

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

THE STATE OF MISSOURI, *et al.*,

Intervenor Plaintiffs,

v.

No. 4:25-CV-01580-CMS

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

Defendants,

and

DANCO LABORATORIES, *et al.*,

Intervenor Defendants.

**REPLY IN SUPPORT OF FEDERAL DEFENDANTS' MOTION
TO STAY OR, ALTERNATIVELY, TO DISMISS THE CASE**

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INTRODUCTION

The U.S. Food and Drug Administration (FDA) is conducting a review of the mifepristone REMS. Mem. in Supp. of Federal Defs.’ Mot. to Stay or, Alternatively, to Dismiss the Case at 1, ECF No. 293-1 (Mot.). If Intervenor Plaintiffs are satisfied with the outcome of that review, this Court’s review will not be necessary. If not, then Intervenor Plaintiffs can seek to challenge the agency’s new decision following review. Either way, this Court should stay its hand until that review is complete, just as another court hearing a related case recently did. *See Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, 2026 WL 936958 (W.D. La. Apr. 7, 2026). Otherwise, the Court should dismiss the case because of the standing, exhaustion, and timeliness problems that pervade the Amended and Supplemental Complaints. None of the arguments in Intervenor Plaintiffs’ Opposition, ECF No. 302 (Opp’n), warrants any outcome other than stay or dismissal.

ARGUMENT

I. The Court Should Stay This Case.

As FDA explained in its opening brief, the Court should stay this litigation while the agency conducts its ongoing review, including a new study. Mot. 1-4, 8-9. As Judge Joseph explained in *Louisiana*, a stay is appropriate in light of FDA’s “good faith, evidence-based, and expeditious review of the mifepristone REMS.” *Louisiana*, 2026 WL 936958, at *2. In responding to FDA’s arguments, Intervenor Plaintiffs baselessly attempt to cast doubt on whether the review is occurring. Opp’n 14-15. They also fault FDA for failing to guarantee the outcome they seek. *Id.* at 15. Neither argument justifies denying the agency’s request for a stay.

First, the Court should reject Intervenor Plaintiffs’ speculation about the review. *See id.* at 14-15. “[I]n the absence of clear evidence to the contrary,’ courts presume that public officers ‘have properly discharged their official duties.’” *McDonough v. Anoka County*, 799 F.3d 931, 948 (8th Cir. 2015) (quoting *United States v. Armstrong*, 517 U.S. 456, 464 (1996)); *see also United States v. Chem.*

Found., Inc., 272 U.S. 1, 14-15 (1926). Here, the Secretary of Health and Human Services and the Commissioner of Food and Drugs have publicly confirmed that FDA is conducting its review and that it will include a new study. ECF No. 293-2. FDA has also publicly explained that the “next steps” following ongoing data collection will include “data exploration, evaluation of data integrity, . . . implementation of the analyses, [and] validation.” FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (#37).¹ Such statements “produced by public officials during the ordinary course of their duties” are “presumptively reliable,” *Kim v. Holder*, 560 F.3d 833, 836 (8th Cir. 2009), and Intervenor Plaintiffs have provided no reason to doubt them. Like Judge Joseph, this Court should credit these statements. *See Louisiana*, 2026 WL 936958, at *6.

Moreover, apart from these public statements, there are additional assurances that FDA will conduct its review in good faith. The United States District Court for the District of Hawaii has ordered FDA to conduct a new review of the mifepristone REMS. *Purcell v. Kennedy*, Civ. No. 1:17-cv-00493 JAO-RT, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025). Notably, in declining to retain jurisdiction during remand, that court found “no indication of recalcitrance or bad faith on the part of the Agency” that would cast doubt on whether FDA would conduct a review as required by the remand order. *Purcell v. Kennedy*, No. 1:17-cv-00493-JAO-RT, ECF No. 262, at 3 (D. Haw. Jan. 21, 2026). And beyond that court-ordered review, FDA’s regulations require the agency to respond to the numerous citizen petitions raising related issues that are pending before the agency. *See* 21 C.F.R. § 10.30(e)(1) (“The Commissioner shall . . . rule upon each petition filed . . .”). Again, Intervenor Plaintiffs provide no evidence—let alone “clear evidence”—that FDA will fail to comply with the *Purcell* remand order or the agency’s regulations.

¹ <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> (last visited Apr. 10, 2026).

