IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL., *Petitioners*,

v.

Alliance for Hippocratic Medicine, et al., Respondents,

DANCO LABORATORIES, L.L.C., *Petitioner*,

v.

Alliance for Hippocratic Medicine, et al., Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

RESPONSE IN OPPOSITION TO THE MOTION FOR LEAVE TO INTERVENE

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INTRODUCTION

Three States—Missouri, Kansas, and Idaho—belatedly seek to intervene in this matter. These States participated as amici through every stage of the proceedings below and in this Court. But after Danco and FDA petitioned for certiorari—and nearly a year after Respondents filed their complaint—the States moved to intervene in the District Court. The States now contend that their after-the-fact intervention below has somehow deprived this Court of the ability to decide the first question presented in Petitioners' favor and would promote efficiency.

The States are wrong on all counts.

First, the fact that the District Court recently granted the States' intervention has no effect on this Court's review of the preliminary injunction entered and appealed months earlier. The States are not parties to that injunction, and the States have already admitted that this Court can vacate the preliminary injunction if Respondents lack standing. Moreover, there is no reason for this Court to litigate the States' claims when dismissing Respondents' suit would effectively dismiss the States' suit, as the States cannot independently satisfy standing and venue.

Second, the States' assertion that their standing is undisputed is wrong, as both Danco and FDA specifically argued the States lacked standing in opposing intervention. The States' purported harms present the same (or worse) problems as Respondents' claims. In any event, the States urged the District Court not to decide the standing issue, and the District Court obliged.

Third, intervention is inappropriate under these circumstances. Post-certiorari intervention requires

extraordinary factors, but nothing here supports the States' request. To the contrary: The States' motion is untimely in the extreme; intervention would not promote judicial efficiency; and allowing the States to join now would severely prejudice Danco.

The States' motion to intervene should be denied.

BACKGROUND

Respondents filed their complaint and motion for preliminary injunction on November 18, 2022. J.A. 114. Missouri, Kansas, and Idaho filed amici briefs urging the District Court to issue the preliminary injunction. D. Ct. ECF Nos. 100, 110. The States did not move to intervene. On April 7, 2023, the District Court entered the preliminary injunction now on review in this Court. Pet. App. 111a-195a.¹

Danco and FDA immediately appealed and sought an emergency stay of the preliminary injunction in the Fifth Circuit. Missouri and Kansas filed amici briefs urging the Fifth Circuit to deny the stay. 5th Cir. ECF Nos. 168, 169. The States did not move to intervene.

After the Fifth Circuit declined to stay the injunction in significant part, Pet. App. 196a-244a, Danco and FDA sought an emergency stay in this Court. See Nos. 22A901, 22A902. Missouri and Kansas filed amici briefs urging this Court to deny the stay. The States did not move to intervene.

This Court stayed the District Court's order in full. Pet. App. 245a. The District Court subsequently stayed Danco's and FDA's responsive pleading

¹ Citations are to FDA's Petition Appendix.

deadlines pending resolution of the preliminaryinjunction appeal. D. Ct. ECF No. 144.

Before the Fifth Circuit merits panel, Missouri and Kansas filed amici briefs urging the court of appeals to uphold the preliminary injunction. 5th Cir. ECF Nos. 478-1, 480-1. The States did not move to intervene.

On August 16, 2023, the Fifth Circuit upheld the preliminary injunction in significant part. Pet. App. 1a-110a. The States did not move to intervene.

Less than a month later, on September 8, Danco and FDA petitioned for certiorari. Nos. 23-235, 23-236. Respondents filed a conditional cross-petition on October 12. No. 23-395. The States did not move to intervene.

On November 3, 2023—nearly a year after Respondents filed their complaint, and less than a week before Respondents' deadline for their brief in opposition in this Court—Missouri, Kansas, and Idaho moved to intervene in the District Court. D. Ct. ECF Nos. 151, 152. Respondents subsequently urged this Court to deny review of Danco's and FDA's petitions because "proposed State intervenors' claims have yet to be litigated in the lower courts." Br. in Opp. 14. By contrast, FDA and Danco asked the District Court to hold the States' intervention motion in abevance. D. Ct. ECF Nos. 155, 157. The States opposed FDA's and Danco's request because "if [the District] Court grants intervention and the Supreme Court later grants certiorari, then the Supreme Court may well consider the States' standing," and "the Supreme Court can consider the petition for certiorari as early as December 8." D. Ct. ECF No. 156 at 3, 9.

