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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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Dated: June 2, 2021

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INTRODUCTION

Under what is commonly known as the "340B Program," drug manufacturers wishing to participate in certain Medicaid and Medicare programs must offer deep discounts on their products to specified hospitals and clinics serving needy patient populations. The 340B statute carefully circumscribes the type of hospitals and health clinics that qualify as "covered entities" entitled to those steep discounts.

In recent years, however, there has been an explosion of "contract pharmacy" arrangements, in which covered entities enter into contractual arrangements with third-party pharmacies—often large, national for-profit chains. Under such arrangements, drugs are not shipped to the covered entity for dispensing to patients. Instead, they are shipped directly to the contract pharmacy—wherever in the country that pharmacy may be. The result has been an exponential increase in "contract pharmacies," a corresponding increase in the amount of drug product subject to the 340B discount, and a similar upsurge in the potential for abuse of the 340B Program.

In response to the proliferation of "contract pharmacies," Novartis announced a new policy in late 2020 under which it voluntarily recognizes [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] an exemption to the 40-mile radius limitation when the facts and circumstances require.

On May 17, 2021, HRSA notified Novartis that it has concluded that Novartis's policy violates the 340B statute. Verified Complaint, Exhibit 1 (the Decision Letter). HRSA's position is wrong. Nothing in the 340B statute contemplates—let alone requires—that manufacturers must agree to ship drugs nominally purchased by covered entities directly to "contract

pharmacies" for dispensing to both patients and non-patients of the covered entity alike. And lest there be any doubt, the agency itself had a long-standing policy that directly contravenes its current position that the statute requires the 340B discount be given in the context of all contract pharmacy arrangements. Because it contravenes the plain language of the statute, lacks a coherent explanation, and is based on a faulty factual record, HRSA's decision is unlawful, arbitrary, capricious, and an abuse of discretion, and otherwise violates the Administrative Procedure Act (APA).

HRSA demanded a response to its Decision Letter by **June 1,** and threatened enforcement action if Novartis did not abandon its contract pharmacy policy. On May 27, Novartis submitted a detailed response to HRSA's Decision Letter explaining that the agency's conclusion was legally and factually unwarranted, and requesting that HRSA withdraw its enforcement threat by May 31. HRSA chose not to respond.

Novartis therefore seeks issuance of a preliminary injunction barring HRSA from taking any enforcement action against Novartis until this Court has had the chance to consider Novartis's challenge on the merits.

FACTUAL BACKGROUND

The 340B Program

In 1992, Congress created the 340B Drug Pricing Program, which requires participating pharmaceutical manufacturers to provide deep discounts on their covered outpatient drugs to qualifying hospitals and clinics generally serving poor, uninsured, underinsured, or otherwise vulnerable patient groups. 42 U.S.C. § 256b(a). The stated purpose of the program was to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep.

No. 102-384 (II), at 12 (1992). As a condition of federal payment being available under Medicaid and Medicare Part B for its covered outpatient drugs, a manufacturer must agree to participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1).

At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a "covered entity" no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. 42 U.S.C. § 256b(a)(1), (a)(4), (b)(1). A participating manufacturer must "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).

The statute defines the term "covered entity" narrowly, to ensure that the 340B program's steep discounts benefit only qualified safety-net providers and the neediest patient populations. *Id.* § 256b(a)(4). To count as a "covered entity," a provider must be a specifically enumerated type of entity. These include entities operating under a federal grant as well as particular types of hospitals, such as certain children's hospitals and freestanding cancer hospitals. *Id.*

The 340B Pharmaceutical Pricing Agreement (PPA), which a manufacturer must execute to participate in the 340B Program, states that "covered entities" means "certain Public Health Service grantees, 'look-alike' Federal Qualified Health Centers, and disproportionate share hospitals." PPA § 1(e).[1] The PPA also clarifies that, "in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall *not* be considered a covered entity unless it, too, meets the" statutory definition of "covered entity" as a qualified hospital. *Id*. (emphasis added).

[1] Available at https://www.hrsa.gov/sites/default/files/opa/manufacturers/pharmaceuticalpricingagreement.pdf.

The 340B statute contains two important limitations to protect against abuse. First, it prohibits "duplicate discounts"—a manufacturer cannot be required to both pay a Medicaid rebate *and* provide a 340B discount on the same unit of drug. To accomplish this, a covered entity is prohibited from requesting payment under Medicaid for a unit of a covered outpatient drug purchased under the 340B Program. 42 U.S.C. § 256b(a)(5)(A)(i).

Second, to prevent diversion, the statute prohibits a covered entity from reselling or otherwise transferring a 340B drug to "a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

Contract Pharmacy Arrangements

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 an in-house pharmacy began lobbying HRSA for permission to enter into a contractual arrangement with a third-party pharmacy (a so-called "contract pharmacy") for purposes of dispensing 340B-purchased drugs. Under these proposed arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, the drugs would be shipped to the contract pharmacy for dispensing to patients there. Verified Complaint ¶ 23.

