UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI et al.,	)	
	)	
Intervenor-Plaintiffs,	)	
	)	
v.	)	Case No. 4:25-CV-1580-CMS
	)	
U.S. FOOD AND DRUG ADMINISTRATION et al.,	)	
	)	
Defendants.	)	

INTERVENOR-PLAINTIFFS' CONSOLIDATED OPPOSITION TO FEDERAL DEFENDANTS' MOTION TO STAY OR, ALTERNATIVELY, TO DISMISS THE CASE; DANCO LABORATORIES, LLC'S MOTION TO DISMISS; AND GENBIOPRO'S MOTION TO DISMISS

Oral Argument Requested

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INTRODUCTION

Since 2016, FDA has regulated the abortion pill under unlawful and utterly inadequate safety regulations. The Biden Administration doubled down on these unlawful regulations—explicitly attempting to displace many States' laws by creating a nationwide, abortion-by-mail scheme. In September 2025, FDA embraced the Biden Administration's policy by approving the abortion pill's second generic version. As the federal government seemingly recognizes, Doc. 293-1 at 6–7, the Fifth Circuit's prior merits ruling leaves little doubt these policies will lose on the merits, *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 245–51 (5th Cir. 2023) ("*Alliance II*"), *rev'd on other grounds*, 602 U.S. 367 (2024). Defendants thus try to dodge a merits ruling by seeking an indefinite stay of this case and alternatively claiming that this Court should dismiss for lack of standing, failure to exhaust administrative remedies, and because challenges to the 2016 administrative actions are allegedly beyond the statute of limitations. Each argument fails.

To start, the States easily plead standing. First, the States have sovereign standing because FDA's actions seek to displace the States' abortion laws—despite the Supreme Court's promise in *Dobbs*[1] that each State would get to choose whether and how to regulate abortion. Danco calls this injury "highly speculative," Doc. 295 at 16, but the Biden Administration expressly said FDA's actions preempt state laws, and federal courts have held the same. Second, the States establish standing through standard pocketbook injuries. FDA has admitted that the abortion drug sends five percent of women to the emergency room. The States as insurers cover those costs and thus are harmed. Defendants' argument that this no longer satisfies the requirements for a pocketbook injury because it is too "attenuated" is foreclosed by *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29

[1] *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022).

(1983). In that "landmark decision," 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). So too here. The States have pleaded concrete facts showing that Defendants' actions will increase their costs as insurers. *See, e.g.*, Doc. 217 ¶¶ 604–725, 736–45. Nor is this surprising; mailing abortion pills into all 50 States—and thus increasing Plaintiff States' insurance costs—was the intended and predictable effect of FDA's actions.

Nor are Defendants' exhaustion and statute of limitations arguments persuasive. The APA does not require the States to exhaust FDA administrative remedies; and, regardless, parties need not exhaust when, as here, FDA has repeatedly delayed acting on petitions for years and has abused the administrative process. And an APA claim does not accrue "until the plaintiff is injured by final agency action." *Corner Post*, 603 U.S. at 825 (majority op.). The earliest the States' harms accrued was in 2022 when *Dobbs* was decided. The States are well within the statute of limitations.

Finally, Defendants' attempt to indefinitely stay this case is merely a tactical move to stall litigation on a contentious issue they would rather ignore. They have fallen far short of proving that they will face hardship or inequity if this case proceeds. The Court should deny their motion.

FACTS

The States challenge four FDA actions: (1) FDA's 2016 rollback of safety precautions regarding the abortion drug, (2) FDA's 2019 shared REMS program and approval of GenBioPro, Inc.'s generic abortion drug, (3) FDA's 2021/2023 removal of the requirement for in-person distribution of the pill, and (4) FDA's 2025 approval of Evita Solutions LLC's generic abortion drug. This case began in the Northern District of Texas with private plaintiffs and is on remand from the Supreme Court, which determined that those plaintiffs lacked standing, following a

change in position by the Federal Government. *All. for Hippocratic Med. v. FDA*, 117 F.4th 336, 341 (5th Cir. 2024) (per curiam) (Ho, J., concurring). With that switch plus the Supreme Court's authoritative interpretation of federal conscience laws, the private plaintiffs no longer faced a harm to conscience or a looming threat of the federal government saying it would take enforcement action if they did not perform abortions. The parties' previous controversy thus disappeared.[2]

Following the remand, the private plaintiffs voluntarily dismissed their suit, Doc. 203, and the States filed an amended complaint, Doc. 217. Defendants and Danco then moved to dismiss the States' amended complaint, Doc. 218, 221, but the original district court instead transferred this case to this Court, Doc. 273. The States then filed a supplemental complaint. Doc. 281.

ARGUMENT

Defendants and the manufacturers now move to dismiss the States' amended and supplemental complaints and to stay this case despite offering no assurance that FDA will initiate a new rulemaking—much less resolve the States' justifiable concerns. Doc. 293, 295, 297. None of Defendants' or the manufacturers' arguments has merit.

I. The States have standing to pursue their claims.

Defendants press the argument that the States lack standing, but they ignore that at the pleading stage, the States' allegations are accepted as true and that the States are given all favorable inferences. *E.g.*, *Carlsen v. GameStop, Inc.*, 833 F.3d 903, 908 (8th Cir. 2016). If the allegations plausibly allege standing, then Defendants' argument fails. *Johnson v. Griffin*, 69 F.4th 506, 510

[2] Defendants and GenBioPro are thus wrong to suggest no party had standing when this case was originally filed. Doc. 293-1 at 14–15; Doc. 297-1 at 6–7; *but see* Doc. 273 at 11–15. Even if the initial plaintiffs did not have standing, this Court need not dismiss the States' claims because the States independently satisfy the jurisdictional requirements. *In re Grand Jury Proceedings (Malone)*, 655 F.2d 882, 886 (8th Cir. 1981) ("[I]f there is an independent basis of jurisdiction as to the intervenor, a district court has discretion to treat the intervention as a separate action."); *Minn. Pub. Interest Research Grp. v. Selective Serv. Sys.*, 557 F. Supp. 925, 936 (D. Minn. 1983) ("By allowing the action to continue with respect to the intervenors, the court can avoid the senseless 'delay and expense of a new suit, which at long last [would] merely bring the parties to the point where they now are.'" (quoting *Hackner v. Guar. Trust Co.*, 117 F.2d 95, 98 (2d Cir. 1941)); 7C Wright & Miller's Federal Practice & Procedure § 1917 (3d ed. 2025).

(8th Cir. 2023). The States have standing because they have pleaded concrete 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).

The FDA's actions have interfered with the States' ability to enforce a host of their laws, Doc. 217 ¶¶ 484–517, including with (1) a prohibition on abortions except in cases of medical emergency, Mo. Rev. Stat. § 188.017.2; (2) requirements that abortion patients make in-person visits before obtaining an abortion, Mo. Rev. Stat. § 188.027; Idaho Code § 18-617; (3) requirements that only physicians may perform abortions, Mo. Rev. Stat. §§ 188.020, 188.080, 334.245, 334.735.3; Idaho Code § 18-608A; and (4) a requirement that before prescribing or administering the abortion drug, physicians must obtain approval of a complication plan "to ensure the safety of any patient," Mo. Rev. Stat. § 188.021.2. 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. Doc. 217 ¶¶ 525–31. This interference with the States' laws was "the whole point of the regulations." *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 110, 114 (2025). FDA "target[ed]" pro-life States through the "conduit" of abortion-drug prescribers—seeking to "impede[]" state pro-life laws. *Id.* at 115–16.

