UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, –v– DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, *et al.*, *Defendants*.	**Case No. 1:21-cv-01479**

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION AND DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists, by and through their undersigned attorneys, hereby file this *amicus* brief in support of Defendants' opposition to the motion for preliminary injunction and Defendants' cross motion for summary judgment.[1]

Amici are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals to serve the needs of underserved populations. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Ex. 1, Decl. of Maureen Testoni (Testoni Decl.) ¶¶ 7–9. These discounts are the subject of a Department of Health and Human Services (HHS) letter[2] that Novartis Pharmaceuticals Corporation (Novartis) challenges, which concluded that the refusal by Novartis to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute.

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[1] Pursuant to Local Rule 7(o)(5), *Amici* confirm that they are not corporations; that no party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and that no person other than *Amici*, their members, or their counsel contributed money that was intended to fund preparing or submitting this brief.

[2] Letter from Diana Espinosa, Acting Administrator, HRSA to Dan Lopuch, Managed Market Finance, Novartis Pharmaceuticals Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf.

Amici submit this brief (1) to address Novartis's argument that the 340B statute does not require drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) to address Novartis's allegation that HHS has changed its position on the issue of contract pharmacies; (3) to address Novartis's argument that the use of contract pharmacies constitutes diversion; and (4) to provide the Court with information regarding the impact of Novartis's policy on the patients of 340B hospitals such as *Amici's* members.

INTRODUCTION AND BACKGROUND

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve patients with low incomes (340B providers or covered entities). The purpose of the program is to stretch the funding 340B providers have available to meet the needs of their patients, H.R. Rep. No. 102-384(II), at 12 (1992), and a 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had this exact effect. Specifically, GAO found that 340B providers have used the benefit made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. GAO, Report to Congressional Committees. GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf (2011 GAO Report).

Since the beginning of the program, Novartis and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract

pharmacies to covered entities' patients, and since 2010 they have sold drugs at the 340B prices to hospitals and other covered entities who used multiple contract pharmacies. For 24 years, between 1996 and August 2020, there is no record that Novartis ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. The benefit is even higher for some providers, such as critical access hospitals (small hospitals in rural areas), which report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. Testoni Decl. ¶ 6. 340B providers use the 340B benefit to provide services to underserved populations in their communities. Recognizing the value of the 340B program, Congress expanded it as part of the Affordable Care Act. *See* Patient Protection & Affordable Care Act, Pub. L. 111-148, §§ 7101, 124 Stat. 119, 821–22 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

Although the 340B statute requires discounts to be offered only to statutorily defined covered entities, it does not otherwise limit the size of the program or authorize a pharmaceutical company to do so. The Conference Committee Report accompanying the original enactment stated that the HHS Secretary was not authorized to limit in any way the volume of purchases of outpatient drugs by covered entities at the discounted price. H.R. Rep. No. 102–384(II), at 16. Importantly, while the statute requires that the drugs be purchased by a covered entity, it does not limit where the drugs are dispensed. *See* 42 U.S.C. §§ 256b(a)(1), (4).

Nevertheless, in the midst of the most devastating pandemic in 100 years, Novartis abandoned its policy of complying with the statute, as interpreted by HHS, and notified the Health Resources and Services Administration (HRSA)—the HHS division that manages the 340B program—that, unless Novartis chose to grant an exception, it would no longer sell drugs to 340B

hospitals at 340B discounted prices if the drugs were dispensed at a contract pharmacy outside a 40 mile radius of the main hospital facility.[3] Five other major drug companies (which are also among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits[4]) adopted policies that also refused to provide discounts when a contract pharmacy is relied on to dispense 340B discounted drugs.[5]

The contract pharmacy arrangements that Novartis and the other drug companies are refusing to honor have existed since the beginning of the program. When a 340B provider uses a contract pharmacy outside its premises, it enters into a written contract. The 340B provider orders and pays for the drugs, which are shipped directly to the contract pharmacy to be dispensed to the provider's patients. The pharmacy receives a fee for performing this service.

Under this arrangement, some providers use a "separate" inventory model, but most use a "replenishment" inventory model. For the separate inventory model, the provider's 340B drugs are kept in stock at the contract pharmacy, separate from non-340B drugs. The contract pharmacy dispenses those drugs to the provider's patients. For the more common replenishment model, no

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[3] *See* Novartis Statement (Oct. 30, 2020), https://www.novartis.us/news/statements/new-policy-related-340b-program.

