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 MOTION TO DISMISS

Oral Argument Requested

Danco Laboratories, LLC moves to dismiss Intervenor-Plaintiffs' Amended Complaint, ECF No. 217, and Supplemental Complaint, ECF No. 281, under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for lack of subject-matter jurisdiction, or, in the alternative, for failure to state a claim upon which relief can be granted. In support of this motion, Danco relies on the accompanying memorandum of law. In light of the history of this case, Danco also requests oral argument.

Dated: March 6, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 6, 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

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
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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 MEMORANDUM IN SUPPORT OF MOTION TO DISMISS INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION

Two years ago, the Supreme Court unanimously held that the doctors who originally brought this suit lacked standing. The Court's ruling was unambiguous: Nothing in the Food and Drug Administration's (FDA) regulation of mifepristone required those doctors to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything," and their attenuated link to FDA's drug approvals did not satisfy Article III. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 391-392 (2024) (*Alliance*). Missouri, Kansas, and Idaho likewise are not required by FDA's actions to prescribe or use mifepristone and are not compelled to do or refrain from doing anything. The Plaintiff States seek to bring a similar challenge to the *Alliance* doctors based on similarly (and more) attenuated allegations. The Plaintiff States' complaint should be dismissed.

The Plaintiff States essentially assert that they suffer a traceable, redressable, and Article III cognizable injury from FDA's actions because FDA's actions do not align with their preferred policies and because other states have different state laws. But divergence in abortion policy at the state level is a natural result of the Supreme Court "return[ing]" abortion policy to the states. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). And states cannot challenge FDA's supposed under-regulation of a drug by asserting "downstream" financial or sovereign injury, as the Ninth Circuit recognized when holding that Idaho lacked standing in a similar lawsuit to challenge one of the same FDA actions that Idaho seeks to challenge here. *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir. 2024). *Alliance* held that doctors who said they provided follow-up care were too far removed to have Article III standing, yet the Plaintiff States premise their standing on an even more attenuated link in claiming that their state Medicaid programs may cover the cost of that follow-up medical care. Adding another layer of attenuation makes their theory less viable than the "doctor standing" theory the Supreme Court unanimously rejected in *Alliance*. And none of the Plaintiff States' alternative theories of sovereign harm assert an injury that is "legally and judicially cognizable." *United States v. Texas*, 599 U.S. 670, 676 (2023) (quotation marks omitted).

The Plaintiff States' complaint has other threshold defects. Although the Plaintiff States

seek review under the Administrative Procedure Act (APA), they are not within the zone of interests for the underlying statute. The Plaintiff States have not administratively exhausted their claims, as FDA regulations require, and their challenge to the 2016 changes is time barred.

The Plaintiff States' amended complaint should be dismissed.

BACKGROUND

A. Factual Background

Danco, a small pharmaceutical company, holds the New Drug Application (NDA) for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of intrauterine pregnancy. FDA approved Mifeprex in 2000 for use through 49 days' pregnancy. ECF No. 217-1, Exs. 16-18 (App. 408-428). FDA imposed certain use restrictions with that approval, which were deemed a Risk Evaluation and Mitigation Strategy (REMS) by the 2007 amendments to the Food, Drug, and Cosmetic Act (FDCA). 73 Fed. Reg. 16,313 (Mar. 27, 2008). In 2015, Danco submitted a supplemental NDA (sNDA) to modify certain aspects of Mifeprex's prescribing information and REMS. *See* ECF No. 217-2, Ex. 23 (App. 511-519). FDA approved these changes in 2016, after considering dozens of studies reporting outcomes for tens of thousands of women under various combinations of the proposed changes and 15 years of data reflecting the drug's safety profile. ECF No. 217-1, Ex. 2 (App. 8-36); ECF No. 217-2, Ex. 23 (App. 511-519).

In 2019, certain associations filed a citizen petition asking FDA to "restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000." ECF No. 217-3, Ex. 29 (App. 606, 631) (2019 citizen petition). FDA denied the petition in December 2021 in a detailed 40-page response. ECF No. 217-3, Ex. 34 (App. 648-688). None of the Plaintiff States were party to that petition or filed its own citizen petition.

