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 PRINCIPAL AND RESPONSE BRIEF

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Danco Laboratories, LLC

July 15, 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**:

   Counsel for State of Louisiana: Liz Murrill; J. Benjamin Aguiñaga; and Caitlin Huettemann of the Office of the Louisiana Attorney General

   Counsel for Rosalie Markezich: Michael T. Johnson of Johnson, Siebeneicher & Ingram

   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**:

Counsel for Danco Laboratories, LLC: Jessica L. Ellsworth; Jo-Ann Tamila Sagar; Alexander V. Sverdlov; Danielle Desaulniers Stempel; Dana A. Raphael; and Katherine T. McKay of Hogan Lovells Cadwalader US LLP; and William Most of Most & Associates

Counsel for GenBioPro, Inc.: Robert J. Katerberg and Daphne O'Connor of Arnold & Porter Kaye Scholer LLP; John Adcock of Adcock Law LLC; and Skye L. Perryman; Carrie Y. Flaxman; and Lisa Newman of Democracy Forward Foundation

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

Amici for Plaintiffs-Appellants/Cross-Appellees

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

Counsel: Andrew L. Schlafly

Family Research Council and Martha Shuping, MD

Counsel: Brian W. Arabie of Sigler, Arabie & Cannon, LLC; Christopher E. Mills of Spero Law LLC

2,796 Women Injured by Abortion; the Justice Foundation and its Center Against Forced Abortions; National Association of Christian Lawmakers; National Institute of Family and Life Advocates

Counsel: T. Houston Middleton, IV and Hunter W. Lundy of Lundy LLP; Mary J. Browning; Allan E. Parker; and R. Clayton Trotter of the Justice Foundation

American Association of Pro-Life Obstetricians and Gynecologists and Samaritan's Purse

Counsel: Brian W. Arabie of Sigler, Arabie & Cannon, LLC; Christopher E. Mills of Spero Law LLC

Women and Families Harmed by Mifepristone and Former Abortion Provider (Carol Everett; Tammi Morris; Monty Patterson; and Leslie Wolbert)

Counsel: Linda Boston Schlueter of the Trinity Legal Center; Brian W. Arabie of Sigler, Arabie & Cannon, LLC

American Center for Law and Justice

Counsel: Jay Alan Sekulow; Olivia F. Summers; Jordan A. Sekulow; Stuart J. Roth; Andrew J. Ekonomou; Nathan J. Moelker; and Walter M. Weber of the American Center for

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

Law and Justice; Kevin S. Vogeltanz of the Law Office of Kevin S. Vogeltanz, LLC

Ethics and Public Policy Center
Counsel: M. Edward Whelan III; Eric N. Kniffin; and Rachel N. Morrison of the Ethics and Public Policy Center; Michelle Ward Ghetti of Ghetti Law

Senator Bill Cassidy, M.D.; Representative Christopher H. Smith; Senate Majority Leader John Thune; Speaker of the House of Representatives Mike Johnson; and 109 Members of Congress[3]
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
Counsel: Michael T. Hilgers; Zachary A. Viglianco; and Cody S. Barnett of the Nebraska Department of Justice; Rachel T. Vogeltanz of the Law Office of Rachel Thyre Vogeltanz, LLC

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

Counsel: Ben E. Clayton of Clayton Law Firm, LLC; J. Marc Wheat and Timothy Harper of Advancing American Freedom, Inc.

Students for Life of America

Counsel: L. Katie Buckner and R. Bradley Lewis of Students for Life of America

Concerned Women for America

Counsel: Mario Diaz of Concerned Women for America; Ben E. Clayton of Clayton Law Firm

Dr. Calum Miller

Counsel: Ben E. Clayton of Clayton Law Firm; Kristine L. Brown

Heartbeat International, Inc.

Counsel: Charles K. Cicero, III of Cicero Law, LLC; Danielle M. White of Heartbeat International, Inc.; B. Tyler Brookes of Thomas More Society

NC Values Institute and World Faith Foundation

Counsel: Deborah J. Dewart

Susan B. Anthony Pro-Life America; Charlotte Lozier Institute; Louisiana Right to Life; Texas Right to Life; March for Life Education and Defense Fund; National Catholic Bioethics Center; Catholic Medical Association; National Association of Catholic Nurses, USA; Christ Medicus Foundation; Catholic Health Care Leadership Alliance; National Catholic Partnership on Disability; Texas Alliance for Life; Texans for Life Coalition

Counsel: Heather Gebelin Hacker of Hacker Stephens LLP

Texas Values and State Representative Jeff Leach

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

Dr. Grazie Pozo Christie and the Catholic Association Foundation

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

Amici for Defendants-Appellees/Cross-Appellants

IGH PLLC d/b/a Abortion on Demand; Hey Jane; and Reproductive Health Initiative for Telehealth Equity & Solutions (RHITES)

Counsel: Meghan Kinney Matt of Murell Law Firm; Sonia W. Murphy of Gilbert LLP; Sapna Khatri of Boston University School of Law Program on Reproductive Justice

National Domestic Violence Hotline; Legal Voice; National Network to End Domestic Violence; Ujima; National Center on Violence Against Women in the Black Community; Center for Survivor Agency & Justice; and Expert Researchers (Liz Tobin Tyler; Samuel Dickman, M.D.; Karen Trister Grace, PhD; Maeve Wallace, PhD; and Julie Dahlstrom)

Counsel: Rebekka Veith of Miller Thibodeaux Dysart Veith & Paschal, LLC; Julia Marks and Robin Turner of Legal Voice; Sharmistha Das; Daniel W. Wolff; Rachel S. Lesser; Madeline P. Reyes; and Karen A. Mawdsley of Crowell & Moring LLP

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

Counsel: Jessica Ring Amunson; Mary Marshall; Varsha Midha; and Emily Merrifield of Jenner & Block LLP; Jamila Johnson of the Lawyering Project

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.)

Counsel: Mandie Landry and Sal Bivalacqua of Bivalacqua, Gele + Ellis; William B. Schultz; Margaret M. Dotzel; and Alyssa Howard of Zuckerman Spaeder LLP

New York; Arizona; California; Colorado; Connecticut; Delaware; Hawai'i; Illinois; Maine; Maryland; Massachusetts; Michigan; Minnesota; Nevada; New Jersey; New Mexico; North Carolina; Oregon; Rhode Island; Virginia; Vermont; Washington; the District of Columbia; and the Governor of Pennsylvania

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

Disability Rights Education and Defense Fund; American Association of People with Disabilities Autistic Self Advocacy Network; Autistic Women and Nonbinary Network; New Disabled South; Women Enabled International; Robyn Powell, PhD; Ruth Colker; Tony Coelho; and Katherine Pérez[6]

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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.

Counsel: Chloé M. Chetta of Barrasso Usdin Kupperman Freeman & Sarver, LLC; Kristen D. Amond of Kristen Amond LLC; Maria Michelle Uzeta of Disability Rights Education & Defense Fund; Mallory Tosch Hoggatt and Elizabeth June of Allen Overy Shearman Sterling US LLP

American College of Obstetricians & Gynecologists and Other Leading Medical Societies[7]

Counsel: Shannon Rose Selden; Kathryn C. Saba; and Nicole A. Marton of Debevoise & Plimpton LLP; Malcolm Lloyd of ACLU Foundation of Louisiana; Molly Meegan; Francisco M. Negrón Jr.; and Meaghan Davant of American College of Obstetricians & Gynecologists

Medical Students for Choice

Counsel: Alexandra D. Moody of Lift Louisiana; Jayme Jonat; Charlotte Baigent; Kathryn Arnett; and Katharine Zeigler of Holwell Shuster & Goldberg LLP

259 Members of Congress[8]

Counsel: Abby F. Rudzin; Camila Tucker; Nancy L. Schroeder; Michael McMillin; Harmukh Singh; Samantha Galván; and Keith Osentoski of O'Melveny & Myers LLP

175 Professors, Health Organizations and Health Care Providers[9]

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

Counsel: Corinne R. Moini; Katherine S. Borchert; Janice Mac Avoy; Laura Israel Sinrod; Anne S. Aufhauser; and Kathryn Sachs of Fried, Frank, Harris, Shriver & Jacobson LLP

360 Reproductive Health Researchers[10]

Counsel: Alexander N. Ely; Doménica Merino; Quynhanh N. Tran; and Leah Godesky of O'Melveny & Myers LLP; Amanda Barrow; Cathren Cohen; Sofia Espinoza; Melissa Goodman; and Diana Kasdan of Center on Reproductive Health, Law, and Policy at UCLA School of Law

National Council of Jewish Women; Religious Community for Reproductive Choice; Catholics for Choice; Hindus for Human Rights; Muslims for Progressive Values; Unitarian Universalist Association; and 46 Other Faith-Based Organizations[11]

Counsel: Michael F. Buchanan; Nicole Scully; Justice Forte; and Rachel Klein of Patterson Belknap Webb & Tyler LLP

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.

Pharmaceutical Research and Manufacturers of America

Counsel: James C. Stansel; Melissa B. Kimmel; and Kelly Falconer Goldberg of Pharmaceutical Research and Manufacturers of America; Marienna Murch; Dalia Deak; Sarah E. Harrington; David M. Zionts; Julie Dohm; Brianne Sullivan; Sameer Aggarwal; and Kristin Oakley of Covington & Burling LLP

Local Governments and Local Government Leaders[13]

Counsel: Jenny S. Ma; Kyriaki Council; and Eliana Greenberg of Public Rights Project

FemInEM Foundation and American Academy of Emergency Medicine

Counsel: Leah R. Bruno; Emily D. Steeb; and Mary Strong of Dentons US LLP

Food and Drug Law Scholars and Professors[14]

Counsel: Lewis A. Grossman; Denise Esposito; Robert A. Long; Julia F. Post; Beth E. Braiterman; Guillaume A. Julian of Covington & Burling LLP

Honeybee Health, Inc.

Counsel: Eugene M. Gelernter; Hilarie M. Meyers; Hadiya Williams; and Jillian F. Horowitz of Patterson Belknap Webb & Tyler LLP

[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]

Counsel: Clara S. Spera; Madeline Verniero; and Kate Epstein of Hecker Fink LLP

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

Counsel: David Boyle (pro se)

/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.

STATEMENT REGARDING ORAL ARGUMENT

This Court has scheduled oral argument for September 9, 2026. ECF.216.

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JURISDICTIONAL STATEMENT

The District Court entered an order on April 7, 2026 granting FDA's motion to stay the case, denying Plaintiffs' motion for a preliminary injunction, and denying Danco's motion to dismiss. ROA.9119-9120. Plaintiffs appealed. Danco cross-appealed the denial of its motion to dismiss on May 1, 2026. ROA.9151. This Court has jurisdiction over Danco's cross appeal under 28 U.S.C. § 1292(a)(1). *See Deckert v. Indep. Shares Corp.*, 311 U.S. 282, 287 (1940) (on appeal of preliminary-injunction order, court of appeals "properly examined the interlocutory order denying the motions to dismiss"); *Mercury Motor Express, Inc. v. Brinke*, 475 F.2d 1086, 1091 (5th Cir. 1973) (recognizing "the power of an appellate court to reach the merits of a case before it on an interlocutory appeal and dismiss the action"); *Munaf v. Geren*, 553 U.S. 674, 691 (2008); *Jiao v. Xu*, 28 F.4th 591, 596 (5th Cir. 2022).

INTRODUCTION

For twenty-six years, Danco has manufactured and distributed Mifeprex (mifepristone), pursuant to FDA's approval of the product as safe and effective for the termination of early pregnancy. FDA has changed the approved conditions of use for Mifeprex several times,

consistent with safety data demonstrating that certain requirements were no longer necessary to ensure the drug's benefits outweigh its risks. This case is about FDA's modification in 2023 of the mifepristone Risk Evaluation and Mitigation Strategy (REMS), which sets the current conditions of use for Mifeprex.

Three years after that decision, Plaintiffs here asked the District Court to preliminarily enjoin it. The District Court declined to do so, citing FDA's ongoing review of the mifepristone REMS in connection with an unrelated court order, several citizen petitions seeking different forms of relief, and FDA's obligations under the REMS statute itself. The District Court explained that the equities and public interest "weigh heavily in favor of FDA completing the job that the law requires it to do," and so declined to engage in "government by lawsuit." ROA.9086 (quoting *United States v. Texas*, 599 U.S. 670, 704 (2023) (Gorsuch, J., concurring)). Plaintiffs have appealed the denial of their request for a preliminary injunction, as well as the District Court's order staying the case pending FDA's review. Danco has cross-appealed, seeking review of the District Court's denial of Danco's motion to dismiss.

