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April 25, 2026

VIA ECF

Lyle W. Cayce
Clerk of the Court
U.S. Court of Appeals for the Fifth Circuit
600 S. Maestri Place
New Orleans, LA 70130

Re: *Louisiana v. FDA et al.*, No. 26-30203 (5th Cir.) – Notice of Supplemental Authority Under Federal Rule of Appellate Procedure 28(j)

Dear Mr. Cayce,

Intervenor-Appellee GenBioPro, Inc. respectfully submits this letter to advise the panel assigned to Louisiana's motion for interim relief of a significant development in parallel related litigation that further supports denial of interim relief here.

In *Florida et al. v. FDA et al.*, No. 7:25-cv-00126-O (N.D. Tex.), Florida and Texas bring APA claims against FDA challenging, *inter alia*, the same FDA mifepristone REMS Louisiana challenges here, based on the same theories of harm and standing. Yesterday, Florida and Texas filed a brief consenting to a seven-month stay pending FDA's ongoing review. As they explained, "[b]ecause the FDA is substantively reconsidering all the Challenged Actions, the States agree that a time-limited stay would promote 'economy of time and effort for [the Court], for counsel, and for litigants.'" Pls.' Resp. to Mot. to Stay or to Dismiss 6, ECF No. 56 (N.D. Tex. Apr. 24, 2026) (attached).

That development confirms that the equities weigh strongly against Louisiana's requested relief. Louisiana seeks sweeping, immediate nationwide relief that other States challenging the 2023 REMS have not sought and do not consider necessary, despite claiming to be adversely affected in the same ways as Louisiana. That Louisiana stands alone in pressing for that result reinforces the district court's conclusion that interim relief that would radically alter the status quo is neither necessary nor equitable. This Court should not countenance Louisiana's attempt to veto national federal health policy, particularly through the extraordinary mechanism of an injunction pending appeal.

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Sincerely,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

STATE OF FLORIDA and STATE OF TEXAS,

Plaintiffs,

v.

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

Defendants,

and

DANCO LABORATORIES LLC and GENBIOPRO, INC.,

Intervenor-Defendants.

Case No. 7:25-CV-00126-O

PLAINTIFFS' CONSOLIDATED RESPONSE TO GOVERNMENT DEFENDANTS' MOTION TO STAY OR, ALTERNATIVELY, TO DISMISS AND INTERVENOR DEFENDANTS' MOTIONS TO DISMISS

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INTRODUCTION AND BACKGROUND

Chemical abortions are accomplished through two drugs: mifepristone and misoprostol. ECF No. 1 ¶ 3. Mifepristone blocks progesterone receptors in the uterus, starving the baby to death. *Id.* Misoprostol brings on dilation and contractions to expel the dead child from the womb. *Id.* In addition to ending the life of the preborn child, abortion drugs endanger the life of the mother. They frequently send women to the emergency room with hemorrhaging, sepsis, and other complications, and sometimes kill women. *Id.* ¶¶ 4–6.

But thanks to the U.S. Food and Drug Administration (FDA), it takes little more than a few clicks of the mouse for these dangerous drugs to arrive on any doorstep in America. The FDA's approval and regressive deregulation of abortion drugs never aimed to "protect the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). It was politics, plain and simple. *See* ECF No. 1 ¶¶ 8–18, 78–197. In 2000, the Clinton FDA approved mifepristone under Title 21, Part 314, Subpart H of the Code of Federal Regulations ("the 2000 Approval"). *Id.* ¶ 107. In 2016, the Obama FDA gutted mifepristone's Risk Evaluation and Mitigation Strategy (REMS) by extending the maximum gestational age from 49 to 70 days, allowing non-physicians to dispense and administer abortion drugs, eliminating the requirement that misoprostol administration occur in-clinic, removing in-person follow-up examination requirements, and relieving physicians of their obligation to report non-fatal complications ("the 2016 Major Changes"). *Id.* ¶ 132. The Biden FDA announced it would no longer enforce the in-person dispensing

requirement for mifepristone in 2021 and eliminated the requirement in 2023 ("the 2021/2023 Dispensing Changes"). *Id.* ¶¶ 164–65, 173–75, 184–85. These actions led to the approval of generic versions of mifepristone in 2019 and 2025 ("the Generic Approvals"). *Id.* ¶¶ 153–54, 198–99.

All these actions ("the Challenged Actions") were illegal.[1] So, on December 9, 2025, Plaintiffs the State of Florida and the State of Texas ("the States") filed suit against the FDA, FDA Commissioner Martin A. Makary, the Department of Health and Human Services ("HHS"), HHS Secretary Robert F. Kennedy, and the director of the Center for Drug Evaluation and Research ("the Government Defendants"). ECF No. 1. On April 10, 2026, this Court granted motions to intervene filed by two of the three FDA-approved manufacturers of mifepristone: Danco Laboratories LLC and GenBioPro Inc. ("the Intervenor Defendants"). ECF No. 51.

[1] The 2000 Approval violated the Federal Food Drug and Cosmetic Act (FFDCA) by approving mifepristone under Subpart H, an expedited review process reserved for products that treat "serious or life-threatening illnesses" and offer "meaningful therapeutic benefit over existing treatments." 21 C.F.R. § 314.500. Mifepristone of course does neither, as the drug's sponsor warned the FDA before its approval. ECF No. 1 ¶¶ 102–06. It also violated the Comstock Act by authorizing the distribution of abortion drugs, 18 U.S.C. §§ 1461–62, the Pediatric Research Equity Act (PREA) by ignoring the sponsor's failure to conduct a safety assessment for relevant pediatric subpopulations, 21 U.S.C. § 355c(a)(2)(A), and the Administrative Procedure Act (APA) by being pretextual and therefore arbitrary and capricious. 5 U.S.C. § 706. Subsequent mifepristone-related FDA actions spring from that illegal 2000 Approval, and are independently illegal. For instance, the 2016 Major Changes violated the APA because the FDA failed to conduct a single clinical trial addressing their cumulative effect. *All. for Hippocratic Med. v. FDA* (*Alliance I*), 78 F.4th 210, 246 (5th Cir. 2023), *rev'd on other grounds by* 602 U.S. 367 (2024) (*Alliance II*). The 2021/2023 Dispensing Changes violated the APA by relying upon unreliable adverse-event data, *id.* at 250–51, and squarely violate the Comstock Act by authorizing prescribers and pharmacies to ship abortion drugs.