Contract pharmacy arrangements typically involve a "virtual inventory" or "replenishment" model. *Id*. ¶ 24. Under this model, the contract pharmacy maintains a single, common inventory—meaning it commingles units purchased at the commercial price with "replenishment" units purchased at the 340B price—and dispenses *all* units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. *Id.*

The contract pharmacy itself typically does not know at the time of dispensing whether an individual is a patient of the covered entity. That determination is made afterwards. *Id.* ¶ 25. Where it is subsequently determined that the individual is a covered-entity patient, the covered entity purchases a "replenishment" unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. The kicker: the 340B replenishment unit is treated as it if had been purchased at the *commercial* price—and thus available for dispensing to anyone, including a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *Id.*; *see also* OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program,* OEI-05-13-00431 at 5 (Feb. 4, 2014), available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

HRSA's Evolving Guidance On Contract Pharmacies

In 1996, four years after the 340B Program began, HRSA issued non-binding guidance suggesting for the first time that a covered entity without an in-house pharmacy may contract with one outside pharmacy site for the purpose of dispensing 340B-purchased drugs to the covered entity's patients. *See* HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

HRSA stated that it was implementing the new contract pharmacy policy because it believed the goals of the 340B Program were better served if a covered entity without an in-house pharmacy could use an outside pharmacy to dispense 340B-purchased drugs to its patients on its behalf. *Id.* at 43,550. Accordingly, HRSA provided that a covered entity could use either an in-house pharmacy or, *if* the covered entity did not have an in-house pharmacy, it could contract with a single outside pharmacy site, to "facilitate program participation for those eligible

covered entities that do not have access to appropriate 'in-house' pharmacy services." *Id.* at 43,550, 43,555.

HRSA did not identify any statutory basis for its 1996 guidance. It stated only that "[t]he statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. It then stated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy." *Id.* at 43,549–50. HRSA also stated that, "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients." *Id.* at 43,550. And the 1996 guidance stopped short of requiring that manufacturers honor contract pharmacy arrangements.

In 2007, HRSA summarized its 1996 guidance as follows: "[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." HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007).

Then things changed. In early 2010, HRSA issued another non-binding guidance that purported to greatly expand the agency's approach to contract pharmacies. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010). Under the 2010 guidance, covered entities are permitted to use contract pharmacies even if they have an in-house pharmacy. *Id.* at 10,275. Covered entities also are permitted to use an unlimited number of outside contract pharmacy sites, so long as there is a written contract between the covered entity and the pharmacy, and the contract pharmacy meets certain

compliance and certification requirements. *Id.* at 10,275, 10,277–278. One of those requirements is 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." *Id.* at 10,277 (emphasis added). *See also* HRSA, *Contract Pharmacy: Important Tips* (Aug. 2016), *available at* https://www.hrsa.gov/opa/updates/2016/august.html.

The 2010 guidance, like its 1996 predecessor, does not state that manufacturers must honor contract pharmacy arrangements, nor (also like its predecessor) does it identify any statutory basis for the contract pharmacy policy. In responding to a commenter suggesting that notice-and-comment rulemaking was required to adopt the policy, HRSA explained that it was not required to proceed via such rulemaking because its contract pharmacy policy does not "impose[] additional burdens upon manufacturers []or create[] any new rights for covered entities under the law." 75 Fed. Reg. at 10,273.

Contract Pharmacy Arrangements Explode In Popularity

Following HRSA's 2010 guidance, the number of contract pharmacy arrangements entered into by hospitals grew exponentially—with little evidence that patients were benefiting as a result. Verified Complaint ¶ 32.

Covered entities have an incentive to maximize 340B utilization because they profit off the "340B spread." *Id.* ¶ 33. Covered entities purchase the unit of the drug at the deeply discounted 340B price, then seek reimbursement from the patient's payer when the patient is insured. *Id.* The covered entity captures the resulting "spread" between the (lower) 340B price and the inevitably higher reimbursement rate. *Id.* The more contract pharmacies, the more opportunities to capture the spread, because more prescriptions can be filled through such

arrangements. And there is no statutory obligation to share any of that revenue with those needy patients the 340B Program is intended to serve, through reduced prescription costs, for example. *Id.*

The contract pharmacies with which covered entities began to contract, starting in 2010, are often national chain sites located hundreds or even thousands of miles from the covered entity and the community that it serves. Indeed, "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" now participating, and the number of contract pharmacy arrangements by hospitals increasing from 193 to more than 43,000 during this period. Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 3–4, 7 (Oct. 2020), available at https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

In a subversion of statutory intent, the savings from the 340B Program—designed to benefit carefully selected beneficiaries—"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." *Id*. at 7. And as a result of the complete absence of transparency within such arrangements, the extent to which the 340B Program savings actually inure to the benefit of these commercial interlopers is unknown. In this way, a statutory regime intended to benefit underserved populations is now being used to advantage large commercial profit-maximizing pharmacy chains and other commercial middlemen.

