No. 26-30203

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FIFTH CIRCUIT**

STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL; ROSALIE MARKEZICH,
*Plaintiffs-Appellants/Cross-Appellees*,

*v.*

U.S. FOOD AND DRUG ADMINISTRATION; KYLE DIAMANTAS, Acting Commissioner, U.S. Food and Drug Administration; MICHAEL DAVIS, in 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; 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 (Hon. David C. Joseph)

# REPLY BRIEF OF APPELLEE/CROSS-APPELLANT GENBIOPRO, INC.

John Adcock
ADCOCK LAW LLC
Louisiana Bar No. 30372
8131 Oak Street, Ste. 100
New Orleans, LA 70118
(504) 233-3125

John P. Elwood
Daphne O'Connor
Robert J. Katerberg
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Ave., N.W.
Washington, D.C. 20001
(202) 942-5000

*Counsel for Intervenor-Appellee/Cross-Appellant GenBioPro, Inc.*

## CERTIFICATE OF INTERESTED PERSONS

Intervenor-Appellee GenBioPro, Inc. 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. **Plaintiffs-Appellants/Cross-Appellees:**

   The State of Louisiana, by and through its Attorney General, Liz Murrill

   Rosalie Markezich

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

   Liz Murrill, Attorney General

   J. Benjamin Aguinaga, Office of the Louisiana Attorney General

   Caitlin Ann Huettemann, Office of the Louisiana Attorney General

   Dalton A. Nichols, Alliance Defending Freedom

   Erik C. Baptist, Alliance Defending Freedom

   Erin Morrow Hawley, Alliance Defending Freedom

   Frank W. Basgall, Alliance Defending Freedom

   Gabriella M. McIntyre, Alliance Defending Freedom

   Julie Marie Blake, Alliance Defending Freedom

   Michael T. Johnson, Johnson Siebeneicher & Ingram

3. **Defendants-Appellees:**

   U.S. Food and Drug Administration

   Martin Makary, M.D., in his official capacity as Commissioner of

Food & Drugs, U.S. Food & Drug Administration

Kyle Diamantas, in his official capacity as Acting Commissioner of Food & Drugs, U.S. Food & Drug Administration

Tracy Beth Høeg, M.D., Ph.D., in her official capacity as Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Michael Davis, in his official capacity as Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

U.S. Department of Health & Human Services

Robert F. Kennedy, Jr., in his official capacity as Secretary, U.S. Department of Health & Human Services

**4. Counsel for Defendants-Appellees:**

Daniel Winik, U.S. Department of Justice, Civil Division, Appellate Staff

Noah T. Katzen, U.S. Department of Justice, Civil Division, Federal Programs Branch

Brett A. Shumate, U.S. Department of Justice, Assistant Attorney General, Civil Division

James W. Harlow, U.S. Department of Justice, Civil Division, Federal Programs Branch

Andrew M. Bernie, U.S. Department of Justice

**5. Intervenor-Appellee/Cross-Appellant:**

GenBioPro, Inc.

Xenia Holdco LLC (parent company of GenBioPro, Inc.)

**6. Counsel for Intervenor-Appellee/Cross-Appellant GenBioPro, Inc.:**

John N. Adcock, Adcock Law

John P. Elwood, Arnold & Porter Kaye Scholer LLP

Daphne O'Connor, Arnold & Porter Kaye Scholer LLP

Robert J. Katerberg, Arnold & Porter Kaye Scholer LLP

Carrie Y. Flaxman, Democracy Forward Foundation

Lisa Nicole Newman, Democracy Forward Foundation

Skye Lynn Perryman, Democracy Forward Foundation

**7. Intervenor-Appellee/Cross-Appellant:**

Danco Laboratories LLC

Danco Investors Group LP

**8. Counsel for Intervenor-Appellee/Cross-Appellant Danco Laboratories LLC**:

Alexander Vladimir Sverdlov, Hogan Lovells Cadwalader US LLP

Dana A. Raphael, Hogan Lovells Cadwalader US LLP

Danielle Desaulniers Stempel, Hogan Lovells Cadwalader US LLP

Jessica L. Ellsworth, Hogan Lovells US Cadwalader LLP

Jo-Ann Tamila Sagar, Hogan Lovells US Cadwalader LLP

Katherine T. McKay, Hogan Lovells US Cadwalader LLP

William Brock Most, Most & Associates

**9. Third Party Manufacturer:**

Evita Solutions LLC

**10. Amici and Counsel:**

100 Reproductive Health Rights & Justice Organizations

Jessica Ring Amunson

Mary Marshall
Varsha Midha
Jenner & Block (DC)
1099 New York Ave. NW, Ste. 900
Washington, DC 20001

Jamila Asha Johnson
Lawyering Project
900 Camp St. 3rd Floor, Ste. 1197
New Orleans, LA 70130

Emily Merrifield
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654

60 Plus Association

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 Actions

Centennial Institute at Colorado Christian University

Center for Urban Renewal & Education

Christian Law Association

Christian Medical & Dental Associations

Democrats for Life

Eagle Forum

Family Council in Arkansas

Family Foundation of Virginia

Family Institute of Connecticut Action

Fran Bevan

Frontline Policy Council

Human Coalition

International Conference of Evangelical Chaplain Endorsers

Tim Jones Former Speaker, Missouri House, Founder, Leadership for America Institute

Alveda King

Louisiana Family Forum

Lutheran Center for Religious Liberty

Maryland Family Institute

Men & Women for a Representative Democracy in America, Inc.

Men for Life

Calum Miller

National Religious Broadcasters

National Right to Life

New York State Conservative Party

North Carolina Values Coalition

Melissa Ortiz

Principal & Founder, Capability Consulting

Phyllis Schlafly's Pennsylvania Eagle Forum

Priests for Life

Rick Santorum

Gregory P. Seltz

Executive Director, LCRL, Speaker Emeritus, The Lutheran Hour

Paul Stam

Former Speaker Pro Tem, NC House of Representatives

Kathy Szeliga

Delegate District 7 A, Vice Chair of the Maryland Freedom Caucus

Suzi Voyles

President, Eagle Forum of Georgia

Wagner Center

Wisconsin Family Action, Inc.

Women for Democracy in America, Inc.

Young America's Foundation

Ben E. Clayton
Clayton Law Firm (Slidell)

893 Brownswitch Rd., Ste. 101
Slidell, LA 70458

Advancing American Freedom, Inc.

