IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1479 (DLF)

NOTICE OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants respectfully move for summary judgment pursuant to Federal Rule of Civil Procedure 56 on all claims contained in Plaintiff's Verified Complaint. The grounds for this Motion are set forth in the accompanying Memorandum. A proposed order is attached.

Dated: June 28, 2021

Respectfully submitted,

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DEFENDANTS' COMBINED MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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This case is the culmination of a collective strategy by a group of large, highly profitable pharmaceutical companies to unilaterally upend the long-settled operation of a statutory program that provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients. Nearly thirty years ago, Congress struck a bargain with drug companies by creating the "340B Program," under which participating manufacturers gain valuable access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs (at or below a statutory ceiling price) to certain safety-net healthcare providers. The providers, in turn, can either generate much-needed revenue through sale of those medications (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has thus served a crucial role in facilitating healthcare for vulnerable patients.

But late in 2020, Plaintiff Novartis Pharmaceuticals Corporation and several of its peers unilaterally imposed onerous and non-statutory restrictions on safety-net providers' access to 340B-discounted drugs, subverting the 340B Program's decades-old operation and spawning a raft of litigation against the Department of Health and Human Services ("HHS"), the agency to which Congress delegated oversight and implementation of the 340B Program. Specifically, the manufacturers announced that they would no longer honor (or honor without significant restrictions) discounted-drug orders placed by eligible healthcare providers but shipped to, and dispensed by, outside, neighborhood pharmacies. These dispensing arrangements with neighborhood pharmacies (called "contract pharmacies") have been an integral part of the 340B Program's operation from its inception, since the vast majority of 340B-eligible providers do not operate in-house pharmacies and thus rely on contract pharmacies to serve patients (who may live thousands of miles from the provider). The drug manufacturers' novel restrictions have choked off access to discounted medications for healthcare providers serving the country's most vulnerable patients in the midst of a global pandemic, and have resulted in providers losing *hundreds of thousands* (and sometimes *millions*) of dollars in savings by having to purchase 340B drugs well above the statutory ceiling price. Novartis has maintained that its actions—which have boosted its profits at the expense of safety-net providers and patients—are permissible under the 340B statute. It now asks this Court to sanction that view by

declaring unlawful HHS's longstanding interpretation of the statute—an interpretation with which Novartis and its peers had complied, without objection, for decades.

There is no cause for this Court to grant that request because Novartis's claims fail. After a thorough, months-long review of Novartis's newly imposed contract-pharmacy restrictions, including assessment of thousands of pages of complaints from safety-net providers, detailed analysis of real-world changes to Novartis's discounted-sales volumes, review of correspondence from Novartis and other manufacturers setting forth the purported basis for their abrupt changes, and meetings with numerous stakeholders, the Health Resources and Service Administration ("HRSA") has determined that Novartis is flouting its obligation under the 340B statute by overcharging covered entities for its drugs and conditioning access to 340B discounts on demands which have no basis in the statute. As shown herein, that conclusion is based on sound statutory interpretation and voluminous evidence. The Court should reject Novartis's challenge to HRSA's 340B-violation determination and allow HRSA's enforcement of the statute to proceed by denying Novartis's request for a preliminary injunction and granting summary judgment to HHS on Novartis's claims.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992, Congress created a program, administered by the Secretary of HHS, through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report), and also may directly benefit uninsured and underinsured patients when covered entities opt to pass along the discounts by helping patients afford costly medications. To achieve these benefits, Congress directed the Secretary to "enter into an

agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for [such] drugs … purchased by a covered entity … does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1). And "[e]ach such agreement … shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* Congress expressly conditioned drug makers' access to an incredibly valuable federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." *Id.* § 1396r-8(a)(1); *id.* § 256b(a). Pharmaceutical companies thus may opt out of providing discounted drugs to safety-net providers and their low-income patients, but then lose access to drug coverage under federal health-insurance programs.

In the beginning of the 340B Program, fewer than five percent of covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies; instead, the vast majority of safety-net providers relied on arrangements with outside, neighborhood pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) ("1996 Guidance"). And because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, [these arrangements were] essential for them to access 340B pricing." *Id.* at 43,549. Covered entities participating in the 340B Program thus began relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to the covered entities' low-income patients. *Id.*

In 1996, HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. 61 Fed. Reg. at 43,549. HHS explained that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. Rather than imposing

any new requirements on manufacturers not found in the 340B statute, the 1996 Guidance confirmed: "If a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at the discounted price," and, "[i]f the entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from *statutory* compliance." *Id.* at 43,549–50 (emphasis added). Thus twenty-five years ago HHS interpreted the 340B statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies, and nothing in the guidance suggested that the agency viewed this statutory obligation as voluntary on the part of drug makers. On the contrary, the choice presented under the guidance was for covered entities to determine whether to establish such arrangements because they remain liable and responsible, "under any distribution mechanism, [for] the statutory prohibition on drug diversion." *Id.* at 43,550. HHS explained that restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not be "within the interest of the covered entities, the patients they serve, [or] consistent with the intent of the law." *Id.* And the agency explicitly rejected the argument, suggested in comments to the proposed guidance, that the use of contract pharmacies constitutes an unauthorized expansion of the 340B Program: "The statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. On the contrary, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.*

The pharmaceutical industry quickly demonstrated its understanding both that HHS considered manufacturers to be *obliged* to honor contract-pharmacy dispensing models and that such transactions involve purchases by *covered entities*, not pharmacies. In 1996, the leading pharmaceutical-industry trade organization, PhRMA, filed suit to challenge the contract-pharmacy guidelines. *See* Compl. ¶ 3, *PhRMA v. Shalala*, No. 1:96-cv-1630 (D.D.C. July 12, 1996).[1] The drug companies

[1] The lawsuit was filed one month before the official Guidance was published in the Federal Register; it challenged guidelines (containing the same statutory interpretation) that first were published on an HHS electronic database. *PhRMA*, Compl. Exs. B, C. This Court can take judicial notice of the

(through their association) alleged that "covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies …, and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities." *Id.* ¶ 18. They further demonstrated awareness that, "[i]f a manufacturer attempted to mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, there is a substantial risk that the [Public Health Service] would terminate the manufacturer's agreement with the Secretary of HHS." *Id.* ¶ 21 (emphasis added). Appended to that complaint was a letter from the Administrator of HRSA confirming that, "recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, [the agency] does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs." *Id.* Ex. D at 2. PhRMA stipulated to dismissal of the suit shortly after filing.

Consistent with HHS's interpretation of the 340B statute and its 1996 Guidance implementing its terms, covered entities have for decades relied on contracts with outside pharmacies to serve their patients and access the discounts Congress provided. Indeed, these arrangements proved so pivotal to covered entities' and their patients' access to drug discounts that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance"). After issuing notice and soliciting comments, the agency agreed with commenters that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more-flexible use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* The 2010 Guidance includes

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complaint and stipulation of dismissal from the *PhRMA* litigation as official judicial records. *See* Fed. R. Evid. 201. Attached to this motion is a true and correct copy from official archives of the Department of Justice. *See* Ex. 1 (Talmor Decl.). Novartis currently is a member of PhRMA. *See* PhRMA, About, Members, https://www.phrma.org/en/About/Members.

"essential elements" to prevent unlawful duplicate discounts or diversion of 340B drugs: a "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ships the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 10,277-78. The guidance makes plain that a covered entity bears full responsibility to ensure adherence to 340B Program requirements and can lose eligibility if violations occur. *Id.*

Most importantly for the present case, the 2010 Guidance again confirmed HHS's earlier interpretation that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* at 10,278 (emphasis added). As before, that interpretation was framed in mandatory terms—the guidance made no suggestion, and in no way supports, the position that manufacturers can choose whether or not to honor 340B purchases by a covered entity that relies on contract-pharmacy arrangements. HHS also explained that the guidance neither created new obligations on manufacturers nor new rights for covered entities because it merely interpreted the 340B statute itself "to create a working framework for its administration," rather than promulgating "a substantive rulemaking under the APA." *Id.* at 10,273. Not only were there *no* legal challenges from drug manufacturers or trade associations to the substance of the 2010 Guidance but, for more than a decade, participating pharmaceutical manufacturers have complied with the guidance by honoring orders placed by covered entities regardless of the dispensing mechanism chosen. And thus for years many covered entities have relied on the ability to contract with multiple pharmacies to best serve their patients and maintain flexibility in accessing 340B discounts.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121–22 (2011). Specifically,

Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to improve "program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted authority to issue new regulations imposing civil monetary penalties ("CMPs") on manufacturers that knowingly and intentionally overcharge covered entities. 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of CMPs, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

II. PHARMACEUTICAL COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS FOR SAFETY-NET PROVIDERS

During the latter half of 2020, several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Eli Lilly (another large pharmaceutical company) that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for only one of its drugs—Cialis, a drug used to treat erectile dysfunction. *See* Compl. ¶¶ 78-80, *Eli Lilly v. HHS*, No. 1:21-cv-81 (S.D. Ind. Jan. 12, 2021), ECF No. 1. But that relatively modest restriction opened the floodgates to further disruptions of the 340B Program: Only one month later, Eli Lilly extended its new contract-pharmacy restrictions to *all* of its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Ex. G, and several other pharmaceutical companies promptly followed suit.

For its part, Novartis initially announced in August 2020 that covered entities purchasing and dispensing 340B-eligible drugs through contract pharmacies would be "required" to provide Novartis with claims data for all 340B orders placed through contract pharmacies in order to "benefit from … 340B discount[s]." Administrative Record ("VLTR") 5640–42; *see also id.* 7630. Novartis later made the provision of claims data voluntary when, in November, the drug manufacturer implemented new restrictions on eligible 340B purchases. *Id.* 7744–51. Under this new policy, Novartis would no longer "honor" purchases by hospital covered entities made through contract-pharmacy arrangements if the

contract pharmacy was located beyond "a 40-mile radius" of the covered entity—a geographic limitation Novartis purportedly "adopt[ed] … as a proxy for the community of patients served by" a hospital. *Id.* 7744–46; *see also id.* 7741–42. When a contract pharmacy is not "recognize[d] … under its approach," Novartis claimed, the drug manufacturer would "not convert a 340B order to a commercial order," but would instead "decline to fill the 340B order, and the hospital will not be charged." *Id.* 7747. Novartis explained further that it would be willing to consider whether to allow a hospital to purchase 340B-eligible drugs through a contract pharmacy located beyond this geographic limitation, but only "[i]f a hospital covered entity were to bring a special circumstance to [its] attention." *Id.* 7746. The drug manufacturer clarified that "federal grantee covered entities" would not be subject to this geographic limitation and could "continue to acquire 340B product through contract pharmacy arrangements," as covered entities of all types had been able to do for decades. *Id.* 7744.

In addition to Eli Lilly and Novartis, other large, global pharmaceutical companies imposed their own unilateral restrictions on covered entities' access to discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, *see id.* 6853–56, and Sanofi-Aventis and Novo Nordisk imposed their own, separate restrictions, *id.* 3160–64, 7618; *id.* 7758—with the combined impact of creating a new cluster of onerous restrictions for providers to navigate in order to receive the discounts to which they are statutorily entitled.

Unsurprisingly, the pharmaceutical manufacturers' abruptly announced, unilateral restrictions on access to 340B prices caused upheaval to the operations of covered entities due to their longstanding reliance on contract-pharmacy arrangements, prompting various safety-net providers to urge HHS to take action by filing emergency motions against the agency seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO & Prelim. Inj., *Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906-KBJ (D.D.C. Nov. 23, 2020)), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806-YGR (N.D. Cal. Dec. 11, 2020), ECF No. 7 (dismissed Feb. 17, 2021). HHS moved to dismiss those suits for lack of jurisdiction while confirming that its investigations of the manufacturers' actions were ongoing.

In response to the growing public outcry, HHS's General Counsel issued legal advice on

December 30, 2020, confirming his view—in alignment with the agency's longstanding guidance—"that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("Advisory Opinion"), VLTR_6832–39. The Advisory Opinion confirmed that this interpretation was compelled by the 340B statute's text—which requires drug manufacturers to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the mechanism by which a covered entity dispenses those drugs to patients—and further supported by the statute's purpose and history. *Id.* But the General Counsel did not assess the legality of any specific contract-pharmacy policy or restriction, opining on drug manufacturers' statutory obligations only as a general matter. The process of evaluating the legality of individual drug manufacturer's restrictions had been initiated by HRSA—a separate entity tasked with administering the 340B program—months before the General Counsel published his legal advice. *See infra.*

Following publication of the Advisory Opinion, several pharmaceutical companies filed suit within days of each other to challenge the General Counsel's legal advice. *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), ECF No. 1; *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No. 1; *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1; *Novo Nordisk, Inc. v. Dep't of Health & Hum. Servs.*, No. 3:21-cv-806 (D.N.J. Jan. 15, 2021), ECF No. 1. These lawsuits alleged (incorrectly) that the General Counsel's interpretation of the 340B statute imposed a new, non-statutory obligation on drug manufacturers to honor 340B purchases by covered entities who dispense drugs to patients through contract-pharmacy arrangements. With the drug manufacturers' allegations creating "confusion about the scope and impact of the [Advisory] Opinion," and to avoid any further confusion in this regard, the Acting General Counsel withdrew the legal advice on June 18, 2021. *See* Notice of Withdrawal (June 18, 2021), *available at* https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf (last visited June 28, 2021).

III. HRSA DETERMINES THAT NOVARTIS'S RESTRICTIONS ON PURCHASES BY COVERED ENTITIES DISPENSING 340B DRUGS THROUGH CONTRACT PHARMACIES HAVE RESULTED IN UNLAWFUL OVERCHARGES AND VIOLATE THE 340B STATUTE

Four months before the Advisory Opinion was issued, and shortly after Novartis and its peers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put drug manufacturers on notice that the agency was "considering whether" their "new [contract-pharmacy] polic[ies] constitute[] a violation of section 340B and whether sanctions apply," including, but "not limited to, [CMPs] pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *See* VLTR_7627; *see also e.g.*, *id.* 7658, 7188. HRSA also expressly disavowed the manufacturers' assertion that their contract-pharmacy restrictions "did not give rise to an enforceable violation of the 340B statute," and warned that the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* 7627. HRSA transparently explained that it "continues to examine" whether drug manufacturers' "actions amount to attempts to circumvent [the] statutory requirement by inappropriately restricting access to 340B drugs." *Id.* Unfazed by the warning and concerns expressed by its regulator, Novartis and its peers proceeded to implement their new contract-pharmacy restrictions.

