharmacies. 501 U.S. at 136-137. And just as in *Burns*, the Government's construction ignores important indicia cutting the other way. *See id.* at 136-138 (Government's interpretation would undermine Congress's goal "of promoting focused, adversarial resolution of" sentencing issues and create due process concerns); *supra*, at 30-31, 34-35.

2. The Government's policy arguments are inapplicable and unavailing.

In its final effort, the Government offers up a buffet of policy arguments. But "no amount of policy-talk can overcome a plain statutory command." *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (2021). Were it otherwise, courts would be transformed "from expounders of what the law *is* into policymakers choosing what the law *should be*." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018). Regardless, these arguments fail.

First, the Government argues that Congress adequately accounted for the risks of diversion and duplicate discounts, and that manufacturers cannot supplement the statutory scheme. Gov. Br. 31-34. That is true only if the Government is correct on its broader statutory interpretation; the Government cannot use this kind of self-reinforcing policy argument to prove that very point. Moreover, before the District Court, the Government invoked this rationale only in reply, and only then "to explain why its actions were not arbitrary and capricious." JA407 & n.5. "[I]t did not argue that the structure shows that the agency's position is in accordance with the statute." *Id.* Because the Government failed to make this argument in the District Court, it cannot do so now. *United States v. Sheffield*, 832 F.3d 296, 303 (D.C. Cir. 2016).

The Government is also wrong on the merits. History—and the Government's own sources—demonstrate that contract-pharmacy arrangements

have significantly increased the risks of diversion and duplicate discounts, risks that HRSA and covered entities have been unable (or unwilling) to mitigate. *Supra*, at 12-13, 35-36; GAO-18-480, at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."); *id.* at 37 ("Without complete information on covered entities' use of contract pharmacies, HRSA does not have the information needed to effectively oversee the 340B Program . . . ."). Nothing in the statute suggests that Congress intended these ineffectual processes to be manufacturers' exclusive means for achieving the 340B statute's goals. *Cf. Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54-57 (1987) (finding "comprehensive" "enforcement scheme" "to be exclusive" based on a "clear expression of congressional intent").

Second, the Government takes aim at certain manufacturers' claims-processing rules. Gov. Br. 34-35. That argument, like any concerning federal grantees, is inapplicable to Novartis. Novartis does not require the submission of claims data, and the 40-mile radius rule applies only to hospitals' contract-pharmacy arrangements. JA37. Because these policy arguments are inapplicable to Novartis, the Violation Letter cannot be upheld on this basis. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463

U.S. 29, 43 (1983) (agency action must rest on "rational connection between the facts found and the choice made" (internal quotation marks omitted)).

Third, the Government suggests that the differences among manufacturers' policies are themselves problematic. Once again, this argument is missing from both the Violation Letter and the District Court briefing. And once again, this argument is a red herring. In the Government's telling, allowing manufacturers to impose different restrictions will create a burdensome "web" of policies for covered entities to navigate. Gov. Br. 36-37. Covered entities are already required to comply with a host of complicated policies in the 340B space—including, for example, varying policies on whether manufacturers use limited distribution networks for their 340B drugs. *See, e.g.*, Apellis Limited Distribution Notice (May 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-limited-distribution-pegcetacoplan.pdf. Additional variations are just par for the course.

Finally, the Government suggests in passing that the manufacturers' contract-pharmacy policies have harmed patients. Gov. Br. 37. The Government's support for this serious contention? A "supra" cite to the background section of its brief. *Id.* To be very clear: Novartis's policy does not in the least affect where patients can fill prescriptions, nor does it affect their copayments. There is simply no need for a patient to travel "hundreds of miles" to reach an in-house pharmacy, Gov. Br. 18—a point the Government *itself* acknowledged in its 340B guidance.

See 61 Fed. Reg. at 43,555 ("If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice."). Patients can get their prescriptions anywhere, for the same copay amount.

