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

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

DANCO LABORATORIES, LLC'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION

The Plaintiff States do not dispute that Missouri is the only plaintiff that makes venue proper in this district. *See* Mot. Dismiss, ECF No. 295 at 5 n.2 (Danco MTD). But nothing in the Plaintiff States' opposition shows that either Missouri or its sister States can continue to litigate this case.

The Plaintiff States lack standing. Each of their standing theories is either directly foreclosed by the Supreme Court's earlier decision in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (*Alliance*), or not cognizable under any existing doctrine. *See* Danco MTD at 5-11. Remarkably, the Plaintiff States barely discuss *Alliance*, as though declining to grapple with its reasoning somehow makes that decision less binding on this Court. They fail to even acknowledge—much less confront—the Supreme Court's central legal holding in *Alliance* that "downstream" expenses related to the Food and Drug Administration's (FDA) regulation of mifepristone do not give plaintiffs Article III standing to challenge the drug's approval. 602 U.S. at 383. This refusal to meaningfully engage with contrary precedent is telling. The Plaintiff States ultimately urge a standing standard that is as limitless as what the original plaintiffs in this case urged.

The Plaintiff States' other defenses fare no better. Plaintiffs do not fall within the relevant zone of interests; they have not exhausted their remedies; and they cannot show that their challenge to FDA's 2016 action is timely. Their Complaint should be dismissed.

ARGUMENT

I. The Plaintiff States Lack Article III Standing.

The Plaintiff States claim they have standing because FDA's actions allegedly increase their costs to provide medical care for some Medicaid beneficiaries and infringe their sovereign interests. Int.-Pl.' Cons. Opp'n, ECF No. 302 at 4-10 (Opp.).[1] Idaho offered these same theories

[1] The Plaintiff States do not argue they have standing based on their complaint allegations that FDA's actions will decrease their populations or infringe their interests in exercising parental rights. *See* Danco MTD at 12.

in Washington District Court and the Ninth Circuit, which rejected them. *See Washington v. FDA*, 108 F.4th 1163, 1174, 1176 (9th Cir. 2024). Just as in that case, the legal defects with these theories are apparent on "the face of the pleadings." *Carlsen v. GameStop, Inc.*, 833 F.3d 903, 908 (8th Cir. 2016).[2]

A. Alleged Medicaid Costs To Provide Care Are Legally Insufficient To Create Article III Standing.

Although Medicaid expenses can satisfy the injury-in-fact prong of the standing inquiry, *see* Opp. at 6-7, not all injuries create Article III standing. Indeed, as the Supreme Court made clear in this very case when it analyzed the original plaintiffs' injury claims, the causal link between FDA's "safety regulations" and people "show[ing] up at emergency rooms or in doctors' offices with follow-on injuries" is "simply too attenuated" for Article III purposes. *Alliance*, 602 U.S. at 391. That is why—contrary to what Missouri now suggests (Opp. at 3 n.2)—the original plaintiffs never had standing to sue FDA based on the cost of treating "patients with mifepristone complications." *Alliance*, 602 U.S. at 390-391. The original plaintiffs lacked standing, at all times, because there "is no Article III doctrine of 'doctor standing'" that allows doctors to challenge anything that could ultimately result in someone needing medical care. *Id.* There is likewise no Article III doctrine of standing for "those-who-pay-doctors" that allows States to challenge anything that could result in someone needing medical care that a State might pay for. The result is clear: The expenditure of Medicaid dollars is insufficient *as a matter of law* to establish the States' Article III standing to challenge FDA's actions on the theory that someone needed medical care at the end of a long chain of independent third-parties' actions.

[2] Notably, the Plaintiff States agree that their standing—like Idaho's in the Ninth Circuit—should be resolved on the face of the pleadings, rather than through a factual inquiry. *See* Opp. at 3 (reciting the facial attack standard in *Carlsen*, 833 F.3d at 908); *see generally Washington*, 108 F.4th at 1174 (resolving jurisdiction on a facial challenge). And they do not dispute that Idaho is precluded from relitigating the issues here. Danco MTD at 11 (explaining that Idaho is "collaterally estopped from raising the same" standing theories that it fully litigated and lost in the Ninth Circuit). Because all the Plaintiff States present identical arguments, this issue makes little practical difference.