The Challenged Actions cannot be defended on the merits. Indeed, Defendants' motions to dismiss do not even try. Instead, they attempt to throw up a series of procedural roadblocks. None are persuasive: (1) res judicata does not bar Texas's claims, (2) the States plead economic, sovereign, and quasi-sovereign injuries traceable to the Challenged Actions and capable of redress, (3) the States are well within the relevant zones of interests, (4) federal law did not require the States to seek administrative remedies, (5) the States' claims are within the APA's six-year statute of limitations, and (6) the States' claims are ripe.

This Court, however, need not yet resolve these issues. Acknowledging previous shortcomings, the FDA has initiated a comprehensive review of mifepristone. ECF No. 20-2 at 2 (admitting "the lack of adequate consideration underlying the prior REMS approvals"); ECF No. 20-1 at 13–14. In fact, the Government Defendants have informed the States that the FDA is substantively reconsidering each Challenged Action. Declaration of Samuel F. Elliott ¶ 5 (Exhibit 1). So the States agree that the circumstances favor staying these proceedings for a *limited* period sufficient for the timely completion of the review.

RESPONSE TO MOTION TO STAY

The Government Defendants request a stay "until after FDA's review of the mifepristone REMS is complete." ECF No. 20-1 at 15. According to their motion, the States oppose a stay, ECF No. 20 at 2, and "threaten to short-circuit the agency's orderly review and study of the safety risks of mifepristone." ECF No. 20-1 at 9.

This mischaracterizes the States' position and is inaccurate. As conveyed

before the motion was filed, the States support a time-limited stay based on the Government Defendants' representations about the scope of the FDA's review. On January 29, 2026, counsel for the States received an email from the Government Defendants' counsel. Ex. 1 ¶ 1. The email contained information about the FDA's review and notified the States that "[t]he government . . . intend[ed] to seek stays of . . . mifepristone cases, including *Florida* [*v. FDA*]." *Id.* The email asked whether the States would consent to a stay. *Id.*

Counsel for the States replied on January 30, 2026, informing the Government Defendants that the States' position "would likely turn on the scope of the FDA's review of the mifepristone REMS." *Id.* ¶ 3. The reply explained that the States' "lawsuit challenges the FDA's regulation of mifepristone going back to the drug's initial approval in 2000. If the FDA's review is reevaluating each of the actions challenged in our lawsuit, the States may be willing to consent to the stay. If the FDA's review is limited to reevaluating only a subset of those actions, it would make little sense for Florida and Texas to consent to the stay." *Id.*

On February 6, 2026, the Government Defendants sent their answer:

> The agency's review of the mifepristone REMS includes reviewing and evaluating issues raised in a number of citizen petitions seeking different actions, ranging from eliminating the REMS entirely to withdrawing the approval of mifepristone for termination of early pregnancy, as well as actions in between, such as reinstating the conditions of use in place before 2016 or reinstating the in-person dispensing requirement. Of course, we do not know what the outcome of that review will be. But whatever the outcome, following its review, FDA will take any steps it determines are appropriate, in accordance with its statutory and regulatory authorities.

Id. ¶ 5.

On March 11, 2026, counsel for the States informed the Government Defendants' counsel that the States were willing to join the motion so long as it (1) set a maximum duration for the stay, and (2) specified that the States' consent was premised on the FDA's representation about the scope of its ongoing review. *Id.* ¶ 7. On March 13, 2026, the Government Defendants' counsel replied: "Thank you for getting back to us. However, we do not agree to attach conditions to the stay. If you agree to a stay without conditions, we will not move to dismiss at this time. Otherwise, we will file our motion to stay or, alternatively, dismiss today." *Id.* ¶ 8. The States did not respond prior to the filing of the Government Defendants' Motion to Stay, or Alternatively, to Dismiss. *Id.* ¶ 9.

The Government Defendants' motion confirms their representation that the FDA's review includes *all* the Challenged Actions:

- It states the review is in response to "citizen petitions pending before the FDA . . . seeking mutually inconsistent actions, such as suspending approval of the drug, restoring previous REMS requirements, or eliminating the REMS entirely." ECF No. 20-1 at 8–9.
- It states that, "if FDA ultimately decides to change course, judicial relief may prove . . . unnecessary." *Id.* at 10.
- It states that "FDA's review will necessarily result in a new agency decision, which could, in turn, obviate the need to consider some or all of Plaintiffs' claims." *Id.*
- It states that "FDA's own review may eliminate any need for the Court's review." *Id.* at 16.
- It states that "*Purcell* is a case in point." *Id.* at 16–17 (describing *Chelius v. Becerra*, No. 1:17-cv-493-JAO-RT, ECF No. 149 (D. Haw. May 7, 2021) (granting a joint motion to stay a challenge to the in-person dispensing requirement imposed by a prior mifepristone REMS after the FDA announced a review of that requirement); Joint Motion to Stay Case Pending Agency Review, *Chelius v. Becerra*, No. 1:17-cv-493-JAO-RT, ECF No. 148 at 2 (D. Haw. May 7, 2021)).

None of these statements are true unless the FDA is substantively reconsidering all the Challenged Actions, including the 2000 Approval.

