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

Alliance for Hippocratic Medicine, *et al.*,

Plaintiffs,

and

State of Missouri, *et al.*,

Intervenor-Plaintiffs,

v.

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

Defendants,

and

Danco Laboratories, LLC,

Intervenor-Defendant.

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

INTERVENOR-PLAINTIFFS' BRIEF IN RESPONSE TO DEFENDANT FDA'S MOTION TO DISMISS AND TO INTERVENOR-DEFENDANT DANCO'S MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases — Page(s)

Statutes

Other Authorities

INTRODUCTION

On a Saturday night, just two days after this Court rejected their first motion, and barely one day before the incoming President's inauguration, the outgoing Biden-Harris administration moved to dismiss. That administration's attempt to displace the laws of the States by creating a nationwide, abortion-by-mail scheme—devoid of adequate safety regulations—is contrary to the promise of *Dobbs* that each State would get to choose whether and how to regulate abortion.

There is no doubt the outgoing administration's policies will lose on the merits—as this Court and the Fifth Circuit already ruled. Indeed, other than arguing about the statute of limitations and exhaustion, Defendants do not even bother to move for dismissal under Rule 12(b)(6) for failure to state a claim. Instead, they try to construct procedural hurdles—principally venue.

The problem for the outgoing administration and Danco is that those procedural roadblocks needed to be satisfied only at the time of intervention. As the Fifth Circuit held, "an intervenor can continue to litigate after dismissal of the party that originated the action" where "the parties are already in court pursuant the statutory scheme." *Harris v. Amoco Production Co*., 768 F.2d 669, 676, 678 (5th Cir. 1985). This is true even for statutes of limitations: "an intervenor seeking review of an administrative rulemaking can continue to litigate after the original party has dismissed its petition—even though the intervenor has waited beyond the statutory period within which it could have filed its own petition for review." *Id.* at 676. So long as the relevant statutes were satisfied at the time of intervention, the intervenor need not resatisfy them simply because the original plaintiffs dismissed their suit. *Id.* at 675–76. Because venue was satisfied when the States intervened, the States need not resatisfy it.

Sensing this problem, the outgoing administration and Danco resort to retroactively attacking this Court's underlying intervention decision. But there they face a high bar: they must

show that this Court's earlier intervention decision was "clearly erroneous." *Lyons v. Fisher*, 888 F.2d 1071, 1075 (5th Cir. 1989). They do not succeed.

Defendants assert that because the Supreme Court determined that the private plaintiffs lacked standing, there was never any suit to intervene in at all. But cases like *Harris* expressly permit an intervenor to continue to litigate, and Defendants' attack rests on the false premise that the private plaintiffs never had standing. As Judge Ho already explained, Defendants are wrong. The private plaintiffs did have standing when they sued. Only after "the Government switched positions before the Supreme Court," disclaiming its previous assertion, and only after the Supreme Court adopted the U.S. Solicitor General's new interpretation of federal conscience laws, did the Supreme Court hold that the private plaintiffs lost standing. *All. for Hippocratic Med. v. FDA*, 117 F.4th 336, 341 (5th Cir. 2024) (Ho, J., concurring).

So Defendants next resort to a variety of new arguments they did not bother to make in their motions filed last fall. Each fails.

On standing, the States easily have sovereign standing because FDA's actions seek to displace the States' laws. Danco calls this injury "wholly speculative," ECF 222 at 19, but the outgoing administration expressly said FDA's actions preempt state laws, and federal courts in West Virginia and North Carolina have held the same.

The States also easily establish standing through standard pocketbook injuries because—as FDA has admitted—the abortion drug sends 5% of women to the emergency room. The States as insurers cover those costs and thus are harmed. Defendants argue that this no longer satisfies the requirements for a pocketbook injury. But that argument cannot be squared with what Justice Kavanaugh referred to as the "landmark" decision in *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), where

the Supreme Court permitted an insurance company to sue over relaxed safety standards because those relaxed safety standards increased the cost to the insurance companies. *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 834 (2024) (Kavanaugh, J., concurring).

Nor are Defendants' exhaustion and statute of limitations arguments persuasive. The FDA statute does not require exhaustion, and under *Harris*, the States satisfied exhaustion anyway because it was satisfied when the States intervened. In addition, parties need not exhaust when, as here, FDA has repeatedly delayed acting on petitions for years. As to the statute of limitations, *Harris* expressly permits the States to rely on the private plaintiffs' satisfaction of the statute of limitations. And in any event, the earliest the States' harms accrued was in 2022 when *Dobbs* was decided. The States are well within the statute of limitations.

FACTS

This case concerns challenges to three FDA actions: (1) FDA's 2016 rollback of safety precautions with respect to the abortion drug, (2) FDA's 2019 shared REMS program and approval of the generic abortion drug, (3) and FDA's 2021/2023 removal of the requirement for in-person distribution of the pill—in effect endorsing nationwide abortion by mail. This case is on remand from the Supreme Court, which determined that the initial private plaintiffs lacked standing following a change in position by the Federal Government.

Before this case went to the Supreme Court, the private plaintiffs' principal theory of standing was harm to conscience. As the Supreme Court reaffirmed, "doctors would have standing to challenge a government action that likely would cause them to provide medical treatment against their consciences." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 387 (2024). This Court and two different panels of the Fifth Circuit readily concluded that the private plaintiffs had standing under that theory. And how could they not? At the time, "the Government insisted that

federal law 'requires doctors to offer abortion.'" 117 F.4th at 340, (Ho, J., concurring) (quotation and emphasis omitted). Although the Federal Government asserted in *this* case that conscience laws would protect the doctors, the Federal Government took the exact opposite position in another case before the Fifth Circuit. The court considered the government's position in that other case, *Texas v. Becerra*, 23 F. Supp. 3d 696 (N.D. Tex. 2022)—that doctors *must* provide abortions in certain circumstances contrary to their consciences—as evidence that the private plaintiffs were not "free to refuse treatment to mifepristone patients" on the basis of conscience. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 237 (5th Cir. 2023).