In considering these appeals, this Court does not write on a clean slate. A series of related Supreme Court orders all but decide this case.

First, just two years ago, the Supreme Court unanimously held that doctors who do not prescribe mifepristone lack Article III standing to challenge the drug's regulatory approvals because they are not regulated by those approvals and accepting their attenuated theories of harm would defy bedrock Article III constraints. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 391-392 (2024). Like the *Alliance* plaintiffs, Louisiana is not required to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" as a result of FDA's actions. *Id.* at 385. Louisiana's citation to its alleged Medicaid costs and the alleged mismatch between federal and state policy on abortion cannot overcome that barrier. In *Alliance*, the Supreme Court rejected such "downstream" effects as "too attenuated." *Id.* at 386, 391.

Second, the merits favor Danco, too. Plaintiffs' merits argument boils down to a misunderstanding of, and a disagreement with, how FDA weighed the scientific evidence before it. But "when an agency makes scientific judgments, a reviewing court must be at its 'most deferential.'" *VDX Distro, Inc. v. FDA*, No. 24-60537, ___ F.4th ___, 2026 WL 1811451,

at *7 (5th Cir. June 24, 2026) (quoting *Seven Cnty. Infrastructure Coal. v. Eagle County*, 605 U.S. 168, 182 (2025) (ellipses omitted)); *see also, e.g.*, *Atchafalaya Basinkeeper v. Army Corps of Eng'rs*, 894 F.3d 692, 701 (5th Cir. 2018) (courts owe agencies "particular judicial deference" on scientific matters). Congress vested FDA—not courts—with the authority to conduct science-based evaluations of the safety and efficacy of new and existing drugs. PhRMA SCOTUS Br. 2.[1] Judicial interference with FDA's expert drug-safety decisions would "introduce[] a profoundly destabilizing force into the Nation's drug regulatory regime" that would "not only distort the administrative process Congress carefully designed but also undermine the reliance interests that make biomedical innovation possible." *Id.* at 2-3.

Finally, in considering Plaintiffs' appeal of the District Court's denial of preliminary relief to the Plaintiffs, this Court is now bound to the Supreme Court's assessment of the equities. The Supreme Court has already concluded that the equities favored keeping the 2023 REMS in place. Order Granting Stay, *Danco Lab'ys, LLC v. Louisiana*, No.

[1] All amicus brief citations are to the amicus briefs filed in the Supreme Court in *Danco Lab'ys, LLC v. Louisiana*, No. 25A1207 (U.S.).

25A1207 (May 14, 2026); *see also Danco Lab'ys, LLC v. Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (granting Danco's request for a stay in earlier, related litigation). "Although [the Supreme Court's] interim orders are not conclusive as to the merits, they inform how a court should exercise its equitable discretion in like cases." *Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025) (per curiam). Here, the Supreme Court's orders granting Danco's application for interim relief suggest that the equities favor Danco. Plaintiffs waited nearly three years after FDA approved the 2023 REMS—and almost five years after FDA first applied the relevant policy—to bring this lawsuit. And Plaintiffs do not need the sweeping injunction that they seek: FDA is already engaged in further review of the mifepristone REMS to address the kinds of concerns Louisiana raises.

This Court should affirm the District Court's denial of preliminary relief to Plaintiffs, reverse the District Court's denial of Danco's motion to dismiss, and remand with instructions to dismiss Plaintiffs' complaint.

STATEMENT OF THE ISSUES

1. Whether the District Court correctly denied Plaintiffs' motion for a preliminary injunction where Plaintiffs lack standing, their claims

are unreviewable and otherwise fail on the merits, Plaintiffs face no impending harm absent an injunction, and Danco and the public will be harmed by an injunction.

2. Whether the District Court erred by failing to grant Danco's motion to dismiss where Plaintiffs lack standing and their claims are unreviewable and otherwise fail on the merits.

PERTINENT STATUTES

Pertinent statutes are reprinted in the Addendum.

STATEMENT OF THE CASE

A. Statutory Background

Through the Food, Drug, and Cosmetic Act of 1938 (FDCA), Congress has vested FDA with exclusive governmental authority to "protect the public health by ensuring that . . . drugs are safe and effective" and to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b). In furtherance of that mission, the FDCA establishes a comprehensive regulatory framework for the review and approval of new drugs through the new drug application (NDA) process. *Id.* § 355. The application

process requires that FDA undertake a rigorous, science-driven evaluation to determine whether the drug is "safe for use" and will have the "effect[s] it purports or is represented to have" under the conditions of use prescribed in the labeling. *Id.* § 355(d).[2]

FDA may also impose certain use restrictions on drugs through its risk evaluation and mitigation strategy (REMS) authority if "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1)-(2). A REMS may include medication guides, communication plans, special packaging or disposal requirements, or elements to assure safe use. *Id.* § 355-1(e)-(f). Congress directed FDA to periodically evaluate a REMS and determine whether the use restrictions in place "assure safe use of the drug," "are not unduly burdensome on patient access to the drug," and "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(B)(i)-(iii).

[2] Because "[f]ew if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk," in this context, "safe" means that "the expected therapeutic gain justifies the risk entailed by its use." *United States v. Rutherford*, 442 U.S. 544, 555 (1979); *see* 21 U.S.C. § 355(d).

B. Factual Background

1. Danco, a small pharmaceutical company incorporated in Delaware, holds the NDA for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of early intrauterine pregnancy. FDA approved Mifeprex in 2000 for use through 49 days' gestation, with certain use restrictions. ROA.604-606 (2000 Approval Letter). Mifeprex's original use restrictions were later deemed a REMS. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008).[3]

2. In 2016, FDA approved a supplemental NDA that modified certain aspects of Mifeprex's labeling and REMS based on numerous studies and 15 years of data. *See* ROA.389-416 (FDA Mar. 29, 2016 Summary Review). "FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks," "approved a dosing regimen that reduced the number of required in-person visits [to] a single visit to receive Mifeprex," and "changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities." *Alliance*, 602 U.S. at 375-376. In 2019, certain entities (not including Plaintiffs) filed a citizen

[3] FDA approved a generic version of Mifeprex in 2019 and another in 2025. *See* ROA.608-613, 2192-2199. The mifepristone REMS today applies to all three companies' mifepristone products.

petition requesting FDA undo the 2016 changes, which FDA denied in 2021. *See id.* at 376; ROA.96.

3. In 2020, during the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG) asked FDA to not enforce a requirement that mifepristone be dispensed in-person. ROA.686. Before FDA responded, ACOG sued to enjoin that requirement. *ACOG v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

Louisiana (and nine other states) moved to intervene. The district court denied Louisiana's motion because Louisiana did "not have a direct interest in th[e] case that would be impaired by its outcome." *ACOG v. FDA*, 467 F. Supp. 3d 282, 288 (D. Md. 2020). Louisiana's laws, the court explained, were not "linked in any way to the enforcement of the FDA's" in-person dispensing requirement, so the "case would not impair those States' ability to enforce their own laws." *Id.* at 286. Nor would any judgment "eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements." *Id.* at 289. The district court preliminarily enjoined the in-person dispensing requirement, *see ACOG*, 472 F. Supp. 3d at 233, but the Supreme Court stayed the injunction, *FDA v. ACOG*, 141 S. Ct. 578 (2021).

4. In April 2021, FDA responded to ACOG's petition. That response analyzed medical literature, postmarketing adverse event reporting, and information about deviations or noncompliance events associated with the REMS. ROA.259-260. FDA found no indication that adverse events occurred with greater frequency when a patient obtained the drug by a method other than picking it up in person. ROA.260. FDA's response to ACOG's petition therefore stated the agency would exercise enforcement discretion as to the in-person dispensing requirement during the public health emergency. *Id.*

In December 2021, FDA came to the same conclusion when responding to a 2019 citizen petition seeking to undo the 2016 changes. FDA explained that "mifepristone may be safely used without in-person dispensing," ROA.374, and that in-person dispensing was "no longer necessary to ensure" the drug's benefits outweigh the risks, ROA.372. FDA relied on data from the nonenforcement periods, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. ROA.1092. FDA pointed to three studies analyzing retail-pharmacy dispensing, three studies evaluating mail-order pharmacy dispensing, and five studies analyzing clinic dispensing by

mail, and concluded the literature supported finding that mifepristone remains safe and effective without in-person dispensing. ROA.1078-1088. FDA directed Danco (and GenBioPro, a manufacturer of generic mifepristone) to submit a supplemental NDA requesting removal of the in-person dispensing requirement from the REMS as unnecessary to ensure the benefits outweigh the risks and "to reduce the burden imposed" on healthcare providers and patients. ROA.382; *see* ROA.1093-1094.

Danco complied, and FDA approved Danco's supplemental NDA in January 2023. ROA.965, 967. Some entities, but not Louisiana, filed citizen petitions asking FDA to reassess in-person dispensing. *See* ROA.2749, 6810. Other states have submitted citizen petitions highlighting recent studies that reinforce the safety and effectiveness of mifepristone dispensed by means other than in person. *E.g.*, Citizen Petition from Attorney General of Massachusetts, et al. (June 6, 2025), https://tinyurl.com/yc6xaxk5.

5. In September 2025, responding to an inquiry from certain state attorneys general, Secretary Kennedy said that HHS is conducting "a study of the safety of the current REMS, in order to determine whether

modifications are necessary." ROA.2201. A month later, a federal district court in Hawai'i held that certain restrictions in the 2023 REMS were unlawfully restrictive under the Administrative Procedure Act (APA) because FDA "fail[ed] to provide a reasoned explanation for its restrictive treatment of the drug" in light of the available evidence that mifepristone is objectively safe. *Purcell v. Kennedy*, No. 1:17-cv-00493, 2025 WL 3101785, at *2 (D. Haw. Oct. 30, 2025). That court did not enjoin or vacate the 2023 REMS in whole or part; it "remand[ed]" the matter to FDA and ordered that "the mifepristone REMS . . . will remain in place pending the outcome of the Agency remand." *Id.* at *28. Separately, the Hawai'i court also ordered FDA to address pending citizen petitions asking the agency to reconsider aspects of the 2023 REMS. *Id.*

C. Procedural History

1. In November 2022, a group of physicians opposed to abortion sued FDA in the Northern District of Texas over various decisions related to mifepristone, including FDA's April 2021 decision to exercise enforcement discretion over in-person dispensing during COVID and FDA's December 2021 decision directing the sponsors to submit

applications to amend the mifepristone REMS to remove in-person dispensing. *See Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex.). Some of the physicians asserted that they provided pregnancy-related health care, including emergency care after unsuccessful medication abortions using mifepristone. Ruling in a preliminary posture without the benefit of the administrative record, the district court issued a preliminary injunction. *Alliance for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023). The Fifth Circuit largely denied a stay of the District Court's injunction, *Alliance for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023), and later affirmed the injunction in part, 78 F.4th 210 (5th Cir. 2023). The Supreme Court stayed the injunction before it took effect and ultimately reversed, unanimously holding the plaintiffs—individual physicians and associations of physicians opposed to abortion—lacked standing to challenge FDA's approval decisions for mifepristone. *Alliance*, 602 U.S. at 374.

The Supreme Court explained that Article III's case-or-controversy requirement limits federal judicial power to disputes in which the plaintiff has a "personal stake." *Id.* at 379 (citation omitted). Because

FDA's actions did not require the plaintiffs to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" with mifepristone, the downstream injuries they asserted flowed from those FDA actions were too attenuated to establish standing. *Id.* at 385-386. The Supreme Court recognized that, for any drug, FDA's approval or lifting of use restrictions may "yield more visits to doctors" because "virtually all drugs come with complications, risks, and side effects." *Id.* at 392. But the Court emphasized that plaintiffs cannot show Article III standing by pointing to such "distant (even if predictable) ripple effects" of an FDA drug-approval decision. *Id.* at 383.