Second, the Court should give no weight to Intervenor Plaintiffs’ assertion that “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.” Opp’n 15; *see also id.* (alleging that is “speculative” whether FDA’s study “will result in new rulemaking”).² Of course, FDA has not predetermined the outcome of its review, and it would be improper for the agency to do so. *McDonnell Douglas Corp. v. EEOC*, 922 F. Supp. 235, 242 (E.D. Mo. 1996) (holding that an agency acted arbitrarily and capriciously by “view[ing] only the facts favorable to its predetermined position”); *see also Friends of Richards-Gebaur Airport v. FAA*, 251 F.3d 1178, 1187 n.3 (8th Cir. 2001). But whatever the ultimate outcome of the review, staying the case until the review is complete is appropriate. If FDA’s decision following review does not eliminate Intervenor Plaintiffs’ concerns, they may seek to challenge that decision at that time based on the new administrative record.

In short, just as Judge Joseph stayed another pending challenge to the 2023 REMS Modification, and just as the *Purcell* court stayed a challenge to the mifepristone REMS during the agency’s 2021-2023 review, *see* Mot. 9, this Court should stay Plaintiffs’ challenge during the current review.

II. Alternatively, The Court Should Dismiss This Case.

If the Court does not stay the case, then the Court should dismiss it. Mot. 9-15. None of Intervenor Plaintiffs’ reasons for denying Defendants’ alternative request (Opp’n 3-10, 11-14) is sound.

² Intervenor Plaintiffs’ references to the REMS as “rulemaking” or “regulations,” *see, e.g.*, Opp’n 1, 4, are inaccurate. “FDA’s approval process for new drugs and modifications to existing drug approvals, such as the REMS, are licensing actions and thus adjudications,” not rulemaking. U.S. Gov’t Accountability Off., B-334995, U.S. Food and Drug Administration—Applicability of the Congressional Review Act to *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* at 1(2023); *see generally* 21 U.S.C. § 355-1.

A. The Court lacks jurisdiction

1. As Judge Kacsmaryk recognized, the Supreme Court held that “the Original Plaintiffs” in this lawsuit “never had a jurisdictionally valid case.” *Missouri v. FDA*, No. 2:22-cv-223-Z, 2025 WL 2825980, at *6 (N.D. Tex. Sept. 30, 2025); *see generally FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024). And “[i]f a jurisdictionally valid case does not exist, then intervention is impermissible.” *Missouri*, 2025 WL 2825980, at *5; *see also United States ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 163-64 (1914) (holding that intervention cannot cure a defect in the original plaintiffs’ claims). From this, it follows that Missouri, Idaho, and Kansas cannot invoke this Court’s jurisdiction through intervention.

Intervenor Plaintiffs dispute this (Opp’n 3 n.2) in two ways, neither of which is tenable. *First*, they disagree with Judge Kacsmaryk that the original Plaintiffs never had jurisdiction; instead, they argue that the Supreme Court held only that the original Plaintiffs’ claims were mooted by “a change in position by the Federal Government.” *Id.* at 2-3. Not so. *Alliance* could not have been clearer that it was a standing decision, not a mootness decision. *Alliance*, 602 U.S. at 390 (“[G]iven 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.”); *id.* (“The causal link between FDA’s regulatory actions and [the original plaintiffs’ alleged monetary and related injuries] is too speculative or otherwise too attenuated to establish standing.”); *id.* at 396-97 (“[T]he plaintiffs have failed to demonstrate that FDA’s relaxed regulatory requirements likely would cause them to suffer an injury in fact. For that reason, the federal courts are the wrong forum for addressing the plaintiffs’ concerns about FDA’s actions.”).

Second, Intervenor Plaintiffs recharacterize their intervention as a “separate action” that can proceed independently, even if there was no valid case in which to intervene. Opp’n 3 n.2 (quoting *In re Grand Jury Procs. (Malone)*, 655 F.2d 882, 886 (8th Cir. 1981)). But *Malone* held only that an

intervenor could maintain an interlocutory appeal where the statute did not permit the original appellant to do so; it said nothing about whether an intervention can be reimagined as a separate action when there was no Article III case or controversy at the outset. Moreover, the Supreme Court has long recognized that an intervention may be “treated as an original suit” only where “service was made or attempted” in the manner required for such suits. *McCord*, 233 U.S. at 164. Here, had Intervenor Plaintiffs filed a separate action, they would have been required to obtain and serve a summons on Defendants. *See* Fed. R. Civ. P. 4. Since they did not do so, any “separate action” would have to be dismissed on that basis. Fed. R. Civ. P. 4(m).