It was not until "the Government switched positions before the Supreme Court" that the Supreme Court determined the private plaintiffs were deprived of their principal theory of standing. 117 F.4th at 341, (Ho, J., concurring). There, the U.S. Solicitor General "disclaimed [its initial] reading" of federal law and advanced the exact opposite position from what it advanced in cases like *Texas v. Becerra*. *Id.* (quoting 602 U.S. at 389) (emphasis omitted). Armed with the Solicitor General's switched position, the Supreme Court interpreted federal conscience laws to protect the private plaintiffs in the relevant circumstances. 602 U.S. at 389–90 ("[T]he Government has disclaimed that reading of EMTALA. And we agree with the Government's view of EMTALA on that point. … In short, given the broad and comprehensive conscience protections guaranteed by federal law, the plaintiffs have not shown—and cannot show—that FDA's actions will cause them to suffer any conscience injury."). With that switch plus the Supreme Court's authoritative interpretation of federal conscience laws, the private plaintiffs no longer faced a harm to conscience; they no longer faced the looming threat of the Federal Government saying it would take enforcement action if they did not perform abortions. The previous controversy between the parties disappeared.

The Supreme Court thus reversed the Fifth Circuit's standing analysis, leaving the merits analysis intact and binding on this Court. *See Central Pines Land Co. v. United States*, 274 F.3d 881, 893 n. 57 (5th Cir. 2001) (noting that Fifth Circuit precedent remains binding when the Supreme Court, as here, reverses on other grounds but does not vacate). The Fifth Circuit then vacated this Court's stay order and remanded for further proceedings. *All. for Hippocratic Med. v. FDA*, 117 F.4th 336, 340 (5th Cir. 2024).

Two relevant things occurred after that: The private plaintiffs voluntarily dismissed their suit, and Defendants moved to dismiss for lack of venue. ECF 198, 200, 203. This Court denied those motions (but permitted leave to refile) and granted the States leave to file an amended complaint. ECF 215. Just two days later—on a Saturday night—and barely one day before President Trump's inauguration, FDA rushed to file a new motion to dismiss, this time raising a number of additional issues beyond venue. ECF 219. Danco followed later with its own motion to dismiss, also raising many new arguments not raised in its previous motion. ECF 222.

ARGUMENT

The Fifth Circuit has expressly recognized "circumstances in which an intervenor can continue to litigate after dismissal of the party that originated the action." *Harris*, 768 F.2d at 676. Those circumstances exist here where Defendants collaterally attack venue, standing, and exhaustion over a year after this Court properly permitted the States to intervene. Each of Defendants' arguments fails.

I. Venue is proper because venue existed at the time the States intervened.

Defendants do not dispute that venue was proper when the States successfully intervened. That is enough. Venue is satisfied if, at the time of intervention, at least one party has venue. *Ry. Lab. Executives' Ass'n v. I.C.C.*, 958 F.2d 252, 256 (9th Cir. 1991). This "is not only the majority view—it is the only the view adopted by the federal courts since 1971." *Sidney Coal Co., Inc. v.*

Soc. Sec. Admin., 427 F.3d 336, 345 (6th Cir. 2005). And intervention is "judged as of the time the motion [i]s ruled upon," not a year later. *Equal Empl. Opportunity Comm'n v. United Air Lines, Inc.*, 515 F.2d 946, 950 (7th Cir. 1975). Because venue was valid when the States intervened, it has been satisfied. As the Fifth Circuit put it in a case permitting an intervenor to "continue to litigate after dismissal of the party that originated the action," "[w]here the parties are already in court pursuant the statutory scheme"—here, the venue statute—"the day for complying with the calisthentics of an alternative route has come and gone." *Harris*, 768 F.2d at 678.

Defendants nonetheless claim, contra *Harris*, that the private plaintiffs' decision to voluntarily dismiss their suit retroactively makes intervention invalid and retroactively creates a venue problem. Those arguments fail.

A. Danco waived any challenge to venue.

By intervening in the first place, Danco waived any challenge to venue. *See, e.g.*, *In re Bayshore Ford Trucks Sales, Inc.*, 471 F.3d 1233, 1248 (11th Cir. 2006) ("Westgate challenges the district court's jurisdiction over its person, but by filing a successful motion to intervene, it acquiesced to such jurisdiction."); *Cnty. Sec. Agency v. Ohio Dept. of Commerce*, 296 F.3d 477, 483 (6th Cir. 2002) ("This attempt, however, was unsuccessful, because a motion to intervene is fundamentally incompatible with an objection to personal jurisdiction."); *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 59 (D.D.C. 2003), *aff'd*, 362 F.3d 817 (D.C. Cir. 2004) ("DCH voluntarily intervened … [and] cannot now be heard to object that the Court lacks jurisdiction over it or that venue is improper." (citations omitted)); 7C Wright & Miller, *Federal Practice & Procedure* § 1920 (3d ed.) ("On the other hand, the intervenor has submitted to the personal jurisdiction of the court by seeking to intervene in the action and cannot move to dismiss on that ground."). The Court should thus not consider Danco's venue arguments.