Because the FDA is substantively reconsidering all the Challenged Actions, the States agree that a time-limited stay would promote "economy of time and effort for [the Court], for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936).[2] However, the States request reasonable parameters for the stay.[3] The States respectfully suggest a stay of no longer than seven months, which would give the FDA more than a year from the date it announced the review. *See* ECF No. 20-2 (FDA letter announcing the review, dated September 19, 2025); ECF No. 20-1 at 3 ("Although studies like these often take approximately a year or more to conduct, FDA plans to complete the study sooner than that timeframe." (quotation omitted)).

RESPONSE IN OPPOSITION TO MOTIONS TO DISMISS

Either now or after the expiration of a stay, this Court should deny the motions to dismiss. Because the Challenged Actions cannot be defended on the merits, Defendants hide behind a menu of procedural arguments. None withstand scrutiny.

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[2] Intervenor Defendants support a stay. ECF No. 53 at 30; ECF No. 55 at 8 n.1.

[3] In *Purcell*, the district court stayed the litigation "until December 1, 2021"—less than seven months from the date of the order—and required the parties "to submit a joint status report every 90 days." *Chelius*, No. 1:17-cv-493-JAO-RT, ECF No. 149. Similarly, the district court in Louisiana's challenge to the 2021/2023 Dispensing Changes recently granted a stay pending the FDA's review but exhorted the agency to "complete its review . . . within a reasonable timeframe" and ordered the Government Defendants to "file a report on or before six (6) months from the date of [its] Order providing the Court with the status of its review in terms of process and any updated timeframe for completion of review." *Louisiana v. FDA*, No. 6:25-CV-01491, 2026 WL 936958, at *17 (W.D. La. Apr. 7, 2026).

I. Texas's Claims Are Not Barred by Res Judicata.

GenBioPro argues that the doctrine of res judicata prevents Texas from establishing standing in this case because the Ninth Circuit decided that Texas lacked standing to intervene in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024). ECF No. 55 at 9. The Government Defendants and Danco Laboratories do not join this argument, and for good reason: it is clearly foreclosed by Fifth Circuit precedent.

First, *Washington* has no preclusive effect because Texas was not a party to that case. "The preclusive effect of a judgment is defined by claim preclusion and issue preclusion, which are collectively referred to as 'res judicata.'" *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008). When a jurisdictional ruling is claimed to have preclusive effect, "issue preclusion is the better framing." *Bank of Louisiana v. Fed. Deposit Ins. Corp.*, 33 F.4th 836, 838 (5th Cir. 2022).

Issue preclusion, also known as "collateral estoppel," "applies to prevent issues of ultimate fact from being relitigated between the *same parties* in a future lawsuit if those issues have once been determined by a valid and final judgment." *Vines v. Univ. of Louisiana at Monroe*, 398 F.3d 700, 705 (5th Cir. 2005) (emphasis added). "While complete identity of all parties is not required, the party against whom the collateral estoppel would be applied generally must either have been a party, or privy to a party, in the prior litigation." *Id.*

GenBioPro does not allege that Texas was a party to *Washington*. Nor could it, for the Fifth Circuit clearly holds that those who are "denied leave to intervene . . . never obtain the status of party litigants." *Edwards v. City of Houston*, 78 F.3d 983,

993 (5th Cir. 1996); *see also Nuclear Regul. Comm'n v. Texas*, 605 U.S. 665, 679 (2025) ("[I]ntervention is the requisite method for a nonparty to become a party to a lawsuit."). And the attempted intervenors in *Washington* (States who sought to set aside the 2023 mifepristone REMS) were obviously not in privity with the defendants (the FDA and other federal agencies) or the plaintiffs (States who sought to eliminate the REMS entirely). *See Sacks v. Texas S. Univ.*, 83 F.4th 340, 346 (5th Cir. 2023) (holding that privity for purposes of res judicata exists "in three circumstances (1) where the non-party is the successor in interest to a party's interest in property; (2) where the non-party controlled the prior litigation; and (3) where the non-party's interests were adequately represented by a party to the original suit.").

Because Texas was not a party to *Washington* and was not in privity with any party to that case, issue preclusion does not apply. *See United States v. Allegheny-Ludlum Indus., Inc.*, 517 F.2d 826, 845 (5th Cir. 1975) (holding that res judicata did not apply because a person refused intervention was not a party to the prior action); *Jones v. Caddo Par. Sch. Bd.*, 704 F.2d 206, 218 (5th Cir. 1983) (same).[4]

[4] Even if Texas had been a party to *Washington*, collateral estoppel would not preclude Texas from asserting standing here. First, the Ninth Circuit only evaluated Texas's standing to challenge the 2023 mifepristone REMS, not any of the other Challenged Actions. Second, Texas asserts facts and theories of standing for its claim against the 2023 REMS that were not asserted in *Washington*. For example, the Ninth Circuit did not evaluate whether Texas's increased investigatory and prosecutorial costs constitute economic injury. ECF No. 1 ¶ 299–304. And while the Ninth Circuit dismissed Texas's allegation that the 2023 REMS "*will* cause the state economic injury in the form of increased costs to the state's Medicaid system" as overly "speculative," *Washington*, 108 F.4th at 1174 (emphasis added), the Complaint here alleges that Texas has already incurred such costs. ECF No. 1 ¶ 289. Regarding sovereign injury, the Ninth Circuit dismissed concerns about shield laws as "contingencies." *Washington*, 108 F.4th at 1175–76. Yet the Complaint cites new

II. The States Have Standing for Each of Their Claims.

To establish standing under "the case-or-controversy requirement of Article III," a plaintiff must demonstrate "(i) that [it] has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *Alliance II*, 602 U.S. at 380. The States satisfy each element for each of their claims.

