IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION and XAVIER BECERRA, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Civil Action No. 1:21-cv-01479

REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND MOTION FOR SUMMARY JUDGMENT
AND
OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Justice Scalia famously observed that Congress does not hide elephants in mouseholes. Yet here HRSA claims to have found a full-grown pachyderm stowed in congressional silence. In asserting that Novartis's policy regarding contract pharmacy arrangements violates the 340B statute, HRSA argues that the statutory silence on contract pharmacy arrangements requires drug manufacturers to recognize *all* contract pharmacy arrangements. The statute says nothing (literally) of the sort.

On its face, the 340B statute does two things relevant here. First, it limits the price that can be charged for covered outpatient drugs "purchased by a covered entity." 42 U.S.C. § 256b(a)(1). Second, it requires participating manufacturers 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." *Id.* HRSA reads the 340B statute to impose an additional obligation on manufacturers: that they ship 340B drugs to any destination—and to as many destinations—as the covered entity directs, for dispensing to both patients *and non-patients* of the covered entity. The result: a dramatic increase in the number of sales purportedly entitled to the 340B discount.

Tellingly, HRSA is not claiming statutory ambiguity and/or *Chevron* deference in support of its position. Instead, it asserts that through its silence, Section 340B *unambiguously compels* the agency's interpretation.

In addition, HRSA's position is not the product of reasoned decisionmaking. The May 17, 2021 Decision Letter under review offers no rational explanation why Novartis's 340B contract pharmacy policy is unlawful. After all, Novartis's policy voluntarily accommodates the vast majority of contract pharmacy arrangements by recognizing [1] all contract pharmacy

arrangements within a 40-mile radius of the covered entity, [2] all contract pharmacy arrangements of federal grantees, regardless of location, and [3] exceptions to the 40-mile radius limitation when appropriate. Nor does the Decision Letter explain, or even acknowledge, HRSA's prior conflicting guidance regarding contract pharmacy arrangements, which recognized that not all contract pharmacy arrangements were permissible. And HRSA's failure to grapple with the very real diversion concerns created by the contract pharmacy model constitutes an independent basis for finding the agency decision arbitrary and capricious.

For all these reasons, HRSA's contract pharmacy policy should be set aside.

ARGUMENT

I. NOVARTIS IS LIKELY TO PREVAIL ON THE MERITS.

A. HRSA's Position Is Contrary to the 340B Statute

As Novartis explained in its opening brief, HRSA's position on contract pharmacy arrangements violates the agency's statutory mandate, and therefore should be set aside as unlawful. *See Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 325–326 (2014). The statute speaks to purchase of covered outpatient drugs by covered entities. It is completely silent on shipments of covered outpatient drugs to non-covered entities. HRSA attempts to parlay that silence into a statutory mandate that covered entities may unilaterally demand any shipment arrangements they desire. That is not how statutory interpretation works.

The Government offers two conflicting responses. On the one hand, it doubles down on HRSA's argument that the 340B statute "requires" its interpretation; it "disagrees that there is ambiguity." Gov. Br. at 9, 20, 22, 34–35, 38. But as Novartis has explained, the statute "requires" nothing close to what HRSA divines. Perhaps recognizing this conundrum, the Government attempts to chart out a new, narrower path elsewhere in its brief, asserting for the first time that

the Decision Letter "does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity)." Gov. Br. at 38–39. Just in case the Court finds ambiguity, the Government claims *Skidmore* deference for its decision.

The Government's litigation counsel cannot disavow the position HRSA staked out below. HRSA is bound by what it said in the Decision Letter, which is that "the 340B statute *requires* manufacturers to honor such purchases regardless of the dispensing mechanism." AR 5 (emphasis added). That position echoed HHS's assertions in the now-scuttled Advisory Opinion that the statute was unambiguous. Although the agency subsequently withdrew the Advisory Opinion, HHS made clear that it was not walking away from the positions spelled out there. To the contrary, HHS stated that it was withdrawing the Advisory Opinion "in light of ongoing confusion about [its] scope and impact." Off. of the Gen. Counsel, U.S. Dep't of Health & Human Servs., *Notice of Withdrawal* 1 (June 18, 2021), *available at* https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf. Either way, the Advisory Opinion remains relevant to understanding HRSA's statutory interpretation at the time it issued the Decision Letter. *See* Gov. Br. at 11 (noting that HRSA "considered" the Advisory Opinion at the time).

HRSA's position therefore rises or falls on whether it can demonstrate that the statute *unambiguously* requires manufacturers to honor contract pharmacy arrangements. It cannot.