B. The States need not resatisfy venue simply because the private plaintiffs dismissed their suit.

1. The outgoing federal administration cannot now assert a venue objection simply because the private plaintiffs dismissed. The settled rule in this Circuit is that, absent a *jurisdictional* reason to dismiss, once a statutory requirement for getting into court has been satisfied, that is enough, and an intervenor can continue a suit after an original plaintiff dismisses. "[T]he propriety of intervention after the dismissal of the original plaintiffs is in large part dependent on whether the intervenor has participated in an existing suit and has an independent *jurisdictional* basis to remain or seeks to join a non-existent suit." *In re Greyhound Sec. Litig.*, 1997 WL 531317, at *5 (N.D. Tex. 1997) (emphasis added); *see also Harris*, 768 F.2d at 675–76. Here, the States have participated and have a jurisdictional basis to continue the suit. Venue, unlike standing, is not jurisdictional. *Brown v. Pyle*, 310 F.2d 95, 96 (5th Cir. 1962) ("Jurisdiction is not to be confused with venue."); *see also Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 168 (1939) (distinguishing jurisdiction from "the locality of a law suit," or venue). So the States need not independently satisfy venue where venue was satisfied when the States intervened.

Harris illustrates this rule well. There, a party intervened, only for the original plaintiffs to settle their suit and successfully dismiss it. 768 F.2d at 673–74. In holding that the intervenor's suit could proceed even though "the main plaintiffs have dropped out," the Fifth Circuit noted that there is a major difference between statutory requirements that are "'procedural' rather than 'jurisdictional' in nature." *Id.* at 675, 679. While jurisdictional requirements would bar an intervenor from continuing a suit, procedural ones would not. *Id.* at 678. The Fifth Circuit noted, for example, that courts have permitted intervenors to continue suits "after the original party has

dismissed its petition—even though the intervenor has waited beyond the statutory period within which it could have filed its own petition for review." *Id.* at 676 (citing sources).[1]

Here, that purpose has already been satisfied. Defendants are in the same venue—the exact same position—they were in when the private plaintiffs brought their suit. The Federal Government routinely defends major actions across the country. *E.g.*, *Trump v. Hawaii*, 585 U.S. 667 (2018). Danco voluntarily came to this venue when it chose to intervene, as did the States. "It would defy reason to require compliance with procedural prerequisites"—again—"whose raison d'etre … is absent." *Harris*, 768 F.2d at 678. Because venue is a procedural rather than jurisdictional requirement, and because venue was already satisfied when the States intervened, the "intervenor can continue to litigate after dismissal of the party that originated the action." *Id.* at 676.

2. Unable to wrestle with the holding that intervenors need not resatisfy nonjurisdictional requirements after dismissal by the original plaintiffs if those requirements were satisfied at the time of intervention, Defendants resort to their principal argument of asking this Court to revisit its earlier intervention decision. They assert that the private plaintiffs never had standing to begin with, so this Court's intervention decision was improper.

That fails because the underlying premise is wrong. As Judge Ho explained, the private plaintiffs *did* have standing when they first brought their suit. *All. for Hippocratic Med.*, 117 F.4th at 340–41, (Ho, J., concurring). They asserted conscience harms because the Federal Government had asserted in another suit that physicians must provide abortions contrary to their consciences. *Id.* at 341. Only after "the Government switched positions before the Supreme Court" and the

[1] Statutes of limitations are generally considered to be "procedural requirement[s]," not jurisdictional, unless Congress "clearly states" otherwise. *Wilkins v. United States*, 598 U.S. 152, 157 (2023).

Supreme Court adopted that position did the private plaintiffs lose standing. *Id.* at 341. In other words, the Supreme Court's construction of federal conscience laws—authoritatively rejecting the Federal Government's previous position that doctors like the private plaintiffs had to perform abortions in violation of their consciences—deprived the private plaintiffs of standing, according to the Supreme Court. *See id.*

Defendants were happy to rely on Judge Ho's opinion in their earlier motion to dismiss, ECF 198 at 3, but now contest this reading of the Supreme Court's decision. Any ambiguity runs against Defendants. *They* ask this Court to revisit its intervention order, so they must show the intervention order was "clearly erroneous," *Lyons*, 888 F.2d at 1075. They have not and cannot.

Defendants provide no adequate authority against this rule. Their "tidal wave of authority" is a mere puddle of cases holding only that a court can transfer or dismiss a case where it determines that the party satisfying venue lacks standing. Defendants critically cite no case suggesting that a district court must transfer or dismiss based on venue when (1) the district court permitted intervention, (2) a preliminary injunction was vacated on appeal for failure to demonstrate a likelihood of standing several months after intervention was granted, and (3) a plaintiff voluntarily dismissed their claims (4) without a court ever definitively holding that the plaintiff lacked standing to begin with. Instead, their cases involve situations where the plaintiff with venue is conclusively determined to lack standing at the outset, the opposite of what happened here. *See, e.g.*, *Miller v. Albright*, 523 U.S. 420, 426–27 (1998). They fail to cite a single case adopting their novel theory that they can assert a venue objection months or years after successful intervention simply because one party drops out of the case.

So Defendants next insist that when a plaintiff's complaint is dismissed, it is as if the suit "had never been filed." ECF 219 at 5 (citing *Ford v. Sharp*, 758 F.2d 1018, 1023–24 (5th Cir.

1985)). But Defendants "misread[ ] those decisions, which stand merely for the proposition that a person may not intervene as of right in a 'jurisdictionally or procedurally defective' suit." *Sommers v. Bank of Am., N.A.*, 835 F.3d 509, 513 n.5 (5th Cir. 2016). "[Fifth Circuit] caselaw does not forbid intervention as of right in a jurisdictionally and procedurally proper suit that has been dismissed voluntarily." *Id.*[2] Defendants cannot on this record show that the original plaintiffs lacked standing at the pleadings stage, before the Federal Government's switch in position.