A. The States' economic injuries are traceable to the Challenged Actions and can be redressed by setting the Challenged Actions aside.

Injury in Fact. An injury in fact is an invasion of a legally protected interest which is "(a) concrete and particularized" and "(b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss [courts] presume that general allegations embrace those specific facts that are necessary to support the claim." *Id.* at 561.

"[A]n economic injury is the quintessential injury upon which to base standing." *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 309 (5th Cir. 2023). And, "[f]or standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'" *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

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data showing that shield laws facilitate thousands of illegal abortions in Texas each year. ECF No. 1 ¶¶ 427–31. These differences defeat preclusion. *See Students for Fair Admissions, Inc. v. Univ. of Texas at Austin*, 37 F.4th 1078, 1089 n.16 (5th Cir. 2022) ("[I]ssue preclusion requires . . . identical issues."); *Bank of Louisiana*, 33 F.4th at 838 ("[T]he dismissal of a complaint for lack of jurisdiction does not make the case res judicata on the substance of the asserted claim. If the jurisdictional problem is later fixed, the suit can be refiled." (quotation omitted)).

These principles apply to States no less than other plaintiffs. *See Texas v. United States* ("*DAPA II*"), 809 F.3d 134, 152 (5th Cir. 2015) (an "effect on the states' fiscs" is an injury in fact); *see also, e.g., Biden v. Nebraska*, 600 U.S. 477, 490 (2023) (a State's "financial harm is an injury in fact").

The States have suffered two forms of textbook economic injury: (1) the actual expenditure of Medicaid funds to treat adverse events suffered by women as a result of FDA-approved abortion drugs, ECF No. 1 ¶¶ 285–90; and (2) costs incurred to investigate and prosecute mail-order abortions, *id.* ¶¶ 299–304.

Causation. These economic injuries are traceable to the Challenged Actions.

1. The States' Medicaid reimbursements fall within the "familiar circumstances where government regulation of a third-party individual or business may be likely to cause injury in fact to an unregulated plaintiff." *Alliance II*, 602 U.S. at 384. "Landmark" Supreme Court precedent holds that "insurers [can] obtain relief from the downstream effects of the agency's rescission of . . . safety standards." *Corner Post, Inc. v. Bd. of Gov'rs of Fed. Rsrv. Sys.*, 603 U.S. 799, 834–35 (2024) (Kavanaugh, J., concurring) (describing *Motor Vehicle Manufacturers Ass'n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29 (1983)).

Defendants argue that the causal link between the Medicaid reimbursements and the Challenged Actions is "too attenuated." ECF No. 53 at 16;[5] *see also* ECF No.

[5] Danco Laboratories concedes that the States' Medicaid reimbursements are traceable to the 2000 Approval but argues that "any alleged 'marginal increase in the rate at which pregnant women require additional medical care' stemming from each of FDA's changes since the initial 2000 approval is simply 'too attenuated to establish the requisite causal connection.'" ECF No. 53 at 17 (quoting *Washington*, 108 F.4th

20-1 at 20–22; ECF No. 55 at 21–22. They rely primarily on two cases: *United States v. Texas* ("*Priorities*"), 599 U.S. 670 (2023), and *Alliance II*. Neither supports their view. *Priorities* involved "both a highly unusual provision of federal law and a highly unusual lawsuit." 599 U.S. at 684. In that case, Texas and Louisiana sought to "require the Executive Branch to make arrests or bring prosecutions" of noncitizens illegally present in the United States. *Id.* The Court reiterated that "[m]onetary costs are of course an injury" and did not reverse the district court's determination that the States' costs were traceable to the federal government's failure to "arrest[] more noncitizens." *Id.* at 676. Instead, the Court decided the injury was not "redressable in federal court" due to the lack of "any precedent, history, or tradition of courts ordering the Executive Branch to change its arrest or prosecution policies." *Id.* at 677. No such redressability problem exists here. The States ask the Court to set aside agency action under the APA, not to order prosecutions.

That leaves *Alliance II*. The doctor plaintiffs there argued that they had standing to challenge the 2000 Approval, 2016 Major Changes, and 2021/2023 Dispensing Changes because the FDA's actions had the potential to "divert[] resources . . . from other patients to treat patients with mifepristone complications" and "increase[e] [their] insurance costs." 602 U.S. at 390. Contrary to Defendants'

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at 1176). The States agree that the Medicaid reimbursements are traceable to the 2000 Approval but disagree that they are traceable *only* to the 2000 Approval. *See* ECF No. 1 ¶¶ 238–64 (explaining how the 2016 Major Changes made abortion drugs more dangerous); *id.* ¶¶ 265–74 (explaining how the 2021/2023 Dispensing Changes made abortion drugs more dangerous); *see also Texas v. United States* ("*DACA*"), 50 F.4th 498, 519 (5th Cir. 2022) ("DACA is not the sole cause of the State's injury, but DACA has exacerbated it. That is sufficient.").

suggestions, however, the Supreme Court did not find the connection between those economic injuries and the FDA's actions too attenuated. Instead, the Court held that the doctors failed to plead facts showing the existence of those economic injuries:

> [T]he claim that the doctors will incur those injuries as a result of FDA's 2016 and 2021 relaxed regulations lacks record support and is highly speculative. The doctors have not offered evidence tending to suggest that FDA's deregulatory actions have . . . caused a . . . diversion of the doctors' time and resources from other patients. Moreover, the doctors have not identified any instances in the past where they have been sued or required to pay higher insurance costs because they have treated pregnant women suffering mifepristone complications. Nor have the plaintiffs offered any persuasive evidence or reason to believe that the future will be different.

Id. at 390–91. Having suffered no concrete injury, according to the Court, the doctors were essentially "concerned bystanders." *Id.* at 382.