2. In any event, Intervenor Plaintiffs lack an independent basis for standing, whether based on sovereign (or quasi-sovereign) harm or economic injury. Mot. 9-14. Their counterarguments (Opp’n 4-10) are unavailing.

First, Intervenor Plaintiffs do not plausibly allege any preemption-related injury. Indeed, Intervenor Plaintiffs expressly *deny* that their laws are preempted by the mifepristone REMS. Am. Compl. ¶ 577, ECF No. 217. And FDA concurs that the mifepristone REMS establishes a regulatory floor, not a ceiling. Mot. 11. In so doing, FDA does not (*contra* Intervenor Plaintiffs) provide a new, post-hoc rationale for the REMS. It simply states the Executive Branch’s view—one that Intervenor Plaintiffs themselves share. Thus, nothing in FDA’s actions prohibits Intervenor Plaintiffs from exercising their sovereign authority to regulate abortion as permitted by *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215 (2022).

Intervenor Plaintiffs fear that *other* parties (not FDA) might contend that their laws are preempted. Opp’n 5. They fail to acknowledge that both district court cases they cite were within the Fourth Circuit, which later held that the mifepristone REMS does *not* preempt laws like Intervenor Plaintiffs’. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274 (4th Cir. 2025). In any event, Article III prohibits basing standing on fears about other, hypothetical lawsuits brought by third

parties. *Alliance*, 602 U.S. at 381 (“[T]he injury must be actual or imminent, not speculative.”). Nor is this case like *Holder v. Humanitarian Law Project*, 561 U.S. 1 (2010), where plaintiffs who credibly feared prosecution could “seek preenforcement review of a criminal statute” in a suit against the officer who might bring that prosecution. *Id.* at 15. No authority permits a plaintiff to “assert [its] own rights offensively” (Opp’n 5) by suing one party to prevent another party from making meritless preemption arguments in a hypothetical future civil lawsuit.

Second, unable to show that FDA’s actions pose any *legal impediment* to enforcement of their laws, Intervenor Plaintiffs cannot assert a sovereign injury based merely on *practical difficulties* in enforcing their laws. Article III “does not license a state to mount a judicial challenge to any federal [policy] with which the state law assertedly conflicts.” *Virginia ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 269 (4th Cir. 2011). Rather, the federal policy must interfere with the state’s “*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) (emphasis added). As FDA explained, Intervenor Plaintiffs’ “limitless theory” posits that “removing a *federal* restriction on certain activity” injures a State by eliminating “one barrier to third parties violating *state* law restricting that same activity,” Mot. 12, even though the State retains all power it had before the removal of the federal restriction. That is untenable. Allowing States to establish standing based on allegations that the mere absence of a federal prohibition on certain conduct emboldens third parties to violate state law or makes violations of state law harder to detect would enable States to challenge virtually any federal deregulation. *Id.*; *see also Alliance*, 602 U.S. at 383 (holding that plaintiffs cannot establish standing through “distant . . . ripple effects” of agency action).³

³ Judge Joseph also found that Louisiana had established standing “at this stage” to challenge the 2023 REMS Modification based on a similar sovereign harm theory. *Louisiana*, 2026 WL 936958, at *10-*11. For the reasons explained here, this Court should not follow that aspect of Judge Joseph’s opinion. Indeed, it would be unnecessary to reach this issue if this Court finds that a stay is

Washington v. FDA, 108 F.4th 1163 (9th Cir. 2024), squarely rejected this theory. Intervenor Plaintiffs attempt to distinguish *Washington* on the ground that, unlike the States seeking to intervene there, Intervenor Plaintiffs allege preemption. Opp’n 5-6. But for the reasons above, preemption is a red herring here—all agree that the mifepristone REMS only establishes a regulatory floor—and Intervenor Plaintiffs identify no other way in which the REMS supposedly interferes with their “authority” to enact or enforce restrictions on abortion.

