IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* NORRIS COCHRAN, *et al.*, *Defendants*.	C.A. No. 21-27 (LPS) ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

PLAINTIFF'S OPPOSITION TO PROPOSED INTERVENORS' MOTION TO INTERVENE

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AstraZeneca Pharmaceuticals LP (AstraZeneca) hereby opposes the motion to intervene filed by the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively, Proposed Intervenors). D.I. 33 (Mot.).

RELEVANT BACKGROUND

This lawsuit concerns whether an Advisory Opinion issued by the General Counsel of the Department of Health and Human Services (HHS) should be declared unlawful and set aside, and whether attempts to enforce it against AstraZeneca should be enjoined. The underlying facts are set forth fully in AstraZeneca's brief in support of its motion for a preliminary injunction. D.I. 15 at 3-10. But the gravamen of AstraZeneca's amended complaint is that Defendants—HHS, the Health Resources and Services Administration (HRSA), and officials of these agencies (collectively, the Government)—acted in excess of their statutory authority under the 340B Drug Pricing Program, 42 U.S.C. § 256b (Section 340B), and the Administrative Procedure Act, 5 U.S.C. § 706 (APA), in issuing the Advisory Opinion. The Government, represented by attorneys from the U.S. Department of Justice, has appeared in this case to defend the legality of the Advisory Opinion. The Court has approved a stipulated expedited briefing schedule under which the parties will brief cross-motions for summary judgment, together with the Government's motion to dismiss. D.I. 23.

On February 26, 2021, Proposed Intervenors—several trade associations representing 340B covered entities—moved to intervene as defendants in this lawsuit, D.I. 33, and submitted a proposed answer to AstraZeneca's amended complaint, Butcher Decl., Ex. H (D.I. 34-8).

SUMMARY OF ARGUMENT

Proposed Intervenors fail to satisfy the requirements either for intervention as of right or for permissive intervention. Proposed Intervenors do not have a legally cognizable interest in this litigation that is both specific to them and direct. Instead, their purported interest in defending the lawfulness of the Advisory Opinion is shared equally with the many thousands of covered entities and contract pharmacies that would like to see the Advisory Opinion upheld. Nor will the relief sought by AstraZeneca here—an order declaring the Advisory Opinion unlawful and enjoining its enforcement—cause Proposed Intervenors direct harm. Rather, Proposed Intervenors' purported injury is contingent on the future, hypothetical actions of third parties (including other drug companies that are not parties to this lawsuit).

Proposed Intervenors also cannot overcome the strong presumption that the Government will adequately represent their interests. Here, Proposed Intervenors and the Government share precisely the same goal—defending the legality of the Advisory Opinion. For similar reasons, the Court should deny Proposed Intervenors' request for permissive intervention: Proposed Intervenors have no "claim or defense" within the meaning of Rule 24(b)(1)(B), nor any argument distinct from those that the Government is now making (or is capable of raising) itself.

While Proposed Intervenors do not satisfy the requirements for attaining party status in this suit through intervention as of right or permissive intervention, AstraZeneca would not oppose any request by Proposed Intervenors to participate as *amici curiae*, insofar as they can satisfy the criteria for such status.

ARGUMENT

I. Proposed Intervenors Are Not Entitled to Intervene Under Rule 24(a)

Under Rule 24(a) of the Federal Rules of Civil Procedure, a proposed intervenor as of right has the burden to establish, by timely motion, that: (1) it has a significantly protectable interest in

the lawsuit; (2) its interest may be impaired by the disposition of the lawsuit; and (3) its purported interest is not adequately represented by the existing parties to the litigation. Fed. R. Civ. P. 24(a)(2); *see Pennsylvania v. President United States of Am.*, 888 F.3d 52, 57-58 (3d Cir. 2018). Proposed Intervenors identify no reason why they waited more than a month before seeking party status in this case, which is proceeding under an expedited schedule. In any event, Proposed Intervenors' motion does not satisfy *any* of Rule 24(a)'s requirements for intervention as of right.