None of Defendants' counterarguments holds water. First, Danco asserts that this concern is "highly speculative." Doc. 295 at 16. To the contrary, the Biden administration *expressly* stated

that FDA's actions preempt state laws. Doc. 217 ¶¶ 250–52. FDA never disavowed that position.[3] Moreover, two federal courts have held that the same FDA actions challenged here preempt state laws. *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D. W. Va., Aug. 24, 2023);[4] *Bryant v. Stein*, 732 F. Supp. 3d 485, 511 (M.D.N.C. 2024). Danco notes that no party has yet challenged Plaintiffs' laws on preemption grounds, *see* Doc. 295 at 16, but 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 federal statutes do *not* preempt their statutes. Indeed, waiting would be procedurally unusual; it would require the States to implead the federal government as soon as Plaintiffs' laws are challenged.

Next, Defendants invoke *United States v. Texas*, 599 U.S. 670 (2023), as a broad anti-sovereign standing case, but that case was "narrow and simply maintain[ed] the longstanding jurisprudential status quo." 599 U.S. at 686. The Supreme Court addressed "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 removed). 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 what would otherwise be illegal under state law.

Relatedly, Defendants' and the manufacturers' reliance on *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024), is unavailing. Doc. 293-1 at 16–18; Doc. 295 at 7, 11; Doc. 297-1 at 9.

[3] Defendants do seemingly disavow this position now. Doc. 293-1 at 16. But, like their *post hoc* study into the safety of mifepristone, that representation "must be viewed critically"—*post hoc* rationalizations for agency actions are impermissible. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 21–23 (2020) (citation omitted).

[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*, Doc. 78 (filing a notice of appeal three days after dropping its successful preemption argument).

There, the Ninth Circuit ruled that the purported intervenor States did "not . . . allege that the 2023 REMS preempts or otherwise interferes with [their] *authority* to enact or enforce restrictions." *Id.* at 1177 (emphasis in original). The States here do allege precisely that. Finding standing requires nothing more than reaffirming the right of States to challenge federal regulatory actions that interfere with enforcement of state laws. *See Texas v. United States*, 809 F.3d at 153 & n.39.

Finally, Danco suggests that some of the States' abortion laws have already been voided by state constitutional abortion rights. Doc. 295 at 17. To start, Missouri has a concrete interest in preventing federal preemption of all its abortion laws—even those preliminarily enjoined in ongoing litigation that is nowhere near a final judgment. *Comprehensive Health of Planned Parenthood Great Plains v. Missouri*, No. 2416-CV31931, 2025 WL 1898975 (Mo. Cir. Ct. July 3, 2025). In any event, many of Missouri's laws regulating mifepristone remain in place. For example, Missouri still bans the dispensing of mifepristone where a complication plan is not in place, Mo. Rev. Stat. § 188.021.2, and requires abortion providers to carry insurance "for personal injury to or death of a child who survives . . . abortion," Mo. Rev. Stat. § 188.044. Defendants' actions jeopardize these laws with preemption, and Missouri has a concrete interest in avoiding such preemption. *See Tex. Off. of Pub. Util. Couns. v. FCC*, 183 F.3d 393, 449 (5th Cir. 1999).

B. The States have suffered traditional economic harms.

1. The States also have standing because they have suffered traditional economic injury. *See Biden v. Nebraska*, 600 U.S. 477, 490 (2023) ("[F]inancial harm is an injury in fact . . . ."). 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. Doc. 217 ¶¶ 593–746.

Defendants "do not dispute that a significant percentage of women who take mifepristone experience adverse effects." *Alliance II*, 78 F.4th at 229; Doc. 217 at 618. Considering FDA's acknowledgment that close to five percent of women taking the abortion drug require emergency room care and 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. Doc. 217 ¶¶ 693–95; Doc. 217-6 at 482–85, 498; *see also* Ex. A. The complication rate is even worse when drugs are mailed. FDA cited studies showing rates as high as 12.5% when pills are mailed. Doc. 217 ¶¶ 191–94. And the States have pleaded that they borne these costs through insurance programs like Medicaid and state-employer insurance. *Id.* ¶¶ 618–725. Further, these tragedies impose costs on States for mental health support, *id.* ¶¶ 736–45, and state-run hospitals, *id.* ¶¶ 726–35. These "monetary harms" "readily qualify as concrete injuries under Article III." *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 425 (2021).

"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) (citation omitted). 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). Plaintiffs' pleadings easily satisfy that standard. As the States allege, their "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." Doc. 217 ¶ 702; *see also id.* ¶¶ 703–25. 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.* Plaintiffs have established by "statistical certainty," Doc. 217 ¶ 700, that FDA's actions harm their pocketbooks.

2. None of Defendants' counterarguments work.

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 lacked standing given the unanimous ruling that plaintiffs in *Department of Commerce v. New York*, 588 U.S. 752 (2019), 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." Doc. 217 ¶ 418.

In other words, the DOJ agrees that 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 five percent of women are forced to seek emergency medical services. Doc. 217 ¶ 65. 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. The States of course experience loss only after private parties engage in certain actions. But the "predictable effect" of FDA's actions, *Dept. of Com.*, 588 U.S. at 768, is that women harmed by mifepristone because of FDA's actions will seek services paid for by the States.

These connections between FDA's actions and loss of revenue (including Medicaid revenue) is much closer than in *Department of Commerce*. The actions of private parties in *Department of Commerce* were a "predictable" but *unintended* effect of the agency action. *Dep't of Com.*, 588 U.S. at 768. But here, FDA openly admitted that it *intended* for private organizations to mail abortion pills into all 50 States. Doc. 217 ¶¶ 55, 230–32, 288; *Diamond*, 606 U.S. at 118. Consistent with the FDA's stated intent, in 2023, organizations started shipping abortion drugs

into all 50 States in large quantities in an attempt to evade state laws—citing the "FDA-approved pipeline." *E.g.*, Doc. 217 ¶¶ 5, 300–70. There is nothing "attenuated" about people doing exactly what FDA expressly encourages them to do.

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. v. FDA*, 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. For example, in *State Farm*, "several insurance companies challenged a federal agency's rescission of safety standards for new motor vehicles." *Corner Post*, 603 U.S. at 834 (Kavanaugh, J., concurring). 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. *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 contraception through state-run programs); *contra Washington*, 108 F.4th at 1175–76 (failing to consider *State Farm*). This is particularly true where, as here, the third party is the object of the regulatory actions. *See, e.g.*, *Diamond*, 606 U.S. at 114; *Mirabelli v. Bonta*, 146 S. Ct. 797, 803 (2026).

Finally, the manufacturers suggests that the States' harms might occur even under the pre-2016 labeling, rendering the States' harms not redressable by the relief the States seek. Doc. 295 at 13–14; Doc. 297-1 at 8. But they assuredly do not believe that; otherwise they would have no right to be here. *Swinton v. SquareTrade, Inc.*, 960 F.3d 1001, 1004 (8th Cir. 2020) (intervention proper only if proposed intervenor shows that its interests would be impaired if it did

not intervene). And the States did plead that these actions increased the use of abortion drugs compared to surgical abortion. *E.g.*, Doc. 217 ¶ 753; *see also id.* ¶¶ 749–51.

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

C. The States fall within the relevant zone of interests.

The manufacturers, but not FDA, claim that the States do not fall within the FDCA's zone of interests. Doc. 295 at 19–20; Doc. 297-1 at 10. A plaintiff need only be "'arguably within the zone of interests to be protected or regulated by the statute' that he says was violated." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (citation omitted). A suit fails this test "only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Badger Helicopters Inc. v. Fed. Aviation Admin.*, 154 F.4th 902, 911 (8th Cir. 2025) (cleaned up).

