

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

STATE OF MISSOURI, *et al.*,
Intervenor Plaintiffs,

v.

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

and

DANCO LABORATORIES, LLC, *et al.*,
Intervenor Defendant,

and

GENBIOPRO, INC.,
Intervenor-Defendant.

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

**INTERVENOR-DEFENDANT GENBIOPRO, INC.'S REPLY IN
SUPPORT OF CONSOLIDATED MOTION TO DISMISS**

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INTRODUCTION

Missouri’s opposition brief only confirms that the amended and supplemental complaints must be dismissed.¹

Article III standing is lacking. The asserted sovereign injury reduces to an abstract disagreement about whether FDA’s actions may preempt some state-law restrictions in some future circumstance. And its claim that FDA’s actions interfere with its ability to restrict abortion is especially insubstantial, ignoring that Missouri’s own Constitution protects the “fundamental right to reproductive freedom,” including “abortion care.” Mo. Const. art. I, § 36(2).

Missouri’s fallback theory of economic injury is no more persuasive. It depends on a chain of contingencies even more attenuated than the chain the Supreme Court in this very case rejected as insufficient. In order for Missouri to prevail, it would need to show that: the specific FDA regulatory actions challenged in this case will lead independent actors to prescribe, dispense, and use mifepristone in particular ways that are different than would have occurred *but for* those FDA actions; patients will experience complications due to those differences; those patients will seek particular forms of treatment; and the resulting costs will be borne by Missouri. Missouri has not established any of these links—let alone all of them.

Indeed, Missouri never grapples with the profoundly overbroad consequences of its theories. A State can always come up with a reason—couched in the language of state sovereign

¹ The opposition brief (ECF No. 302) is signed only by counsel for Missouri, and not counsel for Idaho or Kansas, in contrast to their other filings in this case signed jointly by counsel for all three States. *See, e.g.*, ECF Nos. 281, 298, 320. Counsel for Idaho and Kansas have advised undersigned counsel by email that their States join in Missouri’s arguments. The Federal Rules, however, require briefs to be signed by counsel for all parties on whose behalf they are submitted. And the opposition focuses overwhelmingly on Missouri—with only passing citation to Idaho statutes and not one mention of Kansas. This reply accordingly refers to the opposition brief as Missouri’s. To the extent the opposition is deemed to speak for Idaho and Kansas as well, the arguments herein apply equally to those States.

interests—as to why a federal law is contrary to its policy preferences. And many federal policies could be arguably connected, through some attenuated causal chain, to some impact on public health. If a State could challenge any federal action on the ground that it runs counter to the State’s policy preferences or might cause health complications for its population, Article III’s requirements would be hollow in suits by States against the federal government.

Missouri also cannot excuse its failure to exhaust administrative remedies. Missouri’s references to futility, public policy, and supposed “abuse of process” cannot overcome the basic problem that it did not begin, much less complete, the process FDA’s regulations require. Missouri likewise offers no response to GenBioPro’s separate argument that claims challenging the 2023 REMS are unripe because FDA is currently reconsidering the REMS. And Missouri’s challenge to the 2016 changes is untimely because Missouri did not seek to intervene in this case until November 3, 2023—more than seven years after those changes took effect. Its response that its supposed injuries did not start until the Supreme Court’s decision in *Dobbs* is impossible to square with the complaints’ allegations about those injuries. The amended and supplemental complaints should be dismissed.

ARGUMENT

I. Article III Standing Is Lacking

A. The Original Plaintiffs’ Lack of Standing Requires Dismissal

Article III standing continues to be lacking in this case. *See* GenBioPro Mem. 2-6. To start, Missouri fails to grapple with the threshold problem that “the Original Plaintiffs never had a jurisdictionally valid case” for the States to intervene in. *Missouri v. FDA*, 2025 WL 2825980, at *5 (N.D. Tex. Sept. 30, 2025); *see* GenBioPro Mem. 2. Missouri responds in a footnote that intervenors may proceed so long as they “independently satisfy the jurisdictional requirements.”