The District Court declined to hold the intervention motion in abeyance. D. Ct. ECF No. 159.

On December 13, 2023, this Court granted Danco's and FDA's petitions for certiorari and denied Respondents' cross-petition.

Shortly thereafter, the parties completed briefing on the States' intervention motion in the District Court. In their oppositions to the States' motion to intervene, FDA and Danco argued that the States' belated intervention could not save Respondents' jurisdictionally defunct suit from dismissal, that the States lacked standing and venue to pursue a separate suit, and that the States otherwise failed the standard for intervention.² D. Ct. ECF Nos. 164 (Danco Opp.), 163 (FDA Opp.). In reply, the States urged that the District Court "need not even consider [the States'] standing." D. Ct. ECF No. 172 at 1. The States also conceded that "a Supreme Court ruling that the private plaintiffs lack standing for the preliminary injunction would vacate that injunction." *Id.* at 2.

On January 12, 2024, the District Court granted the States' motion to intervene. D. Ct. ECF No. 175. Consistent with the States' request, the District Court did not address the States' standing.

² Among other things, FDA and Danco pointed out that the States' three "new" developments were not new: (1) the States had long been aware of preemption litigation, and the preemption claim in the case they cited had been dismissed with prejudice; (2) the States had long known that individuals could send mifepristone in the mail; and (3) Kansas has, since at least 1998, annually released statistics for Missouri residents who obtained abortions in Kansas. *See* D. Ct. ECF No. 164 at 10-14; D. Ct. ECF No. 163 at 12-14.

On January 22, the States moved to intervene in this Court. Danco and FDA filed their merits briefs the next day. Argument is set for March 26.

ARGUMENT

I. THE STATES' INTERVENTION BELOW HAS NO EFFECT ON THIS COURT'S REVIEW.

The States' belated intervention has not created a "redressability problem" preventing this Court from vacating the preliminary injunction. Mot. 5 & n.3. As an initial matter, the States already conceded that "a Supreme Court ruling that [Respondents] lack standing for the preliminary injunction would vacate that injunction." D. Ct. ECF No. 172 at 2 (emphasis added). The States were right to concede this point. They are strangers to the injunction on review in this Court. Their after-the-fact intervention in the District Court does not make them parties to the preliminary injunction and cannot deprive this Court of the ability to vacate it. If this Court concludes that Respondents lack standing, it can and should vacate the injunction and order Respondents' suit dismissed.

A. The States Are Not Parties To The Preliminary Injunction On Review.

The States' redressability argument boils down to the assertion that they are "parties to the preliminary injunction," Mot. 2, but the States are plainly not "parties" to an injunction that was entered and appealed in April 2023—eight months before the States sought to intervene.

The District Court never issued an order purporting to make them "parties" to the preliminary injunction. For good reason: The District Court would have lacked jurisdiction to modify and expand the "same judgment" currently on review in this Court. Griggs v. Provident Consumer Disc. Co., 459 U.S. 56, 60 (1982). It is "a longstanding tenet of American procedure" that "[a]n appeal, including interlocutory appeal, 'divests the district court of its control over those aspects of the case involved in the appeal." Coinbase, Inc. v. Bielski, 599 U.S. 736, 740 (2023) (quoting Griggs, 459 U.S. at 58); see also Price v. Dunn, 139 S. Ct. 1533, 1537-38 (2019) (Thomas, J., concurring in denial of certiorari). Because Danco and FDA appealed the preliminary injunction in April 2023, the District Court has long been without power to modify the injunction to encompass other parties.