Over a year after the Supreme Court's decision, Louisiana and Rosalie Markezich moved to intervene in the *Alliance* suit, which the *Alliance* plaintiffs had already voluntarily dismissed after the case was remanded from the Supreme Court. Notice of Voluntary Dismissal, *Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Nov. 19, 2024), ECF No. 203; Intervention Mot., *Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Sept. 19, 2025), ECF No. 264. The Northern District of Texas denied their intervention motion as moot when it transferred a different complaint filed far earlier by three other

states to the Eastern District of Missouri. Order, *Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Sept. 30, 2025), ECF No. 273.[4]

2. On October 6, 2025, Louisiana and Ms. Markezich filed suit in the Western District of Louisiana challenging the 2023 REMS, which FDA approved in January 2023 and which formalized the nonenforcement policy for in-person dispensing by a provider that had been in place since April 2021. ROA.82-132. October came and went. November came and went. On December 17, 2025, Plaintiffs moved for preliminary relief, asking the court to postpone the (years-since-passed) effective date of the 2023 REMS or enjoin the 2023 REMS. ROA.2298-2300.

FDA opposed Plaintiffs' motion and moved for a stay of the litigation while FDA independently reconsiders the 2023 REMS in connection with the *Purcell* court's order to do so, numerous citizen petitions seeking different forms of relief, and the REMS statute itself. ROA.2737-2762.

[4] The Texas district court did not analyze whether those three intervenor states had standing, and FDA, Danco, and GenBioPro each have pending motions to dismiss that complaint for lack of standing, among other things.

Danco intervened, moved to dismiss the complaint, and opposed Plaintiffs' motion for preliminary relief. ROA.2763-2764, 6795-6796, 6797-6832. Danco argued that, like the original *Alliance* plaintiffs, Plaintiffs lack standing. ROA.6811-6819. Danco also argued that Plaintiffs failed to satisfy threshold APA requirements; that the dispute is not ripe; and that their claims fail on the merits. ROA.6819-6828. And Danco emphasized the nationwide harm to the public and to Danco that would result from an injunction of the mifepristone REMS. ROA.6830-6831. GenBioPro likewise moved to intervene and to dismiss the complaint and opposed Plaintiffs' request for preliminary relief. ROA.2828-2829, 6833-6865.

The District Court held a hearing on the motions. ROA.6793-6794. During the hearing, the court probed the asserted potential harms, noting that there have been "many cases" when a safety signal about a drug "comes to the attention of the FDA," and the agency is able to "do something quickly." ROA.9208-9209. The court also asked FDA's counsel whether FDA could take action if "during [FDA's] review process," the agency "sees a public health issue with the 2023 REMS—particularly the . . . in-person dispensing requirement," and in particular,

whether there is "a way for FDA to take immediate action to change it, to restore it, or to alter the 2023 REMS to meet the public health concern." ROA.9207-9208; *see also* ROA.9208-9209 (requesting briefing). Following the hearing, the court received a supplemental brief from FDA confirming its authority to take immediate action in the event of an exigent public health crisis. ROA.8999-9003.

The District Court denied Plaintiffs' motion for preliminary relief without prejudice; denied Danco's and GenBioPro's motions to dismiss without prejudice; and granted the government's motion to stay the litigation during the agency's REMS review. *See* ROA.9084-9120. The District Court thought that Louisiana has standing and that Plaintiffs are likely to succeed on the merits, ROA.9099-9111, but concluded that the equities and public interest "weigh heavily in favor of FDA completing the job that the law requires it to do," ROA.9086, and so declined to engage in "government by lawsuit." ROA.9116 (quoting *Texas*, 599 U.S. at 704 (Gorsuch, J., concurring)); *see also* ROA.9111-9119.

3. Ten days later, on April 17, 2026, Plaintiffs sought a stay or injunction pending appeal from this Court. *See* ECF.12-1. They did not

request expedited briefing and requested a ruling by May 11, over three weeks later. ECF.12 (docket text). Danco, FDA, and GenBioPro filed opposition briefs. ECF.72, 74, 76.

On May 1, ten days earlier than Plaintiffs had requested, a panel of this Court granted their motion for a stay of the 2023 REMS. ROA.9132-9149. The stay panel first concluded that Plaintiffs were not obligated to ask the District Court for a stay or exhaust administrative remedies with FDA before seeking the appellate court's intervention. ROA.9138-9139. It then held that Louisiana has standing because (a) by determining that in-person dispensing by a provider was not necessary under the REMS statute, FDA "opened the door for mifepristone to be remotely prescribed to Louisiana women," and (b) Louisiana said its Medicaid program paid for emergency room care for two women after they experienced "complications caused by out-of-state mifepristone" and sought follow-up care. ROA.9141, 9142. According to the stay panel, the former amounts to intentional federal interference with Louisiana's enforcement of its state laws and is thus a judicially remediable "sovereign" harm to Louisiana, and the latter is a "financial injury" sufficient to create Article III standing for the state. ROA.9139-9142.

Despite lacking the administrative record, the stay panel also concluded that the stay factors favored Louisiana. On likelihood of success, the panel held that FDA "conceded" that it "had failed to adequately study whether remotely prescribing mifepristone is safe" when announcing a new mifepristone REMS review last fall. ROA.9133, 9143-9144. The panel also proceeded to "briefly summarize" the *Alliance* stay and merits panel rulings that had found FDA violated the APA by looking to the same adverse event reporting system for mifepristone that FDA looks to for virtually every other FDA-approved drug and by relying on literature that those panels deemed insufficient "on [its] own" to show dispensing by mail was safe. ROA.9144-9145 (citation omitted).

On irreparable harm, the stay panel held that Louisiana is suffering such harm because abortions cannot be undone "by legal remedy" and because sovereign immunity makes Medicaid expenditures unrecoverable from the federal government. ROA.9145-9146.

The stay panel also rejected the District Court's assessment of the balance-of-equities and the public interest, ROA.9146-9147, and asserted that Danco was wrong that a stay of the 2023 REMS would leave no governing legal framework for distributing mifepristone. The court

ignored the FDA declaration submitted to the Supreme Court that said exactly that. ROA.9147-9148; *see* ROA.2783 (explaining that Danco was relying on "the declaration that FDA submitted to the Supreme Court of the United States in connection with seeking emergency relief in the *Alliance* litigation" in order to understand what FDA would expect of Danco if the court were to order the requested stay or injunction of the 2023 REMS); ROA.2784-2785 (discussing FDA declaration and application to this case); ROA.8900-8903 (Woodcock Decl.).

Finally, the stay panel shrugged off the District Court's concerns about judicial interference with FDA's statutory authority to make science- and medicine-based judgments, especially while FDA's own review is ongoing and its concerns about the sweeping scope of Louisiana's requested relief which would invalidate the 2023 REMS nationwide. ROA.9148-9149.

4. The next day, Danco and GenBioPro sought emergency stays and administrative stays from the Supreme Court. Application for Stay, *Danco Lab'ys, LLC v. Louisiana*, No. 25A1207 (May 2, 2026); Application for Stay, *GenBioPro, Inc. v. Louisiana*, No. 25A1208 (May 2, 2026). Eighteen groups submitted amicus briefs in support of Danco, including

the pharmaceutical industry, former FDA commissioners, and twenty-two states and the District of Columbia.

Justice Alito issued an administrative stay in both cases and subsequently extended it. Order Issuing Administrative Stay, *Danco Lab'ys, LLC v. Louisiana*, No. 25A1207 (May 4, 2026); Order Issuing Administrative Stay, *Danco Lab'ys, LLC v. Louisiana*, No. 25A1207 (May 11, 2026); Order Issuing Administrative Stay, *GenBioPro, Inc. v. Louisiana*, No. 25A1208 (May 4, 2026); Order Issuing Administrative Stay, *GenBioPro, Inc. v. Louisiana*, No. 25A1208 (May 11, 2026).

The Supreme Court granted Danco's and GenBioPro's stay applications on May 14. *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192 (2026). Justices Thomas and Alito each dissented. *Id.* The Supreme Court's order states that the ruling of the panel of this Court enjoining the 2023 REMS is inoperable until disposition of this appeal or disposition of a writ of certiorari, whichever is later. *Id.*

SUMMARY OF ARGUMENT

I. The Supreme Court's grant of interim relief and the Court's earlier holding in *Alliance* should decide this case. Like the plaintiffs in that case, Louisiana cannot establish that it has standing to bring any of

its challenges. Indeed, its theory of financial harm from FDA's action is even more attenuated than the theory the Supreme Court rejected in *Alliance*—and Louisiana's claimed sovereign harms are *neither* cognizable nor fairly traceable to the 2023 REMS. This Court should deny the preliminary injunction and reverse the District Court's order denying Danco's motion to dismiss.

II. Plaintiffs' claims also fail on the merits. At the threshold, their challenge to the 2023 REMS is both unexhausted and unripe. This Court cannot determine whether FDA likely acted arbitrary and capriciously because it lacks the administrative record. Even on the limited record that is available, it is clear that FDA's decision to lift the in-person dispensing requirement was both reasonably explained and supported by evidence that was before the agency at the time. Plaintiffs' arguments otherwise mischaracterize the facts, the law, and FDA practice. Their Comstock Act argument is nonjusticiable. And Plaintiffs have not shown that they are likely to obtain vacatur of the REMS.

III. As the Supreme Court's stay order makes clear, the remaining preliminary injunction factors favor denying relief. Alleged injuries that are not cognizable under Article III cannot constitute irreparable harm.

Mifeprex is Danco's only product, so any pause in distribution while FDA considers a new REMS poses an existential threat to Danco. The public interest also overwhelmingly weighs against granting a stay. A stay would have a profoundly destabilizing effect on the pharmaceutical industry, impose Louisiana's preferences on states with different but equally sovereign policies, and cause harm to women nationwide by impairing access to a safe and effective drug.

LEGAL STANDARD

The Court reviews the denial of a preliminary injunction for abuse of discretion and underlying legal questions de novo. *Cheejati v. Blinken*, 106 F.4th 388, 391 (5th Cir. 2024). A preliminary injunction should be denied unless the plaintiff makes a "clear showing" of likely success on the merits; of irreparable harm absent relief; and that the balance of equities and public interest favor the injunction. *Starbucks Corp. v. McKinney*, 602 U.S. 339, 345 (2024). "Because standing is a prerequisite to success on the merits, Plaintiffs' failure to demonstrate it forecloses injunctive relief." *Vapor Tech. Ass'n v. Graham*, 167 F.4th 302, 305 (5th Cir. 2026).

The Court reviews de novo a ruling on a motion to dismiss. *Harmon v. City of Arlington*, 16 F.4th 1159, 1162 (5th Cir. 2021). Although the court accepts "well-pleaded facts as true," "[t]he court does not . . . 'presume true a number of categories of statements, including legal conclusions; mere labels; threadbare recitals of the elements of a cause of action; conclusory statements; and naked assertions." *Id.* at 1162-63 (citations omitted).

ARGUMENT

Plaintiffs have both failed to establish jurisdiction and to state a claim, and have also failed to "make a 'clear showing'" that they are entitled to extraordinary preliminary relief, as confirmed by the Supreme Court's stay order. *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (citation omitted). This Court should therefore follow the Supreme Court's lead and deny Plaintiffs' request for preliminary relief. Because Plaintiffs lack standing and fail to state a claim on the merits, this Court should also reverse the District Court's order denying Danco's motion to dismiss.

I. PLAINTIFFS LACK ARTICLE III STANDING.

The Supreme Court's decision in *Alliance* controls the outcome here. The "bedrock constitutional requirement" of Article III standing

requires Louisiana to establish that it suffered a cognizable injury-in-fact caused by the FDA REMS and redressable by a court order. *Alliance*, 602 U.S. at 378 (quoting *Texas*, 599 U.S. at 675); *see also Barber v. Bryant*, 860 F.3d 345, 352 (5th Cir. 2017) (plaintiff must make a "clear showing" of standing to obtain a preliminary injunction). Yet the "pocketbook" harm that the District Court and this Court's motions panel relied on as sufficient injury-in-fact is an even more attenuated version of the standing theories *Alliance* rejected. And Louisiana's alternative allegations of sovereign injury are not "legally and judicially cognizable" at all. *Texas*, 599 U.S. at 676 (citation omitted). Like the plaintiffs in *Alliance*, Louisiana therefore cannot show that the 2023 REMS caused them an injury-in-fact that is "traditionally redressable in federal court." *Alliance*, 602 U.S. at 379, 381 n.1 (citation omitted).[5] Plaintiffs' lack of standing is both a reason why their appeal must fail and a reason why

[5] Plaintiffs did not defend Rosalie Markezich's standing below, ROA.5700, and the District Court did not consider it. ROA.9108. Louisiana seeks to establish standing only for itself, and has waived its arguments in favor of Ms. Markezich's standing. In any event, Ms. Markezich alleged backward-looking harm, which is insufficient to create standing for the kind of prospective relief this suit is seeking. *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983).

