UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

–v–

XAVIER BECERRA
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

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 PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT AND DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTERESTS OF *AMICI CURIAE*

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 cross-motion for summary judgment and motion for preliminary injunction filed by Plaintiffs Eli Lilly and Company and Lilly USA, LLC (Lilly).

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. Mot. to Intervene, Ex. A (Decl. of Maureen Testoni in Supp. of Mot. to Intervene (Testoni Decl.)), ¶¶ 7–9, ECF No. 39-1. These discounts are the subject of a Department of Health and Human Services (HHS) letter[1] that Lilly challenges, which concluded that the refusal by Lilly to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute.[2]

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[1] 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 (May 17 Letter).The letter to Lilly was the subject of a motion for a temporary restraining order filed by Lilly, ECF No. 94, which this Court denied on May 27, 2021, ECF No. 102.

[2] Lilly also challenged the HHS General Counsel's December 30, 2020 Advisory Opinion, which reached the same general conclusion, but HHS's General Counsel has since withdrawn the Advisory Opinion. Notice, ECF. No. 119.

Amici submit this brief (1) to address Lilly'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 Lilly's allegation that HHS has changed its position on the issue of contract pharmacies; (3) to address Lilly's argument that concerns about diversion legally support its policy of refusing to provide discounts when 340B drugs are dispensed by contract pharmacies; and (4) to provide the Court with information regarding the impact of Lilly's policy on 340B covered entities such as *Amici's* members.

INTRODUCTION

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). 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).[3]

Since the beginning of the program, Lilly 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 May 2020, there is no record that Lilly 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. For some the benefit is even higher, 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 2010 Affordable Care Act. Patient Protection & Affordable Care Act, Pub. L. 111-148, §§ 7101–7103, 124 Stat. 119, 821–28 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

[3] Citing a law review article, Lilly incorrectly asserts that "the point of the 340B program has always been to 'create a low-cost source of pharmaceutical medication for the indigent patients themselves.'" Pls.' Combined Mem. in Supp. of Pls.' Cross-Mot. for Summ. J. & in Opp'n to Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J. (Pls.' Summ. J. Br.) 3, ECF No. 89 (alterations and citation omitted). While the purpose of the 340B program is certainly to benefit underserved and indigent populations, the legislative history makes clear that this purpose is served by providing covered entities additional resources in order to provide a range of services (which could include lower-cost medications) to those populations. Later in its brief, Lilly recognizes that the 340B statute provides for discounts to covered entities and not to patients themselves. *See id.* at 25.

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, one year ago, in the midst of the most devastating pandemic in 100 years, Lilly 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 it would no longer sell drugs at 340B discounted prices if the drugs were dispensed at a contract pharmacy.[4] 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[5]) followed Lilly's lead.[6]

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[4] *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.

[5] 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.

[6] *See* Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf; Letter from Odalys Caprisecca, Executive Director, AstraZeneca to 340B Partners (Aug. 17, 2020), https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdfld1=0; Novartis Statement (Oct. 30, 2020), https://www.novartis.us/news/statements/new-policy-related-340b-program; 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.

The contract pharmacy arrangements that Lilly 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 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. Lilly has ceased providing 340B discounts for drugs dispensed under either model.[7]

On May 17, 2021, HRSA sent letters to all six pharmaceutical companies reiterating its historical position that the drug companies' refusal to provide 340B discounts for drugs dispensed through contract pharmacies is unlawful.[8] Lilly challenges HRSA's letter in its second amended complaint, ¶¶ 276–310, and in its motion for a preliminary injunction, ECF No. 94.[9]

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[7] According to Lilly, its policy permits covered entities that do not have their own in-house pharmacy to contract with a single contract pharmacy, but Lilly claims that this aspect of its policy is discretionary. Second Am. Compl. 4, ECF No. 103; Pls.' Summ. J. Br. 5.

[8] 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-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 letter to Lilly was the subject of a motion for a temporary restraining order filed by Lilly, ECF No. 94, which this Court denied on May 27, 2021, ECF No. 102.

[9] In addition, on December 14, 2020, HHS finalized its proposed Alternative Dispute Resolution (ADR) regulation. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (codified at 42 C.F.R. pt. 10). Lilly is also challenging that regulation, *see* Second Am. Compl. 73–90, which this Court preliminarily enjoined, ECF Nos. 81, 82.