[4] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

[5] *See* Limited Distribution Plan Notice for Eli Lilly and Company Products (undated), https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf; Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf; Letter from Odalys Caprisecca, Executive Director, Strategic Pricing and Operations, AstraZeneca to 340B Partners (Aug. 17, 2020), https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdfld1=0; Mem. from Kevin Gray, CVP, United Therapeutics Corp. to 340B Covered Entities (Nov. 18, 2020), https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0; Novo Nordisk Notice (Dec. 1, 2020), https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf.

340B drugs are kept in stock. When filling prescriptions for the provider's patients, the contract pharmacy uses drugs from its own stock, and the provider purchases replacement drugs at the discounted price to replenish the pharmacy's stock. The replacement drugs are delivered to the contract pharmacy, which then passes on the payments it received when it dispensed the drugs, less an agreed upon dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended. These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of providers are receiving drugs for which the provider receives the 340B discount. *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx. Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract pharmacy. Novartis's restriction on providing 340B discounts to 340B hospitals applies to drugs dispensed under either model.

On May 17, 2021, HRSA sent letters to all six pharmaceutical companies finding (consistent with its historical position) that the drug companies' refusal to provide 340B discounts for drugs dispensed through contract pharmacies is unlawful.[6] Novartis challenges HRSA's letter

[6] Letter from Diana Espinosa, Acting Administrator, HRSA, to Odalys Caprisecca, Executive Director, US Strategic Price & Operations, AstraZeneca Pharmaceuticals LP (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-astrazeneca-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Company (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA to Dan Lopuch, Managed Market Finance, Novartis Pharmaceuticals Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-

in its verified complaint, Compl. ¶¶ 79–87, ECF No. 1, and in its motion for a preliminary injunction, ECF No. 5.

DISCUSSION

Novartis devotes much of its memorandum to mischaracterizing various guidances and statements that HHS has made about the use of contract pharmacies to deliver 340B drugs to 340B patients. This includes Novartis's unfounded claim that HHS "had a long-standing policy that directly contravenes its current position that the statute requires the 340B discount to be given in the context of all contract pharmacy arrangements." Pl.'s Mem. of Points and Auth. in Supp. of Mot. for Prelim. Inj. (Pl.'s PI Mem.) 2, ECF No. 5-2. Novartis attempts to distract from the central and dispositive issue in this case, which is whether the 340B statute requires drug companies to provide 340B discounts to 340B providers for drugs that are dispensed by a contract pharmacy on behalf of the provider. The answer is yes. Thus, even if Novartis's characterization of the guidances and other HHS statements were correct, Novartis cannot prevail.

I. THE PLAIN MEANING OF THE 340B STATUTE REQUIRES PARTICIPATING DRUG MANUFACTURERS TO GIVE DISCOUNTS ON 340B DRUGS DISPENSED BY CONTRACT PHARMACIES.

As Novartis recognizes, Pl.'s PI Mem. 18, "[w]e start as we must with the plain language of the statute." The statute provides that:

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entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Lynn Robson, VP, Associate General Counsel, Market Access, United Therapeutics Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf.

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by* a covered entity . . . does not exceed an amount equal to the [ceiling price].

42 U.S.C. §256b(a)(1) (emphasis added). The statute does not say "purchased *and dispensed* by" a covered entity. It therefore requires drug manufacturers to offer discounts to all 340B covered entities and does not distinguish between drugs that are dispensed by the entity and drugs dispensed by an outside pharmacy with which the entity has a contract. "As long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989). Thus, contrary to Novartis's assertion otherwise, Pls.' PI. Mem. 18, the 340B statute's plain language *does* require manufacturers to provide discounts for drugs purchased by 340B providers regardless of whether they are dispensed by contract pharmacies.

In fact, an earlier version of the bill that was not enacted would have addressed how or where the 340B drug must be dispensed. That unenacted version stated that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*" a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, the 340B discounts would have been allowed *only* for on-site pharmacy services, since the drugs would have had to have been "purchased *and dispensed by*, or under a contract entered into *for on-site pharmacy services*." *Id.* (emphasis added). The elimination of the phrase "dispensed by" changed the provision to render where the 340B drug is dispensed legally irrelevant—all that matters is that the drug be "purchased by a covered entity." 42 U.S.C. § 256b(a)(1). It is not surprising that Congress decided to drop the additional language and permit dispensing by a contract pharmacy because, at the time the bill was passed, fewer than 5% of 340B providers had on-site dispensing services. *See* Notice Regarding Section 602 of the

