

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

Alliance for Hippocratic Medicine, *et al.*,

Plaintiffs,

v.

Case No. 2:22-cv-00223-Z

U.S. Food and Drug Administration, *et al.*,

Defendants,

and

Danco Laboratories, LLC,

Intervenor-Defendant.

**Defendants' Motion to Hold in Abeyance the Motion to Intervene filed by
States of Missouri, Kansas, and Idaho**

Defendants respectfully request that this Court hold in abeyance the pending motion to intervene filed by the States of Missouri, Kansas, and Idaho, *see* ECF No. 151, pending the resolution of Supreme Court proceedings with respect to this Court's April 7, 2023 Memorandum Opinion and Order, including the petitions for a writ of certiorari and any subsequent proceedings, if applicable. In the alternative, Defendants respectfully request that the Court extend Defendants' deadline for responding to the intervention motion until 30 days after the Court's resolution of this abeyance motion.

Holding this intervention motion in abeyance would be the most efficient manner of proceeding, both for avoiding litigation that is potentially unnecessary and preserving the Court's and the parties' resources. Depending on whether and how the Supreme Court proceedings are resolved, this Court may not need to ever decide the States' intervention motion. At a minimum, awaiting the conclusion of those proceedings will help inform the Court's consideration of the

States' intervention request. The States will not suffer any prejudice from this approach, given that Defendants' deadline to answer or respond to the Complaint in district court is currently stayed pending the outcome of those same proceedings. Thus, the most prudent approach is to hold the States' motion in abeyance. Alternatively, however, Defendants respectfully request an extension of time to respond to the intervention motion—*i.e.*, until 30 days after the Court's resolution of this motion—which is independently justified by the need to review and evaluate the voluminous materials the States have submitted in connection with their intervention motion.

As set forth in more detail in the Certificate of Conference appended hereto, Defendants have conferred with counsel for the parties. Defendant-Intervenor consents to both requests. Counsel for the putative intervenor States indicated that the States would agree to a responsive filing shortly after Thanksgiving, but do not agree to a lengthier extension or holding the intervention motion in abeyance. Counsel for Plaintiffs indicated that Plaintiffs also oppose Defendants' requests but would agree to a deadline shortly after Thanksgiving.

Background

This case was originally filed on November 18, 2022, and Plaintiffs sought a preliminary injunction that same day. *See* ECF Nos. 1, 8. On April 7, 2023, this Court entered an order granting in part Plaintiffs' motion for a preliminary injunction and staying the effective date of the challenged agency actions. *See* ECF No. 137 (April 7 Order). That same day, Defendants and Intervenor-Defendant filed notices of appeal. *See* ECF Nos. 138 & 139. The United States Court of Appeals for the Fifth Circuit issued a partial stay of this Court's April 7 Order on April 12, 2023, *see* 2023 WL 2913725, and on April 21, 2023, the Supreme Court issued a full stay of that same order pending resolution of any petition for certiorari that might be filed following resolution by the Fifth Circuit of the merits of Defendants' appeal. *See Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023). As a result, this Court's order has not taken effect. The Fifth Circuit then issued its decision resolving the merits of Defendants' appeal on August 16, 2023, vacating in part and affirming in part this Court's April 7 Order. *See All. for Hippocratic Medicine v. FDA*, 78 F.4th 210 (5th Cir. 2023).

On September 8, 2023, the United States filed a petition for a writ of certiorari with the Supreme Court, as did Intervenor-Defendant. *See* Supreme Court Case Nos. 23-235, 23-236. Those petitions contend that the Supreme Court should grant review to determine Plaintiffs’ Article III standing to pursue their claims, the merits of the FDA actions as to which the Fifth Circuit affirmed this Court’s April 7 Order, and the appropriate scope of relief, if any. On October 12, 2023, Plaintiffs filed a conditional cross-petition for a writ of certiorari, *see* Supreme Court Case No. 23-395, presenting additional questions regarding the timeliness and merits of those claims as to which the Fifth Circuit vacated this Court’s April 7 Order.

On November 3, 2023, the States of Missouri, Kansas, and Idaho filed a motion to intervene in this action as plaintiffs. *See* ECF No. 151. The motion was accompanied by a 105-page proposed Complaint containing over 400 paragraphs of allegations, *see* ECF No. 151-1, as well as an appendix containing 41 exhibits totaling close to 700 pages, *see* ECF Nos. 151-2 and 151-3. In the memorandum accompanying their motion, the States contend that, although the United States has disputed the private plaintiffs’ theories of standing, the States seek to “press sovereign and economic harms that cannot be asserted by private plaintiffs,” and thus the States should be permitted to intervene to “ensure[] that this Court (or appellate courts) can more cleanly get to the merits of this incredibly important issue.” ECF No. 152 at 1.