Opp. 3 n.2. Missouri quotes language in *In re Grand Jury Proceedings (Malone)*, 655 F.2d 882, 886 (8th Cir. 1981), that “if there is an independent basis of jurisdiction as to the intervenor, a district court has discretion to treat the intervention as a separate action.” But that case is inapposite; the language Missouri relies on is included in a parenthetical describing a Third Circuit case—offered in the course of discussing a narrow issue involving appellate intervention. *See McKay v. Heyison*, 614 F.2d 899, 907 (3d Cir. 1980). As cited in GenBioPro’s opening brief, and not addressed by Missouri, the Eighth Circuit subscribes to a different rule: where the original plaintiff “lacked standing at law to maintain the proceeding as a formal action, . . . there was no basis for intervention.” *Mattice v. Meyer*, 353 F.2d 316, 319 (8th Cir. 1965). That alone is sufficient reason to dismiss because, as the Supreme Court already found, the original plaintiffs here lacked standing.

B. Missouri’s “Sovereign Injury” Theory Fails

Even if the original plaintiffs’ lack of standing was not dispositive, Missouri’s own asserted sovereign injury is too abstract and indirect to support standing—as the Ninth Circuit already concluded when rejecting a materially identical theory advanced by Idaho. *See* GenBioPro Mem. 4-6; *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir. 2024). The opposition also offers no response to GenBioPro’s collateral estoppel argument and therefore concedes it. *See Muller v. Blue Diamond Growers*, 683 F. Supp. 3d 933, 937 (E.D. Mo. 2023) (“failure to respond to arguments raised in a motion to dismiss constitutes an abandonment of that claim or concession to the opposing arguments”).

Missouri’s assertions about “preemption” and “interference” with Missouri law (Opp. 4) are far too abstract to sustain Article III standing. A generalized possibility that FDA’s actions might someday preempt some Missouri law, “abstracted from any concrete actual or threatened

harm, falls outside the scope of the constitutional words ‘Cases’ or ‘Controversies.’” *Alvarez v. Smith*, 558 U.S. 87, 93 (2009). Relying on *Holder v. Humanitarian Law Project*, 561 U.S. 1, 15 (2010), Missouri insists that it is “not required to await and undergo a . . . prosecution” before invoking the threat of preemption. Opp. 5. But *Holder* stands for a fundamentally different proposition: parties facing a “credible threat of prosecution” can “seek preenforcement review of a criminal statute” affecting their First Amendment rights. *Id.* at 15. Missouri, of course, does not face any threat of prosecution at all—nor is the possibility of preemption analogous to criminal prosecution.

Missouri also claims “interference” with enforcement of certain abortion-related statutes. (Opp. 4), but that theory is no less abstract. Critically, several of these restrictions are invalid under Missouri’s own Constitution, which expressly protects the “fundamental right to reproductive freedom,” including “abortion care.” Mo. Const. art. I, § 36(2); see GenBioPro Mem. 3-4. Missouri’s response that litigation challenging these abortion laws has not yet reached final judgment (Opp. 6) falls flat. Regardless of the status of that litigation, a State’s constitution defines the scope of a State’s sovereign authority, and a state cannot reasonably base sovereign injury on an interest in interfering with rights that its constitution expressly protects.²

More fundamentally, Missouri never explains what this supposed “interference” actually consists of. It does not say whether it is presently enforcing these laws, identify any concrete instance in which FDA’s actions have impeded that enforcement, or describe any resulting costs or administrative burdens. Saying only that some statutes “remain in place” (Opp. 6) is not

² Kansas’ failure to respond to GenBioPro’s argument that the Kansas Supreme Court recognized the state Constitution’s protection of the right to terminate a pregnancy means Kansas cannot base standing on an interest in abrogating that right. GenBioPro Mem. 4. That issue is thus conceded. *Muller*, 683 F. Supp. 3d at 937.