The same cannot be said of the States. The States are not "extend[ing] [the doctors'] debunked theory a step further," ECF No. 20-1 at 20, or "adding more links in the chain." ECF No. 53 at 16. Rather, the States have clearly supplied what the *Alliance II* plaintiffs didn't: facts demonstrating concrete economic injury.

2. To mitigate the harm caused by the 2021/2023 Dispensing Changes, the States have investigated and attempted to prosecute the purveyors of mail-order chemical abortions. Causation is satisfied when the plaintiff "reasonably incur[red] costs to mitigate or avoid" a harm caused by government action. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414, n.5 (2013) (collecting cases); *see also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–154 (2010). Accordingly, the States' investigatory and prosecutorial costs are traceable to the 2021/2023 Dispensing Changes. *See Texas v. United States*, 40 F.4th 205, 216–17 (5th Cir. 2022) (States'

increased law enforcement costs were a cognizable economic injury traceable to the challenged agency action), *rev'd on other grounds*, 599 U.S. at 686.

Redressability. Danco Laboratories argues that setting aside the 2016 Major Changes and 2021/2023 Dispensing Changes would not redress the States' Medicaid injuries because "the 2016 changes reduced the dosage of mifepristone, increased the efficacy of medication abortion, and further reduced adverse events." ECF No. 53 at 18. This argument improperly (and erroneously) disputes facts alleged by the Complaint at the motion to dismiss stage, ECF No. 1 ¶¶ 238–74, and forgets that the 2016 Major Changes (i) failed to perform a single clinical trial to determine their cumulative effect, and (ii) eliminated the reporting requirement needed to adequately assess their effects on public health. *Id.* ¶¶ 134, 136–41, 258–64.

B. The States' sovereign injuries are traceable to the Challenged Actions and can be redressed by setting the Challenged Actions aside.

Injury in Fact. The Challenged Actions have also fatally frustrated the States' ability to create and enforce abortion regulations. "[S]tates have a sovereign interest in 'the power to create and enforce a legal code.'" *Texas v. United States* ("*DAPA I*"), 787 F.3d 733, 749 (5th Cir. 2015) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel Barez*, 458 U.S. 592, 601 (1982)); *see also Texas Off. of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 449 (5th Cir. 1999). The States' interest in carrying out this "quintessential function[] of [the] State" is singularly compelling when it comes to regulating abortion—an act intended to extinguish the life of a human being

whom the State exists to protect.[6] *Diamond v. Charles*, 476 U.S. 54, 65 (1986); *see also Massachusetts v. EPA*, 549 U.S. 497, 520 (2007) (a State's sovereign interest "is entitled to special solicitude in our standing analysis").

The Challenged Actions injure the States' sovereign interest in creating and enforcing their legal codes twice over. First, the Challenged Actions threaten to preempt the States' abortion regulations. *DAPA II*, 809 F.3d at 153 (States have standing pursuant to their sovereign interests "based on . . . federal preemption of state law"). This threat is not "conjectural or hypothetical"—the chemical abortion regulations of at least one State are currently enjoined "as an obstacle to the congressional objective of providing a comprehensive regulatory system for the use and distribution of higher-risk drugs under the direction and supervision of the FDA." *Bryant v. Stein*, 732 F. Supp. 3d 485, 502 (M.D.N.C. 2024); *see also* ECF No. 1 ¶ 328.[7]

Under that reasoning, the Challenged Actions would preempt many of the States' abortion regulations. The 2000 Approval would preempt Florida's ban on elective abortion from six weeks' gestation and Texas's ban on elective abortion from conception. The 2016 Major Changes would preempt Florida and Texas laws

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[6] Declaration of Independence ¶ 2 (U.S. 1776) (explaining that "Governments are instituted among Men" to secure the unalienable right to life, among others). The States, at least, take that proposition seriously; the right to life is real, fundamental, and unalienable—not a grandiloquent paper guarantee.

[7] While the Fourth Circuit recently rejected a similar challenge to West Virginia's abortion regulations, *GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025), the appellees in *Bryant v. Stein* continue to argue that the FFDCA preempts North Carolina's laws. *See* Brandon Kingdollar, *Federal appeals court moving forward on North Carolina abortion pill restrictions case* (Apr. 17, 2026), https://ncnewsline.com/2026/04/17/federal-appeals-court-moving-forward-on-north-carolina-abortion-pill-restrictions-case/.

requiring legal abortions to be performed by physicians, requiring an ultrasound prior to an abortion, and requiring reporting of adverse events. And the 2021/2023 Dispensing Changes would preempt Florida and Texas laws prohibiting the use of telehealth to prescribe or mail abortion drugs. *See* ECF No. 1 ¶¶ 311–24, 350–433.

Indeed, as explained by the Complaint, the Government Defendants have taken the official position that the 2021/2023 Dispensing Changes preempt state abortion regulations. ECF No. 1 ¶¶ 196, 354. Such "assertion[s] that federal law preempts state law" create a sovereign injury in fact. *Texas v. Becerra*, 623 F. Supp. 3d 696, 714 (N.D. Tex. 2022) (collecting cases).[8]

The second way the Challenged Actions cause sovereign injury is by inhibiting the States' ability to enforce their abortion regulations. *DAPA II*, 809 F.3d at 153 (States have standing pursuant to their sovereign interests "based on . . . federal interference with the enforcement of state law"). This most obviously arises with the 2021/2023 Dispensing Changes, which immediately created a nationwide mail-order abortion industry. ECF No. 1 ¶¶ 350–433. Illegal mail-order abortions mostly go undetected by law enforcement. While Texas has long required in-person protocols for chemically-induced abortions and passed further restrictions on telehealth abortions in December 2021, third-party data included in the Complaint shows that