In the years following 2010, there has been an exponential increase in the number of contract pharmacies, a corresponding increase in the amount of drug products subject to the

340B discount, and a similar upsurge in the potential for abuse of the 340B Program. *See* Aaron Vandervelde & Eleanor Blalock, BRG, *Measuring the Relative Size of the 340B Program: 2012-2017*, at 1 (Jul. 13, 2017), *available at* https://www.thinkbrg.com/insights/publications/measuring-the-relative-size-of-the-340b-program-2012-2017/; Adam J. Fein, Ph.D., *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://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html;

This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B program integrity concerns. Remember that, under the "virtual inventory" ("replenishment") model, it is unknown at the time of dispensing whether an individual is a patient of the covered entity. This necessitates a retrospective determination (typically performed by third parties) of which units were dispensed to a covered-entity patient and thus would have been eligible for 340B pricing. There is no transparency into whether or how this determination is made. Verified Complaint ¶¶ 35, 37. There is, however, confirmation that the system is being abused. HRSA has identified hundreds of instances of diversion at contract pharmacies through its audit efforts, and many instances of the potential for duplicate discounts. GAO, GAO-18-480, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* at 37 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf. In 2015, the HHS Office of Inspector General (OIG) concluded, in a triumph of understatement, that "contract pharmacy arrangements . . . create complications in preventing diversion . . . [and] duplicate discounts." OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, No. OEI-05-13-00431 at 1–2 (Feb. 2014) (available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

Where a covered entity makes arrangements with pharmacies far outside its community, this risk of diversion is amplified by orders of magnitude. Because there is no reasonable proximity between such pharmacies and the local community of the covered entity (i.e., where patients of the covered entity actually obtain services), such pharmacies are highly unlikely to dispense drugs to patients *of the covered entity*. Verified Complaint ¶ 39.

Novartis's Contract Pharmacy Policy

In response to the runaway proliferation of contract pharmacy arrangements and its attendant programmatic abuses, Novartis revised its contract pharmacy policy effective in November 2020. The new policy better aligns with the 340B statute's purpose and requirements, while guarding against needless abuse. Verified Complaint, Exhibit 2.

Under the new policy, Novartis honors all hospital covered entity contract pharmacy arrangements when the contract pharmacy is located within a 40-mile radius of the covered entity—which is to say, any contract pharmacy within an area that ranges about 5,000 square miles. *Id.* There is no limit on the number of contract pharmacies within that 40-mile radius with which the covered entity may have an arrangement. *Id*. Federal grantee covered entities are exempted from the 40-mile radius policy. *Id.* These entities are subject to independent requirements that encourage them to share the benefits of the 340B Program with their patients.

Finally, if a hospital covered entity brings a special circumstance to Novartis's attention (for example, if it has no in-house pharmacy and no contract pharmacy within 40 miles), Novartis works in good faith with the hospital to ensure appropriate access to a contract pharmacy through an exemption process. *Id.*

In adopting the 40-mile radius as a proxy for the patient community, Novartis drew 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). The 40-mile radius limitation is also consistent with HRSA's statements that its contract pharmacy policy is designed to allow covered entities to enter into "arrangements in their communities" to dispense needed drugs to their patients. *See* 75 Fed. Reg. at 10,273. And the 40-mile radius is a generous policy: The vast majority of contract pharmacy hospitals are located within 40 miles of the covered entity. 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.

Importantly, the Novartis policy does not prohibit any covered entity from purchasing Novartis medicines at 340B prices. Verified Complaint ¶ 47; Exhibit 2. Hospital covered entities are merely offered a choice of having the drug shipped to their own in-house pharmacy, or to an unlimited number of contract pharmacies 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), covered entities are encouraged to apply for an exemption. *Id.*

On October 30, 2020—and again on November 13, 2020—Novartis notified HRSA that it would be implementing this approach to contract pharmacy arrangements. Verified Complaint, Exhibit 2.

The Advisory Opinion

On December 30, 2020, the HHS Office of the General Counsel (OGC) issued a non-binding Advisory Opinion on contract pharmacy arrangements under the 340B statute. *See* OGC, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

In the Advisory Opinion, OGC opined that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." *Id*. at 1. To reach that conclusion, the Advisory Opinion argued 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." *Id.* at 2. In an odd flight of rhetoric, the Advisory Opinion asserted that the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.* at 3.

The agency based its position on its view that the statute is *unambiguous*: "It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise." *Id.* at 2–3 (*citing Kisor v. Wilke*, 139 S. Ct. 2400, 2415 (2019)). In light of what the agency described as "the lack of ambiguity in the plain text of the statute," OGC concluded that "the above analysis is dispositive." *Id.* at 3.

In response to the Advisory Opinion, a number of manufacturers filed lawsuits against HRSA challenging its contract pharmacy policies. *See, e.g., AstraZeneca Pharms. LP v. Azar*, No. 1:21-cv-00027 (D. Del.); *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-00806 (D.N.J.); *Eli Lilly & Co. v. Cochran,* No. 1:21-cv-00081 (S.D. Ind.); *Sanofi-Aventis US, LLC v. HHS*, No. 3:21-cv-00634 (D.N.J.). Those cases remain pending.

HRSA's May 17, 2021 Decision Letter And Novartis's Response

On May 17, HRSA wrote to Novartis, asserting that the agency had "completed its review" of Novartis's contract pharmacy policy. Verified Complaint, Exhibit 1 at 1. HRSA appeared to have reviewed the wrong policy, however; in its Decision Letter, the agency asserted 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.* It does no such thing.[2]

The agency went on to assert that, after reviewing Novartis's policy-which-was-not-actually-its-policy, it had "determined that Novartis's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The Decision Letter argued that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." *Id.*

The Decision Letter demanded that Novartis

> immediately begin offering its covered patient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Novartis must comply with its 340B statutory obligations and the [final rule governing civil monetary penalties (CMPs)] and credit or refund all covered entities for overcharges that have resulted from Novartis's policy. Novartis must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements. [*Id.* at 2.]