Plaintiffs' interests are far more than "marginally related" to the FDCA's purposes. *Id.* The FDCA prohibits the introduction and delivery of adulterated or misbranded drugs into interstate commerce. 21 U.S.C. § 331(a). And its mandates include "protect[ing] the public health," Public Law No. 87-781, 76 Stat. 780; "assur[ing] the safety, effectiveness, and reliability" of FDA-approved drugs, *id.*; and considering the "seriousness of any known or potential adverse events that may be related to the drug," 21 U.S.C. § 355-1(a)(1)(E). Plaintiffs certainly have an interest in protecting public health and safety and in keeping adulterated or misbranded drugs from entering its borders. Moreover, Danco and GenBioPro's objection that the FDCA does not have a provision explicitly protecting a state's interests is misplaced: "[N]o explicit statutory provision [is] necessary." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 155 (1970);

see Doc. 295 at 20; Doc. 297-1 at 10. Accordingly, the manufacturers' zone of interests argument is meritless.

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

Because FDA's own regulations do not trigger an exhaustion requirement, the States did not need to first seek administrative relief. *Darby v. Cisneros*, 509 U.S. 137, 154 (1993). 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*, 509 U.S. at 154; *Kakaygeesick v. Salazar*, 389 Fed. App'x 580, 580 n.2 (8th Cir. 2010) (per curiam). 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.

In addition, 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, 536 (N.D. Tex. 2023). That is exactly what the States are asserting. Doc. 217 ¶¶ 757–88; Doc. 281 ¶¶ 33–38. 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." *All. for Hippocratic Med.*, 668 F. Supp. 3d at 536. All these things apply, as the Texas district court held. *Id.* at 536–39.

Similarly, "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) (citation omitted). The States' claims perfectly fit that bill. *All. for Hippocratic Med.*, 668 F. Supp. 3d at 536–39. 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. Doc. 217-3 at 85–124.

Finally, FDA's abuse of the administrative process excuses exhaustion. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *16 (5th Cir. Apr. 12, 2023) (per curiam); *see Way of Life Television Network, Inc. v. FCC*, 593 F.2d 1356, 1359–60 (D.C. Cir. 1979). FDA's regulations require it to respond to citizen petitions within 180 days. *See* 21 C.F.R. § 10.30(e)(2). The FDA did not follow this rule when it took about three years to respond to the 2019 Citizen Petition. *Id.*; *see* Doc. 217-3 at 85. Indeed, such delays are common with the FDA; one review found that 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.[5] The FDA's dilatory behavior abuses the administrative process and excuses exhaustion here.[6]

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

Defendants and the manufacturers' statute-of-limitations objections fails for five reasons.

First, an intervenor need not re-satisfy the statute of limitations that the original party satisfied. Courts permit an intervenor to rely on parties who "are already in court pursuant the statutory scheme" and to continue litigating if the original party is dismissed. *Harris*, 768 F.2d

[5] Michael Krupka, Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners, 77 Vand. L. Rev. 937, 637, 977–78, 980 (2024).

[6] The States satisfied the exhaustion requirement for yet another reason: Even if the States were required to exhaust all administrative remedies (they were not), an intervenor need not independently satisfy an exhaustion requirement when parties "are already in court pursuant the statutory scheme." *Harris v. Amoco Production Co.*, 768 F.2d 669, 676, 678 (5th Cir. 1985). Because the original private plaintiffs satisfied any exhaustion requirement, the States did too when they intervened. *See id.*

at 678. The States satisfy the statute of limitations because the original plaintiffs did. The original plaintiffs filed a citizen petition in 2019, which was not denied until 2021, a year before they sued. Doc. 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. Only post-*Dobbs* could the States fully regulate abortion within the time frame for chemical abortion. Doc. 217 ¶¶ 54, 254, 256. Accordingly, because the States' cause of action did not accrue until *Dobbs* was decided in June 2022, the States timely filed suit under 28 U.S.C. § 2401(a).[7]

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); *see* Doc. 151. 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 [FDA's] approval of the abortion medication mifepristone that was brought more than two decades after the relevant agency

[7] Additionally, part of the States' injury only arose (and thus accrued) post-*Dobbs*. Pre-*Dobbs*, women could obtain abortion drugs in their own States because abortion at that stage of pregnancy was legal in all 50 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 . . . 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." Doc. 217 ¶¶ 258, 264–67.

action." *Id.* at 861–62 (Jackson, J., dissenting). The States are challenging actions much *later* than the 2000 action Justice Jackson recognized to be "fair game."

Fifth, the States' suit is timely under the reopening doctrine because FDA reopened the 2016 Major Changes in 2021 when it denied the 2019 Citizen Petition challenging the 2016 Major Changes. *Alliance II*, 78 F.4th at 244 (concluding that the denial letter "shows that the agency reviewed the conditions for use that the citizen petition had put at issue"). Accordingly, the States' complaint falls within the six-year statute of limitation.

IV. This Court should deny Defendants' request to stay this case indefinitely.

Seeking to avoid the inevitable vacatur of its actions, FDA seeks to indefinitely stay this case. Doc. 293-1 at 13–14. This Court may stay proceedings upon the balancing of the potential prejudice or hardships to the parties and the interest of judicial economy. *Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936); *St. Louis Health Ctr. v. Athenahealth, Inc.*, No. 4:15-CV-01215-AGF, 2015 WL 6777873, at *4 (E.D. Mo. Nov. 4, 2015). FDA "bears the burden of establishing [a stay's] need," *Clinton v. Jones*, 520 U.S. 681, 708 (1997), and "must make out a clear case of hardship or inequity in being required to go forward," *Landis*, 299 U.S. at 255. FDA has fallen woefully short of its burden.

Defendants claim that Plaintiffs attempt to "short-circuit" its mifepristone review. Doc. 293-1 at 8. Not so. Since January 2025, the federal government has promised that FDA would review the safety of mifepristone.[8] But FDA has provided nothing but empty promises.[9] At no point has FDA produced evidence that it has taken, is taking, or will take any steps to

[8] Andrew Stanton, *RFK Jr. Says He Would Study Abortion Pill Mifepristone Safety Issues*, Newsweek (Jan. 29, 2025), perma.cc/5T8R-MU7S.

[9] *See, e.g.*, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. Food & Drug Administration, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (claiming that "FDA is conducting a safety study of mifepristone" and "continues to work on the collection of" data but failing to provide any evidence that it has requested or commissioned the data).

complete its study. Moreover, FDA *had* a full opportunity to study the safety of mifepristone and review the REMS *before* it promulgated the REMS and approved the mifepristone variants. FDA's *post hoc* study cannot cure its prior unlawful actions. *Dep't of Homeland Sec.*, 591 U.S. at 20–21.

Even if one accepts FDA's seemingly hollow words as true, it is highly speculative that the new study will result in new rulemaking. FDA does not assert that it *will* change the REMS upon completion of the study; it asserts only that it will *consider* whether to change the REMS. Doc. 293-1 at 7–8. It provides no estimate for how long it thinks that consideration will take or whether the rulemaking would address the health and safety concerns raised in the States' live pleadings. *See generally* Doc. 217. Regardless, that review is only the first step under 21 U.S.C. § 355-1. *See* 21 U.S.C. §§ 355-1(g)(4)(B), (h)(4), (j)(2). Any rulemaking will take years to complete and likely be subject to legal challenges for years afterwards.[10] Plaintiff States should not have to wait indefinitely before securing relief for their serious and ongoing harms.

FDA's lack of specificity suggests that its true reason for seeking a stay is stalling litigation on a controversial topic. The federal government has employed this tactic before, leaving cases lingering on court dockets and plaintiffs with no clarity or relief for years.[11] The Court should not allow such dilatory tactics in this case—especially where core state authority is jeopardized and women's safety is at risk. *See, e.g.*, Ex. B.