As part of the original 2000 approval, FDA limited the dispensing of Mifeprex to patients in person. ECF No. 217-1, Ex. 17 (App. 418). It explained that an ultrasound was not mandatory. ECF No. 217-1, Ex. 18 (App. 425). During the COVID-19 public health emergency, the American College of Obstetricians and Gynecologists urged FDA to suspend enforcement of the in-person dispensing requirement because it unnecessarily put patients and providers at risk of COVID-19,

delayed time-sensitive healthcare, and served "as a barrier to accessing this safe, effective medication." ECF No. 217-3, Ex. 31 (App. 640). FDA evaluated that issue, including by analyzing medical literature, postmarketing adverse-event reporting from earlier in the pandemic, and information about deviations or noncompliance events associated with the REMS. ECF No. 217-3, Ex. 32 (App. 644-645). FDA found no indication that forgoing the in-person dispensing requirement increased adverse events. *Id.* FDA's April 2021 response letter therefore stated the agency would exercise enforcement discretion as to that requirement during the public health emergency. *Id.* No Plaintiff State filed a citizen petition challenging this action.

FDA came to the same conclusion in its December 2021 response to the 2019 citizen petition: "mifepristone may be safely used without in-person dispensing," ECF No. 217-3, Ex. 34 (App. 675), and in-person dispensing was "no longer necessary to ensure that the benefits of the drug outweigh the risks," *id.* (App. 673). FDA relied on safety data from the nonenforcement period, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. *Id.* (App. 645). FDA pointed to three studies analyzing pharmacy mail dispensing and five studies analyzing clinic mail dispensing, all of which supported finding that mifepristone remains safe and effective without in-person dispensing. *Id.* (App. 675-683).

Based on its analysis, FDA directed Danco to submit an sNDA proposing modifications to the REMS to remove the in-person dispensing requirement. Danco complied, and FDA approved Danco's sNDA in January 2023. ECF No. 217-1, Ex. 3 (App. 37-211). The Plaintiff States did not file a citizen petition challenging this action, either.

B. Procedural History

Danco's brief in support of its previous Motion to Dismiss provides a fulsome procedural history of this case. *See* ECF No. 222. Briefly, in November 2022, the Alliance for Hippocratic Medicine (the Alliance Plaintiffs) challenged FDA's 2000 approval of Mifeprex, 2016 labeling changes, and 2021 nonenforcement decisions under the APA. After the district court issued an injunction, that injunction never took effect because it was immediately stayed by the Supreme Court. No. 22A902, __ S.Ct. ___, 2023 WL 2942266 (Apr. 14, 2023). The Supreme Court then

heard the case on the merits and held—unanimously—that the Alliance Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374. The Supreme Court rejected all of the Alliance Plaintiffs' theories of standing as a matter of law, explaining (among other things) that "the law has never permitted" plaintiffs "to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." *Id.* at 391.

While the parties' certiorari petitions were pending, Missouri, Kansas, and Idaho moved to intervene in the *Alliance* action, which the Texas District Court granted over Danco and the government's objections. ECF Nos. 100, 110, 151. After the Supreme Court issued its decision, these States moved to file an amended complaint-in-intervention, which the court again granted over Danco and the government's objections. ECF Nos. 215, 217. While that motion was pending, the Alliance Plaintiffs voluntarily dismissed without prejudice "all claims brought in their Complaint as to all defendants." ECF No. 203 at 1.