1. The 340B Statute's Plain Language Does Not Impose a Boundless Delivery Obligation.

Let's start at the very beginning, with the plain language of the statute. The 340B statute limits the price that can be charged for covered outpatient drugs "purchased by a covered entity," and requires participating manufacturers 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). Slimmed down, the statute requires that manufacturers offer the 340B discount on sales to covered entities. Novartis does so.

The Government argues that the statute's broad reference to a "purchase" imposes a third statutory obligation on manufacturers: to ship 340B drugs to non-covered entities, and to any destination the covered entity might unilaterally choose. Gov. Br. at 21. That would be remarkable, if it were true. But HRSA's interpretation wrenches the statute's "purchase" and "offer" language into something unrecognizable. "Purchase" and "offer" do not mean "ship," and Congress's silence on delivery location does not quietly signal a statutory mandate that covered entities may unilaterally force manufacturers to provide the 340B discount on drug products shipped to and dispensed by third parties. Congress also was silent on whether covered entities can demand that manufacturers deliver drug products via carrier pigeon, or package them in green boxes. The statute's silence does not give covered entities leeway to impose unilateral demands on manufacturers like this. If manufacturers are to be required under the 340B regime to ship drugs directly to non-covered-entity contract pharmacies so that they can dispense the drug to non-patients[1] of the covered entity, that is something only Congress, not HRSA, may prescribe.

Far from mandating this arrangement, Congress arguably prohibited it. In order to ensure that the 340B discounts actually benefit covered entities and their patients, Congress imposed rigorous restrictions on a covered entity's ability to redistribute the drugs to third parties after purchase. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting a covered entity from "resell[ing] or

[1] The Government tries to sidestep the fact that the drugs are dispensed to non-patients of the covered entity by asserting that purchases are "tracked and *tied to* dispenses to eligible patients of the covered entity." Gov. Br. at 27 (emphasis added). But HRSA admits elsewhere in its brief that under the replenishment model, after a drug subject to the 340B discount arrives at the contract pharmacy, the drug becomes "neutral inventory" that "may be dispensed to any subsequent patient"—including non-patients of the covered entity. Gov. Br. at 37.

otherwise transfer[ring] the drug to a person who is not a patient of the entity"). It would make no sense to read into Section 340B(a)(1) an escape hatch permitting covered entities to force manufacturers to ship drugs to these same non-covered-entity third parties, who then dispense the drug to customers who are not patients of the covered entity.

2. HRSA Is Not Entitled to Deference.

HRSA is not entitled to deference in this case for two separate reasons.

First, because HRSA continues to assert that the statute unambiguously *requires* the interpretation it offers here, it has disavowed any entitlement to deference. *See Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (noting that *Chevron* deference is reserved only "for those instances when an agency recognizes that Congress's intent is not plain from the statute's face"); *see also American Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021) (per curiam) (a "regulation must be declared invalid" if it is based on the "unjustified assumption that it was Congress' judgment that such a regulations is desirable or required" (cleaned up)), petition for cert. filed, No. 20-1530 (Apr. 29, 2021).

The Government also abdicates any argument for *Chevron* deference in its brief. Gov. Br. at 38. That is wise. To begin with, there is the *Chevron* Step Zero problem.[2] The 340B statute grants HRSA rulemaking authority only with respect to three narrow areas, none of which are implicated here: "(1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling

[2] Before applying *Chevron*, courts first consider whether an agency has authority to "speak with the force of law" on a statute, and whether it acted in exercise of that authority. *See United States v. Mead Corp.*, 533 U.S. 218, 226–227 (2001). Sometimes called "*Chevron* Step Zero," this threshold inquiry considers whether "Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Fox v. Clinton*, 684 F.3d 67, 76 (D.C. Cir. 2012) (internal quotation marks omitted).

prices, and (3) the imposition of monetary civil sanctions." *Pharmaceutical Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014). None of these rulemaking powers allows the agency to force manufacturers to offer the 340B discount on sales shipped to non-covered entities.

HRSA's position also lacks the formality typically associated with *Chevron* deference. The agency relies on two sources as evidence of its interpretation: the Decision Letter issued to Novartis, and HRSA's non-binding contract pharmacy guidances. Gov. Br. at 21. But in undertaking both of these actions, HRSA never "set out with a lawmaking pretense in mind." *United States v. Mead*, 533 U.S. 218, 233 (2001).

Near the end of its brief at page 38, HRSA mentions *Skidmore* deference, in rather a lukewarm way. But even under *Skidmore* deference, HRSA cannot escape its position in the Decision Letter that there is no ambiguity in the 340B statute on this issue. AR 5–6. Again, "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan*, 471 F.3d at 1354 (internal quotation marks omitted). The agency's reasoning as set forth in the administrative record leaves no room for an argument based on statutory ambiguity. In the end, a fundamental principle of law governs: Agency action "cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985).