Discussion

Almost a full year after this case was originally filed, while the case is pending at the Supreme Court, three States now seek to intervene, wanting to pursue a 105-page Complaint supported by close to 700 pages of other materials. Defendants request that this Court hold that motion in abeyance pending resolution of pending Supreme Court proceedings that may obviate the States’ motion and at the very least may shed light on how the motion should be resolved.

1. Defendants have filed petitions for a writ of certiorari that ask the Supreme Court to decide Plaintiffs’ Article III standing to pursue their claims. The States argue that allowing them to intervene and present their own theories of standing will ensure jurisdiction for the courts to “more cleanly get to the merits” of the claims in this case. ECF No. 152 at 1. But the States cannot

maintain the Plaintiffs' claims on their behalf if the Supreme Court determines that the existing Plaintiffs lack standing. And if the existing Plaintiffs lack standing, the States cannot get resolution of their own claims in this district, because the case would have to be dismissed or transferred for improper venue.

It is "well-settled that '[a]n existing suit within the court's jurisdiction is a prerequisite of an intervention, which is an ancillary proceeding in an already instituted suit.'" *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985) (quoting *Kendrick v. Kendrick*, 16 F.2d 744, 745 (5th Cir. 1926)). "Indeed, this rule is so deeply entrenched in our jurisprudence that it is an axiomatic principle of federal jurisdiction in every circuit to have addressed the question." *Disability Advocates, Inc. v. N.Y. Coal. for Quality Assisted Living*, 675 F.3d 149, 160-61 (2d Cir. 2012) (collecting cases). As a corollary, "[i]ntervention cannot cure any jurisdictional defect that would have barred the federal court from hearing the original action." 7C Charles A. Wright et al., *Federal Practice & Procedure* § 1917 (3d ed. Apr. 2023); *see also, e.g., United States ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 163-64 (1914) (holding that "the cause of action had not accrued to the creditors who undertook to bring the suit originally," and "[t]he intervention [of a party with a proper claim] could not cure this vice in the original suit"); *Fuller v. Volk*, 351 F.2d 323, 328 (3d Cir. 1965). Consequently, if the existing Plaintiffs are held to lack standing, this Court cannot rely on the States' standing to resolve the original claims on the merits.

Nor in that event could this Court resolve the States' own claims on the merits. If the Supreme Court determines that Plaintiffs lack standing, this Court could not allow an intervenor to bring its claims in this District if the intervenor does not "satisf[y] *by itself* the requirements of jurisdiction *and venue*." *Federal Practice & Procedure* § 1918 (emphasis added); *cf. Georgia Republican Party v. Sec. & Exch. Comm'n*, 888 F.3d 1198, 1205 (11th Cir. 2018) (transferring case to proper court where the only party that satisfied venue lacked standing). The States plainly cannot satisfy venue requirements given that none of the putative intervenor States (Missouri, Kansas, and Idaho) resides in the Northern District of Texas. *See* 28 U.S.C. § 1391(e); *compare Utah v. Walsh*, No. 2:23-cv-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023)

(Kacsmark, J.) (concluding that two plaintiffs resided within the District and venue was therefore proper). The States’ own motion is premised on the possibility that the Supreme Court could “agree[] with the Federal Government’s standing arguments,” ECF No. 152 at 5, but in that scenario there would be no need for this Court to decide the States’ intervention motion—which highlights why holding the States’ motion in abeyance is the most prudent course.

Moreover, a decision on the merits by the Supreme Court could also obviate the States’ intervention motion. *See, e.g., Flory v. United States*, 79 F.3d 24, 26 (5th Cir. 1996) (per curiam) (holding that because the underlying complaint was dismissed on the merits, a third party’s request to intervene in the case was moot). Additionally, if the Supreme Court were to address the statute of limitations or other threshold arguments Defendants have raised, that might affect the validity of the States’ own claims and, by extension, their intervention request. *See, e.g., Atkins v. Gen. Motors Corp.*, 701 F.2d 1124, 1130 n.5 (5th Cir. 1983) (affirming denial of intervention motion because the intervenors’ claims were time barred). The States seek to challenge FDA’s actions from March 2016, but their proposed Complaint does not identify any attempt by the States to challenge FDA’s actions within the six-year statute of limitations. *See* 28 U.S.C. § 2401(a). The proposed Complaint also does not identify any attempt by the States to present their claims to FDA, which they concede is required under FDA regulations. *See* States’ Prop. Compl., ECF No. 151-1, ¶ 159 (“The FDA’s regulations prohibit a litigant from going straight to court to challenge the agency’s approval of a new drug.”). The States do not explain why they would be excused from satisfying these requirements if they intervened to assert their own claims, and a Supreme Court decision on these issues may affect the analysis that this Court would be required to perform.

Finally, a merits decision also may inform the scope of any proceedings on remand as well as the standard of review governing any remaining claims. Currently, the States contend that allowing their intervention “will not inject significant unrelated questions of law and fact into this Court’s analysis of the unlawfulness of Defendants’ actions.” ECF No. 152 at 20. But the parties (and the Court) will be in a much better position to evaluate that proposition after Supreme Court

proceedings have concluded, and the scope of any further proceedings in this Court (if any) becomes clear.