HRSA's comprehensive review of Novartis's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. *Id.* 5 ("Violation Letter"). That letter informed Novartis that HRSA "has determined that Novartis'[s] actions have resulted in overcharges and are in direct violation of the 340B statute."[2] *Id.* It relies on statutory text to determine that the requirement that Novartis honor covered entities' purchases "is not qualified, restricted, or

[2] HRSA's Violation Letter states that Novartis's contract-pharmacy policy required covered entities to "provide claims data to a third-party platform." *See* VLTR_5. Although Novartis had initially informed covered entities that they would be required to provide claims data to purchase 340B-eligible drugs through contract-pharmacy arrangements, the drug manufacturer had later revised its policy and made its claims-data requirement voluntary. *See id.* 7747. The Violation Letter's misstatement in no way undermines HRSA's conclusion that Novartis's restrictions on the use of contract pharmacies contravenes the 340B statute and that the drug manufacturer's actions have resulted in unlawful overcharges on covered outpatient drugs—a conclusion that is supported by sound statutory interpretation and ample evidence in the administrative record. *See infra.*

dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA's letter directs Novartis to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that CMPs may be imposed. *Id.* 6. Although the letter instructs Novartis to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs.[3] *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on Novartis'[s] willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS has therefore made no determination as to whether sanctions are warranted at all but, should Novartis continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the Violation Letter does not rest upon—or even reference—the General Counsel's now-withdrawn December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, *id.* 8048). Instead, the Violation Letter culminates the evaluative process Novartis had been aware of months before the Advisory Opinion was issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. Alongside the statute and its legislative history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other

[3] Novartis responded to HRSA's Violation Letter on May 27, 2021. ECF No. 1-4. It indicated that it would continue restricting 340B purchases by covered entities through contract-pharmacy arrangements under the geographic limitation imposed by its policy. *Id.*

stakeholders, HRSA also gathered proof of the real-world implications of Novartis's restrictions and the substantial harm they have caused covered entities.

The record contains *over six thousand pages* of complaints from covered entities. *Id.* 110–6,806. Although the entire volume of evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's Violation Letter. To start, Beverly Hospital's complaints alerted HRSA to the fact that "manufacturer(s) [are] deliberately refusing [the] 340B Pric[e]" and explained that the restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] [contract] pharmacy" orders—the highest commercial rate. *Id.* 1470–71; *see also id.* 1465–66. Those complaints included spreadsheets showing specific transactions where the 340B ceiling price[4] was denied and the hospital instead was subject to WAC prices on Novartis's medications of $14,716 and $12,912 per unit; that hospital's orders over two months alone totaled $156,563 in lost 340B savings. *Id.* 1468, 1474.

Strong Memorial Hospital, a safety-net healthcare provider, serves an area with "the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty," and "[n]early 40% of [the hospital's] patients … on Medicaid or low-income Medicare." *Id.* 6396. In April 2021, the hospital alerted HRSA that, since October 2020, it "had paid *more than $2 million* over the 340B ceiling price on covered outpatient drugs purchased from" Novartis and other drug makers. *Id.* 6396 (emphasis added). The hospital provided documentation of specific transactions in which Novartis overcharged on 340B-eligible medications, forcing the safety-net provider to pay up to $5,677 per unit of medication. *Id.* 6410–11. And these orders represented only a fraction of "the lost opportunity and financial impact to the hospital"—which it had estimated to "exceed[] $10 million"—because the hospital's inability to purchase 340B drugs at the ceiling price not only resulted in overcharges, but also deterred it from purchasing medications altogether. *Id.* 6396. The hospital explained to HRSA that "[t]he losses incurred due to manufacturer restrictions puts at risk [its] ability

[4] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record, along with other figures that would allow a reader easily to calculate the ceiling price for any particular drug. Novartis cannot dispute, however, that the ceiling price for medications referenced in this discussion is typically only a tiny fraction of the WAC price.

to maintain a robust charity care program and community services that [it is] able to provide, often operating at a loss, such as comprehensive mental health and wellness care …, substance abuse treatment programs, and Naloxone training." *Id.*

Arnot Ogden Medical Center also documented specific transactions with Novartis that resulted in thousands of dollars of overcharges for the hospital. *Id.* 6229, 6243–44. The safety-net provider, who "provid[es] care for a region with a poverty rate around 30%," explained to HRSA that it "has operated for years in the red," attributing its ability to "keep the doors open" to the help it receives from "the 340B program and largely the benefit from contract pharmacy relationships." *Id.* 6229. Arnot explained that Novartis's 40-mile-radius restriction on these relationships had been "financially damaging" to the hospital. *Id.* 6230. "Novartis is aiming to limit 340B pricing access through specialty contract pharmacy arrangements," Arnot explained, "a model that is often managed via mail order operations." *Id.* "The patients that utilize these [specialty] pharmacies are often receiving medications for complex and specialized disease states, patients that, as a safety net provider, Arnot Ogden Medical Center is required to follow closely." *Id.* As a result of Novartis's and other drug manufacturers' restrictions, the hospital estimated that it had "been charged [approximately]$360k over the 340B ceiling price on covered outpatient drugs." *Id.* 6229.

Many other safety-net providers serving similarly disadvantaged and vulnerable populations echoed Strong's and Arnot's concerns regarding Novartis's and other drug makers' restrictions on the covered entities' purchases of 340B-eligibile drugs, and further documented specific transactions reflecting overcharges by Novartis. *See, e.g.*, *id.* 6280, 6290–91 (Highland Hospital: serving a population with 50% of children living in poverty), 6331 (Jones Memorial Hospital: serving "a rural area" with "among the poorest in New York"; "The 340B program and largely the benefit from contract pharmacy relationships are keeping the hospital's doors open."), 6360, 6368–69 (Noyes Memorial Hospital); *see also id.* 2592 (Gerald Champion Regional Medical Center: Reporting overcharges by drug manufacturers, including Novartis), 4454–55 (Nebraska Medicine: Providing HRSA with documentation "of Novartis products no longer offered at the 340B ceiling price through contract pharmacies"), 5622 (UC Davis Medical Center: Explaining how its "adult and pediatric patients in

Northern California" spread across *65,000* square mile area "rely on pharmacies closer to their homes" and how its contract pharmacies help its "patients to have access to medications"), 5744, 5748.

MaineHealth wrote to HRSA to notify the agency that Novartis and other drug manufacturers were "continuing to withhold 340B pricing for 340B eligible dispenses at contract pharmacies." *Id.* 3518; *see also id.* 3495 (providing a list of affected medications). It also explained that, although Novartis had carved out an exception to its contract-pharmacy restrictions for those pharmacies located "within [a] 40-mile radius of [a] covered entity," Novartis was "well aware that [its] medications are mostly dispensed at national specialty pharmacy chains, which utilize central fill locations that are often not anywhere near a health care facility." *Id.*

A critical-access hospital in Nebraska documented numerous instances where Novartis overcharged by forcing it to pay prices well above the 340B ceiling price. *Id.* 3133, 3136 (spreadsheet of Novartis products where 340B pricing was denied). The hospital explained that, since October 2020, it "had never seen [the] correct price" listed for Novartis's heart medication, for which it had "been consistently charg[ed] … over the ceiling price." *Id.*

St. Charles Health System confirmed for HRSA that Novartis was "pulling [its] drugs out of the [340B] program for" covered entities with "contract pharmacy relationships." *Id.* 5255; *see also id.* 5256–57 (providing a list of Novartis products for which the manufacturer would "not honor [the] 340B pric[e]" for the covered entity's orders made through contract pharmacies). The safety-net provider explained that these restrictions were impacting its "ability to provide expanded care services for [its] underserved and uninsured patients," including "screening programs, diabetes education and other community outreach services" in rural Oregon. *Id.* 5255.

HRSA also relied on evidence regarding the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents a sizeable, rural area and a "medically underserved population," submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. *Id.* 7255-56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for

as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "generate additional revenue" through the spread between the 340B-discount price and the price paid by or on behalf of some patients, as Congress intended,[5] and that it "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[6] *Id.*

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. *Id.* 7260-61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to" its pharmacy partners, under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible … patients." *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261–62. The covered

[5] As explained above, Congress designed the program to allow covered entities to generate revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. As explained herein, this enables covered entities to reinvest in patient care and services.

[6] This covered entity also thoroughly rebutted manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest, predetermined fee to the pharmacy for its services, "as required by HRSA, [it] does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that Novartis and its peers' restrictions have caused. *Id.* 7262–63. The administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270–75; 7277–83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295–98 (safety-net provider with high-poverty population expects to lose $6 million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300–06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309–14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"; further documenting significant harm to patients, *id.* 7312); 7316–20; 7323–25 (explaining that patients are heavily reliant on access to discounted drugs through network of neighborhood and mail-order pharmacies and that covered entity "is responsible for and ensures program compliance in part through daily self-audits of prescription claims and drug purchasing records"); 7331–33; 7347–50.

During its evaluation HRSA also gathered relevant evidence through meetings with stakeholders impacted by Novartis and its peers' restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. *Id.* 7891–92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* The very next day, HRSA officials learned in another meeting that one pharmacy in

West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. In another listening session that same month, HRSA gathered evidence from tribal leaders in multiple states detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[p]atients are having to choose between buying food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894–97. Another tribe reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898. Yet another tribal leader implored HRSA "to take immediate action," pointing out that drug makers are "experiencing record-breaking profit" so it was "unacceptable for them to g[o]uge small entities." *Id.*

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. *Id.* 7957–63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided detailed information on how they use 340B savings to provide more-comprehensive services for medically underserved and low-income patients, such as addiction treatment, oncology treatment, medication management, and outpatient behavioral health for children. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully one-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural hospitals are at even greater risk, since fully three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960–61. Notably, respondents expressly tied financial concerns to six manufacturers' contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most of which expect to lose *more than fifteen percent*

of their annual 340B savings as a result of these restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

Novartis's overcharges are also reflected in aggregate statistics compiled at HRSA's request in "to quantify the loss of units sold and savings." *Id.* 7936–47. That analysis shows a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only 2.9 million in January 2021. *Id.* 7936 (Figure 1). "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* The statistics show the immediate impacts of Novartis and its peers' refusal to honor 340B pricing. Figure 1 shows that, from August to October 2020, when three manufacturers put in place their changes, 340B units sold took a nosedive from 9.6 million units to 5.1 million units sold monthly; WAC-priced units consequently rose sharply, from a negligible volume to 1 million units monthly.[7] *Id.* Figure 2 shows that covered entities' monthly 340B savings fell from $357 million in July 2020, just before restrictions were put in place, to $92 million in January 2021, representing annualized lost savings of $3.2 billion. *Id.* Figure 3 shows that covered entities lost an estimated $234 million in January 2021 *alone* and had lost an estimated $665 million in roughly four months of restrictions. *Id.* The analysis also shows the impact of Novartis's specific changes, which caused 340B sales to decline in only a few months from roughly 1.45 million units to 1.06 million units; during that period, WAC-priced units sold by Novartis saw a marked rise from approximately 12,000 to 66,000 units in a *two-month* stretch. *Id.* 7937. The analysis also quantifies the fiscal impact of Novartis's changes. Monthly savings to covered entities dropped from $58.7 million just before it began overcharging safety-net providers to only about $22 million within three months. *Id.* 7939. By the end of 2020, Novartis's restrictions represented an average lost savings to covered entities of $29.5 million monthly. *Id.* 7940.

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Novartis's neighborhood-pharmacy restrictions and

[7] As the analysis explains, VLTR_7936, WAC-priced units do not fully reflect the loss of 340B-priced sales and thus underrepresent the impact of manufacturers' changes. This is because some sales will be lost entirely and because covered entities' third-party administrators will shift 340B-priced sales to other purchasing accounts rather than pay the highly marked-up WAC price. For this reason, lost 340B sales is a better indicator of impact than increased WAC sales.

their real-world impact on the 340B Program. After evaluating this evidence, alongside Novartis's communications to covered entities, *e.g.*, *id.* 5627–32, and to the agency explaining its policy, *e.g.*, *id.* 7741–51, HRSA concluded that Novartis is violating the 340B statute and issued its May 17, 2021 letter to that effect.

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary and drastic remedy" that is "never awarded as of right," *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008) (citation omitted), and "should not be granted unless the movant, by a clear showing, carries the burden of persuasion," *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted). To obtain a preliminary injunction, the moving party must establish "that four factors, taken together, warrant relief: likely success on the merits, likely irreparable harm in the absence of preliminary relief, a balance of the equities in its favor, and accord with the public interest." *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016) (citation omitted). A plaintiff cannot prevail in its request for a preliminary injunction if it fails to demonstrate either a likelihood of success on the merits or a likelihood of irreparable harm, *Guedes v. ATF*, 356 F. Supp. 3d 109, 126 (D.D.C. 2019); *Zeng v. Mayorkas*, 2021 WL 2389433, at *2 (D.D.C. Apr. 16, 2021), as "there would no justification" in either case "for the Court's intrusion into the ordinary processes of administration and judicial review," *Guedes*, 356 F. Supp. 3d at 126 (citation omitted).

In a case reviewing final agency action under the APA, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Landmark Hosp. of Salt Lake City v. Azar*, 442 F. Supp. 3d 327, 331 (D.D.C. 2020) (citation omitted). The agency "resolve[s] factual issues to arrive at a decision that is supported by the administrative record," and the district court "determine[s] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011) (citation omitted). "[T]he entire case on review is [thus] a question of law," and "the district court sits as an appellate tribunal." *Athenex Inc v. Azar*, 397 F.Supp.3d 56, 63 (D.D.C.

