UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, –v– NORRIS COCHRAN, *et al.*, *Defendants*.	C.A. No. 21-00027 (LPS)

BRIEF OF 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 AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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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 summary judgment filed by AstraZeneca Pharmaceuticals LP (AstraZeneca).

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. 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.[1] These discounts are the subject of the Department of Health and Human Services General Counsel's Advisory Opinion that AstraZeneca challenges, which concluded that the refusal by drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute. The *amici* are filing this brief, as authorized by the Court's May 3, 2021 Order, D.I. 53, to explain why the Advisory Opinion is consistent with the 340B statute.

[1] *See* Declaration of Rebecca L. Butcher in Support of Brief of 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 as *Amici Curiae* in Support of Defendants (Butcher Decl. II), Ex. A (Declaration of Maureen Testoni, dated May 4, 2021 (Testoni Decl.)) ¶ 8.

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 substantially discounted price to certain public and not-for-profit hospitals that serve large numbers of patients with low income and/or living in rural areas (340B providers or covered entities). The purpose of the program is to stretch the funding 340B entities 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. Butcher Decl. II, Ex. B, (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) (2011 GAO Report)).

Recognizing the value of the 340B Program, Congress expanded the program in 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)). Nevertheless, for more than a decade, drug manufacturers have been trying to limit its impact on their bottom line. Articles written by Aaron Vandervelde, a long-time advocate for limiting the 340B Program who has filed

an *amicus* brief in this action, D.I. 46 (Vandervelde Br.), outline what the drug company policies are really trying to accomplish.[2]

Although the 340B statute requires discounts to be offered only to statutorily-defined covered entities that comply with the statute, it does not otherwise limit the size of the program or authorize a pharmaceutical company (or any other entity) to do so. In fact, the Conference Committee Report accompanying the bill that was originally enacted specifically stated that the bill would not authorize the Secretary of the Department of Health and Human Services (HHS) to limit in any way the volume of purchases of outpatient drugs that could be made by covered entities at the reduced price. H.R. Rep. No. 102–384(II), at 16. Similarly, and contrary to AstraZeneca's argument (Pl.'s Br., D.I. 43, at 9–12), while the statute requires that the drugs be purchased by a covered entity, it does not limit how the drugs subject to the discounts are to be dispensed. Likewise, there is nothing in the legislative history that supports AstraZeneca's view.

Since the beginning of the program, 340B providers (including members of *amici*) have dispensed covered outpatient drugs to their patients through both in-house pharmacies and community pharmacies that have entered into written contracts with the 340B providers (contract pharmacies or community pharmacies). Under such arrangements, the 340B provider orders and pays for the 340B drugs, which are shipped to the community pharmacy, where the drugs are then dispensed to the 340B provider's patients. The community pharmacies receive a fee for performing this service.

[2] Butcher Decl. II, Ex. C (Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4 (Oct. 2020)); Butcher Decl. II, Ex. D (Aaron Vandervelde et al., *Revisiting the Pharmaceutical Supply Chain: 2013–2018*, at 8 (Jan. 2020)). Although Aaron Vandervelde purports to be submitting his *amicus* brief "not in support of any party," the brief is mostly comprised of a series of attacks on the 340B Program that have nothing to do with the legal arguments in this case, and clearly supports Plaintiff AstraZeneca.

Although some covered entities use a pre-purchased inventory model, most use a replenishment inventory model. Pursuant to the former, the covered entity's 340B-purchased drugs are kept separately in stock at the contract pharmacy, and the contract pharmacy uses the covered entity's 340B-purchased drugs to fill prescriptions for the covered entity's patients. Pursuant to the more common replenishment inventory model, no 340B-purchased drugs are kept in stock at the contract pharmacy. When filling prescriptions on behalf of the covered entity, the contract pharmacy uses drugs from its own stock, and then the covered entity purchases that quantity of the drug at the discounted 340B price to replenish the stock at the pharmacy. The replacement drugs are then delivered to the contract pharmacy, with the 340B provider receiving the difference between the 340B cost and the non-340B cost from the pharmacy, less an agreed upon dispensing fee. Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the community pharmacy.