As to the Government's other "supra" cites, the vast majority of the referenced portions of the record do not even relate to Novartis. *See* JA280-284, JA302-308, JA750-755 (declarations from federal grantees, which are exempted from Novartis's policy); JA170-174 (report complaining of price changes before Novartis's policy took effect). Of the two other citations, one merely restates Novartis's policy, while acknowledging it is not as "wide-spread" as other policies. JA235. The other is to an assortment of charts HRSA created on supposed losses attributable to manufacturers' policies that (1) combine data from six different manufacturers, (2) incorrectly represent that Novartis's policy began two months earlier than it did (with no explanation for how a nonexistent policy caused sales of 340B drugs to decrease); and (3) erroneously attribute to Novartis drops in 340B contract pharmacy units sold to federal grantees, despite the Government's admission that Novartis's policy does not apply to federal grantees. JA361-362; *see* Gov. Br. 15.

The Government's insinuations about harm to patients also fail on the merits. Hospitals rarely pass on their 340B savings to patients in the form of

reduced drug costs. As the Government recognizes, more than 57% of hospitals do not provide uninsured patients with *any* discounts on 340B drugs purchased at contract pharmacies. GAO-18-480, at 31. An additional 17.8% provide discounts at only "some contract pharmacies"—and it is not clear which or how many contract pharmacies that might include. *Id.* And even those hospitals that do provide some degree of discount at contract pharmacies may still charge uninsured patients more than the 340B price. *Id.*

There is "no evidence" that hospitals use "the surplus monetary resources generated from" their 340B savings to "invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality." Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 New Eng. J. Med. 539, 546 (2018), *available at* https://bit.ly/3NhGg7v. On the contrary, financial help for needy patients is "negatively correlated" with growth of the 340B Program because, unlike federal grantees, nothing prevents hospitals and contract pharmacies from pocketing their 340B-derived-profits. William Smith, Opinion, *A Most Dysfunctional Federal Program*, InsideSources (May 17, 2022) (internal quotation marks omitted), https://insidesources.com/a-most-dysfunctional-federal-program/; *cf.* 42 U.S.C. § 254b(k)(3)(G)(iii). Novartis's policy merely aims to cut

down on the noncompliance and profiteering associated with these contract-pharmacy arrangements.

* * *

The Government's litany of policy concerns is not as dire as the Government claims. And "[t]o the extent Congress is persuaded" otherwise, "it is, of course, free to amend the statute accordingly." *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA*, 559 U.S. 573, 604 (2010). As for this Court, its "job is reading statutes as written, not rewriting them in an effort to achieve that which Congress is perceived to have failed to do." *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 497 (D.C. Cir. 2004) (Roberts, J.) (internal quotation marks omitted).

3. The Government amici's additional arguments do not provide a basis to uphold the Violation Letter.

Apparently unsatisfied with the Government's defense, its amici offer up various other arguments absent from both the Violation Letter and the Government's opening brief. If "courts may not accept appellate counsel's post hoc rationalizations for agency action," surely they may not accept such arguments from amicus counsel. *State Farm*, 463 U.S. at 50. In any event, none of these additional arguments moves the needle.

1. AHA attempts to revive the Advisory Opinion's "purchased by" argument—an argument neither the Violation Letter nor the Government advances. AHA claims this case is not about what manufacturers "shall offer" to covered

entities; it is about "whether the drugs subject to Appellees' policies are 'purchased by' covered entities." AHA Br. 12-13. The Violation Letter (and the Government on appeal) say otherwise. *See* JA65; *see also* Gov. Br. 3 ("The question presented is whether the statute allows drug manufacturers to refuse to offer this discounted price if a covered entity uses one or more contract pharmacies to dispense the drugs that the covered entity purchases."). Although the since-withdrawn "[Advisory] Opinion leans heavily on the 'purchased by' language," the Violation Letter "says nothing about the 'purchased by' language"; it "focuses exclusively on the 'shall offer' requirement." *AstraZeneca II*, 2022 WL 484587, at *5 & n.5; *compare* JA264-271, *with* JA65-66. This Court "cannot sustain" the Violation Letter "on the basis of interpretive theories that the agency might have adopted" but did not invoke. *Env't Def. Fund, Inc. v. Adm'r, U.S. EPA*, 898 F.2d 183, 189 (D.C. Cir. 1990).