A. Proposed Intervenors Do Not Have a Significantly Protectable Interest in Whether the Government's Advisory Opinion Is Lawful

Under Rule 24(a)(2), a proposed intervenor must have "an interest relating to the property or transaction that is the subject of the action." But it is not enough to claim *any* interest; the interest must be "significantly protectable," *Donaldson v. United States*, 400 U.S. 517, 531 (1971), which the Third Circuit has interpreted to mean "a cognizable legal interest, and not simply an interest of a general and indefinite character," *Pennsylvania*, 888 F.3d at 58 (quoting *Brody ex rel. Sugzdinis v. Spang*, 957 F.2d 1108, 1116 (3d Cir. 1992)). "An applicant must therefore demonstrate that its interest is 'specific to [it], is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought.'" *Id.* (quoting *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 972 (3d Cir. 1998)). "In general, a mere economic interest in the outcome of litigation is insufficient to support a motion to intervene." *Liberty Mut. Ins. Co. v. Treesdale, Inc.*, 419 F.3d 216, 221 (3d Cir. 2005) (quoting *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 366 (3d Cir. 1995)). Likewise, "the mere fact that a lawsuit may impede a third party's ability to recover in a separate suit ordinarily does not give the third party a right to intervene." *Id.* (quoting *Mountain Top*, 72 F.3d at 366). Rather, the litigation must have a "direct" effect on the proposed intervenors that follows "immediate[ly]" from "the relief sought by [the] plaintiff[]." *Kleissler*, 157 F.3d at 972.

Proposed Intervenors assert that their "interest in this lawsuit relates only to AstraZeneca's claims regarding the Advisory Opinion." Mot. at 7. But they have identified no cognizable legal interest in defending the Government's Advisory Opinion that is both "specific to them" and "direct," rather than "remote or attenuated." *Kleissler*, 157 F.3d at 972.

First, Proposed Intervenors' purported interest in defending the Advisory Opinion is not "specific to them." They share it not only with HHS, HRSA, and the agency officials against whom this action is maintained—the proper defendants in this suit—but with the many thousands of covered entities and contract pharmacies who stand to benefit financially from the Advisory Opinion's interpretation of Section 340B. These entities all share the same "mere economic interest" in their desired statutory interpretation. *Mountain Top*, 72 F.3d at 366; *see, e.g.*, *Athens Lumber Co., Inc. v. FEC*, 690 F.2d 1364, 1366 (11th Cir. 1982) ("[The union intervenor's] alleged interest is shared with all unions and all citizens concerned about the ramifications of direct corporate expenditures. Because this interest is so generalized it will not support a claim for intervention of right."). If Proposed Intervenors were entitled to intervene *as of right* in this lawsuit, so too would every other covered entity or contract pharmacy in the country (or trade group representing them). The Third Circuit, however, has repeatedly rejected such "general and indefinite" interests as not being "legally cognizable" under Rule 24(a). *Liberty Mutual*, 419 F.3d at 220 (quoting *Mountain Top*, 72 F.3d at 366).

Second, Proposed Intervenors' purported interest is indirect and attenuated. Proposed Intervenors do not claim that a decision in favor of AstraZeneca would require them to do, or to refrain from doing, anything. Proposed Intervenors instead express an interest in the *potential* and *collateral* effects from this suit: that if the Advisory Opinion is declared inconsistent with Section 340B, AstraZeneca will choose to maintain its current policy, which over time will cause Proposed Intervenors to "continue to lose access to 340B discounts when their covered outpatient drugs are

dispensed from a contract pharmacy"; that "the other five drug companies with similar policies" would likewise be "encourage[d] … to continue their policies"; and that still "other drug companies" would "likely [be] encourage[d] … to adopt the same types of policies" in the future. Mot. at 10. But those potential consequences, which largely turn on the anticipated conduct of non-parties to this litigation, are far too indirect and attenuated to give rise to a significantly protectable interest under Rule 24(a).

