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 MOTION TO DISMISS

Oral Argument Requested

Intervenor-Defendant GenBioPro, Inc. ("GenBioPro") hereby moves to dismiss Intervenor-Plaintiffs' Amended Complaint, ECF No. 217, and Supplemental Complaint, ECF No. 281, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). As set forth more fully in the accompanying memorandum, GenBioPro submits that Plaintiffs lack Article III standing; that they have not exhausted their claims; and that certain of their claims are time-barred. Because this motion raises threshold jurisdictional and dispositive issues against the backdrop of this case's complex and extended procedural history, GenBioPro respectfully requests oral argument to assist the Court in resolving the issues presented.

Dated: March 13, 2026

Respectfully submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

/s/ Christopher Nease

Christopher Nease (#57327 MO)
ARNOLD & PORTER KAYE SCHOLER LLP
811 Main St., Suite 1800
Houston, TX 77002-2400
(713) 576-2400
chris.nease@arnoldporter.com

Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
(202) 942-5000
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

Counsel for Intervenor-Defendant GenBioPro, Inc.

Skye L. Perryman*
Carrie Y. Flaxman*
Lisa Newman**
DEMOCRACY FORWARD
FOUNDATION P.O. Box 34553
Washington, D.C. 20043
(202) 448-9090
sperryman@democracyforward.org
cflaxman@democracyforward.org
lnewman@democracyforward.org

* Deemed admitted pro hac vice per Local Rule 12.01 and the Court's Case Opening Notification dated October 23, 2025

** Pro hac vice application forthcoming

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

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INTRODUCTION

For years, the Food and Drug Administration has recognized that mifepristone is safe and effective, including when dispensed without an in-person clinic visit and by non-physician healthcare providers. FDA's numerous regulatory actions reaching these conclusions have been grounded in a robust body of scientific evidence. Yet three states now ask this Court to displace—on a nationwide basis—FDA's congressionally assigned role in favor of their own misplaced views of the science.

This Court should reject that effort at the threshold. The Supreme Court in this very case made clear that federal courts are not the proper forum for generalized objections to FDA's alleged under-regulation of a drug—particularly where the alleged injuries depend on attenuated chains of events involving the choices of independent third parties. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 391-93 (2024) (*Alliance*). That unanimous holding forecloses the States' efforts to sustain this litigation. FDA's actions impose no obligations on the States—just as they imposed none on the doctors who originally brought this case. If the downstream economic and sovereign harms these States assert were sufficient, there would be no meaningful limit on states' ability to challenge federal policy. And the States' claims suffer from additional threshold defects as well. For example, they seek to challenge regulatory actions going back nearly a decade and without first presenting their claims to FDA through the administrative process that Congress and the agency's regulations require.

Since 2019, GenBioPro, Inc. has held an Abbreviated New Drug Application approval authorizing it to market generic mifepristone—a product that is foundational to its business and an important component of healthcare nationwide. GenBioPro intervened in this action to protect those interests and now moves to dismiss the States' amended and supplemental complaints. As

indicated below, GenBioPro adopts many of the arguments raised in the motions and supporting memoranda filed by Intervenor-Defendant Danco Laboratories, LLC, *see* ECF 295 (Danco Br.); and by Federal Defendants, *see* ECF 293-1 (Fed. Defs. Br.) at 9-15. This memorandum briefly highlights the grounds for dismissal most relevant to GenBioPro.[1]

ARGUMENT

I. The Court Lacks Subject Matter Jurisdiction

The States' complaints should be dismissed under Rule 12(b)(1) because there is no basis for Article III jurisdiction over their claims. Danco Br. at 4-13; Fed. Defs. Br. at 9-14. Jurisdiction is lacking for several independent reasons.

First, the Supreme Court held that the original plaintiffs in this action lacked standing—which, as Judge Kacsmaryk recognized, meant "that the Original Plaintiffs never had a jurisdictionally valid case," *Missouri v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, 2025 WL 2825980, at *5 (N.D. Tex. Sept. 30, 2025); *see* Fed. Defs. Br. at 9-10. On remand from the Supreme Court, Judge Kacsmaryk exercised his discretion to consider "venue … before subject-matter jurisdiction," and on that basis transferred the case to this Court rather than dismissing on standing grounds. *Id.* at *4 (citing *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 436 (2007)). But now that the issue of subject matter jurisdiction is squarely presented—and is lacking—"the only function remaining to the court is that of announcing the fact and dismissing the cause." *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868); *see Muff v. Wells*

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[1] Because this Court lacks Article III jurisdiction over this case and the States' claims are unexhausted, the proper remedy is dismissal. But to the extent the Court declines to dismiss the case at this time, GenBioPro would not oppose the FDA's request for a stay of these proceedings pending its ongoing review. *See* Fed. Defs. Br. at 8-9.