Veteran Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

Novartis's principal statutory argument is that the contract pharmacy policy is inconsistent with the statute because "the statute provides no textual support for the notion that the defined term '*covered entity*' includes third parties that enter into contracts with covered entities." Pl.'s PI Mem. 18. *Amici* agree that a contract pharmacy is not a covered entity under the 340B statute, but Novartis's argument ignores the central issue in the case, which is whether the 340B discounted drugs are being "purchased by" the hospital or other covered entity. The answer is plainly yes because regardless of how contract pharmacies are used, the 340B drugs are still purchased by 340B hospitals or other covered entities. The statute does not dictate how or where 340B drugs must be dispensed to a covered entity's patients, and thus the use of contract pharmacies is allowed.[7]

II. THE MAY 17, 2021 LETTER REITERATES HHS'S LONSTANDING POLICY ON CONTRACT PHARMACIES.

Since the inception of the 340B program, HHS has repeatedly recognized the statutory requirement to offer 340B providers covered drugs at or below 340B ceiling prices when they are dispensed by a contract pharmacy, and as far as the record shows, Novartis complied with that requirement until November 2020. *See* Pl.'s PI Mem. 4 (recognizing that contract pharmacies were used since shortly after the statute was enacted). As detailed below, HHS's statements have been

[7] The recent decision in *AstraZeneca Pharms. LP. v. Becerra*, No. 1:21-cv-27 (D. Del. June 16, 2021), ECF No. 79, does not support Novartis's argument. Reviewing AstraZeneca's challenge to the HHS General Counsel's December 30, 2020 Advisory Opinion, which HHS subsequently withdrew, the court rejected both the government's and AstraZeneca's arguments that the statute was clear as to whether pharmaceutical companies participating in the 340B program are required to provide discounts for 340B drugs sold at contract pharmacies, and held that "HHS's current interpretation of the statute is permissible." *Id.* at 23. The court directed the parties to discuss whether vacating the opinion as to AstraZeneca, remanding the case, or some other relief would be appropriate. *Id.*

consistent and comprehensive, and they demonstrate that HHS has never wavered in its interpretation of the statute. Novartis's claim otherwise is wrong.

In 1996, HRSA issued "final guidelines" addressing the use of contract pharmacies. 61 Fed. Reg. 43,549. Those guidelines recalled that since the beginning of the 340B program, HHS had recognized that 340B providers were permitted to use contract pharmacies to dispense 340B drugs, so long as they complied with the prohibition on drug diversion. *Id.* at 43,550 ("As early as 1993, several covered entity groups . . . came forward to assist the Department in developing a workable mechanism to use outside pharmacies. . . ."). At the same time, HRSA noted that "[t]here is no requirement for a covered entity . . . to dispense drugs itself" and that "[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.* at 43,549.

HRSA also recognized that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs." *Id.* at 43,550. HRSA agreed with commenters that "[b]y issuing guidelines [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id.* Finally, HRSA stated that "[u]nder section 340B, . . . *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*." *Id.* at 43,555 (emphasis added). In 2010, HRSA again acknowledged that "[u]nder 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 340B discount price." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) (emphasis added). HRSA's recent letter to Novartis restates this longstanding position.

Novartis is wrong in stating that HRSA did not identify the statutory basis for the 1996 and 2010 guidance documents and that both stopped short of requiring manufacturers to honor contract pharmacy arrangements. Pl.'s PI Mem. 6. Not only did both guidances start by citing to the statute, but both also included the almost identical statement that "[u]nder section 340B, . . . 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." 61 Fed. Reg. at 43,549, 43,555; 75 Fed. Reg. at 10,272, 10,278. HHS could not have been clearer that pharmaceutical companies that choose to participate in the 340B program *must*, pursuant to the statute, provide 340B discounts for drugs delivered at contract pharmacies. For 24 years, Novartis acquiesced.

Novartis argues that the 1996 guidance does not reflect HHS's current position because it limited 340B providers to a single contract pharmacy and required that the provider not have a pharmacy of its own. Pl.'s PI Mem. 19–20. *Amici* question whether HHS had the authority to impose such limitations, which the 340B providers never challenged. As discussed above, HHS corrected any such error in 2010 when it eliminated any limitation on the use of contract pharmacies, as required by the plain language of the statute, which is controlling. The important point is that the 1996 guidance, like the 2010 guidance and the May 17 letter, provided that 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. The reason the 1996 guidance disclaimed that it was creating any rights or imposing any

obligations (a point Novartis claims is relevant, *see id.* at 22) is because the obligation is imposed by the statute, not the guidance.