Ben E. Clayton
Clayton Law Firm (Slidell)
893 Brownswitch Rd. Ste. 101
Slidell, LA 70458

John Marc Wheat
Advancing American Freedom
801 Pennsylvania Ave. NW, Ste. 930
Washington, DC 20004

American Association of Pro-Life Obstetricians & Gynecologists

Family Research Council

Samaritan's Purse

Martha Shuping

Brian Wade Arabie
Sigler Arabie & Cannon
P.O. Box 1550
Lake Charles, LA 70602

Christopher E. Mills
Spero Law
557 E. Bay St., Ste. 22251
Charleston, SC 29413

American Center for Law and Justice

Olivia F. Summers
American Center for Law & Justice
201 Maryland Ave. NE
Washington, DC 20002

Kevin S. Vogeltanz
Law Office of Kevin S. Vogeltanz
428 W. 21st Ave.
Covington, LA 70433

American College of Obstetricians and Gynecologists

Society of Maternal-Fetal Medicine

American Academy of Family Physicians

American College of Physicians

American College of Preventative Medicine

American Gynecological and Obstetrical Society

American Society of Reproductive Medicine

North American Society of Pediatric Adolescent Gynecology
Society of Adolescent Health and Medicine

Society of General Internal Medicine

Council of University Chairs of Obstetrics & Gynecology

Society of Gynecologic Oncology

Society of Gynecologic Surgeons

Society of OB/GYN Hospitalists

America Medical Women's Association

Meaghan Hannan Davant
Molly A. Meegan
American College of Obstetricians & Gynecologists
409 12th St. SW Washington, DC 20024

Malcolm Clark Lloyd

ACLU of Louisiana
1340 Poydras St., Ste 2160
New Orleans, LA 70112

Nicole Amanda Marton
Debevoise & Plimpton (DC)
801 Pennsylvania Ave. NW, Ste. 500
Washington, DC 20004

Kathryn Campbell Saba
Shannon Rose Selden
Debevoise & Plimpton (NY)
66 Hudson Blvd.
New York, NY 10001

States of Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington

Letitia James, Attorney General
Barbara D. Underwood, Solicitor General
Ester Murdukhayeva, Deputy Solicitor General
Galen Leigh Sherwin, Special Counsel for Reproductive Justice
Attorney General of NY (NYC)
28 Liberty St. New York, NY 10005

Jacob Kennedy Weixler
Weixler Law
3640 Magazine St.
New Orleans, LA 70115

States of Nebraska, Alabama, Alaska, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Mississippi, Missouri, Montana, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming

Cody S. Barnett
Attorney General of NE
1445 K St., Rm. 2115

Lincoln, NE 68508

Rachel Thyre Vogeltanz
Law Office of Rachel Vogeltanz
428 W. 21st Ave.
Covington, LA 70433

Former Commissioners and Acting Commissioners of the U.S. FDA Robert M. Califf, Michael A. Friedman, Margaret Hamburg, Jane E. Henney, David A. Kessler, Stephen Ostroff, Joshua M. Sharfstein, Norman E. Sharpless, and Janet A. Woodcock.

Salvador I. Bivalacqua
Mandie E. Landry
Bivalacqua Gele Ellis
650 Poydras St., Ste. 2200
New Orleans, LA 70130

Margaret M. Dotzel
Alyssa Howard
William B. Schultz
Zuckerman Spaeder (DC)
2100 L St. NW, Ste. 400
Washington, DC 20037

Center Against Forced Abortions

Justice Foundation

National Association of Christian Lawmakers

Women Injured by Abortion

Mary Jane Browning
Allan E. Parker, Jr.
R Clayton Trotter
Justice Foundation
8023 Vantage Dr., Ste. 1275
San Antonio, TX 78230

Hunter W. Lundy
Lundy Law
P.O. Box 3010
Lake Charles, LA 70602

Troy Houston Middleton, IV
Lundy Law (LC)
501 Broad St.
Lake Charles, LA 70601

Concerned Women for America

Ben E. Clayton
Clayton Law Firm (Slidell)
893 Brownswitch Rd., Ste. 101
Slidell, LA 70458

Mario Alberto Diaz
Concerned Women for America
1000 N. Payne St.
Alexandria, VA 22314

60 Members of Congress

Heather Gebelin Hacker
Hacker Stephens
108 Wild Basin Rd. S, Ste. 250
Austin, TX 78746

Joseph Scott St. John
St. John LLC
1701 Jefferson Ave., 7th Fl.
New Orleans, LA 70115

Disability Rights Education & Defense Fund

Kristen Diane Amond
Amond Law
3640 Magazine St.
New Orleans, LA 70115

Chloe Marie Chetta
Barrasso Usdin et al. (NO)
909 Poydras St., Ste. 2350
New Orleans, LA 70112

Elizabeth Renee June
Allen Overy Shearman Sterling US LLP
1101 New York Ave. NW
Washington, DC 20005

Mallory Tosch Hoggatt
Allen Overy Shearman Sterling US LLP
800 Capitol St., Ste. 2200
Houston, TX 77002

Maria Michelle Uzeta
Disability Rights Education & Defense Fund
3075 Adeline St., Ste. 210
Berkeley, CA 94703

Ethics and Public Policy Center

Michelle Ward Ghetti
Ghetti Law
139-B James Comeaux Rd., Ste. 802
Lafayette, LA 70508

Martin Edward Whelan, III
Ethics & Public Policy Center
1730 M St. NW, Ste. 910
Washington, DC 20036

Carol Everett, Tammi Morris, Monty Patterson, and Leslie Wolbert

Brian Wade Arabie
Sigler Arabie & Cannon
P.O. Box 1550
Lake Charles, LA 70602

Former U.S. Department of Justice Officials Leslie Caldwell, Michael W. Cotter, Edward L. Dowd Jr., Jamie S. Gorelick, Dwight C. Holton, William C. Killian, James A. Lewis, Kenneth Magidson, Denise E. O'Donnell, David W. Ogden, Sarah R. Saldana, Anne Tompkins, John W. Vaudreuil, John F. Walsh, Seth P. Waxman

Arielle Kay Herzberg
Wilmer Cutler et al. (CO)
1225 17th St Ste 2600
Denver, CO 80202

Kimberly Ari Parker
Wilmer Cutler et al.
2100 Pennsylvania Ave. NW
Washington, DC 20037

Richard Gerard Perque
Law Office of Richard G Perque
700 Camp St.
New Orleans, LA 70130

Alan Evan Schoenfeld
Wilmer Cutler et al. (10007)
250 Greenwich St.
New York, NY 10007

Kyle Edwards Haugh
CA Dept of Justice
455 Golden Gate Ave., Ste. 11000
San Francisco, CA 94102

Heartbeat International, Inc.

Brennan Tyler Brooks
Thomas More Society
309 W. Washington St., Ste. 1250
Chicago, IL 60606

Charles Kenneth Cicero, III
Cicero Law

205 Holiday Blvd., Ste. 100
Covington, LA 70433

Danielle Merry White
Heartbeat International, Inc.
8405 Pulsar Pl., Ste. 100
Columbus, OH 43240

IGH PLLC

Hey Jane

The Reproductive Health Initiative for Telehealth Equity & Solutions

Sapna Khatri
Boston University School of Law
765 Commonwealth Ave., 9th Fl.
Boston, MA 02215

Meghan K. Matt
Murrell Law Firm
4005 St Claude Ave.
New Orleans, LA 70117

Medical Students for Choice

Kathryn Coniglio Arnett
Charlotte Vida Baigent
Jayme Alyse Jonat
Katharine Gene Zeigler
Holwell Shuster & Goldberg
425 Lexington Ave.
New York, NY 10017

Alexandra DiBiase Moody
Lift Louisiana
2831 St. Claude Ave. #203
New Orleans, LA 70117

National Domestic Violence Hotline

Legal Voice

Robin Michelle Turner
Legal Voice
P.O. Box 582 Missoula, MT 59806

Rebekka C. Veith
Miller Thibodeaux et al.
643 Magazine St., Ste. 405
New Orleans, LA 70130

