No. 26-30203

IN THE

United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; MICHAEL DAVIS, ACTING DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

v.

GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court for the Western District of Louisiana, No. 6:25-cv-01491-DCJ-DJA (Joseph, J.)

DANCO LABORATORIES, LLC'S REPLY BRIEF

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August 19, 2026

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

1. **Case Number and Style**: No. 26-30203, *Louisiana v. U.S. Food and Drug Admin.*

2. **Plaintiffs-Appellants/Cross-Appellees**: The State of Louisiana, by and through its Attorney General, Liz Murrill; and Rosalie Markezich

3. **Counsel for Plaintiffs-Appellants/Cross-Appellees**:

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   Counsel for State of Louisiana and Rosalie Markezich: Erin M. Hawley; Erik C. Baptist; Julie Marie Blake; Frank W. Basgall; Gabriella M. McIntyre; and Dalton A. Nichols of Alliance Defending Freedom

4. **Defendants-Appellees**:[1] U.S. Food and Drug Administration; Kyle Diamantas, in his official capacity as Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration; Michael Davis, in

[1] Pursuant to Federal Rule of Civil Procedure 25(d) and Federal Rule of Appellate Procedure 43(c)(2), Mr. Diamantas and Dr. Davis have been automatically substituted for their predecessors.

his official capacity as Acting Director, Center For Drug Evaluation and Research, U.S. Food and Drug Administration; U.S. Department of Health and Human Services; and Robert F. Kennedy, Jr., in his official capacity as Secretary, U.S. Department of Health and Human Services

5. **Counsel for Defendants-Appellees**: Brett A. Shumate; James W. Harlow; and Noah T. Katzen of the U.S. Department of Justice

6. **Intervenors-Appellees/Cross-Appellants**:

Danco Laboratories, LLC. Danco Laboratories, LLC states that its parent corporation is Danco Investors Group, LP. Danco is 100% owned by that parent corporation.

GenBioPro, Inc. In the District Court, GenBioPro, Inc. stated that "its parent company is Xenia Holdco LLC, and that there is no publicly held corporation that owns 10% or more of its stock." ROA.4983.

7. **Counsel for Intervenors-Appellees/Cross-Appellants**:

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8. **Amici and their Counsel**:[2]

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Association of American Physicians and Surgeons and Eagle Forum Education & Legal Defense Fund

Counsel: Andrew L. Schlafly

Family Research Council and Martha Shuping, MD

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[2] This list encompasses amici and their counsel from the District Court, the Supreme Court, and this Court.

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Ethics and Public Policy Center
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Counsel: J. Scott St. John of St. John LLC; Heather Gebelin Hacker of Hacker Stephens LLP

Nebraska; Alabama; Alaska; Arkansas; Florida; Georgia; Idaho; Indiana; Iowa; Kansas; Kentucky; Mississippi; Missouri; Montana; North Dakota; Ohio; Oklahoma; South Carolina; South Dakota; Texas; Utah; West Virginia; and Wyoming
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Advancing American Freedom, Inc.; Alabama Policy Institute; Alaska Family Council; American Association of Senior Citizens; American Values; Americans United for Life; America's Women; Association of Mature American Citizens Action; Fran Bevan; Centennial Institute at Colorado Christian University; Center for Urban Renewal and Education; Christian Law Association; Christian Medical & Dental Associations; Concerned Women for America; Democrats for Life; Eagle Forum; Faith and Freedom Coalition; Family Council in Arkansas; Family Institute of Connecticut Action; Frontline Policy Council; Good Counsel; Human Coalition; Idaho Family Policy Center; International Conference of Evangelical Chaplain Endorsers; James Dobson Family Institute; Live Action; Tim Jones; Dr. Alveda King; Louisiana Family Forum;

[3] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

Lutheran Center for Religious Liberty; Maryland Family Institute; Men and Women for a Representative Democracy in America, Inc.; Men for Life; National Religious Broadcasters; National Right to Life; Nebraska Family Alliance; New York State Conservative Party; North Carolina Values Coalition; Orthodox Jewish Chamber of Commerce; Melissa Ortiz; Priests for Life; Rick Santorum; Robert F. Schwarzwalder, PhD; Dr. Gregory P. Seltz; 60 Plus Association; Paul Stam; Kathy Szeliga; Paul Teller; Texas Right to Life; The Family Foundation of Virginia; The Wagner Center; Kerri Toloczko; Suzi Voyles; Tradition, Family, Property, Inc.; Trusted Voice Podcast; Wisconsin Family Action, Inc.; Women for Democracy in America, Inc.; and Young America's Foundation

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NC Values Institute and World Faith Foundation

Counsel: Deborah J. Dewart

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Counsel: Heather Gebelin Hacker of Hacker Stephens LLP

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Counsel: Jonathan M. Saenz of Texas Values

National Hispanic Christian Leadership Conference and Douglass Leadership Institute

Counsel: Mathew D. Staver; Horatio G. Mihet; and Daniel J. Piedra of Liberty Counsel

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Counsel: David H. Thompson and Megan M. Wold of Cooper & Kirk PLLC

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Over 100 Reproductive Health, Rights, and Justice Organizations[4]

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Former Commissioners and Acting Commissioners of the U.S. Food and Drug Administration (David A. Kessler, M.D.; Jane E. Henney, M.D.; Margaret Hamburg, M.D.; Robert M. Califf, M.D.; Michael A. Friedman, M.D.; Joshua M. Sharfstein, M.D.; Stephen Ostroff, M.D.; Norman E. "Ned" Sharpless, M.D.; Janet A. Woodcock, M.D.)

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Counsel: Jacob K. Weixler of Weixler Law LLC; Letitia James; Barbara D. Underwood; Ester Murdukhayeva; and Galen Leigh Sherwin of the New York Office of the Attorney General; Dana Nessel of the Michigan Office of the Attorney General; Kristin K. Mayes of the Arizona Office of the Attorney General; Kwame Raoul of the Illinois Office of the Attorney General; Rob Bonta of the California Office of the Attorney General; Aaron M. Frey of the Maine Office of the

[4] A full list of participating amici can be found at ROA.6158-6163. In the District Court, amici represented that: "One supporting signatory to the amicus brief, Endora, operates under a fiscal sponsorship arrangement with Aspiration Tech.; however no publicly traded corporation owns ten (10%) or more of its stock." ROA.6790.