2019) (citation omitted). The party challenging final agency action bears the burden of demonstrating a violation of the APA. *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000).

ARGUMENT

After gathering ample evidence demonstrating that Novartis is refusing covered entities statutorily mandated discounts and overcharging them for 340B drugs, HRSA concluded for the first time in its Violation Letter that Novartis's restrictions on 340B-eligible purchases made through contract-pharmacy arrangements directly violate the 340B statute, 42 U.S.C. § 256b(a)(1), and may warrant sanctions, including expulsion from Medicaid and Medicare Part B. As demonstrated below, that conclusion is based on voluminous evidence and a correct interpretation of the statute.

Novartis fails to grapple with the incontrovertible evidence that its actions have resulted in safety-net providers purchasing 340B-eligible drugs well above the statutory ceiling price in violation of the 340B statute, and its contrary reading of the statute conflicts with the statutory text and subverts congressional intent. Novartis also challenges the reasonableness of HRSA's 340B-violation determination based on both factual assertions belied by the administrative record and arguments that attack descriptive language contained in the *General Counsel's withdrawn Advisory Opinion* but nowhere found in *HRSA's Violation Letter*—which interprets the 340B statute directly and does not rely on the withdrawn Advisory Opinion. The dispute between the parties—whether Novartis is, in fact, in violation of its statutory obligation—is squarely presented in the Violation Letter and must be decided on the basis of HRSA's reasoning contained therein and the administrative record supporting it. Because that reasoning is sound and supported by the record, the Court should grant summary judgment in favor of HHS on Novartis's challenge to the Violation Letter and deny Novartis's request for a preliminary injunction to allow HRSA's enforcement efforts to proceed.

I. THE COURT SHOULD ALLOW HRSA'S ENFORCEMENT OF THE 340B STATUTE TO PROCEED AGAINST NOVARTIS.

A. HRSA correctly found that Novartis is violating its statutory obligation.

The question before this Court is not, as Novartis would prefer, whether "the 340B statute contemplates—let alone requires—that manufacturers must agree to ship drugs" to one location

versus another. ECF No. 5-1 at 1 ("Mot."). The 340B statute is (unsurprisingly) silent as to delivery location because Congress's intent was to provide access to discounted medications for safety-net providers—not to detail the minutiae of how such transactions are effectuated. Properly framed, the question before this Court is whether HRSA correctly found that Novartis's contract-pharmacy restrictions violate the statutory prohibition on overcharging covered entities. As shown herein, HRSA correctly found that Novartis cannot evade its statutory obligation by erecting hurdles around covered entities' access to discounted medications—and that its current policy is resulting in *hundreds of thousands*, if not millions, of dollars in overcharges by resource-strapped safety-net providers.

HRSA's Violation Letter was issued only after HRSA—the entity that has administered the 340B program for decades—"completed its review of [Novartis's] policy that places restrictions on 340B pricing to covered entities," including "an analysis of the complaints HRSA has received from covered entities." VLTR_5. The determination "that Novartis'[s] actions have resulted in overcharges and are in direct violation of the 340B statute," is not only consistent with HRSA's interpretation since 1996, but also relies directly on statutory text. *Id.* (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Novartis's adherence to the 340B statutory scheme that Novartis opted into by executing a Pharmaceutical Pricing Agreement ("PPA"), that requires manufacturers to ensure that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1). It also specifies that "[e]ach such agreement shall require … that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As HRSA explained, that straightforward obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. VLTR_5. HRSA also reminded Novartis that compliance with its PPA requires Novartis to "ensure that the 340B ceiling price is available to all covered entities." *Id.*

HRSA further explained that Novartis's restrictions run afoul of its obligation "to provide the

same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because Novartis's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that … drug." *Id.* (citing 42 C.F.R. § 10.11(b)(2)). In short, HRSA's analysis rests on the statute itself and duly promulgated regulations issued through an express grant of rulemaking authority. It does *not* rest on the HHS General Counsel's now-withdrawn Advisory Opinion, *contra* Mot. 20–21.

And HRSA plainly is correct in its statutory interpretation. In urging this Court to find that it can somehow fulfill its duty to honor "purchases by" covered entities while admitting that it now *denies* those very purchases (forcing covered entities instead to pay wholesale acquisition cost) based solely on delivery location or dispensing mechanism, Novartis rips particular words from statutory context and asks the Court to consider them in a vacuum. The statute does not, as Novartis portrays, only require it to *offer* drugs for purchase by covered entities, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access.

Since 1992, the statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). And as demonstrated, *supra* pp. 3–6, the 1996 and 2010 guidances were unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense those drugs (importantly, both guidances were issued *before* Congress amended the statute to include the "offer" language on which Novartis relies throughout its brief). Read "as a whole," *United States v. Atl. Rsch. Corp.*, 551 U.S. 128, 135 (2007), § 256b(a)(1) plainly requires manufacturers to *sell* discounted drugs *to covered entities*.

The "offer" language in § 256b(a)(1) on which Novartis relies, added in 2010, codified an *additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases. *See* VLTR_108, Clarification of Non-Discrimination Policy (May 23, 2012). That amendment in no way changed the substance of Novartis's preexisting obligation. Were it true that a "manufacturer operates in compliance with the statute" "[s]o long as the manufacturer offers to sell the drug to the covered entity" (as Novartis portrays, Mot. 19)—irrespective of whether that offer came with strings that rendered it meaningless in practice—the inescapable conclusion would be that, from 1992 until 2010, the pharmaceutical industry sold deeply discounted drugs to covered entities on a purely voluntary basis (since the "offer" language did not yet exist). But of course that is not the case: From the statute's enactment, drug companies wishing to receive coverage for their products through certain government health-insurance programs have been required by both the statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment. Moreover, Novartis fails to grapple with the fact that its restrictions *do* violate the "offer" provision's non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases, as evidenced by the fact that Novartis places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases.

In addition to the 1996 and 2010 guidances discussed above, additional historic evidence demonstrates that HRSA always has understood the statute (and, as evidenced by their past conduct, so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. Nearly thirty years ago, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. 25,110-01, 25,112–14 (1994). In 1994, HRSA demonstrated the distinction between manufacturer requirements that *facilitate* access versus those that *restrict* access, explaining that manufacturers could "require the covered entities to sign a contract containing only the manufacturer's

normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers." *Id.* But—although the ministerial task of collecting "standard information" such as that needed "to set up … an account" is permissible—HRSA made clear that manufacturers could not deny 340B purchases by covered entities unless non-statutory demands are met. "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and drug companies are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* 25,113-14. HRSA may not yet have conceived in 1994 of the *precise* restrictions Novartis now seeks to impose, whereby it denies sales based on the delivery location and commonplace dispensing mechanism employed by the covered entity, but the agency made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill 340B orders.

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. Contrary to Novartis's suggestion that its obligation to offer discounted drugs first was imposed through the 2010 amendments, *in 1994* HRSA interpreted the statute to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue."[8] *Id.* at 25,113. Furthermore, that guidance—in response to a comment

[8] Novartis insists in its brief that HRSA's current interpretation of manufacturers' obligations is inconsistent with its prior pronouncements. *E.g.*, Mot. 19–20. Novartis is wrong. Not only did HRSA make plain in the 1996 Guidance that "the statute directs [a] manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug," 61 Fed. Reg. at 43,549, but HRSA *also* informed manufacturers *in 1994* that "manufacturers must offer covered outpatient drugs" to covered entities, including when

urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to their patients through outside pharmacies, so too are 340B purchasers. *Id.* It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

Legislative history forecloses Novartis's reading of its statutory obligation, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Novartis's interpretation of the program's proper operation. The draft of what would become § 256b(a)(1) that first was considered by the Senate proposed to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity). *See* S. Rep. No. 102-259, at 1-2 (1992) (emphasis added). In other words, the bill as originally drafted would have restricted covered entities' purchases of 340B drugs to only those dispensed *directly by* the covered entity or *on-site* at the same location. But rather than codify that plain restriction on covered entities' choice of dispensing mechanism—indeed, precisely the constraint Novartis urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity. Congress legislates against the backdrop of real-world facts and surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy and reliance on outside pharmacies was commonplace. 61 Fed. Reg. 43,550. It defies reason to suggest that Congress enacted a comprehensive legislative scheme to aid safety-net

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they "use purchasing agents or contract pharmacies." 59 Fed. Reg. at 25,111–13. Novartis seeks to obscure these plain statements by asking this Court to focus only on the 2010 amendments, which impose a *different* obligation not to discriminate against 340B purchases relative to commercial sales (an obligation Novartis also is violating).

providers and vulnerable patients, but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. The fact that Congress specifically chose to *remove* any restriction on how covered entities dispense medications forecloses Novartis's attempt to read those restrictions back into the statutory scheme.

Novartis's interpretation is equally incompatible with the Supreme Court's depiction of the PPAs manufacturers sign as "uniform agreements that recite the responsibilities § 340B imposes," including "impos[ing] ceilings on prices drug manufacturers *may charge for medications sold to specified health-care facilities*." *Astra*, 563 U.S. at 113 (emphasis added); *accord id.* at 115. That straightforward reading of § 256b(a)(1) mirrors HRSA's interpretation and forecloses Novartis's policy—under which, as evidenced in the record, a covered entity is denied 340B discounts (and must pay full price) anytime the covered entity directs discounted drugs be *shipped to* outside dispensers.

Novartis's claim that covered entities' decades-old, commonplace reliance on outside pharmacies to dispense the drugs they purchase "arguably violates the restriction on transfer of 340B-purchased drugs," Mot. 19 n.3, is meritless. The statute states that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), which quite plainly means that covered entities may not provide discounted drugs for use by non-patients or non-covered healthcare providers for prescribing to their own patients. That straightforward prohibition on use of 340B drugs by non-eligible patients or providers cannot be stretched into an implicit prohibition on patients physically attaining those drugs at neighborhood pharmacies—*i.e.*, the locations where most Americans receive prescription drugs. Pharmacies only store and handle the medications on behalf of eligible patients of eligible covered entities.

Novartis simply misreads the statutory prohibition on transfer of discounted drugs. Its proper understanding has been clear since 1994, when HRSA issued "guidelines regarding drug diversion," explaining that "[c]overed entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity" and that "[t]here are several common situations in which this might occur." 59 Fed. Reg. at 25,112–13. That guidance went on to explain that covered entities must "develop and institute adequate safeguards" to ensure

that discounted drugs are dispensed only to eligible patients, that covered entities must use 340B drugs only in outpatient settings (not for inpatient services), and that a larger provider which contains both a covered entity and non-eligible entity must "maintain separate dispensing records for the eligible entity." *Id.* These situations have in common that they all would involve dispensing and use of 340B-discounted drugs for either ineligible patients, services, or settings—but they certainly would not, as Novartis posits, encompass instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity. As HRSA has confirmed for decades, "the use of contract services is only providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." 61 Fed. Reg. at 43,550. There is no unlawful transfer of discounted drugs when a covered entity purchases drugs for dispensing at outside pharmacies, because pharmacies only are facilitating the exchange of tightly controlled *prescription drugs* on behalf of admittedly eligible patients of admittedly eligible prescribers.

This model does not expand the list of covered entities eligible to participate in, and receive discounts pursuant to, the 340B program because the manufacturer still is charging the covered entity the price of the 340B-eligible drug and those purchases are tracked and tied to dispenses to eligible patients of the covered entity.[9] Novartis seeks to elide this fact by telling the Court that, since 340B "expressly prohibits a covered entity from 'resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the covered entity,'" "the covered entity's options to redirect the drug after purchase are actually severely limited." Mot. 18-19. On the contrary, the prohibition on transfer quite plainly means a covered entity may not resell discounted drugs to non-patients, nor transfer the drugs to other, non-covered healthcare providers for prescribing to their own patients. It does not mean that safety-net providers are statutorily required to ensure that 340B drugs are directly dispensed—*i.e.*,

[9] Novartis claims these transactions involve "drugs nominally purchased by covered entities," Mot. 1. But as evidenced in the administrative record, *it is covered entities* purchasing Novartis's drugs for dispensing to eligible patients—oftentimes including patients with complex needs residing far more than 40 miles from their provider. Novartis's self-serving portrayal of the transactions as occurring for the benefit of pharmacies or patients of other, non-covered-entity providers is not based on evidence and should not be credited.

physically *handed*—to its patients by a pharmacist employed by that covered entity. Nothing in the statute abrogates covered entities' preexisting reliance on commonplace, real-world dispensing models. Had Congress intended to upend the existing models covered entities already used to provide drugs to their patients *when the program was created*, it would have so stated explicitly.

Instead, it is Novartis's policy that violates the will of Congress because, when Novartis refuses to honor purchase requests placed by a covered entity based solely on the "ship to" location specified on an invoice, it forces the covered entity either to pay commercial pricing or forego the needed medication altogether. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"); 59 Fed. Reg. at 25,113 ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective."). Novartis's unsupported assertion that, when it "does not recognize a contract pharmacy under its policy, it does not convert a 340B order to a commercial order," but instead just "declines to fill the 340B order, [so] the hospital is not charged," Mot. 14, is disproven by voluminous record evidence showing that Novartis *is* directly forcing covered entities to pay inflated commercial pricing for its drugs, in some instances to the tune of thousands of dollars per provider.

Novartis studiously avoids any discussion of the real-world impact of its new restrictions, claiming that its "policy does not prohibit any covered entity from purchasing Novartis medicines at 340B prices." Mot. 11. But that assertion ignores the fact that its refusal to deliver its drugs to pharmacies capable of dispensing them on behalf of the covered-entity purchaser renders its "offer" to sell drugs meaningless in practice in many instances. These are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Congress did not need to impose any explicit *delivery* obligation on manufacturers; it is self-evident that prescription drugs *cannot* be delivered to just any location. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, staff pharmacists, appropriate storage space to keep and safeguard medications,

software to bill insurers, etc., that would allow them to take delivery of, and dispense, pharmaceuticals. The majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are legally prohibited from handling their own dispensing or even *taking delivery* of Novartis's medications. And for those providers that do operate a pharmacy, it often is unworkable for all patients to receive prescriptions from their provider or within 40 miles—for instance, the hospitals directly targeted by Novartis's policy often perform specialized care such as organ transplants for patients who may live quite far away and for whom it may be impossible to fill prescriptions in the provider's immediate vicinity. Certain covered entities also serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or within 40 miles of the provider. *E.g.*, VLTR_7260–61 (explaining that covered entity "provide[s] primary health care and related services *across a 10,000 square mile service area*" for population that "is significantly underserved, aging, and impoverished" and who rely on "local retail pharmacies" to obtain medications). Were it as simple as Novartis portrays for covered entities to accept its "offer" through direct, in-house dispensing or limited outside pharmacies located nearby to the provider, 340B sales would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra* pp. 18–19.