The Decision Letter requested a response by June 1, and ended with a threat: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule." *Id.*

Novartis responded on May 27, noting that HRSA's letter had mischaracterized the Novartis policy. Verified Complaint, Exhibit 3. Novartis also explained why its policy is consistent with the 340B statute: The statute requires that manufacturers offer the 340B discount

[2] In August 2020, Novartis had considered requiring covered entities to submit claims data so that eligibility for the 340B discount could be verified; it ultimately decided not to implement that policy. *See* Exhibit 2 at 1.

on sales to covered entities. 42 U.S.C. § 256b(a)(1). Novartis does so. Novartis pointed out that the statute does not require manufacturers to agree to ship the purchased drugs to some remote pharmacy for dispensing to patients (and non-patients) there. Verified Complaint, Exhibit 3. Novartis requested that HRSA withdraw its Decision Letter and threat of enforcement by May 31, in advance of the June 1 deadline set by the agency in the Decision Letter. *Id*. at 5.

HRSA failed to withdraw the Decision Letter.

HRSA's Actions Will Cause Immediate And Irreparable Harm

The Decision Letter ends with a threat: HRSA will move to impose CMPs absent compliance by Novartis. Verified Complaint, Exhibit 1 at 2. That threat is unwarranted: CMPs are permissible only in the event of a knowing and intentional overcharge for a drug purchased by a covered entity. 42 U.S.C. § 256b(d)(1)(B)(vi)(III); 42 C.F.R. § 10.11(a). Novartis has not "overcharged" any covered entities, let alone done so knowingly and intentionally. Verified Complaint ¶ 48. When Novartis does not recognize a contract pharmacy under its policy, it does not convert a 340B order to a commercial order. It simply declines to fill the 340B order, and the hospital is not charged. *Id.*

Novartis nevertheless now faces a Hobson's choice: submit to the agency's demand that it continue to provide steep, unwarranted discounts that benefit large pharmacy chains, or face stiff penalties and a host of reputational harms from an unwarranted and unlawful enforcement proceeding. Verified Complaint ¶ 77. The government's public assertion that Novartis has knowingly and willfully violated its 340B obligations plainly injures Novartis reputation. Even the Decision Letter *threatening* enforcement action garnered immediate media attention highlighting the allegation that Novartis is out of compliance with the 340B program. *See, e.g.,* Jeff Lagasse, *Six Drugmakers Are in Violation of 340B Statute, Says HRSA,* Healthcare Finance

(May 18, 2021), https://bit.ly/3u7qilU; Cathy Kelly, *340B Fight Escalates As Biden Administration Seeks Refunds From Manufacturers, Threatens Them With Fines,* Pink Sheet Daily (May 19, 2021), https://bit.ly/33XE9Rn.

ARGUMENT

To secure a preliminary injunction, a movant must establish (1) "that he is likely to succeed on the merits," (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in his favor," and (4) "that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Council on American-Islamic Rels. v. Gaubatz*, 667 F. Supp. 2d 67, 74 (D.D.C. 2009).

All four factors strongly favor granting a preliminary injunction here.

I. NOVARTIS IS LIKELY TO PREVAIL ON THE MERITS.

The APA requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions" that are determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Judicial review of agency action requires a "searching and careful" inquiry into the basis for the agency's decision. *Zotos Int'l, Inc. v. Young*, 830 F.2d 350, 352 (D.C. Cir. 1987) (citation omitted).

Four important principles control this case. Agency action is routinely set aside as unlawful when it violates a statute. *See Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 315 (2014) (an agency must "stay[] within the bounds of its statutory authority") (citation omitted). Agency action is arbitrary and capricious when it reflects a want of reasoned decision-making. *See Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012). Agency action is arbitrary and capricious when an agency ignores its own policies or changes its position without offering an adequate explanation. *New York Cross Harbor R.R. v. Surface Transp. Bd.*, 374 F.3d 1177, 1183 (D.C. Cir. 2004).

And agency action is arbitrary when it is based on silent presumptions regarding facts not in the record. *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 437 F.3d 75, 81 (D.C. Cir. 2006).

HRSA has violated all of these canons here.

A. HRSA's Position Violates the 340B Statute.

First and foremost, HRSA's position on contract pharmacy arrangements violates the agency's statutory mandate. *Utility Air Regul. Grp.,* 573 U.S. at 315. "Both their power to act and how they are to act is authoritatively prescribed by Congress." *City of Arlington. v. FCC*, 569 U.S. 290, 297 (2013). As a result, agency action is routinely set aside as unlawful when it violates a statute. *See, e.g.*, *Utility Air Regulatory Grp.*, 573 U.S. at 325–326 (setting aside agency action that violated its own statute).

The two steps of the standard *Chevron* analysis are old hat. "First, always, is the question whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837, 842 (1984). To determine Congressional intent, a court is charged with "employing traditional tools of statutory construction," including evaluation of a statute's "text, structure, purpose and history." *Hearth, Patio & Barbecue Ass'n v. U.S. Dep't of Energy*, 706 F.3d 499, 503 (D.C. Cir. 2013) (citations omitted). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-843.