enough. And even if Missouri had supplied those missing details, that still would not establish standing: courts have rejected the notion that “a logistical burden on law enforcement constitutes a cognizable Article III injury.” *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

Missouri’s attempt to recast itself as the “object” of the challenged FDA actions has no basis in reality. Opp. 4-5. Of course, none of the challenged FDA actions before *Dobbs*—as relevant here, the 2016 changes, 2019 approval, or 2021 non-enforcement decision—could possibly have been designed to undermine Missouri’s (or any other state’s) laws. *Contra* Am. Compl. ¶¶ 230-31. The Constitution prohibited undue burdens on the right to abortion in every state under *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992) at the time each of those actions were taken. As to FDA’s 2023 changes to the REMS, Missouri’s premise seems to be that “the Biden administration expressly stated that FDA’s actions preempt state laws.” Opp. 4-5 (emphasis in original). But the 2023 decision merely formalized FDA’s pre-*Dobbs*, 2021 non-enforcement decision. And regardless, the statements Missouri cites (ECF 217 ¶¶ 250-52) are not FDA’s—and judicial review turns on the agency’s action and rationale, not “extrinsic statements” by non-decisionmakers. *Trump v. Hawaii*, 585 U.S. 667, 702-04 (2018). Regardless, none of the cited statements shows that overriding state abortion laws—as opposed to regulating drug safety, efficacy, and access—was the object of the challenged actions.

Finally, Missouri’s theory fails for the additional reasons that it cannot establish traceability or redressability. To the extent the availability of mifepristone causes the State a cognizable sovereign injury, the relief sought here would not allay the claimed injury. Because Missouri has not challenged the original 2000 approval, mifepristone would remain available, just with a reversion to pre-2016 labeling. *See* GenBioPro Mem. 4; Danco Mem. 7-8; Fed. Defs.

Br. 11-12. Missouri’s retort that GenBioPro “assuredly do[es] not believe that; otherwise they would have no right to be here” (Opp. 9) is a *non sequitur*. GenBioPro has a right to be here because, as Judge Kacsmaryk found, Missouri is “directly challeng[ing] [GenBioPro’s] product’s approval.” *Missouri v. FDA*, 2025 WL 1223581, at *5-6 (N.D. Tex. Apr. 28, 2025). The fact that relief would cause great harm to GenBioPro without ameliorating Missouri’s claimed injuries reveals not only the lack of redressability, but the misguided nature of this lawsuit.

C. Missouri’s “Economic Harm” Theory Fails

Missouri’s claim of general “economic harm” from alleged “adverse effects” of mifepristone writ large does not support standing. Missouri asserts that “FDA’s actions” (without specifying which ones) cause “increased public insurance costs for emergency medical procedures and mental health support,” and diverted resources from public hospitals. Opp. 6. But neither Missouri’s complaint nor its opposition makes any effort to tie these alleged costs to the specific 2016, 2019, 2021, and 2023 FDA actions it challenges, as opposed to the initial 2000 approval of mifepristone. “[S]tanding is not dispensed in gross,” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021), and Missouri’s generalized statistics about “adverse effects” fail to demonstrate that Missouri is injured by any of the specific FDA actions it challenges.

For example, while Missouri invokes data showing that “close to five percent of women taking the abortion drug require emergency room care” (Opp. 7), Missouri makes no attempt to connect that figure to costs it has incurred specifically from the 2016, 2019, 2021, or 2023 FDA actions that it challenges—as opposed to the initial 2000 approval it does not challenge, or “unfettered choices made by independent actors not before the courts,” neither of which could support standing. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 415 n.5 (2013)).

Likewise, Missouri makes no effort to explain how its statistics tie to FDA’s 2023 REMS, which has now been in effect for three years. If Missouri claims that organizations are “shipping abortion drugs in large quantities” that are causing complications (Opp. 8-9), it should be able to point to specific examples of women who: (1) illegally received medication by mail from out of state, (2) experienced complications, (3) and sought treatment that was then paid for by Missouri. Missouri offers nothing. Its theory boils down to generalized information about adverse effects—lacking plausible allegations linking them directly to the challenged actions—which is exactly what the Supreme Court previously rejected as insufficient in this case. *See Alliance*, 602 U.S. at 391.