Students For Life of America

L. Katie Buckner
Students for Life of America
1000 Winchester St., Ste. 301
Fredericksburg, VA 22401

R. Bradley Lewis
Law Office of R. Bradley Lewis
248 Richmond St. Bogalusa, LA 70427

Women and Families Harmed by Mifepristone

Former Abortion Providers

Linda Boston Schlueter
Trinity Legal Center
1150 N. Loop 1604 W., Suite 108-208
San Antonio, TX 78248

Brian W. Arabie
Sigler Arabie & Cannon, LLC
630 Kirby Street (70601)
P.O. Box 1550 (70602)
Lake Charles, LA

Dr. Calum Miller

Ben E. Clayton
Suite No. 101
893 Brownswitch Road
Slidell, Louisiana 70458

North Carolina Values Institute

World Faith Foundation
Deborah J. Dewart
Debbie Dewart, Attorney at Law
111 Magnolia Lane
Hubert, North Carolina 28539

National Institute of Family and Life Advocates
Allan E. Parker
R. Clayton Trotter
Mary J. Browning
The Justice Foundation
8023 Vantage Drive, Suite 1275
San Antonio, Texas 78230

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

Christ Medicus Foundation

Catholic Health Care Leadership Alliance

National Catholic Partnership on Disability

Texas Alliance for Life

Texas for Life Coalition

Heather Gebelin Hacker
Hacker Stephens LLP
108 Wild Basin Road South Suite 250
Austin, Texas 78746

National Hispanic Christian Leadership Conference

Douglass Leadership Institute

Mathew D. Staver
Horation G. Mihet
Daniel J. Piedra
Liberty Counsel
P.O. Box 540774
Orlando, Florida 32854

Dr. Grazie Pozo Christie

Catholic Association Foundation

David H. Thompson
Megan M. Wold
Cooper & Kirk, PLLC
1523 New Hampshire Ave., N.W.
Washington, D.C. 20036

NAACP Legal Defense and Educational Fund, Inc.

Pilar Whitaker
NAACP Legal Defense and Educational Fund, Inc.
700 14th Street NW, Suite 600
Washington, DC 20005

Arielle Humphries

NAACP Legal Defense and Educational Fund, Inc.
40 Rector Street, Fifth Floor
New York, NY 10006

Local Governments and Local Government Leaders

Jenny Ma
Kyriaki Council
Eliana Greenberg
Public Rights Project
490 43rd Street, #115
Oakland, CA 94609

168 Reproductive Health, Rights, and Justice Organizations

Jessica Ring Amunson
Varsha Midha
Jenner & Block LLP
1099 New York Ave NW, Suite 900
Washington, DC 20001

Emily Merrifield
Sara Stappert
Jenner & Block LLP
353 N. Clark Street
Chicago, IL 60654

FemInEM Foundation

American College of Emergency Physicians

American Academy of Emergency Medicine

Emergency Medicine Residents' Association

Leah R. Bruno
Emily D. Steeb
Mary Strong
Dentons US LLP
233 South Wacker Drive, Suite 5900

Chicago, IL 60606

159 Professors, Health Organizations, and Health Care Providers

Joseph R. Palmore
Elaine Hou
Morrison & Foerster LLP
2100 L Street NW, Suite 900
Washington, DC 20037

Daralyn J. Durie
Morrison & Foerster LLP
425 Market Street
San Francisco, CA 94105

Jamie A. Levitt
Morrison & Foerster LLP
250 West 55th Street
New York, NY 10019

Megan E. Baffaro
Morrison & Foerster LLP
John Hancock Tower
200 Clarendon Street, Floor 21
Boston, MA 02116

Carmel Dori Schachar
Center for Health Law and Policy Innovation
Harvard Law School
1585 Massachusetts Avenue
Cambridge, MA 02138

Physicians for Reproductive Health

Janice Mac Avoy
Laura Israel Sinrod
Anne S. Aufhauser
Kathryn Sachs
Fried, Frank, Harris, Shriver & Jacobson LLP
One New York Plaza

New York, NY 10004

Corinne R. Moini
Katherine S. Borchert
Fried, Franks, Harris Shriver & Jacobson LLP
801 Seventeenth Street, N.W.
Washington, D.C. 20006

322 Reproductive Health Researchers

Amanda Barrow
Cathren Cohen
Sofia Espinoza
Melissa Goodman
Diana Kasdan
Center on Reproductive Health, Law, and Policy
UCLA School of Law
1060 Veteran Avenue
Los Angeles, CA 90095

Leah Godesky
O'Melveny & Myers LLP
1999 Avenue of the Stars 8th Floor
Los Angeles, CA 90067

Alexander N. Ely
Joshua A. Jordan
Doménica A. Merino
Quynhanh Tran
O'Melveny & Myers LLP
1625 Eye Street NW
Washington, DC 20006

Food and Drug Law Scholars and Professors

Lewis A. Grossman
Denise Esposito
Robert A. Long
Julia F. Post
Beth E. Braiterman

Guillaume A. Julian
Covington & Burling LLP
One CityCenter 850 Tenth Street, NW
Washington, DC 20001

438 State Legislators

Amanda Shafer Berman
Crowell & Moring LLP
600 Fifth Street, NW
Washington, D.C. 20001

Former Military Officials

Former Civilian National Security Leaders

Vet Voice Foundation

Madeline Verniero
Hecker Fink LLP
350 Fifth Avenue, 63rd Floor
New York, New York 10118

Katherine Epstein
Hecker Fink LLP
1050 K Street, NW, Suite 1040
Washington, D.C. 20001

259 Members of Congress

Abby F. Rudzin
O'Melveny & Myers LLP
1301 Avenue of the Americas
New York, NY 10019

Nancy L. Schroeder
O'Melveny & Myers LLP
400 S. Hope Street
Los Angeles, CA 90071

Keith S. Osentoski
O'Melveny & Myers LLP
1999 Avenue of the Stars
Los Angeles, CA 90067

Institute for Policy Integrity at New York University School of Law

Max Sarinsky
Katherine Welty
Institute for Policy Integrity
139 MacDougal Street, 3rd Floor
New York, NY 10012

Information Society Project at Yale Law School

Yael H. Caplan
Genevieve E. Scott
Priscilla J. Smith
Eva Frankel
Katharine Boasberg
Sarah Z. Rosen
Yale Law School
319 Sterling Place
Brooklyn, New York 11238

Pharmaceutical and Biotech Companies, Executives, and Investors

Michael F. Qian
Wilson Miller
Haynes and Boone, LLP
2801 N. Harwood St., Ste. 2300
Dallas, TX 75201

Allison Regan
Haynes and Boone, LLP
675 15th St., Ste. 2200
Denver, CO 80202

Chelsea Corey
Haynes and Boone, LLP

650 S. Tryon Street, Ste. 700
Charlotte, NC 28202

Brian P. Matthews
Alexandra Larkin
Haynes and Boone, LLP
30 Rockefeller Plaza, 22nd Fl.
New York, NY 10112

Honeybee Health, Inc.