Fargo Bank NA, 71 F.4th 1094, 1101 (8th Cir. 2023). And without "the pendency of an action, there was no basis for intervention." *Mattice v. Meyer*, 353 F.2d 316, 319 (8th Cir. 1965).

Second, even if this case could proceed in theory, the States lack Article III standing to challenge any of the FDA actions they identify. Danco Br. at 4-13; Fed. Defs. Br. at 10-14. To start, because Missouri is the only State whose presence makes venue proper in this District, the case cannot proceed unless Missouri itself has Article III standing—which it does not have. *See* Danco Br. at 5 n.2. Indeed, Missouri's standing is *especially* suspect, given its constitutional amendment recognizing a "fundamental right to reproductive freedom," including "abortion care." Mo. Const. art. I, § 36(2); *see* Danco Br. at 11 & n.4.

Regardless, none of the States can establish standing. The Supreme Court held unanimously in *Alliance* that the original plaintiffs in this litigation lacked standing to challenge FDA's regulation of mifepristone because FDA's actions did not require them "to do anything or to refrain from doing anything." 602 U.S. at 385. The States are no different, and their efforts to circumvent *Alliance* fail.

In particular, the States' theory that FDA's actions indirectly increase their Medicaid expenditures for follow-up care is too attenuated to establish standing. Danco Br. at 5-8; Fed. Defs. Br. at 12-13. As the Supreme Court explained in *Alliance*, the law does not permit plaintiffs to challenge the "loosening of general public safety requirements" simply because third parties might later incur medical complications and seek care. 602 U.S. at 391. The States' theory merely adds another link to the causal chain that the Supreme Court rejected: Not only must patients experience injuries that require medical attention, and not only must they seek costly care, but that care must then increase these States' Medicaid expenditures. Fed. Defs. Br. at 12-13. Accepting that theory would effectively grant standing to any state—or any private

entity that finances healthcare—to challenge all manner of federal policies, from drug approvals to firearms restrictions to environmental regulations, based on the speculative downstream costs of treating patients. Danco Br. at 6; Fed. Defs. Br. at 12-13. Indeed, for FDA drug approvals in particular, the States' theory of downstream harm would make standing virtually automatic: All drugs have side effects, and thus *every* drug seemingly could be tied, through some attenuated causal chain, to some amount of Medicaid spending. And the States' causation and redressability problems run even deeper given their decision *not* to challenge the original 2000 mifepristone approval; mifepristone would remain approved and available even if the States secured all of the relief they seek. *See* Danco Br. at 7.

Nor can the States establish standing based on alleged sovereign harms. Danco Br. at 8-11; Fed. Defs. Br. at 10-12. Again, Missouri's own Constitution protects a right to abortion care. *Supra* pp. 1-2. Likewise, and as the amended complaint admits (Am. Compl. ¶¶ 517, 524), the Kansas Supreme Court has held 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); *see* Danco Br. at 11. Given these legal protections, Missouri and Kansas lack cognizable sovereign interests in banning use of mifepristone within their borders. Even if they had such an interest, the States at most speculate that FDA's actions might make it more difficult to detect violations of state law by third parties—but such indirect enforcement burdens do not constitute Article III injuries. *See United States v. Texas*, 599 U.S. 670, 676-77 (2023); *see* Danco Br. at 8-12; Fed. Defs. Br. at 10-12. And this theory, too, suffers failures of causation and redressability, especially because mifepristone's original approval would remain intact even if the States' challenge succeeded. Danco Br. at 10-11; Fed. Defs. Br. at 11-12.

The States also cannot manufacture standing by asserting injuries to their populations, including alleged decreases in births or harms to women or unborn children. Danco Br. at 11-12; Fed. Defs. Br. at 13-14. Those allegations amount to a classic *parens patriae* theory, which the Supreme Court has repeatedly held does not permit states to sue the federal government on behalf of their citizens. *Murthy v. Missouri*, 603 U.S. 43, 76 (2024); *Haaland v. Brackeen*, 599 U.S. 255, 294-95 & n.11 (2023). The States' related assertions about protecting minors in state custody fare no better, as those allegations likewise attempt to assert injuries derivative of individual residents rather than a distinct injury to the States themselves. Fed. Defs. Br. at 13-14.