These practical realities demonstrate that Novartis's purported offer to ship its drugs to each provider's physical location (or within 40 miles) often is meaningless in practice. If Novartis were correct that it only had to *offer* drugs to covered entities, not to also "deliver the product" to a location where the covered entity can accept and use the drugs for its patients, then by the same logic it could refuse to deliver drugs at all and force covered entities to physically pick up prescriptions from its warehouses. Clearly, in mandating that manufacturers provide discounted drugs to covered entities, Congress intended manufacturers to honor real-world, preexisting supply chains (including sales made through wholesale channels for delivery to pharmacies, which Novartis now refuses), not to force safety-net providers to restructure their businesses entirely to allow for in-house drug dispensing *or* to require patients to obtain prescriptions only within a short drive of the *provider* rather than the *patient*. Novartis's restrictions thwart the intent of Congress by erecting barriers to covered entities' ability to

access the program in practice. Certainly nothing in the statute authorizes drug makers to impose their own wholly arbitrary restrictions on which "purchases by" covered entities they will honor, creating an onerous web of requirements that covered entities must navigate to purchase various manufacturers' drugs. On the contrary, Novartis and its peers have known for thirty years that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program," 59 Fed. Reg. at 25,113.

HRSA agrees with Novartis that the statute does not allow contract pharmacies to participate in or become beneficiaries of the 340B Program. But the statute conditions Medicaid and Medicare Part B access on Novartis's agreement to provide its discounted drugs to covered entities, and does not authorize Novartis to place wholly arbitrary barriers that make those purchases inaccessible in practice. HRSA's review of the evidence has demonstrated that Novartis is denying sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies. Novartis remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to flout its statutory obligation.

B. HRSA's Violation Letter is neither arbitrary nor capricious.

HRSA reasonably explained its conclusion that Novartis is violating its statutory obligation in the Violation Letter, and properly grounded its determination in the 340B statute's text. "The APA's arbitrary-and-capricious standard requires that agency action be [only] reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.* (*Prometheus*), 141 S. Ct. 1150, 1158 (2021). Judicial review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citation omitted). A court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citation omitted). Novartis's attempts to pick apart HRSA's reasoning are unpersuasive.

1. HRSA's Determination Has a Reasonable Basis in the Administrative Record.

Novartis's contract pharmacy policy may be less restrictive than that of some other manufacturers, but it is no less in conflict with the 340B statute, *supra* § I.B., and it still inflicts substantial damage to the covered entities and patients who rely on contract-pharmacy arrangements outside of a 40-mile radius. Although Novartis claims HRSA had no "reasoned basis" for rejecting its policy to exclude contract-pharmacy arrangements more than 40 miles away from the covered entity, Mot. 20–21, the administrative record supporting HRSA's Violation Letter tells a different story. Rejecting this limitation was thus entirely reasonable for two primary reasons.

First, Novartis's geographic limitation has a particularly devastating impact on the distribution of drugs from national specialty pharmacy chains. *See, e.g.*, VLTR_3518. Many of Novartis's drugs are dispensed from such chains, "which utilize central fill locations that are often not anywhere near a health care facility." *Id.* So, in addition to financially harming the covered entities, Novartis's policy specifically targets drugs distributed by specialty pharmacies, which are often used to treat "complex and specialized disease states," through "mail order operations." *Id.* 6230. Indeed, multiple covered entities submitted complaints to HRSA specifically identifying drugs that they can no longer access at the 340B ceiling price, despite the geographic limitation. *See, e.g.*, *id.* 4454–55, 4457, 6243–45.

Second, some covered entities serve communities well beyond the 40-mile radius established by Novartis and are disproportionately affected by Novartis's policy. For example, the UC Davis Medical Center, which provides "specialty services in cardiology, diabetes, endocrinology, pulmonology, cancer treatment, [and] transplant," along with having a top-tier trauma center, serves more than 6 million residents over 33 counties and 65,000 square miles. *Id.* 5622. Many of UC Davis's patients reasonably "rely on pharmacies closer to their homes" and UC Davis "has many contract pharmacies" that help their "patients to have access to medications." *Id.* The extra-record Government Accountability Office ("GAO") report that Novartis relies on to justify its 40-mile rule only confirms that Novartis's policy would be expected to have an outsized impact on hospitals such as UC Davis. *See* Mot. 21 (citing 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 ("GAO Report")). There, the GAO concluded that almost half of disproportionate-share hospitals (hospitals serving a high number of low-income patients) had at least one pharmacy that was more than 1000 miles away. GAO Report at 23. And, while HRSA has acknowledged in guidance that contract pharmacies allow for "more inclusive arrangements in [covered entities'] communities," VLTR_101, it never suggested those communities be limited to a specific size (as Novartis suggests). Mot. 21. Indeed, HRSA touted the "significant benefit to patients" and "wider patient access" resulting from contract pharmacies, benefits that defy the arbitrary limit set by Novartis. VLTR_101.

There can be no doubt of the impact that Novartis's policy has on covered entities, and Novartis's overcharges are reflected in aggregate statistics in the record. In November 2020, for example, the number of 340B-priced units of Novartis drugs sold through contract pharmacies shrank from 1.38 million to 1.20 million. *See id.* 7937. This constituted $8.6 million in average lost savings by covered entities on Novartis products in November 2020 alone. *See id.* 7940. The trends continued in the subsequent two months, constituting average lost savings on Novartis products of over $28 million each month. *See id.* These statistics represent thousands of transactions in which Novartis's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices, which further supports HRSA's determination that Novartis has, in fact, overcharged covered entities.

According to Novartis, it is acceptable that some covered entities "would be left without a contract pharmacy under Novartis's policy," because it "would be willing to work with the covered entity through an exemption process." Mot. 21. But nothing in the 340B statute supports Novartis's assertion that it should be the ultimate arbiter of which covered entities may utilize crucial contract-pharmacy arrangements. Indeed it is difficult to imagine that Congress would have intended drug makers with a financial incentive to limit contract pharmacy arrangements to make this decision.

Novartis also attempts to counter HRSA's reasonable conclusions contained in the Violation Letter by ignoring facts underlying those conclusions, and misconstruing language from the withdrawn Advisory Opinion. Novartis accuses HRSA of improperly "asserting that Novartis has treated covered entities differently from other purchasers," Mot. 21. But Novartis conveniently fails to acknowledge that the fact that its restrictions do treat commercial purchases far more favorably than 340B

purchases, as evidenced by the fact that Novartis places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases. That Novartis says it "does not recognize any commercial arrangements equivalent to HRSA's current view of 340B contract pharmacy arrangements," does not change this fact, as Novartis does not claim to impose the same *conditions* on commercial arrangements. *See* Decl. of Daniel Lopuch ¶ 6, ECF No. 5-2.

Novartis also relies on descriptive language from the Advisory Opinion to conclude that the Violation Letter imposes impossible conditions on manufacturers. Mot. 20. This claim borders on the absurd. At the threshold, and regardless of whether the Advisory Opinion had been withdrawn, the Violation Letter does not mention the opinion or purport to rely on the opinion. Nor would one expect it to, as HRSA's enforcement activities began before the Advisory Opinion was even issued, VLTR_7744 (referencing communications beginning in August 2020), and HRSA's process operated independently from the Advisory Opinion, as the withdrawal notice explicitly states. In any event, agencies are free to use colorful language and analogies without being accused of acting arbitrarily and capriciously. *See Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974) (agency's path need only be "reasonably discerned"). Here, the General Counsel's withdrawn legal advice was merely illustrating the point that manufacturers must deliver drugs to contract pharmacies by referencing the lunar surface, not creating an impossible condition that manufacturers must actually develop rockets to deliver their products to outer space; the HRSA Violation Letter challenged here certainly says nothing of the sort. *Cf. All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936 (D.C. Cir. 1991) (finding DEA Administrator's decision not to reclassify marijuana on the schedule of drugs arbitrary and capricious when three out of eight factors in the test he used were impossible to fulfill).

2. Manufacturers' Obligations Have Been Consistent Since At Least 1994.

Despite Novartis's attempt to invent a change in HRSA's position over time, HRSA's guidance makes clear that its view of manufacturers' obligations has not changed in more than twenty-five years—manufacturers are obligated to honor covered entities' arrangements with contract pharmacies and may not impose extra-statutory obligations or conditions on fulfillment of their drug purchases.

Because there has been no "change in position over time" for HRSA to explain, the Violation Letter is not rendered arbitrary and capricious by failure to do so. *See* Mot. 22.

In 1994, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. at 25,112–14. Aside from manufacturer-imposed conditions, that early guidance also confirms that drug makers may not restrict the *methods* by which covered entities obtain and dispense drugs. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

In 1996, HHS issued further guidance, concluding that the 340B statute does not allow drug makers to refuse discounted-drug purchases by covered entities that rely on contract pharmacies. 61 Fed. Reg. 43,549 (confirming if the "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). There is nothing voluntary in that interpretation of the statute, as Novartis suggests, *see* Mot. 22; on the contrary, the only voluntary aspect of the 1996 Guidance was the choice of covered entities whether to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen for covered drugs. *See id.* at 43,549-50. Indeed, PhRMA's lawsuit confirmed the manufacturer industry's understanding of the statute by alleging that the guidance required manufacturers to honor contract-pharmacy arrangements. *See supra* pp. 4–5.

In 2010, HHS once again definitively set forth its statutory interpretation: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug* at a price not to exceed the statutory discount price." 75 Fed. Reg. at 10,278 (emphasis added). That mandatory

language reiterated the agency's considered decision on what the 340B *statute* requires—not, as Novartis portrays, a new position or obligation created by the agency.

Consistent with these prior interpretations, the Violation Letter concluded that: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." VLTR_5. Novartis argues that the Violation Letter represents a shift in prior policy because it is the first time that HRSA explicitly took the position manufacturers must recognize all of covered entities' contract-pharmacy arrangements. Mot. 24–25. But this is not the relevant inquiry. HRSA had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities' purchases based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020 manufacturers universally complied). Whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these guidances consistently explained that "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. The broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit discussion of the number of contract-pharmacy arrangements. Properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, HRSA's interpretation of drug makers' obligations has not shifted over time. That the Violation Letter threatens CMPs if Novartis continues to violate its obligations does not change this analysis. *See* Mot. 24–25. The threat of CMPs is simply HRSA's exercise of statutory authority to enforce the 340B statute—it does not represent a change in HRSA's interpretation of the 340B statute with respect to manufacturers' obligations.

3. HRSA's Decision is Properly Based on Facts in the Administrative Record.

Although covered entities' compliance with non-binding interpretive guidance is irrelevant to the question of whether Novartis's policy violates the 340B statute, and thus was not required to be

considered by HRSA under the APA, the administrative record supporting the Violation Letter contains facts supporting HRSA's understanding of contract pharmacy arrangements, including title transfer and replenishment models. Novartis's claim that HRSA's decision is "arbitrary because it assumes facts not in evidence" is thus meritless. Mot. 24–25.

To survive a claim that HRSA's action was arbitrary and capricious, its conclusions need only be "reasonable and reasonably explained," based on consideration of "the relevant issues." *Prometheus*, 141 S. Ct. at 1158. Here, HRSA's conclusion that Novartis was overcharging covered entities in violation of the 340B statute was reasonably based on the statute itself, along with regulations HRSA promulgated regarding the imposition of CMPs. VLTR_5. Novartis claims that the Violation Letter should have made an explicit finding that covered entities were in compliance with non-binding guidance issued in 2010—specifically, that "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." Mot. 25. Yet, the 2010 Guidance itself makes clear that it is nonbinding, 75 Fed. Reg. at 10,273,[10] and simply concludes that an "essential element[] to address in contract pharmacy arrangements" includes the "purchase" and maintenance of "title" to drugs by covered entities, *id.* at 10,277. Novartis fails to offer any explanation as to why covered entities' compliance with non-binding guidance is relevant to HRSA's determination that Novartis's policy is unlawful. Because reliance on an agency's failure to consider irrelevant factors is not a ground on which to find agency action arbitrary and capricious, Novartis's argument is meritless. *See Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians v. Babbitt*, 116 F. Supp. 2d 155, 165 (D.D.C. 2000) ("Although the agency did not consider other possible interpretations, it was not arbitrary and capricious to not consider materials, which under the interpretation being employed, were irrelevant.").

In any event, facts in the administrative record support the conclusion that covered entities generally maintain title to drugs delivered to their contract pharmacies under the replenishment model

[10] HRSA's website states that it "*recommends* that the written agreement include all essential elements of the contract pharmacy guidelines," not that such elements are required. HRSA, Contract Pharmacy: Important Tips, available at https://www.hrsa.gov/opa/updates/2016/august.html (Aug. 2016).

at least until they reach neutral inventory, contrary to Novartis's claim. Mot. 2526. Generally speaking, under the replenishment model, a covered-entity patient who is 340B eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. *See, e.g.,* VLTR_7323 (declaration of covered entity CEO explaining that "contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used"); *Id.* 7257 (same).