Danco and FDA moved to dismiss the Plaintiff States' amended complaint, asserting among other things that venue was improper in the Northern District of Texas. The *Alliance* district court agreed venue was improper and subsequently transferred the case to this District.[1]

ARGUMENT

I. The Plaintiff States Fail To Establish Article III Jurisdiction.

The Plaintiff States must show that they have standing, which requires a "personal stake" in FDA's approval-related decisions for mifepristone. *Alliance*, 602 U.S. at 379 (citation omitted). To do so, the Plaintiff States must "clearly allege facts demonstrating" that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged" FDA actions "and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quotation marks and alteration omitted). The Plaintiff States attempt to meet this burden by

[1] The Plaintiff States moved to supplement their complaint to challenge the 2025 ANDA approval of Evita, a generic mifepristone product. ECF No. 277. Insofar as that challenge turns on FDA's 2016, 2021, and 2023 decisions, Danco opposes it for all the reasons discussed here.

alleging that FDA's 2016, 2021, and 2023 actions make it harder for them to enforce certain state-law restrictions, leading to various "economic" and "sovereign" injuries. ECF No. 217 ¶¶ 593, 527. None of these theories show Article III standing.[2]

A. *Alliance* Forecloses The Theory That Downstream State Medicaid Payments For Follow-Up Care Create Article III Standing To Challenge FDA's Actions.

Start with the alleged financial injuries. The Plaintiff States assert that "FDA's under-regulation" of mifepristone will result in costs to their Medicaid programs if women experience "complications" and seek follow-up care paid for by Medicaid. ECF No. 217 ¶ 594. This "medical costs" theory is directly foreclosed by *Alliance*—which is why when Idaho made this argument in seeking to challenge the same 2023 REMS that it seeks to challenge here, both a Washington district court and the Ninth Circuit rejected Idaho's argument. *Washington*, 108 F.4th at 1174.

As *Alliance* explained, the causal chain between "FDA's relaxed regulation" of a drug and "downstream economic injuries" for follow-up medical care is too "attenuated" to be a basis for Article III standing. 602 U.S. at 386, 390. Indeed, "the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." *Id.* at 391. In that situation, the "government action is [too] far removed from its distant (even if predictable) ripple effects" to satisfy Article III. *Id.* at 383, 391. The Court was clear: Allowing parties to "challenge general safety regulations as unlawfully lax" based on such distant effects "would be an unprecedented" expansion of Article III requirements, and would have no "principled" endpoint. *Id.* at 391-392.

The Plaintiff States do not attempt to wrestle with this reasoning or the Supreme Court's express rejection of the *Alliance* Plaintiffs' "doctor standing" argument. *Id.* at 391. The Plaintiff

[2] Because Missouri is the only party that makes venue proper in this district, *see* ECF No. 273 at 26-27 (transferring case to this district on the basis that Missouri can independently establish venue), it is Missouri that must have standing. Kansas and Idaho cannot show that venue in Missouri for their claims is proper. *See id.* at 19-21. In any event, neither Kansas nor Idaho have different or better arguments for standing than Missouri does.

States instead proffer anecdotal stories and statistics suggesting their Medicaid programs may pay doctors for providing follow-up care to a patient in the event such care is needed after a medication abortion. ECF No. 271 ¶¶ 595, 718-721. But a causal chain that was already too attenuated for Article III standing at the doctor link cannot create Article III standing by adding *more* links.

The Plaintiff States' monetary theory also runs headlong into another problem. "[I]n our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending." *Texas*, 599 U.S. at 680 n.3. The Supreme Court thus has repeatedly cautioned against granting states standing based on these kinds of downstream effects, which would erode "bedrock Article III constraints." *Id.*; *see also California v. Texas*, 593 U.S. 659, 675-678 (2021) (expressing skepticism of predictive effects on state budgets). This is especially true "in the FDA drug-approval context," where "virtually all drugs come with complications, risks, and side effects." *Alliance*, 602 U.S. at 392. The Plaintiff States' theory would grant states standing to challenge a "limitless" array of agency decisions merely by (1) estimating how many Medicaid-enrolled residents may seek medical care after encountering a particular product—which, in the case of drugs, could involve speculative assumptions about the independent choices of providers and patients not before the Court—and (2) statistically quantifying how much treating each potential individual could cost. *See, e.g.*, ECF No. 217, ¶¶ 691, 694-695, 720-721. The Supreme Court expressly cautioned against starting "down that uncharted path." *Alliance*, 602 U.S. at 392; *see Summers v. Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009) ("statistical probability that some [plaintiffs] are threatened with concrete injury" insufficient even if coupled with allegations of past harm). Other courts agree. *See, e.g.*, *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).