Danco's cross appeal should succeed. The preliminary injunction cannot issue, and the case must be dismissed.

A. *Alliance* Forecloses Louisiana's Standing Theory Based On Downstream State Expenses.

Standing is often straightforward when a plaintiff is challenging government regulations that "require or forbid some action by the plaintiff." *Alliance*, 602 U.S. at 382. But nothing in FDA's 2023 REMS requires Louisiana to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything." *Id.* at 385-386. Thus, to establish Article III standing as an unregulated party, Louisiana faces the "substantially more difficult" task of showing that the downstream effects of the 2023 REMS cause it some judicially cognizable injury. *Id.* at 382-383 (citation omitted). And *Alliance* squarely forecloses Louisiana's assertion of Article III standing based on downstream expenses. *See id.* at 384 (holding that federal courts should "chiefly" evaluate standing "by comparing the allegations of the particular complaint to those made in prior standing cases") (citation omitted).

In *Alliance*, the Supreme Court unanimously held that, as a legal matter, the "chain of causation" between FDA's "safety regulations" and people "show[ing] up at emergency rooms or in doctors' offices with

follow-on injuries" is "simply too attenuated" for Article III purposes. *Id.* at 391-392. Allowing plaintiffs "to challenge FDA's drug approvals simply on the theory that use of the drugs by others may cause more visits to doctors" would be an "unprecedented" expansion of Article III requirements, and would lack any "principled" endpoint. *Id.* That is why there "is no Article III doctrine of 'doctor standing' that allows doctors to challenge" any government action "affecting public health." *Id.*

For the same reason, a state cannot establish standing based on its Medicaid program paying doctors for providing care a state says is linked to a federal government action. *See Washington v. FDA*, 108 F.4th 1163, 1174 (9th Cir. 2024). Louisiana's Medicaid-costs theory is an even more attenuated version of the limitless "doctor standing" theory the Supreme Court rejected. And the same is true of the "enforcement costs" Louisiana claims it incurs to investigate and prosecute violations of its abortion laws by independent third parties. Br. 28. Medicaid and enforcement costs are both indistinguishable from the innumerable other forms of "indirect effects on state revenues or state spending" that are ever present "in our system of dual federal and state sovereignty"—which courts have made clear cannot form the basis for standing without

eroding "bedrock Article III constraints." *Texas*, 599 U.S. at 680 n.3; *see also California v. Texas*, 593 U.S. 659, 675-678 (2021) (expressing skepticism of predictive effects on state budgets).[6]

Neither the District Court nor the motions panel engaged with the relevant portion of *Alliance*'s reasoning. ROA.9102-9108, 9140-9143. Louisiana's discussion of its supposed financial harms likewise ignores *Alliance*'s discussion of what makes harm impermissibly attenuated. Br. 35-40. Instead, Louisiana asserts that it meets the causation requirement of the standing analysis because its expenses would not exist "but for" the 2023 REMS. *Id.* at 38-39. As Louisiana itself admits, however, this formulation is just a different way of saying that the expenses are a downstream "predictable effect" of the challenged action. *Id.* at 39 (quoting *Dep't of Commerce v. New York*, 588 U.S. 752, 768 (2019)). But *Alliance* made clear that "the line of causation . . . must not

[6] *See also, e.g., Washington*, 108 F.4th at 1176 (such theories "would give not just states, but every entity that provides health insurance or subsidized medical care, standing"); *Maryland v. Dep't of Agric.*, 151 F.4th 197, 210 (4th Cir. 2025) (because "[i]nnumerable federal actions impact state budgets and programs," a state's "alleged decline[] in tax revenue" does not constitute "cognizable injury"); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) ("peripheral costs imposed on States" not "cognizable").

be too speculative *or too attenuated*." 602 U.S. at 383 (emphasis added and quotation marks omitted). And unregulated parties' downstream financial effects from FDA's drug approvals fall on the wrong side of the line.

As the Supreme Court noted, such approvals may predictably "yield more visits to doctors" because "virtually all drugs come with complications, risks, and side effects." *Id.* at 392. Yet the Court held, as a categorical rule, that FDA's loosening of safety requirements "is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing." *Id.* at 383. Were it otherwise, every one of the hypotheticals *Alliance* rejected as being too outlandish—from firefighters challenging building safety codes to teachers challenging immigration policy, *id.* at 392—would come out the other way. Louisiana's proposed loose but-for standard would elevate all sorts of speculative and attenuated harms to Article III standing—contrary to any standing analysis the Supreme Court has endorsed.

Louisiana's refusal to engage with the reasoning of a recent Supreme Court decision would be remarkable in any circumstance. It is all the more remarkable here, where the Supreme Court's stay of this

Court's panel decision arose out of the parties' dispute about the application of *Alliance* to these facts. But *Alliance* binds this Court. *NIH v. Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2663 (2025) (Gorsuch, J., concurring in part and dissenting in part) ("Lower court judges may sometimes disagree with this Court's decisions, but they are never free to defy them."). And the Ninth Circuit correctly held it was bound by *Alliance* in holding that "economic injury in the form of increased" downstream costs to states does not give those states standing to challenge the 2023 REMS. *Washington*, 108 F.4th at 1174-76.

B. Louisiana Suffers No Cognizable Sovereign Injury Traceable To The 2023 REMS.

Louisiana cannot circumvent *Alliance*'s central holding by recasting the downstream effects of the 2023 REMS as "sovereign" injury. Br. 42. That injury, as alleged by Louisiana, is not "legally and judicially cognizable"—and does not overcome the *Alliance* traceability problem in any event. *Texas*, 599 U.S. at 676 (citation omitted).

1. Louisiana has not suffered a cognizable sovereign injury.

The states' sovereign interests derive from their status as "independent sovereigns" within the Constitutional framework. *Nat'l Fed'n of Indep. Bus. (NFIB) v. Sebelius*, 567 U.S. 519, 577-578 (2012). As

independent sovereigns, states cannot be "require[d] . . . to govern according to Congress' instructions," *New York v. United States*, 505 U.S. 144, 162 (1992); cannot have their officers "command[ed] . . . to administer" federal law, *Printz v. United States*, 521 U.S. 898, 935 (1997); and cannot be coerced "to implement a federal program," *NFIB*, 567 U.S. at 577-578. *See generally Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982) (noting that a sovereign interest includes "the power to create and enforce a legal code"). It is "invasion of [those] legally protected interest[s]" that has "traditionally been regarded as providing a basis for a lawsuit" in federal court. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339, 341 (2016) (quotation marks omitted); *see, e.g.*, *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 474 (2018) (state challenging law "dictat[ing] what a state legislature may and may not do").

Consistent with these principles, this Court has held that states can suffer cognizable "sovereign" harm if the federal government exerts "pressure to change state law," *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015), or otherwise compromises "the state's interest in the *enforceability* of its laws," such as by asserting preemption, *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023) (emphasis in

original). But Louisiana does not complain of any such injury here. Quite the contrary: Louisiana has repeatedly emphasized that it continues to exercise its authority to investigate and prosecute violations of its laws. Indeed, as District Court noted, FDA's 2023 REMS "does not mean that medical providers . . . [are] free to ignore the laws of [their] states." ROA.9105 n.13. This accords with the Fourth Circuit's conclusion that the 2023 REMS does not displace state laws prohibiting abortion. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 276 (4th Cir. 2025) (holding that the 2023 REMS "leav[es] the question of access to state governance").

That should be the end of the matter. Louisiana suffers no sovereign injury because nothing in the REMS undermines Louisiana's *legal* "authority to regulate or to enforce its laws." *Harrison*, 78 F.4th at 770 (citation omitted); *see also Washington*, 108 F.4th at 1177 (Ninth Circuit reaching the same conclusion with respect to Idaho and six other states). Nor does the 2023 REMS otherwise purport to regulate Louisiana or "compel the State[] to require or prohibit" any conduct or to change its laws. *Printz*, 521 U.S. at 924 (citation omitted).

Nevertheless, both the District Court and the motions panel concluded that Louisiana suffers sovereign injury because the 2023 REMS "facilitates . . . illegal abortions in Louisiana." ROA.9141; *see* ROA.9102-9106. Louisiana now elaborates on that theory by asserting that each violation of its abortion law constitutes a sovereign injury. Br. 43-44. But unlike the *qui tam* actions Louisiana references—where a private relator vindicates the United States's *financial* injury against a private defendant, *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 774 (2000)—Louisiana has "not cited any precedent, history, or tradition of" the Supreme Court accepting voluntary third-party decisions to violate state criminal law as an Article III injury that a state can vindicate in a suit against the federal government. *Texas*, 599 U.S. at 677; *see TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021) ("[H]istory and tradition offer a meaningful guide to the types of cases that Article III empowers federal courts to consider.") (citation omitted).

Louisiana's failure to identify any authority supporting its position is not surprising. Louisiana itself conceptualizes violations of its law as "injur[ies] [to] the community." *Ellingburg v. United States*, 607 U.S. 163, 179 (2026) (Thomas, J., concurring); *see* Br. 42-43. Yet it is well

established that a state can secure such interests "against private defendants" *but not* "against the Federal Government," which also exercises sovereign power over the same community. *Alfred L. Snapp*, 458 U.S. at 610 n.16; *see also Massachusetts v. Mellon*, 262 U.S. 447, 485-486 (1923) ("[I]t is no part of [the State's] duty or power to enforce" citizens' "rights in respect of their relations with the federal government" because "it is the United States, and not the state, which represents them"). For the same reason, a "State does not have standing as *parens patriae* to bring an action against the Federal Government." *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023) (quoting *Alfred L. Snapp*, 458 U.S. at 610 n.16).

Perhaps recognizing as much, Louisiana quickly pivots to arguing that it suffers a sovereign injury because the 2023 REMS supposedly has the practical effect of frustrating the enforcement of its laws. Br. 50. Once again, however, all the precedent it cites in support of this theory deals with instances where a state law is rendered *legally* unenforceable. *Id.* at 48-50; *see, e.g.*, *Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) (irreparable injury exists where "a State is enjoined by a court from effectuating statutes") (citations omitted); *Abbott v. Perez*, 585 U.S. 579,

602 (2018) (same). That is not the situation here, and Louisiana has never suggested otherwise.

And while Louisiana is correct that the Constitution itself allows the federal government to sue states to vindicate federal law under the Supremacy Clause, there is no "storied tradition" of states suing the Federal government over more nebulous "interference" with state statutes. Br. 47-48. To the contrary—as the Ninth Circuit explained when Idaho and other states presented this exact theory in that court—courts "have never held that a logistical burden on [state] law enforcement constitutes a cognizable Article III injury." *Washington,* 108 F.4th at 1177. A state's general "interest in the preservation of sovereign authority" does not confer "standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Id.* at 1176.

For good reason: Our system of dual sovereignty creates boundless variations between federal and state policy on issues ranging from immigration to voting rights to government provision of benefits. Every such variation can, at some level, be characterized as the federal government interfering with the state's chosen policy. *See, e.g.*, *Brackeen*,

599 U.S. at 295 (analyzing allegation that federal statute "injures Texas by requiring it to break its promise to its citizens that it will be colorblind in child-custody proceedings" under state law). But States have no cognizable interest in having the federal policy match theirs. Otherwise, states "would always have standing" to challenge almost any federal policy. *Id.* The "lack of historical precedent" for Louisiana's standing theory is a "telling indication of the severe constitutional problem." *Texas,* 599 U.S. at 677 (citation omitted).

2. Alliance *forecloses Louisiana's sovereign-harm theory.*

In any event, Louisiana's formulation of sovereign injury suffers from the same attenuation problem that prevents Louisiana from relying on its state expenses. *See supra* pp. 26-30; *see also Alliance,* 602 U.S. at 391-392 (The "chain of causation" between FDA's "safety regulations" and people "show[ing] up at emergency rooms or in doctors' offices with follow-on injuries" is "simply too attenuated" for Article III purposes).