Nor do the States cite any District Court order granting them preliminary relief (which would also have jurisdictional problems). And it is not clear that they could secure one. A preliminary injunction "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008) (emphasis added). The States—which freely admit that their purported harms are "distinct from the private plaintiffs' harms," Mot. 10-must "demonstrate that irreparable injury" to the States "is likely in the absence of an injunction," Winter, 555 U.S. at 22 (emphasis omitted), in order to secure that relief. The States never argued in the District Court that they were entitled to injunctive relief, and so the District Court never assessed how the challenged actions "would adversely affect their * * * interests," never "balance[d] the competing claims of injury," never "consider[ed] the effect on each party of the granting or withholding of the requested relief," and never addressed whether the States' purported harms are nevertheless "outweighed by the public interest." *Winter*, 555 U.S. at 22-24 (citation omitted).

The States' sole citations—a footnote in Wright & Miller and an Eighth Circuit case, see Mot. 1-2—refer only to the settled rule that intervenors, like original parties, are subject to "the law of the case" in "subsequent proceedings." Miller v. Alamo, 975 F.2d 547, 551 (8th Cir. 1992). Of course, a general rule binding intervenors to the law of the case does not imply that intervention ipso facto makes the States parties to an injunction litigated and appealed well before their intervention. Such a rule would flatly contradict this Court's repeated admonition that a preliminary injunction is "an extraordinary remedy never awarded as of right." Winter, 555 U.S. at 24 (emphasis added).

B. Respondents' Suit Should Be Dismissed If This Court Finds Respondents Lack Standing.

The States are also wrong to claim that their intervention in the District Court would somehow keep this case alive even if Respondents lack standing. For one thing, that issue has no bearing on whether *this* Court should grant intervention. For the reasons already discussed and those *infra* pp. 9-17, it should not.

In any event, the States are wrong that the District Court order granting them intervention in Respondents' suit means the suit would necessarily "survive" any decision by this Court. See Mot. 6. If this Court concludes that Respondents lack standing, see Danco Merits Br. 19-35; FDA Merits Br. 15-34, then this Court can and should order Respondents' suit dismissed. It has "long been the rule" that review

of a preliminary injunction extends to "determining whether there is any insuperable objection, in point of jurisdiction or merits, *** and, if so, to directing a final decree dismissing" the suit. *Munaf* v. *Geren*, 553 U.S. 674, 691 (2008) (citation omitted). And given the litigation history here, "[t]his is one" of the occasions when it is appropriate to "terminate the litigation now." *Id.* at 691-692. If Plaintiffs lack standing, intervention cannot "cure this vice in the original suit" and the States "must abide the fate of that suit"—including dismissal. *U.S. ex rel. Texas Portland Cement Co.* v. *McCord*, 233 U.S. 157, 163-164 (1914).

The narrow exception the States invoke—continuing their case "as if it were a separate suit," Mot. 6 (citation omitted)—requires an intervenor to independently meet "the requirements that a plaintiff must satisfy—e.g., filing a separate complaint" and demonstrating it "clearly has Article III standing"—before the court may "reach the merits." Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31, 138 S. Ct. 2448, 2462-63 (2018).3

Every circuit agrees that intervenors must establish "a separate and independent jurisdictional basis" for their action before the court may exercise its "discretion to treat an intervention as a separate action." Arkoma Assocs. v. Carden, 904 F.2d 5, 7 (5th Cir. 1990); see Indus. Commc'ns & Elecs., Inc. v. Town of Alton, 646 F.3d 76, 79 (1st Cir. 2011); Disability Advocs., Inc. v. N.Y. Coal. for Quality Assisted Living, Inc., 675 F.3d 149, 160-162 (2d Cir. 2012); Fuller v. Volk, 351 F.2d 323, 328-329 (3d Cir. 1965); Atkins v. N.C. Bd. of Educ., 418 F.2d 874, 876 (4th Cir. 1969); Horn v. Eltra Corp., 686 F.2d 439, 440-442 (6th Cir. 1982); Buckley v. Ill. Jud. Inquiry Bd., 997 F.2d 224, 227 (7th Cir. 1993); Mattice v. Meyer, 353 F.2d 316, 319 (8th Cir. 1965); Benavidez v. Eu, 34 F.3d 825, 830-831 (9th Cir. 1994); Miller & Miller Auctioneers, Inc. v. G. W. Murphy Indus., Inc.,

But the States' complaint-in-intervention cannot "satisf[y] by itself the requirements of jurisdiction and venue." Charles Alan Wright & Arthur R. Miller, 7C Fed. Prac. & Proc. Civ. § 1918 (3d ed. Apr. 2023 update) (emphasis added); see infra pp. 9-13; 28 U.S.C. § 1391(e)(1). Take venue, for example. The Northern District of Texas is clearly an improper venue for Missouri, Idaho, and Kansas to challenge FDA's actions. No party on either side of the "v" resides in that district. 28 U.S.C. § 1391(e)(1)(A), (C).