[8] Of course, the States do not agree that the Challenged Actions preempt any of their laws. But the fact that federal district courts have held otherwise creates a "substantial risk" of preemption. *Clapper*, 568 U.S. at 414 n.5 ("Our cases do not uniformly require plaintiffs to demonstrate that it is literally certain that the harms they identify will come about. In some instances, we have found standing based on a 'substantial risk' that the harm will occur[.]").

more than 45,000 illegal telehealth abortions were performed in Texas between July 2022 and December 2024. *Id.* ¶ 429. The data also shows that 10,290 illegal telehealth abortions were performed in Florida between May 2024 (when Florida's law against telehealth abortions took effect) and December 2024. *Id.* ¶ 430. Law enforcement will never identify all the perpetrators of these illegal abortions, and any perpetrators that law enforcement may manage to identify are likely to be protected from prosecution by the "shield laws" enacted by pro-choice States contemporaneously with the 2021/2023 Dispensing Changes. *Id.* ¶¶ 302–03, 354–55, 431. In short, the States cannot effectively enforce their abortion laws in the face of the 2021/2023 Dispensing Changes. This constitutes cognizable sovereign injury. *See Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.").[9]

Causation. "Article III requires no more than de facto causality." *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019) (quotation omitted); *see also Alliance II*, 602 U.S. at 385 ("[T]o establish causation, the plaintiff must show a predictable chain of events leading from the government action to the asserted injury[.]"). Therefore, traceability is satisfied when the plaintiff shows that its injury resulted from third parties reacting to agency action "in predictable ways . . . even if they do so

[9] The other Challenged Actions also undermine the States' ability to detect, prevent, and prosecute illegal abortions within their borders. Under the 2000 Approval and 2016 Major Changes, chemical abortions begun at an abortion clinic in another State can be completed in Florida and Texas. ECF No. 1 ¶¶ 339–43, 347. And the 2019 and 2025 Generic Approvals have exacerbated the States' enforcement difficulties by decreasing the price of abortion drugs, thereby increasing their use. *Id.* ¶¶ 275–82.

unlawfully." *Dep't of Com.*, 588 U.S. at 768.

Defendants argue that "the connection between FDA's actions and supposed downstream violations of state law by third parties is too speculative and too attenuated to be traceable to FDA." ECF No. 53 at 21. Specifically, Defendants claim that the States' current inability to enforce their abortion regulations is the result not of the 2021/2023 Dispensing Changes but rather "'unfettered choices made by independent actors'—i.e., medical providers who, acting in reliance on shield laws . . . ship mifepristone to women who have requested it in Florida or Texas." *Id.* (quoting *Clapper*, 568 U.S. at 414 n.5).

This argument is unavailing. While the Supreme Court has observed that establishing standing can be "more difficult" for unregulated parties, *Louisiana*, 2026 WL 936958, at *9 (quoting *Lujan*, 504 U.S. at 562), "it has also made clear that standing may exist where such actors predictably respond to the challenged action." *Id.* (quoting *Lujan*, 504 U.S. at 560–61; *Dep't of Com*, 588 U.S. at 768; *California v. Texas*, 593 U.S. 659, 675 (2021)). After *Dobbs*, it was entirely predictable that, if authorized by the FDA, abortionists and others would begin sending abortion drugs into States that restrict elective abortion. In fact, that reaction was expressly predicted—and intended—by the Government Defendants. ECF No. 1 ¶¶ 176–97, 354, 364. And it came as no surprise when pro-choice States promptly moved to immunize their residents for this practice. *Id.*[10]

[10] To support their claim that the States' sovereign injuries are not traceable to the 2021/2023 Dispensing Changes, Defendants return to *Washington*. That reliance is misplaced, for three reasons. First, the States that attempted to intervene in

Redressability. GenBioPro argues that the States' injuries are not redressable because "[e]ven if the challenged FDA actions were vacated, nothing would prevent third parties from continuing to prescribe, distribute, or obtain mifepristone in other jurisdictions or through other lawful channels." ECF No. 55 at 18. But there can be no doubt that setting aside the 2021/2023 Dispensing Changes would lessen the flow of illegal mail-order abortions into the States, "which is all that is required for [the States] to show injury-in-fact and traceability." *Louisiana*, 2026 WL 936958, at *11 (citing *DACA*, 50 F.4th at 519 ("DACA is not the sole cause of the State's injury, but DACA has exacerbated it. That is sufficient.")).

In conclusion, Defendants' arguments against standing fall flat. The Complaint pleads facts sufficient to establish injury in fact, causation, and redressability for each of its claims.

C. The States' quasi-sovereign injuries are traceable to the Challenged Actions and can be redressed by setting the Challenged Actions aside.

States have a "quasi-sovereign" interest "in the health and well-being—both physical and economic—of [their] residents in general." *Texas v. Becerra*, 577

Washington did "not . . . allege that the 2023 REMS preempt[ed] or otherwise interfere[d] with [their] authority to enact or enforce restrictions." 108 F.4th at 1177. Here, the States point to the substantial risk of preemption as a distinct sovereign injury. Second, the Ninth Circuit concluded that the States' "prediction that elimination of the in-person dispensing requirement will lead to illegal use of mifepristone depends heavily on speculation that doctors and pregnant women will break state law." *Id.* Here, the Complaint contains facts and data showing that illegal mail-order abortions are no longer a "prediction"; they are a daily occurrence. ECF No. 1 ¶¶ 427–31. Third, the Ninth Circuit does not bind this Court, and its decision in *Washington* cannot be reconciled with the Fifth's Circuit's robust sovereign standing doctrine.

F.Supp.3d 527, 559 (N.D. Tex. 2021) (quoting *Snapp*, 458 U.S. at 607). Intervenor Defendants argue that the States cannot assert their quasi-sovereign interests in this case because, under the *Mellon* bar, "a 'State does not have standing as *parens patriae* to bring an action against the Federal Government.'" ECF No. 53 at 23 (quoting *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023)); *see also* ECF No. 55 at 20.