Applying these standards, the Ninth Circuit correctly recognized that Idaho's alleged "economic injury in the form of increased costs to the state's Medicaid system" did not give it

standing to challenge FDA's elimination of the in-person dispensing requirement in the 2023 REMS approval. *Washington*, 108 F.4th at 1174. "Allowing Idaho to proceed based on predictions of increased emergency-room visits alone would give not just states, but every entity that provides health insurance or subsidized medical care, standing 'to challenge any FDA decision approving a new drug.' " *Id.* at 1176 (quoting *Alliance*, 602 U.S. at 392). Taken to its logical end, the Plaintiff States' standing argument would mean that every state has "standing to challenge virtually every government action that they do not like—an approach to standing that [the Supreme] Court has consistently rejected as flatly inconsistent with Article III." *Alliance*, 602 U.S. at 392. The "lack of historical precedent" for "the States' assertion of standing" is a "telling indication of the severe constitutional problem." *Texas*, 599 U.S. at 677 (citation omitted).

All of these problems are further exacerbated here by the Plaintiff States' failure to show an "[in]direct pocketbook injury" that is "fairly traceable" to *each* of FDA's 2016, 2021, and 2023 actions, as opposed to decisions (like the original 2000 mifepristone approval) that "operate independently." *Haaland v. Brackeen*, 599 U.S. 255, 296 (2023) (citation omitted). "[S]tanding is not dispensed in gross," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021), and as a result, the Plaintiff States must show they are "injured in fact *by the action* [they] sought to have reviewed," *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 38-39 (1976) (emphasis added); *see Hershey v. Jasinski*, 86 F.4th 1224, 1229 (8th Cir. 2023) ("standing must exist 'as to each challenged provision' "). Given the contingencies in the causal chain, any alleged "marginal increase in the rate at which pregnant women require additional medical care" stemming from each of FDA's changes is simply "too attenuated to establish the requisite causal connection." *Washington*, 108 F.4th at 1176.

As a flip side of this same problem, the Plaintiff States also fail to allege a "substantial likelihood that victory in this suit would" redress their alleged Medicaid expenditures associated with follow-up care. *Simon*, 426 U.S. at 45-46. The Plaintiff States seek to return to the pre-2016 mifepristone labeling, but the 2016 changes reduced the dosage of mifepristone, increased the efficacy of medication abortion, and further reduced adverse events. *Compare* ECF No. 28-1 at

32 (92% need no intervention under original labeling), *with id.* at 31, 33 (97.4% of U.S. women need no intervention following 2016 changes). On the Plaintiff States' own speculative and attenuated logic, the marginally lower efficacy rate under the pre-2016 labeling would make it more, not less, likely that women prescribed mifepristone may require some follow-up care and that the Plaintiff States' Medicaid programs would be "injured." Both common sense and precedent dictate that states lack standing if "doing away" with the challenged provision "will only make it harder, not easier, for [the state] to remedy its claimed injury." *Noem v. Haaland*, 41 F.4th 1013, 1018 (8th Cir. 2022); *see also Waterkeeper All., Inc. v. Regan*, 41 F.4th 654, 662 (D.C. Cir. 2022) (no standing where "plaintiffs' requested relief might exacerbate their alleged injuries"); *see generally Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 n.5 (1998) (parties must show that they will "benefit in a tangible way from the court's intervention"); *cf. Plesha v. Ascension Health All.*, No. 4:24-cv-01459, 2026 WL 279321, at *7 (E.D. Mo. Feb. 3, 2026) (Stevens, J.) (no standing where "Plaintiff would be in the exact same place with or without" requested relief).

In short, the Plaintiff States' theory of financial injury flouts the Supreme Court's admonitions in the earlier part of this case litigated by the *Alliance* plaintiffs and fails multiple times over. Alleged future costs of follow-up care that could be covered by Medicaid do not create Article III standing to challenge FDA's actions.