Eugene M. Gelernter
Hilarie M. Meyers
Hadiya Williams
Jillian F. Horowitz
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, New York 10036

Doctors for America

Janet K. Levit
Reproductive Justice Practicum
The University of Tulsa College of Law
3120 E. 4th Place
Tulsa, OK 74104

Thomas S. Leatherbury
Thomas S. Leatherbury Law, PLLC
Cumberland Hill School Building
1901 N. Akard St
Dallas, TC 75201

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, JD, Assistant Professor, Stetson University College of Law

Ruth Colker, Distinguished University Professor and Heck Faust Memorial Chair in Constitutional Law at Moritz College of Law, Ohio State University

Tony Coelho, former U.S. Congressman, Founder of The Coelho Center for Disability Law, Policy, and Innovation

Katherine Pérez, PhD, JD, Independent Disability Rights Scholar

Maria Michelle Uzeta
Disability Rights Education and Defense Fund
3075 Adeline Street, Suite 210
Berkeley, CA 94703

/s/ *John P. Elwood*
John P. Elwood

*Counsel for Intervenor-Appellee/ Cross-Appellant GenBioPro, Inc.*

# TABLE OF CONTENTS

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## Cases

**Other Authorities**

## INTRODUCTION

This case is fundamentally flawed because Louisiana lacks standing. Louisiana objects to abortions in Louisiana using mifepristone prescribed by out-of-state providers, and to other States' refusal to assist Louisiana in prosecuting those providers. But Article III does not permit a State to convert its disputes with third parties into a federal case against an agency that regulates someone else. That principle is especially important here, where Louisiana seeks to use its claimed downstream injuries to alter the conditions governing an FDA-approved drug nationwide.

Louisiana's reply confirms that it lacks any cognizable injury traceable to FDA's determination that mifepristone need not be dispensed in-person at a clinic or hospital to ensure its safe use. Each of Louisiana's asserted economic and sovereign injuries depends on an attenuated chain of independent choices by parties not before this Court—out-of-state prescribers, pharmacies, patients, and other States. Louisiana responds that those choices are "predictable"—a bare assertion that Louisiana never backs up and erroneously describes FDA as having "concede[d]." *See* Reply (Doc. 371) at 8, 17. What FDA's brief actually says, however, is that "[*e*]*ven assuming* Louisiana's costs were completely predictable, these sorts of ripple effects of government action are simply too far removed from the action to establish standing to challenge it." FDA Br. (Doc. 245) at 28 (cleaned up) (emphasis

added). Indeed, even if these choices were "predictable," the Supreme Court made clear in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) ("*Alliance*"), that Article III requires *more* than predictability. *Id.* at 383. Just like in *Alliance*, Louisiana's purported injuries are "too far removed" from the challenged government action to support standing. *Id.*

Unable to satisfy conventional Article III requirements, Louisiana stakes its claim to standing on the strained theory that it was the "target" or "object" of FDA's determination that in-person dispensing is unnecessary for safe use—a theory Louisiana calls "central" to its standing. Reply 13. But this is not an "object" case. Unlike the fuel producers in *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), whose injury flowed from a regulation where "the whole point" was to restrict use of their product, *id.* at 114, Louisiana claims no injury that flows so directly from the challenged action. The 2023 REMS is a safety-and-access regulation governing pharmaceuticals. And it carries forward a policy that this Court previously emphasized had been in place since 2021. *See All. for Hippocratic Med. v. FDA* (*AHM I*), No. 23-10362, 2023 WL 2913725, at *13-14 (5th Cir. Apr. 12, 2023); *All. for Hippocratic Med. v. FDA* (*AHM II*), 78 F.4th 210, 255 (5th Cir. 2023) (stating that by the end of 2021 FDA "was committed to implementing" the policy). That was before *Dobbs* and before Louisiana had enforceable laws to "target."

Louisiana's misleading and irrelevant citations to political statements criticizing *Dobbs*—statements made years *after* FDA had stopped enforcing the in-person dispensing requirement—cannot transform FDA's determination into action targeting particular States. And even if they could, "targeting" is not an exemption from Article III. Louisiana still must identify a cognizable injury caused by the challenged REMS and likely redressed by the requested relief. *Diamond* did not hold otherwise.

Louisiana's targeting theory fails on its own terms and, in any event, does not cure the defects in its asserted injuries. Under controlling precedent, States cannot challenge a federal regulation of third parties by pointing to alleged violations of state law by other third parties. It does not change things if the State claims—under the invented label of "functional preemption" (Reply 30)—that the federal policy does not displace Louisiana laws but (in conjunction with other states' laws) simply makes them more difficult to enforce. The Ninth Circuit rejected essentially the same theory in *Washington v. FDA*, 108 F.4th 1163, 1176-77 (9th Cir. 2024). Nor can States recast policy disagreements as pocketbook injuries based on attenuated downstream expenditures they claim are indirectly influenced by the federal policy. Over twenty States, hundreds of legislators, nine former FDA Commissioners, medical associations representing hundreds of thousands of physicians, and pharmaceutical industry groups have all weighed in as amici to explain why that

theory is untenable—and why accepting it would destabilize federal regulation across countless policy domains.

Because Louisiana cannot establish standing under settled Article III principles, the district court erred in holding that it could, and this Court should reverse and remand with instructions to dismiss.

## ARGUMENT

Louisiana does not dispute that the appeal of GBP's motion to dismiss is properly before this Court and that, if this Court agrees that Louisiana lacks standing, the only available course is to remand with instructions to dismiss. GBP Br. (Doc. 247) at 66-68. Louisiana cannot establish standing, so the case must be dismissed.

### I. LOUISIANA'S "TARGETING" THEORY FAILS TO ESTABLISH STANDING

Louisiana's "central" theory (Reply 13) is that the REMS was designed to circumvent Louisiana's abortion restrictions, and thus that Louisiana *necessarily* has established causation and redressability. But Louisiana's targeting theory is irreconcilable with controlling precedent, premised on a misreading of *Diamond*, and unsupported by the preliminary record.

#### A. *Diamond* Does Not Hold that Standing is Automatic for the "Object" or "Target" of Regulation

Louisiana's case hinges on *Diamond*, but the case does not do the work Louisiana assigns it. *Diamond* did not hold that anyone whom the government knows will be affected (or even allegedly intends to affect) becomes an "object" of

regulation—or that being an "object" is sufficient for standing. The Court held only that the fuel producers there "might be considered" objects of California's regulations because those regulations "explicitly" sought to restrict the use of the very product the fuel producers sold. 606 U.S. at 114-15. But the Court expressly declined to resolve even that question, holding that the fuel producers had standing under the ordinary causation and redressability principles that Louisiana cannot satisfy. *Id.* at 116.

That point alone is fatal to Louisiana's reliance on *Diamond*. The Court did not treat "target" or "object" status as *bypassing* Article III causation and redressability. It expressly declined to decide whether the fuel producers were "objects" of the regulation, *id.*, and instead held that ordinary standing principles were satisfied because the challenged rules would predictably reduce purchases of the producers' own product and thereby reduce their revenues, *id.* at 112-18. Louisiana must likewise establish that its asserted injuries are sufficiently direct consequences of the 2023 REMS. Post hoc political statements about state policies cannot supply the missing causal connection.