Defendants also misconstrue Wright & Miller by insisting that this Court can entertain the States' suit only "if [a State] satisfies by itself the requirements of jurisdiction and venue." 7C Wright & Miller, *Federal Practice & Procedure* § 1918; ECF 222 at 13. That argument ignores cases like *Harris* and *In re Greyhound*, which say that the intervenor need only satisfy jurisdiction, not venue. That argument also ignores that the treatise makes the quoted statement to explain that intervention cannot cure venue defects but that courts may entertain an intervenor's suit separately to discourage gamesmanship. *Id.* By contrast, here, venue was proper when this Court permitted the States to intervene. And after the part of Wright & Miller that Defendants cite, the same source goes on to say that absent cases involving gamesmanship (where a party seeks to cure jurisdiction of another party), if a case involves a federal question (as this one does), then "venue objections should not be entertained." *Id.* Here, the States are not trying to keep the private plaintiffs in the suit (which is what Wright & Miller discusses) but instead are advancing the States' own arguments in a forum already well familiar with all the issues.

[2] Citing a concurrence in an unpublished decision, Danco (but not FDA) asserts this is true only when a suit is dismissed "with prejudice." ECF 222 at 12 n.2 (citing *Odle v. Flores*, 705 F. App'x 283, 285 (5th Cir. 2017) (Graves, J., concurring in rehearing denial)). Danco misreads that concurrence, which merely distinguished an intervention action from a collateral action by the same parties (such as a motion for attorney's fees). 705 F. App'x at 285.

There is also a strong connection to this venue. FDA suggests there is "no plausible connection" between this forum and the dispute, ECF 219 at 4, but they ignore that this Court has been handling this case for two years, both this Court and the Fifth Circuit have assessed the merits, and the Fifth Circuit's merits analysis is binding on this Court because the Supreme Court did not vacate the Fifth Circuit's decision. *Central Pines*, 274 F.3d at 893 n. 57. While Defendants understandably do not want to be in a court and circuit that has already preliminarily construed the merits against them, that is no justification to raise a venue challenge when there is no dispute venue was satisfied at the only relevant time: when the States intervened.

Ultimately, Defendants' cases are inapposite. They stand for the proposition that an intervening party, *at the time of intervention*, cannot intervene to cure a standing defect of the original plaintiff. But the States do not seek to confer jurisdiction on the private plaintiffs. Rather, the States seek to assert their own interests, which the States have standing to do. And the mere fact that Defendants assert that the party with venue should be dismissed a year *after* intervention does not mean this Court should dismiss or transfer—especially when both this Court and the Fifth Circuit have already carefully assessed the merits.

II. The States have standing to pursue their claims.

For the first time, Defendants press the argument that the States lack standing. Defendants have not satisfied the high standard—at the motion-to-dismiss stage—of proving that it is "certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle plaintiff to relief." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). The States have standing because they have both sovereign and pocketbook injuries.

A. The States have suffered sovereign harms.

FDA's actions harm the States' "sovereign interests" in "the power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc.* v. *Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601 (1982).

"[F]ederal preemption of state law" and "federal interference with the enforcement of state law" both create standing. *Texas* v. *United States*, 809 F.3d 134, 153 (5th Cir. 2015). That is because "a State clearly has a legitimate interest in the continued enforceability of its own statutes." *Maine* v. *Taylor*, 477 U.S. 131, 137 (1986). Specifically here, the Supreme Court has recognized state interests in respecting life, protecting maternal health, preserving the integrity of the medical profession, and protecting groups from neglect or mistakes. Compl., ECF 217 ¶¶ 471–81 (citing sources). The States have sovereign authority to pursue all these interests, yet FDA's actions have interfered with these sovereign interests in at least three ways.

1. A number of the States' laws are threatened by FDA's unlawful actions. *Id.* ¶¶ 484–517. These include (but are not limited to), (1) Idaho's prohibition on abortions except in cases of medical emergency, Idaho Code § 18-622; (2) Missouri's and Idaho's requirements that abortion patients make in-person visits before obtaining an abortion, Mo. Rev. Stat. §§ 188.027, 188.039; Idaho Code § 18-617; and (3) the requirements in Missouri and Idaho that only physicians may perform abortions, Mo. Rev. Stat. §§ 188.020, 188.080, 334.245, 334.735.3; Idaho Code § 18-608A.[3] FDA's actions directly interfere with the States' ability to create and enforce a legal code—both through a substantial risk of federal preemption and federal interference with enforcement of state law. ECF 217 ¶¶ 525–531.

None of Defendants' counterarguments holds water.

[3] Defendants raise the recently enacted constitutional amendment in Missouri, which creates a right to obtain an abortion. But neither mentions that a trial court in Missouri *denied* a preliminary injunction against Missouri's laws requiring that abortion patients make in-person visits before obtaining an abortion and that only physicians can perform abortions. Order granting in part and denying in part motion for preliminary injunction, *Comprehensive Health v. Missouri*, No. 2416-CV31931 (Dec. 20, 2024) at 18-20, https://www.courts.mo.gov/fv/c/2416-CV31931.COMP%20HEALTH.Prelim%20Injuction%20ORDER_FINAL.pdf?courtCode=16&di=26642271.

Danco asserts that this concern is "wholly speculative." ECF 222 at 19. To the contrary, the outgoing administration *expressly* stated that FDA's actions preempt state laws. ECF 217 ¶¶ 250–51. It did not disavow that position. Moreover, two federal courts have held that the same FDA actions challenged here preempt state laws. One court ruled that a West Virginia law similar to Missouri's and Idaho's laws was preempted by FDA's actions. *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D.W.Va., Aug. 24, 2023).[4] Similarly, a federal court in North Carolina last year held that FDA's challenged actions preempt state laws prohibiting non-physicians from performing abortions, requiring in-person appointments, or requiring reporting of complications—again, laws similar to those enacted by the Intervenor States. *Bryant v. Stein*, 732 F. Supp. 3d 485, 511 (M.D.N.C. 2024). Defendants note that no party has yet challenged the States' laws on preemption grounds. But they cite nothing to suggest that the States need to wait, and just yesterday, the plaintiff in the West Virginia case, GenBioPro, informed Missouri that it intends to seek intervention in this case. The States are not "required to await and undergo a … prosecution" by some other party. *Holder v. Humanitarian L. Project*, 561 U.S. 1, 15 (2010) (quotation omitted). States can assert their own rights offensively, not just defensively, to ensure that their statutes are *not* held preempted. Indeed, waiting would be procedurally unusual; it would require the States to implead the Federal Government as soon as the States' laws are challenged.