Contract pharmacy arrangements using the replenishment inventory model generally use computerized tracking systems. 340B providers have developed rules for dispensing to ensure that only 340B eligible patients are receiving 340B drugs. *See, e.g.*, Butcher Decl. II , Ex. E (Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019)).

For more than 20 years, all drug companies, including AstraZeneca, worked cooperatively with 340B providers and in accordance with the statute and provided discounts for drugs dispensed through contract pharmacies to covered entities' patients. Overall, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements, and for some types of hospitals, the benefit is even higher. For example, critical access hospitals (small hospitals in rural areas) report that an average of 51% of their 340B benefit from the 340B discount comes from drugs distributed through contract pharmacies.

Butcher Decl. II, Ex. A (Testoni Decl.) ¶ 6. The 340B hospitals use the 340B benefit to provide services to underserved populations in their communities.

Starting ten months ago, in the midst of the most devastating pandemic in 100 years, six major drug companies (which are among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits[3]) unilaterally and substantially cut the 340B benefit to public and not-for-profit hospitals that serve large numbers of patients with low-income and/or living in rural areas. Eli Lilly and Company (Lilly) was the first drug company to abandon its over 20-year compliance with the statutory requirement to provide 340B providers with drugs at or below 340B ceiling prices when dispensed through contract pharmacies. Shortly thereafter, AstraZeneca and four other drug companies followed Lilly's lead.[4]

Despite repeated requests by *amici* and their members, HHS refused to take any action to stop this illegal conduct, precipitating a lawsuit by *amici* and three hospitals. That lawsuit sought a ruling that the refusal by AstraZeneca and the other drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies was illegal and that the statute required HHS to develop an enforcement plan aimed at stopping the drug companies from

[3] Butcher Decl. II, Ex. F (Fred D. Ledley, *et al*., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–843 (Mar. 3, 2020)).

[4] *See* Am. Compl., Ex. A at 2, D.I. 13-1; Rebecca L. Butcher Decl. in Supp. of Mot. to Intervene, dated Feb. 26, 2021 (Butcher Decl. I), Ex. C (Sanofi Notice (July 2020)), D.I. 34-3; Butcher Decl. I, Ex. D (New policy related to the 340B program, Novartis Statement (Oct. 30, 2020)), D.I. 34-4; Butcher Decl. I, Ex. E (Mem. from Kevin Gray, SVP, United Therapeutics Corp. to 340B Covered Entity (Nov. 18, 2020)), D.I. 34-5; Butcher Decl. I, Ex. F (Notice Regarding Limitation on Hosp. Contract Pharm. Distribution, Novo Nordisk (Dec. 1, 2020)), D.I. 34-6.

continuing to implement these illegal policies.[5] *See* Compl., *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020), D.I. 1.[6]

Following the filing of that lawsuit, HHS formally agreed with *amici* that the refusal by AstraZeneca and the other drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute. HHS took this step on December 30, 2020, in an Advisory Opinion issued by its General Counsel (Advisory Opinion). Butcher Decl. I, Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020)), D.I. 34-7. AstraZeneca challenges the Advisory Opinion in its motion for summary judgment. D.I. 43.[7]

DISCUSSION

I. The Advisory Opinion Is Consistent with the Plain Meaning and HHS's Longstanding Interpretation of the 340B Statute.

This is a case about whether HHS has the authority to require drug companies that have chosen to participate in the 340B Program to provide 340B discounts when the 340B drugs are dispensed by a community pharmacy on behalf of the 340B provider. Although the briefs filed by AstraZeneca and *amicus* Aaron Vandervelde argue otherwise, this is not a case about whether

[5] Two other lawsuits challenged HHS's failure to issue an Administrative Dispute Resolution (ADR) regulation, which was required by 2010 congressional legislation in order to afford providers and pharmaceutical companies a forum to resolve disputes about compliance with the 340B Program's requirements. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 1:20-cv-3032 (D.D.C.).