It is only when the statute is ambiguous or leaves gaps for the agency to fill that a court moves on to *Chevron* Step Two, where the question becomes whether the agency's interpretation is "based on a permissible construction of the statute." *Id*. at 843. A court defers to an agency's permissible interpretation under Step Two only "if the agency has offered a reasoned explanation

for why it chose that interpretation." *Amarin Pharms. Ire. Ltd. v. FDA*, 106 F. Supp. 3d 196, 217 (D.D.C. 2015) (citation omitted).

HRSA has boxed itself into a *Chevron* corner in this case. In its Decision Letter, HRSA asserted that "the 340B statute *requires* manufacturers to honor such purchases regardless of the dispensing mechanism." Verified Complaint, Exhibit 1 at 1 (emphasis added). This position echoes the assertion made in the Advisory Opinion that the language of the statute is unambiguous. OGC Advisory Opinion at 2; *see also id.* ("It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise."); *id.* at 3 ("Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive."). By asserting definitively (and repeatedly) that the statute is unambiguous, the agency has disavowed any argument that its interpretation of the statute is entitled to deference under *Chevron* Step Two. The agency's position therefore rises or falls on whether it can demonstrate that the statute *unambiguously requires* manufacturers to honor all contract pharmacy arrangements, of whatever ilk. *See, e.g., Peter Pan Bus Lines, Inc. v. Federal Motor Carrier Safety Admin*., 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("*Chevron* step 2 deference" is reserved only "for those instances when an agency recognizes that the 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 answer: It can't.

1. The Plain Language of the Statute Forecloses the Government's Position.

We start, as we must, with the plain language of the statute. On its face, the 340B statute 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) (emphases added). The statute provides no textual support for the notion that the defined term "covered entity" includes third parties that *enter into contracts* with covered entities, nominally in order to dispense drugs on their behalves. If Congress had intended to reference *both* covered entities *and* their contract parties, it would have said so.

HRSA does not overtly argue otherwise. Instead, it argues that the statute separately entitles a covered entity to "purchase" covered outpatient drugs at the 340B price, and that the statute does not restrict "how the covered entity chooses to distribute the covered outpatient drugs." Exhibit 1 at 1, citing 42 U.S.C. § 256b(a)(1). From there, HRSA extrapolates an additional statutory obligation on manufacturers to ship 340B drugs to any destination the covered entity directs.

First of all, it is not true that the 340B statute doesn't restrict "how the covered entity chooses to distribute" 340B drugs. The statute in fact expressly prohibits a covered entity from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). In light of this statutory restriction, the agency cannot reasonably have concluded that there is no statutory limit on "how the covered entity chooses to distribute the

covered outpatient drugs"; to the contrary, the covered entity's options to redirect the drug after purchase are actually severely limited.[3]

HRSA also is wrong to conflate whatever minimal latitude covered entities have after purchasing the drug with a right to *require* manufacturers to *ship* drugs directly to non-covered-entity contract pharmacies. So long as the manufacturer offers to sell the drug to the covered entity at or below the 340B-discounted price, the manufacturer operates in compliance with the statute. That is all the weight that the term "purchase" can bear. And here, Novartis has expressed its willingness to ship drug product purchased at the 340B discounted price not only to covered entities, but also to [1] *any* contract pharmacy within 5,000 square miles of a covered entity; [2] *any* contract pharmacy, anywhere, affiliated with a federal grantee; and [3] *any* other contract pharmacy, when circumstances warrant making an exception to the general policy.

It can hardly be argued that these accommodating delivery terms are somehow so unreasonable as to prohibit covered entities from being able to "purchase" drugs at the 340B-discounted price. And it certainly cannot be argued that a statute that requires manufacturers to *offer drugs for purchase at a specified price* to covered entities secretly—yet unambiguously—*requires* manufacturers to *agree to ship* the purchased drugs to someone else entirely.

2. HRSA's Position Is Inconsistent with Its Prior Guidance Documents.

As noted above, HRSA now maintains that the statute is "unambiguous" and "requires" the outcome the agency now desires. *See* OGC Advisory Opinion at 2–3; Verified Complaint,

[3] Take the contract pharmacy "virtual inventory" scheme as an example. The contract pharmacy maintains a single, common inventory—it commingles units purchased at the commercial price with "replenishment" units purchased at the 340B price—and dispenses *all* units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. Verified Complaint ¶ 25. That arrangement arguably violates the restriction on transfer of 340B-purchased drugs. 42 U.S.C. § 256b(a)(5)(B); *see also id.* § 256b(a)(4) (defining a "covered entity" as an entity in compliance with the diversion prohibition), § 256b(a)(1) (obligating a manufacturer to offer 340B pricing only to a "covered entity").

Exhibit 1. But that position is belied by the agency's own prior guidance documents. HRSA's 1996 guidance permitted only covered entities lacking an in-house pharmacy to contract with a single contract pharmacy site, in an effort to "facilitate program participation for those eligible covered entities that do not have access to appropriate 'in house' pharmacy services." 61 Fed. Reg. at 43,550, 43,555. HRSA reiterated that position in 2007. 72 Fed. Reg. at 1540. The 1996 guidance would make no sense if the statute mandates that all contract pharmacy arrangements be recognized, regardless of number and regardless of whether the covered entity has an in-house pharmacy.

The agency's statutory arguments, such as they are, therefore are unavailing.