Even if the Court determines that *Skidmore* deference is available here, HRSA's position is not entitled to deference because it lacks the necessary "power to persuade." *Orton Motor, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1211 (D.C. Cir. 2018) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Under *Skidmore*, courts consider "the thoroughness

evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140.

First, on its face, the agency's consideration of Novartis's policy was the polar opposite of thorough. The agency in fact appears to have reviewed the wrong policy. *See* Novartis Br. at 12–13.

Second, the agency has been consistently inconsistent over the years in its interpretation of what the 340B statute "requires." The 1996, 2007, and 2010 guidance documents imposed varying restrictions on contract pharmacy arrangements, culminating in the agency's current posture—contrary to its 1996 guidance—that the statute *prohibits* any such restrictions. The agency's lawyers claim that HRSA's letter was based on "its decades of expertise administering the statute," Gov. Br. at 38; those decades were marked by rigorous restrictions on contract pharmacy arrangements. This inconsistency "count[s] against" the persuasiveness of HRSA's position. *Orton*, 884 F.3d at 1214.

Third, HRSA's lawyers' current hedging weighs against HRSA's position having the "power to persuade." HRSA's reasoning in the Decision Letter turned on its belief that the 340B statute lacked ambiguity. Now, for the first time, its lawyers argue the position is based on agency discretion. It is too late for that. *See Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate."). HRSA's counsel's position thus is based on discretion that the agency repeatedly and expressly disavowed. *Cf. United States v. Ross*, 848 F.3d 1129, 1134 (D.C. Cir. 2017) ("Where a statute grants an agency discretion but the agency erroneously believes it is

bound to a specific decision, we can't uphold the result as an exercise of the discretion that the agency disavows.").

Marked by inconsistency and post-hoc rationalization, HRSA's interpretation is not entitled to any deference, under any standard.

3. HRSA's Position Is Inconsistent with Its Prior Guidance.

HRSA's own contract pharmacy guidance from 1996 through 2010 restricted covered entities to one contract pharmacy site—and even then only if the covered entity lacked an in-house pharmacy. And over time, HRSA's position shifted from the view that the obligations were non-binding to the view that they were binding on manufacturers. Novartis Br. at 5–11.

In its brief, the Government attempts to reconcile the 1996 and 2010 policies by asserting that both were "unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense those drugs." Gov. Br. at 22. Unequivocal? HRSA's 1996 guidance permitted covered entities to enter into contract pharmacy arrangements *only* if they lacked an in-house pharmacy, and only with a single contract pharmacy. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). If the contract pharmacy had multiple locations, the covered entity had to choose one site. *Id.* HRSA reiterated this one-pharmacy, one-site limitation in 2007. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg 1540, 1540 (Jan. 12, 2007) ("[A] covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services."). It is impossible to reconcile these guidance documents with the agency's current position, which is that the statute *unambiguously* requires

recognition of *all* contract pharmacy arrangements, regardless of number, and regardless of whether the covered entity has an in-house pharmacy.

HRSA instead puts all its weight on the statement in the 1996 guidance that "the statute directs the manufacturer to sell[3] the drug at the discounted price," and, "[i]f the entity directs the drug shipment to its contract pharmacy" (note the singular), that in no way "exempts the manufacturer from statutory compliance." 61 Fed. Reg. 43,549–550. HRSA argues this language reflects the statute's mandate that manufacturers cannot place restrictions on the number or location of contract pharmacy arrangements. Gov. Br. at 34. But obviously that is not true; otherwise, HRSA itself would have had no authority to limit covered entities to a single contract pharmacy, and even then only if they lacked an in-house pharmacy. Instead, HRSA's 1996 guidance means what it says: if (and only if) the covered entity lacks an in-house pharmacy, it may designate one contract pharmacy, and manufacturers may ship drug products to that contract pharmacy. 61 Fed. Reg. 43,549–550. The 1996 guidance is completely inconsistent with HRSA's current position that the statute requires manufacturers to recognize an unlimited number of contract pharmacies.

Indeed, the 1994 guidance relied upon in the Government's brief further highlights the inconsistency of the agency's guidances. Gov. Br. at 23–24. The 1994 guidance purported to prohibit manufacturers from conditioning the offer of 340B discounts upon certain assurances, like assurances from the covered entity of its 340B compliance. *See* HHS, *Final Notice Regarding*

[3] The Government repeatedly characterizes the obligation as a "sale" rather than an "offer." Gov. Br. at 22–23. Congress could have used a term other than "offer" if it wanted to. *See, e.g.*, 38 U.S.C. § 8126(a)(1) and (2) (adopted by Section 603 of the Veterans Health Care Act of 1992, the same Act that created the 340B program, and separately requiring the manufacturer to "make available for procurement"). And even with the more specific "procurement" language in the VA context, Congress had to enact legislation to expand that term to regulate transactions with third party pharmacies. *See* 10 U.S.C. § 1074g(f).

Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113–114 (May 13, 1994). But the 1994 guidance specifically allowed manufacturers to enter into agreements with covered entities that contain "the manufacturer's normal business policies" and "other appropriate contract provisions." 59 Fed. Reg. at 25,112. And this makes sense: it would be unreasonable to require manufacturers to offer drugs for sale without any ability to protect themselves against outlandish terms of sale or delivery like, for example, requiring delivery to the "lunar surface." AR 8050.

Both the 340B statute and its related historical guidance documents establish that the statute does not unambiguously require manufacturers to honor contract pharmacy arrangements, however many and wherever they are.

B. HRSA's Decision Is Arbitrary and Capricious.

HRSA's decision that Novartis's 340B contract pharmacy policy violates the 340B statute "runs counter to the evidence before the agency," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983), "fail[s] to consider an important aspect of the problem," *id.*, and represents an unexplained departure from an existing policy, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). *See* Novartis Br. at 20–26.

1. HRSA Has Not Provided A Reasoned Basis In The Record For Its Decision.

Because Section 340B dictates only the price at which manufacturers must offer drugs to covered entities, manufacturers retain the right to include other reasonable terms in their offer. Novartis's policy is reasonable and then some. It recognizes *all* contract pharmacies within a 40-mile radius of the covered entity, no matter how many; *all* contract pharmacy arrangements of federal grantees, regardless of location; and provides for exceptions to the 40-mile radius limitation when appropriate. AR 5627.

HRSA acknowledges that its conclusion that Novartis's accommodating policy nevertheless violates the 340B statute "must be decided on the basis of HRSA's reasoning contained [in the Decision Letter] and the administrative record supporting it." Gov. Br. at 20; *see also CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014). But nothing in the Decision Letter or the record supplies a roadmap by which "the agency's path may be reasonably discerned." *Bowman Transp. Inc. v. Arkansas-Best Freight Sys.*, 419 U.S. 286, 281 (1974).

a. *The Decision Letter.* The Decision Letter, for its part, fails to offer any reasoned basis for HRSA's conclusion that Novartis's policy violates Section 340B. In fact, it misstates Novartis's policy. AR 5; Dkt. 1-4.

b. *The Advisory Opinion.* Nor is the now-withdrawn Advisory Opinion of any use to the Government here. This is the agency statement averring that the 340B statutory requirements include, *sub silentio*, an obligation to deliver drugs anywhere and everywhere, including intergalactically. Novartis Br. at 20–21. The Government knows that was a cringe-worthy overreach. And so, as predicted, *id.*, HRSA dismisses the Advisory Opinion's reference to the lunar surface as merely "colorful language and analogies," Gov. Br. at 33, and notes that the Advisory Opinion has been withdrawn. Gov. Br. at 20.

HRSA's shuffle away from the Advisory Opinion after the fact, and its attempts to minimize the Advisory Opinion's influence on its Decision Letter, are unpersuasive. Yes, the Advisory Opinion was withdrawn—but only *after* HRSA issued its Decision Letter (and after this lawsuit was filed). *See Blue Ocean Inst. v. Gutierrez*, 502 F. Supp. 2d 366, 369 (D.D.C. 2007) (an "agency may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made"). And HRSA concedes that the Advisory Opinion was a component of its decision-making process. Gov. Br. at 11. It also is

irrelevant that the Advisory Opinion was issued during HRSA's review of Novartis's policy, *id.* at 33—in fact, that timing would have made the Advisory Opinion the most recent agency pronouncement on the issue, and therefore of keen interest to agency decisionmakers. Nor is it relevant that the Decision Letter does not explicitly cite the Advisory Opinion. *Id.*

In the end, for all of HRSA's maneuvering away from the Advisory Opinion's language, it cannot help but embrace the Advisory Opinion's logic. Indeed, HRSA is unwilling to say the Advisory Opinion got it wrong. *See id.* Restating an arbitrary and capricious position in less "colorful language" does not make it any less arbitrary and capricious.

c. *The rest.* Conceding that its Decision Letter lacks any explanation, and distancing itself from the colorful, cancelled Advisory Opinion, the Government now attempts to string together support for its decision from the administrative record after the fact. *See* Gov. Br. at 31–32. But agency "counsel may not now 'supply a reasoned basis for the agency's action that the agency itself has not given.'" *Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634, 648 (D.C. Cir. 2020) (quoting *Bowman Transp., Inc.*, 419 U.S. at 285–286)).