Attorney General; Philip J. Weiser of the Colorado Office of the Attorney General; Anthony G. Brown of the Maryland Office of the Attorney General; William Tong of the Connecticut Office of the Attorney General; Andrea Joy Campbell of the Massachusetts Office of the Attorney General; Kathleen Jennings of the Delaware Office of the Attorney General; Keith Ellison of the Minnesota Office of the Attorney General; Anne E. Lopez of the Hawai'i Office of the Attorney General; Aaron D. Ford of the Nevada Office of the Attorney General; Jennifer Davenport of the New Jersey Office of the Attorney General; Charity R. Clark of the Vermont Office of the Attorney General; Raúl Torrez of the New Mexico Office of the Attorney General; Nicholas W. Brown of the Washington Office of the Attorney General; Dan Rayfield of the Oregon Office of the Attorney General; Brian L. Schwalb of the District of Columbia Office of the Attorney General; Jeff Jackson of the North Carolina Office of the Attorney General; Jay Jones of the Virginia Office of the Attorney General; Josh Shapiro, Governor of the Commonwealth of Pennsylvania; and Peter F. Neronha of the Rhode Island Office of the Attorney General

Former U.S. Department of Justice Officials[5]

Counsel: Alan Schoenfeld; M. L. Io Jones; Kimberly A. Parker; Kyle Edwards Haugh; and Arielle Herzberg of Wilmer Cutler Pickering Hale & Dorr LLP; Richard G. Perque of the Law Office of Richard G. Perque

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[5] A full list of amici appears at ROA.6303.

[6] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

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Counsel: Jamie A. Levitt; Megan E. Baffaro; Joseph R. Palmore; Elaine Hou; and Daralyn J. Durie of Morrison & Foerster LLP; Carmel Dori Shachar of Center for Health Law and Policy Innovation at Harvard Law School

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[7] A full list of amici appears at ROA.6360.

[8] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

[9] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

Physicians for Reproductive Health

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Information Society Project at Yale Law School

Counsel: Priscilla J. Smith; Yael H. Caplan; and Genevieve E. Scott of Yale Law School

163 Reproductive Health, Rights, and Justice Organizations[12]

Counsel: Emily Merrifield; Sara Stappert; Jessica Ring Amunson; and Varsha Midha of Jenner & Block LLP

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[10] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

[11] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

[12] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

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[13] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

[14] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

Former Military Officials; Former Civilian National Security Leaders; and Vet Voice Foundation[15]

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Blood Cancer United and Nine Other Advocacy Groups[16]

Counsel: Caroline L. Wolverton; Nathan A. Brown; Laura E. Hill; Kristen E. Loveland; Maddy L. Bolger; and May Johnson of Akin Gump Strauss Hauer & Feld LLP

Amici for Neither Party

David Boyle

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/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

Counsel for Intervenor-Appellee/Cross-Appellant Danco Laboratories, LLC

[15] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

[16] A full list of amici can be found in the amicus brief filed at the United States Supreme Court under docket no. 25A1207.

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INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs repeatedly invoke remarks the Attorney General made about the 2023 REMS during his recent confirmation hearing. *See* Plaintiffs-Appellants Resp. 1, 5-6, 31, 36, 41 (Opp.). Those statements reinforce that this Court should not grant Plaintiffs' requested relief: "[C]rucial decisions" about the REMS are currently being "debate[d]" through "the political processes." *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 380 (2024) (*Alliance*) (citation and quotation marks omitted). This Court should not short-circuit that process.

Indeed, FDA is the right place for these issues to play out because Louisiana lacks standing, which means this Court lacks jurisdiction. Louisiana's standing theories are directly analogous to those the Supreme Court found legally insufficient in *Alliance*. Like the *Alliance* plaintiffs, Louisiana is not required to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" because of FDA's actions. *Id.* at 385. Louisiana's citation to its alleged Medicaid costs and the alleged mismatch between federal and state abortion policy do not somehow turn the state into a regulated party. Those "downstream" effects are "too attenuated" to create standing. *Id.* at 386, 391.

Plaintiffs nevertheless insist that Louisiana has standing because it was "targeted" by the Biden Administration in the 2023 REMS. *See Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 115 (2025). That argument defies both law and logic. Plaintiffs overread *Diamond*, which expressly declined to hold that the "indirect[] target" of a regulation stands in the same shoes as a regulated party for the causation analysis. *Id.* at 115-116. And, in any event, it makes no sense to say that the Biden Administration "targeted" Louisiana in response to the Supreme Court's June 2022 decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), because FDA had stopped enforcing in-person mifepristone dispensing in April 2021—*over a year* before *Dobbs* was decided. The District Court erred by not granting Danco's motion to dismiss on that basis.

Plaintiffs' merits arguments are likewise unavailing. As before, they breeze past the other threshold justiciability bars to their two APA challenges—exhaustion and ripeness. And Plaintiffs outright ignore the distinct (but overlapping) doctrines that foreclose their Comstock Act claim. Third parties categorically cannot bring lawsuits to enforce federal criminal laws, and Plaintiffs are outside the Comstock Act's zone

of interests. Plaintiffs likewise fail to state an arbitrary-and-capricious claim: It would be an astonishing rule of administrative law to hold that FDA could not consider FAERS data as part of the body of information available when making determinations about a drug it regulates, and FDA's 2023 REMS decision was not a change in position.

This Court should reverse the District Court's denial of Danco's motion to dismiss.