The Plaintiff States ignored these basic principles of standing in their complaint, and ignore them again in their opposition. Instead, the States treat the Supreme Court's rejection of "doctor standing" as an open invitation to craft an alternative "insurance" standing theory. Opp. at 9. Pointing to *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Plaintiff States argue that "third-party insurers or payers" like state "health insurance programs" can have standing to sue over relaxed safety standards that statistically increase their costs, Opp. at 1-2, 9. But *State Farm* was not a standing decision: it does not even mention, much less purport to analyze, Article III requirements. *State Farm*, 463 U.S. at 34. Nor does Justice Kavanaugh's concurrence that the Plaintiff States cite (Opp. at 9) suggest that *State Farm* should be understood as doing so. *See Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 834 (2024) (Kavanaugh, J., concurring) (explaining that *State Farm* implicitly recognized the availability of "vacatur" as a remedy under the APA). These decisions thus do not even rise to the level of a "'drive-by jurisdictional rulin[g],'" and can "receive[] 'no precedential effect'" on the standing issue. *Wilkins v. United States*, 598 U.S. 152, 160 (2023) (quoting *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 511 (2006)).

Even more to the point, the Supreme Court expressly *rejected* the original plaintiffs' invocation of higher "insurance costs" as a basis for standing in this very case. *Alliance*, 602 U.S. at 391. For good reason. Those costs, like the other costs the doctors alleged, are part and parcel of treating *any* drug's "complications or side effects." *Id.* at 392. Recognizing standing based on such costs would adopt the same "unprecedented and limitless approach" to Article III requirements that lacks a logical end point. *Id.* at 391-392. Indeed, as Danco observed in its motion to dismiss (at 6), such costs are indistinguishable from the innumerable other forms of "indirect effects on state revenues or state spending" that are ever-present "in our system of dual federal and state sovereignty." *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023); *Maryland v. Dep't of Agric.*, 151 F.4th 197, 210 (4th Cir. 2025) (because "[i]nnumerable federal actions impact state budgets and programs," a state's "alleged decline[] in tax revenue" does not constitute

"cognizable injury"); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) ("peripheral costs on a State" do not satisfy Article III). The Plaintiff States offer no response. Opp. at 8-9.

Instead, the Plaintiff States invoke *Department of Commerce v. New York*, 588 U.S. 752 (2019), but that case's analysis does not apply here. Opp. at 8-9. In *Department of Commerce*, the Court concluded that certain states established they had standing because "evidence at trial established" that placing a citizenship question on the census would "predictabl[y]" undercount their populations—leading directly to a loss of representation and other related injuries. *Id.* at 767-768. California showed a similar populational change in the other case cited byMissouri. Opp. at 9 (citing *California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018) (federal rule would lead to increase in population "seek[ing] contraceptive care through state-run programs")). But the FDA actions the Plaintiff States seek to challenge here logically would not increase the overall population of state residents eligible for Medicaid—leading the Plaintiff States to engage in various gymnastic routines to estimate how the FDA's actions may affect costs. Opp. at 7-8. The latter is a categorically different sort of claim because it relies on far more layers of speculation about the choices of independent third parties. *See Washington*, 108 F.4th at 1175 (explaining that Idaho's Medicaid cost theory "depend[s] on the independent actions of doctors and pregnant women whose medical decisionmaking is informed by a wide range of individualized considerations that are difficult to predict"). And established precedent dictates that mere reliance on "population-wide statistics and probabilities," Opp. at 8, is impermissible to show Article III standing. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009) ("[S]tatistical probability that some [plaintiffs] are threatened with concrete injury" insufficient even if coupled with allegations of past harm).

