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)

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' REPLY IN SUPPORT OF MOTION TO INTERVENE

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 (collectively, the Hospital Associations or Proposed Intervenors) submit this reply in support of their motion to intervene. For the reasons outlined below, the Court should reject Plaintiff AstraZeneca Pharmaceuticals LP's (AstraZeneca) and the government Defendants' (collectively, HHS or Defendants) opposing arguments and grant Proposed Intervenors' motion.

I. Proposed Intervenors Meet the Rule 24(a) Standard for Intervention.[1]

Last summer, AstraZeneca became one of six drug manufacturers to upset twenty years of industry-wide compliance with the 340B statute by brazenly refusing to offer statutorily required discounts when 340B drugs are dispensed through contract pharmacies. AstraZeneca has now filed this lawsuit, asking the Court to declare "that AstraZeneca is not required to offer 340B discounts to contract pharmacies"[2] and "that AstraZeneca's approach of either selling direct to covered entities that have their own in-house pharmacy or, if the covered entity lacks an in-house

[1] Neither AstraZeneca nor HHS contends that the Hospital Associations' motion to intervene is untimely. AstraZeneca mentions in passing that "Proposed Intervenors identify no reason why they waited more than a month before seeking party status in this case," Pl.'s Opp'n to Proposed Intervenors' Mot. to Intervene (Pl.'s Opp'n), at 3, D.I. 37, but AstraZeneca does not argue timeliness, and, in any event, Proposed Intervenors filed their motion just fourteen days after AstraZeneca filed its amended complaint; two days after the Court issued its Order granting the parties' stipulated schedule; and more than nine weeks before any opposition to a motion for summary judgment is due.

[2] AstraZeneca misrepresents the nature of contract pharmacy arrangements. Contract pharmacies do not purchase 340B drugs. Rather, "the 340B provider orders and pays for the 340B drugs, which are then shipped to the contract pharmacy where the drugs are dispensed to the 340B provider's patients." Proposed Intervenors' Mot. to Intervene (Mot.) at 1, D.I. 33; *see also* Decl. of Rebecca L. Butcher in Supp. of Proposed Intervenors' Mot. to Intervene (Butcher Decl.), Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* ("Advisory Opinion") (Dec. 30, 2020)) at 6, D.I. 34-7 ("[T]he covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy.").

pharmacy, allowing the covered entity to designate a single contract pharmacy through which to purchase AstraZeneca medicines at the 340B price, complies with Section 340B." Am. Compl. at 54–55, D.I. 13. The Hospital Associations' members are thousands of hospitals that use contract pharmacies and purchase AstraZeneca's drugs as part of the 340B program. These members would be directly impacted by the order AstraZeneca seeks.

A. The Hospital Associations Have a Substantial Interest in the Outcome of this Action.

On December 30, 2020, after the Hospital Associations had urged HHS for months to take some action and had finally sued the agency, HHS's then General Counsel issued an Advisory Opinion declaring unlawful the policies that AstraZeneca and other pharmaceutical companies had adopted of refusing to provide 340B discounts for drugs dispensed at most or all contract pharmacies dispensing their drugs. Since an average of about a quarter of the benefit 340B hospitals, including the Hospital Associations' members, derive from 340B discounts comes from the use of contract pharmacies, Proposed Intervenors have a strong interest in preserving HHS's interpretation of the law. *See* Butcher Decl., Ex. A (Decl. of Maureen Testoni in Supp. of Intervenors' Mot. to Intervene (Testoni Decl.)) ¶ 6, D.I. 34-1.

The Hospital Associations' interest in this case "is specific to them, is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought." *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 972 (3d Cir. 1998). Should the Court grant AstraZeneca the relief it seeks and declare that the company is not required to offer 340B discounts to covered entities that dispense 340B drugs using contract pharmacies, or that its current policy complies with the 340B statute, the Hospital Associations' members will be directly affected in a substantially concrete fashion. *See, e.g.*, Testoni Decl. ¶¶ 6–10 (explaining that "the reduction or elimination of

the discounts for drugs dispensed through contract pharmacies would lead to cuts in programs and services" and "could lead the hospital[s] to close").