ARGUMENT

I. PLAINTIFFS LACK ARTICLE III STANDING.

Throughout this case, Plaintiffs have looked for different ways to evade *Alliance*. Having simply disregarded the Supreme Court's reasoning in earlier briefing, Plaintiffs now attempt to distinguish *Alliance* by leaning on the factual record in this case. But these efforts ignore the Supreme Court's admonition that "assessing standing" for unregulated parties (like Louisiana here) should "be facilitated by [the] clarifying principles or even clear rules developed in prior cases." *Alliance*, 602 U.S. at 384 (citation and quotation marks omitted). *Alliance* itself sets the clear rule that Louisiana cannot establish standing to challenge the 2023 REMS based on downstream economic injuries. *See* Danco Br. 26-28. And Louisiana's attempts to establish

standing based on abstract claims of sovereign injury follow no practice or precedent at all.

A. *Alliance* Makes Clear That Louisiana's Financial Injuries Are Too Attenuated To Establish Standing.

Alliance precludes challenges to "FDA's drug approvals simply on the theory that use of the drugs by others" leads to downstream "monetary and related injuries." 602 U.S. at 384, 390-392. That principle decides this case.

Like the doctors in *Alliance*, Louisiana is not forced to do or refrain from doing anything because of the 2023 REMS—and therefore "suffer[s] no direct monetary injuries from FDA's actions relaxing regulation of mifepristone." *Id.* at 385-386. To incur the costs it claims, Louisiana must either pay doctors who provide follow-up care to someone who experiences rare complications from mifepristone prescribed by a different provider, or pay state employees to investigate who the prescribing provider was and whether to take state action against that provider. But *Alliance* expressly held that non-prescribing doctors' claims of injury are too removed from FDA's decisions for standing. *Id.* at 386-387. And Louisiana's investigators are no different than "[p]olice officers . . . su[ing] to challenge a government decision to legalize certain

activities that are associated with increased crime," which the Court noted is plainly impermissible. *Id.* at 392. Louisiana's standing theories necessarily fail because they are more attenuated than the causal chains that *Alliance* rejected. Just as in *Alliance*, accepting such an extended chain between FDA's actions and "downstream economic injuries" would leave "no principled way to cabin" standing at all. *Id.* at 386, 392.

Each path that Louisiana tries in its search for a way around *Alliance* lacks merit.

1. Louisiana was not the "target" of the 2023 REMS within the meaning of Diamond Alternative Energy.

The heart of Plaintiffs' argument is that Louisiana is more similar to the plaintiffs in *Diamond Alternative Energy*, whose product (fuel) was the "target" of California's fuel efficiency regulations, than Louisiana is to the *Alliance* plaintiffs. Opp. 9-13. This line of argument fails multiple times over.

1. As an initial matter, the facts undercut Louisiana's targeting theory. Louisiana never endeavors to reconcile its "targeting" claim with the undisputed fact that the 2023 REMS merely continued a pre-existing FDA policy dating back to 2021. Opp. 10-12. Indeed, the *Alliance* plaintiffs (represented by the same counsel as Plaintiffs here) told the

Supreme Court that FDA's non-enforcement decisions in April and December 2021—which predated *Dobbs*—"*permanently* removed the in-person dispensing requirement." Resp. Br. 57-58, *FDA v. Alliance for Hippocratic Med.*, Nos. 23-235, 23-236, 2024 WL 811351 (U.S. Feb. 22, 2024) (emphasis added). So did Louisiana, as amicus curiae in that litigation. *See* Mississippi et al. Br. 13, 2024 WL 945352 (U.S. Feb. 29, 2024).

In addition, despite extensively quoting FDA's decision memorandum approving the 2023 REMS elsewhere in its brief, Louisiana offers no support from that document for the proposition that FDA intended to undermine state law. *See* ROA.964-1052. Louisiana's "targeting" theory instead relies on statements wholly outside of the administrative record. But courts "may not consider evidence outside of the administrative record" when reviewing agency decisionmaking. *Sierra Club v. Dep't of Interior*, 990 F.3d 909, 918 (5th Cir. 2021) (quoting *Harris v. United States*, 19 F.3d 1090, 1096 n.7 (5th Cir. 1994)).

Greenlighting that sort of "judicial inquiry into 'executive motivation'" to establish standing would be just as much of "'a substantial intrusion' into the workings of another branch of

Government" as it is on the merits, *see Dep't of Com. v. New York*, 588 U.S. 752, 781 (2019) (citation omitted)—one without any established "historical precedent," *see United States v. Texas*, 599 U.S. 670, 677 (2023) (citation omitted). And it is a "limitless approach," *Alliance*, 602 U.S. at 391-392, that would grant standing any time an unregulated party could point to statements by a politician about "an Administration's priorities," *Dep't of Com.*, 588 U.S. at 781. That simply cannot be a basis for the exercise of Article III powers. *Cf. Maloney v. Carnahan*, 45 F.4th 215, 219 (D.C. Cir. 2022) ("Congress's subjective policy goals in passing a law have no role in the standing analysis.") (Millett, J. concurring in denial of rehearing en banc).

2. In any event, Louisiana overreads *Diamond*. There, the Supreme Court expressly declined to hold that the "indirect[] target" of a regulation stands in the same shoes as a directly regulated party for the causation analysis. 606 U.S. at 115-116 ("[W]e ultimately need not further consider th[e] argument in this case" that "the government might seek to indirectly target a product or service through a conduit in addition to regulating it directly") (quotation marks omitted).

Rather, noting that causation was not "meaningfully dispute[d]" by the parties, *Diamond* held that the fuel producers fell within "the 'familiar' circumstance where government regulation of a business" "cause[s] downstream or upstream economic injuries to others in the chain, such as certain manufacturers, retailers, suppliers, competitors, or customers." *Id.* at 113, 116 (quoting *Alliance*, 602 U.S. at 384). This reasoning does not help Louisiana. The 2023 REMS sets conditions on the distribution of mifepristone for mifepristone manufacturers. Louisiana is not a manufacturer, retailer, supplier, competitor, or customer of a mifepristone manufacturer. Moreover, the Supreme Court has articulated limits on standing even for "market participant[s]"—which Louisiana is not; the Court has "never accepted such a boundless theory of standing" that would allow third parties to sue simply because a directly regulated party "benefits from [an] allegedly unlawful" government decision. *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 99 (2013).