[6] Responding to the government's arguments (which during oral argument included a plea to give the new Administration more time to develop a response to the associations' request for action), on February 17, 2021, the court dismissed this action without prejudice, ruling that "plaintiffs may be able to maintain a narrower action seeking general enforcement of the statute in the future." *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020), D.I. 91 at 13.

[7] In addition, on December 14, 2020, HHS finalized its proposed ADR regulation. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (codified at 42 C.F.R. pt. 10).

Congress adopted the right policy when it created the 340B Program. Both AstraZeneca and Mr. Vandervelde spend large portions of their briefs citing statistics and studies criticizing the Program's size and impact. These arguments are irrelevant.[8] What matters here is what the statute requires.

A. *The Plain Meaning of the 340B Statute Requires Drug Manufacturers to Provide Discounts on 340B Drugs Dispensed via Contract Pharmacies.*

"We begin with the text. We look to the statutory provision's language and to the ordinary meaning of the words it uses." *Vorchheimer v. Philadelphian Owners Ass'n*, 903 F.3d 100, 105 (3d Cir. 2018). The 340B statute explicitly requires drug manufacturers to offer 340B 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 manufacturers 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, when unambiguous, the plain language of the statute controls, irrespective of the legislative history or other tools of

[8] Also irrelevant are Mr. Vandervelde's attempts to argue that 340B providers are not complying with HHS's contract pharmacy notices. Contrary to his assertion (Vandervelde Br. at 10, 13), HHS has never required the covered entity to verify patient eligibility at the time of service. In fact, when raised in 2010, it specifically chose not to do so. 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). Even in 1996, it was merely suggested as one potential model and HHS was clear that other possibilities existed. 61 Fed. Reg. 43,411, 43,551 (Aug. 23, 1996). Likewise HHS has never prohibited the use of the replenishment inventory model in the context of contract pharmacies, and Mr. Vandervelde's assertion that replenishment is inconsistent with the 2010 notice (Vandervelde Br. at 13) is inaccurate. And his reference to a program notice stating that 340B hospitals could not initially purchase drugs from a group purchasing organization (GPO) and then replenish them with 340B drugs due to the statutory prohibition on using a GPO for 340B (*id.* at 13, n.35) has nothing to do with contract pharmacies and is misleading.

statutory construction. *DirectTV v. Pepe*, 431 F.3d 162, 168 (3d Cir. 2005). "[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).

AstraZeneca maintains that an earlier version of the legislation not enacted into law supports its argument that contract pharmacies fall outside of the statutory scheme. Pl.'s Br.at 3,10. That unenacted bill, as reported by the Senate Labor Committee, 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). AstraZeneca argues that the absence of the italicized language from the enacted bill demonstrates that Congress meant to exclude off-site contract pharmacies because, while the term "contract" was included in the unenacted bill, off-site pharmacies were not. Pl.'s Br. at 3, 10.

Even if the language of the statute were sufficiently ambiguous to leave an opening to consider AstraZeneca's argument, a careful reading of the language in the Committee bill supports the HHS General Counsel and *amici*'s interpretation, and provides further support for the position that Congress did not intend to exclude 340B discounts when covered outpatient drugs are dispensed by contract pharmacies. If the Committee bill 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*." The elimination of the phrases "dispensed by" and "on-site pharmacy services" 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." 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, less than 5% of 340B providers had on-site dispensing services. 61 Fed. Reg. at 43, 549, 43,550.

AstraZeneca argues in the alternative that the "purchased by" language in the 340B statute is irrelevant because it does not appear in the provision establishing what drug companies "must offer" to covered entities and instead appears only in a provision that imposes obligations on the Secretary of HHS. Pl.'s Br. at 6, 12. This argument also does not survive a reading of the statute. While the sentence with the "purchased by" language directs the Secretary to enter into an agreement with the drug manufacturer, it also describes what that agreement—to which the manufacturer is a party—requires. For AstraZeneca to argue that the language does not apply to manufacturers is beyond comprehension.