B. The Plaintiff States' Alleged Sovereign Injuries Do Not Create Article III Standing.

The Plaintiff States cannot circumvent *Alliance* by recasting their asserted injuries as "sovereign." ECF No. 217 ¶ 527. Like the Plaintiff States' Medicaid-cost theory, none of the supposedly "sovereign" harms they assert is "traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion*, 594 U.S. at 417.

The plain and straightforward reason FDA's regulation of mifepristone does not cause any sovereign injury is that FDA's regulation does not preempt or otherwise interfere with any Plaintiff State's authority to enact or enforce restrictions on medical abortion within its boundaries. Each Plaintiff State, like the other 47 states in our country, can determine what state laws or state

constitutional rights or restrictions govern within its boundaries. As a result, no sovereign harm flows from FDA's actions, which leave each state free to establish its own governing framework.

When courts speak about a state's "sovereign interests," they are referring to states having the "power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982). Such sovereign interests are implicated when federal law overrides a state law and makes it unenforceable—a situation not present here. As the Fifth Circuit has explained: "when speaking about the sovereign's interest in enforcing its laws, the Supreme Court has spoken about the state's interest in the [laws'] *enforceability*." *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023); *see also Maine v. Taylor*, 477 U.S. 131, 137 (1986) (constitutional challenge implicates state's "interest in the continued enforceability of its" laws). Thus, as the Plaintiff States' cited cases make clear, states may experience a sovereign injury sufficiently cognizable under Article III if the federal government preempts or seeks to force changes to state law. *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (citation omitted).

No such sovereign injury is alleged here, and certainly not one that is "imminent" or "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). The Plaintiff States "vigorously dispute" that the FDA actions they challenge carry any preemptive effect. ECF No. 217 ¶¶ 572, 577. And the district court decision they cite as finding otherwise (*id.* ¶ 574) was reversed by the Fourth Circuit, which held that FDA's regulation of mifepristone "aligns with [the agency's] traditional function of ensuring the safety of drugs on the market while leaving the question of access to state governance." *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 276 (4th Cir. 2025).[3] No Plaintiff State can show that any of the challenged FDA actions actually override or "interfere[ ] with [the state's] *authority* to enact or enforce" any state-law restriction. *Washington*, 108 F.4th at 1177; *see, e.g.*, *Harrison*, 78 F.4th at 770 ("for a sovereign interest" to support standing, the defendant's acts must result "in some tangible interference with [the state's]

[3] The Plaintiff States also cite a district court decision predating *GenBioPro* that found a North Carolina law was preempted, but that decision is currently on appeal in the Fourth Circuit. *See* Compl. ¶ 576 (citing *Bryant v. Stein*, No. 1:23-cv-00077, 2024 WL 1886907, at *15 (M.D.N.C. Apr. 30, 2024), *appeals filed*, Nos. 24-1576, 24-1600, 24-1617 (4th Cir. 2024)).

authority to regulate or to enforce its laws") (citation omitted); *Louisiana v. Biden*, 64 F.4th 674, 683-684 (5th Cir. 2023) (requiring "a direct effect on [state] law or policy" or " 'substantial pressure' for [plaintiff-states] to change their laws") (citation and emphasis omitted). At most, the Plaintiff States have articulated a "highly speculative fear" that someone could someday raise a preemption challenge to some unidentified state law or regulation based on the challenged FDA actions and convince a court to agree. But it is black-letter law that such "allegations of *possible* future injury are not sufficient" for Article III purposes. *Clapper*, 568 U.S. at 409-410 (brackets and quotation marks omitted).

The Plaintiff States fall back on claiming that FDA has denied them the "benefit" of being able to "rely on the backdrop of federal law." ECF No. 217 ¶¶ 556-557. At its core, this argument amounts to complaining the Plaintiff States have to use state resources to enforce state laws. But having to use state resources to enforce state policy is entirely normal in our system of dual sovereignty—and it is the *default* for the kinds of health and safety laws that the Plaintiff States claim to want to enforce. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (protecting citizens' "health and safety" is "primarily" a "matter of local concern") (citation omitted); *GenBioPro*, 144 F.4th at 271-272 (same). States that wish to exercise their sovereign authority to establish and enforce state laws and policies generally must commit state resources to doing so. States have no *sovereign* interest in being able to piggyback on federal regulation to avoid having to spend state resources effectuating state law.