The Plaintiff States cannot overcome all these problems with the passing suggestion that they are supposedly the "object" of FDA's actions in 2016 and 2023. Opp. at 9. As the very cases the Plaintiff States cite make clear, an entity is the object of a regulation when that regulation is designed to affect that entity's product—as was the case when fuel producers challenged fuel standards that forced the design and sale of more vehicles that would use less gas. *Diamond Alt.*

Energy, LLC v. EPA, 606 U.S. 100, 116 (2025).[3] Yet the Plaintiff States do not—and cannot—plausibly allege that FDA's regulation of mifepristone in 2016 and 2023 was designed to impact the Plaintiff States at all, much less affect their Medicaid spending. Indeed, the 2016 action far predates the Supreme Court "return[ing]" abortion policy to the states in 2022. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). And the 2023 REMS merely formalized FDA's lifting of in-person dispensing that started in April 2021, and reflected the culmination of an administrative process that began in December 2021. Thus, any suggestion that FDA's regulations target the States just does not work temporally: FDA had no reason to supposedly "target" the Plaintiff States while abortion was protected at the Federal level. The Plaintiff States have not identified any nonconclusory facts that, if proved, would demonstrate the requisite causal link. *Cf. Department of Com.*, 588 U.S. at 767 (extensive trial record showed that the predictable result of a census citizenship question would be the undercounting of certain households).

These inherent defects in the Plaintiff States' argument are why the Ninth Circuit held that "economic injury in the form of increased costs to the state's Medicaid system" did not give Idaho standing to challenge FDA's 2023 REMS. *Washington*, 108 F.4th at 1174-1176. As the Ninth Circuit explained, this conclusion necessarily follows from the *Alliance* decision and the Supreme Court's admonition in *Texas*, 599 U.S. at 680 n.3. *Id.* Indeed, as the Ninth Circuit observed, allowing "every entity that provides health insurance or subsidized medical care" to challenge FDA decisions would be exactly the kind of "boundless conception of Article III's" requirements that *Alliance* emphatically rejected. *Id.* The only substantive objection the Plaintiff States now offer is that the Ninth Circuit did not analyze the (irrelevant) *State Farm* decision. Opp. at 9. Like with the Supreme Court's *Alliance* decision, the Plaintiff States' refusal—or inability—to engage with the underlying logic of *Washington* speaks volumes.

A District Court in the Fifth Circuit recently came to a different conclusion, finding that Louisiana likely had standing to challenge FDA's 2023 REMS. *See Louisiana v. FDA*, No. 25-

[3] Plaintiffs also cite *Mirabelli v. Bonta* (Opp. at 9), but that interim decision merely applies the *Diamond* standard. 146 S. Ct. 797, 803 (2026) (per curiam).

cv-1491, ECF No. 258 at 22-25 (W.D. La. Apr. 7, 2026) (granting stay of proceedings and denying preliminary injunction as moot given the stay). But this portion of the District Court's opinion neither discusses nor explains how this conclusion is consistent with the Supreme Court's *Alliance* decision. *See id.* Nor does the District Court mention the Ninth Circuit's *Washington* decision. *Id.* Respectfully, the District Court's analysis is far less persuasive and probative than the Ninth Circuit's opinion, which addresses standing of one of the very States in this litigation.

Given all this, the Court does not need to reach the additional legal shortcomings in the Plaintiff States's claim to have Article III standing—i.e., their failure to adequately connect any alleged increased Medicaid cost to *each* of the FDA actions they challenge, as Article III requires, and their failure to show that returning to the pre-2016 labeling would actually ameliorate their supposed injuries. Danco MTD at 7. Notably, the Plaintiff States have nothing to say on the first point—and merely state, without elaborating, that their complaint adequately pleads that FDA's actions "increase[] the use of" mifepristone. Opp. at 9-10. But, as Danco already observed, the complaint *does not* address the fact that the 2016 labeling and REMS changes *reduced* the dosage of mifepristone and *reduced* complication rates. Danco MTD at 7-8. These two flaws, in addition to the *Alliance* decision, underscore that the Plaintiff States have not shown Article III standing.

B. The Plaintiff States Have Not Pled A Cognizable Sovereign Injury.

The Plaintiff States' barebones assertion of a sovereign injury falls equally short. Although the Plaintiff States continue to claim, in a single conclusory sentence (at 4), that FDA's actions create "a substantial risk of federal preemption" of their laws, they fail to show how any such preemption is "imminent" or "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted).