Moreover, the language that AstraZeneca refers to as the "'must offer' provision" (*id.* at 12–13), even if read in isolation, does not support its argument. That provision states that the agreement entered into by the Secretary "*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." 42 U.S.C. § 256b(a)(1) (emphasis added). This language addresses the price at which the drug must be offered (no higher than the best price available), but it does not condition that offer on whether the drug is dispensed on the covered entity's premises. It provides no support for AstraZeneca's position.

Equally inapposite is AstraZeneca's argument that the Advisory Opinion's statement that, in effect, community pharmacies act as agents for the covered entities, undercuts HHS and *amici*'s interpretation of the statute. Pl.'s Br. at 10–13 (arguing that "[t]he status of any particular relationship between a covered entity and a contract pharmacy is case-specific and fact-dependent—the opposite of purported 'straightforward textual interpretation,'" and that if

Congress wanted to allow the use of pharmacies as agents, it would have said so). First, as noted above, it is the statute that dictates the drug companies' obligations. Moreover, the nomenclature used to characterize the relationship between a covered entity and a contract pharmacy through which the covered entity dispenses its 340B drugs is irrelevant so long as the statutory requirement that the drug is "purchased by a covered entity" for its patients is met. The Advisory Opinion states that "the covered entity and contract pharmacy are not distinct, but function as principal-agent." Butcher Decl. I, Ex. G (Advisory Opinion) at 6. In other words, the Advisory Opinion provides a general principle but does not opine on any particular arrangement that the covered entity must have with a contract pharmacy to comply with the 340B statute. Nothing in the Advisory Opinion suggests that it is limited to specific contracts or specific state law.

As to the argument that Congress would have included contract pharmacies in the statute if it wanted them to be covered (Pl.'s Br. at 11), *amici* agree that if Congress wanted to include contract pharmacies as covered entities, it would have said so in the statute. But that is not what this case is about. Instead, this case is about whether it matters how the covered entities, as defined in the statute, dispense their 340B drugs; and the statute does not dictate how 340B drugs have to be dispensed to the covered entity's patients. Also, contrary to AstraZeneca's argument (*id.* at 10–11), there was no need for Congress to include language in the 340B statute referring to contract pharmacies the way it referenced contracts in 38 U.S.C. § 8126(h)(3)(A), an unrelated statute involving contracts between commercial entities and certain federal agencies.

Finally, AstraZeneca's argument that it is being required to treat contract pharmacies like covered entities is nonsensical. Pl.'s Br. at 3. Neither HHS nor *amici* have ever taken the position that a contract pharmacy is a covered entity under the 340B statute. 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.

B. *HHS's Longstanding Interpretation of the 340B Statute Is Consistent with Its Plain Meaning and Supports the Requirement that Drug Manufacturers Provide 340B Discounts on Drugs Dispensed via 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. These statements have been consistent and comprehensive, and they show how, since the inception of the 340B Program, HHS has never wavered in its interpretation of the statute. AstraZeneca's claim to the contrary is erroneous.

In 1996, the Health Resources and Services Administration (HRSA), the HHS agency tasked with overseeing the 340B program, issued "final guidelines" which recalled that since the beginning of the 340B Program, HHS had recognized that 340B providers are permitted to use contract pharmacies to dispense 340B drugs, so long as they comply with the prohibition on drug diversion. 61 Fed. Reg. 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.

In fact, HRSA 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*." 75 Fed. Reg. at 10,278 (emphasis added). The 2020 Advisory Opinion restates this longstanding position.[9]

II. The 340B Statute Provides Drug Manufacturers and HHS Effective Tools to Protect Against Diversion and Duplicate Discounts, and AstraZeneca Has No Authority to Impose Limitations on the Availability of Discounts to Address Those Issues.