Proposed Intervenors' speculation about the potential follow-on effects from a loss by the Government in this case are also too contingent to justify intervention under the appropriate standard. In *Liberty Mutual*, for instance, those injured by a manufacturer's asbestos-containing products sought to intervene in a dispute between the manufacturer and its insurer. 419 F.3d at 218-19. Though recognizing that the proposed intervenors had an "economic interest" in the dispute's outcome, based on their "statutorily created" rights in the contested insurance policies, the Third Circuit nonetheless held that the proposed intervenors' interest was too indirect. *Id.* at 222. Any financial recovery would depend on the outcome of a "separate suit," to be filed *after* the insurance dispute was resolved, and the Third Circuit deemed such a prospect too "speculative" to justify intervention. *Id.* at 224-25 (quotation marks omitted); *see id.* at 223 ("That bridge has not yet been crossed."). The same is true here.[1]

[1] Proposed Intervenors here are thus unlike those in *Kleissler*, where the relief sought would have had "an immediate, adverse financial effect" on the proposed intervenors themselves. 157 F.3d at 972. The local-government intervenors there possessed a legal interest in proceeds of federally regulated logging operations by virtue of a "state law command[]," *id.* at 973, and the logging companies could point to direct "contractual relations with the [Government]" that were "unique to them," *id.* Unlike this case, therefore, the intervenors' interests in *Kleissler* were "*directly* affected in a substantially concrete fashion *by the relief sought*." *Id.* at 972 (emphasis added). Nor are Proposed Intervenors like the condominium owners in *Mountain Top*, who had had a "property" interest "in a specific fund" created by the condominium association on behalf of all the owners—namely, a "trust" fund of "$250,000 held in the district court registry"—which had been put in jeopardy by the underlying suit. 72 F.3d at 366-67.

Finally, Proposed Intervenors invoke their purported interest in vindicating the view that HHS has an "obligation to enforce" the interpretation of the 340B statute reflected in the Advisory Opinion. Mot. at 10. But Proposed Intervenors' desire for more vigorous "enforce[ment]" is not at issue in this suit, which concerns only the lawfulness of the Advisory Opinion itself.

Nor may Proposed Intervenors intervene here to vindicate their supposed interest in some *future* enforcement action brought by the Government on their behalf against AstraZeneca. Indeed, another district court recently dismissed a lawsuit brought by Proposed Intervenors seeking to force the Government to initiate enforcement proceedings against AstraZeneca and other manufacturers. *See Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021). In dismissing that suit, the court explained that "Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling." *Id.* at *5 (quoting *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011)). Proposed Intervenors accordingly could not circumvent Section 340B's limitations by instead filing suit against the Government, which the court characterized as "nothing more than an *indirect action* against the drug manufacturers themselves." *Id.* In this suit, Proposed Intervenors are once again "creatively recast[ing] their claims," *id.*, to circumvent *Astra USA's* prohibition of overcharging actions against drug manufacturers—this time by aligning themselves as putative *defendants*. But their "if you can't beat them, join them" attempt must be rejected here as well.

B. Denial of Proposed Intervenors' Request Will Not Impair Their Interests

As demonstrated above, Proposed Intervenors cannot show that they have any protectable interest in this lawsuit, which alone is sufficient basis to deny the motion. "Where no protectable interest is present, there can be no impairment of the ability to protect it." *Am. Ass'n of People with Disabilities v. Herrera*, 257 F.R.D. 236, 252 (D.N.M. 2008). As Proposed Intervenors note,

moreover, the impairment inquiry turns on the "practical consequences of denying intervention." *Clean Earth, Inc. v. Endurance Am. Ins.*, No. 15-cv-6111, 2016 WL 5422063, at *4 (D.N.J. Sept. 28, 2016). Here, denying Proposed Intervenors' motion would have *no* practical consequences; precisely the same arguments will be made in defense of the Advisory Opinion's legality by the Justice Department. *See* Part I.C, *infra*.

Nevertheless, AstraZeneca would not object to Proposed Intervenors participating in this lawsuit as *amici curiae*, insofar as they can satisfy the criteria for *amicus* status, which would ensure that their views are put before the Court and would thus alleviate any conceivable risk to their purported interests. *See Ohio Valley Envtl. Coal., Inc. v. McCarthy*, 313 F.R.D. 10, 26 (S.D. W. Va. 2015) ("[T]he impairment prong is not met if the would-be intervenor could adequately protect its interests in the action by participating as amicus curiae.") (citing *McHenry v. Comm'r*, 677 F.3d 214, 227 (4th Cir. 2012)).