Missouri takes the position that it “need not identify *specific* women for whom they have paid and will pay for emergency medical care caused by FDA’s policies,” (Opp. 8 (emphasis in original)), relying on *Department of Commerce v. New York*, 588 U.S. 752 (2019), as well as statements that government counsel made about that case during oral argument before the Supreme Court in this case. But *Department of Commerce* does not greenlight state standing based on generalized statistics about health risks. The Court looked to “population level” statistics (Opp. 8) for a specific reason not germane here: the states’ asserted injury was that *fewer people* would respond to the Census in light of a newly added question, leading to an “inaccurate *population* count.” *Dep’t of Com.*, 588 U.S. at 767 (emphasis added). That reduced population count was *itself* a cognizable injury because a smaller population meant “losing a seat in Congress or qualifying for less federal funding.” *Id.* The statistical evidence about population-level response rates thus tracked the injury: If fewer people would respond to the Census, that would directly affect the states’ representation in Congress and funding.

The same is not true here. Pointing to data that some “population” experiences side effects from a drug does not show that *FDA’s challenged actions* are causing those side effects. And even if Missouri could draw that connection, it would support only *one* link of the causal chain necessary to show economic injury. To have standing, Missouri would need to establish multiple steps in a lengthy causal chain: that (1) the challenged FDA actions would lead independent actors to prescribe and dispense mifepristone for use in Missouri in ways that they otherwise would not do; (2) those actions would cause medical complications; (3) those complications would result in a patient seeking medical care; *and* (4) that the costs of that care would be borne by Missouri.

Missouri falls back on an analogy to the Supreme Court’s decision in *Motor Vehicle Manufacturers Association of U.S., Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), which is as untenable as it is sweeping. *Opp.* 9. Missouri says that because it participates in Medicaid, it is like an insurer and may therefore challenge any federal action that it predicts will increase healthcare costs. But every State participates in Medicaid. If that were enough, then any State could challenge virtually any federal policy touching on health or safety—from drug approvals to food safety to vaccine policy to environmental rules to firearms policy—on the theory that the federal policy sets in motion a chain of events that might ultimately result in additional Medicaid expenditures. That boundless theory is irreconcilable with Article III and with the limits the Supreme Court has emphasized in cases involving our “system of dual federal and state sovereignty.” *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023).

Finally, Missouri’s declarations do not cure the defects in its complaint. Defendants have challenged Missouri’s standing facially, based on the allegations in the complaint. Declarations

attesting to facts not in the complaint are inappropriate at the motion to dismiss stage—which Missouri seems to recognize, as its brief only cites the declarations in passing without explanation. And what the declarations say only confirms the complaint’s standing deficiencies. One of them summarizes abortion complication reports, but again does not connect those rates to concrete increases in Missouri spending attributable to the specific FDA actions challenged here. The other alleges a troubling series of events involving an individual allegedly given unspecified abortion medication against her will. But the account in that declaration—like the amicus brief describing harm caused by coercive criminal conduct of third parties, *see* Doc. 316—plainly describes injury caused by illicit actions by “independent actors,” not any regulatory decision by FDA. *Alliance*, 602 U.S. at 383.

II. Missouri’s Claims Are Unexhausted and Unripe

Even if the Court had jurisdiction, Missouri’s claims must still be dismissed because the State never exhausted its administrative remedies with FDA. *See* GenBioPro Mem. 6-7.

Surprisingly, Missouri claims that “FDA’s own regulations do not trigger an exhaustion requirement.” Opp. 11. That is flatly incorrect. 21 C.F.R. § 10.45(b) provides that “[a] request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act.” 21 C.F.R. § 10.45(b); *see id.* § 10.25(b) (requiring issue exhaustion by recognizing the agency’s “primary jurisdiction to make the initial determination on issues within its statutory mandate”). Missouri does not address that regulation, which belies its lead argument.