*Diamond*'s facts confirm that its rationale does not support Louisiana. California's regulations required automakers to "manufacture more electric vehicles and fewer gasoline-powered vehicles." *Id.* at 104. Their "entire purpose"—their "whole point"—was to reduce the use of gasoline and other liquid fuels. *Id.* at 112-

14. The fuel producers' claimed injury arose directly from that explicit objective: Requiring automakers to produce fewer gasoline-powered vehicles predictably meant fewer gasoline sales and thus less revenue for fuel producers. *Id.*

With that direct connection in mind, the Supreme Court explained that a plaintiff can sometimes be the "object" of regulation even though another entity is the one *named* in the regulation. "When the government prohibits or impedes Company A from using Company B's product," the Court explained, "then both Company A and Company B might be deemed objects of the government action." *Id.* at 115. Thus, "[i]f the government bans bookstores from selling certain publishers' books, then those publishers, not just bookstores, might be objects of the regulation." *Id.* The same logic applied to the fuel producers: California regulated automakers at the assembly line precisely to suppress use of the fuel producers' product at the gas pump.

Nothing comparable is true here. The 2023 REMS regulates manufacturers, prescribers, and pharmacies nationwide, including in the states where abortion is legal. It imposes no obligation on Louisiana and restricts no product or service Louisiana sells or provides. And Louisiana's asserted economic injuries—Medicaid expenditures and investigative costs—are not the direct result of any regulatory transaction created by the REMS. They arise, if at all, only after numerous

intervening independent decisions by third parties—including to prescribe, ship, use, seek medical treatment, and submit claims for reimbursement.

### B. Assorted Political Statements Do Not Transform FDA Safety-and-Access Conditions Into Targeted Action Against Louisiana

Unable to find targeting in the REMS itself, Louisiana turns to political statements by Biden Administration officials issued after *Dobbs*. Reply 10-14. But for three independent reasons, these statements cannot establish that FDA's update to safety-and-access conditions was designed to target Louisiana.

*First*, Louisiana ignores the fact most starkly incompatible with its theory: The removal of the in-person dispensing requirement *predated Dobbs* by more than a year. The in-person requirement was first lifted by court injunction in 2020, then voluntarily suspended by FDA in April 2021—when abortion was still protected nationwide, including in Louisiana. *See Alliance*, 602 U.S. at 376. FDA initiated the scientific review leading to the 2023 REMS "[i]n connection with the *Chelius v. Becerra* litigation," a lawsuit filed in 2017. ROA.1008. This Court has recognized that the review process leading to eliminating in-person dispensation was commenced for reasons having nothing to do with state prohibitions (which were impermissible at the time) and the safety review underlying the decisionmaking was complete by the end of 2021. *See AHM II*, 78 F.4th at 226; ROA.372.

Louisiana's brief offers no response to this chronology. It cannot plausibly claim that a generally applicable regulatory decision initiated years before *Dobbs*—

and before Louisiana even had the restrictive abortion laws it now invokes—was designed to "target" Louisiana or an abortion ban that did not yet exist.

*Second*, the statements Louisiana invokes are not statements in the REMS, about the REMS, or by the FDA decisionmakers who adopted it. And Louisiana identifies no authority permitting courts to divine the "object" of a facially neutral regulation from later political statements by non-decisionmakers. To the contrary, the "object" of the regulation in *Diamond* depended on what the regulation *said*, not on what political officials said about it. *Diamond*, 606 U.S. at 114-15 ("explicit[]" language in regulation established targeting).

It is a bedrock principle of administrative law that agency actions should be judged based on the agency's own (contemporaneous) reasoning. Louisiana invokes *Department of Commerce v. New York*, but the Court there permitted inquiry into materials outside the agency record only upon a "strong showing of bad faith" revealing a "significant mismatch" between rationale and action. 588 U.S. 752, 781-83 (2019). Here, FDA's stated rationale—ensuring safe access to mifepristone while reducing unnecessary barriers—is exactly what governing law requires and what the 2023 REMS accomplishes. And Louisiana itself argued in *Trump v. Hawaii* that the *agency's* rationale is paramount: "[o]nly the 'clearest proof' will suffice to override the stated intent of government action." Br. for the States of Texas et al. as Amici Curiae at 3-4, 25-26, *Trump v. Hawaii*, 585 U.S. 667 (U.S. Feb. 28, 2018). The

Supreme Court agreed with Louisiana's position: It considered plaintiffs' "extrinsic evidence"—"a series of statements by the President and his advisers casting doubt on the official objective of the Proclamation"—but only to *reject* that evidence and uphold the policy because it could "reasonably be understood to result from a justification independent of unconstitutional grounds." *Id.* at 699, 705. Under that standard, Louisiana's theory would plainly fail: The 2023 REMS—by its stated purpose and actual effect—is a safety-and-access regulation of a drug, not a regulation of Louisiana.

*Third*, even if those statements were relevant, they do not show that the 2023 REMS targeted Louisiana. Louisiana principally relies on a White House fact sheet that postdates FDA's 2021 suspension of the in-person requirement, acknowledges that *legislative action* would be necessary to restore abortion rights in states with bans ("the only way to secure a woman's right to choose is for Congress to restore the protections of *Roe*"), and says nothing about the REMS Louisiana challenges. ROA.955-956. A statement that expressly defers to Congress and is silent on the regulation at issue is not a pledge to override state law using the unmentioned regulation.

The other statements Louisiana invokes are no different. Louisiana cites the HHS Secretary's criticism of *Dobbs* and statement that HHS had been "preparing for" the decision. Reply 11. But the five "steps" HHS announced had nothing to do

with the REMS. ROA.960-961. Louisiana cites President Biden's reference to a prior Attorney General statement that States "may not ban mifepristone." Reply 11. But the Attorney General's statements were about FDA's overall approval of mifepristone, not the REMS specifically, and opined only that States could not ban mifepristone "based on *disagreement* with the FDA's expert judgment *about its safety and efficacy*." ROA.1230 (emphasis added). Louisiana truncates its quote to elide that key qualifying language, and does not contend that its abortion ban is based on determinations of mifepristone's safety or efficacy. And Louisiana cites HHS's description of working to "protect and expand access to reproductive care." Reply 11. But the "key actions" HHS listed make no reference to the REMS and several relate to birth control, not abortion. ROA.1226-1227. In short, Executive Branch critiques of a Supreme Court decision and commitments to longstanding policy goals do not transform FDA's scientific safety-and-efficacy decision (which was largely complete before *Dobbs* in 2021) into an action targeting Louisiana and laws enacted post-*Dobbs*.

### C. The District Court's "Finding" About the REMS's Purpose Is Not Entitled to Clear-Error Deference and Is Clearly Erroneous Regardless

Louisiana asserts that the district court made a "factual finding" that "the 2023 REMS was approved . . . as part of an effort to circumvent anti-abortion states' ability to regulate abortion," ROA.9104—and that this "finding" is insulated from

review absent clear error. *See* Reply 12-13. But Louisiana overstates both what the district court said and what follows from it. The court stated only that "there is evidence" that, "in that post-*Dobbs* regulatory environment," the 2023 REMS "was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion." ROA.9104. It made no finding that FDA adopted the challenged policy for that purpose, much less that Louisiana was an "object" of FDA regulation within the meaning of *Diamond*. And even if the court had made the finding Louisiana attributes to it, the record would not support it and its Article III significance would remain a question for this Court to decide independently.