No better are Defendants' assertions that *United States v. Texas*, 599 U.S. 670 (2023), somehow bars sovereign standing. FDA tellingly relies not on arguments the Supreme Court rejected, but instead on arguments raised in the district court. ECF 219 at 10. In any event, *United*

[4] Although the plaintiff later voluntarily dismissed its (successful) preemption claim, it appears the plaintiff did so because it needed to drop the one count that was not dismissed so that the district court's ruling dismissing all other counts would become a final judgment that could be appealed. See *GenBioPro*, ECF 78 (filing a notice of appeal three days after dropping its successful preemption argument).

States v. Texas was "narrow and simply maintains the longstanding jurisprudential status quo." 599 U.S. at 686. The Supreme Court there noted that the case concerned "both a highly unusual provision of federal law and a highly unusual lawsuit" because Texas sought to "*require* the Executive Branch to make arrests or bring prosecutions," contrary to the "deeply rooted history of enforcement discretion." *Id.* at 684 (emphasis in original). Here, in contrast, the States are not seeking to require FDA to take enforcement action. Rather, the States seek to block FDA's affirmative and unlawful attempt to make legal *under state law* what used to be illegal.[5]

Indeed, the States have adequately pleaded that FDA's previous position allowed the promise of *Dobbs* to flourish. Different States could make different decisions on abortion. But FDA's decision to enable private parties to distribute abortion drugs nationwide through the mail has propped up a robust industry designed to evade the States' laws. Beginning in summer 2023, organizations started shipping abortion drugs into all 50 States in large quantities in an attempt to evade state laws. These organizations expressly relied on what they called "an FDA-approved pipeline" created by the FDA actions challenged here. *E.g.*, Compl., ECF 217 ¶¶ 5, 300–370. According to just one report, in less than a month, seven U.S. based providers mailed 3,500 doses of mifepristone to States that have banned the use of chemical abortions or have prohibited distribution of those chemical by mail. *Id.* ¶ 317. Their capacity has only grown since then.

Just a few years ago, the Supreme Court unanimously held that States establish standing when they raise claims based not on "mere speculation" but "instead on the predictable effect of Government action on the decisions of third parties." *Department of Commerce v. New York*, 588

[5] For several reasons, Defendants' reliance on *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024), is unavailing. There, the Ninth Circuit ruled that the purported intervenor States did "not, however, allege that the 2023 REMS preempts or otherwise interferes with the [intervenor States'] *authority* to enact or enforce restrictions." *Id.* at 1177 (emphasis in original). The States here do allege that.

U.S. 752, 768 (2019). When FDA unlawfully removed its previous requirements for in-person distribution, it was "predictable" that private parties would start mailing those pills. There is nothing "attenuated" about people doing exactly what FDA expressly encourages them to do.

Indeed, the link here is much more direct than in *Department of Commerce*. There, the Supreme Court unanimously held that States could sue under the theory that a citizenship question would cause private parties to "unlawfully" decline to fill out the Census, causing an undercount in various States. *Id.* Here, FDA expressly (and wrongly) told the world it is *lawful* to mail abortion drugs into all 50 States. ECF 217 ¶¶ 55, 230–232, 288. The actions of private parties in *Department of Commerce* were a "predictable" but *unintended* effect of the agency. Here, mailing abortions into all 50 States is the *intended* effect of FDA's actions.

2. FDA's decisions have similarly deprived Plaintiff States of their sovereign "benefits that are to flow from participation in the federal system." *Snapp*, 458 U.S. at 608. One benefit is uniform application of federal law and the ability of States to rely on the backdrop of federal law when enacting their own regulations. *See id.*; *Crow Indian Tribe v. United States*, 965 F.3d 662, 676–77 (9th Cir. 2020). FDA's actions have the direct effect of enabling and encouraging third parties to provide, through the mail, mifepristone to citizens of Plaintiff States for the purpose of inducing abortions that are riskier than surgical abortions and that are expressly contrary to the policies expressed in many of those States' statutes. Indeed, for all their mention of Missouri's recent constitutional amendment permitting abortion in *some* circumstances, neither FDA nor Danco acknowledges that Missouri's amendment expressly permits regulation consistent with "accepted clinical standards of practice." Mo. Const. art. I § 36. Missouri has a vested interest in the standards that FDA establishes. Those standards are "benefits that are to flow from

participation in the federal system." *Snapp*, 458 U.S. at 608. FDA's unlawful decision has restricted those benefits.

3. Finally, "Plaintiff States also suffer injuries from the loss of fetal life and potential births, leading to a resulting reduction in the actual or potential population of each state." ECF 217 ¶ 746. If the mere undercounting of a State's population creates standing, as the Supreme Court unanimously concluded, *Department of Commerce*, 588 U.S. at 766–67, it is even more clearly true that the actual loss of population creates standing too. Contrary to Danco's suggestion, the States are not arguing that the shifting population from one State to another (such as by closure of a military base) confers standing. Courts surely can distinguish government actions *designed* to cause loss of life from those designed for some other purpose that has only an attenuated connection to population. After all, the Supreme Court has expressly recognized "States' interest in protecting fetal life." *Dobbs v. Jackson Women's Health Org*., 597 U.S. 215, 262 (2022).

B. <u>The States have suffered traditional economic harms.</u>

1. The States have standing because they have suffered traditional economic injury. *See Biden v. Nebraska*, 143 S. Ct. 2355, 2366 (2023) ("financial harm is an injury in fact"); *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. The most obvious are traditional tangible harms, such as physical harms and monetary harms.").