Intervenor Plaintiffs also overlook the crucial respect in which *United States v. Texas*, 599 U.S. 670 (2023), parallels this case. In *Texas*, the States lacked a cognizable interest in federal prosecutions. *Id.* at 680. They sought to overcome that problem by pointing to, among other things, an alleged increase in state crime resulting from non-prosecution. Br. for Respondents, *United States v. Texas* (No. 22-58), 2022 WL 12591050, at *11 (U.S. Oct. 18, 2022) (“[T]he States bear costs related to *law enforcement, recidivism, healthcare, and education that are traceable to the Final Memorandum and redressable by vacatur.*”) (emphases added). The Supreme Court rejected that “novel” standing argument. *Texas*, 599 U.S. at 681. Here, Intervenor Plaintiffs similarly lack a cognizable interest in federal restrictions on a drug they do not use or prescribe. Like the States in *Texas*, they try to overcome that defect by blaming the lack of federal restriction for an increase in state crime. But that maneuver fails to “overcome[] the fundamental Article III problem with this lawsuit.” *Id.* at 680 n.3.

Third, Plaintiffs’ theory of economic harm is, as FDA explained, squarely foreclosed by *Alliance*. There, the Supreme Court held that plaintiffs who do not use or prescribe mifepristone must allege injuries that are *both* predictable *and* not “too attenuated.” *Alliance*, 602 U.S. at 383. The

appropriate. In any event, even if this Court were to agree with Judge Joseph, that would give Intervenor Plaintiffs standing to challenge only the 2023 REMS Modification, and not earlier agency actions. *See id.* at *10 (finding standing based on allegations unique to the 2023 REMS Modification).

plaintiff doctors alleged that they incurred costs in having to treat patients who suffer complications from mifepristone. *Id.* at 391. The Court held that this alleged injury, *even if predictable*, was too attenuated to satisfy Article III. *Id.* Intervenor Plaintiffs’ theory involves precisely the same attenuated chain of causation plus one additional step—that the doctors also pass their costs on to the States through Medicaid. Mot. 12-13. It therefore fails *a fortiori*.

In response, Intervenor Plaintiffs argue that, unlike the doctors, the nature of the alleged injury allows States to satisfy the *predictability* element of causation based on statistical evidence. Opp’n 8; *see also Louisiana*, 2026 WL 936958, at *12 (endorsing similar theory). But regardless of whether Intervenor Plaintiffs’ alleged economic injuries are predictable, they still rely on the same too-attenuated chain of causation (plus one more step) that the Supreme Court squarely rejected. Nothing in the Intervenor Plaintiffs’ Opposition addresses this crucial point.

B. Plaintiffs failed to administratively exhaust their claims

The States do not dispute that they failed to exhaust any of their claims by asking FDA to consider the new evidence they identify—a step FDA is now undertaking. For example, the Amended Complaint asserts that the REMS is insufficient based in part on a 2024 study published after the 2023 REMS Modification. Am. Compl. ¶ 66.

Instead, they principally deny that there is an “exhaustion requirement,” Opp’n 11, wholly ignoring the numerous authorities dismissing claims brought by parties that similarly failed to exhaust. *See* Mot. 14. The States contend that exhaustion is required only if the agency action is inoperative while the administrative process is ongoing, Opp’n 11, but that applies only to administrative appeals—*i.e.*, “an appeal to superior agency authority,” 5 U.S.C. § 704—not when a party has failed to initiate agency review in the first instance as required by agency regulations, 21 C.F.R. § 10.45.

None of the “exceptions” Intervenor Plaintiffs rely on accounts for the fact that the Amended Complaint asks the Court to evaluate FDA’s action based on evidence and arguments that were not before FDA at the time FDA approved the 2023 REMS, and that FDA thus never had the opportunity to review. Mot. 15. Moreover, Eighth Circuit precedent does not give these exceptions the breadth Intervenor Plaintiffs would assign them.⁴ For example, Intervenor Plaintiffs argue that they are exempt from exhaustion because they claim to be challenging agency action in excess of statutory authority. Opp’n 11. In the Eighth Circuit, “[a] person cannot evade agency process simply by claiming [that] the agency is operating [u]ltra vires.” *West v. Bergland*, 611 F.2d 710, 717 (8th Cir. 1979); accord *Key Med. Supply, Inc. v. Burnwell*, 764 F.3d 955, 962-63 (8th Cir. 2014); *Neb. State Legis. Bd., United Transp. Union v. Slater*, 245 F.3d 656, 659-60 (8th Cir. 2001).