The Government's decision to forgo further reference to the "purchased by" argument is understandable, because it is unpersuasive. The statute thrice references drugs "purchased by" a covered entity. The first is in the statute's title, which "cannot limit the plain meaning of the text." *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (internal quotation marks omitted). The second, in subsection (a)(1), "is directed to the Secretary of HHS," "does not directly act on covered entities," does not reference "the amount of such

drugs purchased or the model by which the drugs are distributed," and "says nothing of the permissible role (if any) of contract pharmacies." *AstraZeneca I*, 543 F. Supp. 3d at 59. The third, in subsection (a)(3), simply defines "[d]rugs provided under State Medicaid plans." None of these references says anything about whether covered entities may unilaterally force manufacturers to ship 340B-purchased drugs to third parties.

Accepting AHA's interpretation of "purchased by" would also render the phrase "shall offer" superfluous. AHA claims that, by using "purchased by," Congress required drug manufacturers to provide drugs to covered entities at the 340B price, condition-free (except, apparently, for those conditions HHS has already said are acceptable). *See* AHA Br. 9-10, 15. If manufacturers are required to *sell* covered drugs condition-free, why use the word "offer"?

The better reading of this provision, which gives effect to both terms, is that when manufacturers *offer* their drugs to covered entities, they must do so "for purchase at or below the" 340B "ceiling price." *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("[a] statute should be construed so that effect is given to all its provisions" (internal quotation marks omitted)). The offer cannot be conditioned on a higher price. As even HHS has admitted, however, the statute does not prevent manufacturers from conditioning their offers on "other appropriate contract provisions." *See* 59 Fed. Reg. at 25,112. So just as nothing in the word "offer"

precludes a manufacturer from imposing reasonable delivery limitations, nothing in the word "purchase" does either.

2. Congress's decision to ascribe to the States certain implementation responsibilities does not implicitly authorize the States to crown themselves exclusive regulatory sovereigns. *Contra* States' Br. 22. To be sure, States do have an enforcement role to play. Because covered entities serve patients who receive care through Medicaid, covered entities are *supposed* to report to HRSA when they dispense 340B-purchased drugs to Medicaid beneficiaries. OIG Report, *supra*, at 6-7. And the States are *supposed* to use that information to "exclude those drugs from rebate requests to drug manufacturers." *Id.* at 4. But that system is not working as intended. Covered entities' reporting is inaccurate and does "not necessarily" include drugs dispensed by contract pharmacies, *id.* at 7, so contract-pharmacy arrangements are necessarily hindering the States' enforcement efforts, too.

HRSA, the entity best positioned to address these issues through audits or oversight, has made little effort to correct these problems. *Supra*, at 12-13, 35-36, 44-45. The same is true of the States—perhaps because there is little financial incentive for them to do so. *See* 61 Fed. Reg. at 43,554; States' Br. 17-21. That leaves manufacturers "at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions." GAO-18-480, at 40. According to the

States, the only remedy is for a manufacturer to individually audit each covered entity—at the manufacturer's own expense, with no opportunity for reimbursement. Only if the audit reveals an actual instance of diversion or duplicate discounts can the manufacturer then proceed through HRSA's administrative dispute resolution process—meaning a covered entity with sloppy recordkeeping or incorrect data can escape oversight. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,638 (Dec. 14, 2020); *see also* GAO-21-107, at 3, 14 (noting that roughly 75% of covered entities HRSA audited reported incorrect information). And *each* manufacturer must do this *each time* it suspects noncompliance by *each* covered entity, or any of its contract pharmacies—a task even HHS recognizes is "burdensome" and "not feasible." *See* 42 U.S.C. § 256b(a)(5)(C); 61 Fed. Reg. at 43,552.

Nothing in the statute prevents manufacturers from choosing a different path. Section 340B does not state that these ineffectual audits are manufacturers' "only" option to address program abuses by covered entities using contract pharmacies, or use other similarly limiting language. *See* 42 U.S.C. § 256b(a)(5)(C). Moreover, the manufacturers' complementary policies do not upset the States' own role in ensuring compliance with the 340B Program.