Like its Medicaid expenses, the State's claimed violations of Louisiana law involve a speculative chain of third-party discretionary actions, including (at a minimum): (a) someone in Louisiana choosing to seek a medication abortion from an out-of-state provider via telemedicine

(as opposed to traveling to the out-of-state provider); (b) the out-of-state provider electing to prescribe mifepristone to the patient; (c) the out-of-state provider then choosing to mail FDA-approved mifepristone to the individual in Louisiana; and (d) the individual taking the drug while physically in Louisiana.[7]

The chain is further stretched by other states' independent decisions to enact "shield" laws that protect medical practitioners in their states from extradition for prescribing mifepristone. Louisiana's own papers make clear that these laws not only affect providers' behavior but also stand as the main obstacle to Louisiana enforcing its criminal prohibitions. Br. 16-17; *see also* ROA.109-111 (Louisiana's complaint). But, just as the 2023 REMS does not require doctors to prescribe mifepristone, so too it does not direct states to shield their identities. As a result, Louisiana's asserted injuries are traceable not to FDA but to the "unfettered choices made by independent actors," including Louisiana's

[7] Because Louisiana is not challenging mifepristone's approval generally, it must establish that the injury flows from the elimination of in-person dispensing in the 2023 REMS, given that there are other ways an individual could receive the product. *See California*, 593 U.S. at 669 (plaintiff must trace its injury to the specific "'allegedly unlawful conduct' of which they complain").

co-equal sovereign states pursuing different abortion policies. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 & n.5 (2013) (citation omitted).

Finally, Louisiana's asserted logistical enforcement burden is, at bottom, an argument that pursuing and prosecuting violations requires additional state resources. That is the same type of "indirect effects on state revenues or state spending" the Supreme Court has cautioned against as a basis for standing in "our system of dual federal and state sovereignty." *Texas*, 599 U.S. at 680 n.3. Nothing in the 2023 REMS compels or directs any third party to violate Louisiana law. And the difference in state policies that supposedly frustrates Louisiana's objectives is a natural result of the Supreme Court "return[ing]" abortion policy to the states. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022).

II. PLAINTIFFS' CLAIMS FAIL ON THE MERITS.

This Court need not reach the merits because Plaintiffs lack standing. In any event, their claims also fail on the merits. Those claims are unexhausted and unripe. FDA's approval of the 2023 REMS was not arbitrary and capricious. The Comstock Act claim is non-justiciable and is not relevant to the lawfulness of FDA's decision. And Plaintiffs are

unlikely to obtain vacatur. For each of these reasons, Plaintiffs were not entitled to preliminary relief, and Danco's motion to dismiss should have been granted.[8]

A. Plaintiffs' Claims Are Unexhausted And Unripe.

1. Parties must "exhaust[] all administrative remedies expressly prescribed" before seeking APA review. *Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993). But Plaintiffs never did. They never filed a citizen petition regarding either the 2023 REMS or the 2021 nonenforcement decisions, even though any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a [citizen] petition" before suit is filed. 21 C.F.R. §§ 10.45(b), 10.25(a). Courts have dismissed suits in such circumstances. *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). Plaintiffs' failure to exhaust independently shows they are unlikely to succeed on the merits of their APA claims.

[8] All of the arguments in Section II except II.B.1 and II.D address Danco's cross appeal challenging the denial of its motion to dismiss, in addition to also responding to Plaintiffs' appeal arguments.

The stay panel sought to excuse that failure based on this Court's prior conclusion in the *Alliance* litigation that exhaustion by the *Alliance* plaintiffs would have been futile. ROA.9139. That conclusion was wrong when this Court issued its decision in *Alliance* and is doubly wrong now. The fact of FDA's ongoing review—including in response to citizen petitions from *other* states, *see* ROA.2749, in compliance with a court order issued in the *Purcell* litigation, and on Secretary Kennedy's own initiative—proves this is not the "exceptional" case when "a certainty of an adverse decision" from an agency can excuse exhaustion. *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (citations omitted).

2. For similar reasons, Plaintiffs' suit is unripe. Ripeness considers "the hardship to the parties of withholding court consideration," and the fact that Plaintiffs waited for several years through FDA's nonenforcement policy and after FDA's approval of the 2023 REMS before filing this lawsuit underscores they "will suffer no irreparable harm pending completion of [FDA's] inquiry." *New Orleans Pub. Serv., Inc. v. Council of City of New Orleans*, 833 F.2d 583, 586, 588

(5th Cir. 1987) (citation omitted); *see Pennzoil Co. v. FERC*, 742 F.2d 242, 244-245 (5th Cir. 1984).

The other ripeness consideration is whether the issue is "fit for judicial decision." *Walmart Inc. v. DOJ*, 21 F.4th 300, 311 (5th Cir. 2021). FDA's ongoing review of the mifepristone REMS leaves Plaintiffs unable to satisfy any of the three indicators of fitness—and "[f]ailure on even one of the three prongs can render a case unfit for judicial review." *Id.*

On the first "fitness" consideration, Plaintiffs' claims are not "purely legal," *see id.*; Plaintiffs attack FDA's scientific assessments, which "involve[] primarily issues of fact," *Seven Cnty.*, 605 U.S. at 180-181 (citation omitted).

Second, FDA's ongoing review means that the agency's action on the mifepristone REMS is not "sufficiently final" at this time to warrant judicial review. *Walmart*, 21 F.4th at 311 (citation omitted). A case is generally unripe where, as here, the agency "will have another opportunity to rule on [the plaintiff's] contentions." *Pennzoil*, 742 F.2d at 244-245. FDA's ongoing consideration of the REMS demonstrates that the agency "is not unwilling to listen to [Plaintiffs'] arguments," even

though FDA may ultimately "remain[] unconvinced by them." *Id.* at 244 n.7.

Third, judicial review "would benefit from a more concrete setting" after FDA's ongoing review concludes. *Walmart*, 21 F.4th at 311 (citation omitted). If FDA reaffirms that a requirement to dispense in-person by a provider is not warranted under FDA's REMS authority, that would "allow[] for more intelligent resolution" of Plaintiffs' claims. *Am. Petrol. Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012). In that scenario, FDA's "supplemental analysis" would be part of the "administrative record" for any challenge, *El Puente v. Army Corps of Eng'rs*, 100 F.4th 236, 251-252 (D.C. Cir. 2024), and FDA's later decision would show that any defect in the 2023 REMS was harmless, *see* 5 U.S.C. § 706, and that vacatur of the 2023 REMS is inappropriate because FDA further "justif[ied]" its decision, *Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000). Hearing Plaintiffs' claims now would thus "contravene sound policies favoring judicial and administrative economy." *Pennzoil*, 742 F.2d at 244-245.

B. Plaintiffs' Arbitrary And Capricious Claims Fail.

Plaintiffs are not likely to succeed on the merits of their arbitrary and capricious claims, which they ask the Court to address without reviewing the full administrative record. Even the limited record before the Court, however, shows that FDA did not act arbitrarily or capriciously. Plaintiffs have not pointed to any evidence that was before FDA, yet FDA failed to consider in approving the 2023 REMS. Instead, like the prior panels of this Court, Plaintiffs take issue with FDA's assessment of the evidence. But FDA's decision to remove in-person dispensing from the REMS was no different from how FDA reviews other REMS modifications. That FDA has not defended the 2023 REMS on the merits does not make the 2023 decision arbitrary, *contra* Br. 53, especially since FDA (a) has not yet answered Plaintiffs' complaint and (b) argued against preliminary relief on the basis that Plaintiffs lack Article III standing, which obviates any need to reach the merits.

Like any agency action, FDA's 2023 REMS approval must "stand or fall . . . on the administrative record" before the agency at the time the decision was made. *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 549 (1978) (citation omitted). FDA's objective, reasoned analysis is

supported by even the excerpts of the administrative record that were before the District Court. Those excerpts amply satisfy the APA's "deferential arbitrary-and-capricious standard." *Seven Cnty.*, 605 U.S. at 179-180.[9]

1. A preliminary injunction on this record would be inappropriate.

The APA instructs that courts "shall review the whole record" in determining whether agency action is arbitrary or capricious. 5 U.S.C. § 706. The documents before this Court do not constitute the complete administrative record. The same was true for the stay panel and the two *Alliance* panels. *Contra* Br. 53. Preliminary relief is unwarranted where a court "cannot tell on what basis the Food and Drug Administration took the agency action the plaintiff[s] seek[] to enjoin." *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001). Assessing whether FDA

[9] Plaintiffs also invoke the change-in-position doctrine. Br. 53. But FDA did not reverse any "longstanding position." *Contra id.* FDA already determined two years earlier that in-person dispensing was unnecessary and unduly burdensome, ROA.259-260, 348-387, 1055-1096; FDA acted consistently with that decision when it officially removed in-person dispensing from the REMS in 2023. FDA did not "deviate[] from a prior policy *sub silentio* or simply disregard[] what it had previously said." *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 575 (2025) (citation and quotation marks omitted).

"adequately explain[ed]" its decision to remove in-person dispensing in the 2023 REMS, Br. 53, requires knowing what evidence FDA had before it and how FDA evaluated that evidence. After all, "[e]ven when an agency explains its decision with less than ideal clarity, a reviewing court will not upset the decision on that account if the agency's path may reasonably be discerned." *Alaska Dep't of Env't Conservation v. EPA*, 540 U.S. 461, 497 (2004) (quotation marks omitted). And the full administrative record—which FDA has since produced to the parties—includes numerous documents the District Court and stay panel did not consider that further support FDA's decision.[10]

2. FDA does not act arbitrarily and capriciously by considering FAERS data in a REMS review.

Plaintiffs' principal objection is that FDA considered data from FAERS, or the Federal Adverse Event Reporting System, showing "[no] new safety concerns . . . during the time when in-person dispensing was not enforced." ROA.373; *see* Br. 54-57. But FDA's use of FAERS data

[10] That record contains more than 7,500 pages. Among other things missing from the abbreviated preliminary-injunction record, the full administrative record includes the manufacturers' applications to modify the REMS and months of correspondence with FDA, FDA's follow-up questions and comments, and the manufacturers' responses—underscoring the detailed review FDA undertook.

was both appropriate and consistent with the agency's statutory authority and standard practice. Because Plaintiffs' claim depends on inventing a nonexistent prohibition on FDA using FAERS data in approving a REMS modification, they fail to state a claim.

Federal law directs FDA to maintain a system for reporting adverse events for marketed drugs. *See* 21 U.S.C. § 355(k). Pursuant to that authority, FDA created FAERS, which collects adverse-event data from healthcare professionals, manufacturers, patients, and the public. ROA.1106; *see* 21 U.S.C. § 352(n); 21 C.F.R. §§ 314.80, 314.81, 314.98. FDA uses FAERS as the sole source of adverse event reporting for virtually all drugs. Fmr. FDA Comm'rs SCOTUS Br. 14.

FAERS data is a "useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product." ROA.1106. FDA uses FAERS data to, for example, identify trends and emerging concerns and provide transparency to the public. Fmr. FDA Comm'rs SCOTUS Br. 14. And FDA routinely considers FAERS data in analyzing whether to modify or discontinue a REMS for all types of drugs. *Id.*; *e.g.*, FDA, Lotronex supplemental NDA Approval 2 (Sep. 2023), https://perma.cc/RNU4-6WRK. Indeed, the REMS statute obligates FDA

to consider adverse event reports when determining whether to initially implement a REMS. 21 U.S.C. § 355-1(a)(1)(E); *see id.* § 355-1(b)(3) (defining the new drug safety data that FDA must review to include "adverse event report[s]"). FDA reasonably considers that same data when it "periodically evaluate[s]" whether a drug's REMS continues to "assure safe use of the drug," "[is] not unduly burdensome on patient access," and "minimize[s] the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(5)(B).

FAERS data have limitations, because they do not capture every adverse event associated with a drug and may be overinclusive in other respects. ROA.1106 (FDA's website noting that "there is no certainty that the reported event . . . was due to the product"). Still, "it is not unusual"—let alone unlawful—for agencies to act without "perfect empirical or statistical data." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). Consider what Plaintiffs' argument would mean: In a situation where FAERS data did show an emerging safety concern with a drug, FDA would be powerless to consider that data when determining whether to add or modify a REMS for that drug.