That is not categorically true. *See Becerra*, 577 F. Supp. 3d at 559 (approving Texas's standing to bring APA claims against an HHS mask and vaccine mandate due to its "*parens patriae* interest in protecting the welfare of its neediest children").

And it is not true here. The States assert a quasi-sovereign interest in protecting the health and safety of *both* pregnant women *and* preborn children from abortion drugs. ECF No. 1 ¶¶ 3–4, 30, 32, 305–24, 384. The *Mellon* bar clearly does not prevent the States from suing the federal government on behalf of the latter. While Florida and Texas women are "citizens of the United States" represented as *parens patriae* by the federal government, *Massachusetts v. Mellon*, 262 U.S. 447, 486 (1923), preborn children are not currently recognized as United States citizens or legal persons enjoying the *parens patriae* protection of the federal government. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 263 (2022) (expressing no "view about if and when prenatal life is entitled to any of the rights enjoyed after birth"). Unless this Court finds that preborn children are legal persons represented by the federal government as *parens patriae*,[11] *Mellon* does not apply.

[11] Scholarship shows that the American public considered preborn children to be rights-bearing "persons" when the Fourteenth Amendment was ratified. *See, e.g.*, John Finnis & Robert P. George, *Equal Protection and the Unborn Child: A Dobbs*

State-banned yet FDA-approved chemical abortions claim the lives of tens of thousands of preborn children in Florida and Texas each year. ECF No. 1 ¶¶ 429–30. This is a "sufficiently substantial segment of [the States'] population" to constitute quasi-sovereign injury. *See Snapp*, 458 U.S. at 607; *see also id.* ("One helpful indication in determining whether an alleged injury to the health and welfare of its citizens suffices to give the State standing to sue as *parens patriae* is whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers."). In line with *Snapp*, both States have attempted to address this problem through their respective sovereign lawmaking powers, ECF No. 1 ¶¶ 311–24, and have been thwarted by the FDA's regulations. This loss of preborn life is traceable to the Challenged Actions. And because the *Mellon* bar does not apply, this Court can redress the States' injuries by granting the relief sought.

III. The States Are Within the Relevant Zones of Interests.

Next, Intervenor Defendants argue that the States are outside the zone of interests of the FFDCA, the PREA, and the Comstock Act. ECF No. 53 at 24–26; ECF No. 55 at 22. An ambitious claim, given the zone of interests test is "not especially demanding." *Lexmark, Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014). In the context of the APA, a plaintiff need only be "*arguably* within the zone of interests to be protected or regulated by the statute in question." *Id.*

Brief, 45 Harv. J. L. & Pub. Pol'y 927 (2022); Joshua J. Craddock, *Protecting Prenatal Persons: Does the Fourteenth Amendment Prohibit Abortion?*, 40 Harv. J. L. & Pub. Pol'y 539 (2017); C'Zar Bernstein, *Fetal Personhood and the Original Meanings of "Person,"* 26 Tex. Rev. L & Politics 485 (2022).

Dismissal is warranted only when the plaintiff's interests "are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399 (1987).

The States' interests here are far more than "marginally related" to the purposes of the relevant statutes. Take the FFDCA, the purpose of which is to "protect the public health" by "assur[ing] the safety, effectiveness, and reliability of drugs." Pub. L. No. 87-781, 76 Stat. 780 (1962); *see also* 21 U.S.C. § 355. The States unquestionably share that interest in protecting public health. *See BST Holdings, LLC v. OSHA, United States Dep't of Lab.*, 17 F.4th 604, 618 (5th Cir. 2021). Both States dedicate a chapter of their codes to regulating drugs and cosmetics. *See* Fla. Stat. § 499.001; Tex. Health & Safety Code § 431.001. This interest also places the States within the zone of interests for the PREA, which exists to ensure the safety of drugs consumed by minors. *See* 21 U.S.C. § 355c.

Same goes for the Comstock Act. That statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 70 n.19 (1983) (the "thrust" of the Act was "to prevent the mails from being used to corrupt the public morals"). Florida and Texas have similar interests in promoting public morals, *see Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569 (1991), and protecting preborn life, *see Dobbs*, 597 U.S. at 262. This symmetry of interests easily overcomes the low bar set by the zone of interests test.

IV. The States Were Not Required to Pursue Administrative Remedies.

Defendants next argue that "the Complaint should be dismissed under Rule 12(b)(6) because [the States] failed to first present their arguments to FDA through a citizen petition." ECF No. 20-1 at 22; *see also* ECF No. 53 at 26–28; ECF No. 55 at 22–25. This argument fails for multiple reasons.

First, the APA imposes no such exhaustion requirement. The APA subjects "final agency action" to judicial review. 5 U.S.C. § 704. Agency action "otherwise final is final for the purposes of [§ 704] whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration," with two exceptions: (1) "[e]xcept as otherwise expressly required by statute" or (2) "unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority." *Id.*; *see also Darby v. Cisneros*, 509 U.S. 137, 154 (1993); *MCR Oil Tools, L.L.C. v. Dep't of Transportation*, 110 F.4th 677, 691 (5th Cir. 2024).

Neither exception applies here. The FFDCA does not mandate a citizen petition as a prerequisite to judicial review. And while the FDA's regulations do condition judicial review on the denial of a citizen petition, the regulations do not provide that the challenged action is inoperative during the agency's review of the citizen petition. *See* 21 C.F.R. § 10.45. So, under § 704 of the APA, the States were not required to pursue administrative remedies before filing suit.