The sole appellate decision to address state standing in the context of FDA's mifepristone actions rejected the very same economic, sovereign, and population-based theories on which these States rely. *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir. 2024). In that case, Idaho—one of the plaintiff States here—sought to intervene based on materially identical theories of "increased Medicaid costs, interference with state law enforcement, and harms to women and fetal life." *Id.* at 1174. The Ninth Circuit rejected each of these theories. For Medicaid costs, even "taking Idaho's highly speculative allegations as true," the complaint "depend[ed] on an attenuated chain of healthcare decisions by independent actors that will have only indirect effects on state revenue." *Id.* at 1174-75. For "sovereign" harm, "nothing in the 2023 REMS impairs Idaho's sovereign authority to enact or enforce its own laws regulating chemical abortion." *Id.* at 1176. And for population-based harms, those assertions "concern the interests of individual citizens—not the separate interests of the state itself." *Id.* at 1177. Thus, even if these theories were tenable for any of the States, Idaho is collaterally estopped from relitigating these same jurisdictional issues that have been conclusively rejected. *See*

Underwriters Nat. Assur. Co. v. N. Carolina Life & Acc. & Health Ins. Guaranty Ass'n, 455 U.S. 691, 706 (1982) (estoppel applies to jurisdictional issues); Danco Br. at 11.

Finally, even if the States had standing, their claims fail because their asserted interests fall outside the zone of interests protected by the provisions of the Food, Drug, and Cosmetic Act (FDCA) they invoke. Danco Br. at 13-14. The FDCA's drug-approval and REMS provisions are designed to protect patients by ensuring that drugs are safe and effective—not to protect the states' asserted interests in regulating abortion or limiting Medicaid expenditures. Because the States seek to use the FDCA to vindicate interests unrelated to the statute's purposes, their claims cannot proceed.

II. The States Have Not Exhausted Their Claims with FDA

The States' complaints also should be dismissed under Rule 12(b)(6) because they have failed to exhaust any of their claims with FDA—which under FDA regulations is a strict "prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 153 (1993); *see* Danco Br. at 14-15; Fed. Defs. Br. at 14-15. The States were required to file a citizen petition with FDA "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(a) (citizen petition procedures). FDA regulations also include "an issue exhaustion requirement," under which the agency has "primary jurisdiction to make the initial determination on issues within its statutory mandate." *Id.* § 10.25(b); *see Laxton v. Teva Pharms. USA, Inc.*, 2017 WL 914255 (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, 180-81 (D.C. Cir. 2009) (per curiam) (similar).

Under these exhaustion rules, this case cannot proceed. None of the States filed a citizen petition, and so FDA could not have reached a "final administrative decision based on" that

petition, as FDA's regulations require. 21 C.F.R. § 10.45(b). Meanwhile, other parties (including GenBioPro) have played by the rules, submitting a host of petitions seeking a variety of actions from FDA related to mifepristone. *See, e.g.*, GenBioPro, Citizen Petition, FDA-2025-P-2162 (July 7, 2025), https://www.regulations.gov/document/FDA-2025-P-2162-0001.[2] Those petitions allow FDA to do its job of collecting data, assessing stakeholders' interests, and evaluating scientific literature. *See Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997).

For similar reasons, the States' claims challenging the REMS that the agency is currently reconsidering, Fed. Defs. Br. at 8-19, are not ripe; those claims "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (quotation omitted).

III. The States' Challenge to the 2016 Changes Is Time Barred

Finally, the States' claims challenging FDA's 2016 changes must be dismissed because they are untimely under the applicable six-year statute of limitations, 28 U.S.C. § 2401(a). The States' claims challenging the 2016 changes accrued six years after those changes, on March 29, 2022, yet they did not seek intervention to assert their claims until November 3, 2023. Danco Br. at 14; *see* Fed. Defs. Br. at 15.

[2] Courts "routinely take judicial notice of ... documents which are publicly available on the FDA's website," including citizen petitions. *Kouyate v. Harvard Drug Grp. LLC*, No. 1:24-CV-6223-GHW, 2025 WL 2773159, at *5 (S.D.N.Y. Sept. 26, 2025).

CONCLUSION

For the foregoing reasons and those stated in Danco's and Federal Defendants' motions and supporting memoranda, the Court should dismiss the amended and supplemental complaints.

Dated: March 13, 2026

Respectfully submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

/s/ Christopher Nease

Christopher Nease (#57327 MO)
ARNOLD & PORTER KAYE SCHOLER LLP
811 Main St., Suite 1800
Houston, TX 77002-2755
(713) 576-2400
chris.nease@arnoldporter.com

Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
(202) 942-5000
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

Counsel for Intervenor-Defendant GenBioPro, Inc.

Skye L. Perryman*
Carrie Y. Flaxman*
Lisa Newman**
DEMOCRACY FORWARD
FOUNDATION P.O. Box 34553
Washington, D.C. 20043
(202) 448-9090
sperryman@democracyforward.org
cflaxman@democracyforward.org
lnewman@democracyforward.org

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** Pro hac vice application forthcoming

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[PROPOSED] ORDER

Upon consideration of Intervenor-Defendant GenBioPro, Inc.'s Motion to Dismiss and the Memorandum of Law in Support thereof,

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**. The clerk is **DIRECTED** to close the case.

So ordered this ____ day of _________________, 2026.

____
HON. CRISTIAN M. STEVENS
UNITED STATES DISTRICT JUDGE