*First*, Louisiana conflates the standard governing underlying historical facts with the standard governing whether they suffice to establish Article III standing. Even assuming particular underlying facts are reviewed for clear error, whether those facts make Louisiana an object of the 2023 REMS within the meaning of *Diamond*—and whether Louisiana has "standing under Article III of the Constitution"—are legal questions this Court reviews de novo. *Crawford v. Hinds Cnty. Bd. of Supervisors*, 1 F.4th 371, 375 (5th Cir. 2021). The district court's inference about the purpose of the 2023 REMS therefore cannot insulate Louisiana's standing theory from independent appellate review. Tellingly, even *Louisiana* did not identify this supposed "finding" as something subject to clear-error review in its

opening brief. La. Br. (Doc. 147) at 33-34.

Nor would the court's supposed "finding" be reviewed for clear error in any event. Clear error is reserved for findings that require courts to "marshal and weigh evidence, make credibility judgments, and otherwise address . . . 'multifarious, fleeting, special, narrow facts that utterly resist generalization.'" *U.S. Bank Nat'l Ass'n ex rel. CWCapital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC*, 583 U.S. 387, 396 (2018). *Lakeridge* itself illustrates why: The Court held that clear-error review applied there precisely because the bankruptcy court's insider-status determination followed a live evidentiary hearing at which the key witnesses testified, and the court had to weigh their credibility and the character of their relationship. *Id.* at 391-99. The district court's determination does not fit that mold. It was not based on testimony, credibility determinations, or witness accounts—it was a legal inference drawn from publicly available press releases and fact sheets that this Court can review with no less acuity than the district court.

*Second*, in any event, the district court's characterization is clearly erroneous. The targeting conclusion rests on statements that (1) were not made by FDA decisionmakers; (2) did not direct a specific REMS outcome or purport to summarize its rationale, let alone were in any way tethered to a targeting of anti-abortion states; and, most critically, (3) post-dated a regulatory process initiated years before *Dobbs*. *Supra* pp. 6-10; *see AHM II*, 78 F.4th at 248 (noting 2023 REMS

was a "formalization of the policy [FDA] announced in 2021"). Any finding of "targeting" based on political rhetoric by non-decisionmakers—untethered from evidence of actual direction of the REMS process—would be clearly erroneous.

## II. LOUISIANA LACKS STANDING UNDER ORDINARY ARTICLE III PRINCIPLES

Whether deemed "targeted" by FDA's safety-and-access determination or not, Louisiana must satisfy Article III's requirements of injury, causation, and redressability. It cannot.

### A. Louisiana's Economic Injury Theories Fail

Louisiana does not seriously dispute that its alleged economic injuries depend on a long chain of choices by independent third parties—out-of-state prescribers, pharmacies, patients, providers, and Medicaid billers—none of whom are before this Court. *See Alliance*, 602 U.S. at 383. Nor does Louisiana contest that the Ninth Circuit rejected materially indistinguishable standing theories. *See Washington v. FDA*, 108 F.4th 1163, 1176-77 (9th Cir. 2024). This Court should do the same.

**1.** Louisiana's attempts to distinguish controlling precedent uniformly fail. It claims (at 14) that *United States v. Texas*, 599 U.S. 670 (2023), "said nothing about when indirect effects on state revenues or state spending become too attenuated." But the Supreme Court expressly stated there that state claims of standing are "more attenuated" where they rest on such indirect effects. *Id.* at 680 n.3. Louisiana dismisses *Arizona v. Biden*, 40 F.4th 375 (6th Cir. 2022) (Sutton, C.J.), as

"unilluminating," but the Sixth Circuit correctly framed the question that is dispositive both there and here: "Are we really going to say that any federal regulation of individuals through a policy statement that imposes peripheral costs on a State creates a cognizable Article III injury?" *Id.* at 386. The answer was no—and nothing suggests the result would differ if the state alleged farfetched theories of subjective targeting. *See* GBP Br. 37-38.

Louisiana also attempts to distinguish *Washington v. FDA* based on Idaho's failure to produce Medicaid receipts and to allege targeting. Reply 15-16. Neither distinction is material: The Ninth Circuit rejected standing because the "causal chain [was] too attenuated," *Washington*, 108 F.4th at 1176, and a "cognizable interest in the preservation of sovereign authority . . . does not convey standing to challenge federal action that affects state law enforcement indirectly," *id.*—a holding that did not depend on the absence of targeting allegations or the lack of receipts. Allowing Louisiana to sue here would create a circuit split.

**2.** Louisiana's theories of economic harm suffer from additional, fatal defects, and neither its Medicaid expenditures nor its investigative costs establish that the State has suffered cognizable harm traceable to the 2023 REMS. GBP Br. 25-33. Louisiana's responses do not cure those defects.

As to its Medicaid expenditures, Louisiana never answers the basic *Alliance* problem. The Supreme Court held that physicians could not establish standing based

on the downstream economic consequences of treating patients who suffered complications from mifepristone. 602 U.S. at 386, 391-92. Louisiana cannot transform that rejected theory into a valid one merely because Medicaid ultimately receives a bill from that treating provider. Two receipts establish that Louisiana paid two claims; they do not establish that either claim had the requisite causal connection with FDA's elimination of the in-person dispensing requirement.

Louisiana's Medicaid theory also assumes rather than proves that the challenged REMS increased the State's expenditures. The relevant comparison is not between paying these two claims and paying nothing; it is between Medicaid costs under the 2023 REMS and the costs Louisiana would incur if mifepristone again had to be dispensed in person. Louisiana offers no evidence Medicaid expenditures are more frequent or more costly when mifepristone is dispensed by mail rather than in person. Its two claims therefore establish, at most, that Louisiana sometimes incurs healthcare costs after Medicaid beneficiaries use mifepristone. They do not establish an economic injury caused by FDA's elimination of the in-person dispensing requirement. And even if those Medicaid expenditures could be considered in the standing analysis, Louisiana paints only half the picture. Reply 19-20. The State does not dispute that mifepristone is associated with significantly fewer and less severe complications than a full-term pregnancy, ROA.6897. Nor can Louisiana turn its policy preferences into proof that the challenged dispensing rule

increased the State's fiscal burden. *Cf. Gen. Land Off. v. Biden*, 71 F.4th 264, 274 (5th Cir. 2023) (quoting *Texas v. United States*, 809 F.3d 134, 153-55 (5th Cir. 2015)).