The Government's reasoning is unpersuasive in any event. The rest of the record is a motley collection of documents pertaining to a number of different manufacturers' different contract pharmacy policies. But to enforce its Decision Letter against Novartis, HRSA needs to show that *Novartis*'s policy violates the statute. The record falls far short of that.

HRSA argues in general terms, for example, that the 340B program saw cuts to the volume of drugs subject to the discount following manufacturers' implementation of various contract pharmacy policies. Gov. Br. at 31. But there is a reason HRSA keeps it vague in this case; the record makes clear that this assertion is exaggerated when it comes to Novartis's accommodating policy. That is because the vast majority of contract pharmacies are located within a 40-mile radius

of the covered entities they serve. *See* GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 22–23 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf.

That generous geographic scope matters to the analysis. The agency itself says so. HRSA has repeatedly stated that its contract pharmacy policy is designed to allow covered entities to enter into "arrangements in their communities." *See* HRSA, *Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). The Government's opposition makes regular use of this concept; it mentions eleven times that allowing contract pharmacy arrangements facilitates covered entities' use of "neighborhood pharmacies." Gov. Br. at 1, 3, 14–15, 16, 18, 26, 30, 35, 37, 41. Novartis's policy recognizes all contract pharmacies within a 40-mile radius, meaning a *5,000-square mile area* surrounding a covered entity. And if a covered entity's in-house pharmacy is unable to stock and dispense a particular product for any reason, and the covered entity has no contract pharmacy within 40 miles, Novartis will grant an exception to allow the covered entity to use a contract pharmacy outside of the 40 mile radius. HRSA does not explain why that nevertheless is inadequate to capture a covered entity's "community" and "neighborhood."

For many of the same reasons, HRSA is wrong to argue in its brief that it was reasonable to reject Novartis's policy because "some covered entities serve communities well beyond [a] 40-mile radius." Gov. Br. at 31. Again, that reasoning is absent from the Decision Letter. *Physicians for Social Responsibility*, 956 F.3d at 648. Moreover, the administrative record does not support HRSA's conclusion that Novartis's policy has prevented any patients from accessing needed drugs. The UC Davis Medical Center's complaint, which the Government cites, Gov. Br. at 31, cited no instance where 340B pricing was actually denied with respect to a patient. AR 5622–27.

And HRSA's conclusion (again) fails to account for Novartis's exception policy. Reasoned decisionmaking requires both record support and consideration of all relevant factors. *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 599 (D.C. Cir. 2007).

There is also a total lack of support for HRSA's conclusion that Novartis's policy treats commercial purchases more favorably than 340B purchases. In its brief, the Government repeats the Decision Letter's conclusion that Novartis's policy treats covered entities differently than other purchasers, in violation of Section 340B. Gov. Br. at 32–33. The Decision Letter did not explain the basis for that conclusion, and neither does the Government's brief. *Id.* In response to Novartis's statement that it "does not recognize any commercial arrangement equivalent to HRSA's current view of the 340B contract pharmacy arrangements," Lopuch Decl. ¶ 6, ECF No. 5-2, the Government simply, and cite-lessly, says "not true." *See* Gov. Br. at 32–33. But it is true: There is no such thing as a contract pharmacy arrangement in the commercial world. In Novartis's experience, that type of arrangement is a creature of the 340B universe alone. And more generally, Novartis does not allow any commercial purchasers to unilaterally direct delivery to an unlimited number of third-party locations. Lopuch Decl. ¶ 6. HRSA's contrary ipse dixit is arbitrary and capricious. *See Safe Extensions, Inc.*, 509 F.3d at 599 (the record before the agency must support the agency decision).

2. HRSA Has Not Adequately Explained Its Change In Position.

HRSA's refusal to acknowledge, let alone explain, its change in position is also arbitrary and capricious in its own right. *Dillmon v. National Transp. Safety Bd.*, 588 F.3d 1085, 1089–90 (D.C. Cir. 2009). In 1996, HRSA issued guidance outlining the kinds of contract pharmacy arrangements that were allowed under 340B. 61 Fed. Reg. at 43,549. To facilitate participation in the program by covered entities without an in-house pharmacy, HRSA allowed only those covered entities to contract with only one outside pharmacy. *Id.* at 43,549–50, 43,555. HRSA