The Fourth Circuit has held that FDA's regulation of mifepristone "leav[es] the question of [drug] access to state governance," *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 276 (4th Cir. 2025), and the Plaintiff States do not point to any state law or regulation that they say is definitively preempted by FDA's 2016 or 2023 actions. Opp. at 4. At most, the Plaintiff States have a "subjective fear" that such a lawsuit could someday be filed and might be successful, but the

Supreme Court has been definitive that such concern does not "give rise to standing." *Clapper*, 568 U.S. at 418.[4]

That leaves the States' more nebulous assertions about FDA's actions "interfere[] with enforcement of state law." Opp. at 4. But here too, the Plaintiff States offer no specifics facts to support that conclusory statement. In fact, they do not even explain what kind of "interference" they mean. *Id.* Danco's motion noted the complaint's vague assertion that FDA's actions make it more difficult for states to "detect and deter" state-law violations, MTD 10, but the Plaintiff States do not invoke that allegation or offer any specifics.[5] The States seemingly have some other kind of "interference" in mind—but never explain what exactly they mean.

This pleading failure would be fatal in any circumstance. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("[L]abels and conclusions," "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," and "naked assertions devoid of further factual enhancement" are insufficient to plead a plausible claim). And it is doubly so here, where the very case the Plaintiff States cite makes clear that sovereign injury occurs only when such interference is "analogous to pressure to change state law." *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015). The response does not come close to plausibly alleging that FDA's actions in 2016 or 2023 created any pressure to change any state law. And the Plaintiff States fail to identify any precedent showing that vague and generalized interference "has a 'close relationship' to a harm 'traditionally' recognized as providing a basis for a lawsuit in American courts." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021) (citation omitted); *see also Harrison v. Jefferson Par. Sch.*

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[4] This basic pleading failure is only highlighted by Missouri's protestations that its Constitution's provisions still leave "many of Missouri's laws regulating mifepristone" in place. Opp. at 6. The State does not come close to explaining how its ban on dispensing mifepristone in Missouri "where a complication plan is not in place" or the requirement that abortion providers in Missouri "carry insurance 'for personal injury to or death of a child who survives . . . abortion'" would be in any way "jeopardized" by FDA's regulations. *Id.* (citations omitted).

[5] As another example, the Plaintiff States have submitted a declaration from a woman who asserts that she was coerced by her partner into taking some unidentified drugs that likely induced an abortion. *See* ECF No. 302-2. Yet the States do not claim that they are unable to prosecute the perpetrator—much less explain how FDA's actions would stand in the way of doing so.

Bd., 78 F.4th 765, 767 (5th Cir. 2023) (plaintiffs "fail[] to point to 'any precedent, history, or tradition' establishing that" a general interest in enforcing compliance with state "laws is the equivalent of an Article III sovereign interest in maintaining [the] right to govern in the face of competing authority").

In short, the Plaintiff States' allegations fail for all the same reasons that Idaho's did in the Ninth Circuit. The Plaintiff States do not plausibly allege that FDA's regulations of mifepristone "encroach[] on [their] authority to govern." *Washington*, 108 F.4th at 1177. Accordingly, they do "not have standing based on" sovereign harm. *Id.*

II. The Plaintiff States Fail To State An APA Claim.

Beyond jurisdiction, the Plaintiff States also fail to state a viable claim on the merits. Indeed, their response does not—and cannot—overcome the multiple threshold defects Danco identified.

A. The Plaintiff States Are Not Within The FDCA's Zone Of Interests.

The Plaintiff States attempt to show they are in the FDCA's zone of interests by misstating the legal standard. Danco MTD at 13-14. The zone-of-interests test does not ask whether this lawsuit is related to the FDCA's general purposes. Opp. at 10. The Supreme Court rejected that view decades ago: whether a plaintiff is within a statute's zone of interests is "determined ***not*** by reference to the overall purpose of the Act in question . . . but by reference to the particular provision" the plaintiff claims was violated. *Bennett v. Spear*, 520 U.S. 154, 175-176 (1997) (emphasis added). Although the zone of interests test is not "especially demanding," *Badger Helicopters Inc. v. FAA*, 154 F.4th 902, 911 (8th Cir. 2025) (quotation omitted), the Plaintiff States do not meet it.