The model works in three main steps. First, a contract pharmacy dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient was eligible for 340B product. *See, e.g., id.* 7261. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *See, e.g., id.* 7317 (covered entity CEO explaining "virtual inventory" system where "each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the covered entity] places an order via our 340B wholesaler to replenish the contract pharmacies' stock"). Importantly, the replenishment order is placed on a covered entity's 340B account and the covered entity is billed for that order. *See, e.g., id.* 7323 ("The cost of the 340B purchases are billed to [the covered entity] and the drugs are shipped to the contract pharmacies."). Finally, the "replenished" drug is shipped to the contract pharmacy, where it becomes neutral inventory and may be dispensed to any subsequent patient. *See, e.g. id.* 7279 (covered entity CEO explaining that some contract pharmacies "dispense a retail pharmacy product to patients" and then are "replenished" with a covered entity-purchased "340B drug for that dispense").

Under this replenishment model, covered entities generally maintain title to the drugs at least until they reach neutral inventory, but contract pharmacies continue to handle "storage distribution, and patient-related information." *Id.* 7296; *see also, e.g., id.* 7279, 7261. Thus, Novartis's claim "that the administrative record is completely devoid of any factual evidence" on the subject is unavailing. Mot.

25.[11] And neither the Office of Inspector General ("OIG") report nor the GAO Report cited by Novartis compel a different conclusion. *Id.* 25-26. These reports do not so much as mention the "title" of 340B drugs, and provide no basis to invalidate the record evidence cited herein.

C. The *Astra* decision does not compel a different result.

The district court's recent decision in *AstraZeneca Pharmaceuticals LP v. Becerra*, does not answer the statutory question before this Court—whether HRSA correctly found that Novartis is overcharging covered entities—indeed, the Violation Letter was not even before that Court. *See* No. 21-27-LPS (D. Del.), ECF No. 78 (June 16, 2021) ("*Astra* Op."). On the contrary, the *Astra* court made plain that its "role" in that opinion was "to decide only the narrow question[]" whether "the position outlined in the [Advisory Opinion] [is] compelled by the unambiguous text of the 340B statute." *Id.* at 1. Answering that question, the court found the Advisory Opinion to be "legally flawed" because its "analysis is not the sole reasonable interpretation of the statute." *Id.* at 17, 2. Far from setting forth a position *contrary* to law, however, the court confirmed that "HHS's current interpretation of the statute is permissible." *Id.* at 19. Thus not only did the *Astra* court have neither any claims regarding HRSA's Violation Letter nor the administrative record before it, the Court expressly found that the General Counsel's view regarding manufacturers' obligations represents a permissible reading, albeit not an unambiguous one.[12]

Although HHS disagrees that there is ambiguity regarding whether manufacturers can deny 340B-priced drugs to covered entities based on the dispensing mechanism or delivery location chosen by the purchaser, even if this Court agrees that the statute is ambiguous, HRSA's letter is based on the best reading of the statute and its decades of expertise administering the statute and thus is entitled to

[11] To the extent that Novartis argues that the replenishment model violates the 340B statute's prohibition on unlawful transfer, this argument is neither relevant to their claim of an inadequate record, nor accurate, as explained more fully *supra* § I.A.

[12] For reasons explained above, *see supra* § I.B.2, HRSA respectfully contends that the relevant inquiry is not whether "the Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *Astra* Op. 12.

deference. Moreover, the HRSA letter does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity), so HRSA's rationale would not suffer from the same "flaw" identified by the *Astra* court. As demonstrated *supra* § I.A, HRSA's conclusion that Novartis is overcharging covered entities by refusing discounted-drug orders and imposing unlawful, extra-statutory conditions is well-grounded on statutory text, historic evidence of the agency's interpretation, and material in the administrative record, even if this Court agrees with the *Astra* opinion's finding of ambiguity.

To the extent this Court finds ambiguity in the 340B statute, it should afford deference to HRSA's statutory interpretation under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), under which informal interpretations such as this one "are 'entitled to respect' … to the extent that [they] have the 'power to persuade.'" *Orton Motor, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1211 (D.C. Cir. 2018) (citation omitted). Because HRSA's interpretation is based on its "specialized experience" and the "broader … information available to [it]," *see Ctr. for Bio. Diversity v. Jackson*, 815 F.Supp.2d 85, 90–91 (D.D.C. 2011) (citation omitted), evidenced HRSA's "thorough[]" consideration and "valid[]" reasoning, and was "consisten[t] with earlier … pronouncements," the interpretation has the "power to persuade" and should be accorded deference, *Orton Motor*, 884 F.3d at 1211 (citation omitted).

The *Astra* court's other observations do not undermine HRSA's conclusions in the Violation Letter. True, as the court found, 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Astra* Op. 18. But as explained above, that that overlooked the fact that Congress considered *and explicitly removed* a provision from the statute that would have limited 340B purchases to drugs dispensed in-house or on-site at a covered entity;[13]

[13] The *Astra* court wrote that Congress considered including this restriction when it "added the 'must offer' requirement to the statute in 2010." *See Astra* Op. 21. In actuality, Congress considered restricting covered entities to in-house or on-site dispensing *when the statute was enacted in 1992*. Rather than "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies," *id.*, Congress's *removal* nearly three decades ago of any restriction on delivery site or dispensing mechanism can best be interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme.

this, coupled with the fact that 95% of covered entities at the time of enactment did not have an in-house pharmacy, makes it unlikely that Congress created a novel social-safety-net program that the majority of beneficiaries had no means to access in practice.[14] Similarly, the fact that § 256b(a)(1) is directed to the Secretary of HHS, requiring him to enter agreements obligating manufacturers to honor covered-entity purchases, *see Astra* Op. 18, does not displace HRSA's finding because HRSA is acting (through delegation from the Secretary) to enforce against Novartis the requirement in the statute and its PPA to provide discounts to safety-net providers. In other words, the Violation Letter is HRSA's effort to effectuate § 256b(a)(1)'s command to the Secretary, and there is no question that the statute instructs the Secretary to ensure that covered entities are not charged more than the 340B ceiling price.

Because the *Astra* Opinion was limited to the narrow ground of finding the Advisory Opinion erred in concluding its interpretation was compelled by unambiguous statutory text, and the court explicitly found that "HHS's current interpretation of the statute is permissible," *id.* at 22, *Astra* does not undermine HRSA's determination that Novartis is violating the statute.

II. THE COURT SHOULD NOT PRELIMINARILY ENJOIN HRSA'S ENFORCEMENT OF THE 340B STATUTE

A. Novartis has not established irreparable harm.

Setting the merits aside, Novartis is not entitled to preliminary relief because it has failed to show that it is likely to suffer irreparable harm in the absence of a preliminary injunction. "[T]he basis

[14] HRSA respectfully disagrees with the *Astra* court's statement that "[t]he statute's total omission of contract pharmacies renders it ambiguous *with respect to the central issue in this case*." *Astra* Op. 19. The central issue in that case (and this one) is not the role of contract pharmacies under 340B, but the obligation of drug makers to honor purchases by covered entities. Similarly, that court's statement that "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication," *id.* at 20, is inapposite to HRSA's conclusion. HRSA is not including contract pharmacies as a "type of covered entity" nor allowing pharmacies to participate in 340B. Congressional silence strongly supports HRSA's conclusion: At time of enactment the overwhelming majority of healthcare providers relied on outside pharmacies to serve their patients. Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medications in-house) surely it would have said so explicitly. Finally, Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers—who plainly *are* permitted to serve patients through outside dispensers.

of injunctive relief in the federal courts has always been irreparable harm." *CityFed Fin. Corp. v. Off. of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995) (citation omitted). The harm must be "certain and great, actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm." *League of Women Voters v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (citation omitted). Additionally, "the movant must show that the alleged harm will directly result from the action which the movant seeks to enjoin." *Wis. Gas. Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). And importantly, a plaintiff "cannot simply make 'broad conclusory statements' about the existence of harm," but must instead "submit[] … competent evidence into the record … that would permit the Court to assess whether [the plaintiff], in fact, faces irreparable harm." *Aviles-Wynkoop v. Neal*, 978 F. Supp. 2d 15, 21 (D.D.C. 2013) (citation omitted); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 211 (D.D.C. 2012) ("Bare allegations of what is likely to occur are of no value since the court must decide whether the harm will *in fact* occur." (quoting *Wis. Gas Co.*, 758 F.2d at 674)).

Novartis begins by claiming that HRSA's accusation that the drug manufacturer has committed "knowing and intentional violations of its 340B obligations … irreparably harm[s] Novartis's reputation among its customers, covered entities, and investors." Mot. at 26–27. To be clear, HRSA has made no such accusation. HRSA will determine whether Novartis *knowingly* and *intentionally* overcharged covered entities for 340B-eligible drugs in evaluating whether CMPs are warranted under 42 U.S.C. § 256b(d)(1)(B)(vi) based on Novartis's denial of purchases by covered entities with contract-pharmacy arrangements. *See* 42 C.F.R. § 10.11(a) (permitting CMPs only for overcharges that are "knowing[] and intentional[]"). HRSA has yet to conduct that evaluation, and will only do so in the event that Novartis is unwilling "to comply with its [statutory] obligations." VLTR_6.

What HRSA *has* determined—based on ample evidence—is that Novartis has overcharged covered entities for 340B-eligible drugs. It is worth noting here that Novartis's claims of reputational damage reflect self-inflicted injuries, brought about by its own decision to unsettle safety-net healthcare providers' and their patients' decades-old reliance on neighborhood pharmacies to provide access to 340B-eligible medications. At any rate, preliminary relief cannot retroactively retract HRSA's 340B-violation determination or nullify its alleged reputational consequences for Novartis.

In so far as Novartis alleges that additional enforcement efforts will cause it "a host of reputational harms," Mot. at 27, it points to no concrete, "competent evidence" from which the Court can assess whether Novartis "in fact, [will] face" such harms in the absence of a preliminary injunction. *See Aviles-Wynkoop*, 978 F. Supp. 2d at 21 (citation omitted). Although "[i]njury to reputation can, at least at times, rise to the level necessary to support the issuance of an injunction," *Atlas Air, Inc. v. Int'l Bhd. of Teamsters*, 280 F. Supp. 3d 59, 103 (D.D.C. 2017), "[a]s with all other forms of irreparable harm, the showing of reputational harm must be concrete and corroborated, not merely speculative," *Trudeau v. FTC*, 384 F.Supp.2d 281, 297 (D.D.C. 2005); *accord Cardinal Health*, 846 F. Supp. 2d at 213. In support of its allegations of reputational injury, Novartis cites only a few news articles covering HRSA's 340B-violation determination, Mot. at 27, and a declaration stating in conclusory fashion that "[s]uch [media] coverage is injurious to Novartis's reputation" and that HRSA's determination "plainly injures Novartis reputation," Decl. of Daniel Lopuch ¶ 10. But these bald allegations are the epitome of the type of "'vague and unsupported' assertions" that are insufficient to support a finding of irreparable harm to a plaintiff's reputation, *see Jones v. Dist. of Columbia*, 177 F. Supp. 542, 548 (D.D.C. 2016) (citation omitted) (finding no "great, concrete, corroborated and certain reputational injuries absent the injunctive relief," despite evidence that the defendants' adverse actions against the plaintiffs had "been reported in the media"); *accord Toxco Inc. v. Chu*, 724 F. Supp. 2d 16, 30–31 (D.D.C. 2010) (finding "the plaintiff's claims of reputational harm … far too vague, speculative and uncorroborated to support a finding of irreparable harm," where the plaintiff relied "solely on the uncorroborated and speculative assertions made in an affidavit of … one of the plaintiff's vice-presidents"). By "failing to supply [actual] evidence of the loss of reputation or good will beyond [its] own conclusory averments, [Novartis] has not made a sufficient showing that irreparable harm is likely" absent a preliminary injunction. *See Rush v. Hillside Buffalo, LLC*, 314 F. Supp. 3d 477, 486 (W.D.N.Y. 2018).[15]

Novartis also alleges that, absent preliminary relief, CMPs will continue to "pile up" based on

[15] Without demonstrating that it will suffer irreparable injury to its reputation in the absence of preliminary relief, Novartis cannot further show that such unproven harms will "hinder[]" the drug manufacturer's "ability to recruit talent and build relationships with the stakeholders." *See* Mot. at 27.

its persistent overcharging of covered entities for 340B drugs, and that it will be unable to recover for these financial losses because of the government's sovereign immunity. Mot. at 28. As an initial matter, enjoining HRSA's enforcement efforts during the pendency of this litigation will have no practical impact on the potential of ever-increasing CMPs. Should HHS prevail on the merits of Novartis's challenge to the Violation Letter, a preliminary injunction will not prevent HHS from imposing CMPs based on Novartis's unlawful actions during the pendency of this litigation. On the other hand, in the unlikely event that Novartis prevails, there would be no grounds for HHS to impose CMPs, whether or not the Court issued a preliminary injunction. Thus, preliminary relief would be meaningless in practice because any alleged threats of CMPs will not abate in the interim as long as Novartis continues to charge covered entities inflated prices or deny 340B-eligible purchases altogether.

Furthermore, Novartis's bare allegations of unrecoverable financial harms are far "too vague and speculative to support a finding of irreparable harm."[16] *See Cardinal Health*, 846 F. Supp. 2d at 213. As Novartis appears to concede, the mere "fact that economic losses may be unrecoverable does not, in and of itself, compel a finding of irreparable harm," *id.* at 211, for such a rule would "effectively eliminate the irreparable harm requirement" against the federal government, in that "[a]ny movant that could show any damages against an agency with sovereign immunity—even as little as $1—would satisfy the standard," *Air Trans. Ass'n of Am., Inc. v. Exp.-Import Bank of the U.S.*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012). Instead, to support a preliminary injunction, economic harm must "be great, certain and imminent," *Cardinal Health*, 46 F. Supp. 2d at 211, "even where it is irretrievable because a defendant has sovereign immunity," *Air Trans.*, 840 F. Supp. 2d at 335. But although Novartis appears to acknowledge that it must show it will suffer "substantial and imminent financials harms," Mot. at 28, it offers no concrete estimates regarding the financial impact that HRSA's enforcement efforts will have absent a preliminary injunction. Indeed, Novartis does not even venture a *guess* as to

[16] Similarly, Novartis cannot establish irreparable harm based on the vague and unsupported assertion that it "will need to consider reallocating [an indeterminate amount of] resources away from research and development" to "account for" any potential CMPs. Mot. at 28. This allegation also fails because it identifies no *imminent* harm, as there is no concrete indication that Novartis will need to begin shifting resource priorities during the pendency of this litigation. *See League of Women Voters*, 838 F.3d at 7–8.

the loss it may incur, stating simply that CMPs "will stack up in a hurry" and that the possibility it could lose coverage for its drugs under Medicaid and Medicare Part B would cause "significant financial harm." *Id.* But even if Novartis had offered the Court more than bare allegations on this score, the alleged monetary losses Novartis would suffer as a result of enforcement efforts taken during the pendency of this ligation would have to rise far above "a minuscule portion of the company's worldwide revenues" to support a preliminary injunction. *See LG Elec. U.S.A., Inc. v. Dep't of Energy*, 679 F. Supp. 2d 18, 36 (D.D.C. 2010); *accord Cardinal Health*, 46 F. Supp. 2d at 211. And yet, Novartis has "offered no indication of the magnitude of economic harm it has suffered or will suffer as a result of" any enforcement efforts. *See Toxco Inc.*, 724 F. Supp. 2d at 31–32 (collecting cases).