confirmed that understanding of its 1996 guidance in 2007 when it sought comments on a proposal that would expand the kinds of contract pharmacy arrangements it deemed permissible under 340B72 Fed. Reg. at 1540. After comments closed on its 2007 proposal, HRSA issued guidance in 2010 allowing covered entities to contract with an *unlimited* number of contract pharmacies regardless of whether the covered entities also maintained an in-house pharmacy. 75 Fed. Reg. at 10,275, 10,277–278. HRSA, however, continued to require that contract pharmacy arrangements meet a number of conditions (including that the covered entity retains title to the 340B-purchased drugs). 75 Fed. Reg. at 10,275, 10,277–278. By the time of its Decision Letter, however, HRSA had also done away with those requirements, *see infra*, and for the first time, HRSA concluded that the language of 340B *compels* accommodating contract pharmacy arrangements that would have flunked its rigid 1996 rubric. *See* AR 8048–55; AR 5–6; Novartis Br. at 22–24. With regard to its position on manufacturers' obligations to recognize contract pharmacy arrangements HRSA has flipped, then flopped, and then flopped again.

Of course, an agency may change its mind, where the statute permits, but only if the agency provides a reasoned analysis justifying its departure from its prior position. *Ramaprakash v. FAA*, 346 F.3d 1121, 1124-25 (D.C. Cir. 2003). The first step of any such reasoned analysis "necessarily requires the agency to acknowledge . . . its departure from the established precedent." *Dillmon*, 588 F.3d at 1089-90; *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing positions."). HRSA has refused to do even that. Gov. Br. at 33–35. That failure constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'" *Ramaprakash*, 346 F.3d at 1125 (citation omitted). Instead, HRSA offers a revisionist history of its past positions, *see* Gov. Br. at 35 (arguing that

"[p]roperly viewed," HRSA's "interpretation of drug makers' obligations has not shifted over time"), in an attempt to braid together a thread of coherence where there is none.

The Government has little to say in response. HRSA first points to guidance from 1994 as purported evidence that the agency has always held that manufacturers must deliver product purchased by covered entities to an unlimited number of third-party pharmacies. *See* Gov. Br. at 23–24, 34. The Government concedes that the 1994 guidance does not actually say that; it reads between the lines to find that message. Gov. Br. at 24, 33–34. But HRSA's 1994 guidance merely introduces an extra turn in the serpentine history of the agency's position on contract pharmacy arrangements. That guidance specifically allowed manufacturers to enter into agreements with covered entities that contain "the manufacturer's normal business policies" and "other appropriate contract provisions." 59 Fed. Reg. at 25,112. Thus, HRSA is wrong that it has consistently disallowed *any* reasonable manufacturer sale-condition. Gov. Br. at 35. And among the "normal business policies" Novartis has reasonably included in its 340B contract pharmacy policy is to not allow purchasers the unilateral authority to direct delivery to an unlimited number of third-party locations.

Even if HRSA's 1994 guidance could be retrofitted to the agency's current position, the Government fails to account for its conflicting guidance in between. In 1996, HRSA offered specific guidance on contract pharmacy arrangements limiting covered entities to one contract pharmacy if the entities themselves lacked an in-house pharmacy. HRSA confirmed that understanding again in 2007. 72 Fed. Reg. at 1540. Thus, even under HRSA's (mis)reading of the 1994 guidance, the 1996 guidance represented a significant shift in the agency's position.

The Government also contends that, although HRSA's "allowance for the number of contract pharmacies a covered entity may engage has changed over time," Gov. Br. at 35 (emphasis

removed), it has consistently held that "*the statute directs the manufacturer to sell the drug* at a price not to exceed the statutory discount price." *Id.* at 34 (quoting 75 Fed. Reg. at 10,278) (emphasis added in Gov. Br.). But HRSA's consistent position about the *price* at which manufacturers must offer their drugs to covered entities does not equate to a consistent position about a manufacturer's ability to include *other* reasonable terms in its offer where contract pharmacies are involved. As demonstrated, the agency has been all over the map on that issue. *Supra* 8–10, 14–16; Novartis Br. at 5–7, 22–24. The APA does not permit an agency to change its mind so frequently and drastically without providing an adequate explanation. *Ramaprakash*, 346 F.3d at 1125

The Decision Letter offers no explanation for this agency flip-flopping. *National Cable & Telecomms. Assn. v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2016) (an "[u]nexplained inconsistency" in agency policy is "a reason for holding an interpretation to be an arbitrary and capricious change from agency practice"). It offers instead yet another shift in course, erasing all conditions on contract pharmacy arrangements—including the title-retention requirements—such that *all* contract pharmacy arrangements are eligible for 340B discounts, and manufacturers must comply with whatever those arrangements are. *See* AR 5; Novartis Br. 22–23. This further unexplained change in position is arbitrary and capricious. *Friedman v. Sebelius*, 686 F.3d 813, 828 (D.C. Cir. 2012) (agency decision arbitrary and capricious because "it failed to explain its departure from the agency's own precedents"). That new twist also introduces a third arbitrary and capricious element, as we explain next.

