

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC,

Plaintiff,

–v–

NORRIS COCHRAN, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634-FLW-LHG

**REPLY IN SUPPORT OF THE MOTION TO
INTERVENE BY 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**

Justin P. Walder
James W. Boyan III
PASHMAN STEIN WALDER
HAYDEN
A Professional Corporation
Court Plaza South
21 Main Street, Suite 200
Hackensack, NJ 07601
Telephone (201) 488-8200
Facsimile (201) 488-5556
jboyan@pashmanstein.com

William B. Schultz (*pro hac vice pending*)
Margaret M. Dotzel (*pro hac vice pending*)
Casey Trombley-Shapiro Jonas
(*pro hac vice pending*)
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
cjonas@zuckerman.com

Attorneys for Proposed Intervenors

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.

Plaintiff Sanofi-Aventis U.S., LLC (Sanofi) does not oppose intervention and requests only that Proposed Intervenors' participation be limited to Sanofi's claims regarding the December 30, 2020 Advisory Opinion; that Proposed Intervenors comply with the Court's briefing schedule; and that the Court not resolve factual disputes at this stage. *See* Pl.'s Resp. to Mot. to Intervene at 1–2, ECF No. 47. The Hospital Associations agree with these requests. *See also* Mem. in Supp. of Proposed Intervenors' Mot. to Intervene (Mem.) at 7, 10, ECF No. 34-1. For the reasons outlined below, the Court should reject the government Defendants' (collectively, HHS or Defendants) opposing arguments and grant Proposed Intervenors' motion.

I. HHS's Arguments that It Will Adequately Represent Proposed Intervenors' Interest and that the Supreme Court Has Barred Intervention Should Be Rejected.

There are four factors that must be met to intervene as of right. *See Clean Earth, Inc. v. Endurance Am. Ins.*, Civ. No. 15-6111, 2016 WL 5422063, at *3 (D.N.J. Sept. 28, 2016). Defendants do not contest that the Hospital Associations have met three of the elements: the motion is timely, the Hospital Associations have

an interest in this action, and the disposition of this action has the potential to impair that interest. The only question remaining is whether HHS will adequately represent the Hospital Associations' interest. Not only should the Court reject HHS's claim that it will adequately represent the Hospital Associations' interest, the Court also should reject HHS's attempt to impose the additional requirement for intervention that would-be intervenors must have a cause of action against an existing party, as it exists nowhere in the law.

A. HHS Will Not Adequately Represent the Hospital Associations' Interest.

Last summer, Eli Lilly and Company upset 20 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. On October 1, 2020, Sanofi became one of five additional drug manufacturers to follow Eli Lilly's lead. For the three months before Sanofi's unlawful policy went into effect, the Hospital Associations had been at odds with HHS over how HHS should address these types of new policies. One reason for the Hospital Associations' requests for prompt action was their concern that if HHS continued to do nothing, other companies would follow Eli Lilly's lead, which is exactly what happened.

After numerous communications with HHS, which led to no action by the government or even an acknowledgment that policies similar to Sanofi's 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 the six drug companies to comply with their statutory 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 an 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. *See* Am. Decl. of James W. Boyan III in Supp. of Proposed Intervenors' Mot. to Intervene (Boyan Decl.), Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020) (Advisory Opinion)), ECF No. 50.

Yet, three months later, HHS *still* has taken no action, except to defend itself in that lawsuit and others, to oppose the drug companies' intervention in the lawsuit that the Hospital Associations filed in the Northern District of California, and to oppose the Hospital Associations' intervention in this and the three other lawsuits that the drug companies have filed since. Proposed Intervenors cannot know whether or how vigorously HHS will 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 v. U.S. Forest Serv.*, 157 F.3d 964, 967 (3d Cir. 1998).

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 8, ECF No. 48, Defendants’ representation of the Hospital Associations’ interest is presumptively adequate. It may be true that both HHS and the Hospital Associations agree that the 340B statute requires Sanofi 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 Sanofi from denying Proposed Intervenors’ members the statutory discounts to which they are entitled.” Mem. at 3. 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 Intervenor’s interest in this lawsuit relates only to Sanofi’s claims regarding the Advisory Opinion,” Mem. 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 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. Mem. at 11. HHS, by contrast, is tasked with enhancing the health and well-being

of all Americans, among other things. The Hospital Associations’ interest thus diverges 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 a 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, and it does not claim 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.¹

B. 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. *See* Defs.’ Opp’n at 5–7. 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

¹ 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 10 (quoting Mem. at 14), 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 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 continues to refuse to enforce the statute against Sanofi and the other companies with similar policies. No. 4:20-cv-8806, 2021 WL 616323, at *8 (N.D. Cal. Feb. 17, 2021).

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 6. 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 Defendants. *See King v. Governor of N.J.*, 767 F.3d 216, 245 (3d Cir. 2014), *abrogated on other grounds*

by *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361 (2018) (noting that “intervenors need not [even] possess Article III standing”).²

Defendants also argue that the Court should first decide their motion to dismiss before deciding Proposed Intervenors’ motion. *See* Defs.’ Opp’n at 7–8. 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.

“Rule 24(b), unlike intervention as of right under Rule 24(a), ‘is expressly concerned with consolidating common legal or factual issues,’” *Hemy v. Perdue Farms, Inc.*, No. 11-888, 2011 WL 6002463, at *8 (D.N.J. Nov. 30, 2011) (alteration and citation omitted), and “the court has broad discretion to permit intervention by anyone who ‘has a claim or defense that shares with the main action a common question of law or fact,’” *Tansey v. Rogers*, No. 12-1049-RGA, 2016 WL 3519887, at *2 (D. Del. June 27, 2016) (quoting Fed. R. Civ. P. 24(b)(1)(B)).

HHS argues 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

² Proposed Intervenors do not concede that there is no claim they could bring against Sanofi or HHS but argue only that they need not be able to do so to intervene in this case.

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 et al., 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. The Hospital Associations also share “a common question of law or fact with” the existing parties, as the correct interpretation and enforcement of the 340B statute is central to this action. Finally, the Hospital Associations share defenses with HHS, including that the Advisory Opinion Sanofi challenges “is consistent with and required by the 340B statute.” Boyan Decl., Ex. B (Intervenors’ Proposed Answer in Intervention to Pl.’s 1st Am. Compl.), at 21. Defendants 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 12, 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.* at 13—is unsupported by any legal authority. Sanofi 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).

Dated: March 29, 2021

Respectfully submitted,

/s/ James W. Boyan III

Justin P. Walder

James W. Boyan III

PASHMAN STEIN WALDER HAYDEN, P.C.

Court Plaza South

21 Main Street, Suite 200

Hackensack, NJ 07601

Telephone (201) 488-8200

Facsimile (201) 488-5556

jboyan@pashmanstein.com

jpwalder@pashmanstein.com

William B. Schultz (*pro hac vice pending*)

Margaret M. Dotzel (*pro hac vice pending*)

Casey Trombley-Shapiro Jonas

(*pro hac vice pending*)

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1800 M Street NW, Suite 1000

Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
cjonas@zuckerman.com

Attorneys for Proposed Intervenors