CONCLUSION

For these reasons, Plaintiffs request that this Court deny the pending motion to stay and motions to dismiss. Doc. 293, 295, 297.

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[10] *See*, *e.g.*, *Texas v. Becerra*, No. 3:22-CV-419, 2024 WL 1221168, at *2–3 (S.D. Tex. Mar. 21, 2024) (noting that the court dismissed a prior challenge as moot because HHS issued a notice of non-enforcement and notice of proposed rulemaking, only for the subsequent rule to be vacated three and a half years later before it could take effect).

[11] *Compare* Defs.-Appellees' Mot. to Hold Appeal in Abeyance, *Victim Rts. L. Ctr. v. Cardona*, No. 21-1777 (1st Cir. Feb. 25, 2022) (requesting abeyance of case so the Department of Education could conduct review of the challenged regulation), *with* Defs.-Appellees' Status Rep., *Victim Rts. L. Ctr. v. McMahon*, No. 21-1777 (1st Cir. Feb. 20, 2026) (explaining that appeal remains in abeyance four years later).

Date: March 27, 2026

Respectfully submitted,

CATHERINE HANAWAY
Missouri Attorney General

/s/ Louis J. Capozzi, III
Louis J. Capozzi, III, 77756MO
Solicitor General
Kathleen Hunker, 24118415TX
Principal Deputy Solicitor General
Alexandria L. Overcash, 97153VA
Madeline S. Lansdell, 78538MO
Assistant Solicitors General

Office of the Attorney General
815 Olive St. Suite 200
St. Louis, Missouri 63101
Phone: (573) 645-9662
Fax (573) 751-1774
Louis.Capozzi@ago.mo.gov
Kathleen.Hunker@ago.mo.gov
Alexandria.Overcash@ago.mo.gov
Madeline.Lansdell@ago.mo.gov

Counsel for Intervenor-Plaintiff State of Missouri

CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2026, a true and accurate copy of the foregoing was electronically filed by using the Court's CM/ECF system to be served on all counsel of record entered in the case.

/s/ *Louis J. Capozzi, III*

THE STATE OF MISSOURI)
)ss.
COUNTY OF COLE)

AFFIDAVIT

Before me, the undersigned authority, personally appeared Emily Hollis, who being by me duly sworn, deposed as follows:

1. My name is Emily Hollis, I am of sound mind, capable of making this affidavit, and personally acquainted with the facts stated herein:

2. I am the interim custodian of records of the Missouri Department of Health and Senior Services.

3. Attached hereto are fifteen (15) pages of records from the Missouri Department of Health and Senior Services, consisting of:

- Missouri Abortion Complication Reports, January 1, 2023 – February 28, 2026 (1 page)
- Graph D. Resident Abortion Ratios per 1,000 Live Births: Missouri, 1971-2022 (1 page)
- Explanation for removal of Graph D from 2023 Vital Statistics Report (1 page)
- Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2022 (2 pages)
- Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2023 (2 pages)
- Table 12A. Resident Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2022 (1 page)
- Table 12A. Resident Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2023 (1 page)
- Table 12B: Recorded Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2022 (1 page)
- Table 12B: Recorded Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2023 (1 page)
- Table 12C. Post-Abortion Complication Report: Missouri, 2022 (1 page)
- Table 12C. Post-Abortion Complication Report: Missouri, 2023 (1 page)
- Table 13: Resident Abortions by Age, Marital Status, and Education by Race and Hispanic Origin: Missouri, 2022 (1 page)
- Table 13: Resident Abortions by Age, Marital Status, and Education by Race and Hispanic Origin: Missouri, 2023 (1 page)

4. These fifteen (15) pages of records are kept by the Missouri Department of Health and Senior Services in the regular course of business, and it was the regular course of business of the Missouri Department of Health and Senior Services for an employee or representative of the Missouri Department of Health and Senior Services with knowledge of the act, event, condition, opinion, or diagnosis recorded to make the record or to transmit information thereof to be included in such record; and the record was made at or near the time of the act, event, opinion, or diagnosis. The records attached hereto are the original or exact duplicates of the original.

I declare under penalty of perjury that the foregoing is true and correct.

Affiant, Emily Hollis, Interim Custodian of Records

In witness whereof I have hereunto subscribed by name and affixed by official seal this.
Subscribed and affirmed before me this 24th day of March, 2026.

Notary Public

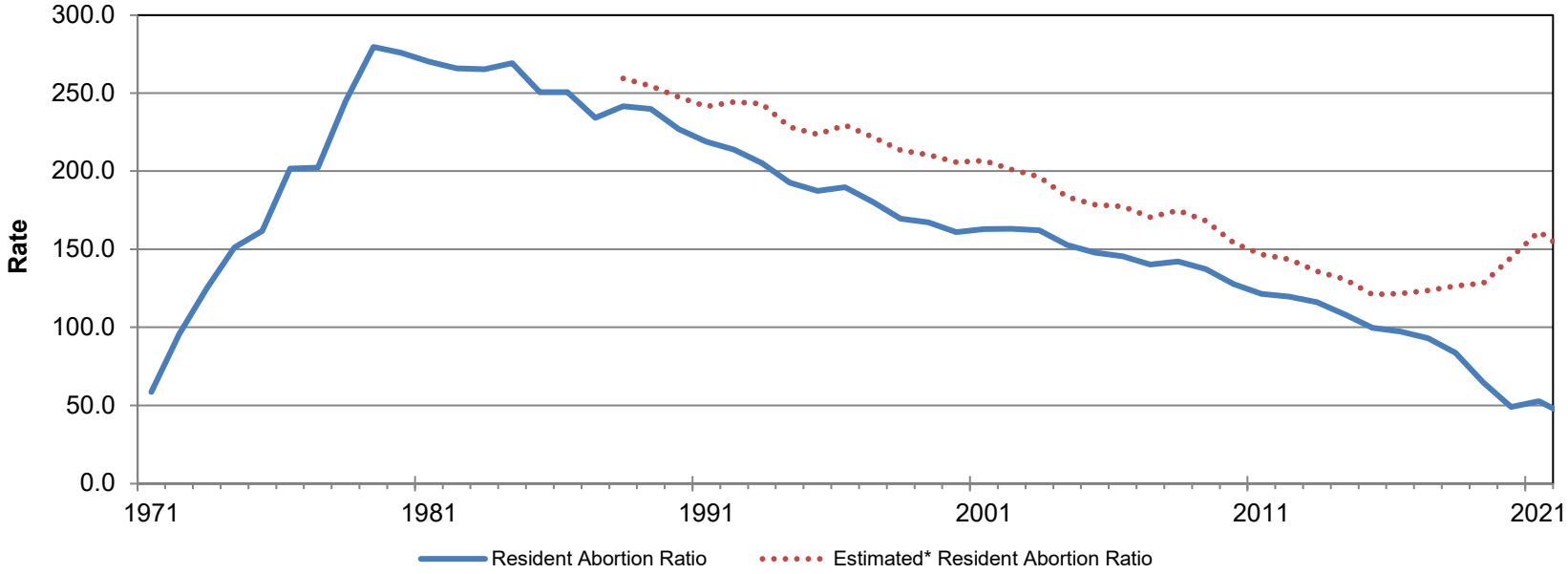
My commission expires:

KYRA DELUCA
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
COMMISSION EXPIRES JUNE 15, 2029
COLE COUNTY
COMMISSION #25579927

Missouri Abortion Complication Reports, Jan 1, 2023 – Feb 28, 2026			
Year	Total Complication Reports	Total Complication Reports for Medication Abortions	Total Complication Reports for Medical Abortions Reported by Public Hospitals
2023	71	35	17
2024	48	20	7
2025	47	13	4
2026	7	2	0