3. HRSA's Position Increases The Risk of Diversion.

Separate from imposing pricing obligations on manufacturers, 340B disallows resale or diversion of discounted drugs by covered entities. 42 U.S.C. § 256b(a)(5)(B). And because statutes must be interpreted to give effect to all provisions, *Husted v. A. Philip Randolph Inst.*, 138

S. Ct. 1833, 1842 (2018), HRSA may allow only contract pharmacy arrangements that avoid diverting discounted drugs. HRSA has accordingly directed that "[t]he covered entity will purchase the drug, *maintain title to the drug* and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State, and local laws." 75 Fed. Reg. at 10,277 (emphasis added). *See also* HRSA, Contract Pharmacy: Important Tips, available at https://www.hrsa.gov/opa/updates/2016/august.html (Aug. 2016). But the Decision Letter fails to assess whether covered entities actually retain title to discounted drugs under the replenishment model widely used by contract pharmacies, as required by the statute and HRSA's guidance. *See* Novartis Br. 22–23. HRSA has thus concluded that Section 340B requires Novartis to make deliveries to an unlimited number of third-party pharmacies who then dispense the drug to both patients and non-patients of the covered entity without ever considering whether that model conflicts with other statutory requirements. That is arbitrary and capricious. Novartis Br. at 25–27; *State Farm*, 463 U.S. at 43 (agencies may not "fail to consider an important aspect of the problem").

HRSA responds that, because it articulated covered entities' obligation to retain title to, and avoid diversion of, discounted drugs in a guidance document, that obligation is nonbinding. Gov. Br. at 36. HRSA's guidance might not be binding, but the statute is. 42 U.S.C. § 256b(a)(5)(B). Covered entities' non-diversion obligations—an "essential element[] to address in contract pharmacy arrangements," 75 Fed. Reg. at 10,277—derive from a congressional mandate. Compliance with the diversion prohibition is a condition of qualifying as a covered entity. 42 U.S.C. §§ 256b(a)(4) and (5)(b). And whether the replenishment model complies with Section 340B's anti-diversion requirements is relevant to weighing HRSA's interpretation of manufacturer's obligations under Section 340B. HRSA's conclusion that Section 340B requires

manufacturers to recognize contract pharmacy arrangements does not square with a determination that the most prevalent contract pharmacy arrangements violate the statute. *See Corely v. United States*, 556 U.S. 303, 314 (2009) ("[O]ne of the most basic interpretative canons [is] that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant."). HRSA refused to undertake that inquiry.

Agency counsel's attempt to do HRSA's homework after the fact is unavailing. *Physicians for Social Responsibility*, 956 F.3d at 648. In any event, the Government undersells the serious diversion concerns surrounding the replenishment model. By HRSA's telling, there is a perfect continuity of title from manufacturer to 340B covered entity to patient. Gov. Br. at 36–37. The reality is far less clear. HHS's Office of the Inspector General has recognized the difficulty of assessing 340B eligibility across covered entities given the variety of contract pharmacy arrangements and data types, OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 9–10 (Feb. 4, 2014), available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. The GAO has noted that "HRSA does not have complete data on all contract pharmacy arrangements in the 340B Program to inform its oversight efforts." *See* GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf. Yet nowhere in either the Decision Letter or the administrative record did HRSA contend with whether the covered entities at issue actually retained title to the drugs at issue or otherwise comply with the requirements spelled out in the agency guidance implementing the 340B statute. Because HRSA's decision therefore is not "the product of reasoned decisionmaking," it should be set aside. *Fox*, 684 F.3d at 74-75. *See* Novartis Br. at 25–26.

II. NOVARTIS WILL SUFFER IRREPARABLE HARM ABSENT PRELIMINARY INJUNCTIVE RELIEF.

Absent injunctive relief, Novartis will suffer irreparable harm. In addition to the harm to Novartis's reputation from HRSA's false accusation that the company has knowingly and intentionally violated the 340B program, Novartis faces significant civil monetary penalties unless it acquiesces to the Government's demand that it provide steep, unwarranted discounts that may end up benefiting large pharmacy chains. Novartis Br. at 26–29.

Courts have recognized that "the prospect of severe and unrecoverable reputational harm" supports a finding of irreparable harm "justifying preliminary relief"; as does the prospect of substantial and imminent financial harms based on unlawful agency actions. *Everglades Harvesting & Hauling v. Scalia*, 427 F. Supp. 3d 101, 115-116 (D.D.C. 2019); *see* Novartis Br. at 28. And particularly devastating is the threat that Novartis's Medicaid National Drug Rebate Agreement could be canceled for non-compliance with the 340B program, meaning that federal payment under Medicaid and Medicare Part B would be unavailable for Novartis's covered outpatient drugs. 42 U.S.C. § 1396r-8(a)(1).