The States will suffer no prejudice from holding their motion in abeyance. As their motion acknowledges, Defendants' deadline to respond to the Complaint is stayed, and there are no other district court proceedings scheduled to occur before the conclusion of all appellate proceedings. *See* ECF No. 152 at 10.¹ Given the absence of upcoming district court proceedings, forgoing litigation and consideration of this motion until the conclusion of Supreme Court proceedings will not prejudice the States in any way. Indeed, the States' own conduct in waiting a year after suit was instituted to seek intervention highlights that there is no particular urgency to considering their request, particularly while the next step in district court (responding to the Complaint) is stayed and appellate proceedings are ongoing. To the extent the States would somehow suffer prejudice from delayed action on their intervention motion pending completion of appellate proceedings in this case, they remain free to file their own suit in a proper forum.

2. In the alternative, to the extent the Court is not inclined to hold this motion in abeyance, Defendants respectfully request an extension of time to respond to the States' intervention motion—specifically, until 30 days after resolution of this abeyance request. This additional time is warranted to allow Defendants to review and evaluate the voluminous materials submitted in connection with the States' intervention motion, including a 105-page proposed Complaint and almost 700 pages of additional supporting materials. *See* ECF Nos. 151-1, 151-2, and 151-3. Although some of the supporting materials appear to be identical to what Plaintiffs have already submitted, the States have also submitted some new materials as well—including at least six new

¹ The States' intervention motion requests only to participate in this district court action to protect their interests prior to any final judgment, without seeking to "reconsider phases of the litigation that had already concluded." ECF No. 152 at 9 (quotation marks omitted). Resolution of the intervention motion therefore would not, by itself, entitle the States to participate in the ongoing appellate proceedings regarding the April 7 Order, for which the States would need to seek permission from the relevant appellate court and in which the States may participate as amici, as Missouri and Kansas already have.

declarations, totaling almost 100 pages, at least some of which appear to be purported expert opinions. *See* ECF No. 151-3, App. 585 – 680.

Even on the States’ own account, they took at least “two months” to prepare and file their motion for intervention. ECF No. 152 at 9. It is hardly unreasonable, therefore, for Defendants to request 30 days to prepare an opposition in the event the Court denies the abeyance request. Moreover, this additional time will also ensure that Defendants have sufficient time to prepare their opposition notwithstanding the upcoming holidays, given that Defendants’ opposition is currently due Friday, November 24, which is the Friday after Thanksgiving.

In sum, given the upcoming calendar and the States’ own decision to take at least several months to prepare their intervention motion, Defendants respectfully submit that their alternative request for 30 days following any denial of the abeyance request is warranted here.

Conclusion

The Court should hold the States’ intervention motion in abeyance, pending the resolution of Supreme Court proceedings with respect to this Court’s April 7, 2023 Order, including the petitions for a writ of certiorari and any subsequent proceedings, if applicable. Consistent with this Court’s Order staying Defendants’ answer deadline, *see* ECF No. 144, no later than two weeks after the resolution of all Supreme Court proceedings concerning this Court’s April 7, 2023 Order, the parties shall propose a new deadline for Defendants to respond to the States’ intervention motion.

November 9, 2023

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel

MARK RAZA
Associate General Counsel
U.S. Department of Health
and Human Services

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

JULIE STRAUS HARRIS
ERIC B. BECKENHAUER
Assistant Directors

/s/ Daniel Schwei
DANIEL SCHWEI
Special Counsel

Chief Counsel
Food and Drug Administration

CHRISTOPHER A. EISWERTH
EMILY NESTLER
KATE TALMOR
Trial Attorneys
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
202-305-8693
daniel.s.schwei@usdoj.gov

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Acting Director

HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch

Certificate of Conference

Pursuant to Local Civil Rule 7.1, undersigned counsel (Daniel Schwei) conferred with counsel for the other parties regarding this motion on November 8 and 9, 2023. Counsel for Defendant-Intervenor (Jessica Ellsworth) consented to both of Defendants' requests.

Counsel for the putative intervenor States (Joshua Divine) indicated that the States would be willing to "agree to a responsive filing shortly after Thanksgiving" but "cannot agree to a lengthier extension or holding this in abeyance," because "the vast majority of the complaint and attached exhibits are identical to the materials filed by the plaintiffs in this case" and because they "believe judicial efficiency is best served by an intervention." Counsel for Plaintiffs (Erik Baptist) also indicated that Plaintiffs oppose Defendants' requests but "would also agree to a responsive filing deadline shortly after Thanksgiving if necessary."

Defendants disagree for the reasons previously set forth, and therefore file this motion.

/s/ Daniel Schwei
DANIEL SCHWEI
Special Counsel
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
202-305-8693
daniel.s.schwei@usdoj.gov