The States offer various ways they apparently intend to cure their venue problems—including "add[ing] a party." Mot. 7; but see Charles Alan Wright & Arthur R. Miller, 14D Fed. Prac. & Proc. Juris. § 3815 (4th ed. Apr. 2023 update) ("venue cannot be based on the joinder of a * * * plaintiff who has been improperly and collusively joined for the purpose of creating venue in the district"). Yet whatever the States' future plans, the District Court should have the first opportunity to adjudicate them.

II. THE STATES LACK STANDING.

The States are not only strangers to the injunction on review; they are also strangers to this dispute. The States say that granting intervention here would allow the Court to reach the merits of the preliminary injunction because—although no court has addressed it—they say they have standing. Mot. 8-9. But the States' claims of economic and sovereign injuries

⁴⁷² F.2d 893, 896 (10th Cir. 1973); Nat'l Ass'n of State Util. Consumer Advocs. v. FCC, 457 F.3d 1238, 1250 (11th Cir. 2006), as modified, 468 F.3d 1272 (11th Cir. 2006); Aeronautical Radio, Inc. v. FCC, 983 F.2d 275, 283 (D.C. Cir. 1993).

suffer from the same attenuation, traceability, and redressability issues as Respondents' claims.

On economic injury, the States offer no actual and concrete facts about women located in their territorial boundaries who were prescribed mifepristone after FDA's 2016 or 2021 actions, who would not otherwise have been prescribed the drug under its 2000 approval, and who sought follow-up care that imposed costs on the State through a public hospital or insurance program; nor do the States offer actual and concrete details about "the medical judgment of thirdparty healthcare providers who choose to prescribe mifepristone, or the discretionary actions of thirdparty patients who choose to have a medication abortion." Danco Merits Br. 24-26, 30. If this Court rejects Respondents' standing assertions as too speculative. the States' standing assertions necessarily fail on the same grounds.

The States actually stand in a worse position than Respondents on these issues because the States introduce even more independent actors speculative events into the causal chain purportedly linking FDA's actions to any asserted injury. The States' asserted injuries turn on whether the rare woman who received mifepristone as a result of FDA's 2016 and 2021 actions, and who is experiencing a serious adverse event, and who chooses to seek further care in an emergency room instead of through her provider, will also choose to receive that care at a public hospital in one of the three States, or also be a Medicaid participant or a state government employee, so that the State will be required to pay for that care. See D. Ct. ECF No. 176 (Intervenors' Compl.) ¶¶ 278, 290, 299, 307. The States do not identify even one woman—and one resulting cost—fitting that description.⁴

The alleged injury to the States' sovereign interests is no more concrete. Nothing in FDA's 2016 or 2021 actions limits the States' ability to regulate abortion within their States. FDA evaluated whether certain use restrictions remained necessary for safe and effective use of mifepristone—nothing more. It did not address in any way state laws that regulate and restrict abortion access within a State's own borders. And the States do not cite any authority holding that the federal government impinges state sovereignty when, relying on decades of studies and substantial expertise, it evaluates the continuing necessity of certain use restrictions for safe and effective use of a drug. Instead, the States cite a district court decision⁵ addressing a different State's laws and suggest that they have standing because some other plaintiff might one day rely on that decision to assert that these States' abortion laws are preempted. Mot. 9. That theory is too speculative to create standing. See Clapper v. Amnesty Int'l USA,

⁴ The purportedly "concrete example[s]" in the States' motion are anything but. Mot. 8-9. Merely citing the number of Missourians who had any type of abortion in 2022 and the number of Missourians enrolled in Medicaid does not say anything about how—or if—those numbers are related, or whether they are causally linked to the challenged 2016 and 2021 FDA actions. The Idaho example is similarly flawed; no evidence shows that any asserted "medical costs" stem from FDA's 2016 and 2021 actions. See Mot. 9.