The Plaintiff States cite the general FDCA provision prohibiting the introduction of adulterated or misbranded drugs into interstate commerce, 21 U.S.C. § 331(a). Opp. at 10. But none of the Plaintiff States' claims are based on § 331, *see generally* ECF Nos. 217, 281, so that provision is not relevant to the zone-of-interests test. *See Bennett*, 520 U.S. at 175-176. The only other provision Plaintiff States invoke in their opposition is 21 U.S.C. § 355-1(a)(1)(E), which

narrowly requires FDA to consider the "seriousness of any known potential adverse events that may be related to the drug." Opp. at 10. That provision, like the FDCA overall, was designed to safeguard and advance public health by protecting consumers taking drugs that are found to have certain risks, not to protect states from economic or sovereign harms. The Plaintiff States are, of course, correct that they are not obligated to point to a provision in the FDCA expressly protecting their interests. *Id.* But even under that generous standard, the Plaintiff States fall short of showing that Congress intended states be permitted to bring private suits to challenge FDA's determination of whether a particular drug is safe and effective under its approved label or whether a drug's REMS ensures that the benefits outweigh the risks for that drug. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014).

B. The Plaintiff States Cannot Excuse Their Failure To Exhaust Administrative Remedies.

The Plaintiff States failed to exhaust their claims before FDA and no exception to exhaustion applies.

First, the Plaintiff States attempt to rewrite the APA by claiming that exhaustion is necessary only where an agency rule or statute "provides that the [challenged] action … is inoperative" pending administrative review. Opp. at 11 (quoting 5 U.S.C. § 704). But, as the Supreme Court explained in *Darby v. Cisneros*, the APA's "inoperative" provision applies only to optional administrative remedies; the APA still requires exhaustion of administrative remedies that a "statute or rule clearly mandates." 509 U.S. 137, 146 (1993); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (APA is a "statute requiring exhaustion"); *see also Acura of Bellevue v. Reich*, 90 F.3d 1403, 1408 (9th Cir. 1996) ("*Darby* held that a person aggrieved by an agency decision is not required to exhaust *nonmandatory* administrative remedies . . . before seeking judicial review.") (emphasis added). Here, the FDA's citizen petition requirement is mandatory. *See* 21 C.F.R. § 10.45(b). Accordingly, the "inoperative" exception is inapplicable. *Ctr. Food Safety v. Hamburg*, 142 F. Supp. 3d 898, 906 (N.D. Cal. 2015), *aff'd in relevant part and rev'd on other grounds*, 696 F. App'x 302, 303 (9th Cir. 2017); *see, e.g., Laxton v. Teva*

Pharms. USA, Inc., No. 16-cv-193, 2017 WL 914255, at *2-3 (E.D. Mo. Mar. 8, 2017) (dismissing complaint because plaintiff had not filed citizen petition with FDA).[6]

Second, the Plaintiff States ask the Court to excuse their failure to exhaust because the original *Alliance* District Court decision concluded that exhaustion is not required where the agency acts in excess of its authority. Opp. at 11 (citing *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 536 (N.D. Tex. 2023)). But this argument maps to no established legal standard—and the Plaintiff States tellingly do not cite any supporting Eighth Circuit law. *Id.* at 11-12. At bottom, the Plaintiff States' argument on this ground is a blatant appeal to policy. The Court should decline the invitation to create a gaping hole in the APA's exhaustion rule based on the States' preferred policy.

Third, the Plaintiff States are wrong to claim that the FDA's delay in responding to the original plaintiffs' citizen petitions somehow excuses non-exhaustion. *Id.* FDA's alleged failure to timely respond to *other parties'* past petitions has no bearing on exhaustion. For one thing, the original *Alliance* plaintiffs' citizen petitions did not raise all of the claims that the Plaintiff States now bring, or rely on the same evidence. ECF No. 219 at 13-14. More fundamentally, if FDA's response were truly "unreasonably delayed," the proper remedy would have been for those parties to bring a suit to compel agency action under 5 U.S.C. § 706(1), not for a *different* set of plaintiffs to claim a free pass to skip over administrative review entirely.[7]

Fourth, the Plaintiff States summarily assert (at 11-12) that exhaustion would be futile. "Unsupported and speculative claims of futility do not excuse a claimant's failure to exhaust his

[6] The Plaintiff States cite (Opp. at 11) a one-paragraph decision where the Eighth Circuit concluded that an administrative law judge's order was *not* subject to judicial review because the plaintiff had not exhausted administrative remedies. *See Kakaygeesick v. Salazar*, 389 F. App'x 580, 580 n.2 (8th Cir. 2010) (per curiam). That non-precedential decision is irrelevant to the FDA's scheme, and it also reinforces the general rule.