Indeed, Plaintiffs' focus on the limits of FAERS data is telling as to the weakness of their claims. Br. 54-57. For starters, nothing in the REMS statute prohibits FDA from considering FAERS data, among other sources, to "determine[]" that mifepristone's in-person dispensing requirement should be "removed" to "minimize the burden on the health care delivery system," while still "ensur[ing] the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(g)(4)(B). As noted, the statute highlights the importance of analyzing adverse event information—which is exactly what FAERS data is.

If Plaintiffs' position were correct, it "would preclude FDA from ever relying on the FAERS database to modify or release a REMS" or from taking other routine regulatory actions for drugs *without* REMS. Food & Drug Law Scholars SCOTUS Br. 11, 12 n.6. Virtually every REMS modification or labeling change would be an APA violation. Plaintiffs do not attempt to justify such a radical and disruptive departure from FDA practice. Nor do Plaintiffs identify what other "adverse event reports" FDA is supposed to consider if FAERS does not qualify. Br. 57.

Plaintiffs' more targeted attacks on the FAERS data also miss their mark. *First*, Plaintiffs' conclusory assertion that FDA gave "dispositive

weight to adverse event data in FAERS" is both wrong and insufficient to show an APA violation. Br. 54. FDA did not use "FAERS data by themselves" in assessing the REMS. *Contra* Br. 55. In addition to FAERS data, FDA considered REMS assessment reports, studies, literature, and public reports; and it determined that taken together, these sources of information showed that in-person dispensing was (1) "no 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, 1073-0190, 1093-1094. That is exactly the "kind[] of speculative assessment[] or predictive or scientific judgment[]" where "a reviewing court must be at its most deferential." *Seven Cnty.*, 605 U.S. at 182 (quotation marks omitted).

Second, Plaintiffs assert that FDA could not rely on FAERS data for mifepristone because FDA made prescribers' reporting obligations voluntary in 2016. Br. 56. But voluntary adverse event reporting through FAERS is the same standard applicable to virtually all of the many thousands of FDA approved drugs on the market. ROA.2785-2786; *see* PhRMA SCOTUS Br. 18-19. Danco, like other drug manufacturers,

still must report to FDA every adverse event it learns of from any source, including providers, patients, clinical investigations, epidemiological surveillance studies, scientific literature, and unpublished scientific papers. 21 C.F.R. §§ 314.80, 314.81; *see id.* § 201.57(a)(11)(ii)-(iii) (requiring drug labels to contain contact information for reporting suspected adverse reactions to the manufacturer). Patients, providers, and the public can report adverse events directly to FDA, too. *See* FDA, MedWatch Online Voluntary Reporting Form, https://perma.cc/3M5HJLZ5. Treating one regulated product in the same manner it treats other regulated products is not arbitrary or capricious. *See Shenzhen Youme Info. Tech. Co., Ltd. v. FDA*, 147 F.4th 502, 514 (5th Cir. 2025) ("It is a bedrock principle of administrative law that an agency must 'treat like cases alike.' ") (citation omitted). And, in any event, FDA still requires greater monitoring of mifepristone than it requires for virtually all other drugs, including, among other things, mandatory reporting by prescribers and pharmacies of any deaths regardless of causality. ROA.988-989; Fmr. FDA Comm'rs SCOTUS Br. 14.

Finally, Plaintiffs wrongly claim that the fact mifepristone has a boxed warning alters how FDA can approach a REMS modification.[11] *Contra* Br. 56-57. Many commonly used drugs with boxed warnings have no REMS at all. *E.g.*, Adderall XR Prescribing Information 1 (Apr. 2026), https://perma.cc/YR9B-Z4F6; Cipro (ciprofloxacin hydrochloride) Prescribing Information 1 (Sept. 2024), https://perma.cc/NA7L-3DL6. For those that do, FDA routinely uses FAERS data in deciding whether to eliminate a REMS entirely, *e.g.*, FDA, *FDA Removes REMS Program For The Antipsychotic Drug Clozapine* (Aug. 2025), https://perma.cc/ZM6R-Y43M ("Data to support the removal of the Clozapine REMS included . . . a review of the FDA Adverse Event Reporting System . . . ."), or to modify a REMS, *e.g.*, Lotronex supplemental NDA Approval, *supra*, at 2; FDA, Letter Directing REMS Modifications for Isotretinoin (Nov. 2023), https://perma.cc/TW7U-YT3H. FDA's actions here looked to FAERS just as FDA did for those drugs.

Plaintiffs make the same error in misrepresenting rates of emergency-room visits. Br. 56. Since 2016, mifepristone's labeling has

[11] FDA may require that "[c]ertain contraindications or serious warnings . . . be presented in a box" on a drug's label. 21 C.F.R. § 201.57(c)(1).

noted that three studies reported "ER visit[s]" of 0%, 2.9%, and 4.6%, ROA.335, but cautions that these data "may not reflect the rates observed in practice," ROA.333, and notes that across all 10 studies referenced in that section of the label, "[s]erious adverse reactions were reported in <0.5% of women," ROA.334. ER visits capture patient behavior—like seeking follow-up care for observation, pain medication, or to confirm they are no longer pregnant—not clinical harm. FemInEM SCOTUS Br. 18; Yale L. Sch. Info. Soc'y Project SCOTUS Br. 15; Reproductive Health Researchers SCOTUS Br. 6-13. Every prescription drug entails some risk; that does not impugn FDA's use of FAERS data to make decisions.

3. FDA did not act arbitrarily and capriciously by reviewing the scientific literature at the time of its decision.

Plaintiffs' objection to FDA's consideration of scientific literature gets the standard wrong out of the gate: They fault FDA's 2023 REMS decision as lacking "'adequate tests,' test 'results,' and 'sufficient information' [to] demonstrate the drug safe for use." Br. 58-59 (quoting 21 U.S.C. § 355(d)) (brackets omitted). But *§ 355-1* governed FDA's decision removing in-person dispensing from the REMS, not § 355(d); FDA can decide on its own "initiative" to require a REMS modification where it determines that an element of the existing REMS is no longer

necessary to "ensure the benefits of the drug outweigh the risks," or to "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(g)(4)(B)(i), (ii). Those are precisely the reasons FDA gave for its decision. ROA.1044; *see* Food & Drug Law Scholars SCOTUS Br. 14-15.

Nothing in the REMS statute overrides black-letter administrative law deferring to agency decision-making in the absence of "perfect empirical or statistical data," *Prometheus Radio Project*, 592 U.S. at 427. Here, even though FDA had no obligation to consider clinical evidence in modifying the REMS, the agency did so—and concluded that its "review of the published literature" supported removing in-person dispensing from the REMS. ROA.1039; *see* ROA.372-383 (same conclusion in 2021). FDA reviewed data from three studies evaluating retail-pharmacy dispensing, which had "efficacy and safety outcomes within labeled frequency." ROA.1028. FDA also reviewed three studies evaluating mail-order pharmacy dispensing, none of which "raise[d] serious safety concerns," and which supported finding "that the efficacy of medical abortion is maintained." ROA.1031. And FDA considered five studies evaluating clinic dispensing by mail, which FDA concluded further "support that dispensing by mail is safe and effective." ROA.1037. FDA

acknowledged limitations in the studies, but none identified any new or increased risks associated with dispensing mifepristone outside of an in-person visit to the prescriber. After a "comprehensive review of the published literature," FDA concluded that the studies "generally support a conclusion that dispensing by mail is safe." ROA.1007, 1042.

None of Plaintiffs' three attacks on FDA's conclusion meet their heavy burden of demonstrating FDA acted unlawfully. First, Plaintiffs seize on the fact that FDA acknowledged limitations in the studies it reviewed. But an agency's candid assessment of the limits of scientific knowledge does not "violate[] the APA." *Contra* Br. 61, 57. FDA said only that the studies it considered were not "adequate on their own to establish the safety of the model of dispensing mifepristone by mail." ROA.1042. That does not help Plaintiffs; the question before FDA was not whether clinical studies conclusively established safety of dispensing by mail, but rather whether a REMS condition mandating in-person dispensing was still 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). The absence of serious safety issues in the studies FDA

reviewed was consistent with a conclusion that in-person dispensing was unnecessary.

Moreover, FDA did not rely on those studies *on their own*. FDA "reviewed multiple different sources of information" in addition to "published literature," including "safety information" submitted during the COVID-19 public health emergency, REMS assessment data, FAERS data, and other "information provided by advocacy groups, individuals, and the Applicants"—all of which collectively showed the "benefits of" removing the in-person dispensing requirement "outweigh[ed] the risks while minimizing the burden imposed by the REMS on healthcare providers and patients." ROA.1013, 1044. Agencies "must have the freedom to make 'a reasonable predictive judgment' based on the available evidence." FDA Br. 44, *FDA v. Alliance for Hippocratic Med.*, Nos. 23-235, 23-236, 2024 WL 305380 (U.S. Jan. 23, 2024) (quoting *Prometheus Radio Project*, 592 U.S. at 427). And FDA was right: "The scientific evidence collected and published since 2023 has only further confirmed the safety and effectiveness of removing the in-person dispensing requirement." Reproductive Health Researchers SCOTUS Br. 16-19.

Second, Plaintiffs mischaracterize the studies FDA reviewed. Br. 59-61. But courts are "ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard." *Cytori Therapeutics, Inc.* v. *FDA*, 715 F.3d 922, 927 (D.C. Cir. 2013) (Kavanaugh, J.); *see VDX Distro,* 2026 WL 1811451, at *7 (refusing to "second-guess FDA's" "scientific judgments") (citation omitted).

Plaintiffs' ad-libbing of the science is also wrong on its own terms. Plaintiffs tout what they see as an "*increase* in risk" from non-in-person dispensing because some studies suggested a chance of more frequent ER or urgent-care visits. Br. 59. But Plaintiffs ignore FDA's very next sentence, which explained the increase may be because "a substantial proportion of participants [in the study] lived significant distances from their providers," which is "associated with higher use of ED following treatment." ROA.1037; *see* ROA.1088 (same FDA conclusion in 2021). That study further showed that "half the participants who had an ED/urgent care visit did not require medical treatment." ROA.1037. And FDA explained that another study Plaintiffs point to (at 59-60) showed that only four women who received mifepristone by mail visited an emergency room, compared to two women who picked up the medication

in-person, which FDA cautioned did *not* support finding "an increased rate of ED visits compared to the labeled rate," especially as the study reported other labeled serious adverse events "occur[ed] infrequently (<1%)." ROA.1035; *see* ROA.1086. As for what Plaintiffs call a "soar[ing]" rate of 3% of women hospitalized in an Australian study, Br. 60, Plaintiffs ignore that the "reasons for hospitalization are not discussed by the authors" and the study did "not report any other adverse events"; its authors "conclude[d] use of the telemedicine medical abortion service is safe." ROA.1031; *see* ROA.1082.

Plaintiffs also point (at 59) to a study finding some difference in outcomes between women who had an ultrasound or in-person examination prior to abortion and those who did not, but any slight[12] difference is beside the point: The pre-2023 REMS did not include an ultrasound or in-person examination requirement, and every woman in

[12] The rate of study participants "hospitalized and/or [requiring] blood transfusion" was 1 out of 125 for the cohort *with* an ultrasound or examination (0.8%), and *even less* for the no-test cohort—2 out of 287 (<0.7%). ROA.1034. In the examination cohort, 10 of the 125 (8%) had an "unplanned clinical encounter (participant sought in-person medical care related to abortion and the visit was not planned prior to abortion)"; in the no-test cohort, 36 of the 287 (12.5%) had an unplanned clinical encounter. *Id.*

that study received mifepristone by mail. ROA.1027; *see* ACOG SCOTUS Br. 4. *Contra* Br. 59 (citing FDA review in 2021 of same study, ROA.1085). And FDA "warned that [study] needed to be interpreted carefully," Br. 60, precisely because "the two cohorts"—no-test vs. examination—"were not randomized" and "had different baseline characteristics." ROA.1033; *see* ROA.1084.