The States allege many economic harms caused by Defendants, including (1) increased public insurance costs for emergency medical procedures and mental health support for women who experience complications from chemical abortions; and (2) diversion of resources by public hospitals to care for those who experience complications. ECF 217 ¶¶ 593–746.

Defendants "do not dispute that a significant percentage of women who take mifepristone experience adverse effects," with close to 5 percent requiring emergency room care. *All. for*

Hippocratic Med., 78 F.4th at 229. It is even *worse* when drugs are mailed. FDA cited studies showing rates as high as 12.5% when pills are mailed. ECF 217 ¶¶ 191–94. And the States have pleaded that these costs, at the population level, are borne by the States through insurance programs like Medicaid and state-employer insurance. *Id.* ¶¶ 618–725. The States also alleged that these tragedies impose costs on States for mental health support, *id.* ¶¶ 736–745, and state-run hospitals, *id*. ¶¶ 726–735. These "monetary harms," under established precedent, "readily qualify as concrete injuries under Article III." *TransUnion*, 594 U.S. at 425.

Based on FDA's acknowledgment that close to 5 percent of women taking the abortion drug require emergency room care, and based on data about how many women obtain chemical abortions in the States, Missouri pays for emergency room care for about a dozen women every year, with Idaho paying for about half of that. ECF 217 ¶¶ 694–95. These figures do not even include the costs paid for by other state insurance programs, such as insurance for state employees. As the States allege, "Plaintiff States pay for some of the emergency medical costs associated with chemical abortions for women who are on Medicaid or other public insurance, such as insurance programs provided to government employees." *Id.* ¶ 702; *see also id.* ¶¶ 703–725. HHS has said that the covered charge of each of these visits in 2017 ran $420 on average. *Id.* ¶ 704. That number is higher now after inflation, and "[o]f course, a Medicaid 'covered charge' figure may be a fraction of total costs for that visit." *Id.* "For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'" *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

Similarly, the States pay for treatments at public hospitals (which are required under federal law to provide stabilizing treatments) and pay "for mental health care for the increasing number of women suffering negative effects from chemical abortion drugs." *Id.* ¶¶ 726–45.

The States need only plead a "'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (citation omitted). The States have established by "statistical certainty," ECF 217 ¶ 700, that FDA's actions harm the States.

2. None of Defendants' counterarguments work. Indeed, it is telling that Danco, unable to contest the well-pleaded allegations, resorts to factual assertions *outside* the pleadings. *E.g.*, ECF 222 at 16–18. Those arguments are all improper at this stage.

Defendants argue that the statistically certain harms to the States are too indirect. But FDA previously conceded this kind of statistical argument is sufficient. At oral argument before the Fifth Circuit, FDA was asked why the private plaintiffs lack standing given the unanimous ruling that plaintiffs in *Department of Commerce* had standing. FDA responded that, in *Department of Commerce*, "the plaintiffs were states," meaning "the effects [of challenged federal action] on them happened at the population level," and the States could thus "rely on population-wide statistics and probabilities." ECF 217 ¶ 418; Oral Arg. Rec. at 17:16–17:42 (May 17, 2023).[6]

In other words, the States need not identify *specific* women for whom they have paid and will pay for emergency medical care caused by FDA's policies—just like the States in *Department of Commerce* did not identify specific people who would refuse to fill out the Census. It is enough that FDA acknowledges that close to 5 percent of women are forced to seek emergency medical services. The States can rely on those "population-wide statistics and probabilities" to show that the States bear costs because of FDA's decision to remove safety precautions. It is of course true that the States experience loss only after private parties engage in certain actions. But it is the "predictable effect of Government action," *Dept. of Com.*, 588 U.S. at 768, that women harmed by mifepristone because of FDA's actions will seek services paid for by the States.

[6] https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3

These connections between FDA's actions and loss of revenue (including Medicaid revenue) is much closer than in *Department of Commerce*. "Medicaid … is designed to advance cooperative federalism." *Wisconsin Dep't of Health and Fam. Servs. v. Blumer*, 534 U.S. 473, 495 (2002). And yet FDA's actions increase the number of women who must seek emergency medical care, including care paid for by Medicaid. At the same time that the States have agreed to operate a cooperative-federalism program to cover emergency medical costs, FDA has taken action to drain state resources that go into that program.

Against all this, Defendants argue that insurance organizations have no standing in this context because the Supreme Court ruled that "doctors" lack standing "to challenge the government's loosening of general public safety requirements." *All. for Hippocratic Med.*, 602 U.S. at 391. But in the same opinion, the Supreme Court reiterated "familiar circumstances where government regulation of a third-party individual or business may be likely to cause injury in fact to an unregulated plaintiff." *Id.* at 384.[7] "One example is the Court's landmark decision in *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983)." *Corner Post*, 603 U.S. at 834 (Kavanaugh, J., concurring). "That case arose when several insurance companies challenged a federal agency's rescission of safety standards for new motor vehicles." *Id.* While *doctors* may not have standing to sue over rescission of safety standards, insurance organizations under the "landmark" *State Farm* decision do. *Cf. California v. Azar*, 911 F.3d 558, 571–73 (9th Cir. 2018) (State had standing based on injury to its economic interests where the State was responsible for reimbursing women who seek

[7] FDA is thus wrong to assert (ECF 219 at 11–12) that a plaintiff may *never* satisfy standing by relying on "indirect effects." *Alliance for Hippocratic Medicine* and a host of other cases expressly reject that argument. *E.g.*, 602 U.S. at 382.

contraception through state-run programs); *contra Washington*, 108 F.4th at 1175–76 (failing to cite or consider *State Farm*).