DISCUSSION

Lilly devotes much of its briefs 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 Lilly's unfounded claim that HHS's conclusion (reflected in the May 17, 2021 letter) that HHS has the authority to require drug companies to provide discounts for 340B drugs dispensed at contract pharmacies came "after years of telling everyone involved that Defendants lacked authority to do so." Pls.' Mem. in Supp. of Mot. for Prelim. Inj. & Temp. Restraining Order (Pls.' PI Br.) 14, ECF No. 95. This is an attempt 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 Lilly's mischaracterization of the guidances and other HHS statements were correct, Lilly 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 Lilly recognizes, Pls.' Summ. J. Br. 24, "when interpreting a statute, we begin with the text," *Loja v. Main Street Acquisition Corp.*, 906 F.3d 680, 683 (7th Cir. 2018), and assume that the ordinary meaning of the language accurately expresses the legislative purpose, *Middleton v. City of Chicago*, 578 F.3d 655, 658 (7th Cir. 2009). The 340B statute explicitly requires drug manufacturers to offer discounts to 340B covered entities regardless of whether the drugs are dispensed by the entity or by an outside pharmacy with which the entity has a contract. Specifically, the statute provides that:

> 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, and the fundamental rule of statutory construction is that the "statute's language is conclusive" unless "Congress expressed a clear intention to the contrary." *Middleton*, 578 F.3d at 658. "[A]s 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 Lilly's assertion otherwise, Pls.' Summ. J. Br. 24, 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).

Lilly's principal statutory argument is that the contract pharmacy policy is inconsistent with the statute because contract pharmacies are not listed as covered entities, Pls.' Summ. J. Br. 25–26, but Lilly's argument merely side steps the real issue in this case. A contract pharmacy is not a covered entity under the 340B statute, and neither HHS nor *Amici* have ever argued otherwise. And the 340B drugs are *not* being sold (or offered) to the contract pharmacies; they are being sold to 340B hospitals and other covered entities. That is what the statute requires. The statute does not dictate how or where 340B drugs must be dispensed to a covered entity's patients.

Lilly also wrongly argues that HHS's "agency" theory has no basis in the statute and that Congress would have specified contract pharmacies in the statute if it wanted them to be covered. *Id.* at 27. The nomenclature used to characterize the relationship between a covered entity and a contract pharmacy is irrelevant so long as the statutory requirement that the drug is "purchased by a covered entity" for its patients is met. An analysis of the provisions in the statute that refer to other "agency-like relationships" relied on by Lilly, *id.* at 27–28, demonstrate that they do not support Lilly's claim that Congress would have referenced contract pharmacies if it had meant them to be part of the statutory scheme. The reason the statute specifically provides at section (d)(3)(B)(vi) that associations or organizations that represent the interests of covered entities can bring claims on the covered entities' behalf through the ADR process is because without it, associations could not bring claims since they are not covered entities. Similarly, the reason the statute at section (d)(1)(B)(v) references wholesalers as being subject to auditing is because without that reference, the wholesalers would not be subject to auditing since they are not drug manufacturers. For the same reason, Congress referenced distributors in section (d)(2)(B)(iv) since

they, like manufacturers, need to be able to identify covered entities. The fact that Congress references entities other than drug manufacturers and covered entitie, in three places in the statute is irrelevant to whether the statute requires drug manufacturers to provide 340B discounts for drugs dispensed by contract pharmacies. Likewise, the absence of references to contract pharmacies in the statute is irrelevant because contract pharmacies are not purchasing the 340B drugs, and a covered entity's entitlement to the 340B discount does not depend on how or where the drug is dispensed to its patients.

Lilly's assertion that the government's argument "boils down to a contention that, so long as a covered entity ***prescribes*** a covered outpatient drug, manufacturers must deliver the product wherever and to whomever directed" and that the "covered entity simply lends its name to the prescription" is wrong. Pls.' Summ. J. Br. 28 (emphasis in original). The statute requires the covered entity to purchase the drug that is the subject of the 340B discount and to ensure that it is not provided to a person who is not a patient of the covered entity. 42 U.S.C. §§ 256b(a)(1), (5)(B). When a covered entity uses a contract pharmacy, it is complying with these requirements. What the statute does *not* dictate is that the drug can *only* be delivered directly to the covered entity or that the covered entity must provide the drug directly to the patient. Lilly cannot add these requirements to the statute.[10]

[10] Last week's decision in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. June 16, 2021), ECF No. 79, does not support Lilly's argument. Reviewing AstraZeneca's challenge to the 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, but held that "HHS's current interpretation of the statute is permissible." Mem. Op. at 23 (D. Del. June 16, 2021), ECF No. 78. In light of its rejection of the government's argument that its decision was compelled by the statute, 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.*

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 the ceiling prices when they are dispensed by a contract pharmacy. As detailed below, these statements have been consistent and comprehensive and demonstrate that HHS has never wavered in its interpretation of the statute. Lilly's claim otherwise is wrong.