Finally, Plaintiffs invoke a letter Secretary Kennedy sent to state attorneys general opposed to abortion that referenced a supposed "lack[] [of] adequate consideration" underlying the prior REMS approvals. Br. 62 (citing ROA.2201). But FDA's decision to reconsider the available evidence today does not suggest, let alone establish, that its prior analysis of the record before it in 2023 fell short of the APA's standards. To the contrary, FDA previously defended its decision as "the result of a thorough scientific review by agency experts." FDA Br. 7, 42-43, *FDA v. Alliance for Hippocratic Med.*, Nos. 23-235, 23-236, 2024 WL 305380 (U.S. Jan. 23, 2024) (quoting ROA.352) (brackets omitted).

And while FDA, like all agencies, has inherent discretion to re-evaluate the evidence before it, the agency's choice to exercise that discretion cannot justify upending the REMS via court order. There is a

mandatory process FDA must use to change a drug's REMS. 21 U.S.C. § 355-1(g), (h). Allowing an *ad hoc* letter to political stakeholders to invalidate FDA's years-earlier expert determination would improperly short-circuit that process and transform Congress's carefully calibrated regulatory regime into an unsanctioned form of drug-regulation-by-lawsuit.

C. Plaintiffs' Comstock Argument Fails.

Plaintiffs' Comstock Act argument likewise fails as a matter of law because Plaintiffs have no enforceable right under the statute for at least three separate reasons, and the statute's provisions are not relevant to the lawfulness of FDA's decision in any event.

As a threshold matter, even when a state seeks to press an APA challenge on the ground that an agency decision does not comport with "statutory mandates," *Texas*, 599 U.S. at 674, 676, the claim is unreviewable if it would functionally direct the Executive's "enforcement" of criminal prohibitions, *id.* at 678-681; *see, e.g.*, *Maine v. Taylor*, 477 U.S. 131, 137 (1986) ("private parties, and perhaps even separate sovereigns, have no legally cognizable interest in the prosecutorial decisions of the Federal Government"); *Heckler v. Chaney*,

470 U.S. 821, 831 (1985) (recognizing "general unsuitability for judicial review of agency [nonenforcement] decisions"). That is precisely the argument that Plaintiffs press here. Br. 62 (arguing that "the 2023 REMS independently violates the APA" because "mailing drugs that cause abortion is 'precisely what the Comstock Act prohibits' ") (quoting *Alliance*, 78 F.4th at 268 (Ho, J., concurring in part and dissenting in part)). Plaintiffs' Comstock Act claim is simply nonjusticiable.

The unreviewability of Plaintiffs' claim is all the more obvious here, where the criminal statute sits outside the factors Congress expressly directed FDA to consider in the statute governing REMS modifications. Like any agency, FDA has only the authority Congress granted it. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126, 161 (2000). When it comes to REMS modifications, FDA's obligation is to consider whether a requirement is necessary to "ensure the benefits of the drug outweigh the risks of the drug," and whether eliminating that requirement will "minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B). Nothing in this framework indicates that Congress intended or authorized FDA to consider whether a drug's distribution might be

restricted under other laws administered by another entity. *Cf.* 21 C.F.R. § 314.125(b) (listing reasons to deny applications); *see generally* ROA.6657-6676 (amicus brief of former DOJ officials explaining why Plaintiffs' Comstock Act arguments are "erroneous").[13]

Plaintiffs' claim cannot proceed because they are outside the Comstock Act's zone of interest. The zone-of-interests test asks "whether Congress 'intended for a particular class of plaintiffs to be relied upon to challenge agency disregard of the law,'" *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399 (1987) (citation and brackets omitted), and it forecloses suit when an unregulated "plaintiff's 'interests are [only] marginally related to or inconsistent with the purposes implicit in the statute,'" *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (quoting *Clarke*, 479 U.S. at 399). Plaintiffs' interests

[13] Nor has FDA interpreted the FDCA to permit that. FDA routinely and validly approves drugs that are subject to restrictions under other statutes or regulations that FDA does not administer, like fentanyl, methadone, and alprazolam, all of which are subject to the Controlled Substances Act. 21 U.S.C. § 812; *see id.* §§ 811(a), 841(a)(1), 844(a). Whatever the scope of the Comstock Act's prohibitions, Congress assigned it no role within the FDCA or REMS framework. Imposing a REMS based on the Comstock Act would mean FDA "relied on factors which Congress has not intended it to consider," rendering its decision invalid. *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

here are wholly unrelated to the Comstock Act. The Act is a criminal statute, which is not being enforced against Plaintiffs, and Plaintiffs "lack[] a judicially cognizable interest in the prosecution . . . of another." *Texas*, 599 U.S. at 677 (citation omitted). Further, unlike other contexts, such as immigration—where Congress "has explicitly allowed states to" limit their costs by refusing "benefits to illegal aliens"—the Comstock Act envisions no role or participation by states. *Texas*, 809 F.3d at 163.

Even if Plaintiffs could jump high enough to clear each of those hurdles—compelling a federal law-enforcement decision, forcing FDA to consider non-statutory factors in its decision-making, and showing that Congress intended these particular Plaintiffs to challenge FDA's take on the Comstock Act—Plaintiffs' Comstock Act claim would still fail because, as courts have long recognized, the Comstock Act prohibits only the distribution of items intended to produce *unlawful* abortions. *See, e.g.*, *Poe v. Ullman*, 367 U.S. 497, 546 n.12 (1961) (Harlan, J., dissenting) (noting "judicial interpretation" that Comstock Act's "prohibitions . . . exclude professional medical use"). Congress has ratified that established construction by repeatedly amending the Act without material change after that construction had been called to Congress's

attention in a 1948 Historical and Revision Note. 18 U.S.C. § 1461 note ("invit[ing]" the "attention of Congress" to multiple "decisions of the Federal courts construing" the Comstock Act and holding that "sending through the mails of contraceptive articles or publications is not forbidden absolutely, but only when such articles or publications are unlawfully employed"); *see* Off. of Legal Counsel, *Application of the Comstock Act to the Mailing of Prescription Drugs That Can be Used for Abortions* 12-15 (Dec. 23, 2022), https://perma.cc/TZ98-5T46. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lamar, Archer & Cofrin, LLP v. Appling*, 584 U.S. 709, 722 (2018) (citation omitted).

Plaintiffs do not wrestle with any of this. Instead, they cite to the Fifth Circuit's stay decision in *Alliance* suggesting a different interpretation, and Judge Ho's separate opinion. Br. 62. But these opinions lack precedential value following the Supreme Court's holding that the *Alliance* plaintiffs lacked standing. And, respectfully, they 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. It would also significantly interfere with states' traditional power to enact their own "health and welfare laws." *Dobbs*, 597 U.S. at 301. Plaintiffs' sweeping, historically baseless interpretation should be rejected.

D. Plaintiffs Are Unlikely To Obtain Vacatur.

Also integral to the likelihood of success on the merits of Plaintiffs' APA claims—or lack thereof—is the scope of remedy Plaintiffs are likely to obtain at the end of this suit. *Cf. Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 674 (D.C. Cir. 2019) (courts "have a 'duty' to ensure the propriety of the APA remedy") (quoting 5 U.S.C. § 702). Here, Plaintiffs have not clearly shown that even if they ultimately prevail on any of their claims, they will be entitled to vacatur of the 2023 REMS. That shortcoming makes a preliminary injunction with the same effect especially inappropriate. *See De Beers Consol. Mines v. United States*, 325 U.S. 212, 220 (1945) (preliminary injunction cannot award a party more relief than would be available on the merits).

As the Supreme Court recently underscored, where an agency's analysis "falls short in some respects, that deficiency may not necessarily require a court to vacate the agency's ultimate approval." *Seven Cnty.*,

605 U.S. at 185; *see also Cent. & S. W. Servs.*, 220 F.3d at 692 (an APA violation "does not require vacatur"). Indeed, there are cases "when equity demands" that the agency's decision "be left in place" while the agency corrects its errors. *Nat. Res. Def. Council v. EPA*, 808 F.3d 556, 584 (2d Cir. 2015). And remand to the agency—not vacatur—is "generally appropriate when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so, and when vacating would be disruptive." *Cent. & S. W. Servs.*, 220 F.3d at 692 (cleaned up).

Both considerations weigh decisively against vacatur being an appropriate remedy in this case. Regardless of any defect in FDA's decision to remove in-person dispensing from the REMS in 2023, there is "at least a serious possibility" FDA would "be able to substantiate its decision" to eliminate in-person dispensing on remand, *Nat'l Ass'n of Priv. Fund Managers v. SEC*, 151 F.4th 252, 273 (5th Cir. 2025) (citation omitted), particularly as "[t]he scientific evidence collected and published since 2023 has only further confirmed the safety and effectiveness of

removing the in-person dispensing requirement," Reproductive Health Researchers SCOTUS Br. 16-19; *see* ACOG SCOTUS Br. 7-13.[14]

Moreover, "it would be disruptive to vacate" the 2023 REMS that has for years governed "the regulated community." *Cent. & S. W. Servs.*, 220 F.3d at 692. Reverting to some previous REMS would be enormously disruptive. *See* ROA.9216 (Plaintiffs acknowledging that manufacturers "would need to . . . notify their prescribers to recertify"). Vacatur may require Danco to relabel its products, raising questions about existing product stock; it would require prescribers to get recertified to prescribe and dispense mifepristone, including the logistical set-up to do so; it would prevent brick-and-mortar pharmacies like Walgreens and CVS from handing the drug to a pharmacy customer who has a prescription in hand; it would trigger complex return and refund processes of product to

[14] As the District Court acknowledged, "the substance of the alleged deficiencies" in FDA's analysis, even if true, would "show only that the 2023 REMS was 'taken without sufficient consideration of the effects those changes would have on patients' due to a lack of underlying data." ROA.9116 (citation omitted). As a result, nothing about these asserted deficiencies would show that in-person dispensing "is scientifically necessary to ensure mifepristone is 'safe' and 'effective.'" *Id.* (citation omitted). Agencies, after all, can and do regularly make predictive judgments about scientific matters within their expertise on imperfect data. *Seven Cnty.*, 605 U.S. 168 at 182.

Danco by prescribers and pharmacies if they can no longer dispense mifepristone; and it would severely limit access to the drug in rural and underserved areas. And vacatur would force those changes nationwide even though FDA may soon conclude (again) that in-person dispensing is unnecessary and unduly burdensome—initiating yet another series of REMS changes.

Courts routinely hold vacatur unwarranted to avoid that kind of regulatory whipsaw. *See, e.g.*, *Cent. & S. W. Servs.*, 220 F.3d at 692; *Solar Energy Indus. Ass'n v. FERC*, 80 F.4th 956, 998 (9th Cir. 2023) (concluding agency erred but refusing to order vacatur because investments by "the regulated community" "might then need to be repeated if [the agency] were to readopt the rules"); *Cent. Maine Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001) (concluding agency erred but refusing to order vacatur given uncertainties from "[a]n on again-off again" change); *Massachusetts v. U.S. Nuclear Regul. Comm'n*, 924 F.2d 311, 336 (D.C. Cir. 1991) (concluding agency erred but refusing to order vacatur because it would "impos[e] an immensely disruptive interim status quo that may itself be displaced by the [agency's] subsequent reasoning").

III. THE EQUITABLE FACTORS WEIGH AGAINST GRANTING A PRELIMINARY INJUNCTION TO LOUISIANA.

Even setting the merits aside, the Supreme Court's stay order makes clear that Louisiana has not made the "clear showing" necessary for preliminary relief, *Starbucks*, 602 U.S. at 345, nor has it identified any abuse of discretion in the District Court's conclusion that the equities do not warrant preliminary relief here. The Supreme Court's "interim orders . . . inform how a court should exercise its equitable discretion." *Boyle*, 145 S. Ct. at 2654. And in considering a case that turns on the same equities, the Supreme Court has said that its stay decisions are "squarely controll[ing]." *Id.* By granting a stay in Danco's favor, the Supreme Court has unequivocally concluded that the equities favor Danco.[15] Plaintiffs cannot obtain the preliminary injunction that they seek.