The *Diamond* Court had no reason to consider attenuation because California's regulation explicitly sought to restrict the use of fuel in cars and flowed, at most, through one intermediary: car manufacturers. 606 U.S. at 114-115 ("The fuel producers here might be considered an object

of the California regulations because the regulations explicitly seek to restrict the use of gasoline and other liquid fuels in automobiles."). Nothing in the decision overrides the Supreme Court's repeated admonition against relying on multi-link causal chains. *See, e.g.*, *Texas*, 599 U.S. at 680 n.3 (cautioning that "federal policies frequently generate indirect effects on state revenues or state spending"). *Diamond* thus does not solve Louisiana's attenuation problem.

More fundamentally, *Diamond* cannot help Louisiana because the State's causation theory is based on the supposed subjective intent of government actors to "disparage[]" Louisiana's "commitment to life." Opp. 10-11. Such a rule flies in the face of *Diamond*, which looked to "commonsense economic realities," not regulators' suspected intentions. 606 U.S. at 116. And Louisiana cites no "historical practice" of courts analyzing causation this way. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340-341 (2016); *see supra* pp. 6-7. *Diamond* gets Louisiana nowhere.[1]

[1] Notably, neither the District Court nor the motions panel relied on *Diamond*, much less read it to create the standard Louisiana now advocates. ROA.9099-9108; ROA.9140-9143. Rather, those courts held (incorrectly) that Louisiana established causation because its injuries were the predictable effect of the 2023 REMS.

2. Louisiana's evidence cannot rescue its flawed standing theory.

Next, Louisiana points to documents it offered below regarding its supposed Medicaid costs to treat complications of mifepristone. Opp. 8, 15-16, 21-23. Louisiana implies this evidence is so overwhelming that FDA conceded Louisiana's standing. Not so. In its brief, FDA reiterated its consistent position that Louisiana has not established a judicially cognizable injury. FDA Br. 5-6, 14, 27-43. Indeed, FDA devoted half its argument to explaining why this Court should "reject[]" the " 'attenuated' theories of state standing" Louisiana postulates. *Id.* at 27-43. That is far from "nominally oppos[ing]" the state's claims of cognizable harm. *Contra* Opp. 6.

Nor is Louisiana's evidence persuasive. Without its unsupported and misconceived targeting theory, Louisiana has no way to distinguish *Alliance*'s admonition that "virtually all drugs come with complications, risks, and side effects," which means that changes in prescription drug guidelines may "yield more visits to doctors to treat complications or side effects," and that there is "no principled way to cabin" a standing theory premised on that basis. *Alliance*, 602 U.S. at 392. *Alliance* therefore dictates that states "cannot establish standing" to challenge the 2023

REMS "based on the alleged costs to the state's finances," *Washington v. FDA*, 108 F.4th 1163, 1176 (9th Cir. 2024), which is all that Louisiana's "Medicaid receipts" offer. Opp. 15-16.

Louisiana's observation (at 12) that this Court can review "the district court's factual finding[s] . . . only for clear error" misunderstands that there is no factual finding under review. The District Court's determination regarding causation rests on a legal mistake—applying the wrong standard—that is subject to de novo review.

3. State investigatory costs are not a cognizable Article III injury.

Louisiana also invokes "investigatory costs" incurred in enforcing its abortion laws. Opp. 20-21. But Louisiana's investigators are just like the "[p]olice officers . . . su[ing] to challenge a government decision to legalize certain activities that are associated with increased crime," which *Alliance* rejected. 602 U.S. at 392. Like private organizations, states cannot "spend [their] way into standing," *id.* at 394, by pursuing state policies that differ from federal law. If states lack standing to sue the federal government based on their "costs" of "continu[ing] to incarcerate or supply social services," *Texas*, 599 U.S. at 674, they must also lack standing based on "investigatory costs."

B. Louisiana's Asserted Sovereign Injuries Are Insufficient.

1. Louisiana's assertions of sovereign injury fare no better. Opp. 26-36. Because the "doctrine of standing . . . is grounded in historical practice," Louisiana must show that the type of sovereign injury it alleges—violations of its laws by third parties and its difficulty prosecuting those violations—has "traditionally been regarded as providing a basis for a lawsuit" in Article III courts. *Spokeo*, 578 U.S. at 341. But Louisiana has not identified any history or tradition of suits against the United States "on the basis of [such] claimed injur[ies] to official authority or power." *Raines v. Byrd*, 521 U.S. 811, 826 (1997).

For good reason. For "a sovereign interest to serve as a cognizable injury for federal standing, the acts of the defendant must invade the government's sovereign right." *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 770 (5th Cir. 2023) (cleaned up). Louisiana certainly has a sovereign right to regulate individuals by "creat[ing] and enforc[ing] a legal code." *Alfred L. Snapp & Son, Inc. v. Puerto Rico,* 458 U.S. 592, 601 (1982). But Louisiana has only limited rights with respect to the United States. Defined by the Constitution's "dual sovereignty" structure, these rights are essentially those protected by the "anticommandeering

doctrine." *Murphy v. NCAA*, 584 U.S. 453, 470-471 (2018). States suffer injury to those rights only when the federal government "directly commands a State to regulate or indirectly coerces a State to adopt a federal regulatory system as its own." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 577-578 (2012); *see also Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (describing "sovereign" harm as "analogous to pressure to change state law").