Decisions like *State Farm* show that third-party insurers or payers like State Medicaid and health insurance programs have standing to seek redress from deregulatory actions that harm them. "At no point in that landmark opinion on the judicial review of agency actions did the Court state (or need to state) the obvious: Because the agency did not regulate the insurers themselves, the insurers could obtain relief from the downstream effects of the agency's rescission of the safety standards only if the insurers could obtain vacatur of that rescission." *Corner Post*, 603 U.S. at 834–35 (Kavanaugh, J., concurring).

Finally, Danco suggests (at 22 n.4) that the States' harms might "have occurred anyway based on mifepristone's original approval." But Danco assuredly does not believe that; otherwise Danco would have no right to be here. And the States did plead that these actions increased the use of abortion drugs compared to surgical abortion. *E.g.*, ECF 217 ¶ 753 ("By approving a generic version of the drug, the FDA increased supply and availability, lowering cost and thus increasing use of chemical abortions."); *see also id.* ¶¶ 749–51 (discussing overall increase of abortions, especially abortions by pill, from all of FDA's actions).

For all of these reasons, the States' complaint should not be dismissed for want of standing.

III. The States' challenge to the 2016 Major Changes is not time barred.

Defendants also raise statute-of-limitations objections to the States' challenge to the FDA's 2016 Major Changes. They note that the statute of limitations is six years, and they argue that the States did not satisfy that limit. That argument fails for five reasons.

First, *Harris* has already rejected the idea that an intervenor needs to resatisfy the statute of limitations originally satisfied by the original party. As noted above, the Fifth Circuit permits an intervenor to rely on parties who "are already in court pursuant the statutory scheme." *Harris*,

768 F.2d at 678. In support of this rule, *Harris* favorably cited a number of decisions for the proposition that "an intervenor seeking review of an administrative rulemaking can continue to litigate after the original party has dismissed its petition—even though the intervenor has waited beyond the statutory period within which it could have filed its own petition for review." *Id.* at 676. The States satisfy the statute of limitations because the original plaintiffs did. They filed a citizen petition in 2019, which was not denied until 2021, a year before they sued. ECF 217 ¶ 176.

Second, the States' claims arose at the earliest when the Supreme Court decided *Dobbs* in 2022, one year before the States intervened. An APA claim does not accrue "until the plaintiff is injured by final agency action." *Corner Post*, 603 U.S. at 825. The States' injuries were not realized until *Dobbs* enabled States to regulate and prohibit abortion. Abortion drugs are available up to ten weeks gestation under the 2016 Major Changes, which is considerably before viability. ECF 217 ¶¶ 54, 254, 256. Only post-*Dobbs* could the States fully regulate abortion within the time frame for chemical abortion, and only post-*Dobbs* do States that have few abortion restrictions see an influx of women seeking abortion from States with many abortion restrictions.

This is relevant because the complaint partly turns on the effect of *Dobbs* on women traveling out of state to get abortions and returning to hospitals in their home States. Pre-*Dobbs*, women could obtain abortion drugs in their own States because abortion at that stage of pregnancy was legal in all fifty States. Following *Dobbs*, abortion providers in States with legal abortion "confirmed that they now dispense abortion drugs to residents of Plaintiff States who travel to them outside of Plaintiff States and then leave follow-up care to Plaintiff States' emergency providers—all because the FDA enabled these abortion providers not to provide continuous follow-up care or three in-person doctor visits." ECF 217 ¶ 258. Accordingly, the cause of action

did not accrue until at least June 2022, when the Supreme Court decided *Dobbs*. Thus, the States brought suit well within the six-year statute of limitation provided by 28 U.S.C. § 2401(a).

Third, even if the action accrued before *Dobbs*, federal law expressly tolls the statute of limitations for any party "under legal disability" and says an action "may be commenced within three years after the disability ceases." 28 U.S.C. § 2401(a). The States were "under legal disability" while *Roe v. Wade* was on the books.

Fourth, the States are newly injured every time their statutes are put at risk or they have to pay for complications created by the abortion drug. Each State "suffers an injury from final agency action" every time one of these things occurs. *Corner Post*, 603 U.S. at 809. As Justice Jackson recognized, *Corner Post* makes "fair game" the "APA challenge to the Food and Drug Administration's approval of the abortion medication mifepristone that was brought more than two decades after the relevant agency action." *Id.* at 861 (Jackson, J., dissenting). The States are challenging actions much *later* than the 2000 action Justice Jackson pronounced to be "fair game."

Fifth, the States' suit is timely because FDA denied the 2019 Citizen Petition challenging the 2016 Major Changes in 2021, which reopened the 2016 Major Changes. The administrative reopening doctrine can restart the statute of limitations clock if "the agency opened the issue up anew, and then reexamined and reaffirmed its prior decision," or "if the revision of accompanying regulations significantly alters the stakes of judicial review as the result of a change that could not have been reasonably anticipated." *Natural Resources Defense Council v. EPA*, 571 F.3d 1245, 1265 (D.C. Cir. 2009). As the Fifth Circuit already concluded, FDA's letter dated December 16, 2021, in response to the 2019 Citizen Petition reopened the 2016 Major Changes because the letter "shows that the agency reviewed the conditions for use that the citizen petition had put at issue," *All. for Hippocratic Med.*, 78 F.4th at 244. Thus, FDA reopened the matter of the 2016 Major

Changes, meaning that the statute of limitations began running in December 2021 after FDA ruled on the 2019 Citizen Petition. Accordingly, the States' complaint falls well within the six-year statute of limitation provided by 28 U.S.C. 2401(a).

IV. The States did not need to exhaust administrative remedies before filing suit, and if they did, an exception applies.