The Plaintiff States also claim, more generally, that FDA's determinations that fewer mifepristone use restrictions were necessary for safety and efficacy "facilitated" violations of state laws and made it more difficult for states "to detect and deter" state-law violations. ECF No. 217 ¶¶ 527, 548. But this argument runs headfirst into an *Alliance* causation problem: the connection between FDA's challenged actions and supposed downstream violations of *state law* involving discretionary actions by several independent "third parties" is both too speculative and too attenuated. *Id.* ¶ 538; *Alliance*, 602 U.S. at 390-393. Nothing about FDA's 2016, 2021, or 2023 decisions compelled or directed any third party to violate any state law, leaving the Plaintiff States'

standing theory to impermissibly "rest on speculation about the decisions of independent actors" not before this Court. *Clapper*, 568 U.S. at 414. As the Ninth Circuit explained when Idaho presented this same exact theory, a state's general "interest in the preservation of sovereign authority" does not confer "standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Washington*, 108 F.4th at 1176. "[E]ven if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, [courts] have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury." *Id.* at 1177.

The Plaintiff States' causation problem is compounded by their failure to articulate any particular law that has been rendered unenforceable or any details about a supposed drain on their "resources." ECF No. 217 ¶ 549.[4] This failure is particularly acute for Missouri, where the state Constitution now recognizes a "fundamental right to reproductive freedom," including "abortion care." Mo. Const. art. I, § 36(2); *see Comprehensive Health of Planned Parenthood Great Plains v. State*, No. 2416-CV31931, 2025 WL 1898975, at *4 (Mo. Cir. Ct. July 03, 2025), *aff'd*, 726 S.W.3d 716, 741-742 (Mo. Ct. App. 2025) ("Missouri voters approved Section 36 of the Missouri Constitution through the democratic process, demonstrating a clear intent to establish a fundamental right to reproductive freedom that shall not be denied or infringed by the Government.") (quotation marks and brackets omitted), *transfer denied* (Mo. Dec. 16, 2025). The same goes for Kansas, whose Supreme Court has affirmed that the state's constitution "protects . . . a pregnant person's right to terminate a pregnancy." *Hodes & Nauser, MDs, P.A. v. Kobach*, 551 P.3d 37, 46 (Kan. 2024). And Idaho has already fully litigated these theories of injury and lost, *see generally Washington*, 108 F.4th 1163, so it is collaterally estopped from raising the same arguments again here, *see, e.g.*, *Turner v. DOJ*, 815 F.3d 1108, 1113 (8th Cir. 2016) (plaintiff was precluded from relitigating subject matter jurisdiction where both "suits relied on the same basis

[4] As other states noted when they moved to intervene in this case before its transfer to this Court, the constitutional amendment that the people of Missouri voted into effect significantly undermines Missouri's claim to Article III standing based on the cost of enforcing Missouri law. *See* ECF No. 255 at 7 (Brief of Texas and Florida); ECF No. 265 at 3, 8, 13-14 (Brief of Louisiana).

of subject matter jurisdiction," making the issues "the same for collateral estoppel purposes").

C. The Plaintiff States' Remaining Standing Theories Fail.

The Plaintiffs States theorize that they have Article III standing because FDA's actions "are causing a loss in potential population." ECF No. 217 ¶ 747. This theory fails for all the same reasons—and more. The Supreme Court rejected an analogous theory nearly a century ago, when Florida alleged that a challenged federal action could cause "withdrawal of property from the state with the consequent loss to the state of subjects of taxation." *Florida v. Mellon*, 273 U.S. 12, 16-18 (1927). Just as in that case, the Plaintiff States' theory here is, by definition, "purely speculative, and, at most, only remote and indirect" given how many layers (upon layers upon layers) of speculation it involves as to discretionary, independent decisions of innumerable individuals—on a decades-long scale. *Id.* at 18. No court has held that the door to federal court is open anytime a state asserts that a federal action might affect birthrates, life expectancy, the willingness of people to move in or out of a state, or other population statistics. Everything from closing military bases to loosening federal firearms laws to relaxing air-quality standards could affect a state's total population decades down the road. Truly, "this is 'turtles all the way down.' " *Rapanos v. United States*, 547 U.S. 715, 754 (2006) (plurality op.). The Supreme Court rejected exactly this type of "unprecedented and limitless approach" to standing. *Alliance*, 602 U.S. at 392.