Here, however, all parties agree that Louisiana's laws remain in full legal effect and that its regulatory machinery has not been commandeered. And—despite repeated challenges to do so, *e.g.*, Danco Br. 33—Louisiana cites no case holding that a violation of state law by third parties creates a cognizable sovereign injury for a suit against the United States. *Cf. Harrison*, 78 F.4th at 770 ("[W]hat has traditionally counted as an injury to a sovereign interest does not include every act of disobedience to a state's edicts."). Invoking (at 29) the Supreme Court's statement that the *federal government* suffers sovereign injury "from violation of its laws," *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 771 (2000), is of little value to *Louisiana* because the Constitution vests the United States with a unique right to enforce law

in its own courts. *See* Danco Br. 35.[2] That is why a violation of federal law "suffices to support a criminal lawsuit by the" United States, *Stevens*, 529 U.S. at 771, but "it [is] unheard of . . . for States to bring criminal actions in federal court," *Saginaw County v. STAT Emergency Med. Servs., Inc.*, 946 F.3d 951, 956 (6th Cir. 2020).[3]

2. As FDA points out, conduct by out-of-state providers occurring out of state "is not a violation of Louisiana's laws" to begin with, FDA Br. 42, and in any event, there is no "historical or common-law analogue for" states suing the federal government based on private parties' disobedience of state law, *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021). No case says that asserting a "hindrance" to the

[2] *See, e.g.*, *In re Debs,* 158 U.S. 564, 584 (1895) ("Every government . . . has a right to apply to its own courts for any proper assistance"). The right of the federal government to sue in its own courts sheds no light on whether a *state* can apply to *federal* court to enforce violations of *state* law. *See* Tara Leigh Grove, *Standing Outside of Article III*, 162 U. Pa. L. Rev. 1311, 1321-23 (2014) (explaining that the United States' "judicially cognizable interest in the enforcement and defense of federal law" stems from "accommodat[ing] the executive's Article II responsibilities").

[3] Louisiana criticizes Danco for analogizing Louisiana's sovereign-harms theory to an impermissible *parens patriae* suit. Opp. 34. But the prohibition against *parens patriae* actions by states against the federal government further shows that states are more limited in bringing suits to federal courts for resolution. Danco Br. 34. Louisiana has no answer to that point.

enforcement of state laws suffices to create Article III sovereign injury vis-à-vis the federal government. *Harrison*, the case Louisiana cites, analyzed when a state may "invoke federal jurisdiction to enforce . . . state law against a *subordinate*." 78 F.4th at 771 (emphasis added). This is not an attempt to enforce state law against a subordinate.

In fact, *Harrison* expressly distinguished *states'* interests in enforcing federal law from the *federal government's* own interest in enforcing federal law. *Id.* And although the Court noted that "federal interference with the enforcement of state law" is a "type of" sovereign injury, it explained that "the Supreme Court has spoken about the state's interest in the enforceability of its [own] laws." *Id.* at 770, 772 (citations and emphasis omitted). As the Court has explained in such cases, this means the legal validity of state law, not the practical administrability. *See, e.g.*, *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 277-278 (2022) (discussing state "sovereign interests" in "defend[ing] the constitutionality" of a state statute); *Maine v. Taylor*, 477 U.S. 131, 137 (1986) (recognizing state's "interest in the continued enforceability of its own statutes" as against legal challenge). Were it otherwise, state standing to challenge federal policy would be virtually unlimited.

Louisiana's assertion (at 30-31) that the 2023 REMS amounts to "functional preemption" of Louisiana law is a giveaway. There is no "functional preemption" doctrine. "[F]ederal courts have not traditionally entertained lawsuits of this kind." *Texas*, 599 U.S. at 681. No case recognizes nebulous interference with state-law administration as an injury "traditionally amenable to, and resolved by" a suit against the United States. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). Louisiana remains free to prohibit abortion and to enforce those prohibitions. Neither the downstream violations of its laws nor the practical difficulties it faces in enforcing them gives Louisiana Article III standing to sue FDA. *See Washington*, 108 F.4th at 1176-77 (rejecting asserted state sovereign interests because FDA's decisions do not "interfere[] with [a] state's authority to enact or enforce restrictions on medical abortion within its boundaries").

3. Louisiana brushes off the attenuation between the 2023 REMS and its asserted injuries, which it insists are "predictab[ly]" linked to FDA's decision. Opp. 35. But Louisiana's claimed sovereign injuries depend on the same attenuated chain of independent decisions as its claimed financial injuries. Danco Br. 36-37. In addition, Louisiana's

asserted "functional nullification" of its laws (at 35) rests almost exclusively on the decisions of *other* states to enact shield laws that protect prescribing doctors. *See* Danco Br. 37. Louisiana has no response to that.

II. PLAINTIFFS OTHERWISE FAIL TO STATE A CLAIM.

Even if Plaintiffs could establish Article III jurisdiction, dismissal would still be necessary. Each of Plaintiffs' APA claims has insurmountable justiciability defects and falls short on the merits.

A. Plaintiffs' Claims Are Unexhausted And Unripe.

1. FDA regulations unequivocally require unregulated parties to exhaust administrative remedies by filing a citizen petition. *See* 21 C.F.R. §§ 10.45(b), 10.25(a). Plaintiffs say no petition was necessary here because the 2023 REMS would have remained in effect during the petition process. Opp. 37. But the authorities Plaintiffs cite—5 U.S.C. § 704 and *Darby v. Cisneros,* 509 U.S. 137, 154 (1993)—speak to a different question, which is whether courts can require exhaustion once an agency action against a *regulated party* becomes final. *See Darby,* 509 U.S. at 152, 154 (explaining that [a]gencies may avoid the finality of an

initial decision . . . by providing that the initial decision would be 'inoperative' pending" administrative appeal).

Plaintiffs are not regulated parties. Neither § 704 nor any other authority Plaintiffs cite limits the procedural steps that an agency may require of *unregulated* parties. *See, e.g.*, *MCR Oil Tools, LLC v. Dep't of Transp.,* 110 F.4th 677, 691 (5th Cir. 2024) (discussing exhaustion for a regulated party). Plaintiffs ignore the authorities Danco cited showing that courts regularly require such parties to proceed through the citizen-petition process when challenging FDA's approvals. *See, e.g., Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017) (mem. op.); *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 358 F. App'x 179, 180-181 (D.C. Cir. 2009) (per curiam).

Nor do Plaintiffs fall within any exception to the exhaustion requirement. *Contra* Opp. 37-39. FDA's alleged failure to timely respond to some past petitions is not an excuse for Plaintiffs to skip the process altogether. Unlike in the original *Alliance* litigation, where FDA delayed responding to the *plaintiffs'* petitions, Louisiana never even filed a citizen petition. *See Alliance for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *16 (5th Cir. Apr. 12, 2023) (per curiam). Plaintiffs'

proposed rule rewards skipping administrative exhaustion to cut those who filed citizen petitions and delays those petitions' resolution.