3. Contrary to the States' claim (at 10), there is no reason to believe that Congress's failure to mention contract pharmacies in Section 340B somehow implicitly blessed tens of thousands of these arrangements (and their concomitant problems)—let alone requires manufacturers to unconditionally honor them. For one, it was only in the "months following [Section 340B's] enactment" that the contract pharmacy issue "became clear." 61 Fed. Reg. at 43,550. Even if Congress legislated against a backdrop of *some* contract pharmacy use, however, no one foresaw the explosive growth and attendant abuses rampant today. Congress cannot legislate against a background "understanding" that does not exist. States' Br. 10. *Cf. Doe v. Exxon Mobil Corp.*, 654 F.3d 11, 22 (D.C. Cir. 2011) (Congress does not legislate against "novel" concepts of which it is unaware), *vacated on other grounds*, 527 F. App'x 7 (D.C. Cir. 2013).

4. Finally, a collection of federal grantees supplement the Government's erroneous policy arguments with affidavits not in the Administrative Record that purport to demonstrate harm from Novartis's policy. Nat'l Ass'n Cmty. Health Ctrs. et al. Br. 1 n.1, 25-30. But Novartis's policy does not apply to federal grantees. And even if it did, these arguments fail on the merits, for all the reasons explained. *Supra*, at 44-49.

II. HRSA'S DECISION IS ARBITRARY AND CAPRICIOUS.

The agency's decisionmaking process was also arbitrary and capricious in several respects. The District Court did not need to reach this issue, but it is yet another reason to affirm. *See, e.g.*, *Jones v. Bernanke*, 557 F.3d 670, 674 (D.C. Cir. 2009) (this Court "may affirm on any ground properly raised" (internal quotation marks omitted)).

The Violation Letter does not provide a reasoned basis for HRSA's decision. It misstates Novartis's policy. *See* JA65 (referring to a claims data requirement); *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 83 (D.C. Cir. 2006) (agency action based on "unsupported assertions or unstated inferences" lacks a "reasoned basis"). It rests on a statutory reading that, if true, would require Novartis to deliver 340B drugs to the moon. *See* JA266; *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 930 F.2d 936, 940 (D.C. Cir. 1991) ("Impossible requirements imposed by an agency are perforce unreasonable . . . ."). And it fails to offer any reasonable interpretation to support its conclusion that Novartis's policy violates Section 340B. *Supra*, at 46-48; *see, e.g.*, *Tripoli Rocketry*, 437 F.3d at 83.

The Violation Letter also failed to acknowledge—let alone explain—HRSA's change in position over time. *See* JA408-409; *AstraZeneca II*, 2022 WL 484587, at *5-9. Where the statute permits, an agency is of course allowed to

change its mind. But it is black-letter administrative law that "the agency must at least display awareness that it is changing position," "explain[ ] its changed position," "show that there are good reasons for the new policy," and account for any reliance interests. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-222 (2016) (internal quotation marks omitted). Thus, an agency's "failure even to acknowledge its past practice" and changed position, "let alone to explain its reversal of course" is "arbitrary and capricious." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017). HRSA has refused to acknowledge that its current position is inconsistent with its prior guidance limiting covered entities to the use of, at most, one contract pharmacy—let alone explain its course-reversal. *See, e.g.*, Gov. Opp. 34 ("there has been no change in position over time for HRSA to explain" (internal quotation marks omitted)); JA65 (claiming HRSA's position has remained the same since 1996); *see also supra*, at 31-34 (identifying additional inconsistencies).

Nor does the Violation Letter account for the serious risks of diversion and duplicate discounts created by the explosion of contract pharmacies. As the statute makes clear, *see* 42 U.S.C. § 256b(a)(5)(B), that is "an important aspect of the problem" that HRSA was required to consider in evaluating Novartis's policy, *State Farm*, 463 U.S. at 43. HRSA did not discuss the significant and familiar problems with contract-pharmacy arrangements—including its own inability to

effectively police these arrangements. *Supra*, at 12-13, 35-36, 44-45; *see, e.g.*, GAO-18-480, at 36. Because HRSA refused to acknowledge this issue, it likewise did not consider whether Novartis's policy furthers the statute's aims by reasonably addressing these concerns. This, too, renders the Violation Letter arbitrary and capricious. *See, e.g.*, *United Parcel Serv., Inc. v. Postal Regul. Comm'n*, 955 F.3d 1038, 1050-51 (D.C. Cir. 2020) ("A statutorily mandated factor, by definition, is an important aspect of any issue before an administrative agency . . . ." (internal quotation marks omitted)).