A. Louisiana Has Not Demonstrated Irreparable Harm.

Plaintiffs' asserted harms merely rehash their flawed theories of standing. These theories fail for all the reasons described above, *supra* pp. 24-38—and certainly fall short of the "clear showing" of irreparable

[15] Like their standing arguments, Plaintiffs' equities arguments focus exclusively on harms to Louisiana. Br. 63-71. Plaintiffs have therefore waived any argument with respect to Ms. Markezich.

injury required for the "drastic remedy" that Plaintiffs seek. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (citation omitted); *see, e.g.*, *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 279 (5th Cir. 2012) (for preliminary injunction, threatened harm must be more than de minimis). Louisiana's alleged sovereign injuries are not cognizable at all, and therefore cannot establish that Louisiana is *likely* facing irreparable harm. And if the types of boundless claims of indirect financial injury Louisiana claims were enough to establish irreparable harm, states would *always* be entitled to an injunction if they can show a likelihood of success on the merits—contrary to the Supreme Court's repeated admonitions that courts should not conflate success on the merits and irreparable harm. *Winter v. NRDC*, 555 U.S. 7, 32 (2008) ("An injunction is a matter of equitable discretion; it does not follow from success on the merits as a matter of course.").

Louisiana's long delay in bringing suit undermines its claim that irreparable harm will befall the State without preliminary relief. Louisiana waited nearly *three years* after FDA approved the 2023 REMS—and almost *five years* after FDA first lifted the in-person dispensing requirement—to bring this lawsuit. That "years-long delay

in asking for preliminary injunctive relief weigh[s] against [Louisiana's] request." *Benisek v. Lamone*, 585 U.S. 155, 160 (2018) (per curiam); *see Texas v. EPA*, No. 23-60069, 2023 WL 7204840, at *11 (5th Cir. May 1, 2023) (per curiam) ("multi-year delay" "undercuts any claim that time is of the essence").

Louisiana's claim to impediments collecting data on mifepristone and to FDA's statement that the agency would independently reconsider the REMS are unavailing. Br. 67-68. The statistical report Louisiana relies on for its claim of impending harms has been published eight times since October 2022, so Louisiana had access to data on in-state abortions long before it brought this lawsuit in 2025. *See* Soc'y of Family Planning, #WeCount Reports, https://societyfp.org/research/wecount/wecount-reports/ (last visited July 15, 2026). Indeed, three similarly situated states sued years earlier. *See* Intervention Mot., *Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Nov. 11, 2023), ECF No. 151. Meanwhile, Louisiana's argument (at 68) about FDA's independent review cannot withstand scrutiny, because FDA announced its decision to review the REMS in 2025—years after Louisiana allegedly began to

suffer its injuries. And Louisiana did not wait for FDA to complete its review before bringing this lawsuit in any event.

If anything, FDA's ongoing review undercuts Louisiana's claimed need for a sweeping injunction. As Louisiana itself concedes, FDA has committed to reviewing the 2023 REMS and considering the kinds of concerns Louisiana seeks to raise in this lawsuit. Br. 68; *see* ROA.2717. In FDA's words, this "review may eliminate the need for the Court's" intervention—presumably because the agency might re-impose the kinds of restrictions Louisiana is seeking or might analyze the underlying data in a way that would satisfy the State. ROA.2724.

B. Danco Faces Substantial, Certain, Unrecoverable Harm.

Danco—like all pharmaceutical manufacturers—is subject to a complex regulatory regime. Based on FDA's representations in the *Alliance* litigation, Danco understands that it faces enforcement risk if it distributes Mifeprex without an approved REMS. ROA.2783-2785. At the very least, because no court has ever enjoined an approved REMS (other than the stay panel, whose order was quickly stayed by the Supreme Court within one business day), Danco faces substantial uncertainty about what its obligations would be if a court granted

Plaintiffs' requested relief, which could include revising product labels, packaging, and promotional materials; recertifying providers; and amending its supplier- and distributor-contracts and policies, among other things. *See* ROA.8900-8903 (FDA's sworn declaration in the Supreme Court in *Alliance* that an old REMS does not just "snap back" to some prior version). Yet Danco's failure to comply with those obligations would risk severe penalties, including potential criminal liability. *See* 21 U.S.C. § 333 (imposing criminal and civil penalties for misbranded prescription drugs).

Mifeprex is Danco's *only* product. Impairment of Danco's ability to distribute that product thus threatens Danco's only source of revenue and its continued operations. ROA.2782, 2786. Such harm is irreparable. *See Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 765 (2021) (per curiam) (recognizing "risk of irreparable harm" from "significant financial cost[s]" and loss of "elements of property ownership"); *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (financial costs that threaten the "very existence of" business are irreparable injury) (citation omitted). Because Danco sells no other products, it goes well beyond a run-of-the-mill business expense. *Contra* Br. 63.

Plaintiffs are wrong that Danco's supposed "real fear" is lower sales in anti-abortion states. *Contra* Br. 63-66. Because the FDCA does not envision or permit different drug approvals or REMS in different states, the threat Danco faces is the inability to sell its product in *any state*—including ones that take a different approach to abortion than Louisiana. That risk poses an existential threat to Danco.

C. The Public Interest Weighs Against Granting Extraordinary Relief To Louisiana.

1. The public interest overwhelmingly favors denying preliminary relief. As an initial matter, the public interest favors denial because the 2023 REMS is lawful and adequately supported by the evidence. *Supra* pp. 43-50; Reproductive Health Researchers SCOTUS Br. 4; Food & Drug Law Scholars SCOTUS Br. 2-4; Fmr. FDA Comm'rs SCOTUS Br. 7. As FDA explains on its website, "Mifepristone is safe" under the current REMS. FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (Apr. 8, 2026), https://perma.cc/UCX4-AFQM; *see* Fmr. FDA Comm'rs SCOTUS Br. 9; ACOG SCOTUS Br. 7-13; Physicians for Reproductive Health SCOTUS Br. 6-14. If FDA were to reverse course and conclude that mifepristone poses a health risk despite the REMS, FDA has tools

to respond, like initiating label changes or directing Danco to submit a new proposed REMS. 21 U.S.C. §§ 355(o)(4), 355-1(g)(4)(B). That FDA has not done so necessarily reflects the agency's judgment that the current REMS ensures mifepristone's benefits outweigh its risks while "minimiz[ing] the burden on the health care delivery system." *See id.* § 355-1(g)(2)(C), (g)(4)(B).

2. The public interest also favors denial because any injunction would have consequences that extend beyond this case. An order enjoining the REMS would inject profound and structural uncertainty into the pharmaceutical industry, "broadly undermining patients' access to medicine." PhRMA SCOTUS Br. 2, 8. "Opening the door to state-by-state second-guessing of drug regulation would place [drug] sponsors in an untenable position between potentially conflicting state positions," "threatening the substantial investments necessary to sustain innovation in the biopharmaceutical sector" and "destabiliz[ing] the regulatory framework that underpins the development and marketing of safe and effective medicines." *Id.* at 3-4, 14.

The injunction Louisiana seeks would also harm women across the nation by imposing medically unnecessary barriers to access a drug that

is the standard of care for "medication abortion and miscarriage management" and that for decades "has been found safe and effective when used for abortion care and miscarriage management, *regardless of whether it is dispensed in person*." ACOG SCOTUS Br 2-3. Hospitals, clinics, and patients have long relied on telemedicine in prescribing mifepristone, particularly for women from rural areas and those who face barriers accessing providers in person. *See* 21 U.S.C. § 355-1(f)(2)(C) (obligating FDA to ensure that REMS are not "unduly burdensome on patient access to the drug"); *id.* § 355-1(g)(4)(B)(ii) (modification appropriate to "minimize the burden on the health care delivery system of complying with the" REMS); *see also* Disability Rights Educ. & Def. Fund SCOTUS Br. 12-13 (enjoining the REMS would functionally exclude many disabled people from accessing mifepristone altogether). Enjoining the 2023 REMS would significantly limit those patients' ability to obtain mifepristone in the time-sensitive fashion this context demands—including in states and localities far from Louisiana that have chosen different policies. New York SCOTUS Br. 13-14; Local Gov't SCOTUS Br. 14-15. Such a deprivation of "necessary medical care"

thwarts the public's interest. *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759-760 (5th Cir. 2018) (per curiam).

3. It is also not in the public interest for federal courts to sit as super-legislatures deciding between states' competing policy views. Louisiana favors an abortion ban. But as 22 states and the District of Columbia told the Supreme Court, the stay panel's order "improperly elevated the policy preferences of States that have banned or restricted abortion over the preferences of other States that have made the different but equally sovereign determinations to promote access to abortion care." New York SCOTUS Br. 16. Danco, unlike Louisiana, does not ask the Court to arbitrate a policy dispute. It simply asks the Court to allow FDA's regulatory process to operate as Congress has instructed.

The District Court is correct that Plaintiffs seek unprecedented and nationwide relief in a "rushed, high-stakes, [and] low-information" posture. ROA.9115 (quoting *CASA*, 606 U.S. at 855-856, in turn quoting *Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 927 (2024) (Gorsuch, J., concurring in grant of stay)). It was also correct that courts do not possess "the expertise to evaluate scientific evidence and make public health judgments." ROA.9116-9117 & n.19 (citing *ACOG,* 141 S. Ct. at

578-579 (Roberts, C.J., concurring in grant of application for stay) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" (citation omitted)), and *Cytori*, 715 F.3d at 927 (Kavanaugh, J.) ("A court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard.")).

Presented with the same claims and the same equities, the Supreme Court stayed this Court's order enjoining the 2023 REMS. *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192 (2026). And the Supreme Court similarly halted the *Alliance* panel's order preliminarily enjoining the 2021 nonenforcement decisions. *Danco Lab'ys, LLC v. Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023). Those decisions necessarily reflect the Supreme Court's judgment that the equities favor denying preliminary relief. Plaintiffs are not entitled to a different result this time. *NIH*, 145 S. Ct. at 2663 (Gorsuch, J., concurring in part and dissenting in part) (a decision by the Supreme Court granting a stay "constitutes a precedent that commands respect in lower courts").

CONCLUSION

For the foregoing reasons, the Court should affirm the District Court's denial of preliminary relief to Plaintiffs, reverse the District Court's denial of Danco's motion to dismiss, and remand with instructions to dismiss Plaintiffs' complaint.

Respectfully submitted,

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July 15, 2026

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STATUTORY ADDENDUM

21 U.S.C. § 355-1. Risk evaluation and mitigation strategies (excerpts)

***

(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable

***

(2) Assuring access and minimizing burden

Such elements to assure safe use under paragraph (1) shall—

(A) be commensurate with the specific serious risk listed in the labeling of the drug;

(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

(C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

(i) patients with serious or life-threatening diseases or conditions;

(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

(iii) patients with functional limitations; and

(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

(i) conform with elements to assure safe use for other drugs with similar, serious risks; and

(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

***

(5) Evaluation of elements to assure safe use

The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) or other advisory committee of the Food and Drug Administration, shall—

(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be—

(i) unduly burdensome on patient access to the drug; and

(ii) to the extent practicable, minimize 2 the burden on the health care delivery system;

(B) periodically evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

(i) assure safe use of the drug;

(ii) are not unduly burdensome on patient access to the drug; and

(iii) to the extent practicable, minimize the burden on the health care delivery system; and

(C) considering such input and evaluations—

(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

(ii) modify elements under this subsection for 1 or more drugs as appropriate.

***

(g) Assessment and modification of approved strategy

(1) Voluntary assessments

After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to

paragraph (2), submit to the Secretary an assessment of the approved strategy for the drug involved at any time.

(2) Required assessments

A responsible person shall submit an assessment of the approved risk evaluation and mitigation strategy for a drug—

***

(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that an assessment is needed to evaluate whether the approved strategy should be modified to—

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

(3) Requirements for assessments

An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

(4) Modification

(A) On initiative of responsible person

After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

(B) On initiative of Secretary

After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug;

(ii) minimize the burden on the health care delivery system of complying with the strategy; or

(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 355(j) of this title, and the applicable listed drug.

***

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2026, I electronically filed the foregoing using the CM/ECF system, which will send notification of this filing to the attorneys of record.

/s/ Jessica L. Ellsworth
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No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

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Ms. Lisa Newman
Ms. Daphne O'Connor
Mr. Allan Edward Parker Jr.
Ms. Dana A. Raphael
Ms. Jo-Ann Tamila Sagar
Ms. Linda Boston Schlueter
Ms. Clara Simone Spera
Mr. Mathew D. Staver
Ms. Danielle Desaulniers Stempel
Ms. Olivia F. Summers
Mr. David H. Thompson
Ms. Maria Michelle Uzeta
Mr. John Marc Wheat
Mrs. Hadiya Williams
Mr. Daniel Winik
Ms. Megan Marie Wold
Mr. Daniel W. Wolff