Source: Missouri Vital Statistics

Graph D. Resident Abortion Ratios per 1,000 Live Births: Missouri, 1971-2022



Year	Recorded	Resident	Resident Ratio	Estimated* Resident	Estimated* Resident Ratio	Year	Recorded	Resident	Resident Ratio	Estimated* Resident	Estimated* Resident Ratio
1971	---	4,582	58.5	---	---	**2010**	6,163	9,796	127.7	11,823	154.1
1975	10,245	11,077	161.8	---	---	**2015**	4,765	7,474	99.6	9,083	121.0
1980	19,043	21,671	275.8	---	---	**2017**	3,903	6,790	93.0	9,029	123.6
1985	19,482	19,210	250.5	---	---	**2018**	2,910	6,125	83.6	9,271	126.5
1990	16,366	17,947	226.8	19,582	247.5	**2019**	1,471	4,660	64.6	9,254	128.3
1995	11,203	13,635	187.3	16,281	223.6	**2020**	167	3,391	48.9	10,018	144.6
2000	7,884	12,292	161.0	15,710	205.8	**2021**	150	3,653	52.7	11,185	161.5
2005	7,977	11,619	147.9	14,025	178.6	**2022**	88	3,012	43.7	10,255	148.7

Source: 1971-1974 Centers for Disease Control; 1975-2022 Missouri Department of Health & Senior Services.

Graph D Abortion Definitions:

Recorded: Abortions performed in a facility located in Missouri.

Resident: Abortions to Missouri residents regardless of where the abortions occurred as indicated on the individual record level data reports.

*Estimated Resident: Resident abortions as defined above plus estimated Missouri resident counts from Illinois for 1988-2022 and Tennessee in 1997-2005, Arkansas 2014-2017, and Oklahoma 2019-2022. See Appendix under Vital Records for more information.

NEW TABLES ON POST-ABORTION COMPLICATIONS (TABLE 12C)

In 2018, a new table was added entitled Post-Abortion Complication Report Results. Since 1980, Missouri statutes have allowed health care providers (hospitals, clinics, and physicians) to complete and submit “Complication Report for post-Abortion Care” forms after treating patients for complications following induced abortions. However, reporting from this form has been very sporadic through the years. In 2017, MDHSS revised the form and the regulations related to post-abortion complications in a major effort to improve our understanding of these procedures. Table 12C shows the results of this data for the 2023 calendar year. Data collected includes the type of complication, whether the original abortion procedure was surgical or medical, and whether the patient was hospitalized. In 2023, MDHSS received 69 complication reports representing 96 complications. The post-abortion care for all of the reported complications took place in Missouri, but most of the original abortions were performed in other states. The completeness of reporting is still uncertain, and other states do not exchange this type of data with MDHSS.

GRAPH D ON MISSOURI RESIDENT ABORTION TRENDS DROPPED

In 2023, a new abortion law in Illinois was implemented which excluded state of residence as a data variable for Illinois recorded abortions. From 2020 to 2022, Illinois abortions accounted for about two-thirds of Missouri estimated resident abortions. Therefore, without counts on Illinois abortions to Missouri residents, Graph D on Missouri resident abortion trends became rather meaningless, and thus was dropped from the Missouri Vital Statistics report beginning with 2023 data.

The resident abortion data in Tables 11-15 come from individual data reports. We receive those records from Missouri, Kansas, and a few other states. With the tremendous decrease in Missouri recorded abortions (only 37 in 2023) and several surrounding states also passing abortion bans, well over 95 percent of the Missouri reported resident abortions appearing in Tables 11-15 take place in Kansas and most occur to Missourians living in Western Missouri. These tables need to be interpreted with that in mind.

Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2022

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
State Total	3,565	883	2,682	256	50	206
Adair	10	3	7	0	0	0
Andrew	11	3	8	2	0	2
Atchison	2	1	1	0	0	0
Audrain	18	6	12	0	0	0
Barry	31	7	24	1	0	1
Barton	8	3	5	1	0	1
Bates	12	4	8	1	0	1
Benton	14	4	10	0	0	0
Bollinger	7	2	5	0	0	0
Boone	68	19	49	7	3	4
Buchanan	75	21	54	7	1	6
Butler	50	15	35	0	0	0
Caldwell	8	2	6	1	0	1
Callaway	18	6	12	0	0	0
Camden	23	8	15	1	0	1
Cape Girardeau	57	23	34	0	0	0
Carroll	4	0	4	1	0	1
Carter	2	1	1	0	0	0
Cass	72	13	59	14	2	12
Cedar	10	3	7	0	0	0
Chariton	8	2	6	1	0	1
Christian	33	8	25	1	0	1
Clark	6	1	5	0	0	0
Clay	114	24	90	25	8	17
Clinton	14	3	11	3	1	2
Cole	43	13	30	2	1	1
Cooper	8	0	8	0	0	0
Crawford	20	7	13	0	0	0
Dade	7	2	5	0	0	0

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
Dallas	14	2	12	0	0	0
Daviess	4	1	3	0	0	0
Dekalb	9	2	7	1	0	1
Dent	11	0	11	0	0	0
Douglas	9	1	8	0	0	0
Dunklin	36	15	21	1	0	1
Franklin	50	19	31	0	0	0
Gasconade	7	5	2	0	0	0
Gentry	5	0	5	0	0	0
Greene	203	49	154	8	0	8
Grundy	7	2	5	0	0	0
Harrison	2	0	2	2	0	2
Henry	14	1	13	0	0	0
Hickory	3	0	3	1	0	1
Holt	1	0	1	0	0	0
Howard	4	2	2	0	0	0
Howell	44	8	36	0	0	0
Iron	6	2	4	0	0	0
Jackson	589	152	437	138	26	112
Jasper	129	31	98	3	1	2
Jefferson	73	18	55	0	0	0
Johnson	36	4	32	7	0	7
Knox	2	0	2	0	0	0
Laclede	37	2	35	0	0	0
Lafayette	18	4	14	2	0	2
Lawrence	29	3	26	0	0	0
Lewis	4	0	4	0	0	0
Lincoln	24	3	21	0	0	0
Linn	7	0	7	0	0	0
Livingston	9	2	7	0	0	0

Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2022

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
Macon	12	5	7	2	1	1
Madison	10	5	5	0	0	0
Maries	8	0	8	0	0	0
Marion	11	2	9	0	0	0
McDonald	29	3	26	1	0	1
Mercer	4	1	3	0	0	0
Miller	23	5	18	1	0	1
Mississippi	15	6	9	0	0	0
Moniteau	9	4	5	0	0	0
Monroe	7	1	6	0	0	0
Montgomery	7	2	5	0	0	0
Morgan	10	4	6	1	0	1
New Madrid	15	2	13	0	0	0
Newton	64	16	48	1	0	1
Nodaway	6	0	6	0	0	0
Oregon	9	3	6	0	0	0
Osage	1	1	0	0	0	0
Ozark	7	2	5	0	0	0
Pemiscot	23	3	20	0	0	0
Perry	9	0	9	0	0	0
Pettis	29	11	18	1	0	1
Phelps	39	6	33	0	0	0
Pike	7	1	6	0	0	0
Platte	32	4	28	6	2	4
Polk	17	3	14	0	0	0
Pulaski	37	8	29	0	0	0
Putnam	2	0	2	0	0	0
Ralls	3	1	2	1	0	1
Randolph	18	3	15	0	0	0
Ray	10	1	9	1	0	1
Reynolds	2	0	2	0	0	0