In support of its argument that HHS has changed its position, Novartis also claims that there was a time that HHS did not recognize contract pharmacies at all, *id.* at 24, but Novartis cites no evidence to support that claim, which is contradicted by Novartis's own statement earlier in its brief where it recognized that contract pharmacies were used "since shortly after the statute was enacted" in 1992. *Id.* at 4. As demonstrated above, HRSA's position has always been that the statute requires manufacturers to provide discounts when a covered entity dispenses discounted drugs through a contract pharmacy arrangement.

Novartis next argues that HHS changed its position in 2010 when it decided to permit the use of multiple contract pharmacies, without providing a "reasoned analysis" or "display[ing] an awareness that it is changing position." *Id.* at 22. In fact, when HHS made the change in 2010, it issued a proposal, solicited comment, and then responded to the comments. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007). There is no merit to Novartis's argument that HHS failed to explain the position it announced in 2010. *See* Pl.'s PI Mem 24.

Novartis also claims that the HHS General Counsel's December 30, 2020 Advisory Opinion—which concerned the use of contract pharmacies but was recently withdrawn—reflected a change from the 2010 guidance because, according to Novartis, the agency for the first time took the position that the statute unambiguously compelled the current policy. *Id.* at 22–23. This is hardly an argument that HHS changed its position, since Novartis implicitly acknowledges that both the 2010 guidance and the now-withdrawn Advisory Opinion interpreted the statute as permitting providers to use an unlimited number of contract pharmacies. At most, the Advisory

Opinion for the first time stated that the statute was unambiguous. Although the HHS General Counsel has withdrawn the advisory opinion, *see AstraZeneca Pharms. LP. v. Becerra*, No. 1:21-cv-27 (D. Del. June 18, 2021), ECF No. 81, HHS continues to maintain the position that the statute requires manufacturers to provide discounts on drugs dispensed through contract pharmacies, correctly in *Amici*'s view. *See, e.g.*, Defs.' Mot. for Summ. J. on Pls.' New Claims 10–11, *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-806 (D.N.J. June 22, 2021), ECF No. 53 (stating that "the [Advisory Opinion] now has been withdrawn, yet HRSA fully intends to proceed with enforcement of *the statute* against" the drug companies) (emphasis in original).

Finally, Novartis argues that HHS changed its position again in its May 17 letter by saying that manufacturers are required on pain of civil money penalties to comply with contract pharmacy arrangements. Pl.'s PI Mem. 22–23. Civil money penalties were not mentioned in the 1996 and 2010 guidance documents because they were not added to the statute until passage of the Affordable Care Act in 2010 after the 2010 guidance had been issued. Patient Protection & Affordable Care Act, Pub. L. 111-148, § 7102, 124 Stat. 119, 823–25 (2010) (codified at 42 U.S.C. § 256b(d)(1)(B)(vi)). Moreover, HRSA's May 17, 2021 letter does not say that Novartis is subject to civil money penalties but that "continued failure to provide the 340B price to covered entities utilizing contract pharmacies . . . may result in [civil money penalties (CMPs)]. HHS will determine whether CMPSs are warranted." Letter from Diana Espinosa to Dan Lopuch, *supra* n.1. Contrary to Novartis's assertion, Pl.'s PI Mem. 22, nothing in the HRSA letter indicates that HRSA is abandoning the factors listed in its 2010 guidance in determining whether covered entities have appropriate arrangements with contract pharmacies. The guidance that Novartis cites to support its argument remains in effect and still applies to covered entities. Novartis fails to show how the May

17 letter conflicts with that guidance. *See* Contract Pharmacy: Important Tips, HRSA, https://www.hrsa.gov/opa/updates/2016/august.html.

As demonstrated above, Novartis's argument that HHS changed its position (and that Novartis has a reliance interest in the prior guidance) depends entirely on the change between the 1996 guidance limiting contract pharmacies to a single pharmacy and the 2010 guidance allowing 340B providers to have multiple pharmacies. *See* Pl.'s PI Mem. 23, 24. But Novartis fails to acknowledge that HHS's position regarding whether covered entities may use multiple pharmacies has been consistent for the past 11 years, and Novartis never explains why it waited so long to challenge the HHS policy announced in the 2010 guidance. It is difficult to sympathize with Novartis's reliance argument when the pharmaceutical manufacturer waited more than a decade to even raise the issue.