AstraZeneca argues that its new policy is justified by its need to prevent drug diversion (selling 340B drugs to persons who are not patients of the covered entity) and duplicate discounts (drug manufacturers are not required to offer a drug at the 340B discount rate to covered entities and pay rebates to state Medicaid programs for the same drug) (Pl.'s Br. at 16), but this argument also has no support in the language of the 340B statute. Congress considered these concerns and provided the drug companies and HHS tools to address them, but it did not authorize a drug manufacturer to refuse to provide the discounts because it believed that diversion or duplicate discounts was occurring. Thus, the number of incidents of drug diversion and duplicate discounts

[9] AstraZeneca argues that it is significant that HHS described its initial guidance as "gap-filling." Pl.'s Br. at 14. What matters here is what the 340B statute requires, and HHS has consistently taken the position that the statute requires drug manufacturers to sell 340B drugs to 340B providers at the discounted price regardless of where that drug is dispensed. AstraZeneca also references the fact that HHS initially limited 340B providers to a single contract pharmacy. *Id.* It is unclear whether HHS had the authority to limit 340B providers to one pharmacy, but that is also irrelevant to the issues in this case because the limitation no longer exists.

is irrelevant to the question of whether the statute permits use of contract pharmacies, and in any event, the data upon which *amicus* Vandervelde relies overstates the incidents of diversion, and Mr. Vandervelde misrepresents 340B providers' responsibility with respect to duplicate discounts.

With respect to findings of diversion, *amicus* Vandervelde cites to audit findings between 2012 and 2019. Vandervelde Br. at 15. Before 2019, however, HRSA was issuing audit findings on diversion based on rules that it has since rejected.[10] Since HRSA's enforcement policies have more tightly followed the 340B statute, diversion findings for 340B hospitals have plummeted to only ten (10) for fiscal year 2020, and five of the ten (10) involve issues completely unrelated to contract pharmacies. Butcher Decl. II, Ex. A (Testoni Decl.) ¶¶ 11–12.

Amicus Vandervelde claims that duplicate discounts under Medicaid-managed care remain a risk under contract pharmacy operations, stating that HRSA has not issued guidance "outlining how covered entities are to prevent duplicate discounts on managed Medicaid utilization" and does not currently audit covered entities for such duplicate discounts. Vandervelde Br. at 16. These claims misrepresent HRSA's and covered entities' responsibilities with respect to 340B drugs dispensed to patients under Medicaid-managed care. The statute governing the Medicaid drug rebate program (MDRP) expressly prohibits states from collecting rebates from manufacturers for 340B discounted drugs that are provided to patients under Medicaid-managed care. 42 U.S.C. § 1396r-8(j)(1). The Centers for Medicare & Medicaid Services, which is responsible for administering the MDRP, issued implementing regulations that require states and Medicaid-

[10] As a result of a legal challenge by a covered entity to HRSA's authority to enforce such audit findings, HRSA determined that audit findings based on certain rules could not withstand legal review, and starting in fall 2019, HRSA no longer applied these rules. *See* Butcher Decl. II, Ex. G (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) (2020 GAO Report)).

managed care organizations to create mechanisms to prevent Medicaid-managed care duplicate discounts. *See* 42 C.F.R. § 438.3(s)(3). *Amicus* Vandervelde's brief fails to acknowledge, let alone discuss, that the responsible federal agency has issued regulations on the issue, and that responsibility for prevention of duplicate discounts rests on the states, not covered entities. Moreover, the most recent GAO report found that between 2012 and 2019 only 23 of the 429 duplicate discount findings related to contract pharmacies. Butcher Decl. II, Ex. G (2020 GAO Report) at 14 (Table 1).

Even if AstraZeneca and Mr. Vandervelde's claims about drug diversion and duplicate discounts were accurate, nothing in the 340B statute gives drug manufacturers the authority to address those concerns by unilaterally withholding 340B discounts. Instead, the 340B statute accounts for this possibility by giving both the Secretary and the manufacturers the authority to conduct an audit. 42 U.S.C. § 256b(a)(5)(D). If after such 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 recognized 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. 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017).

CONCLUSION

Astra Zeneca's refusal to offer 340B drugs at discounted prices when dispensed through contract pharmacies is inconsistent with the language in the 340B statute and with HHS's longstanding, correct interpretation of the statute, jeopardizing 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.

Dated: May 4, 2021

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