Plaintiffs' futility-exception argument has another obvious flaw: FDA is currently reviewing the 2023 REMS, and FDA officials have said the agency is open to changing its position. That the 2023 REMS remains in effect during this review shows that FDA is following the law as it reviews the materials submitted with several citizen petitions seeking different outcomes. *See Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (exhaustion must be "clearly useless" because "it is certain [a] claim will be denied") (citations and quotation marks omitted). If FDA's response is "unreasonably delayed," the citizen-petition filers can move to compel FDA's action under 5 U.S.C. § 706(1).

Finally, Louisiana's fallback claim that exhaustion would cause it irreparable injury is wrong for all the reasons Danco previously explained—including the half-decade Louisiana was content to wait before challenging the removal of in-person dispensing. Danco Br. 68-71. Plaintiffs' failure to exhaust warrants dismissal.

2. Traditional ripeness considerations—namely, the fitness of issues for judicial review and the hardship of withholding consideration,

see Walmart Inc. v. DOJ, 21 F.4th 300, 311 (5th Cir. 2021)—likewise counsel dismissal here.

First, Plaintiffs' assertion (at 39) that their challenge is ripe because it "asks the Court to apply . . . settled APA principle[s]" is self-refuting. Plaintiffs' brief attacks FDA's scientific assessments at length. Opp. 45-49. That necessarily requires the Court to delve into fact-based issues in the administrative record—of which this Court currently has only a small part. *See* Danco Br. 41.

Second, that the 2023 REMS is final agency action for purposes of the APA (Opp. 39-40) does not make it fit for review given FDA's ongoing evaluation, which gives FDA "another opportunity to rule on" similar arguments made by others in citizen petitions. *Pennzoil Co. v. FERC*, 742 F.2d 242, 244-245 (5th Cir. 1984). Ripeness concerns and the APA's judicial review requirements are different doctrines; the core of the ripeness problem here is that Louisiana brought this lawsuit only *after* FDA announced that it was going to review its prior decision.

Third, rushing to "judicial review before the agency has an opportunity to express its final views" on a contentious and technical issue runs contrary to "sound policies favoring judicial and

administrative economy." *Id.* FDA's ongoing review could, among other things, clarify whether any error in the 2023 REMS decision was harmless or whether vacatur is inappropriate. *See* Danco Br. 42. Plaintiffs' confusing assertion (at 40) that awaiting FDA's further analysis would somehow "waste" resources does not wrestle with this remedy issue. And Plaintiffs' decision to file this lawsuit almost three years after FDA issued the REMS discredits their assertion about the need for an immediate decision.

Contrary to Plaintiffs' suggestion (at 39), the ripeness doctrine continues to govern; Plaintiffs simply ignore the numerous cases that Danco cited applying it. Danco Br. 40-42. And even the District Court agreed that waiting for FDA to complete its scientific review was the prudent course. ROA.9118. Plaintiffs' suit should have been dismissed.

B. Plaintiffs' Arbitrary And Capricious Challenge Fails.

Plaintiffs focus on recent statements of certain Executive Branch officials. *E.g.*, Opp. 1. But Plaintiffs seemingly concede (at 41) that those statements cannot themselves establish the 2023 REMS approval was arbitrary or capricious. That is exactly right: Black-letter law dictates that APA review is on "the administrative record already in existence,

not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam); *see supra*, p. 6. Plaintiffs' claim rests on a nonexistent rule that FDA cannot use FAERS data and on a change-in-position that never occurred. Plaintiffs fail to state a claim.

1. FDA properly relied on FAERS data.

Plaintiffs do not—and cannot—dispute that FDA routinely considers FAERS data in analyzing whether to modify or discontinue a REMS for all types of drugs. Danco Br. 46-47. This reflects that FAERS data is FDA's sole statutorily required source of adverse event reporting for virtually all drugs. *Id.; see generally* 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81, 314.98. Adverse event reporting by anyone other than the manufacturer is almost always voluntary for all drugs, while all manufacturers must report to FDA every adverse event they learn of from any source. Danco Br. 49-50. Plaintiffs do not argue that the use of FAERS data for REMS modifications or other decisions is generally unlawful. Opp. 41-44.

As a result, Plaintiffs' complaints about FAERS data limitations merely ask the Court to craft a unique rule for revisions to the

mifepristone REMS. Notably, however, Plaintiffs identify no statutory authority that singles out abortion drugs for special treatment or requires FDA to consider different types of data for them. *Id.*[4] Their arguments are a barely-disguised effort to second-guess FDA's decision about how to weigh imperfect data in making a predictive scientific judgment about the safety of mifepristone. That is quintessentially the kind of determination where the "reviewing court must be at its most deferential." *Seven Cnty. Infrastructure Coal. v. Eagle County,* 605 U.S. 168, 182 (2025) (citation and quotation marks omitted).

That FAERS data does not capture every adverse event cannot undermine FDA's decision to eliminate in-person dispensing requirements for another reason: FDA did not rely solely on the FAERS data. Danco Br. 49. It also considered REMS assessment reports, studies, literature, and public reports—and determined that taken together, these sources showed that, consistent with FDA's nonenforcement decisions in 2021, in-person dispensing was (1) "no

[4] Plaintiffs again gesture at mifepristone's boxed warning as somehow triggering special REMS-approval considerations, Opp. 44, but, as Danco observed, Danco Br. 51, many commonly used drugs with boxed warnings have no REMS at all—a point that Plaintiffs ignore.

longer necessary to ensure that the benefits of the drug outweigh the risk" and (2) should be removed "to reduce the burden" of complying with the REMS on the health care delivery system. ROA.4007-4009; *see also* ROA.972, 1017-1039, 1042-1043, 1073-1090, 1093-1094.

Plaintiffs complain that these sources of data also have shortcomings, Opp. 42, but agency consideration of all available data—perfect or not—does not amount to arbitrary-and-capricious decisionmaking. The APA does not require "perfect empirical or statistical data" for an agency to act. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021).