Missouri invokes *Darby v. Cisneros*, 509 U.S. 137 (1993), but that case underscores that Missouri is required to exhaust its administrative remedies. Opp. 11. The first sentence in *Darby*

makes clear that it is about “the question whether federal courts have the authority to require that a plaintiff exhaust available administrative remedies before seeking judicial review under the Administrative Procedure Act (APA), 5 U.S.C. § 701 *et seq.*, where neither the statute nor agency rules specifically mandate exhaustion as a prerequisite to judicial review.” 509 U.S. at 138 (emphasis added). Here, FDA’s regulations—which Missouri ignores—specifically mandate exhaustion as a prerequisite to judicial review. Contrary to Missouri’s suggestion, *Darby*’s discussion of the finality requirement embedded in 5 U.S.C. § 704 is irrelevant here. Section 704 governs when an agency action is sufficiently “final” for APA review notwithstanding the availability of further *intra-agency* review—*i.e.*, when agency rules permit an “appeal to superior agency authority.” 5 U.S.C. § 704. FDA’s citizen-petition framework is not an optional *intra-agency* appeal. It is a threshold prerequisite to suit, designed to ensure that FDA has the *first* opportunity to consider the request for agency action and the issues to be raised in court.

Indeed, Missouri fails to confront the court decisions cited in GenBioPro’s brief enforcing FDA’s exhaustion rules as written. *See, e.g., Laxton v. Teva Pharms. USA, Inc.*, 2017 WL 914255, *3 (E.D. Mo. Mar. 8, 2017) (dismissing because “FDA did not have an opportunity to consider and potentially resolve plaintiff’s concerns”); *Ass’n of Am. Physicians v. FDA*, 358 F. App’x 179, 180-181 (D.C. Cir. 2009) (affirming dismissal where plaintiffs failed to file a “citizen petition with FDA contesting the SNDA approval of Plan B and . . . proffer[ing] no legally viable excuse for this failure”).

Missouri’s retreat to assorted exhaustion “exceptions” fares no better. Opp. 11-12. Missouri first invokes a supposed exception for challenges to agency action as “in excess of the agency’s authority.” Opp. 11 (quoting *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023)). But in this Circuit, it is well-settled that “[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). In any event, Missouri’s theory is that FDA incorrectly assessed the scientific and medical evidence regarding the safety and effectiveness of mifepristone and appropriate REMS conditions, not that it lacks statutory authority to approve drugs like mifepristone or to issue a REMS. And the decision Missouri relies on was vacated following the Supreme Court’s unanimous ruling that the plaintiffs lacked standing. *See* 117 F.4th 336, 340 (5th Cir. 2024). The narrow *ultra vires* exception invoked there—which relied on *Myron v. Martin*, 670 F.2d 49 (5th Cir. 1982)—also involves a multi-factor analysis and is available only in “exceptional circumstances,” which Missouri does not even attempt to demonstrate. *Id.* at 52.

Missouri’s “abuse of the administrative process” argument is equally weak. Opp. 12. Its reliance on purported delay in adjudicating *other parties’* citizen petitions years ago (*id.*) only underscores Missouri’s own failure to file one at all. And Missouri cannot claim prejudice from FDA’s purportedly “dilatory behavior” when it is challenging FDA actions dating back a decade. Nor do any of Missouri’s authorities actually support its theory. Other than the vacated 2023 Fifth Circuit decision in this case and a D.C. Circuit decision that did not address abuse of the administrative process, *Way of Life Television Network, Inc. v. FCC*, 593 F.2d 1356, 1360 (D.C. Cir. 1979), the principal support Missouri offers is a law review article advocating a *change* in existing doctrine. The article candidly acknowledges what the law already is: “courts across the country have dismissed plaintiffs’ claims for failure to exhaust administrative remedies when they failed to file citizen petitions with the FDA or failed to wait until the Agency responded to the petition before suing.” Michael Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA’s REMS Petitioners*, 77 Vand. L. Rev. 937, 956 (2024). Under existing law, Missouri was required to exhaust. It did not.