These harms are neither speculative, Gov. Br. 41-43, nor aimed at third parties, *id.* 44. Rather, they are concrete and imminent, and because this is an APA case, Novartis will never be able to recover for its losses. *See, e.g.*, *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) ("even if the claimed economic injury did not threaten plaintiffs' viability, it is still irreparable because plaintiffs cannot recover money damages against FDA").

III. THE PUBLIC INTEREST AND BALANCE OF EQUITIES FAVOR PRELIMINARY INJUNCTIVE RELIEF.

The public interest and balance of equities also favor an injunction. Novartis's 340B contract pharmacy policy is designed to maximize covered entities' access to discounted drugs,

while safeguarding program integrity by ensuring that benefits flow only where intended, and not to commercial interlopers. This serves the public interest. As does Novartis's continued participation in 340B Program and the Medicaid Drug Rebate Program, which grants needy patients access to Novartis's drugs. And while the public may have an interest in proper implementation of laws passed by Congress, *see* Gov. Br. at 44, the public interest is not served when an agency steps outside of its authority. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) ("There is generally no public interest in the perpetuation of unlawful agency action. To the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" (citations omitted)).

The balance of equities also supports Novartis. HRSA cannot claim any real harm from delaying implementation of its unlawful policy, particularly because it has taken the position that any civil monetary penalties (CMPs) will apply to alleged overcharges made even before the Decision Letter, and presumably, during the pendency of this case. By contrast, Novartis will face significant reputational and financial burdens absent injunctive relief. *See supra*. The harms to Novartis far outweigh any harm to HRSA in maintaining the status quo pending a decision from this Court. *See Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 235 (D.D.C. 2014) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held.").

The Government argues that "covered entities and their patients are harmed every day Novartis denies access to 340B-discounted drugs, as demonstrated by the countless complaints of safety-net providers contained in the administrative record." Gov. Br. at 45. But again, those "countless" complaints largely don't pertain to Novartis at all; recall (*see supra* at 13–14) that in

its brief, the Government has alleged no instances in which patients were unable to access drugs and few instances where covered entities actually suffered real-world harm as a result of Novartis's policy. For good reason. Between the blanket exemption for all federal grantees and its recognition of an unlimited number of contract pharmacies covering an area nearly 5,000 square miles, not to mention its exception process, Novartis's policy covers the field.

Finally, the Government argues that the terms "enforcement" and "action" are too "vague" to support a preliminary injunction. Gov. Br. at 45. That is odd. The proposed order is five pages long; it seeks an injunction against Defendants and others acting in concert with them "from taking enforcement or any other action against Novartis based on HRSA's determination that Novartis's 340B contract pharmacy policy violates the 340B statute and/or applicable regulations." Dkt. 5-3 at 4. The 340B statute, implementing regulations, and the 340B Pharmaceutical Pricing Agreement (PPA) spell out the enforcement mechanisms available to HRSA in detail. *See, e.g.*, 42 U.S.C. § 256b(d)(1)(B)(vi), 42 C.F.R. § 10.11, PPA.[4] These are the enforcement mechanisms Novartis is seeking to enjoin. No reasonable person would interpret Novartis's proposed order enjoining any action "against Novartis" as enjoining "internal assessment and consideration of potential CMPs" or "memoranda analyzing the basis for a 'knowing' violation." Gov. Br. at 45.

For this reason, the cases cited by the Government are inapposite. *Emrit v. NIH*, 2014 WL 12802602 (D.D.C. Dec. 30, 2014), involved a motion for preliminary injunction where the plaintiffs failed to address "any of the factors for issuing a preliminary injunction" and where the "motion [was] simply too vague to support a preliminary injunction." *Patriot Homes, Inc. v. Forest River Hous., Inc.,* 512 F.3d 412, 415 (7th Cir. 2008), involved a preliminary injunction in

[4] Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

a trade secret case that failed to identify the trade secret. And *Ideal Toy Corp. v. Plawner Toy Mfg. Corp*., 685 F.2d 78, 83 (3d Cir. 1982), involved a preliminary injunction in a trademark case that failed to identify the trademark. These cases simply have no relevance here.

CONCLUSION

For all the foregoing reasons, as well as those set forth in Novartis's opening brief, Novartis's motions for preliminary injunction and summary judgment should be granted, the May 17, 2021 Decision Letter should be vacated, and the Government should be enjoined from taking any enforcement action against Novartis.

Respectfully submitted,

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