⁵ The preemption claim in that case was since dismissed with prejudice. See Mot. to Amend 2, GenBioPro, Inc. v. Sorsaia, No. 3:23-cv-00058 (S.D.W. Va. Oct. 18, 2023), ECF No. 73; Order, GenBioPro, Inc. v. Sorsaia, No. 3:23-cv-00058 (S.D.W. Va. Oct. 19, 2023), ECF No. 74.

568 U.S. 398, 413-414 (2013) (no standing based on theories that "require guesswork" about how courts "will exercise their judgment" because "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case" (quoting *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-160 (1990))).

For those reasons (and many others), neither Danco nor FDA have "conceded" that the States demonstrated their standing to challenge FDA's 2016 and 2021 actions. See Mot. 8. To the contrary, both Danco and FDA vigorously argued the States lacked standing in opposing their intervention. In fact, this issue was the lead argument in both opposition briefs. See D. Ct. ECF No. 164 at 1-8; D. Ct. ECF No. 163 at 1-10. And, as part of those arguments, both Danco and FDA clearly "dispute[d] that a significant of women who take mifepristone percentage experience adverse effects," and that "these costs, 'at the population level,' are born[e] by the States through Medicaid and the like." Mot. 8 (citations omitted); see D. Ct. ECF No. 164 at 5, 18; D. Ct. ECF No. 163 at 6-7.

The States attempt to fabricate a concession out of FDA's response at oral argument in the Fifth Circuit to a question about the plaintiff-States in *Department of Commerce* v. *New York*, 139 S. Ct. 2551 (2019). *See* Mot. 7. But even if Danco or FDA *had* conceded standing below (and they did not), this Court has "an independent obligation to assure that standing exists, regardless of whether it is challenged by any of the parties." *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 499 (2009). And nothing in *Department of Commerce* grants States a free ticket to this Court in this case.

Nor does it stand for the proposition that States can rely on "statistics and probabilities" where private plaintiffs cannot. Mot. 7 (citation omitted). To the contrary, "federal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer," precisely because "our system of dual federal and state sovereignty" necessarily means that "federal policies frequently generate indirect effects on state revenues or state spending." United States v. Texas, 599 U.S. 670, 680 n.3 (2023); see also id. at 688-689 (Gorsuch, J., concurring in the judgment) (observing that "the notion that States enjoy relaxed standing rules had no basis in our jurisprudence," and "courts should just leave that idea on the shelf in [the] future" (citation, quotation marks, and brackets omitted)).

As Danco has already explained, this Court found standing in Department of Commerce because "[t]he multi-thousand-page administrative record showed that the challenged [census] question historically resulted in significant undercounting and would continue to do so at a predictable rate." Danco Merits Br. 31. But the States—much like Respondents—"do not use historical data to predict a specific rate of emergency-room visits for a declarant's hospital based on FDA's 2016 and 2021 actions," and "offer no facts demonstrating that the rate of emergency-room visits to that hospital will necessarily affect" them "or require that [the States] *** provide any specific care." Id. at 31-32. The States therefore cannot lean on Department of Commerce to support their intervention bid.

III. INTERVENTION IS INAPPROPRIATE HERE.

Although there have been "rare occasions" in which this Court has granted post-certiorari intervention, "every such instance is of the unusual variety, and neither intervention nor the addition of new parties can be considered a procedure available in cases containing no extraordinary factors." Stephen M. Shapiro et al., Supreme Court Practice § 6.16.(C) (11th ed. 2019). The States' move to intervene here presents no reason to break from this Court's usual practice. In addition to the reasons already explained, the States' motion should be denied for several others.

First, the States' motion is untimely. Although the States claim that timeliness "cannot be disputed," Mot. 10, Danco and FDA can, have, and continue to dispute it. See D. Ct. ECF No. 164 at 9-17; D. Ct. ECF No. 163 at 11-18. The States note that 10 days passed between the District Court's grant of their intervention motion and their corresponding motion to intervene in this Court. See Mot. 10. What the States fail to mention is that their intervention motion in District Court was about one year too late. Respondents filed their complaint on November 18, 2022. The States moved to intervene one year later, on November 3, 2023. And that delay was not due to lack of knowledge of the case: The States filed amicus briefs in support of Respondents at every stage of the litigation. See supra pp. 2-3.