[7] The Court should not credit the Plaintiff States' passing suggestion (Opp. at 12 n.6) that they can piggyback off the original *Alliance* plaintiffs' exhaustion for the same reasons. Because those plaintiffs are no longer part of this case, the Plaintiff States must independently satisfy the APA's requirements.

or her administrative remedies." *Midgett v. Washington Grp. Int'l Long Term Disability Plan*, 561 F.3d 887, 898 (8th Cir. 2009) (quotation and alterations omitted). Here, the Plaintiff States claim that it would have been futile for them to challenge the agency's 2016 decision after FDA "reconsidered [it] by means of the 2019 Citizen Petition"—but that argument only highlights that the Plaintiff States have been untimely in their challenges all along. Opp. at 11-12. Again, the States' claims are not identical to those in the original *Alliance* plaintiffs' citizen petition. ECF No. 219 at 13-14. And the original plaintiffs did not file a petition challenging the 2023 REMS, so there is no basis for the Plaintiff States to claim futility as to their 2023 claims. Many other interested parties—including other states—followed FDA's rules and filed citizen petitions over FDA's mifepristone decisions. *See, e.g.*, Citizen Petition from Students for Life of America (Oct. 17, 2025), https://tinyurl.com/5x9br66h; Citizen Petition from Nicholas W. Brown, Attorney General of Washington, et. al. (Aug. 26, 2025), https://tinyurl.com/2nz6bh9j; Citizen Petition from Attorney General of Massachusetts, et al. (June 6, 2025), https://tinyurl.com/yc6xaxk5; Citizen Petition from American College of Obstetricians and Gynecologists et al. (Jan. 31, 2025), https://tinyurl.com/4e2483w7. Courts cannot be in the business of rewarding the parties that break those rules.

C. The Plaintiff States' Challenge To The 2016 Changes Is Time Barred.

Finally, the Plaintiff States attempt to evade the APA's six-year statute of limitations for their challenge to the FDA's 2016 action. None of their arguments hold water.

First, just as with venue, the States cannot capitalize on the original *Alliance* plaintiffs' satisfaction of the statute of limitations. *See* ECF No. 273 at 14 (holding that "Intervenor Plaintiffs cannot piggyback on the Original Plaintiffs' venue when the Original Plaintiffs were never properly before this Court"). *Harris v. Amoco Production Co.*, 768 F.2d 669, 678 (5th Cir. 1985) (cited at Opp. at 12-13) had nothing to do with statutes of limitations. Because the original *Alliance* plaintiffs' suit was jurisdictionally invalid, *see generally Alliance*, 602 U.S. 367, the Plaintiff States' complaint-in-intervention is treated as "the operative complaint in a new lawsuit." *See Janus v. American Fed'n of State, Cnty., and Mun. Emps., Council 31*, 585 U.S. 878, 890 (2018);

cf. Mattice v. Meyer, 353 F.2d 316, 319 (8th Cir. 1965) (if original plaintiff lacks standing, "there [is] no basis for intervention under Rule 24"). The Plaintiff States cannot "benefit from the Original Plaintiffs" satisfying the statute of limitations because they "did not intervene in a jurisdictionally valid case." ECF No. 273 at 13-14.