In 1996, HRSA issued "final guidelines" specifically 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 purchase drugs directly from the manufacturer or 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 Lilly restates this longstanding position.

Lilly is wrong in stating that the 1996 and 2010 guidances addressed only what covered entities could do and did not address manufacturers' obligations. Pls.' Summ. J. Br. 15. As the language quoted above demonstrates, both guidances clearly recognized the manufacturers' statutory obligation to provide discounts. Not only did both 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 43,555; *see also* 75 Fed. Reg. at 10,278. HHS could not have been clearer that pharmaceutical companies that choose to participate in the 340B program must provide discounts for drugs delivered at contract pharmacies.

Lilly argues that the 1996 guidance does not reflect HHS's current position because it limited 340B providers to a single contract pharmacy. Pls.' Summ. J. Br. 15. *Amici* question whether HHS had the authority to impose such a limitation, however, and 340B providers never challenged it. 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 thing is that the 1996 guidance, like 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.

Finally, contrary to Lilly's argument otherwise, it is irrelevant that HRSA repeatedly stated that its guidance is not binding and that its authority to enforce 340B guidances is limited. *See id.* at 6–7, 16–17. Although they have value in informing regulated industry of the agency's thinking and of its interpretation of the statute, guidances are never binding and cannot by themselves be enforced. The statute, however, *is* binding, and here the statute requires manufacturers to sell 340B drugs at discounted prices to providers that contract to have the drugs they prescribe dispensed to their patients at pharmacies not on their premises. Finally, the fact that HHS did not immediately enforce the statute or tell Lilly that its policy violates the statute is also, contrary to Lilly's assertion, irrelevant. *See id.* at 17. An agency's delay in enforcing a statutory requirement does not make that requirement disappear.[11]

[11] Also irrelevant (and incorrect) is Lilly's claim that a recent GAO report noted that HRSA had stopped auditing contract pharmacies for diversion because the 340B statute does not specifically mention contract pharmacies. Pl.'s Summ. J. Br. 16–17 (citing GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107 (Dec. 2020) (2020 GAO Report), https://www.gao.gov/assets/gao-21-107.pdf). Lilly misrepresents what the report actually stated. The portion of the report cited by Lilly concerned providers' obligation to conduct internal audits of contract pharmacies and did not state that HRSA had stopped auditing contract pharmacies for diversion. *See* 2020 GAO Report 15–16. As the audit findings posted on HRSA's website show, HRSA is still issuing audit findings for diversion related to contract pharmacies. *E.g.*, HRSA, *Program Integrity: FY20 Audit Results* (updated May 19, 2021), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results.

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

Lilly's argument that covered entities' use of contract pharmacies violates the statutory prohibition on diversion also has no merit. First, Lilly asserts that covered entities cannot direct a manufacturer to deliver 340B-priced drugs to a contract pharmacy without violating the statute's prohibition on diversion. Pls.' Summ. J. Br. 5, 25. The statutory prohibition on diversion, however, 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). When a covered entity contracts with a pharmacy to dispense their 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.

In an effort to explain why it believes dispensing through contract pharmacies constitutes unlawful diversion but that its policy of allowing covered entities to use a single contract pharmacy does not constitute diversion, Lilly claims that because the prohibition on diversion does not extend to manufacturers, they can "lawfully opt to deliver discounted product to a dispensing pharmacy of the covered entity's choosing." Pls.' Summ. J. Br. 5. This makes no sense. Delivery of drugs purchased by a covered entity to contract pharmacies either constitutes diversion or does not (it does not).

It is also significant that the statute treats diversion as a separate issue, rendering Lilly's concerns about diversion an indefensible basis for refusing to provide discounts to covered entities that use contract pharmacies. 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. 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, drug manufacturers cannot lawfully impose conditions on the sale of 340B drugs to 340B providers. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017). Lilly's arguments to the contrary are wrong.

CONCLUSION

Lilly's refusal to offer 340B drugs at discounted prices when dispensed through 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 and deny Lilly's motions for a preliminary injunction and summary judgment.

Dated: June 23, 2021

Respectfully submitted,

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