Contrary to Defendants' assertion, FDA's own regulations do not trigger an exhaustion requirement. Accordingly, the States did not need to first seek administrative relief. The APA directs parties to exhaust administrative remedies only if required by statute or an agency rule that "provides that the action meanwhile *is inoperative*, for an appeal to superior agency authority." 5 U.S.C. § 704 (emphasis added); *see also Darby v. Cisneros*, 509 U.S. 137, 154 (1993). No such statute or FDA rule exists; all the challenged FDA actions remain operative during the pendency of an administrative appeal. Thus, the States' suit is proper.

Even if the States were required to exhaust all administrative remedies (they were not), Defendants' arguments again flout *Harris*. When parties "are already in court pursuant the statutory scheme," the intervenor need not independently satisfy that scheme. *Harris*, 768 F.2d at 678. Because the private plaintiffs satisfied any exhaustion requirement, the States did too when they intervened. FDA's argument that the 2019 Citizen Petition did not include all the States' claims is wrong and irrelevant. The 2019 petition expressly asked FDA not only to reverse the 2016 changes, but also not to relax any other standards. ECF 1-36 at 3. It fully encompasses the relief the States are seeking. Also, in its response to that petition, FDA stated that it undertook a "full review of the Mifepristone REMS Program." Ex. 34 to ECF 217. That review necessarily encompassed both the effect of mifepristone on minors and approval of the generic drug.

In addition, this Court has already recognized that many exceptions to exhaustion apply here. Most notably, "exhaustion is not required where the agency action is 'in excess of' the

agency's authority." *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 538 (N.D. Tex. April 7, 2023), ECF 137 at 27. That is exactly what the States are asserting. The same is true "where the agency action is 'likely to result in individual injustice' or is 'contrary to an important public policy extending beyond the rights of the individual litigants,'" or where a separate party raised the issue "with sufficient clarity to allow the decision maker to understand and rule on the issue raised." *Id.* at 27–28. All these things apply, as this Court already held. *Id.* at 27–31.

Similarly, the Fifth Circuit has held that "there is a judicial exception to exhaustion when exhaustion would be futile or inadequate." *Gardner v. Sch. Bd. Caddo Par.*, 958 F.2d 108, 112 (5th Cir. 1992). This exception is available "when the plaintiff demonstrates that 'it would be futile to comply with the administrative procedures because it is clear that the claim will be rejected.'" *DCP Farms v. Yeutter*, 957 F.2d 1183, 1189 (5th Cir. 1992) (cleaned up). The States' claims perfectly fit that bill. Indeed, this Court already determined that exhaustion would have been futile. ECF 137 at 30–31.

It would have been futile for States to bring an administrative challenge to the 2016 Major Changes after FDA already reconsidered them by means of the 2019 Citizen Petition, which FDA responded to in 2021 by stating that it undertook a "full review of the Mifepristone REMS Program." Ex. 34 to ECF 217. Exhaustion would also be futile with respect to the 2019, 2021, and 2023 changes because of FDA's dilatory practices in responding to administrative petitions urging review of its actions. For instance, FDA did not respond to the 2019 Citizen Petition until the end of 2021. *Id.* And that timeline is the average, not an anomaly. One review found that the FDA responds to fewer than one-third of REMS petitions before 180 days, "with petitioners languishing

for an average of 937.6 days (2.56 years) before the FDA" permits exhaustion.[8] Indeed, FDA waited nearly *fourteen years* before responding to a petition about the underlying 2000 decision to authorize mifepristone in the first place. Ex. 22 to ECF 217.

Finally, many other exceptions apply. As this Court concluded, exhaustion does not apply when an agency exceeds its authority,

CONCLUSION

This Court did not clearly err in granting the States' motion to intervene. At that time, venue, the statute of limitations, and any exhaustion requirement were secured. The private plaintiffs' dismissal does not require the States to resatisfy procedural requirements that were satisfied when the States intervened. And the States have standing by virtue of their sovereign and economic injuries. The Court should deny Defendants' motions to dismiss.

[8] Michael Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, 77 Vanderbilt L. Rev. 937, 937 (2024).

Dated: February 20, 2025

Respectfully submitted,

ANDREW BAILEY
Missouri Attorney General

/s/ *Joshua M. Divine*
*Joshua M. Divine, #69875MO
Solicitor General
Maria Lanahan, #65956MO
Deputy Solicitor General
*Samuel C. Freedlund, #73707MO
Deputy Solicitor General

Office of the Attorney General
Supreme Court Building
207 W. High Street
P.O. Box 899
Jefferson City, MO 65102
(573) 751-8870
(573) 751-0774 (fax)
Josh.Divine@ago.mo.gov
Maria.Lanahan@ago.mo.gov
Samuel.Freedlund@ago.mo.gov

KRIS W. KOBACH
Attorney General of Kansas

/s/ Erin B. Gaide
James Rodriguez, #29172KS
Assistant Attorney General
*Erin B. Gaide, #29691KS
Assistant Attorney General

Office of the Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, KS 66612
(785) 296-7109
(785) 296-3131 (fax)
Erin.Gaide@ag.ks.gov

RAÚL R. LABRADOR
Idaho Attorney General

/s/ *Michael A. Zarian*
Michael A. Zarian #24115978
Deputy Solicitor General
**James E.M. Craig, #6365ID
Chief, Civil Litigation and Constitutional Defense

Office of the Attorney General
700 W. Jefferson St., Suite 210,
PO Box 83720
Boise, Idaho 83720
(208) 334-2400
michael.zarian@ag.idaho.gov
james.craig@ag.idaho.gov

Counsel for Plaintiff-Intervenors

* *admitted pro hac vice*
** *pro hac vice application forthcoming*

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with Local Rule 7.2 in that the brief does not exceed 25 pages (it is 25 pages), excluding the cover, tables, signature block, and certificates.

/s/ Joshua M. Divine

CERTIFICATE OF SERVICE

I hereby certify that, on February 20, 2025 the foregoing was filed electronically through the Court's electronic filing system and served by email on all parties.

/s/ Joshua M. Divine