Finally, the Plaintiff States cannot establish standing on the basis of an asserted interest in exercising parental rights for teen girls in foster care who become pregnant. ECF No. 217 ¶ 578. These allegations are merely a "thinly veiled attempt to circumvent" black-letter law that "States do not have standing as *parens patriae* to bring an action against the Federal Government." *Murthy v. Missouri*, 603 U.S. 43, 76 (2024) (quotation marks omitted). Whether characterized as a general concern for their residents' health and welfare or as a specific interest on behalf of teens in foster care, such claims are all part of the same effort by the Plaintiff States to vindicate the rights of their citizens against the federal government. That is exactly what states may not do. *See Alfred L. Snapp*, 458 U.S. at 610 n. 16 ("[I]t is no part of [state] duty or power to enforce their [citizens'] rights in respect of their relations with the Federal Government.") (citations omitted); *Paxton v.*

Dettelbach, 105 F.4th 708, 715-716 (5th Cir. 2024) (state's "quasi-sovereign interests in its citizens' health and well-being" is "wholly derivative of the personal . . . interests of its citizens and therefore not a valid quasi-sovereign interest at all"); *accord Harrison*, 78 F.4th 765 (similar).

* * *

At bottom, the "federal courts are the wrong forum for addressing the [Plaintiff States'] concerns about FDA's actions." *Alliance*, 602 U.S. at 396-397. The Plaintiff States may "take th[ose] concerns to the Executive and Legislative Branches"—and may "also express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes." *Id.* at 393; *see, e.g.*, Citizen Petition from Attorney General of Massachusetts, et al. (June 6, 2025), https://tinyurl.com/yc6xaxk5 (citizen petition filed with FDA by Massachusetts and other states asking FDA to eliminate the mifepristone REMS). But this Court lacks Article III jurisdiction over the Plaintiff States' complaint.

II. Other Threshold Grounds Bar The Plaintiff States' Claims.

Because the Plaintiff States bring this suit under the APA, they must also show (1) that the interests they assert are "'arguably within the [FDCA's] zone of interests," *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (citation omitted); (2) that they exhausted the appropriate administrative remedies; and (3) that their suit is timely. The Plaintiff States can make none of these showings.

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

The zone-of-interests test asks "whether Congress intended for a particular class of plaintiffs to be relied upon to challenge agency disregard of the law." *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399 (1987) (quotation marks and brackets omitted). Thus, a court must analyze the relationship between "the injury [the plaintiff] complains of" and the specific "statutory provision whose violation forms the legal basis for [the] complaint." *Bennett v. Spear*, 520 U.S. 154, 176 (1997). The test is not "especially demanding," but it forecloses suit when an unregulated "plaintiff's 'interests are [only] marginally related to or inconsistent with the purposes implicit in the statute.'" *Patchak*, 567 U.S. at 225 (quoting *Clarke*, 479 U.S. at 399).

Here, the Plaintiff States are challenging actions that FDA took under various provisions of the FDCA, including the REMS provisions. *See* ECF No. 217 ¶¶ 757-788. Those provisions authorize FDA to approve safe and effective drugs, 21 U.S.C. § 355; to impose use restrictions when the agency finds such restrictions are necessary to "ensure that the benefits of the drug outweigh the risks," *id.* § 355-1(a)(1); to periodically assess any imposed use restrictions, *id.* § 355-1(c), (g)(2)-(3); and to modify use restrictions based on the benefit-risk balance and to "minimize the burden on the health care delivery system of complying with the [REMS]," *id.* § 355-1(g)(4)(B). This overall framework was designed to safeguard and advance public health by protecting consumers taking drugs that are found to have specific risks. Noticeably absent is an intent to protect states that want to impose additional access restrictions on FDA-approved drugs. Nor does the FDCA attempt to regulate Medicaid expenditures. *See Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 18 (D.D.C. 2008) ("alleged competitive and economic injuries do not fall within the [FDCA's] zone of interests"), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009).