The States offer no good reason for their delay. They say "three events" that occurred "[m]onths" after the preliminary injunction order should excuse their delay: (1) a nonprecedential district court decision,

issued "in late August," (2) news articles from "summer 2023" reporting that organizations were mailing mifepristone across state lines, and (3) a "June 2023" data set regarding Kansas abortion statistics. Mot. 3. None of that was news to the States. They knew about the preemption case at least six months earlier, having filed a motion for leave to participate as amici in that court. See States' Amici Mot., GenBioPro, Inc. v. Sorsaia, No. 3:23-cv-00058 (S.D.W. Va. Feb. 28, 2023), ECF No. 24. The cited news articles offer no facts about mailing mifepristone into Missouri, Kansas, or Idaho. See D. Ct. ECF No. 152 at 3-5. And the data set regarding abortion statistics was published by Kansas, one of the proposed intervenors. See D. Ct. ECF No. 164 at 10-11; D. Ct. ECF No. 163 at 12.

Second, judicial efficiency is not served by intervention. Neither the Fifth Circuit nor even the District Court have heard and considered the States' standing or merits arguments. To the extent that the States' merits arguments overlap with Respondents' arguments, intervention is inappropriate because Respondents will adequately represent the States' position. See Fed. R. Civ. P. 24(a)(2) (no intervention when "existing parties adequately represent th[e] interest"). And to the extent that the States' arguments are new and different from Respondents' arguments, intervention is inappropriate because the States' failure to intervene at an earlier stage has deprived this Court of the benefit of the lower courts' analysis. See Frank v. Gaos, 139 S. Ct. 1041, 1046 (2019) (per curiam) ("We are a court of review, not of first view." (citation and quotation marks omitted)).

Even if the States were correct in their assertion that granting intervention would ensure that this Court could reach the merits, contra supra pp. 5-9, that would not be a reason to grant intervention here. Both Danco and FDA sought certiorari so that this Court could review the jurisdictional question posed by the Fifth Circuit's decision. See Danco Pet. i (asking this Court "[w]hether an association can demonstrate Article III standing to enjoin a government action by arguing that some unspecified member may be injured at some future time by the challenged action"); FDA Pet. I (similar). As Danco explained, the Fifth Circuit's decision created a division of authority in the courts of appeals, which are "confus[ed] about Summers' reach." Danco Pet. 26. The standing issues in this case are a feature of the certiorari grant, not a bug.

This Court's decision to grant certiorari on a standing question makes this case fundamentally different from the cases collected by the States. See Mot. 10-11, see also, e.g., Mullaney v. Anderson, 342 U.S. 415, 416 (1952) (allowing intervention because "[h]ere, for the first time, petitioner questioned the standing of respondent union and its Secretary-Treasurer to maintain this suit"). And that makes this case fundamentally consistent with a case in this Court recently denied a intervention request. See Murthy v. Missouri, 144 If this Court were to grant S. Ct. 32 (2023). intervention so that "no standing issue would prevent the Court reaching the merits," Mot. 10, the Court would necessarily lose the opportunity to provide guidance on the first question presented in both petitions.

Third, permitting the States to belatedly intervene would prejudice Danco. This case is already well under way and set for argument in less than two months. Danco, FDA, and their amici have already filed their opening briefs addressing Respondents' lack of standing and the errors in the Fifth Circuit's merits analysis. By contrast, the States will not suffer prejudice if this Court denies their intervention request. "The obvious alternative for one who desires to intervene in a pending Supreme Court proceeding is to seek to file an amicus curiae brief." Supreme Court Practice § 6.16.(C). The States have already done just that at earlier stages of this case and acknowledge they can do so again now. Mot. 1, 14.6

CONCLUSION

The States' motion to intervene should be denied.

Respectfully submitted,

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⁶ This Court should deny Americans En Ventre Sa Mere's intervention motion for many of the same reasons.