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
Ripley	13	3	10	0	0	0
Saline	16	8	8	2	1	1
Schuyler	7	3	4	2	2	0
Scotland	2	0	2	0	0	0
Scott	36	10	26	0	0	0
Shannon	7	3	4	0	0	0
Shelby	3	1	2	0	0	0
St. Charles	75	18	57	1	0	1
St. Clair	6	1	5	0	0	0
St. Francois	45	8	37	0	0	0
St. Louis City	188	64	124	1	0	1
St. Louis County	324	91	233	1	0	1
Ste. Genevieve	6	1	5	0	0	0
Stoddard	29	5	24	0	0	0
Stone	17	1	16	0	0	0
Sullivan	3	0	3	0	0	0
Taney	36	7	29	0	0	0
Texas	20	3	17	0	0	0
Vernon	17	4	13	2	1	1
Warren	12	3	9	0	0	0
Washington	26	5	21	0	0	0
Wayne	5	2	3	0	0	0
Webster	37	4	33	0	0	0
Worth	1	0	1	0	0	0
Wright	19	3	16	0	0	0

Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2023

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
State Total	3,457	921	2,536	231	65	166
Adair	9	0	9	0	0	0
Andrew	4	1	3	0	0	0
Atchison	3	0	3	0	0	0
Audrain	26	5	21	0	0	0
Barry	26	3	23	1	1	0
Barton	7	3	4	0	0	0
Bates	7	1	6	1	0	1
Benton	11	1	10	1	0	1
Bollinger	9	1	8	0	0	0
Boone	75	15	60	4	0	4
Buchanan	78	18	60	6	1	5
Butler	51	8	43	0	0	0
Caldwell	4	2	2	0	0	0
Callaway	30	12	18	1	0	1
Camden	24	7	17	1	1	0
Cape Girardeau	56	22	34	0	0	0
Carroll	7	2	5	1	0	1
Carter	5	1	4	0	0	0
Cass	39	12	27	7	5	2
Cedar	13	3	10	0	0	0
Chariton	3	1	2	1	0	1
Christian	48	6	42	3	0	3
Clark	1	0	1	0	0	0
Clay	113	38	75	19	6	13
Clinton	11	3	8	0	0	0
Cole	45	15	30	1	0	1
Cooper	10	0	10	1	0	1
Crawford	24	9	15	0	0	0
Dade	1	0	1	0	0	0

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
Dallas	12	3	9	0	0	0
Daviess	3	0	3	0	0	0
Dekalb	5	0	5	0	0	0
Dent	7	2	5	0	0	0
Douglas	10	2	8	0	0	0
Dunklin	42	17	25	0	0	0
Franklin	45	9	36	0	0	0
Gasconade	8	2	6	0	0	0
Gentry	4	0	4	0	0	0
Greene	176	43	133	4	0	4
Grundy	9	1	8	0	0	0
Harrison	10	1	9	1	0	1
Henry	9	3	6	0	0	0
Hickory	6	1	5	0	0	0
Holt	0	0	0	0	0	0
Howard	8	0	8	0	0	0
Howell	40	13	27	2	0	2
Iron	3	0	3	0	0	0
Jackson	586	190	396	134	43	91
Jasper	130	39	91	7	2	5
Jefferson	71	15	56	0	0	0
Johnson	32	5	27	11	3	8
Knox	1	1	0	0	0	0
Laclede	46	11	35	0	0	0
Lafayette	26	5	21	1	0	1
Lawrence	40	8	32	0	0	0
Lewis	6	1	5	0	0	0
Lincoln	23	5	18	0	0	0
Linn	6	1	5	0	0	0
Livingston	12	3	9	1	0	1

Table 11. Resident Teen-Age Pregnancies and Abortions by Selected Ages by County of Residence: Missouri, 2023

	Total Pregnancies			Abortions		
	Under 20	Under 18	18-19	Under 20	Under 18	18-19
Macon	10	2	8	0	0	0
Madison	8	3	5	0	0	0
Maries	2	1	1	0	0	0
Marion	21	5	16	0	0	0
McDonald	21	6	15	0	0	0
Mercer	1	0	1	0	0	0
Miller	22	7	15	0	0	0
Mississippi	21	5	16	0	0	0
Moniteau	7	0	7	0	0	0
Monroe	7	1	6	0	0	0
Montgomery	3	1	2	0	0	0
Morgan	8	3	5	0	0	0
New Madrid	13	4	9	0	0	0
Newton	47	10	37	2	0	2
Nodaway	8	1	7	1	0	1
Oregon	9	2	7	0	0	0
Osage	3	1	2	0	0	0
Ozark	8	2	6	0	0	0
Pemiscot	23	8	15	0	0	0
Perry	14	5	9	0	0	0
Pettis	33	5	28	2	0	2
Phelps	22	2	20	0	0	0
Pike	11	3	8	0	0	0
Platte	30	4	26	9	2	7
Polk	18	4	14	0	0	0
Pulaski	28	3	25	1	0	1
Putnam	3	0	3	0	0	0
Ralls	4	1	3	0	0	0
Randolph	14	4	10	0	0	0
Ray	20	9	11	0	0	0
Reynolds	6	3	3	0	0	0
Ripley	12	3	9	0	0	0
Saline	16	2	14	1	0	1
Schuyler	0	0	0	0	0	0
Scotland	0	0	0	0	0	0
Scott	36	12	24	0	0	0
Shannon	5	2	3	0	0	0
Shelby	1	1	0	0	0	0
St. Charles	69	19	50	0	0	0
St. Clair	8	2	6	0	0	0
St. Francois	42	10	32	0	0	0
St. Louis City	179	65	114	0	0	0
St. Louis County	292	89	203	0	0	0
Ste. Genevieve	7	1	6	0	0	0
Stoddard	28	4	24	0	0	0
Stone	18	3	15	1	1	0
Sullivan	8	2	6	0	0	0
Taney	38	4	34	2	0	2
Texas	23	9	14	0	0	0
Vernon	20	2	18	0	0	0
Warren	16	3	13	0	0	0
Washington	15	5	10	0	0	0
Wayne	12	1	11	0	0	0
Webster	28	4	24	0	0	0
Worth	0	0	0	0	0	0
Wright	20	3	17	0	0	0

Table 12A. Resident Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2022

	Total	Weeks of Gestation								
		Under 9	9-10	11-12	13-14	15-16	17-19	20	21 and Over	Unknown
State Total	3,012	1,792	620	224	141	82	100	28	25	0
Patient's Race										
White, Non-Hispanic	1,428	903	273	85	64	34	45	11	13	0
Black, Non-Hispanic	1,067	584	247	93	52	35	35	13	8	0
Other, Non-Hispanic	293	172	57	26	16	5	13	3	1	0
Unknown, Non-Hispanic	0	0	0	0	0	0	0	0	0	0
Hispanic, Any Race	224	133	43	20	9	8	7	1	3	0
Patient's Age										
Under 15	6	4	1	1	0	0	0	0	0	0
15	5	1	3	1	0	0	0	0	0	0
16	12	5	3	2	1	0	0	1	0	0
17	27	15	5	2	3	0	1	1	0	0
18	82	47	21	2	4	1	4	0	3	0
19	124	83	17	10	3	5	3	1	2	0
20-24	930	532	222	59	43	29	29	11	5	0
25-29	802	496	152	67	33	24	16	6	8	0
30-34	607	376	114	45	28	12	24	5	3	0
35-39	312	179	62	33	14	7	13	3	1	0
40 and Over	104	54	19	2	12	4	10	0	3	0
Unknown	1	0	1	0	0	0	0	0	0	0
Type of Procedure										
Curettage	915	457	203	194	48	7	5	1	0	0
Intrauterine Instillation	0	0	0	0	0	0	0	0	0	0
Hysterotomy/Hysterectomy	1	0	0	0	0	0	1	0	0	0
Laminaria D & E	246	1	0	2	92	72	61	11	7	0
Medical/Nonsurgical	1,792	1,334	417	27	1	2	3	2	6	0
Unknown	0	0	0	0	0	0	0	0	0	0
Other	58	0	0	1	0	1	30	14	12	0