Likewise, Intervenor Plaintiffs cannot show that exhaustion would be futile. There is no “doubt” that FDA “could grant effective relief” through its administrative process—which, again, confirms the prudence of staying this action. *Bartlett v. U.S. Dep’t of Agric.*, 716 F.3d 464, 472-73 (8th Cir. 2013) (quoting *Ace Prop. & Cas. Ins. Co. v. Fed. Crop Ins. Corp.*, 440 F.3d 992, 1000 (8th Cir. 2006)). Nor do Intervenor Plaintiffs provide any reason to think it would be futile to require them to await FDA’s consideration of evidence that was not before the agency at the time FDA approved the 2023 REMS. They also provide no authority for the proposition that a court may excuse a plaintiff from exhaustion based on allegations that the agency delayed in resolving another party’s administrative process. Opp’n 12 (accusing FDA of “abuse of the administrative process” based on the time it took FDA to issue a final decision on another party’s citizen petition).⁵ Finally, in a

⁴ Intervenor Plaintiffs rely exclusively on out-of-circuit authority, including the district court’s opinion in *Alliance*, see Opp’n 11 (citing *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 536 (N.D. Tex. 2023)), which the Supreme Court later reversed for lack of jurisdiction.

⁵ In any event, Intervenor Plaintiffs’ accusation of delay is based on a false assumption that FDA’s regulations require it to make a final decision on a citizen petition within 180 days. Opp’n 12. In fact,

footnote, Intervenor Plaintiffs suggest that they need not exhaust because the original Plaintiffs did. But since the original Plaintiffs never had a jurisdictionally valid suit, Intervenor Plaintiffs cannot rely on their alleged exhaustion. *Missouri*, 2025 WL 2825980, at *7.

C. Intervenor Plaintiffs' challenge to the 2016 action is time barred

Even if Intervenor Plaintiffs have standing and were not required to exhaust, the applicable statute of limitations bars their challenge to the 2016 action. The statute of limitations requires that a plaintiff challenge agency action within six years of when the plaintiff's cause of action "first accrues." 28 U.S.C. § 2401(a). If Intervenor Plaintiffs have a right of action, it first accrued in 2016 when they say they were first injured. Am. Compl. ¶ 563 (alleging that "[e]ach" challenged action caused a sovereign injury), *id.* ¶ 605 (alleging that the 2016 "removal of three in-person doctor visits results in" Medicaid expenditures). Accepting that as true, then the six-year limitations period began to run in 2016 and thus expired before Intervenor Plaintiffs sought to intervene in this suit in 2023. Mot. 15. Under a straightforward application of *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, 603 U.S. 799 (2024), Intervenor Plaintiffs' challenge to the 2016 action is time-barred. *Id.* at 811; Mot. 15.

Intervenor Plaintiffs offer five reasons for ignoring their untimeliness. None is valid.

First, relying on pre-*Corner Post* out-of-circuit authority, Intervenor Plaintiffs claim that they are exempt from the statute of limitations because the original Plaintiffs' challenge to the 2016 action was timely. Opp'n 12-13 (citing *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 678 (5th Cir. 1985)). But *Corner Post* clarified that § 2401(a) is "plaintiff-centric," 603 U.S. at 816, and "looks to when" a "particular plaintiff" has a cause of action, *id.* at 817.⁶ In any event, the Intervenor Plaintiffs cannot

FDA's 180-day response need not be its final decision on the citizen petition. *See* 21 C.F.R. § 10.30(e)(2)(iv).

⁶ Even before *Corner Post*, it is not clear that, in this Circuit, an intervenor plaintiff could piggyback on an original plaintiff's claim for statute of limitations purposes. *See Shelter Mut. Ins. Co. v. Pub. Water*

piggyback on the original Plaintiffs' claims here because (1) those claims were never properly before a court, *Missouri*, 2025 WL 2825980, at *7, and (2) they were voluntarily dismissed, *Curtis v. United Transp. Union*, 648 F.2d 492, 495 (8th Cir. 1981) (noting “the rule that the entry of a voluntary dismissal without prejudice leaves the action as if suit had never been brought for purposes of the statute of limitations”); *Ford v. Sharp*, 758 F.2d 1018, 1023-24 (5th Cir. 1985) (“If a plaintiff voluntarily dismisses an action without prejudice, it is considered that the suit had never been filed.”).

Second, Intervenor Plaintiffs assert that they were not injured (and hence their claims did not accrue) until the Supreme Court decided *Dobbs*. Opp’n 13. Not so. Notwithstanding judicial constraints on States’ authority to enforce some types of abortion regulations before *Dobbs*, Intervenor Plaintiffs allege that “[e]ach of Defendants’ challenged actions”—including the 2016 action—“removed Defendants’ assistance in enforcing federal and state restrictions on abortion drugs.” Am. Compl. ¶ 563. So even if removal of that assistance were to establish standing (which it does not), then Intervenor Plaintiffs’ own allegations would establish that they acquired that standing in 2016. Likewise, if Intervenor Plaintiffs’ pocketbook injury theory is valid, the Intervenor Plaintiffs first incurred that injury in 2016. Am. Compl. ¶ 605; *see also id.* ¶ 720 (alleging Medicaid expenses in 2016).