Finally, Novartis argues that termination of drug coverage under federal health-insurance programs would "inhibit access to Novartis's drugs by vulnerable Medicaid and Medicare beneficiaries having therapeutic need for them." Mot. at 29. But "[t]his argument fails because it shows irreparable harm not to [Novartis], but to third parties." *See Cardinal Health*, 846 F. Supp. 2d at 213–14. "[I]njuries to third parties are not a basis to find irreparable harm." *Alcresta Therapeutics, Inc. v. Azar*, 318 F.Supp.3d 321, 326 (D.D.C. 2018). A plaintiff's "burden is to show irreparable harm to *itself*." *Postal Police Officers Ass'n v. U.S. Postal Serv.*, 502 F.Supp.3d 411, 426 (D.D.C. 2020) (emphasis added). Simply put, Novartis cannot obtain a preliminary injunction based on purported harms to individuals who use its drugs.

B. The balance of the equities and the public interest weigh against the requested preliminary injunction.

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. at 435. There is an "inherent harm" to HRSA in preventing it from enforcing the laws that Congress charged to it. *See Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). Novartis provides no authority supporting its attempt to have this Court preemptively enjoin HRSA's enforcement process *in totem*. The APA permits this Court only to review final agency action—not to forestall enforcement in its infancy.

And because HRSA, in its expert judgment, has determined that Novartis has unlawfully overcharged covered entities for 340B-eligible drugs, it is in the public's interest that the Court not

upset the agency's enforcement efforts unless and until it has determined HRSA's approach to be unlawful. This is particularly appropriate because the Violation Letter is before this Court for review and the Court will hear argument on the letter in just a few weeks' time. Novartis fails to consider the critical interests of the public in HRSA's enforcement of the 340B Program's rights and obligations. Contrary to what Novartis suggests, 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. *See supra* pp. 11–17. And Novartis has known for many months that HRSA was considering whether the drug manufacturers' contract-pharmacy restrictions constitute a violation of the 340B statute and whether sanctions apply. Novartis should not be permitted to halt that process before the Court determines the merits of HRSA's position.

Moreover, Novartis's request that the agency be "enjoined from taking enforcement or any other action against Novartis based on HRSA's determination that Novartis's" actions have violated the 340B statute, ECF No. 5-3 at 4, would contravene the specificity requirements of Federal Rule of Civil Procedure 65(d). Rule 65(d) requires an injunction to "state its terms specifically" and "describe in reasonable detail … the act or acts restrained or required." The terms "enforcement … action," "any other action," and "based on," ECF No. 5-3 at 4, are "simply too vague to support a preliminary injunction." *See Emrit v. Nat'l Inst. of Health*, 2014 WL 12802602, at *2 (D.D.C. 2014). And it would be impossible for HRSA to determine what such an order restrained, because the requested injunction "fails to detail what the conduct is, *i.e.,* the substance of the [adverse action]" to which the requested relief refers. *See Patriot Homes, Inc. v. Forest River Hous., Inc.*, 512 F.3d 412, 415 (7th Cir. 2008); *see also Ideal Toy Corp. v. Plawner Toy Mfg. Corp.*, 685 F.2d 78, 83 (3d Cir. 1982). For example, would internal assessment and consideration of potential CMPs qualify? Or memoranda analyzing the basis for a "knowing" violation? This demonstrates why injunctions of *enforcement proceedings*, as opposed to *specific agency actions*, are impermissible. This Court should deny Novartis's request for preliminary relief.

CONCLUSION

Because each of Novartis's claims is meritless, the Court should grant summary judgment for HHS and should deny Novartis's request for preliminary injunctive relief.

Dated: June 28, 2021

Respectfully submitted,

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Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1479 (DLF)

DECLARATION

I, Kate Talmor, make the following Declaration pursuant to 28 U.S.C. § 1746, and state that under the penalty of perjury the following is true and correct to the best of my knowledge and belief:

1. In 1996 the Pharmaceutical Research and Manufacturers of America sued the Department of Health and Human Services and its Secretary, challenging the agency's guidelines on use of contract pharmacies under the 340B Program. The docket number is 1:96-cv-1630 (D.D.C.).
2. Attached to this declaration is a true and correct copy, obtained from official archives of the Department of Justice, of the Complaint and Stipulation of Dismissal for that litigation.

Dated: June 28, 2021

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
1100 15th Street, N.W.
Washington, D.C. 20005

Plaintiff,

v.

DONNA SHALALA, in her official capacity as Secretary, United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendants.

CASE NUMBER 1:96CV01630
JUDGE: June L. Green
DECK TYPE: Civil General
DATE STAMP: 07/12/96

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), as representative of its member companies, brings this action against Defendants Donna Shalala and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

Nature of the Action, Jurisdiction and Venue

1. This is an action brought pursuant to 5 U.S.C. § 706(2)(A) and 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment that the contract pharmacy

guidelines adopted by the Office of Drug Pricing Program ("ODPP") of the Public Health Service ("PHS") of HHS are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA seeks a declaration that HHS has violated the Administrative Procedure Act (the "APA") and the Federal Register Act (the "FRA") by failing to comply with the statutory notice, comment, and publication provisions concerning rulemaking in issuing the contract pharmacy guidelines and that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA also seeks a preliminary and permanent injunction directing HHS to withdraw the contract pharmacy guidelines and to give them no force or effect, and to refrain from facilitating or encouraging any entity from taking action based on the contract pharmacy guidelines in a manner that is contrary to law.

2. Jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1331, 1337, and 1361, and venue is proper in this district under 28 U.S.C. § 1391(e).

Parties and Related Persons

3. The Pharmaceutical Research and Manufacturers of America is an organization that represents the country's leading research-based pharmaceutical and biotechnology companies. Investing nearly $16 billion a year in discovering and developing new medicines, PhRMA companies are the source of nearly all new drug discoveries worldwide. The interests that PhRMA seeks to protect in this litigation are germane to its organizational purposes in representing and protecting the interests of companies that discover, develop and bring

prescription drug products to market. As explained more fully below, members of PhRMA are directly affected by, and suffer substantial injury from, the actions complained of herein.

4. Defendant Donna Shalala is Secretary, United States Department of Health and Human Services, and is sued in her official capacity.

5. Defendant HHS is an agency of the United States within the meaning of the APA and is charged with the responsibility of administering a wide variety of federal programs related to health and human services, including programs implemented by the Public Health Service. The Public Health Service is responsible for overseeing and administering a variety of programs concerned with public health and health care services, including the Health Resources and Services Administration ("HRSA").

6. ODPP, an office of the Health Resources and Services Administration of the Public Health Service, is responsible for implementing the pharmaceutical price controls established by Congress under Section 340B ("Section 340B") of the Public Health Service Act (the "PHS Act"), 42 U.S.C. § 256b.

Factual Allegations

7. Section 340B provides that the Secretary of HHS "shall enter into an agreement with each manufacturer of" outpatient prescription drugs under which the manufacturer agrees to sell such drugs to "covered entities" at a discounted price determined by a statutory formula, for their use in treating "patients of the entity." Under the statutory formula, the discounted price is at

least 15.1 percent lower than the weighted average price available from the manufacturer for drugs distributed to the retail pharmacy class of trade. 42 U.S.C. §§ 256b(a)(1) & 1396r-8(c).

8. Copies of the "Pharmaceutical Pricing Agreement" are available from the Secretary and neither the form nor specific terms may be modified by participating manufacturers. Upon information and belief, certain members of PhRMA have entered into such agreements. Under the statute, if a manufacturer fails to enter into such an agreement, no federal funding will be available to states to pay for that manufacturer's covered outpatient drugs furnished to any Medicaid beneficiaries.

9. Section 340B defines "covered entities" to include a variety of recipients of identified federal grants under the PHS Act, State block grant programs, and various health care providers to whom Congress has given special Medicare and/or Medicaid reimbursement status.

10. Section 340B also includes restrictions intended to protect participating manufacturers from certain types of economic harm that could result from abuse of the pricing program. The statute prohibits diversion of the discounted drugs to the greater commercial market by prohibiting a covered entity from "resell[ing] or otherwise transfer[ing] the drug to a person who is not a patient of the covered entity." 42 U.S.C. § 256b(a)(5)(B). In addition, the statute seeks to protect manufacturers from the harm of "double discounting" by prohibiting a covered entity from submitting a claim for Medicaid reimbursement for drugs

purchased at the discounted price where the state Medicaid agency, under separate statutory authority, will itself claim a comparable rebate from the manufacturer based on its reimbursement of the entity for such drug. 42 U.S.C. § 256b(a)(5)(A)(i).

11. Some entities included on the list of entities that may participate in the PHS pricing program do not purchase or directly furnish outpatient drugs to their patients. Many of these entities are not licensed by the state in which they are located to purchase and dispense prescription drugs and do not employ personnel who are authorized to do so. Historically, some of these entities, such as community health centers, have referred patients to nearby retail pharmacies for prescriptions. Such pharmacies are not "covered entities" under Section 340B and the statute makes no provision for sales of discounted drugs to such pharmacies.

12. In implementing the statute through the standard Pharmaceutical Pricing Agreement signed on behalf of the Secretary on December 14, 1992, PHS made arrangements only to enable participation by those covered entities that can purchase and dispense prescription drugs; it made no arrangements to enable entities that use contract pharmacies to obtain the benefits of the PHS price. PHS acknowledged this in a February 23, 1993 letter to PhRMA (attached as Exhibit A), in which the Director of ODPP stated: "The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed."

13. PHS published "proposed guidelines" on contract pharmacy issues for notice and comment in the Federal Register on November 1, 1995, with the statement that "[a]fter consideration of the comments submitted, the Secretary will issue the final guidelines."

14. PhRMA and several of its member companies, as well as non-member companies, covered entities and competitors of the covered entities which are ineligible to participate in the PHS pricing program, submitted comments in this proceeding. The comments identified numerous substantive problems with the proposed contract pharmacy guidelines. In particular, comments filed by manufacturers noted that the guidelines provided no effective mechanism for preventing or detecting diversion of drugs to ineligible entities or patients or for preventing duplicate discounting. Some commented that the inclusion of contract pharmacies in the program was in violation of the statute.

15. Some time thereafter, without publicly acknowledging or responding to many of the comments, PHS posted an undated copy of the proposed contract pharmacy guidelines on the electronic bulletin board that ODPP uses to disseminate information necessary for day-to-day operation of the PHS pricing program. This electronic bulletin board, known as the Electronic Data Retrieval System ("EDRS"), is accessed by means of a computer with a modem. While EDRS has been available to manufacturers to verify the eligibility of entities to participate in the PHS pricing program, upon information and belief, PHS is aware that some

manufacturers do not or cannot use EDRS, but obtain current eligibility information by calling ODPP.

16. The electronic file initially posted by PHS (attached as Exhibit B) stated that "[p]ending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy guidelines." PhRMA has met with ODPP and HRSA staff in an attempt to persuade the agency to comply with the notice and comment procedures and to revise the posted guidelines to correct deficiencies before requiring manufacturers to comply with any such guidelines. PhRMA's counsel also has written to the Administrator of HRSA to express PhRMA's concerns and, to no avail, has sought a meeting with the Administrator to discuss these concerns.

17. Some time after the initial posting, in an undated file, PHS revised the preamble of the electronically-posted guidelines to state that the guidelines constitute a "suggested model agreement provided for informational purposes only," and stated that it was reviewing the comments that had been received in response to its initial notice of proposed rulemaking. A copy of the revised posting is attached as Exhibit C.

18. Despite the agency's efforts, in light of the legal inadequacies of its procedures, to minimize the effect of the guidelines by (belatedly) claiming that they were posted only "for informational purposes," the guidelines are currently in effect. Upon information and belief, covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies by

following the requirements of the electronically-posted guidelines, and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities. A letter written by the Administrator of HRSA (attached as Exhibit D), responding to a specific request by PhRMA's counsel for clarification of PHS policy, states: "If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." The guidelines therefore constitute final agency action.

19. Issuance of the contract pharmacy guidelines has had and will have an immediate and detrimental impact upon members of PhRMA. Among other things, as a direct and immediate result of the contract pharmacy guidelines, entities other than those permitted by statute are able to take advantage of the PHS discounted prices by requesting that prescription drugs purchased in the entity's name be shipped to contract pharmacies, which are commercial establishments that are in business to make money on the purchase and dispensing of prescription drugs. Such pharmacies purchase drugs for their own patients at commercial prices, not the discounted prices mandated by section 340B, and the guidelines fail to provide safeguards that would ensure the accountability of these independent businesses for their actions, or for agency oversight or monitoring of contract pharmacy arrangements. The lack of accountability and oversight will subject PhRMA's members to economic harm from the potential diversion of PHS-priced products to patients of the pharmacy, and from potential double discounting

through the combined effect of the PHS discount program and state Medicaid programs.

20. The damage to PhRMA members from implementation of the guidelines is irreparable. While the guidelines provide that a manufacturer may recover economic damages, such damages are payable to the manufacturer only by the covered entity, and recovery is authorized only after the manufacturer audits a covered entity and its contract pharmacy. Neither the statute nor ODPP guidelines provide for the manufacturer to recover the costs of any such audits, or to recover interest on any amount found to have been illegally diverted.