2. FDA properly analyzed the scientific literature.

Plaintiffs' arguments about the scientific studies do not move the needle either. Plaintiffs spend pages quibbling with the details of those studies. Opp. 45-50. But to what end? As Plaintiffs themselves admit, they cannot "ask the Court to second-guess the science." Opp. 50. And none of their arguments show that FDA changed its position, failed to consider "the relevant [statutory] factors," or "offered an explanation for its decision that runs counter to the evidence before" it. *Motor Vehicle*

Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (citation omitted).

Plaintiffs' arguments are based on a fundamental misreading of the statutory framework. A REMS modification requires applying the standard set forth in § 355-1(g), not § 355(d). Danco Br. 52-53; GenBioPro Br. 55. Section 355(d) merely establishes general testing requirements to support new drug applications. 21 U.S.C. § 355(d). The more specific provisions of § 355-1(g) set forth the actual standard that FDA is required to assess when modifying a REMS.[5] *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (in "statutory construction," "the specific governs the general," especially where "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions") (citations and quotation marks omitted). The relevant question before FDA was

[5] Plaintiffs quote (at 45-46) a recent FDA brief as suggesting otherwise. That brief clearly states that FDA "can approve a supplemental application modifying a REMS" based on the criteria in § 355-1(g)(4)(B). Defs.' Reply in Supp. of Cross-Mot. for Summ. J. 11, *Washington v. FDA,* No. 1:23-cv-03026-TOR (E.D. Wash. May 3, 2025), ECF No. 181. And as FDA explained to the Supreme Court, relying on § 355(d) "misunderstands the governing statutory standard" of § 355-1(g)(4)(B). FDA Reply Br. 19, *FDA v. Alliance for Hippocratic Med.*, Nos. 23-235, 23-236, 2024 WL 1158797 (U.S. Mar. 15, 2024).

thus whether the record as a whole showed that mandating in-person dispensing was necessary to "ensure the benefits of the drug outweigh the risks" and whether eliminating in-person dispensing would "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(g)(4)(B).

FDA's detailed analysis of the various studies, which Plaintiffs attached to their complaint, shows a thorough and balanced examination of these value-laden questions. ROA.1043-1044. Plaintiffs' continued second-guessing of FDA stubbornly ignores the agency's explanations—and Danco's efforts to draw Plaintiffs' attention to Plaintiffs' mistakes.

For example, Plaintiffs continue to insist that one study "saw hospitalization rates soar 330%" without in-person dispensing, Opp. 47, while ignoring Danco's citation to the rest of the paragraph where FDA noted that the "reasons for hospitalization [were] not discussed by the authors" who themselves "conclude[d] use of the telemedicine medical abortion service is safe." ROA.1031; ROA.1082; Danco Br. 57. Likewise, Plaintiffs again quote FDA's observation that some studies suggest that "there may be an increase in [ER]/urgent care visits with telemedicine visits and dispensing by mail," Opp. 47 (quoting ROA.1037)—yet fail to

acknowledge the rest of the paragraph where FDA explained that those studies do not indicate an increase in serious adverse events, with one study indicating that "half of the participants who had an [ER]/urgent care visit did not require medical treatment." ROA.1037; *see* Danco Br. 56. Finally, Plaintiffs emphasize a study suggesting some difference in outcomes between women who had an in-person examination prior to abortion and those who did not, Opp. 47, but disregard that the pre-2023 REMS did not have any in-person examination requirement. Danco Br. 57-58.

Plaintiffs' critique of Danco's observations about other studies (at 48-49) follows the same general pattern. At bottom, Plaintiffs' arguments all boil down to conflating isolated—and decontextualized—findings about increases in follow-up care *appointments* with an increase in serious adverse events. Opp. 48-49. But, as FDA explained in detail, the studies' limitations do not justify that connection. ROA.1037. The information before FDA revealed that such visits have multiple causes—and are not a good proxy for adverse events.[6]

[6] Plaintiffs' blame-game assertion, Opp. 44, is just bizarre. There are millions of emergency room visits every year for non-urgent care, particularly among people who lack a primary care doctor.

Finally, Plaintiffs' critique of FDA's reasoning again ignores the fact that FDA was conducting a holistic assessment. The limitation of each individual study was something FDA candidly recognized in balancing all sources of information to conclude that mandating in-person dispensing at a clinic was not appropriate under its limited REMS authority. Plaintiffs disagree, but FDA need not "draw the inferences" Plaintiffs "might wish" from imperfect data. *Crooks v. Mabus*, 845 F.3d 412, 424 (D.C. Cir. 2016). Agencies are free to operate without "perfect empirical or statistical data," especially when making "predictive judgment[s]," like the kind that § 355-1(g) requires. *Prometheus*, 592 U.S. at 427; *see also Archer W. Contractors, LLC v. Dep't of Transp.*, 45 F.4th 1, 6 (D.C. Cir. 2022) (agency's factual findings may stand "even though a plausible alternative interpretation of the evidence would support a contrary view") (citation omitted).

The materials FDA reviewed were consistent with its conclusion that in-person dispensing was unnecessary to ensure that the benefits of mifepristone outweigh the risks. That is sufficient.

C. Plaintiffs' Comstock Act Claim Warrants Dismissal.

Plaintiffs cannot rescue their Comstock Act claim either. Their brief misunderstands *Texas*, 599 U.S. 670; does not even attempt to show that they fall within the statute's zone of interest; and rehashes a merits position that contradicts how Congress, the Executive, and courts have long read the law.