III. THE STATUTORY PROHIBITION ON DIVERSION DOES NOT PRECLUDE THE USE OF CONTRACT PHARMACIES.

Novartis argues that the statutory prohibition on diversion severely limits a covered entity's option to redirect drugs after purchase. Pl.'s PI Mem. 18–19. Novartis even goes so far as to claim that the "virtual inventory" (*i.e.*, replenishment) model arguably violates the diversion provision. *Id.* at 19 n.3. Novartis's argument that covered entities' use of contract pharmacies violates the statutory prohibition on diversion has no merit.

The statutory prohibition on diversion provides that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). This prohibition imposes an obligation on covered entities to avoid reselling discounted drugs to nonpatients or transferring drugs to other non-covered healthcare providers for prescribing to their patients. It does not require a 340B provider to ensure that 340B drugs are physically dispensed by the employees of the covered entity. When a covered entity contracts with

a pharmacy to dispense its 340B drugs, the contract pharmacy is, on behalf of the covered entity, selling the 340B drug to a person who *is* a patient of the covered entity, and thus is acting in a manner consistent with the statute. There is no diversion.

Citing to a 2018 GAO report, Novartis claims that HRSA audits identified hundreds of instances of diversion at contract pharmacies, Pl.'s PI Mem. 9, but Novartis fails to acknowledge that before 2019, HRSA was issuing audit findings on diversion based on rules that it has since abandoned after a legal challenge to its methodology. As a result of that challenge, in fall of 2019, HRSA changed its rules to more closely follow the 340B statute. *See* GAO, Report to Congressional Committees, GAO Report No. 21-107, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, 15 n.26, 21 (Dec. 2020). Since that time, diversion findings for 340B hospitals have plummeted to only 10 for fiscal year 2020, and half involved issues completely unrelated to contract pharmacies. Testoni Decl. ¶¶ 11–12. Without citing to a single study or to any evidence, Novartis also claims in its Verified Complaint that contract pharmacies that are not in close proximity to the covered entity are highly unlikely to dispense drugs to patients of the covered entity. Verified Compl. ¶ 39; *see also* Pl.'s PI Mem. 10 (stating, without any citation, "Where a covered entity makes arrangements with pharmacies far outside its community, this risk of diversion is amplified by orders of magnitude"). Including this unsupported allegation in a verified complaint does not make it so.

Moreover, if dispensing 340B drugs to a 340B hospital's patients via a contract pharmacy qualified as diversion, Novartis fails to explain how its policy of shipping drugs to contract pharmacies used by 340B entities that are not hospitals, without any geographic limitation (which its policy permits), or to contract pharmacies within a 40-mile radius of the main facility of a 340B

hospital (which its policy also permits) would not also constitute diversion. Delivery to contract pharmacies either constitutes diversion or does not (it does not).

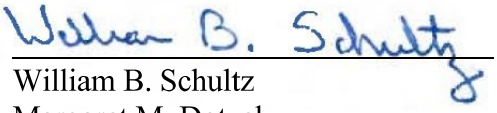
Novartis also fails to acknowledge that the statute provides that diversion should be addressed by audits conducted by HRSA and the manufacturers, rendering Novartis's plan to address its concerns about diversion by placing restrictions on discounts to 340B hospitals that use contract pharmacies indefensible and inconsistent with the statute. Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities on this basis; rather, it provided them and HHS with authority to address suspected diversion through audits. *See* 42 U.S.C. §§ 256b(a)(5), (d)(2). If after an audit and a hearing, the Secretary (not the manufacturer) finds that the covered entity has violated the prohibition on diversion (or duplicate discounts), the covered entity must pay a refund to the manufacturer. *Id.* As HHS stated in the preamble to its final regulation establishing civil money penalties, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017), drug manufacturers cannot lawfully impose conditions on the sale of 340B drugs to 340B providers.

CONCLUSION

Novartis's refusal to offer 340B drugs at discounted prices when dispensed through certain contract pharmacies is inconsistent with the 340B statute, at odds with HHS's longstanding interpretation of the statute, and jeopardizes 340B hospitals' ability to care for patients during the most serious public health crisis in the last century. For the reasons set forth above, this Court should uphold HHS's correct interpretation of the statute, deny Novartis's motion for a preliminary injunction and grant summary judgment to Defendants.

Dated: June 28, 2021

Respectfully submitted,



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