Table 12A. Resident Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2023

	Total	Weeks of Gestation								
		Under 9	9-10	11-12	13-14	15-16	17-19	20	21 and Over	Unknown
State Total	3,029	2,024	491	204	129	78	70	14	18	1
Patient's Race										
White, Non-Hispanic	1,336	923	209	85	46	33	31	5	3	1
Black, Non-Hispanic	1,078	688	191	74	50	33	27	5	10	0
Other, Non-Hispanic	321	214	48	23	16	8	8	1	3	0
Unknown, Non-Hispanic	0	0	0	0	0	0	0	0	0	0
Hispanic, Any Race	294	199	43	22	17	4	4	3	2	0
Patient's Age										
Under 15	3	1	1	0	1	0	0	0	0	0
15	13	3	4	4	2	0	0	0	0	0
16	19	9	4	3	1	1	0	0	1	0
17	30	14	5	0	6	1	3	0	1	0
18	58	30	14	3	6	2	0	1	2	0
19	108	79	13	9	2	3	2	0	0	0
20-24	914	588	160	75	38	29	20	1	3	0
25-29	891	619	133	51	35	22	17	7	6	1
30-34	588	403	102	36	21	9	14	1	2	0
35-39	313	214	43	18	14	8	10	3	3	0
40 and Over	92	64	12	5	3	3	4	1	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Type of Procedure										
Curettage	1,083	596	168	180	93	23	13	6	3	1
Intrauterine Instillation	0	0	0	0	0	0	0	0	0	0
Hysterotomy/Hysterectomy	2	0	0	0	0	2	0	0	0	0
Laminaria D & E	154	3	2	2	35	51	51	6	4	0
Medical/Nonsurgical	1,774	1,422	321	22	1	2	3	1	2	0
Unknown	0	0	0	0	0	0	0	0	0	0
Other	16	3	0	0	0	0	3	1	9	0

Table 12B. Recorded Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2022

	Total	Weeks of Gestation								
		Under 9	9-10	11-12	13-14	15-16	17-19	20	21 and Over	Unknown
State Total	88	13	3	3	9	14	22	9	15	0
Patient's Race										
White, Non-Hispanic	42	5	0	0	5	9	10	4	9	0
Black, Non-Hispanic	36	6	3	3	3	4	7	5	5	0
Other, Non-Hispanic	7	1	0	0	1	1	4	0	0	0
Unknown, Non-Hispanic	0	0	0	0	0	0	0	0	0	0
Hispanic, Any Race	3	1	0	0	0	0	1	0	1	0
Patient's Age										
Under 15	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0
18	3	0	0	1	1	0	1	0	0	0
19	1	0	0	0	0	0	0	0	1	0
20-24	18	4	0	0	0	3	4	3	4	0
25-29	21	4	2	1	0	3	4	2	5	0
30-34	20	2	1	0	2	3	8	2	2	0
35-39	15	3	0	1	2	3	3	2	1	0
40 and Over	10	0	0	0	4	2	2	0	2	0
Unknown	0	0	0	0	0	0	0	0	0	0
Type of Procedure										
Curettage	25	13	3	3	4	2	0	0	0	0
Intrauterine Instillation	0	0	0	0	0	0	0	0	0	0
Hysterotomy/Hysterectomy	1	0	0	0	0	0	1	0	0	0
Laminaria D & E	42	0	0	0	5	10	13	8	6	0
Medical/Nonsurgical	16	0	0	0	0	2	6	1	7	0
Unknown	0	0	0	0	0	0	0	0	0	0
Other	4	0	0	0	0	0	2	0	2	0

Table 12B. Recorded Abortions by Race, Age, and Type of Procedure by Weeks of Gestation: Missouri, 2023

	Total	Weeks of Gestation								
		Under 9	9-10	11-12	13-14	15-16	17-19	20	21 and Over	Unknown
State Total	37	2	3	1	2	9	12	3	4	1
Patient's Race										
White, Non-Hispanic	18	2	0	0	1	2	10	2	0	1
Black, Non-Hispanic	12	0	0	0	1	7	1	1	2	0
Other, Non-Hispanic	5	0	3	0	0	0	1	0	1	0
Unknown, Non-Hispanic	0	0	0	0	0	0	0	0	0	0
Hispanic, Any Race	2	0	0	1	0	0	0	0	1	0
Patient's Age										
Under 15	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0
18	1	0	0	0	0	0	1	0	0	0
19	0	0	0	0	0	0	0	0	0	0
20-24	5	0	1	1	0	2	1	0	0	0
25-29	10	1	1	0	0	3	2	0	2	1
30-34	9	0	1	0	0	1	5	1	1	0
35-39	10	1	0	0	2	2	2	2	1	0
40 and Over	2	0	0	0	0	1	1	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Type of Procedure										
Curettage	8	2	3	1	1	0	0	0	0	1
Intrauterine Instillation	0	0	0	0	0	0	0	0	0	0
Hysterotomy/Hysterectomy	3	0	0	0	0	2	1	0	0	0
Laminaria D & E	11	0	0	0	0	3	6	1	1	0
Medical/Nonsurgical	14	0	0	0	1	4	5	2	2	0
Unknown	0	0	0	0	0	0	0	0	0	0
Other	1	0	0	0	0	0	0	0	1	0

Table 12C. Post-Abortion Complication Report: Missouri, 2022

	Procedure Type			
	Surgical	Medical	Not Specified	Total
Total Complications	55	60	0	115
..Incomplete Abortion	7	12	0	19
..Hemorrhage	17	9	0	26
..Endometritis	7	5	0	12
..Parametrititis	0	0	0	0
..Pyrexia	0	1	0	1
..Pelvic Abscess	0	0	0	0
..Uterine Perforation	6	0	0	6
..Failed Abortion, Pregnancy Undisturbed	1	11	0	12
..Retained Products	12	16	0	28
..Cervical Laceration	3	0	0	3
..Psychiatric	0	0	0	0
..Other Complication	2	6	0	8
No Complication Reported	0	0	0	0
Total Complication Reports Received	34	31	0	65

	Count
Patients Hospitalized	36

	Count	Percent with Complications*
Complication Reports for Abortions Recorded in Missouri	2	2.3

Refer to Appendix Section "New Tables on Post-Abortion Complications" for more information.

**** Rate is calculated as total complication reports for abortions performed in Missouri out of all abortions performed in Missouri.***

Table 12C. Post-Abortion Complication Report: Missouri, 2023

	Procedure Type			
	Surgical	Medical	Not Specified	Total
Total Complications	42	49	5	96
..Incomplete Abortion	1	11	2	14
..Hemorrhage	17	8	0	25
..Endometritis	2	0	0	2
..Parametrititis	0	0	0	0
..Pyrexia	0	0	0	0
..Pelvic Abscess	0	0	0	0
..Uterine Perforation	10	0	0	10
..Failed Abortion, Pregnancy Undisturbed	3	10	0	13
..Retained Products	2	10	1	13
..Cervical Laceration	3	0	0	3
..Psychiatric	0	0	0	0
..Other Complication	4	10	2	16
No Complication Reported	0	0	0	0
Total Complication Reports Received	31	33	5	69

	Count
Patients Hospitalized	28

	Count	Percent with Complications*
Complication Reports for Abortions Recorded in Missouri	3	8.1

Refer to Appendix Section "New Tables on Post-Abortion Complications" for more information.