21. The manufacturers, moreover, have no adequate remedy at law. If a manufacturer attempted to mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, there is a substantial risk that the PHS would terminate the manufacturer's agreement with the Secretary of HHS. Under the Pharmaceutical Pricing Agreement, a manufacturer is entitled only to a post-termination hearing. A termination would preclude states from receiving federal Medicaid funds to reimburse providers for the manufacturer's products, resulting in both irreparable losses to manufacturers and irreparable problems with continuity of access to covered health care for needy patients. The contract pharmacy guidelines will also cause irreparable damage to the relationship between each member of PhRMA and its commercial customers, such as retail pharmacies and others not eligible for PHS prices, whose business will be captured by those with access to PHS prices.

22. In addition, as explained more fully below, the contract pharmacy guidelines expand the scope of Section 340B by requiring manufacturers to fill orders at the mandatory discount on behalf of entities to whom manufacturers cannot legally sell under the laws of various states. Complying with the guidelines therefore places the members of PhRMA in the position of being required to violate the laws of these states, subjecting themselves to civil and criminal penalties, as well as potential loss of licenses to engage in their primary business of selling prescription pharmaceuticals in interstate commerce.

23. An actual controversy exists between the parties, and PhRMA and its members have no adequate remedy at law.

Count I

24. Plaintiff incorporates by reference the allegations contained in paragraphs 1-23 above as if fully set forth herein.

25. The Federal Register Act requires the publication in the Federal Register of any "order, regulation, rule, certificate, code of fair competition, license notice or similar instrument, issued, prescribed, or promulgated by a Federal agency," 44 U.S.C. § 1501, and of "documents or classes of documents that may be required to be published by Act of Congress." 44 U.S.C. § 1505(a)(3). The APA, in turn, requires the publication in the Federal Register of "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D).

26. Under these provisions of law, the contract pharmacy guidelines are required to be published in the Federal Register whether they are considered substantive rules of general applicability, statements of general policy, interpretations of general applicability, or an order, regulation, rule or similar instrument issued by PHS.

27. HHS failed to publish the final contract pharmacy guidelines in the Federal Register, in violation of the APA and the FRA.

Count II

28. Plaintiff incorporates by reference the allegations contained in paragraphs 1-27 above as if fully set forth herein.

29. The contract pharmacy guidelines constitute a rule under the APA, which defines a "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy * * * ." 5 U.S.C. § 551(4).

30. Section 340B makes the discounted price available on "purchases" by covered entities, while the guidelines expand the scope of the program to make the benefits of such prices available to entities that cannot, under state law, purchase prescription drugs. For this and other reasons, therefore, HHS in issuing the contract pharmacy guidelines has done more than simply state what it believes the statute means, but has instead attempted to fill in what it views as statutory gaps based on policy rationales. *See* Exhibit D. The contract pharmacy guidelines accordingly do not constitute either interpretive rules or general

statements of policy, but rather substantive rules which the APA requires to be issued only after following notice and comment procedures. 5 U.S.C. § 553. These procedures include a requirement that in issuing final rules the agency must "consider [ ] the relevant matter presented" including comments received, and provide a "statement of their basis and purpose" 5 U.S.C. § 553(c).

31. While HHS recognized the applicability of the APA's notice and comment procedures when it first proposed the contract pharmacy guidelines -- requesting comments and announcing its intention to publish final guidelines after consideration of comments received -- it has bypassed the required procedures by largely ignoring the comments and purporting to promulgate the guidelines without publicly responding to comments received. HHS failed to comply with the notice and comment requirements of the APA, therefore, by failing to consider many of the comments that were submitted, publicly respond to comments, or publish a statement of the basis for and purpose of the guidelines in light of the comments received.

Count III

32. Plaintiff incorporates by reference the allegations contained in paragraphs 1-31 above as if fully set forth herein.

33. Even if the guidelines are considered to be statements of general policy or interpretive rules, rather than substantive rules, the APA nevertheless requires their publication in the Federal Register "for the guidance of the public" 5 U.S.C. § 552 (a)(1). *See* Count I above. The APA further provides that a person

without actual and timely notice of the terms of any such agency action "may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." Id.

34. The EDRS system has failed to provide the actual and timely notice, as required by 5 U.S.C. § 552(a)(1), to bind all manufacturers to honor contract pharmacy arrangements in making Section 340B prices available to covered entities.

35. Upon information and belief, many manufacturers -- including members of PhRMA -- have no actual or timely notice of the contract pharmacy guidelines yet have been or will be adversely affected by the guidelines, in violation of the APA.

Count IV

36. Plaintiff incorporates by reference the allegations contained in paragraphs 1-35 above as if fully set forth herein.

37. Upon information and belief, there are a number of state laws that prohibit manufacturers from selling prescription drugs or controlled substances to covered entities that are not licensed by the state to purchase and dispense such drugs. *See, e.g.*, GA. CODE ANN. § 16-13-72(1) (Any drug manufacturer * * * may sell, give away, exchange, or distribute dangerous drugs within this state, but only to a pharmacy, pharmacist, a practitioner of the healing arts, and educational institutions licensed by the state * * *"); FLA. ADMIN. CODE. ANN. r.10D-45.0365 ("Prohibited Acts. (10) Selling or distributing a medicinal drug

to a person or establishment not licensed, permitted, or otherwise authorized by state law to possess, manufacture, repackage, wholesale, store, stock, distribute, use, sell, offer for sale, expose for sale or use, keep for sale or use, or use medicinal drugs.").

38. Nothing in Section 340B preempts state laws prohibiting manufacturers from selling drugs to unlicensed entities. Under the contract pharmacy guidelines, however, a manufacturer is *required* to make sales to unlicensed entities or be in violation of its Pharmaceutical Pricing Agreement with the Secretary -- which would jeopardize states' ability to receive federal Medicaid funding for the manufacturer's drugs, 42 U.S.C. § 1396r-8(a)(1) & (5), and consequently the manufacturer's future sales in all states.

39. As a result of the issuance of the contract pharmacy guidelines, and without authorization in the PHS Act, HHS has purported to permit entities not authorized under state laws to purchase prescription drugs and controlled substances to make such purchases, and has required manufacturers to sell to such unlicensed entities in ways that would cause manufacturers to be in violation of state licensing laws. This point was raised in the Comments filed by PhRMA in response to the Federal Register notice and has not been addressed by the agency in posting the guidelines and making them binding on manufacturers. The guidelines are for this reason arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

40. Alternatively, if the purchase is construed as a purchase by the pharmacy rather than the covered entity, the contract pharmacy guidelines exceed the authority delegated by section 340B of the Public Health Service Act, and for this reason are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count V

41. Plaintiff incorporates by reference the allegations contained in paragraphs 1-40 above as if fully set forth herein.

42. The agreement entered into by manufacturers with the Secretary of HHS pursuant to Section 340B provides that "covered entity" is defined as specified in the PHS Act and makes the discounted price available for "covered drugs * * * *purchased by* a covered entity." Section 340B(a)(1), 42 U.S.C. § 256b(a)(1). The February 25, 1993 letter from ODPP to PhRMA, quoted above, makes it clear that at the time the agreement was signed, participating manufacturers were not required to make the discounted price available to entities using contract pharmacies. Any modification of the agreement must be in writing and signed by both parties. The contract pharmacy guidelines do not comply with this requirement, but modify and expand the program by making it possible for entities not authorized to purchase prescription drugs and controlled substances to participate in the pricing program.

43. The guidelines for this reason are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Count VI

44. Plaintiff incorporates by reference the allegations contained in paragraphs 1-43 above as if fully set forth herein.

45. The contract pharmacy guidelines do not provide adequate protection against diversion of drugs sold at the mandatory discount or double discounting, as required by Section 340B. Accordingly, the guidelines are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Claim for Relief

WHEREFORE, plaintiff PhRMA prays that the Court award judgment as follows:

A. Declaring that HHS violated the provisions of the FRA and the APA in failing to publish the contract pharmacy guidelines in the Federal Register, as required by statute.

B. Declaring that HHS violated the APA in issuing the contract pharmacy guidelines, without complying with the statutory notice and comment provisions.

C. Declaring that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and that the guidelines are, therefore, null and void;

D. Preliminarily and permanently enjoining HHS and its successors, agents, employees, representatives and others acting in concert with it or them from in any way facilitating or encouraging the purchase of outpatient

drugs through the PHS pricing program by entities not entitled to do so in a manner violative of Section 340B of the PHS Act, 42 U.S.C. § 256b, and ordering HHS during the pendency of this action to withdraw the contract pharmacy guidelines and to give them no force and effect;

E. Awarding Plaintiff PhRMA its costs incurred herein; and

F. Granting Plaintiff PhRMA such other relief as the Court deems appropriate.

HOGAN & HARTSON L.L.P.

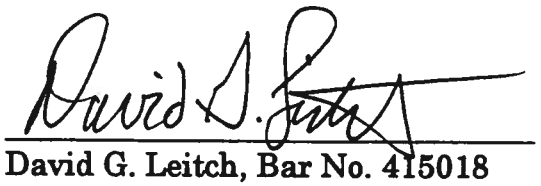

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EXHIBIT A

DEPARTMENT OF HEAL[illegible] & HUMAN SERVICES
Public Health Service
BUREAU OF PRIMARY HEALTH CARE

Health Resources and
Services Administration
Rockville MD 20857

FEB 25 1993

Mr..Joel Bobula
Manager, Public Studies
1100 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Bobula:

You have asked us to respond to a compilation of questions frequently asked by drug manufacturers regarding the implementation of section 602 of the Veterans Health Care Act of 1992. The answers reflect our current understanding of the issues and policy views and may be subject to re-evaluation. The following is a list of the Pharmaceutical Manufacturers Association's (PMA) questions followed by our answers:

1. The Public Health Service (PHS) provisions of this Act require a discount for certain eligible PHS agencies. The Department of Veterans Affairs (DVA) provisions establish another discount system. I am confused over whether those "eligible" PHS agencies can purchase under the DVA discount system instead of the PHS discount system. I am further confused as to whether the "non-eligible" PHS entities can purchase under the DVA discount system. Are PHS entities allowed to select between the PHS discount and the DVA discount? Or does this legislation and the resultant pharmaceutical pricing agreements now establish separate and different prices to the Department of Veterans Affairs and the Public Health Service?

   ANSWER: The entities eligible for discounts under the section 602 program are non-Federal recipients of specific grant assistance and certain disproportionate share hospitals. The section 603 discounts, on the other hand, are for the Federal providers within the PHS (e.g., Indian Health Service, Gillis W. Long Hansen's Disease Center and the National Institutes of Health).

2. Will PHS facilities expect a price list that is separate from (or in addition to) the Federal Supply Schedule (FSS)?

   ANSWER: If your question addresses section 603, we are not in a position to respond. As to section 602, it is the manufacturer's decision whether to provide a separate price list to each covered entity.

3. If State AIDS drug purchasing programs are qualified as PHS entities and contract with wholesaler to purchase drugs off the FSS, would they be eligible for a 24% discount or just the 15.7% price discount?

ANSWER: Unless the State AIDS drug purchasing program is a qualified FSS purchaser, they would only qualify for the PHS statutory discount. However, manufacturers may offer a greater discount, such as that offered to the FSS, if they choose to do so.

4. Section IV(a) of the draft pharmaceutical pricing agreement (page 6) states that if "a manufacturer does not sign a pharmaceutical pricing agreement with a covered entity...[it] will not be deemed to have met the requirements for a Medicaid rebate agreement." This implies a need for a separate agreement with each covered entity? Is this interpretation correct?

ANSWER: No, this was a typographical error. Signing and complying with the PHS Pharmaceutical Pricing Agreement will meet the requirements.

5. Does the PHS discount include both the basic and the CPI-U discount given to Medicaid?

ANSWER: Yes. Section 340B(a)(2)(A)(ii) of the Public Health Service Act (the "Act") describes the rebate percentage as "the average total rebate required under section 1927(c) of the Social Security Act..." Both elements are components of the section 1927(c) discount.

6. Please describe the calculations for determining the PHS discount prices for generic and over-the-counter (OTC) products.

ANSWER: To calculate the price for an over-the-counter or generic drug, the rebate percentage will be 10% of the Average Manufacturer's Price (AMP) for calendar quarters between January 1, 1991 and December 31, 1993 and 11% of the AMP for calendar quarters beginning on or after January 1, 1994. See section 340B(a)(2)(B) of the Act.

7. Is a drug that was classified as innovator multi-source under the Medicaid rebate program that now is sold as an OTC drug discounted differently under the pharmaceutical pricing agreement with PHS?

ANSWER: This determination will follow the same guidelines as utilized by the Health Care Financing Administration (HCFA). It will depend upon how the drug is reported to HCFA. If the drug is reported as an innovator multi-source product, the discount will be determined by reducing the AMP by the rebate percentage (15.7% or "best price" plus CPI-U), section 340B(a) of the Act. If the drug is reported as an OTC, the AMP is reduced by 10% between January 1, 1991 and December 31, 1993. If the drug is reported as an innovator multi-source OTC, the drug will be considered OTC.

8. The Act requires a discount to PHS entities not to exceed the preceding quarter's Medicaid effective discount. Since a quarter's Medicaid discount is not known until 30 days following a quarter, this calculation cannot be done for the first part of the quarter. How will PHS address this issue?

ANSWER: The discount should be calculated utilizing data from the most current quarter available to the manufacturer.

9. What calendar quarter do we use to calculate PHS prices effective December 1, 1992 and January 1, 1993? How often will we need to recalculate?

ANSWER: Calculations are to be performed quarterly utilizing data from the most current quarter available to the manufacturer.

10. What is to be done when the Medicaid basic rebate amount changes a few quarters after the "covered entities" price has been determined and purchases made? Do adjustments need to be made to those units purchased by "covered entities"?

ANSWER: Purchases made when a new quarterly price is in effect are governed by the new price. See section 340B(a)(1) of the Act.