C. The Government Is Adequately Defending the Advisory Opinion's Legality

Even if Proposed Intervenors had a cognizable legal interest that could be impaired by this litigation, they cannot overcome the strong presumption that the Government is adequately representing their purported interest in defending the legality of the Government's Advisory Opinion. "Where official policies and practices are challenged, it seems unlikely that anyone could be better situated to defend than the governmental department involved and its officers." *Pennsylvania v. Rizzo*, 530 F.2d 501, 505 (3d Cir. 1976). The Third Circuit has thus consistently reaffirmed that "[a] government entity charged by law with representing a national policy is *presumed adequate* for the task, particularly when the concerns of the proposed intervenor . . . closely parallel those of the public agency." *Kleissler*, 157 F.3d at 972 (emphasis added). In such cases, "the 'would-be intervenor [must make] a *strong showing* of inadequate representation.'" *Id.* (quoting *Mausolf v. Babbitt*, 85 F.3d 1295, 1303 (8th Cir. 1996)) (emphasis added).

Proposed Intervenors do not even attempt to make such a showing here, nor could they. The Government is represented by capable lawyers from the U.S. Department of Justice who are preparing to file a combined cross-motion for summary judgment and motion to dismiss. D.I. 23. Proposed Intervenors do not identify any legal argument that they intend to make but the Government would not. To the contrary, Proposed Intervenors and the Government are perfectly aligned in their views: that the Advisory Opinion is a correct interpretation of Section 340B; that the Advisory Opinion was lawfully promulgated; and that enforcement of the Advisory Opinion should not be enjoined. Courts are particularly reluctant to grant party status where a proposed intervenor "share[s] the same objective as the United States" and desires intervention "merely to ensure that [the law] is strictly enforced." *United States v. City of Los Angeles*, 288 F.3d 391, 402 (9th Cir. 2002).

Here, Proposed Intervenors have not provided any reason why the Government is not up to the task of presenting their shared legal position.[2] In fact, the Government is in a *better* position to defend this lawsuit. Whereas Proposed Intervenors have submitted a proposed answer to the amended complaint, under which any threshold defenses would be waived under Rule 12(b), D.I. 34-8, the Government intends to move to dismiss on threshold grounds in addition to seeking summary judgment, *see* D.I. 23.

[2] For this reason, this case is unlike the other 340B suits in which AstraZeneca sought to intervene, which Proposed Intervenors reference. Mot. at 5-6. In those cases, the plaintiffs asked the court to order the Government to take action *against AstraZeneca* specifically, and *no party* shared AstraZeneca's view that its contract pharmacy policy was lawful. That also distinguishes this case from *Kleissler*, in which the proposed intervenors' position conflicted with the "thicket of sometimes inconsistent [Forest Service] policies" that the Government was defending, causing "reasonable doubt whether the government agency would adequately represent [intervenors'] concerns." 157 F.3d at 974, 967; *see United States v. Territory of Virgin Islands*, 748 F.3d 514, 522-23 (3d Cir. 2014) (discussing *Kleissler*). Here, AstraZeneca's lawsuit presents a "binary choice": Either the Advisory Opinion is a lawful exercise of the Government's statutory authority (as the Government and Proposed Intervenors both believe) or it is not (as AstraZeneca believes). *Kane County v. United States*, 928 F.3d 877, 893 (10th Cir. 2019).

Proposed Intervenors nevertheless argue that their interests are not aligned with the Government's because the Government has (thus far) "never taken the position that it can or will enforce [Section 340B] as interpreted." Mot. at 11. But that is a *non sequitur*. The *only* issues presented in this litigation concern: (1) whether the Advisory Opinion violates the APA because the Government issued it without engaging in notice-and-comment rulemaking, *see* First Am. Compl. (FAC) ¶¶ 141-47 (D.I. 13); (2) whether the Advisory Opinion is contrary to the text, history, and purpose of Section 340B, *id.* ¶¶ 148-54; and (3) whether the Advisory Opinion is arbitrary and capricious, *id.* ¶¶ 155-62. Proposed Intervenors' desire to establish that "HHS has the authority and obligation to enforce" Section 340B against AstraZeneca, Mot. at 10, is simply not at issue. Indeed, elsewhere in their motion Proposed Intervenors correctly admit that their "interest in this lawsuit relates *only* to AstraZeneca's claims regarding the Advisory Opinion," Mot. at 7 (emphasis added), which have nothing to do with the Government's supposed enforcement obligation.[3]