**** Rate is calculated as total complication reports for abortions performed in Missouri out of all abortions performed in Missouri.***

Table 13. Resident Abortions by Age, Marital Status, and Education by Race and Hispanic Origin: Missouri, 2022

	Total	Patient's Race			
		White, Non-Hispanic	Black, Non-Hispanic	Other, Non-Hispanic	Hispanic, Any Race
State Total	3,012	1,428	1,067	293	224
Patient's Age					
Under 15	6	3	3	0	0
15	5	1	2	1	1
16	12	5	2	2	3
17	27	14	9	2	2
18	82	42	28	1	11
19	124	59	35	16	14
20-24	930	423	326	97	84
25-29	802	370	301	77	54
30-34	607	286	229	57	35
35-39	312	161	106	32	13
40 and Over	104	63	26	8	7
Unknown	1	1	0	0	0
Marital Status					
Never Married	38	10	22	4	2
Currently Married	353	216	62	48	27
Formerly Married	2	1	1	0	0
Unmarried, Unspecified	2,619	1,201	982	241	195
Years of Education					
0-8	16	5	4	3	4
9-11	160	81	51	11	17
12	1,066	428	458	96	84
13-15	1,067	536	370	84	77
16 or More	473	297	103	50	23
Unknown	230	81	81	49	19

Table 13. Resident Abortions by Age, Marital Status, and Education by Race and Hispanic Origin: Missouri, 2023

	Total	Patient's Race			
		White, Non-Hispanic	Black, Non-Hispanic	Other, Non-Hispanic	Hispanic, Any Race
State Total	3,029	1,336	1,078	321	294
Patient's Age					
Under 15	3	0	3	0	0
15	13	9	1	3	0
16	19	10	7	2	0
17	30	10	14	2	4
18	58	27	16	9	6
19	108	48	31	12	17
20-24	914	394	313	90	117
25-29	891	401	334	83	73
30-34	588	240	235	64	49
35-39	313	145	102	44	22
40 and Over	92	52	22	12	6
Marital Status					
Never Married	12	5	5	0	2
Currently Married	341	214	64	47	16
Formerly Married	1	0	1	0	0
Unmarried, Unspecified	2,675	1,117	1,008	274	276
Years of Education					
0-8	35	7	12	8	8
9-11	167	82	46	20	19
12	1,092	413	454	95	130
13-15	1,062	505	379	91	87
16 or More	449	250	114	59	26
Unknown	224	79	73	48	24

UNITED STATES DISTRICT COURT
FOR THE EASTERN DIVISION OF MISSOURI
EASTERN DISTRICT

MISSOURI, KANSAS, and IDAHO,
Intervenor-Plaintiffs,
v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants,
and

DANCO LABORATORIES, LLC,
Intervenor-Defendant.

Case No. 4:25-cv-01580-CMS

DECLARATION OF [redacted] IN SUPPORT OF INTERVENOR-PLAINTIFFS' RESPONSE TO INTERVENOR-DEFENDANT'S MOTION TO DISMISS AND MEMORANDUM IN SUPPORT THEREOF AND IN SUPPORT OF INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

My name is [redacted]. I live in St. Louis, Missouri and I have personal knowledge of the facts stated herein:

1. On July 1, 2025, I discovered I was pregnant. My boyfriend kept asking me if I was and then I started thinking I might be. He ghosted me. I texted him on his alternate phone that I thought I was pregnant. He got that text and called me right away. He picked up a pregnancy test and brought it to my place. I took the test and it was positive.

2. It was early morning when he got there (3:00a.m.-ish).
3. I had seen abortion pills in his house, previously. It was early on when we were dating. We started dating in December, 2024. When I asked him about them, he indicated they were for his previous girlfriend.
4. My response to him was that was really dangerous and you can't be doing that. He indicated he got the abortion pills in case his prior girlfriend needed an abortion.
5. He had ghosted me on an off, but, after the positive pregnancy results on July 1, he was around more but left, again, after what I thought was a miscarriage on the night of July 1 into July 2.
6. On the night of July 1 through the morning of July 2, I had cramping and bleeding and I thought I had lost the baby.
7. Later in the day on July 2, around 4:16pm, I confronted him about looking up abortion pills because I was aware he had looked them up right away after we found out I was pregnant. At first, he denied it, then he admitted it. I told him to leave my apartment. He left and blocked me, again, right away.
8. On July 4, 2025, I went to my doctor's office for blood work to see about the baby. Later that day, it was confirmed that I was still pregnant.
9. Later that night, I ran into him (the boyfriend) and he ignored me.
10. Early morning July 5, 1:00a.m.-ish, he texted and called. In that text he apologized, again, for looking up abortion. When I saw the text, around 10:51a.m., I knew he met the pills, because he had apologized before via text for looking up abortion pills. I asked him to come over. He came over around 3:00p.m. When he got there, I told

him the baby was still alive and the color went out of his face. He hadn't asked me anything about the baby or how I was doing.

11. July 7, 2025, I went to the Baptist Medical Center. They gave me the Rhogam shot and I had an ultrasound and it was determined the baby was still alive and the baby's approximate age was 14 weeks. Due date 2/22-24/26.
12. The relationship was more on than off until the weekend of the 11th. We spent time back and forth from his place and mine, mostly at my place. I had cramps and they were worse at some times than others. At some point, he brought 2 bottles of "pre-natal vitamins" and arthritis cream to me. They "vitamins" had both already been opened. He advised me to put the arthritis cream on my stomach and put a heating paid over it. I knew this would not be safe because I knew you couldn't use the cream and a heating pad, together, because it causes burns. I was surprised he didn't know that because he is a nurse. I told him I couldn't do that. Later, after else that happened, I saw the box said right on it not to use if you are pregnant.
13. After July 7 and before the 11th, he sat 3 "pre-natal vitamins" on the counter for me. I thought that was weird but I took them. I had been cramping and bleeding and by July 11, it was so severe I thought I might need medical attention. I was concerned I might be losing the baby. He was uncaring while I had agonized in pain and bled. He flipped through videos on his phone and laughed as I rocked back and forth in pain. He went to sleep. He had done that the previous time, as well – watched the videos and slept.

14. This time, there was so much blood, I knew the baby probably couldn't have survived. The pain, the cramping, the clotting, the amount of blood was so much worse. By July 13, he ghosted me, again.
15. During these days (July 7-11), he had me hike on 2 occasions in the heat, even though I was cramping and bleeding the whole time. I was telling him I thought I was going to faint. I felt so bad. It just kept getting worse. He was callous and refused to even acknowledge my physical condition.
16. On July 14, 2025, I let the doctor know that I thought I lost my baby over the weekend. I went in at 10:15a.m. I had an ultrasound and realized the baby's heart was not beating. The doctor prescribed me something to empty the contents of my uterus. I got the prescription and went to my car in the parking garage.
17. When I opened the prescription and put it on my thigh, I knew I had seen that pill, before. It looked like the "vitamins" he had given me and I started connecting the dots of what had happened. I called the doctor but didn't get to talk to the doctor, then. I wanted to know if he could tell if that was already in my system. I left the parking garaged but I was shaking….
18. My boyfriend had blocked, me again.
19. For obvious reasons, he is no longer my boyfriend.
20. As I processed what he had done, I reached out to the Center Against Forced Abortion. This whole ordeal has been one of the worst things that has ever happened to me.
21. How is it possible a man could get these drugs? The pain was so bad and he was laughing!

22. It has been several months of processing what happened to me and my baby, several months of processing the betrayal of my boyfriend and the loss of my child. Several months of processing the conversations and what he said about his former girlfriend.
23. I am sure he got the pills online and has probably done it to other women before me. If something isn't done to protect women from predators like him, he and others will continue to do this to other women.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

3-24-26
Date

[redacted]