At best, then, the Plaintiff States' asserted interests have nothing to do with the FDCA's purposes. More realistically, allowing the Plaintiff States to pursue their asserted interests in enforcing state-law abortion restrictions via this suit would "severely disrupt" the FDCA's "complex and delicate administrative scheme." *Clarke*, 479 U.S. at 399 (citation omitted). That warrants dismissal.

B. The Plaintiff States Failed To Exhaust Administrative Remedies.

The Plaintiff States' suit should also be dismissed because they have not "proceeded through each step of the [agency's] administrative review scheme and received a 'final decision' before seeking judicial review." *Carr v. Saul*, 593 U.S. 83, 88 n.2 (2021); *see Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993) (APA requires an "aggrieved party" to "exhaust[ ] all administrative remedies").

FDA regulations clearly mandate that any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based

on a [citizen] petition . . . before any legal action is filed in a court." 21 C.F.R. § 10.45(b); *see id.* §§ 10.25(a), 10.30. Unlike other states and many other interested parties,[5] the Plaintiff States did not file a citizen petition challenging any of the FDA decisions at issue. Courts routinely dismiss suits in such circumstances. *See, e.g., Ass'n of Am. Physicians*, 358 F. App'x at 180-181 (plaintiffs that failed to file citizen petition challenging FDA's approval "failed to exhaust their administrative remedies"); *Laxton v. Teva Pharms. USA, Inc.*, No. 1:16-cv-00193, 2017 WL 914255, at *3 (E.D. Mo. Mar. 8, 2017) (similar); ECF No. 219 at 12 (collecting cases).

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

APA challenges must be brought "within six years after the right of action first accrues." 28 U.S.C. § 2401(a). The limitations period begins running when "the plaintiff is injured by [the] final agency action." *Corner Post, Inc. v. Bd. of Governors of Fed. Res. Sys.*, 603 U.S. 799, 825 (2024). The Plaintiff States allege that FDA's 2016 REMS changes had immediate ramifications on women's health—which forms the heart of the Plaintiff States' alleged injuries. *See, e.g.*, ECF No. 217, ¶ 254 ("FDA's 2016 actions resulted in . . . harmed women . . . seek[ing] emergency care in Plaintiff States."). Accepting that allegation as true means the Plaintiff States' challenge to the 2016 changes first accrued on March 29, 2016, when FDA approved the challenged changes. *See* ECF No. 217-2, Ex. 23 (App. 513). The Plaintiff States thus had until March 29, 2022, to file their complaint. Yet they did not seek to intervene until more than a year and a half later, on November 3, 2023, *see* ECF No. 151, and their complaint was not docketed until January 12, 2024, *see* ECF No. 176. The Plaintiff States' challenge to the 2016 changes is untimely.

CONCLUSION

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

[5] *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, *supra*; Citizen Petition from American College of Obstetricians and Gynecologists et al. (Jan. 31, 2025), https://tinyurl.com/4e2483w7.

Dated: March 6, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 6, 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

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

[PROPOSED] ORDER ON DANCO LABORATORIES, LLC'S MOTION TO DISMISS

Before the Court is Danco Laboratories, LLC's motion to dismiss in this matter. Having reviewed the motion and all relevant papers, and upon due deliberation, it is hereby ORDERED that the motion is GRANTED.

Intervenor-Plaintiffs' Amended Complaint, ECF No. 217, and Supplemental Complaint, ECF No. 281, are hereby DISMISSED without leave to amend. The clerk is directed to close the case.

SO ORDERED.

Dated: _____

_____
Hon. Cristian M. Stevens
United States District Judge