11. Can you please address how PHS will assure the confidentiality of the Medicaid best price (which is assured under the Medicaid Rebate Law) and at the same time provide a discounted price to thousands of PHS entities that is based on the effective Medicaid rebate?

ANSWER: "Best Price" and AMP information will be requested only from those manufacturers who do not participate in the Medicaid program, and then, only for audit purposes to ascertain compliance with statutory requirements. PHS will consider this data and pricing data obtained from HCFA as confidential. Further, the Secretary will require, under a reasonable schedule of implementation, that covered entities not reveal confidential drug pricing information. See the PHS Pharmaceutical Pricing Agreement, section III(f).

12. The Medicaid Rebate Law exempts certain drugs. Does the PHS Act include or exclude such drugs?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." The term incorporates both section 1927's general definition, (k)(2), and the limiting definition, (k)(2), of "covered outpatient drug." Section 340B of the Act does not incorporate the list of drugs subject to restriction, section 1927(d)(2) of the Social Security Act; therefore, these are not excluded.

13. How has the interpretation been made that generic drugs are covered under the PHS provisions of the Act, but not under the VA provisions?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." This definition does not exclude generic drugs. The DVA program is governed by a different statute.

14. Is the discount to PHS entities for "outpatient" drugs only?

ANSWER: Yes. See section 340B(a)(2) of the Act.

15. Does a manufacturer have to provide discounts to disproportionate share hospitals for "covered outpatient drugs" used by inpatients, or are the discounts limited to drugs utilized by outpatients?

ANSWER: A covered outpatient drug does not include any drug, biological product or insulin provided as part of, or incident to and in the same setting as inpatient services (and for which payment is made

as part of payment for the services and not as direct reimbursement for the drug). See section 340B(b) of the Act and section 1927(k)(3) of the Social Security Act.

16. Is only a portion of the hospital's drug purchases, that is the disproportionate share portion, covered by the Act?

ANSWER: The discount is for all covered outpatient drugs, without regard to whether they are for low-income individuals who are not Medicare or Medicaid beneficiaries.

17. How will PHS validate that a disproportionate share hospital does not obtain outpatient drugs through a group purchasing organization?

ANSWER: After receiving a list of eligible disproportionate share hospitals, a manufacturer may verify what covered outpatient drugs, if any, are purchased through a group purchasing organization or other group purchasing arrangement. See PHS Pharmaceutical Pricing Agreement, section IX(c). These drugs need not be sold at a discount to the hospitals.

18. When will manufacturers receive a list of covered disproportionate share hospitals?

ANSWER: On December 15, 1992, a PHS Pharmaceutical Pricing Agreement along with a computer disc containing a list of covered entities (including a list of covered disproportionate share hospitals) was mailed to all manufacturers participating in the Medicaid program. Other manufacturers will be notified by Federal Register Notice to contact the Drug Pricing Program for a copy of the list.

19. With respect to the other covered entities, how many entities are included? What are their 1991 estimated pharmaceutical purchases?

ANSWER: There are approximately 9,800 entries on the disc of covered entities mailed to Medicaid-participating manufacturers. This disc lists covered entities receiving grant funds in the eligible programs. Because entities can receive funds from several grant programs, this list contains some entities entered more than once. An unduplicated list of approximately 7,000 covered entities has been prepared and will be mailed to manufacturers.

At this time, we do not have the estimated pharmaceutical purchases for the covered entities.

20. When will the pharmaceutical companies receive the list of eligible PHS entities? If it is after December 1, 1992, does the manufacturer need to rebate the entities?

ANSWER: A computer disc of covered PHS entities was mailed to Medicaid-participating drug manufacturers on December 15, 1992. All entities contained on the disc are eligible for drug discounts retroactive to December 1, 1992.

21. What are we supposed to do about customers that say that they are a "covered entity" and entitled to provisions under the law before we have the list of covered entities (between December 1, 1992 and the date the list is available)?

ANSWER: Medicaid-participating drug manufacturers should have received a copy of the disc containing the covered entities. Any manufacturer who has not as yet received a list of covered entities may contact:

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

22. If hospitals that initially do not qualify as disproportionate share hospitals later meet the necessary requirements, will HCFA send notices of the newly qualified hospitals eligible for the PHS discounts, or is it up to the hospital and the manufacturer to make this determination?

ANSWER: HCFA will notify PHS of changes in entity eligibility, and the Drug Pricing Program will provide timely notification to participating drug manufacturers of additions to and deletions from the list of disproportionate share hospitals.

23. If we have a question concerning whether a clinic or health center is a covered entity, who can we call and what is their phone number?

ANSWER: Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

24. When a community health center has multiple service sites, who purchases drugs for those sites? Do they purchase as a group and distribute drugs to individual sites?

ANSWER: For information concerning the community health center drug distribution system, you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

25. What is the PHS intent regarding the discounting of drugs dispensed by retail pharmacies to community and migrant health center patients? Will we be required to give contract prices to all of the covered entities regardless of type of pharmacy (in-house, contracted, physician dispensing)?

ANSWER: Discount pricing for covered outpatient drugs must be offered to all in-house pharmacies and in-house physician dispensing systems of eligible covered entities. The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed.

26. Since the vast majority of entities listed as community and migrant health centers have contract pharmacies, how can these pharmacies segregate drugs purchased by patients of PHS entities and other patients? It would appear that there is a tremendous potential for diversion, fraud and unfair competition to other local retailers. How will PHS address this issue?

ANSWER: PHS is sensitive to the potential for drug diversion and is currently considering mechanisms for its prevention. The issue of including contract pharmacies in the drug discount chain has yet to be resolved.

27. When a community health center arranges for pharmacy services through a commercial retail pharmacy, who purchases the drug that is dispensed to the patient? Does the community health center "reimburse" the retailer, or does the retailer file the Medicaid claim if the beneficiary is eligible?

ANSWER: For information concerning the community health center drug distribution system you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

28. Hasn't the duplicate discount prohibition of H.R. 5193 financially handicapped PHS clinics with a significant percentage of Medicaid patients?

ANSWER: We interpret section 340B(a)(5)(A)(i) of the Act to refer to Medicaid rebates and not Medicaid reimbursements.

29. How will a PHS covered entity that contracts for pharmaceutical services with a retail pharmacy benefit (if at all) from H.R. 5193?

ANSWER: The issue of including a contract pharmacy in the drug discount chain has yet to be resolved.

30. The duplicate discount provision precludes requests for payments for covered drugs subject to a Medicaid rebate. How will PHS enforce this provision?

ANSWER: The statute gives the Secretary one year from the date of enactment to devise a mechanism to prevent potential duplicate discount/rebates, section 340B(a)(5) of the Act. The Secretary of PHS has agreed to develop this mechanism within 120 days after the effective date of the PHS Pharmaceutical Pricing Agreement or the provisions of section 1927(a)(5)(C) of the Social Security Act will become effective.

31. What is the manufacturer supposed to do about potential duplicate discounts before an enforcement mechanism is in place?

ANSWER: The manufacturer and the entity can, in good faith, attempt to resolve the dispute. If unsuccessful, the manufacturer may provide written notice of the discrepancy to the Secretary. The manufacturer and the Secretary will devote their best efforts to resolving the dispute within sixty days. If the Secretary believes that a violation

has occurred, the Secretary will initiate the notice and hearing process. If a violation is found to have occurred, the entity will be liable to the manufacturer of the covered drug that is the subject of the violation in an amount equal to the reduction in the price as required by section 340B(a) of the PHS Act. See the PHS Pharmaceutical Pricing Agreement, section VI(a).

32. How are manufacturers to know that the PHS clinics are only purchasing products for non-Medicaid use?

ANSWER: A drug discount is available for all clinic patients, Medicaid or not, provided that a Medicaid rebate is not also requested for the discounted drug.

33. Example: In March a clinic is added as a covered PHS entity, and as of March the state excludes the clinic's drug purchases from Medicaid rebate invoices. Do we have to provide that clinic the "effective Medicaid price" for sales that occurred in January or February? If so, why, especially given that the manufacturer has already paid a rebate to the state. In general, who comes first, the state or the clinic?

ANSWER: Only those entities included on the initial computer list mailed to drug manufacturers on December 15, 1992, are eligible for retroactive drug discounts to December 1, 1992. All entities added to the list of covered entities at a later date will be eligible for drug discounts as of the date of their inclusion on the list.

34. Is the manufacturer permitted to terminate an agreement to any PHS facility that violates the resale prohibition?

ANSWER: No. See answer #31.

36. Some manufacturers do not sell to retail pharmacies, doctors and other entities identified in H.R. 5193. How can these entities participate in a prime vendor arrangement?

ANSWER: The prime vendor program has not as yet been developed.

37. Is the "prime vendor" requirement applicable only to specifically identified PHS eligible entities?

ANSWER: The prime vendor program has not as yet been developed.

38. Do manufacturers have the right to audit wholesalers under the prime vendor requirement? Where is this spelled out for the parties in question?

ANSWER: The prime vendor program has not as yet been developed.

We hope the answers have clarified our current position regarding implementation of the Act. If you have any further questions, please do not hesitate to contact Kathryn Lotfi, Office of General Counsel (tel: (301) 443-2006).

Sincerely yours,

Marsha Alvarez

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program

EXHIBIT B

Guideline: Contracted Pharmacy Services

Pending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy service guidelines. These guidelines are designed to facilitate program implementation in covered entities that wish to utilize contracted pharmacy services to dispense section 340B outpatient drugs but do not have access to an "in-house" pharmacy. The agreement between the covered entity and the pharmacy should include the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each facility which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per facility does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these facilities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding

office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services

Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain

to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

File: CONTRACT.GDL

EXHIBIT C

Guideline: Contracted Pharmacy Services

The following is a suggested model agreement provided for informational purposes. The Department is currently reviewing comments to the proposed contract pharmacy model agreement published in the Federal Register on November 1, 1995 (60 FR 55586). All comments received in response to the notice will be considered in developing the final model agreement. Covered entities that do not have access to an appropriate "in-house" pharmacy, and wish to use contracted pharmacy services to access section 340B pricing, are encouraged to sign and have in effect an agreement with the pharmacy contractor which includes the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these entities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records, if applicable.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal panalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a notarized self certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

MAY 7 1996

Mr. Russel A. Bantham
General Counsel and Senior Vice President
Pharmaceutical Research
and Manufacturers of America
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

Dear Mr. Bantham:

This is in response to your letter of April 4 concerning the contracted pharmacy interpretative policy guideline drafted by the Office of Drug Pricing (ODP). These guidelines were published in the Federal Register for notice and comment on November 1, 1995.

You state that the ODP "has gone forward without modifications of its proposal as if no comments were received." On the contrary, PhRMA comments, as well as all other comments submitted in response to the request for public comment, were considered in drafting the final contracted pharmacy services guideline. During this review process, the ODP revised the guideline in response to comments and placed the revised guideline on the Electronic Data Retrieval System (EDRS).

Public comments with program responses will be posted on the EDRS in the near future. We anticipate publishing a further notice in the Federal Register which will include a discussion of the comments received and the reasons for accepting or not accepting particular comments.

In addition, you characterize the contracted pharmacy services guideline as a "substantive rule," subject to the rule-making requirements of the Administrative Procedure Act. We believe this guideline is an interpretative policy guideline and was published in the Federal Register for informational purposes and to determine any need for further safeguards. Therefore, we do not believe this guideline generates regulatory concern.

It is important to understand that section 340B requires manufacturers to use a ceiling price for covered outpatient drugs purchased by the covered entity. The statute is silent as to permissible drug distribution systems and does not require the entity to purchase directly from the manufacturer or dispense the drug itself. It is apparent that Congress envisioned various types of drug delivery mechanisms - those that would be appropriate to meet the needs of the various covered entities.

In addition, the legislation would be advantageous only to a very small percentage of the covered entities, if it were to limit the program to only those entities which use in-house pharmacies. Therefore, recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, ODP does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs. However, because of concerns expressed to ODP about the potential for drug diversion in the contract pharmacy approach, ODP thought it wise to develop guidelines (with public input) which would recognize at least one arrangement for contract pharmacy services that greatly reduces the risk of such diversion.

The guidelines were made available for the benefit of both participating manufacturers and covered entities. The mechanism described in the guidelines has been used by a number of large organizations such as the American Red Cross, the National Association of Community Health Centers, the Association for Utah Community Health Center, and the New York Blood Consortium.

Of course, this mechanism is not the only method of reducing the potential for drug diversion, but it is the system developed by ODP. If entities can propose other systems which would be equally as effective, ODP is very willing to review all proposed mechanisms.

If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs that shipment to its contracted pharmacy, we see no basis to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from compliance with the agreement.

We hope that this information has been helpful. Should you have further questions, please do not hesitate to call Stephen Wickizer, Acting Director, ODP, at (301) 594-4353.

Yours sincerely,

Ciro V Sumaya

Ciro V. Sumaya, M.D., M.P.H.T.M.
Administrator

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

DONNA SHALALA, et al.

Defendants.

Let this be filed this 7th day of Oct. 1996

C.A. No. 96-1630 (JLG)

STIPULATION OF DISMISSAL

The parties to this litigation hereby stipulate, pursuant to Federal Rule of Civil Procedure 41(a)(1), to the dismissal without prejudice of this action and all claims asserted herein, each party to bear its own attorney's fees and costs.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

DIANA ESPINOSA, *et al.*,

Defendants.

No. 21-cv-1479 (DLF)

PROPOSED ORDER

Upon consideration of Defendants' Motion for Summary Judgment, Plaintiff's Motion for Preliminary Injunction, the parties' memoranda of points and authorities, and the administrative record, the Court hereby GRANTS Defendants' Motion for Summary Judgment as to all claims contained in Plaintiff's Verified Complaint and DENIES Plaintiff's Motion for Preliminary Injunction.

SO ORDERED.

Dated: _____

Signed:_____
The Honorable Dabney L. Friedrich
United States District Judge

NAMES OF PERSONS TO BE SERVED WITH PROPOSED ORDER

Pursuant to LCvR 7(k), the following attorneys are entitled to be notified of the entry of the foregoing proposed order:

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