The Hospital Associations' interest is specific to their members, and for purposes of satisfying the criteria for intervention, it does not matter that thousands of their members share the same interest in the outcome of this lawsuit. Nor does it matter that their interest is financial, as the very purpose of the 340B statute is to provide a financial benefit to 340B covered entities. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992); *cf. also Liberty Mut. Ins. Co. v. Treesdale, Inc.*, 419 F.3d 216, 220–21 (3d Cir. 2005) ("While a mere economic interest may be insufficient to intervene, an intervenor's *interest in a specific fund* is sufficient to *entitle intervention in a case affecting that fund*.") (emphasis added) (quoting *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 366 (3d Cir. 1995)); *Kleissler*, 157 F.3d at 973 (finding sufficient interest where state law required money to be forwarded to intervenors, "money that they will lose . . . if plaintiffs are successful in this lawsuit"). The Hospital Associations' interest lies at the very heart of the case, which is about whether AstraZeneca may lawfully deprive their members of significant discounts for drugs dispensed at pharmacies across the country.

AstraZeneca selectively quotes from Third Circuit case law, but those cases when read in context demonstrate that the Hospital Associations have a sufficient, threatened interest in this action warranting intervention. This is not a scenario where would-be intervenors point only to "the mere fact that a lawsuit may impede a third party's ability to recover in a separate suit." *Liberty Mut.*, 419 F.3d at 221 (quoting *Mountain Top*, 72 F.3d at 366). And unlike in *Liberty Mutual*, where the would-be intervenors "have no property interest in the Liberty Mutual [insurance] policies nor do they have any other legally protectable interest in the policies," *id.* at 222, the Hospital Associations' members have a legally protectable interest in statutorily required

340B discounts—whether that requirement covers 340B drugs dispensed at contract pharmacies is a central question in this case. "The relief sought by plaintiff[] . . . would have an immediate, adverse financial effect on the [Hospital Associations' members]. That result is not speculative, intangible or unmeasurable." *Kleissler*, 157 F.3d at 972–73; *see also id.* at 973 (finding interest sufficient where intervenors "have a considerable stake in ensuring that" a government policy "remains in place" and "a victory for plaintiffs could destroy their business").

That some of the threat to the Hospital Associations' interest comes from the anticipated actions of non-parties to this suit—insofar as a ruling in AstraZeneca's favor would make it more likely that the other five drug companies would continue their policies and that other companies would follow—does not alter the fact that AstraZeneca's conduct alone results in immediate, non-speculative effects. The company's policy has been in place since October 1, 2020, and a potential outcome of this lawsuit is that the Court would rule that the Advisory Opinion is correct and that AstraZeneca's policy is illegal. Another potential outcome would give AstraZeneca the greenlight to continue denying 340B discounts to the Hospital Association's members when they use contract pharmacies. Either way, the Hospital Associations' interest will be directly, immediately affected.

B. HHS Does Not Adequately Represent the Hospital Associations' Interest.

Even before AstraZeneca issued its own unlawful policy last summer, the Hospital Associations had been at odds with HHS over how HHS should address these types of new policies. After numerous communications with HHS over several months, which led to no action by the government or even an acknowledgment that AstraZeneca's and similar policies are unlawful, the Hospital Associations filed a lawsuit in federal court over HHS's failure to take any action to enforce the statute and require AstraZeneca and other pharmaceutical companies to comply with their obligations. *See* Compl., *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020), ECF No. 1. Only after that lawsuit was filed did HHS on December 30, 2020,

publish the Advisory Opinion declaring, as Proposed Intervenors had argued, that pharmaceutical companies could not eliminate 340B discounts when covered entities dispense 340B drugs using contract pharmacies. Yet, three months later, HHS *still* has taken no action, except to defend itself in that lawsuit and others. Proposed Intervenors cannot know whether or how HHS will vigorously defend the Advisory Opinion. Given this history, and as reflected in the tone of HHS's opposition, there is certainly a basis for finding "a reasonable doubt" that HHS will adequately represent the Hospital Associations' interest in this matter. *Kleissler*, 157 F.3d at 967.

Defendants insist that because HHS "shares the Covered Entities' goal of repelling this lawsuit," Defs.' Opp'n to Mot. to Intervene ("Defs.' Opp'n"), at 13, D.I. 38. Defendants' representation of the Hospital Associations' interest is presumptively adequate. *See also* Pl.'s Opp'n at 7. It may be true that both HHS and the Hospital Associations agree that the 340B statute requires AstraZeneca to offer 340B discounts for 340B drugs when they are dispensed via contract pharmacies, but this is not enough to show that HHS will adequately represent Proposed Intervenors' interest in this case. Indeed, the Hospital Associations' interest lies in the correct interpretation and enforcement of the 340B statute, not just in the mere existence of the Advisory Opinion. Yet HHS "has refused to take any action to stop AstraZeneca from denying Proposed Intervenors' members the statutory discounts to which they are entitled." Mot. at 4. To the extent the Court must decide issues concerning HHS's authority and obligations under the 340B statute, there is a substantial basis to doubt that HHS will adequately represent the Hospital Associations' interest, as HHS and the Hospital Associations have been at odds over those very questions for most of the past year. *Cf. Kleissler*, 157 F.3d at 973–74 (finding representation inadequate where "the government represents numerous complex and conflicting interests in matters of this nature,"

and "[t]he straightforward business interests asserted by intervenors here may become lost in the thicket of sometimes inconsistent governmental policies").