In any event, the States satisfy the FDA's regulations because, "on their own terms, the FDA regulations specify that a person . . . who 'asks to participate . . . in a

court action' can sue in court as soon as there is a final administrative decision on any [citizen] petition filed under § 10.25(a)—even if the 'interested person' suing is not the one who filed the initial petition." *Vanda Pharms. Inc. v. FDA*, No. 23-CV-2812 (CRC), 2024 WL 4133623, at *16 (D.D.C. Sept. 10, 2024). Here, the FDA had already rejected citizen petitions complaining of each of the Challenged Actions before the States filed suit. *See* ECF No. 1 ¶¶ 200–04; Students for Life, FDA-2023-P-1528 (Jan. 15, 2025). 21 C.F.R. § 10.45(b) did not require the States to file a redundant citizen petition before seeking judicial review.[12]

V. The States' Claims Are Not Time-Barred.

Civil actions against the United States are generally "barred unless the complaint is filed within six years after the right of action first accrues." 28 U.S.C. § 2401(a). Defendants argue that the States' "challenges to the approval of mifepristone in 2000 (Count I), the 2016 action (Count II), and the approval of the first generic in April 2019 (Count IV) are barred by the six-year statute of limitations." ECF No. 20-1 at 23; *see also* ECF No. 53 at 28–29; ECF No. 55 at 25.

Not so. "A claim accrues when the plaintiff has the right to assert it in court—and in the case of the APA, that is when the plaintiff is injured by final agency action."

[12] Exceptions to the exhaustion requirement also apply. Exhaustion is not required when "the action of an administrative agency is in excess of statutory authority," *Bd. of Pub. Instruction of Taylor Cnty. v. Finch*, 414 F.2d 1068, 1073 (5th Cir. 1969) (cleaned up), or where the agency action is "likely to result in individual injustice" or "contrary to an important public policy extending beyond the rights of the individual litigants." *Myron v. Martin*, 670 F.2d 49, 52 (5th Cir. 1982). And if the FDA fails to correct the Challenged Actions through its ongoing review, the futility exception will also apply. *See Alliance I*, 78 F.4th at 255 (no exhaustion requirement "when resort to administrative remedies would be clearly useless").

Corner Post, 603 U.S. at 804. The injuries alleged in the Complaint all occurred within six years of the Complaint's filing on December 9, 2025. Florida's sovereign and quasi-sovereign injuries began on May 1, 2024, when its Heartbeat Protection Act took effect. ECF No. 1 ¶ 320. Texas's sovereign and quasi-sovereign injuries began on August 25, 2022, when its Human Life Protection Act became effective, prohibiting abortions from conception. ECF No. 1 ¶ 323.[13] The earliest economic injury alleged by Florida occurred in 2020. *Id.* ¶ 287. Texas has not alleged any economic injury occurring more than six years prior to the suit. *Id.* ¶ 289. Under the four corners of the Complaint, the claims accrued in the limitations period.[14]

In any event, the FDA's ongoing review has reopened the Challenged Actions. The reopening doctrine "allows a plaintiff to challenge an agency action past the ordinary timeline if the agency substantively reconsiders the original action in a subsequent decision." *Alliance I*, 78 F.4th at 242; *see also Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021) ("If the agency . . . reexamined and reaffirmed its prior decision, the agency's second action (the reaffirmance) is reviewable." (quotation omitted)), *rev'd on other grounds*, 597 U.S. 785 (2022).

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[13] Neither law could have been enforced prior to June 24, 2022, when the Supreme Court decided *Dobbs*. This is why the States "waited 25 years to challenge the [2000] approval [and] nearly ten years to challenge FDA's 2016 action." ECF No. 20-1 at 11.

[14] The Government Defendants argue that "[a]ccording to [the States], they suffered an injury sufficient to give them standing at the time of each challenged agency action" because the Complaint "alleg[es] that the 2000 approval and 2016 action each caused emergency room visits leading to Medicaid costs." ECF No. 20-1 at 23 (citing ECF No. 1 ¶¶ 295–96). This is false. The States do not allege that their Medicaid programs incurred any mifepristone-related Medicaid costs prior to December 9, 2019, in paragraphs 295–96 or elsewhere.

Alliance I held that the doctors' challenge to the 2000 Approval was time-barred because "neither the 2016 Amendments nor the 2021 Petition Denial reevaluated FDA's decision in 2000 to approve mifepristone." 78 F.4th at 244. The FDA's current review, on the other hand, is "evaluating issues . . . ranging from eliminating the REMS entirely to withdrawing the approval of mifepristone for termination of early pregnancy, as well as actions in between." Ex. 1 ¶ 5. In context, this representation clearly reveals the FDA's "intention to put the [Challenged Actions] back on the chopping block and rethink things." *Biden*, 20 F.4th at 955.

VI. The States' Claims Are Ripe.

Finally, after claiming the State's claims are stale, Intervenor Defendants dispute that they are ripe. ECF No. 53 at 29–30; ECF No. 55 at 22–25. Yet in the Fifth Circuit, "disagreements over final, specific agency action[s] are necessarily ripe." *Sierra Club v. Peterson,* 185 F.3d 349, 362 n.16 (5th Cir. 1999); *see also Melissa Indus. Dev. Corp. v. N. Collin Water Supply Corp.*, 256 F. Supp. 2d 557, 567 (E.D. Tex. 2003); *Natural Resources Defense Council, Inc. v. Thomas,* 845 F.2d 1088, 1091 (D.C. Cir. 1988) (ripeness and final agency action "are inextricably intertwined"). As no party contests the finality of the Challenged Actions, the States' claims are ripe.

CONCLUSION

In light of the FDA's substantive reevaluation of all the Challenged Actions, the States agree that this case should be stayed for a reasonable amount of time. If a stay is not granted, the Court should deny the motions to dismiss.

Date: April 24, 2026

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been furnished by electronic service through the CM/ECF Portal on April 24, 2026, to all counsel of record.

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