Second, the Plaintiff States suggest (at 13) that their claim against FDA's 2016 action did not accrue until the Supreme Court issued *Dobbs*, but that suggestion is inconsistent with their complaint. A cause of action accrues when the plaintiff suffers the injury underlying the claim. *Corner Post*, 603 U.S. at 811. Here, the Plaintiff States' complaint asserts that "the FDA's 2016 actions resulted [in] … harmed women [] seek[ing] emergency care in Plaintiff States," ECF No. 217 ¶ 254; that the 2016 changes "increase[d] the number of chemical abortions and resulting complications," *id.* ¶ 632; and that those increased complications "inflict[] substantial injury on Plaintiff States as the payers' or insurers of residents' medical expenses." *id.* ¶ 593; *see also*, *e.g.*, *id.* ¶¶ 257, 261, 267, 403, 426, 604-745. Even assuming for the sake of argument that the Plaintiff States' supposed sovereign injuries materialized only after *Dobbs*, their alleged financial injuries are not limited to that period. *See, e.g.*, *id.* ¶¶ 694, 712. Just the opposite: their complaint expressly claims that Missouri expended Medicaid funds to treat complications from medication abortions in 2016, 2017, 2018, 2019, 2020, and 2021. *Id.* ¶ 720. The APA's statute of limitations period begins when "the right of action *first* accrues." 28 U.S.C. § 2401(a) (emphasis added); *Corner Post*, 603 U.S. at 811. Based on the Plaintiff States' own theory of the case—under which they assert that they are "injured every time … they have to pay for complications created by the abortion drug," Opp. at 13—those injuries began when FDA issued the 2016 changes. *See* Danco MTD at 15.

Third, the Plaintiff States grossly misstate the law when summarily asserting (at 13) that they were "under legal disability" within the meaning of 28 U.S.C. § 2401(a) "while *Roe v. Wade* was on the books." The term "legal disability" is a statutory term of art that means "a condition of mental derangement." *Tansil v. United States*, 113 Fed. Cl. 256, 264 (2013) (quoting *Goewey v. United States*, 612 F.2d 539, 544 (Ct. Cl. 1979) (per curiam)) (interpreting materially identical

tolling provision in the Tucker Act); *see Corner Post*, 603 U.S. at 819 (quoting *Goewey* in interpreting § 2401(a)'s tolling provision). That standard is facially inapplicable to sovereign states. And the notion that Supreme Court decisions bear on the "presume[ption] [of] sanity and competency" is certainly puzzling. *Goewey*, 612 F.2d at 544.

The Plaintiff States' fourth argument—that the limitations period to challenge FDA's 2016 action resets every time "their statutes are put at risk or they have to pay for complications created by the abortion drug"—is not the law either. Opp. at 13-14. The Supreme Court has been emphatically clear that the APA's statute of limitations begins to run when a cause of action first accrues, not from "the last culpable act or omission of the defendant." *Corner Post*, 603 U.S. at 812 (quotation omitted). Unlike the circumstances Justice Jackson envisioned in her *Corner Post* dissent—which, obviously, is not controlling, *contra* Opp. at 13-14—the Plaintiff States allege that they started suffering injury at the time FDA issued the 2016 changes. *Corner Post*, 603 U.S. at 861-862 (Jackson, J., dissenting) (explaining that, under the majority's rule new legal entities could potentially challenge old regulations). So this line of attack gets the Plaintiff States nowhere.

Fifth, and finally, the Plaintiff States attempt (Opp. at 14) to invoke the "reopening doctrine." This doctrine has not been applied outside of the D.C. Circuit. *See Biden v. Texas*, 597 U.S. 785, 809 n.8 (2022) (noting that "this Court has never adopted" the doctrine); *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210, 242 n.6, 244 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024) (same). In any event, the reopening doctrine is a narrow exception to exhaustion that applies when an agency treats its existing decision "as a proposed regulation" and then solicits and responds to comments in re-examining the existing decision. *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008) (quotation omitted). The FDA did not do that in denying the 2019 citizen petition—nor did it alter "the basic regulatory scheme" in a way that would constitute constructive reopening. *Natural Res. Def. Council v. EPA*, 571 F.3d 1245, 1266 (D.C. Cir. 2009) (per curiam). Even under the most sweeping interpretation of the doctrine, the Plaintiff States' untimely challenge cannot be excused.

CONCLUSION

The Court should grant Danco's motion and dismiss the Plaintiff States' amended complaint.

Dated: April 10, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 10, 2026, I electronically filed the foregoing using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all counsel of record.

/s/ Kurt S. Odenwald
Kurt S. Odenwald