B. HRSA's Decision is Arbitrary and Capricious.

HRSA's decision also is arbitrary and capricious, for several reasons.

1. HRSA's Decision Lacks a Reasoned Basis.

It is arbitrary and capricious for an agency to require the impossible. *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991). *See also PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) ("We have stressed that '[u]nless the [agency] answers objections that on their face seem legitimate, its decision can hardly be classified as reasoned.'" (citation omitted)). HRSA's new policy is Exhibit A. It is hard to imagine an agency position more arbitrary and capricious than one that —quite literally—says that drug manufacturers must agree to deliver drugs *to the lunar surface* in order to satisfy a statutory requirement that they offer their drugs to covered entities for purchase at the 340B price. OGC Advisory Opinion at 3.

Presumably, HRSA will say in huffy response that no one could *actually* have thought it was *serious* when it said in an official opinion that drug manufacturers are required to deliver

product, at a deep discount, to the surface of the moon. Fine, forget the moon: The agency has also provided no explanation of why a covered entity needs to enter into contractual arrangements with contract pharmacies located outside of a *5,000-square mile area* surrounding the covered entity. The 40-mile radius limitation is fully consistent with HRSA's repeated statements that its contract pharmacy policy is designed to allow covered entities to enter into "arrangements in their communities." *See* 75 Fed. Reg. at 10,273. And GAO data reveal that the vast majority of contract pharmacies are located within 40 miles of the covered entity. GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 23 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf. Finally, if there *were* a particular factual circumstance in which a covered entity would be left without a contract pharmacy under Novartis's policy, Novartis would be willing to work with the covered entity through an exemption process. In short, Novartis's geographic limitations are reasonable in scope, and the agency has failed to articulate a rational explanation for rejecting them.

The agency's failure to explain why drugs must be shipped by manufacturers across the country (and the galaxy) in order to allow covered entities to contract with pharmacies "in their communities" is fatal to its position.

HRSA's Decision Letter also cites a program policy prohibiting discrimination against covered entities, and argues that "manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs." Exhibit 1. The agency identified no basis for asserting that Novartis has treated covered entities differently than other purchasers. Nor could it. Novartis offers the same opportunity for covered entities to purchase drugs as it does for any other purchaser. Declaration of Daniel Lopuch

(Lopuch Decl.) ¶ 6. And Novartis does not recognize any commercial arrangements equivalent to HRSA's current view of 340B contract pharmacy arrangements, where the purchaser is empowered to unilaterally direct shipment to some distant third-party location. *Id*.

2. HRSA Has Failed to Adequately Explain Its Change in Position.

Second, HRSA's conduct is arbitrary and capricious because it has failed to offer an adequate explanation for its change in position over time. To review the bidding:

In its 1996 guidance, the agency asserted that covered entities lacking an in-house pharmacy (and only such entities) may contract with one (1) contract pharmacy site. 61 Fed. Reg. at 43,549–550, 43,555. And even with respect to this limited universe of contract pharmacy arrangements, the guidance did not purport to require manufacturers to recognize any contract arrangement entered into by a covered entity under its terms. Indeed, the 1996 guidance expressly disclaimed that it was creating any rights or imposing any obligations at all. *Id*. at 43,550.

In its 2010 guidance, the agency changed its position. It stated that covered entities may contract with an unlimited number of contract pharmacies, regardless of whether they also maintain an in-house pharmacy, so long as the 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. Again, the agency asserted that "[t]his guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law." *Id*. at 10,273.

In the Advisory Opinion, the OGC paid lip service to the requirement for covered entities to retain title—but glossed over the other conditions. OGC Advisory Opinion at 3. The Advisory Opinion also instituted a more fundamental shift: The agency asserted, for the first

time, that the statute *unambiguously compels* the agency's current policy—even though a contrary policy had been in place for many years under the same statutory regime. *Id.* at 2–3.

The Decision Letter reflects the culmination of all of this agency flip-flopping. In the letter, HRSA took the position that *all* contract pharmacy arrangements are eligible for the 340B discount, at *all* times, *and* that manufacturers are required—on pain of civil monetary penalties and the attendant harm to reputation from a federal enforcement action—to comply with whatever those arrangements are. Verified Complaint, Exhibit 1. That is a seismic shift from the 1996 guidance, to put it mildly.

Where the statute permits, an agency is of course allowed to change its mind. However, an agency must justify its departure from a prior pronouncement by providing a "reasoned analysis." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124–25 (D.C. Cir. 2003) (citation omitted). *See also 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 in turn "necessarily requires the agency to acknowledge and provide an adequate explanation for its departure from established precedent." *See Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089–90 (D.C. Cir. 2009). When an agency changes its position, it "need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate." *FCC v. Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009). But the agency must at least "display awareness that it is changing position" and "show that there are good reasons for the new policy." *Id.* (emphasis omitted). *See Encino Motorcars LLC v. Navarro*, 136 S. Ct. 2117, 2125–126 (2016).

In explaining its changed position, an agency must also be cognizant that longstanding policies may have "engendered serious reliance interests that must be taken into account." *Id.*

"In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Fox Television Stations*, 556 U.S. at 515–516. "An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'" *Ramaprakash*, 346 F.3d at 1125 (citation omitted).