Third, and relatedly, Intervenor Plaintiffs claim that the statute of limitations should be tolled before *Dobbs* because they “were ‘under legal disability’ while *Roe v. Wade* was on the books.” Opp’n 13. But *Roe* did not preclude Intervenor Plaintiffs’ APA claims about FDA’s statutory drug approval authority and decision-making. *Roe* did not, for example, hold that FDA was constitutionally

Supply Dist. No. 7 of Jefferson Cnty., 569 F. Supp. 310, 313 (E.D. Mo. 1983) (“Since the defendants have raised the statute of limitations defense, the burden then shifts to the plaintiff . . . and the plaintiff-intervenor[s] . . . to assert that *their* claim is not time-barred . . .”) (emphases added).

required to approve mifepristone without Intervenor Plaintiffs' desired safety restrictions. (Nor, as just explained, did it make it impossible for Intervenor Plaintiffs to assert their theories of standing.)

Fourth, Intervenor Plaintiffs claim that they “are newly injured” every time a nonparty violates one of their laws or requires them to spend money to treat complications from mifepristone. Opp’n 13-14. But the statute of limitations begins to run when “the right of action *first* accrues.” 28 U.S.C § 2401(a) (emphasis added). That occurred when Intervenor Plaintiffs first acquired “the right to bring suit in court,” *Corner Post*, 603 U.S. at 821, which under Intervenor Plaintiffs’ theories of standing was 2016. *Supra* pp. 10, 11. Intervenor Plaintiffs cite no authority that a right to challenge a discrete agency action *continuously* “first accrues” for as long the injury is experienced. To the contrary, the “current effects” of a discrete action do not restart a statute of limitations every time a plaintiff allegedly experiences those effects. *Ledbetter v. Goodyear Tire & Rubber Co.*, 550 U.S. 618, 628 (2007).

Fifth, Intervenor Plaintiffs argue that their suit is timely “under the reopening doctrine” because, in 2021 FDA denied a citizen petition challenging the 2016 action. Opp’n 14. Like the Supreme Court, the Eighth Circuit has never adopted the reopening doctrine. *See Biden v. Texas*, 597 U.S. 785, 809 n.8 (2022) (noting that “this Court has never adopted” the “reopening doctrine”); *N.D. Retail Ass’n v. Bd. of Governors of the Fed. Rsv. Sys.*, 55 F.4th 634, 639 (8th Cir. 2022) (“This court has not adopted or even referenced the D.C. Circuit’s reopening doctrine.”), *vacated on other grounds*, 113 F.4th 1027 (8th Cir. 2024) (per curiam). Even the Fifth Circuit authority on which Intervenor Plaintiffs rely expressed doubts. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 244 (5th Cir. 2023) (“we are not sure that” the reopening doctrine “is a valid exception to the statute of limitations”). And the logic of *Corner Post*—which focuses on when a particular plaintiff acquires a right to sue rather than when an agency considered a matter—is at odds with recognizing such a doctrine.

But even if the reopening doctrine were valid, it would not apply here. FDA's response to the citizen petition upholding the 2016 action does not, by itself, trigger that doctrine. *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1352 (D.C. Cir. 1995) (holding that an agency's response denying a petition for rulemaking did not trigger reopening doctrine because "[a]n agency is normally obliged under the [APA] to issue some sort of explanation when it denies a petition"). Moreover, the reopening doctrine simply holds that "[i]f . . . the agency reopens a matter and . . . issues a new and final order, *that order* is reviewable on its merits, even though the agency merely reaffirms its original decision." *Sendra Corp. v. Magan*, 111 F.3d 162, 167 (D.C. Cir. 1997) (emphasis added). Intervenor Plaintiffs cannot take advantage of that doctrine because they have not challenged FDA's 2021 denial of the 2019 citizen petition.

In short, no valid basis exists for entertaining Intervenor Plaintiffs' untimely challenge to the 2016 action.

CONCLUSION

For the foregoing reasons, the Court should either stay or dismiss this case.

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Respectfully submitted,

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