Louisiana also does not show that its claimed Medicaid injuries are likely to recur. In *Summers v. Earth Island Institute*, the Supreme Court made clear that past harms alone cannot confer standing, even when the plaintiff alleges "a statistical probability that some [plaintiffs] are threatened with concrete injury" in the future. 555 U.S. 488, 497 (2009). Louisiana does not distinguish *Summers* or offer countervailing authority, and instead points only to the district court's statement—summarizing a smattering of claims in Louisiana's declarations—that Medicaid patients beyond the two Louisiana has highlighted "likely . . . have required similar care due to complications from mifepristone." Reply 21 (citing ROA.9107-9108). But again, showing that mifepristone sometimes leads to complications for some patients is not enough—the doctors made an indistinguishable argument in *Alliance*. *See* 602 U.S. at 386, 391-92. Rather, Louisiana must show that it faces a "certainly impending" threat of future injury that stems from the REMS decision specifically—the elimination of the in-person dispensing requirement—not the availability of mifepristone *writ large*. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Louisiana has never done so. As detailed by *amici* FemInEM, a nonprofit organization focused on improving reproductive care in emergency departments, and

mail-order pharmacy Honeybee Health, Inc., complications from mifepristone are rare, but may occur regardless of how mifepristone is dispensed—with no "measurable increase" in "serious adverse events" in patients who received mifepristone via telehealth. Doc. 308 at 21, 25 (FemInEM brief); *see* Doc. 260 at 10-13 (Honeybee Health brief).

Louisiana also doubles down on its speculation about the volume of emergency room visits among Medicaid-covered mifepristone patients, asserting it would "plummet" absent the 2023 REMS. Reply 22-23. But Louisiana cites no evidence that there is currently a mifepristone ER visit rate high enough to "plummet," and the fact that it has included allegations related to only *two* actual Medicaid patients is telling. More broadly, Louisiana's emphasis on the rates of ER visits identified in the FDA's labeling and the studies FDA reviewed for the 2023 REMS is a distraction. Louisiana ignores clear evidence in the FDA's supporting analysis of the 2023 REMS that any increased rate of hospital visits among patients who received mifepristone without an in-person visit does *not* mean those patients have more adverse events. *See* ROA.1037, ROA.1042 (FDA 2023 REMS modification summary review document analyzing studies of mifepristone distributed via mail and telemedicine).

That distinction is unsurprising. When mifepristone is provided remotely, some patient-provider contact that otherwise might occur before or during an in-

person visit may instead occur after the patient takes the medication. Indeed, it is well-established that patients often visit medical providers, including emergency rooms, merely to confirm that their response to mifepristone is normal—not because they are experiencing a medical emergency or a harmful side effect. *See, e.g.*, Doc. 253 at 16-19 (amicus brief by Doctors for America explaining that "[s]imply counting emergency room visits by those who have taken mifepristone does not equate to actual emergencies caused by the medication."); *see also* Doc. 300 at 14, Doc. 308 at 13 (similar discussion in amicus briefs submitted by Physicians for Reproductive Health and emergency physician groups). In ignoring inconvenient facts and mischaracterizing FDA's reasonable analysis of the literature, Louisiana makes clear that its grievance with FDA's safety-conditions determination boils down to a "policy objection," which is not a basis for standing. *Alliance*, 602 U.S. at 381, 396.

**3.** Louisiana also attacks the notion that its alleged injury is traceable to other states' "shield laws," not the 2023 REMS. Reply 23-24. But that is the only fair reading of Louisiana's own complaint, which asserts that its harm from medication abortions began to accrue only after shield laws were adopted. *See* ROA.106-107. That chronology matters. FDA had stopped enforcing the in-person dispensing requirement in April 2021, yet Louisiana does not identify the surge in conduct of

which it complains until shield laws altered the incentives and protections facing out-of-state prescribers two years later.

The news article the complaint relies on proves the point. It notes that foreign-produced mifepristone was already being supplied from abroad to patients across the United States even before FDA suspended enforcement of in-person dispensing in April 2021. *See* ROA.106 ¶¶ 84-85 & nn.118-19 (citing Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023), perma.cc/49J6-3CZS). And between the April 2021 suspension and the adoption of shield laws beginning in 2023, exclusively foreign mifepristone was reportedly still being supplied to patients in states that prohibited telemedicine abortion care—until, according to the article, shield laws led to the growth of domestic options. *See id.*; *see also* ROA.106-107 ¶ 86 & n.123 (citing additional article with similar reporting). In other words, Louisiana's *own sources* state that abortion medication has long been available by mail, including in states with restrictions, because of independent choices by third parties—and that those parties changed their practices because of laws enacted by Louisiana's co-equal sovereign states, not because of the 2023 REMS.

**4.** As for its investigative-costs theory, Louisiana defends it only half-heartedly. *See* Reply 20. Because spending by private litigants to avoid harm can confer standing, Louisiana says, states *a fortiori* have standing arising from the costs

of investigating suspected violations of state law. *Id.* But Louisiana cites no authority for that assertion, instead claiming only that GenBioPro has not supported its contrary position. The burden is on *Louisiana*, as the plaintiff invoking federal jurisdiction, to substantiate its novel and unprecedent theory of standing—not on defendants to disprove it. Moreover, as the only case Louisiana does cite makes clear, while "'States are not normal litigants for the purposes of invoking federal jurisdiction,'" it remains the case that "they, too, are bound by Article III's standing requirements." *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 769 (5th Cir. 2023) (quoting *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007)). Louisiana offers nothing to support that a few thousand dollars in costs expended to pursue its chosen policies establishes a cognizable injury. *See* GBP Br. 30. And that would remain true even if Louisiana were the "object" of the 2023 REMS, which it is not. *See supra* pp. 4-8. Nothing in sovereignty converts ordinary law-enforcement expenditures into a cognizable injury caused by federal regulation of third parties.

**5.** Louisiana falls back on irrelevant attacks on the manufacturers—claiming, for example, that their sole interest in defending the 2023 REMS is to preserve the ability to supply mifepristone to patients in Louisiana or other states *with* restrictions. Reply 24-25. But as Louisiana consistently refuses to acknowledge, mifepristone is prescribed and distributed to patients without an in-person visit in states whose "people and their elected representatives" have made different policy

choices about access to reproductive healthcare than Louisiana. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). Indeed, the vast majority of the U.S. population lives in states where abortion is permitted—many of which have rural areas where access to healthcare is limited and an in-person dispensing requirement would severely limit options.

Yet Louisiana nevertheless seeks *nationwide* suspension of the 2023 REMS, which would block access to mailed mifepristone in *every* state. Amici representing the interests of over 20 States and the District of Columbia explain that reinstating the in-clinic dispensing requirement would disrupt their laws, their public-health systems, and their judgments about how best to safeguard the health, safety, and rights of their residents. *See* Doc. 276 at 2-5. *Dobbs* returned abortion policy to "the people and their elected representatives," 597 U.S. at 292; it did not empower one State to impose its policy judgments on its coequal sovereigns through expansive theories of state standing.

Louisiana resorts to inflammatory insinuations that GenBioPro "aid[s] and abet[s]" unlawful conduct because its website links to third-party resources. Reply 24. But Louisiana has not asserted claims against GenBioPro, so its Article III standing for a hypothetical suit against GenBioPro is not at issue. In any event, Louisiana identifies no evidence to back its meritless aiding-and-abetting theory, much less that such conduct establishes an injury caused by FDA.

### B. Louisiana's Sovereign Injury Theories Fail

Louisiana's attempts to rehabilitate its sovereign injury theories are similarly unavailing. Its opening brief advanced two supposedly "distinct" theories of standing—one based on third parties' violations of its laws, La. Br. 42-47, and the other based on the State's alleged inability to enforce those laws, La. Br. 47-52. In its reply, Louisiana all but abandons the first, and rightly so. As GenBioPro explained, Article III standing must turn on what *FDA* did to Louisiana, not what *independent third parties* did after FDA regulated others. GBP Br. 33-34. Alleged violations of Louisiana law by prescribers or patients are acts of third parties, not injuries inflicted by FDA. The 2023 REMS neither violates Louisiana law nor requires anyone else to do so.