Indeed, relying on considerations that overlap heavily with exhaustion and ripeness, on April 7 another federal court—in a similar lawsuit brought by the State of Louisiana challenging the 2023 REMS—granted FDA’s motion for a stay pending the agency’s ongoing review. *Louisiana v. FDA*, 2026 WL 936958, at *14, *16-17 (W.D. La. Apr. 7, 2026). The court emphasized that the issues “implicate scientific and medical judgments committed by Congress to an agency with specialized knowledge,” and that “it is FDA, not this Court, that possesses the expertise to evaluate scientific evidence and make public health judgments.” *Id.* at *14, *16. While the Louisiana court declined to specifically address exhaustion or ripeness, its reasoning strongly supports finding Missouri’s claims unexhausted and unripe here.³

Missouri also suggests in a footnote that, as an intervenor, it need not independently satisfy exhaustion at all. Opp. 12 n.6. But the case Missouri cites, *Harris v. Amoco Production Co.*, 768 F.2d 669, 678 (5th Cir. 1985), has nothing to do with exhaustion of administrative remedies. The intervenor in *Harris* was the EEOC, which as an administrative agency itself is of course not subject to any agency exhaustion requirement.

Finally, GenBioPro separately explained that Missouri’s claims are not ripe given FDA’s ongoing consideration of the mifepristone REMS. GenBioPro Mem. 7. Missouri does not respond to that argument, and so has forfeited any opposition. *Muller*, 683 F. Supp. 3d at 937.

³ The court also declined to dismiss Louisiana’s action on standing grounds, concluding that the State’s allegations of sovereign and pocketbook injuries sufficed at that “earl[y] stage” of the litigation, but permitting the renewal of motions to dismiss after FDA’s review or a lifting of the stay. 2026 WL 936958, at *9-12. We respectfully submit that that aspect of the *Louisiana* decision is mistaken, including because it is inconsistent with the Supreme Court’s standing decisions in this case and *United States v. Texas*; did not grapple with the Ninth Circuit’s rejection of the same state standing theories as here in *Washington v. FDA*; incorrectly credited statements from actors outside FDA as evidence of the agency’s intent; and found standing despite acknowledging that Louisiana’s asserted harms would persist even if FDA’s actions were enjoined. *See id.* at *10, *15.

III. Missouri's Challenge to the 2016 Changes Is Time-Barred

The first two words of Missouri's opposition—"[s]ince 2016"—highlight the timeliness problem with this case. Missouri asserts that FDA has regulated mifepristone unlawfully and inadequately since 2016, causing harms to Missouri. Yet Missouri did not seek to intervene in this case until November 3, 2023, more than seven years after that claim accrued. None of its responses is persuasive.

First, contrary to Missouri's arguments, intervenors are not exempt from statutes of limitations. *See* Opp. 12-13. As the Supreme Court explained in *Corner Post* (the main case Missouri relies upon as to the limitations issue), statutes of limitations and time of accrual are "*plaintiff specific*" and § 2401(a)'s text "focuses on a specific plaintiff: '*the* complaint is filed within six years after *the* right of action first accrues.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 817 (2024) (emphases in original). The sole case Missouri cites is *Harris v. Amoco*, the same case Missouri relies on for a supposed intervenor exemption from exhaustion requirements. But *Harris* has no more to do with statutes of limitations than it does with exhaustion—which is to say, nothing at all.