First, Plaintiffs insist that *Texas* has no bearing here because they are seeking an APA remedy instead of an order directing enforcement of the Comstock Act. Opp. 51. But *Texas* was *also* an APA action in which the plaintiffs asked for vacatur of an agency decision that they argued "contravene[d] two federal statutes." 599 U.S. at 674. And the district court there did not issue a mandatory order directing the government to initiate more prosecutions or arrests; it "set[] aside" the challenged memorandum establishing the federal policy. *Texas v. United States*, 606 F. Supp. 3d 437, 501 (S.D. Tex. 2022). The Supreme Court nevertheless held that "precedents and longstanding historical practice establish" that the suit was "not the kind redressable by a federal court" because it *functionally* sought greater enforcement of the underlying statutes. *Texas*, 599 U.S. at 677-678. Plaintiffs do not—and cannot—explain how

their Comstock claim is any different.[7] Like the *Texas* plaintiffs, they are asking this Court to set aside an agency decision on the grounds that it underenforces a criminal statute. *Texas* forbids that.

Second, Plaintiffs' asserted interests fall well beyond "the zone of interests to be protected or regulated by" the Comstock Act. *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp,* 397 U.S. 150, 153 (1970); *see* Danco Br. 61. Louisiana neither faces a threat of enforcement under the statute nor has "a judicially cognizable interest in the" application of that law to others. *Texas,* 599 U.S. at 677 (citation omitted). And the Comstock Act, which establishes a federal criminal prohibition, has nothing to do with protecting states' (or individual citizens') interests at all. *See Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 227-228 (2012) (zone of interest satisfied when "decisions under the statute are closely enough and often enough entwined with" the interests

[7] Plaintiffs' objections that they are bringing an APA claim and not seeking to direct prosecutions echo the three-Justice concurrence in *Texas*, which did not carry the day. *See Texas*, 599 U.S. at 691 (Gorsuch, Thomas, and Barrett, J.J., concurring) (noting that a "judicial decree rendering the Guidelines a nullity does nothing to . . . require federal officials to" perform arrests).

plaintiff asserts). So "it cannot reasonably be assumed that Congress intended to permit" this type of suit. *Id.* at 225 (citation omitted).

Plaintiffs offer no response. *See* Opp. at 51-53. That forfeiture is sufficient to dispose of their Comstock claim. *See United States v. Devaney*, 109 F.4th 322, 330 n.11 (5th Cir. 2024) ("failing to address . . . responsive contentions in reply briefing is tantamount to abandonment"); *Lewis v. Bickham*, 91 F.4th 1216, 1222 n.3 (5th Cir. 2024) (per curiam) (responding party "forfeited an issue by failing to raise [it] in its brief").

Third, and finally, Plaintiffs' merits arguments are unavailing. Plaintiffs misconstrue (at 51-52) the Supreme Court's observation that APA review of an action "not in accordance with law" refers to "*any* law[] and not merely those laws that the agency itself is charged with administering." *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) (citation omitted). The Supreme Court's point was that an agency could not violate law applicable *to that agency*—there, a provision of the Bankruptcy Code prohibiting any "governmental unit" from taking the very action the FCC had taken. *Id.* at 300-301; *see* 11 U.S.C. § 525(a). Here, no law requires or permits FDA to formulate the substance of a drug's REMS around the Comstock Act (or any other criminal law). To

the contrary, Congress directed FDA to eliminate REMS restrictions that are no longer necessary to "ensure the benefits of the drug outweigh the risks" and to "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(g)(4)(B)(i), (ii).

The distinction Plaintiffs attempt to draw—between FDA approving drugs subject to the Controlled Substances Act and FDA removing a requirement to dispense mifepristone in person in specific locations notwithstanding the Comstock Act—is an empty one. Opp. 51-52. A drug can be validly approved for medical uses and still subject to other prohibitions under other laws. FDA approval does not speak to, let alone override, other legal prohibitions.

Courts have not accepted Plaintiffs' argument about what they say the Comstock Act prohibits. And Congress has repeatedly declined to amend the law despite being aware of multiple "decisions of the Federal courts construing" the Act narrowly. 18 U.S.C. § 1461 note; *see* Danco Br. 62-63. In fact, Congress has repeatedly amended FDA's organic statute without limiting the agency's authority to approve the types of drugs enumerated in the Comstock Act—most recently in 2007, when Congress "deemed" drugs like mifepristone to have an enforceable

REMS. FDA Amendments Act of 2007, Pub. L. No. 110-85, § 909(b), 121 Stat. 823, 950-951. Congress knew that by doing so, it was authorizing mifepristone's distribution system to continue. *See, e.g.*, 153 Cong. Rec. S5765 (daily ed. May 9, 2007) (Sen. Coburn recognizing that mifepristone "is deemed to have a REMS and is subject to periodic review"). The "plain import" of this decision is that the Comstock Act does not bar those same activities. *Dorsey v. United States*, 567 U.S. 260, 274-275 (2012).[8]

CONCLUSION

For these reasons, the Court should reverse the District Court's denial of Danco's motion to dismiss.

[8] The single-judge concurrence and single-Justice dissent that Plaintiffs cite (at 53) suggesting otherwise lack precedential value and are not persuasive. Making it a federal crime to mail drugs for lawful medical purposes contravenes nearly a century of precedent and all indicia of Congressional intent. Any such interpretation should be rejected.

Respectfully submitted,

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August 19, 2026

CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2026, I electronically filed the foregoing using the CM/ECF system, which will send notification of this filing to the attorneys of record.

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CERTIFICATE OF COMPLIANCE

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August 19, 2026

Ms. Jessica Lynn Ellsworth
Hogan Lovells Cadwalader US, L.L.P.
555 13th Street, N.W.
Columbia Square
Washington, DC 20004

No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

Dear Ms. Ellsworth,

You must submit the 6 paper copies of your brief required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1. Failure to timely provide the appropriate number of copies may result in the dismissal of your appeal pursuant to 5th Cir. R. 42.3. Exception: As of July 2, 2018, Anders briefs only require 2 paper copies.

If your brief was insufficient and required corrections, the paper copies of your brief must **not** contain a header noting "RESTRICTED". Therefore, please be sure that you print your paper copies **from this notice of docket activity** and not the proposed sufficient brief filed event so that it will contain the proper filing header. Alternatively, you may print the sufficient brief directly from your original file without any header.

Sincerely,

LYLE W. CAYCE, Clerk
Amanda M. Duroncelet
By: _____
Amanda M. Duroncelet, Deputy Clerk
504-310-7636