**1.** Louisiana offers no meaningful rebuttal. Instead, the State launches into a convoluted attempt to simultaneously distinguish and rely upon this Court's decision in *Harrison v. Jefferson Parish School Board*, 78 F.4th 765 (5th Cir. 2023). But *Harrison* does not suggest that a State has standing to sue the federal government whenever federal regulation of third parties allegedly makes downstream violations of state law more likely. In *Harrison*, Louisiana intervened in private suits challenging the constitutionality of a parish school board's virtual-learning disciplinary policy and, after the private plaintiffs settled and dropped out, attempted to pursue the case alone on the theory that the board's violations of state and federal

law were themselves an injury to the State's sovereign interest in compliance with its laws. 78 F.4th at 767-69. This Court disagreed, explaining that injury to a sovereign interest "does not include every act of disobedience to a state's edicts," and that the board's alleged failure to follow state and federal law was "not currently injuring Louisiana's sovereign interest." *Id.* at 770, 772. An abstract governmental interest in obedience to the law, the Court explained, is different from injury to the State's sovereign authority: "for a sovereign interest to serve as a cognizable injury for federal standing," the State must establish that the defendant's actions "tangibl[y] interfere[] with [the State's] *authority* to regulate or to enforce its laws." *Id.* at 770 (emphasis added) (quoting *Saginaw Cnty. v. STAT Emergency Med. Servs., Inc.*, 946 F.3d 951, 957 (6th Cir. 2020)). Louisiana conspicuously never claims that the 2023 REMS limits the scope of its regulatory authority over abortion. Indeed, its second theory of sovereign injury depends entirely upon the State *retaining* that authority; otherwise, it could not fairly be heard to complain of difficulties with *enforcing* its authority.

*Harrison* also establishes that where, as here, a state retains a "full arsenal of enforcement mechanisms to force [others] to comply with state law," it cannot claim injury within the meaning of Article III. *Id.* Louisiana's own briefing explains (at 29) that it has filed enforcement actions, obtained arrest warrants, and issued extradition requests for out-of-state prescribers whom it accuses of sending

mifepristone into Louisiana illegally. To be sure, the State complains that "those enforcement actions have gone nowhere." Reply 29. But to the extent Louisiana has had trouble getting other states to aid its enforcement efforts, *see id.* (citing La. Br. 16-17), those practical difficulties are attributable to independent factors (*e.g.*, other States' shield laws), not the 2023 REMS. The Ninth Circuit rejected a materially indistinguishable theory concerning this same REMS. *Washington v. FDA*, 108 F.4th at 1176-77.

**2.** Louisiana cannot avoid that conclusion by relabeling this rejected theory as "functional preemption." Reply 30-31, 35. Functional preemption is, of course, not actual preemption—that is, a claim that Louisiana's laws are entirely "without [legal] effect," *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Rather, Louisiana's "functional preemption" argument is simply a repackaging of its claim that FDA's decisions about how to regulate third parties have made state enforcement *more difficult*, which is precisely the theory *Texas* forecloses. GBP Br. 26-27. And Louisiana effectively concedes that Article III does not open the courthouse doors to a state any time a federal policy incrementally increases the practical burdens of enforcing state law. *See Texas*, 599 U.S. at 680 n.3. Instead, it argues that the 2023 REMS has rendered Louisiana's abortion restrictions "practical[ly] unenforceab[le]" and thereby "functionally preempted" them. Reply 27, 30.

Louisiana's inability to identify precedent recognizing this supposed category of sovereign injury is revealing. *Texas* treated the absence of historical precedent for a novel theory of state standing as a "telling indication of the severe constitutional problem." 599 U.S. at 677 (citation omitted). Louisiana points to cases involving preemption or other direct interference with sovereign authority. But it identifies no tradition of States suing federal agencies because regulation of private parties allegedly makes violations of state law more frequent or enforcement against out-of-state actors more difficult. Relabeling a failed theory does not supply the missing precedent.

**3.** Louisiana's only other answer is that the 2023 REMS enables out-of-state prescribers to remain outside the State. *See* Reply 32-33. Yet in the same breath, Louisiana insists that it has the authority to prosecute out-of-state actions intended to cause in-state harms. *See* Reply 32 (citing *Strassheim v. Daily*, 221 U.S. 280, 285 (1911)). And even if the in-person dispensing requirement were reinstated, nothing would prevent out-of-state actors from continuing to prescribe and dispense mifepristone to Louisiana residents while outside Louisiana's borders—the only difference would be that the residents would need to travel out-of-state. That fact defeats redressability, *see* GBP Br. 38-39, an issue Louisiana almost entirely fails to address.

* * *

At bottom, Louisiana asks the federal courts to enjoin a federal agency action that does not regulate Louisiana and is not causing the State's grievances. Its complaint rests on purported difficulties enforcing its abortion laws against people in other States who are not subject to Louisiana's jurisdiction and whose home States have chosen not to assist Louisiana's enforcement efforts. But FDA's determination that mifepristone can be safely dispensed outside a clinic (which predated *Dobbs* and the specific laws Louisiana seeks to enforce) did not create those interstate disputes. And if Louisiana's theory sufficed, states could challenge virtually any federal regulation of private conduct so long as it could trace some downstream cost—to its treasury, its enforcement budget, or its policy preferences—back to the regulation. Article III is not so limitless. The remedy for Louisiana's disagreement is the political process, not a federal suit to upend the nationwide regulatory status of an FDA-approved drug.

## CONCLUSION

The Court should reverse the denial of GenBioPro's motion to dismiss and remand this case with instructions to dismiss the complaint for lack of Article III standing.

Dated: August 19, 2026

Respectfully submitted,

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

John Adcock
ADCOCK LAW LLC
Louisiana Bar No. 30372
8131 Oak Street, Ste 100
New Orleans, LA 70118
Tel: (504) 233-3125
jnadcock@gmail.com

*Counsel for Intervenor-Appellee/*
*Cross-Appellant GenBioPro, Inc.*

## CERTIFICATE OF SERVICE

This is to certify that the foregoing brief has been served via the Court's CM/ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on August 19, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

*/s/ John P. Elwood*
John P. Elwood

*Counsel for Intervenor-Appellee/*
*Cross-Appellant GenBioPro, Inc.*

## CERTIFICATE OF COMPLIANCE

I hereby certify that this Reply Brief of Cross-Appellant complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e)(2) and Fifth Circuit Rule 32.2 because it contains 5,941 words, according to the count of Microsoft Word. I further certify that this principal and response brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font.

*/s/ John P. Elwood*
John P. Elwood

*Counsel for Intervenor-Appellee/*
*Cross-Appellant GenBioPro, Inc.*

# *United States Court of Appeals*

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**Suite 115**
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August 19, 2026

Mr. John Patrick Elwood
Arnold & Porter Kaye Scholer, L.L.P.
601 Massachusetts Avenue, N.W.
Washington, DC 20001

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

Dear Mr. Elwood,

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

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Sincerely,

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