In the present case, HRSA has failed even to *acknowledge* its change in position, let alone justify it. Instead, the agency has asserted that its policy has remained consistent all along. *See, e.g.*, Verified Complaint, Exhibit 1 at 1 ("HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism."). To state the obvious: There is nothing "consistent" about [a] first not recognizing contract pharmacy arrangements at all; [b] then, in 1996, recognizing them only where the covered entity lacks an in-house pharmacy and contracts with a single contract pharmacy site, but disclaiming any intent to impose new obligations on manufacturers; [c] then, in 2010, recognizing them in a far broader set of circumstances as long as certain program requirements are met, but similarly disclaiming any intent to impose new obligations on manufacturers; and [d] then, in 2021, demanding that all contract pharmacy arrangements be recognized at all times, on pain of civil monetary penalties.

Even if the agency were correct that the "unambiguous" 340B statute is flexible enough to accommodate the agency's machinations, the APA does not permit an agency to change its mind that frequently and that drastically without providing an adequate explanation—starting with an acknowledgment that the agency's position is indeed changing. HRSA did none of that here. That is the definition of arbitrary and capricious. *Ramaprakash*, 346 F.3d at 1125.

3. HRSA's Decision Is Based on a Faulty Record.

Finally, HRSA's decision is arbitrary because it assumes facts not in evidence. As the D.C. Circuit has explained, where an agency "action is founded on unsupported assertions or unstated inferences[,] we will not 'abdicate the judicial duty carefully to 'review the record to ascertain that the agency has made a reasoned decision based on reasonable extrapolations from some reliable evidence.'" *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 437 F.3d 75, 83 (D.C. Cir. 2006); *see also AT&T Wireless Servs., Inc. v. FCC*, 270 F.3d 959, 968 (D.C. Cir. 2001) (explaining that to survive arbitrary and capricious review the agency must "articulate . . . a rational connection between the facts found and the choice made" (citation omitted)).

In its 2010 guidance document, HRSA made clear that the 340B discount is available only where a contract pharmacy arrangement meets a number of specified program requirements, including that the covered entity retains title to the drugs in question. Specifically, HRSA requires 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 made no finding that—nor did it even address whether—any of 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. There is a serious open question whether the covered entities retained title, as required, to 340B drugs shipped to contract pharmacies, given that the replenishment model generally involves shipping 340B-purchased units to contract

pharmacies, at which point those contract pharmacies place those units into their common stock for use in filling prescriptions of both patients and non-patients of a covered entity.

This is not just a hypothetical problem. OIG's own analysis shows that covered entities use a variety of different models for contract pharmacy arrangements, and that "[t]he variety of data types and comparison methods used to identify 340B-eligible prescriptions can result in differing determinations of 340B eligibility across covered entities." 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.

And yet neither HRSA nor any manufacturers has sufficient information to identify those transactions that qualify. As GAO has noted, "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. That lack of transparency means that the scheme that HRSA has set up—one in which the covered entities are the only parties able to determine their own eligibility for 340B discounts—is an irrational and arbitrary one. And the fact that the administrative record is completely devoid of any factual evidence to support HRSA's conclusion that the contract pharmacy arrangements at issue comport with the agency's own guidance documents is fatal to the agency's decision.

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

Novartis formulated its 340B contract pharmacy policy to better protect the program's integrity and ensure that the program's discounts benefit vulnerable patients—not contract pharmacies or other third-party intermediaries. *See* Lopuch Decl. ¶ 3. HRSA, however, has

accused Novartis of knowing and intentional violations of its 340B obligations. Such allegations irreparably harm Novartis's reputation among its customers, covered entities, and investors by suggesting that the company is willfully subverting a program aimed at helping uninsured, low-income, and other vulnerable patients. *Id.* ¶¶ 10–12.

Despite the fact that HRSA's threat lacks merit, Novartis now faces an impossible choice: submit to the agency's demand that it continue to provide steep, unwarranted discounts that may end up benefiting large pharmacy chains, or face stiff penalties and a host of reputational harms from an unwarranted and unlawful enforcement proceeding. Even the Decision Letter *threatening* enforcement action garnered immediate media attention highlighting the allegation that Novartis is out of compliance with the 340B Program. *See, e.g.,* Jeff Lagasse, *Six Drugmakers Are in Violation of 340B Statute, Says HRSA,* Healthcare Finance (May 18, 2021), https://bit.ly/3u7qilU; Kristen Coppock, *HRSA Finds 6 Pharmaceutical Manufacturers in Violation of 340B Requirements,* Pharmacy Times (May 17, 2021), https://bit.ly/2SJ4srP. Harm to Novartis's reputation also hinders the company's ability to recruit talent and build relationships with the stakeholders necessary to develop pharmaceuticals that patients need. Lopuch Decl. ¶ 10. These harms will only increase if HRSA is permitted to continue its course of action, even if Novartis ultimately succeeds on its claims.

Courts have recognized that "the prospect of severe and unrecoverable reputational harm" supports a finding of irreparable harm "justifying preliminary relief." *Everglades Harvesting & Hauling v. Scalia,* 427 F. Supp. 3d 101, 116 (D.D.C. 2019); *Tate Access Floors v. Interface Architectural Res., Inc.*, 132 F. Supp. 2d 365, 378 (D. Md. 2001) (finding irreparable harm based in part on the "loss of long-term relationships with major customers, beyond the short-term loss of individual sales"), *aff'd,* 279 F.3d 1357 (Fed. Cir. 2002); *Beacon Assocs., Inc.*

v. Apprio, Inc., 308 F. Supp. 3d 277, 288 (D.D.C. 2018) (damage to business reputation supports finding of irreparable harm); *Patriot, Inc. v. HUD*, 963 F. Supp. 1, *5 (D.D.C. 1997) (same).