At this stage of the proceedings, there is nothing to indicate that the Government will fail to zealously defend the lawfulness of its Advisory Opinion. In the unlikely event that circumstances change such that the interests of Proposed Intervenors and the Government diverge, Proposed Intervenors would be free to seek intervention at that time. But so long as their interests remain fully aligned with the Government's, they are not entitled to intervene as of right.

[3] AstraZeneca does seek an injunction barring the Government from "implementing or enforcing the Advisory Opinion," *see* FAC Prayer for Relief ¶ E, but that requested relief is based entirely on the *unlawfulness* of the Advisory Opinion, not on the Government's enforcement obligations, *see* FAC ¶¶ 141-62. The amended complaint also challenges the Government's refusal to post AstraZeneca's notice to manufacturers regarding its policy on HRSA's website. *See* FAC ¶¶ 163-65. But Proposed Intervenors do not assert any interest in that issue. *See* Mot. at 7 ("Proposed Intervenors' interest in this lawsuit relates only to AstraZeneca's claims regarding the Advisory Opinion.").

II. The Court Should Deny Permissive Intervention Under Rule 24(b)

Proposed Intervenors' alternative request for permissive intervention fares no better. The sole provision that Proposed Intervenors claim to satisfy, Mot. at 12-13, is Federal Rule 24(b)(1)(B), which permits intervention only where an applicant asserts a "claim or defense that shares with the main action a common question of law or fact." But Proposed Intervenors have no claim or defense of their own in this APA action.

In any event, under Rule 24(b)(1)(B), "defenses [that] are not unique" to the proposed intervenor and "can be adequately represented by [the named] defendants" do not justify permissive intervention; otherwise, "numerous third-parties [could] seek intervention on the same bases." *Hodes & Nauser, MDs, P.A. v. Moser*, No. 2:11-cv-02365, 2011 WL 4553061, at *4 (D. Kan. Sept. 29, 2011); *see New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 472-73 (5th Cir. 1984) (en banc) (similar); *Menominee Indian Tribe of Wis. v. Thompson*, 164 F.R.D. 672, 678 (W.D. Wis. 1996) (similar); *see also Allen Calculators, Inc. v. Nat'l Cash Register Co.*, 322 U.S. 137, 141-42 (1944) (noting that permitting a "multitude" of interventions in a case "of large public interest . . . may result in accumulating proofs and arguments without assisting the court"). Proposed Intervenors have not identified any defense that is *distinct* from those that the Government is now making (or is capable of raising) itself. Instead, they identify only a "common question of law," namely, "whether the 340B statute requires pharmaceutical manufacturers to offer 340B discounts to covered entities that dispense their 340B drugs through contract pharmacies." Mot. at 12. But Proposed Intervenors' general interest in how the Court interprets Section 340B—shared in common not only with the Government, but also with all other covered entities and contract pharmacies—is not the type of "claim or defense" that justifies intervention under Rule 24(b). *See Coal. to Defend Affirmative Action v. Granholm*, 501 F.3d 775, 782 (6th Cir. 2007); *see also* 25 John Bourdeau et al., Federal Procedure, Lawyers' Ed. § 59:376. And even

if it were, Proposed Intervenors have not explained why they would be "unique[ly]" situated to raise it. *Hodes & Nauser, MDs*, 2011 WL 4553061, at *4.

Rather than grant party status to Proposed Intervenors, despite their being identically situated to thousands of other covered entities and contract pharmacies, the more appropriate course would be to permit them to participate as *amici curiae* (insofar as they satisfy the criteria for *amicus* status). That approach would allow consideration of their views while minimizing any disruption to the expedited briefing and proceedings that this Court has approved. Indeed, Proposed Intervenors identify no respect in which *amicus* status would leave them worse off or less capable of protecting their interests.

CONCLUSION

The Court should deny the motion to intervene.

Dated: March 12, 2021

Respectfully submitted,

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