That "Proposed Intervenors' interest in this lawsuit relates only to AstraZeneca's claims regarding the Advisory Opinion," Mot. at 7, does not mean, as HHS insists, that the only disagreement that may arise between the Hospital Associations and HHS would be "about the minutiae of litigation strategy," Defs.' Opp'n at 14; *see also* Pl.'s Opp'n at 9. In *Pennsylvania v. President of the United States*, the Third Circuit analyzed a dispute over "the degree of divergence between the interests" of the would-be intervenors and the government defendant, 888 F.3d 52, 61 (3d Cir. 2018), "with an eye toward the 'elasticity' and 'flexibility' that Rule 24 contemplates and cognizant of the highly fact-bound nature of requests to intervene under Rule 24(a)," *id.* at 62 (quoting *Kleissler*, 157 F.3d at 970, 971). Such an analysis is required here.

Though not precisely equivalent, the Hospital Associations' and HHS's interests in this case are in line with those in *Pennsylvania*. As was the government agency in that case, HHS is tasked with serving "related interests that are not identical," *id.* at 61, including ensuring drug manufacturers' and covered entities' compliance with the 340B statute, *see* 42 U.S.C. §§ 256b(d)(1), (2). Additionally, the Hospital Associations' members must protect the interests of their underserved and disadvantaged patients, which the 340B discounts enable them to do. The Hospital Associations' members use 340B discounts to allow them to serve their patients and vulnerable communities better and to keep their hospitals operational. Mot. at 9. HHS, by contrast, is tasked with enhancing the health and well-being of all Americans, among many other things. The Hospital Associations' interests thus diverge enough from HHS's to warrant intervention. *See also Am. Farm Bur. Fed. v. EPA*, 278 F.R.D. 98, 110–11 (M.D. Pa. 2011) (finding inadequate representation where "the interests of numerous stakeholders are implicated" by the challenge to

an agency decision); 6 James William Moore et al., Moore's Federal Practice § 24.03[4][a] (3d ed. 2016) (government's representation "frequently" not adequate "when one group of citizens sues the government, challenging the validity of laws or regulations, and the citizens who benefit from those laws or regulations wish to intervene and assert their own, particular interests rather than the general, public good").

Defendants' reliance on *United States v. Territory of Virgin Islands*, 748 F.3d 514 (3d Cir. 2014), for the proposition that HHS will adequately represent the Hospital Associations' interest is misplaced. *See also Pennsylvania*, 888 F.3d at 62 ("[O]ur decision in *Virgin Islands* is inapposite."). In *Virgin Islands*, the court applied a presumption of adequate representation because "one party is a government entity charged by law with representing the interests of the applicant for intervention," and the would-be intervenor failed to make the required "compelling showing to demonstrate why the government's representation is not adequate." 748 F.3d at 520 (alterations and citations omitted); *see also id.* at 522 (noting that the would-be intervenor's "reliance upon the United States' pleadings belies [his] argument that his interests diverge from those of the United States" and finding that their interests "are essentially identical"). In contrast, HHS is not defending this case on behalf of 340B covered entities; neither AstraZeneca nor HHS claims as much. Moreover, "when an agency's views are necessarily colored by its view of the public welfare rather than the more parochial views of a proposed intervenor whose interest is personal to it, the burden is comparatively light." *Id.* at 521 (quoting *Kleissler*, 157 F.3d at 972). The Hospital Associations have met that burden.[3]

[3] Defendants' contention that they "successfully rebutted" Proposed Intervenors' "assertion that 'HHS has never taken the position that it can or will enforce the statutes as interpreted,'" Defs.' Opp'n at 15 (quoting Mot. at 11), is wrong and is not supported by the court's decision in *American Hospital Association v. Department of Health and Human Services*. The court rejected plaintiffs' argument that HHS had abdicated its statutory responsibilities, ruling that "an action brought

C. The Argument that *Astra USA, Inc. v. Santa Clara County* Bars Intervention Has No Basis in Law.

Defendants attempt to impose an additional hurdle to intervention by insisting that *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), bars intervention in this case. Defs.' Opp'n at 9–11; *see also* Pl.'s Opp'n at 6. But the Third Circuit's four-pronged test for intervention as of right contains no requirement that the would-be intervenor be able to bring its own lawsuit against one of the existing parties. *See Kleissler*, 157 F.3d at 969. Indeed, "[t]he strongest case for intervention is *not where the aspirant for intervention could file an independent suit*, but where the intervenor-aspirant *has no claim* against the defendant yet a legally protected interest that could be impaired by the suit. For it is here that intervention may be essential." *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'r's*, 101 F.3d 503, 507 (7th Cir. 1996) (emphasis added) (citation omitted). *Astra* does not undermine the clear precedent in favor of intervention.