Second, Missouri's claims challenging the 2016 changes accrued long before *Dobbs*. *Contra* Opp. 13. Missouri recognizes that, under *Corner Post*, an APA claim accrues when the plaintiff is first "injured by final agency action." 603 U.S. at 804. Missouri alleges economic injury on the theory that the 2016 changes increased Missouri's Medicaid expenditures. To the extent the 2016 changes had those effects, they would have occurred as soon as the 2016 changes went into effect. Missouri responds that it could not have been injured until *Dobbs* because only then could it "fully regulate abortion." Opp. 13. But Missouri's cause of action accrued when it was *first injured* at all, not when it acquired what it now regards as its fullest possible authority.

Third, Missouri’s suggestion that *Dobbs* placed it under “legal disability” that tolled the statute of limitations strains credulity. Opp. 13. “Legal disability” for purposes of tolling a statute of limitations means a “personal handicap or impediment affecting the individual litigant and preventing him from bringing a timely suit.” *Goewey v. United States*, 612 F.2d 539, 544 (Ct. Cl. 1979). That a later development such as *Dobbs* may have increased Missouri’s interest in bringing litigation did not toll the statute of limitations.

Fourth, Missouri’s theory that it is “newly injured” each time a Missouri statute is “put at risk” or it has to “pay for complications” (Opp. 13-14) is antithetical to both the statutory text and *Corner Post*. Section 2401(a) requires suit within six years after the right of action “*first* accrues.” 28 U.S.C. § 2401(a) (emphasis added). That language forecloses the notion that each later consequence of the same agency action restarts the clock. *Corner Post* confirms that a claim accrues when the plaintiff *first* suffers injury from final agency action—not each time the plaintiff later experiences another effect of that same action. 603 U.S. at 809, 817.

Indeed, the central point of *Corner Post* was that the plaintiff business’s ability to sue the Federal Reserve in 2021 over a 2011 debit card fee rule turned on the fact that it opened in 2018, and only then “swiped its first debit card.” *Id.* at 806. Under Missouri’s theory, any business—regardless of when it opened—would be “newly injured” and restart the six-year clock for a lawsuit every time it swiped a debit card. If that reading were right, the entire analysis in *Corner Post* would have been pointless.

The concerns Justice Jackson expressed in dissent about challenges to dated FDA regulatory actions becoming “fair game” do not help Missouri either: those concerns centered on the ability of “*new* regulated entit[ies]” like the convenience store in *Corner Post* to bring suit.

Id. at 861 (Jackson, J., dissenting). Missouri is not a regulated entity, let alone a new one, and was fully capable of challenging the 2016 changes before the six-year period expired in 2022.

Finally, the reopening doctrine does not save Missouri’s stale challenge. Missouri argues that FDA “reopened” the 2016 changes in 2021 when it denied the 2019 citizen petition. Opp. 14. But neither the Supreme Court nor the Eighth Circuit has ever “adopted” the “reopening doctrine” Missouri attempts to invoke. *See Biden v. Texas*, 597 U.S. 785, 809 n.8 (2022); *N.D. Retail Ass’n v. Bd. of Governors of the Fed. Rsrv. 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). And even where the doctrine has been accepted, courts have explained that “[t]he mere act of repeating old reasons for an old policy in response to unsolicited comments is not the equivalent of reconsidering, and therefore reopening, the old issue.” *Nat’l Ass’n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 145 (D.C. Cir. 1998); *see id.* at 145 (“petitioners can[not] comment on matters . . . goad an agency into a reply, and then sue on the grounds that the agency had re-opened the issue” (quoting *Am. Iron & Steel Inst. v. U.S. EPA*, 886 F.2d 390, 398 (D.C. Cir. 1989))). That principle applies here. FDA’s 2021 response to the 2019 petition did not reopen the 2016 decision for all future challengers. Otherwise, any plaintiff could revive a time-barred challenge to long-settled agency action simply by pointing to a later petition denial and calling it reopening. Section 2401(a) does not permit that end run around the statute of limitations.

CONCLUSION

For the foregoing reasons and those stated in Danco’s and Federal Defendants’ briefing, the Court should dismiss the amended and supplemental complaints.

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Respectfully submitted,

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** Pro hac vice application forthcoming