III. THIS COURT SHOULD NOT AND NEED NOT REACH THE QUESTION OF WHETHER NOVARTIS'S POLICY VIOLATES SECTION 340B.

In a final bid for reversal, the Government urges this Court to ignore the usual rules of appellate procedure and decide for the first time on appeal whether Novartis's *specific* policy violates Section 340B. That gambit is both belated and wrong.

Throughout this litigation, the Government has insisted that the 340B statute does not allow manufacturers to impose *any* conditions on offers to sell 340B drugs to covered entities. The District Court flatly—and correctly—rejected that claim. As a consequence of its absolutist position, the Government never argued in the alternative that the statute "prohibits the *specific* conditions that Novartis and United Therapeutics have imposed." JA408. As a result, the District Court expressly "decline[d] to decide whether Section 340B permits or prohibits any of

the specific conditions at issue here," instead holding that, on this record, those "policies do not violate Section 340B." JA408, JA410. Having forfeited this argument below, the Government cannot belatedly contest Novartis's specific policy now. *See, e.g.*, *Capitol Servs. Mgmt., Inc. v. Vesta Corp.*, 933 F.3d 784, 789 (D.C. Cir. 2019) ("[W]e are a court of review, not of first view." (internal quotation marks omitted)).

In any event, Novartis's policy satisfies Section 340B. As the District Court explained, Novartis still makes "meaningful, *bona fide* offers" of 340B drugs to covered entities. JA404. Under its 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." *Id.* Further, the record did "not show that any of [the covered] entities were not offered 340B pricing upon compliance with the manufacturers' policies." JA404 n.2.

The Government offers no argument as to why Novartis's policy is illegal; instead, it merely repackages the same argument that the statute's silence requires that manufacturers deliver 340B drugs on demand to contract pharmacies, and again asks this Court to consider its unpreserved "structural" argument. *See* Gov. Br. 37-38; *see* JA407-408 & nn.5-6.

As to the first argument, because the statute does not prohibit the imposition of reasonable delivery limitations, Novartis's policy is lawful. *Supra*, at 23-29.

As to the second, having twice failed "to spell out its arguments squarely and distinctly"—first in its opening brief before the District Court, and again on reply before the District Court in support of its statutory argument—the Government must now "hold its peace." *Schneider v. Kissinger*, 412 F.3d 190, 200 n.1 (D.C. Cir. 2005). Even if this Court were inclined to overlook that dual forfeiture, however, nothing in the statute requires Novartis to accede to covered entities' delivery demands, or otherwise prevents Novartis from imposing reasonable delivery limitations that, by combatting diversion, furthers "the operation of the 340B Program." *See* JA408 n.6; *supra*, at 23-54.

For all these reasons, Novartis's policy satisfies the statutory "shall offer" requirement.

CONCLUSION

For the foregoing reasons, the District Court's judgment should be affirmed.

Respectfully submitted,

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June 8, 2022

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limits of Fed. R. App. P. 32(a)(7) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 12,965 words.

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/s/ Catherine E. Stetson
Catherine E. Stetson

ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 256b

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and 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.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

* * *

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section

1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

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.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs 1 (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs 1 (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

*** * ***

(b) Other definitions--

(1) In general

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

*** * ***

(d) Improvements in program integrity

(1) Manufacturer compliance

* * *

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

* * *

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

* * *

(2) Covered entity compliance

* * *

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

* * *

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

* * *

(3) Administrative dispute resolution process

* * *

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

* * *

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

* * *

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.

* * *

CERTIFICATE OF SERVICE

I certify that, on June 8, 2022, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson