**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, and ROSALIE MARKEZICH,
*Plaintiffs-Appellants*,
v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,
*Defendants- Appellees*,

and

GENBIOPRO, INC.; DANCO LABORATORIES, LLC.
*Intervenors- Appellees*,

---

On Appeal from the United States District Court
for the Western District of Louisiana
No. 6:25-cv-01491 (Hon. David C. Joseph)

---

# AMICUS CURIAE BRIEF ON BEHALF OF STUDENTS FOR LIFE OF AMERICA IN SUPPORT OF PLAINTIFFS

R. Bradley Lewis
Counsel for Amicus Curiae
STUDENTS FOR LIFE OF AMERICA
248 Richmond Street
Bogalusa, LA 70427
(985) 735-9003
rbl@bradlewislaw.com

## CERTIFICATE OF INTERESTED PERSONS

Appellee 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:**

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

   Rosalie Markezich

2. **Counsel for Plaintiffs-Appellants:**

   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, in his official capacity as 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

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:**

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

**5. Intervenor-Defendant-Appellee:**

GenBioPro, Inc.

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

**6. Counsel for Intervenor-Defendant-Appellee 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-Defendant-Appellee:**

Danco Laboratories LLC

**8. Counsel for Intervenor-Defendant-Appellee Danco Laboratories LLC:**

Alexander Vladimir Sverdlov, Hogan Lovells US LLP

Dana A. Raphael, Hogan Lovells US LLP

Danielle Desaulniers Stempel, Hogan Lovells US LLP

Jessica L. Ellsworth, Hogan Lovells US LLP

Jo-Ann Tamila Sagar, Hogan Lovells US LLP

William Brock Most, Most & Associates

**9. Third Party Manufacturer:**

Evita Solutions LLC

**10. Amici and Counsel:**

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

100 Reproductive Health Rights & Justice Organizations

Jessica Ring Amunson
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

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

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

Ester Murdukhayeva
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

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

Katherine 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

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

Maitland Lilja Io Jones
Wilmer Cutler et al. (10007)
250 Greenwich St.
New York, NY 10007

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

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

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

Trinity Legal Center

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

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

Former Commissioners and Acting Commissioners of the U.S. FDA

Mandie Landry
Sal Bivalacqua
Bivalacqua, Gele + Ellis
650 Poydras Street, Suite 2200
New Orleans, LA 70130

William B. Schultz
Margaret M. Dotzel
Alyssa Howard
Zuckerman Spaeder LLP
2100 L Street NW, Suite 400
Washington, DC 20037

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

Respectfully submitted,

*/s/ R. Bradley Lewis* (La. Bar #8657)
R. Bradley Lewis

Counsel for Amicus Curiae
STUDENTS FOR LIFE OF AMERICA
248 Richmond Street
Bogalusa, LA 70427
(985) 735-9003
rbl@bradlewislaw.com

## TABLE OF CONTENTS AND AUTHORITIES

CERTIFICATE OF INTERESTED PERSONS……..…..…….ii

TABLE OF CONTENTS…….…..xix

TABLE OF AUTHORITIES…….…,……..xx

INTEREST OF AMICUS CURIAE…….…….1

SUMMARY OF ARGUMENT…….3

ARGUMENT…….4

I. The FDA's Approval of Mifepristone Failed to Comply with the ESA…..6

A. The 2000 Approval of Mifepristone…….6

B. The 2023 Changes to the Mifepristone Regimen and REMS were not in accordance with the ESA……..….7

II. The Legally Necessary Consultation with the Services Regarding the Impact of Mifepristone on Listed Endangered or Threatened Species or Designated Critical Habitats……8

III. Section 7 Regulations and Further Case Law on ESA Consultations…….11

IV. Examples of Endangered Species Potentially Affected by the FDA's Improper Approval of Mifepristone……18

CONCLUSION…….22

CERTIFICATE OF COMPLIANCE…….24

## TABLE OF AUTHORITIES

Cases

*Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*,
515 U.S. 687 (1995)..... 13

*Bennett v. Spear*,
520 U.S. 154 (1997)..... 15

*Ctr. for Biological Diversity v. U.S. Dep't of Interior*,
563 F.3d 466 (D.C. Cir. 2009)…….12, 15

*Ecological Rts. Found. v. Fed. Emergency Mgmt. Agency*,
384 F. Supp. 3d 1111 (N.D. Cal. 2019)..... 16

*Growth Energy v. Env't Prot. Agency*,
5 F.4th 1 (D.C. Cir. 2021)..... 13

*Inst. for Fisheries Res. v. United States Food & Drug Admin.*,
499 F. Supp. 3d 657 (N.D. Cal. 2020)..... 12

Karuk Tribe of California v. U.S. Forest Service,
681 F.3d 1006 (9th Cir. 2012……13, 14, 15

*Nat'l Ass'n of Home Builders v. Defenders of Wildlife,*
551 U.S. 644, 127 S.Ct. 2518, 168 L.Ed.2d 467 (2007)….14

*Nat'l Wildlife Fed'n v. Coleman*,
529 F.2d 375 (5th Cir. 1976) ..... 6, 9

*Pac. Rivers Council v. Thomas,*

30 F.3d 1050 (9th Cir.1994) ..... 13

*Shafer & Freeman Lakes Env't Conservation Corp. v. FERC*,

992 F.3d 1071 (D.C. Cir. 2021)..... 17

*Sierra Club v. Glickman*,

156 F. 3d 606 (5th Cir. 1998…….. 16, 22

*Sierra Club v. US Fish and Wildlife Service*,

245 F. 3d 434 (5th Cir. 2001) ..... 16

*Sierra Club v. Yeutter*,

926 F. 2d 429 (5th Cir. 1991) ..... 6

*Tenn. Valley Auth. v. Hill*,

437 U.S. 153 (1978)..... 5

Statutes

16 U.S.C. § 1531 ..... 4

16 U.S.C. § 1532(19) ..... 13

16 U.S.C. § 1536 ..... 8

16 U.S.C. § 1536(a)(1) and (2) ..... 3, 4

16 U.S.C. § 1536(c) ..... 17

16 U.S.C. § 1540(g)(1)(A) ..... 6

Regulations

50 C.F.R. § 402 *et seq*. .....11

50 C.F.R. § 402.02 .....11

50 C.F.R. § 402.03 .....14

50 C.F.R. § 402.14(a).....12, 17

50 C.F.R. § 402.14(b)(1).....17

50 C.F.R. §§ 402.10–402.13 .....17

Other Authorities

*1996 Environmental Assessment and/or FONSI* App. Number 20-687 page 1 of Cover Letter…….. 7

*Interagency Cooperation—Endangered Species of 1973, as Amended*, 51 Fed. Reg. 19,926 (June 3, 1986…… 12

Joel Millman, "Fish Boom Makes Splash in Oregon: Population Surge Comes Despite Forecasts of Decline; Salmon at the Food Bank," *Wall Street Journal*, (January 21, 2010), available at https://www.wsj.com/articles/SB10001424052748703657604575005562712284 7…... 22

U.S. Fish & Wildlife Service *California Condor Recovery Program*, available at https://www.fws.gov/program/california-condor-recovery.....20

U.S. Fish & Wildlife Service Environmental Conservation Online System (ECOS) *Conserving the Nature of America* Listed Animals 1493 Records, available at https://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=E.....18

## INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Students for Life of America ("SFLA") is the nation's largest pro-life youth organization that uniquely represents the generation most targeted for abortion. SFLA, a 501(c)(3) charity, exists to recruit, train, and mobilize the Pro-Life Generation to abolish abortion and provide policy, legal, and community support for women and their children, born and preborn. Founded in 1977 as a student-run organization and headquartered in Fredericksburg, VA, SFLA has more than 1,400 student groups with thousands of members on middle school, high school, college, university, and law school campuses in all 50 states. Today, SFLA is a full-time operation with a nation-wide network of staff, volunteers, and more than 150,000 pro-life SFLA-trained advocates.

SFLA and its members are uniquely harmed as the generation most targeted for abortion. A legal prejudice in favor of abortion prevents women from having access to all the information about how abortion harms women and preborn children and what services and support can be made available to them. SFLA thus works to overcome the bias in favor of abortion in critical social institutions, including the courts. SFLA is an organization made up primarily of women, many who are

[1] Rule 37 statement: The parties were notified and consented to the filing of this brief. *See* Sup. Ct. R. 37.2(a). No party's counsel authored any of this brief; amici alone funded its preparation and submission. *See* Sup. Ct. R. 37.6.

working mothers. The mission to build up each generation of women to succeed at home and at work is undermined by misogynist presuppositions—including statements in court findings—that abortion contributes to women's prosperity.

Of particular relevance in this case, as an organization committed to the well-being of the next generation, SFLA and its members desire to protect the environment from Mifepristone and its active metabolites. SFLA's members nationwide have a vested interest in protecting the environment from pollution, protecting endangered species and habitats from destruction, and preserving these species and habitats for future generations to see and experience. SFLA seeks to prevent releases of Mifepristone into the waterways of the United States and the inevitable harm that has and will continue to result to endangered species and the environment from releases of this dangerous chemical. The approval of Mifepristone in 2000 and the alteration of the Risk Evaluation and Mitigation Strategies in 2023 were all done inappropriately and in contravention of the Endangered Species Act's mandate under §7 that relevant agencies must first consult with the United States Fish and Wildlife Service and National Marine Fisheries Service to determine the effects that the usage of this drug has had on listed endangered or threatened species or designated critical habitats.

## SUMMARY OF ARGUMENT

The Food and Drug Administration failed to consider the impact Mifepristone could have on the environment, specifically on endangered species or listed habitats, when approving Mifepristone in 2000, and its generic form in 2019, and when making changes to the Mifepristone Risk Evaluation and Mitigation Strategy ("REMS") in 2023.

The Endangered Species Act requires federal agencies to follow certain restrictions when undertaking "actions" that may harm listed species or habitats. 16 U.S.C. § (a)(1) and (2). This process has been thoroughly litigated and set out since 1973 and no federal agency is exempt from its provisions. Despite this, on at least five occasions the Food and Drug Administration did not conduct the statutorily required consultation with the United States Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (collectively, "Services") as it relates to Mifepristone.

Amicus offer information to assist this Court in fully reckoning with the legal and public policy implications of its decision. For all these reasons, this Court should grant the Plaintiffs' Motion for Preliminary Injunction staying the FDA's unlawful approval of Mifepristone as an abortifacient in both its name-brand and generic form and to grant all of the Plaintiff-Appellees' other prayers for relief.

## ARGUMENT

Under Section 7 of the Endangered Species Act of 1973 (16 U.S.C. § 1531 et seq.) (hereinafter, "ESA") the Commissioner of the Food and Drug Administration ("FDA") must revoke the 2023 changes to the Mifepristone REMS in light of the FDA's failure to comply with the requirements of the ESA when taking these actions. The ESA requires all Federal agencies to consult with the Secretary of Interior before taking any "agency action" to insure such agency action is not likely to cause harm to endangered or threatened species or their habitat:

> **(a) Federal agency actions and consultations**
>
> (1) The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter. All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this chapter by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 1533 of this title.
>
> (2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

16 U.S.C. § 1536 (a)(1) and (2)

The FDA must be barred from approving Mifepristone or modifying the associated regimen (including the REMS) until after conducting the required consultation with the Services as required by the ESA. Before allowing Mifepristone for human consumption, use outside of a medical setting, and disposal into the environment, the FDA must first consult with the Services to determine the extent and effects that such actions may have on listed endangered or threatened species or designated critical habitats in the FDA's action area (*i.e.*, the United States and its territories). Without the required consultation, the FDA should not take action such as approval of a drug or updates to a drug's REMS.

The FDA has a legal obligation to comply with the ESA. The consultation requirement reflects "a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978). The FDA's actions on Mifepristone have failed to meet the requirements of the ESA and, therefore, must be revoked until the agency can implement measures to ensure that its actions do not adversely affect listed endangered or threatened species or designated critical habitats. Failure to do so could lead to the extinction of these species. This Court has the authority to order a federal agency to comply with the ESA.

Clearly, the district court has the authority to enjoin an agency from violating section 7 of the ESA. 16 U.S.C. § 1540(g)(1)(A). As part of that authority, the court may enjoin the agency from continuing activity that has resulted in past violations and, to the extent necessary, may dictate temporarily the actions the agency must take with regard to that activity until the party has submitted to the court an acceptable plan of its own. *See, e.g., Nat'l Wildlife Fed'n v. Coleman*, 529 F.2d 375 (5th Cir. 1976). Once an agency submits a plan that has been agreed to through the section 7 consultation process, the court then, applying the arbitrary and capricious standard of review, must approve or disapprove it. If the latter, the court should send the consulting parties back to the drawing board to compose a plan that provides reasonable assurance against continuation of the section 7 violations. *Sierra Club v. Yeutter,* 926 F. 2d 429, 439-440 (5th Cir. 1991). Thus, this Court should grant Plaintiffs' Motion for Preliminary Injunction staying the FDA's unlawful approval of Mifepristone regimen as an abortifacient in both its name-brand and generic form until the FDA conducts the proper consultation with the Services.

## I. The FDA's Approval of Mifepristone Failed to Comply with the ESA.

### A. The 2000 Approval of Mifepristone.

When the FDA approved Mifepristone in 2000 for chemical abortions, the FDA did not consult the Services to determine the effects of Mifepristone on listed

endangered or threatened species. The FDA merely relied on a conclusory environmental assessment inadequately performed by the Population Council, a non-government international nonprofit organization which has as one of its main purposes, reducing the human population.

In a document entitled, "ENVIRONMENTAL ASSESSMENT AND FINDING OF NOT SIGNIFICANT IMPACT FOR NDA 20-687 MIFEPRISTONE TABLETS," the FDA stated without support that "[a]dverse effects are not anticipated upon endangered or threatened species." This conclusion runs afoul of the requirements of the ESA relying upon numerous incorrect assumptions about how Mifepristone could enter the environment. Indeed, the FDA did not conduct an environmental study regarding the potential impact Mifepristone could have on the nation's wastewater. The FDA reviewed only the impact that packaging, production waste, and pharmaceutical waste would have on the environment, failing to examine the impact the excretion of Mifepristone itself would have on the environment.[2] Further, the assessment underestimated the number of chemical abortions due to Mifepristone, which are today the most popular form of abortion.

### B. The 2023 Changes to the Mifepristone Regimen and REMS were not in accordance with the ESA.

[2] *1996 Environmental Assessment and/or FONSI* App. Number 20-687.

When the FDA made significant changes to the Mifepristone regimen and REMS in 2023, the agency failed to conduct any ESA consultation or environmental assessment. This failure clearly violated the ESA and must be corrected immediately—especially in light of the FDA's removal of the in-person dispensing requirement, which opened the floodgates to do-it-yourself home abortions, leading to a massive increase in the disposal of Mifepristone into our nation's waterways.

## II. The Legally Necessary Consultation with the Services Regarding the Impact of Mifepristone on Listed Endangered or Threatened Species or Designated Critical Habitats.

The purpose of the ESA is to preserve the ecosystems upon which endangered and threatened species depend and provide a program for the conservation of such species. Section 7 of the ESA, codified at 16 U.S.C. § 1536 ("Section 7"), directs all federal agencies to participate in conserving endangered species. Specifically, Section 7(a)(1) of the ESA charges federal agencies to aid in the conservation of listed species, and Section 7(a)(2) requires all federal agencies to cooperate and consult with the Services to aid in the conservation of listed species and ensure that their activities are not likely to jeopardize the continued existence of federally listed species or destroy or adversely modify critical habitats. The Fifth Circuit, in an early case handling Section 7 of the ESA, explained:

> Section 7 of the Endangered Species Act of 1973 imposes on Federal agencies the duty to 'insure that actions authorized, funded, or carried out' by them do not jeopardize the continued existence of any endangered species or result in the destruction or modification of habitat of such species which the Secretary of Interior determines to be critical. Hence, s[ection] 7 imposes on federal agencies the mandatory duty to insure that their actions will not either (i) jeopardize the existence of an endangered species, or (ii) destroy or modify critical habitat of an endangered species.

*Nat'l Wildlife Fed'n v. Coleman*, 529 F.2d 359, 371 (5th Cir. 1976). Thus, the Fifth Circuit has affirmed the obligation of federal agencies under Section 7 of the ESA.

First, in order to ensure compliance with the ESA, before taking action such as approving a drug or medication, a federal agency such as the FDA must first define the action area and submit a proposed list of impacted species or request from the Services a list of impacted species. The purpose is to encompass all listed species that may be impacted by the proposed agency action. The species list must include all listed and proposed species and designated critical habitats that may be present in the action area. The action area must not neglect indirect effects, such as stormwater run-off, or the effect felt in wastewater or wastewater effluent and the route it takes to public waterways. Since there are no geographical limitations to the FDA's approval of Mifepristone, the relevant action area is the entire United States and its territories.

Second, the FDA must determine whether the proposed action may affect a Section 7 resource, or a species on the aforementioned list. This is done through

assessments of the direct or indirect effects mentioned previously.[3] Every listed species or habitat must be analyzed through this lens. As discussed below, the "may affect" designation is a low bar. The "no effect" determination applies only in very limited circumstances, such as when the species ranges and critical habitat do not overlap with the action area. Given the nationwide action area and known potential effects of Mifepristone, a "no effect" determination cannot apply to the FDA's actions on Mifepristone.

Third, if the proposed action may affect a Section 7 resource, the FDA must enter "information consultation" with the Services to analyze the aforementioned potential direct and indirect, adverse, and beneficial effects of the action on the Section 7 resources that may be affected. The ESA requires clear documentation (*i.e.*, a Biological Assessment or Biological Evaluation) that there is a determination being made, regardless of the effect itself. For any determination that the action is not likely to adversely affect any Section 7 resources, the agency must obtain from the Services an express concurrence in writing.

Finally, in instances where an adverse effect is likely, the ESA requires a "formal consultation" between the FDA and the Services wherein the FDA would submit further documentation to the Services and provide a full Biological Opinion

[3] Direct effects are those that are caused by the action, while indirect effects are those that are caused by the action and are later in time, but still are reasonably certain to occur.

on the impact that, in this case Mifepristone, would have on any listed species or habitats. Beyond this, the FDA would be required to show Mifepristone would not jeopardize, destroy, or adversely affect listed species or habitats, and if it does, then either seek an exemption or provide for reasonable and prudent alternatives.

## III. Section 7 Regulations and Further Case Law on ESA Consultations.

Section 7 consultation requirements apply to federal agency actions, including actions on federal land and actions on private land with a federal nexus. The Services' joint regulations[4] on Section 7 consultations define an agency action as all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

> (a) actions intended to conserve listed species or their habitat;
> (b) the promulgation of regulations;
> (c) **the granting of licenses,** contracts, leases, easements, rights-of-way, **permits**, or grants-in-aid; or
> (d) actions directly or indirectly causing modifications to the land, water, or air.

50 C.F.R. § 402.02. This regulation defines an "action" as anything that "includes any activity authorized, funded, or carried out by a federal agency, including permits and licenses." Federal courts in other Circuits interpret agency action requiring

[4] 50 C.F.R. § 402 *et seq*.

consultation in the context of the ESA to be a low threshold, lower than that of other Federal environmental protection statutes, including the National Environmental Policy Act (NEPA):

> It is instructive to compare the requirements under the ESA to those under NEPA. Whereas NEPA asks the agency to identify and prepare an environmental impact report for "significant" impacts on any aspect of the environment, the ESA requirements are triggered by a lower threshold, but for a narrower set of impacts. The agency must identify any potential effect, however small, on listed species and consult with the relevant agencies about the proposed action. See Karuk Tribe of California v. U.S. Forest Service, 681 F.3d 1006, 1027 (9th Cir. 2012).

*Inst. for Fisheries Res. v. United States Food & Drug Admin.*, 499 F. Supp. 3d 657, 668 (N.D. Cal. 2020). Similarly, the D.C. Circuit found in 2021 that:

> Implementing regulations promulgated pursuant to the Endangered Species Act require an agency to "determine whether any action **may affect** listed species or critical habitat," and, if so, to **consult with the Services**. 50 C.F.R. § 402.14(a); *see* 16 U.S.C. § 1536(a)(2). Only if an agency determines that its action will have no effect on listed species or critical habitat can it dispense with consultation. *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 475 (D.C. Cir. 2009). "May affect" purposefully sets a low bar: **"Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement."** *Interagency Cooperation—Endangered Species of 1973, as Amended*, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986). "Thus, actions that have any chance of affecting listed species or critical habitat — even if it is later determined that the actions are 'not likely' to do so — require at least some consultation under the ESA." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012).

*Growth Energy v. Env't Prot. Agency*, 5 F.4th 1, 30 (D.C. Cir. 2021) (emphasis added). The ESA defines "take" to include a wide range of actions, such as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect an endangered wildlife species, or any attempt to engage in such conduct. 16 U.S.C. § 1532(19). Likewise, the United States Supreme Court has stated that "take" must be interpreted in the broadest possible way, as "Congress intended 'take' to apply broadly to cover indirect as well as purposeful actions." *Babbitt v. Sweet Home Chapter of Communities for a Great Oregon,* 515 U.S. 687, 704 (1995).

Thus, every conceivable way that an agency may harm a listed species can meet the definition of "take" in the Act. Thus, an agency's action proceeding without guidance from the Services puts that agency at great risk for the substantial civil or criminal liabilities enumerated in the Act in the event the agency action harms an endangered species or listed habitat. *See Babbitt* at 697 n.9. In the above referenced *Karuk* case, the Ninth Circuit in explaining that the definition of agency "action" can cover a variety of activities found that:

> [t]here is "little doubt" that Congress intended agency action to have a broad definition in the ESA, and we have followed the Supreme Court's lead by interpreting its plain meaning "in conformance with Congress's clear intent." *Pac. Rivers Council v. Thomas,* 30 F.3d 1050, 1054–55 (9th Cir.1994) (citing *Tenn. Valley Auth.,* 437 U.S. at 173, 98 S.Ct. 2279).
>
> The ESA implementing regulations limit Section 7's application to "'actions in which there is discretionary Federal involvement or

> control.'" *Nat'l Ass'n of Home Builders v. Defenders of Wildlife,* 551 U.S. 644, 666, 127 S.Ct. 2518, 168 L.Ed.2d 467 (2007) (quoting 50 C.F.R. § 402.03). The Supreme Court explained that this limitation harmonizes the ESA consultation requirement with other statutory mandates that leave an agency no discretion to consider the protection of listed species. *Home Builders,* 551 U.S. at 665–66, 127 S.Ct. 2518.

*Karuk* at 1020–21 (9th Cir. 2012). It is clear that many courts have established that under the ESA, "agency action" is a low bar that an agency will very likely cross but also a broad one that encompasses many activities. "Any possible effect" triggers the FDA's duty to consult with the Services; and there is no doubt that Mifepristone has "any possible effect" on endangered species.

Federal courts define the requirements of Section 7 as a two-fold burden. The first is a procedural burden: the agency seeking to take an action, known as the "Action Agency," is to engage in consultation with the Services as the experts in the field. The second is a more substantive requirement: to ensure that the proposed action will not jeopardize a listed species or its critical habitat.

At the onset, the Action Agency and Services engage in "informal consultation." Informal consultation is a wide-ranging term, and generally covers the conversations, correspondence, and discussions between the Services and Action Agency at the early stages to see whether or not the next step is necessary – formal consultation, as oftentimes the two parties can determine then and there that there will be no impact on a listed species or habitat.

In the event the proposed action requires "formal" consultation, the first step in this process is to undertake a "biological assessment" followed by a biological opinion from the Services. This opinion summarizes the information needed to show the potential impact the agency action might have. Only at this point, if the action will not jeopardize an endangered species or habitat, may the Action Agency proceed. If there is a chance of endangerment, the Services will provide "reasonable and prudent" alternatives, and the Action Agency is encouraged to adopt those alternatives, or risk civil and criminal penalties for failing to comply with the ESA. *See Bennett v. Spear*, 520 U.S. 154, 170 (1997).

The purpose of Section 7's consultation provision is to determine if any agency may adversely affect an endangered species or habitat. By failing to conduct even an informal consultation, the FDA did not ensure that the approval of Mifepristone would not harm potential listed species.

The purpose of the consultations is to "draw on the expertise of 'wildlife agencies to determine whether [an] action is likely to jeopardize a listed species' or its habitat, and 'to identify reasonable and prudent alternatives' to avoid those harmful impacts." *Ctr. for Biological Diversity*, 847 F.3d at 1075 (quoting *Karuk Tribe*, 681 F.3d at 1020). NMFS provides consultation on actions involving marine and anadromous species and habitats, and FWS for all other species and habitats.

*Ecological Rts. Found. v. Fed. Emergency Mgmt. Agency*, 384 F. Supp. 3d 1111, 1115 (N.D. Cal. 2019). Similarly, this Court has found previously that:

> regardless of whether critical habitat is designated, an agency must consult with the Secretary where an action will 'jeopardize the continued existence' of a species. If critical habitat has been designated, the statute imposes an additional consultation requirement where an action will result in the 'destruction or adverse modification' of critical habitat.

*Sierra Club v. US Fish and Wildlife Service*, 245 F. 3d 434, 439 (5th Cir. 2001). The ESA thus requires federal agencies to "draw on the expertise" of the Services when a proposed action may harm an endangered species, doubly so when it may also harm a critical habitat. This did not occur in FDA's handling of Mifepristone.

The ESA is clear that some amount of consultation is required. The Fifth Circuit previously found in *Glickman* that:

> § 7(a)(1) contains a clear statutory directive (it uses the word "shall") requiring the federal agencies to consult and develop programs for the conservation of each of the endangered and threatened species listed pursuant to the statute. That Congress has passed a statute that is exceptionally broad in its effect, in the sense that it imposes a tremendous burden on the federal agencies to comply with its mandate, however, does not mean that it is written in such broad terms that in a given case there is no law to apply. On the contrary, given the specific requirements of § 7(a)(1), in any given case there is more than enough law against which a court can measure agency compliance.

*Sierra Club v. Glickman*, 156 F. 3d 606, 618 (5th Cir. 1998). Certainly, in not every case will formal consultation be required, but to not even perform informal

consultation is a clear violation of the ESA. When the consultation process does not proceed to the formal stage, as in the case of *Shafer*, it is only when the Action Agency and the wildlife agency agree it is not necessary:

> While the consultation process can take a variety of forms, the Action Agency often performs a preliminary review to determine whether the proposed action could affect any listed species. *See* 50 C.F.R. § 402.14(a); *see also* 16 U.S.C. § 1536(c); 50 C.F.R. §§ 402.10–402.13. If the Action Agency determines—and the wildlife agency concurs—that no listed species or critical habitats are likely to be adversely affected, then no formal consultation is required. 50 C.F.R. § 402.14(b)(1). But if either the Action Agency or the wildlife agency concludes that the proposed action "may affect" a listed species or its critical habitat, then a formal consultation begins. *Id.* § 402.14(a).

*Shafer & Freeman Lakes Env't Conservation Corp. v. FERC*, 992 F.3d 1071, 1079 (D.C. Cir. 2021). The case law is clear that not every time there is an agency action will there be even a formal consultation, but in failing to even begin the informal process, the FDA failed to comply with a Congressional mandate placed upon all federal agencies.

Federal courts have interpreted the triggering of ESA's Section 7 protections to be a low bar, lower than similar federal statutory constructs, but the Act's mandate to protect endangered species and threatened habitats does require action agencies that propose new actions to consult with the relevant Service. In approving Mifepristone, the FDA bypassed this requirement on at least five occasions. Amicus

requests that the FDA comply with the ESA and conduct the appropriate consultation with the Services.

## IV. Examples of Endangered Species Potentially Affected by the FDA's Improper Approval of Mifepristone.

The current list of endangered species recognized by the Services contains nearly 1,500 different species and can be found on the Fish and Wildlife Service's website.[5] Multiple endangered species may be affected by the approval of Mifepristone, but the extent is unknown due to the FDA's failure to consult as required by Section 7 of the ESA. By way of some specific examples, Canis rufus[6] (more commonly known as the red wolf) is a canine native to the Southeastern United States, intermediate in size between the grey wolf and coyote. Originally listed in 1967 under the Endangered Species Preservation Act of 1966 (the predecessor act to the ESA) the red wolf is critically endangered with fewer than 50 currently in the wild, and around 200 in captivity. The red wolf is gradually being

[5] U.S. Fish & Wildlife Service Environmental Conservation Online System (ECOS) *Conserving the Nature of America* Listed Animals 1493 Records.

[6] *Canis rufus*

reintroduced into the Southeastern United States, and often inhabits wetlands, forest, and some agricultural lands. The red wolf is at one of the more sensitive stages of reintroduction into these ecosystems.

Similarly, Lepidochelys kempii[7], or Kemp's ridley sea turtle, listed since 1970, is the world's rarest and most endangered species of sea turtle, finds its range along the Gulf Coast region of the Southeastern United States, and often employs the coasts of Texas as a primary nesting range. The Kemp's ridley sea turtle numbers fewer than 10,000 and faces critical habitat loss from human impact on the Gulf of ~~Mexico~~ America. Percina pantherine[8], or leopard darter, is a freshwater fish originally found throughout Oklahoma and Arkansas, and listed as an endangered species since 1978. The leopard darter's habitat throughout these states is often

[7] *Lepidochelys kempii*

[8] *Percina pantherine*

connected to outflows from sewage processing plants and other human elements that can cause disruption.

Gymnogyps californianus[9], the California condor, is another listed species within the United States that has a long history of conservation having being listed since 1967 (similar to the red wolf above). According to the Fish and Wildlife Service, over $35 million has been spent on California condor conversation efforts, making it one of the most expensive conservation projects in American history.[10] With fewer than 600 living in captivity and the wild, the condor remains one of the world's rarest bird species. Originally inhabiting regions across North America, including Texas, they can now only be found in small portions of Southern California. California condor feed off of a variety of carrion across their habitat in

[9] *Gymnogyps californianus*

[10] U.S. Fish & Wildlife Service *California Condor Recovery Program*.

Southern California, and will consume nearly any non-bird carcass they come across, including aquatic creatures.

Grus americana[11], the Whooping crane, inhabits portions of Texas and Louisiana as well as other parts of the central United States while on migration. Its status on the endangered species list is owed to 20th Century over-hunting and destruction of habitat by human action. There are fewer than 1,000 Whooping cranes living in the wild and captivity; they forage in shallow waters and fields and generally inhabit marshes throughout the Gulf Coast region of Texas. Finally, Oncorhynchus nerka[12], the sockeye salmon, is one of the most popular salmon used for food, and a listed species in locations within the United States. Compared to soho

[11] *Grus americana*

[12] *Oncorhynchus nerka*

salmon, steelhead trout, and Chinook salmon, populations of sockeye in the Pacific Northwest are not experiencing a resurgence in population.[13] In fact, populations in Idaho and Oregon have become completely extinct. In recent years populations across North America have been at 50-year lows in some places. Sockeye inhabit many fresh and saltwater locations across the Pacific Northwest and Alaska and are heavily impacted by human activity in those waters.

All of these listed species depend on ecosystems within the United States that are impacted by human activity. Amicus SFLA and its members are concerned that the failure of the FDA to conduct consultation with the Services has led to irreparable harm to listed species and habitats and may lead to the destruction of some of these species. When federal agencies propose actions that could impact these ecosystems, they are required to consult with the Services to determine if the actions will harm these species. FDA did not do this when approving Mifepristone in 2000, nor when loosening the regimen in 2023.

## CONCLUSION

As this Honorable Court pointed out in *Glickman, supra,* Section 7 of the ESA uses the word "shall" in imposing a requirement of consultation between the

[13] *Joel Millman*, "Fish Boom Makes Splash in Oregon: Population Surge Comes Despite Forecasts of Decline; Salmon at the Food Bank," *Wall Street Journal*, (January 21, 2010).

Secretary of Interior and other Federal agencies about any actions they take affecting endangered or threatened species. In the instant case, the FDA did not engage in the mandatory requirement of consultation.

For this reason and for the other reasons stated herein, this Court should grant Plaintiffs' Motion for Preliminary Relief and stay the 2023 REMS.

Respectfully submitted,

*/s/ R. Bradley Lewis* (La. Bar #8657)
R. Bradley Lewis

Counsel for Amicus Curiae
STUDENTS FOR LIFE OF AMERICA
248 Richmond Street
Bogalusa, LA 70427
(985) 735-9003
rbl@bradlewislaw.com

## CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2026, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all parties or their counsel of record have been served via the appellate CM/ECF system.

*/s/ R. Bradley Lewis*
R. Bradley Lewis

## CERTIFICATE OF COMPLIANCE

I certify that this *Amicus Curiae* brief complies with Fed. R. App. P. 32 (a)(7)(D) because it has been prepared in 14-point Times New Roman, a proportionally spaced font, and that it complies with the type-volume limitation of Fed. R. App. P. 32 (a)(6) because it contains 5,269 words, excluding the parts of the brief exempted by Fed. R. App. P. 32 (F).

*/s/ R. Bradley Lewis*
R. Bradley Lewis