Civil monetary penalties are a harsh sanction, and the process for imposing them is public. The Decision Letter states that *for each instance* in which the government believes Novartis has "overcharged" a 340B covered entity, the government may seek a nearly $6,000 penalty. Verified Complaint, Exhibit 1 at 2 n.3. Given the proliferation in 340B purchases by covered entities with far-flung contract-pharmacy arrangements, those penalties will stack up in a hurry. To account for that, Novartis will need to consider reallocating resources away from research and development for important products. Lopuch Decl. ¶ 11. And if the erroneous penalties are allowed to pile up without an injunction, Novartis will be forced to consider even deeper research cuts. *Id.*

Because this is an APA case, Novartis will never be able to recover for these losses. For this reason, courts have repeatedly recognized that substantial and imminent financial harms to regulated entities based on unlawful agency action are irreparable. *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"); *Everglades Harvesting & Hauling*, 427 F. Supp. 3d at 115 ("where economic loss will be unrecoverable, such as in a case against a Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable"); *Clarke v. Office of Fed. Hous. Enter. Oversight,* 355 F. Supp. 2d 56, 65-66 (D.D.C. 2004) (economic losses constitute irreparable injury where they are unrecoverable due to government immunity); *Nat'l Med. Care, Inc. v. Shalala,* No. 95-0860, 1995 WL 465650, at *3 (D.D.C. June 6, 1995) ("[T]he policy considerations behind the judiciary's general reluctance to label

economic injuries as 'irreparable' do not come into play in APA cases: even if the Plaintiffs ultimately prevail on the merits, they cannot bring an action to recover the costs of their compliance with the Defendant's unlawful retroactive rule, and thus will not be able to alleviate their economic damage through subsequent litigation."); *Woerner v. Small Bus. Admin.*, 739 F. Supp. 641, 650 (D.D.C. 1990) (finding irreparable injury where government is immune from damage suits to recover for economic losses).

Finally, without an injunction, HHS could determine that Novartis has violated its 340B pharmaceutical pricing agreement based on HRSA's erroneous decision and terminate Novartis's participation in the 340B Program. That would, in turn, lead to termination of Novartis's Medicaid National Drug Rebate Agreement, in which case 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). That outcome would deny the company the ability to participate in important federal programs, cause the company significant financial harm, and exact further damage to Novartis's reputation. It also would inhibit access to Novartis's drugs by vulnerable Medicaid and Medicare beneficiaries having therapeutic need for them.

III. GRANTING PRELIMINARY INJUNCTIVE RELIEF WOULD ADVANCE THE PUBLIC INTEREST.

Novartis implemented its 340B contract pharmacy policy to benefit the public—by shoring up program integrity and ensuring that the program's benefits flow where intended, and not to commercial interlopers.

Moreover, as explained above, HRSA has acted outside of its authority, and the public has an interest in ensuring the faithful application of laws by public officials. *See, e.g.*, *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)); *Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1066 (D.C. Cir. 1998) (highlighting "the public's interest in the 'faithful application of the laws'"); *Fund for Animals, Inc. v. Espy*, 814 F. Supp. 142, 152 (D.D.C. 1993) ("there is a strong public interest in meticulous compliance with the law by public officials"); *O'Donnell Constr. Co. v. District of Columbia*, 963 F.2d 420, 429 (D.C. Cir. 1992) (same); *N. Mariana Islands v. United States,* 686 F. Supp. 2d 7, 21 (D.D.C. 2009) ("The public interest is served when administrative agencies comply with their obligations under the APA.").

The public also has an interest in Novartis remaining in the 340B Program and the Medicaid Drug Rebate Program, which grants needy patients access to Novartis's drugs.

For all of these reasons, this factor weighs in favor of granting a preliminary injunction.

IV. THE BALANCE OF THE EQUITIES FAVORS PRELIMINARY INJUNCTIVE RELIEF.

The balance of equities also tips in favor of the requested relief. HRSA cannot contend that it will be burdened if a preliminary injunction is issued. HRSA does not have any legitimate interest in engaging in unlawful action. Granting this motion would merely preserve the status quo pending further consideration by this Court. *See Dist. 50, United Mine Workers v. International Union, United Mine Workers*, 412 F.2d 165, 168 (D.C. Cir. 1969) ("The usual role of [an] injunction is to preserve the *status quo*."); *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.").

By contrast, Novartis will face significant reputational and financial burdens absent injunctive relief. *See supra*; *National Ass'n of Farmworkers Orgs v. Marshall*, 628 F.2d 604, 613 (D.C. Cir. 1980) (court must balance burdens in deciding whether to grant preliminary relief). The

attendant harms to Novartis far outweigh the burden to defendants from the requested temporary injunction.

CONCLUSION

For these reasons, Novartis's motion for preliminary injunction should be granted, and the government should be enjoined from taking any enforcement action against Novartis pending a decision on the merits.

Respectfully submitted,

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Dated: June 2, 2021