Intervention was not at issue in *Astra*, where the Supreme Court held that "suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime." 563 U.S. at 113. Here, by contrast and despite HHS's assertions otherwise, the Hospital Associations are not attempting to "sue . . . to enforce their statutory entitlement to 340B discounted drugs." Defs.' Opp'n at 11. Rather, the Hospital Associations are seeking to intervene to protect their interest, which might be impaired by the outcome of this case. HHS cites no authority for the application of *Astra* to this motion or for this new hurdle to intervention. The Hospital Associations have a significant interest that is the subject of this action; there is no requirement that they also have an independent claim against Plaintiff or

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against HHS on this ground is premature," specifically dismissing the case *without prejudice* in order to leave open the option for the Hospital Associations to renew that claim if HHS continued to refuse to enforce the statute against AstraZeneca and the other companies with similar policies. No. 4:20-cv-8806, 2021 WL 616323, at *8 (N.D. Cal. Feb. 17, 2021).

Defendants. *See King v. Governor of N.J.*, 767 F.3d 216, 245 (3d Cir. 2014), *abrogated on other grounds by Nat'l Instit. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (noting that "intervenors need not [even] possess Article III standing").[4]

Defendants also argue that the Court should first decide their motion for summary judgment before deciding Proposed Intervenors' motion. *See* Defs.' Opp'n at 12-13. Because HHS's yet-to-be-filed motion will, among other things, address the merits arguments on which the Hospital Associations seek intervention, the Hospital Associations oppose HHS's request.

II. Alternatively, the Court Should Grant Permissive Intervention.

"Pursuant to Fed. R. Civ. P. 24(b)(1)(B), the Court may permit anyone to intervene who 'has a claim or defense that shares with the main action a common question of law or fact.'" *Intellectual Ventures I LLC v. AT&T Mobility LLC*, No. 12-193, 2014 WL 4445953, at *2 (D. Del. Sept. 8, 2014). AstraZeneca and HHS argue that the Hospital Associations cannot raise any defenses in this case, and thus the Court should not permit intervention. However,

> a permissive intervenor does not even have to be a person who would have been a proper party at the beginning of the suit, since of the two tests for permissive joinder of parties, a common question of law or fact and some right to relief arising from the same transaction, only the first is stated as a limitation on intervention.

7C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1911 (3d ed. 2020) (footnote omitted); *see also id.* ("Permissive intervention may be permitted when the intervenor has an economic interest in the outcome of the suit.") (footnote omitted). The Hospital Associations plainly have "an economic interest in the outcome of the suit," as the case turns on whether their members have a statutory right to 340B drug discounts when dispensing those drugs via contract pharmacies, and they also share "a common question of law or fact with" the existing

[4] Proposed Intervenors do not concede that there is no claim they could bring against AstraZeneca or HHS but argue only that they need not be able to do so to intervene in this case.

parties, as the correct interpretation and enforcement of the 340B statute is central to this action. The Hospital Associations similarly share defenses with HHS, including that the Advisory Opinion AstraZeneca challenges "is consistent with and required by the 340B statute." Butcher Decl., Ex. H (Intervenors' Proposed Answer in Intervention to Pl.'s First Am. Compl.) at 25, D.I. 34-8. Defendants and Plaintiff cite no cases in which permissive intervention has been denied in a situation such as this.

Defendants' arguments that the Court should exercise its discretion to deny permissive intervention should also be rejected. HHS first decries "the potential for the addition of another party to complicate the proceedings and further burden the Court and the parties," Defs.' Opp'n at 17, but HHS fails to identify any prejudice that would be imposed by the Hospital Associations' participation in this case. HHS's other argument—that permitting intervention "would severely curtail the discretion and authority Congress bestowed," *id.*—is unsupported by any legal authority. AstraZeneca has raised claims going to the heart of how to interpret and enforce the 340B statute with respect to the Hospital Associations' members, and they should be permitted to intervene to defend against those claims.

CONCLUSION

For the foregoing reasons, the Hospital Associations respectfully request that the Court grant their motion to intervene as of right under Federal Rule of Civil Procedure 24(a) or, in the alternative, to permit intervention under Federal Rule of Civil Procedure 24(b).

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