No. 23-10362

In the United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,
Plaintiffs-Appellees,

v.

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, *Commissioner of Food and Drugs*; JANET WOODCOCK, M.D., *in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration*; PATRIZIA CAVAZZONI, M.D., *in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, *Secretary, U.S. Department of Health and Human Services*,
Defendants-Appellants,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellant.

On Appeal from the United States District Court
for the Northern District of Texas, Amarillo Division
No. 2:22-CV-223

BRIEF OF AMICI CURIAE SUSAN B. ANTHONY PRO-LIFE AMERICA, ET AL., IN SUPPORT OF APPELLEES

Heather Gebelin Hacker
HACKER STEPHENS LLP
108 Wild Basin Road South
Suite 250
Austin, Texas 78746
(512) 399-3022 (phone)
heather@hackerstephens.com
Counsel for Amici Curiae

CERTIFICATE OF INTERESTED PERSONS

No. 23-10362

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMININISTRATION, ET AL.,
Defendants-Appellants,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellant.

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

Plaintiffs-Appellees	**Former or present counsel**
• Alliance for Hippocratic Medicine • American Association of Pro-Life Obstetricians and Gynecologists • American College of Pediatricians • Christian Medical and Dental Associations • Shaun Jester, D.O. • Regina Frost-Clark, M.D. • Tyler Johnson, D.O. • George Delgado, M.D.	Alliance Defending Freedom • Erik C. Baptist • Julie M. Blake • Matthew S. Bowman • Denise Harle • Erin M. Hawley • Erica Steinmiller-Perdomo Burdett Morgan & Williamson LLP • Christian D. Stewart

Defendants-Appellants	**Former or present counsel**
• Food and Drug Administration • U.S. Department of Health and Human Services • Robert M. Califf, Commissioner of Food and Drugs • Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration • Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration • Xavier Becerra, Secretary, U.S. Department of Health and Human Sercices	U.S. Department of Justice • Brian M. Boynton • Sarah E. Harrington • Leigha Simonton • Michael S. Raab • Cynthia A. Barmore • Noah T. Katzen • Christopher A. Eiswerth • Daniel Schwei • Emily B. Nestler • Julie Straus Harris • Kate Talmor • Elizabeth B. Prelogar
Intervenor-Appellant	**Former or present counsel**
• Danco Laboratories, L.L.C.	Hogan Lovells LLP • Catherine E. Stetson • Jessica L. Ellsworth • Kaitlyn A. Golden • Lynn Whipkey Mehler • Marlan Golden • Philip Katz • Danielle Desaulniers Stempel • Delia Scoville • Eva M. Schifini • Ryan Patrick Brown, Attorney at Law

Amici Curiae	**Former or present counsel**
• Susan B. Anthony Pro-Life America • Catholic Health Care Leadership Alliance • National Catholic Bioethics Center • Catholic Bar Association • Coalition for Jewish Values • Catholic Benefits Association • Christ Medicus Foundation	Hacker Stephens LLP • Heather Gebelin Hacker Clayton Law Firm, LLC • Ben E. Clayton • Joshua P. Clayton Weycer, Kaplan, Pulaski & Zuber, PC • Murphy S. Klasing

/s/ Heather Gebelin Hacker
HEATHER GEBELIN HACKER
Counsel for Amici Curiae

TABLE OF CONTENTS

Page(s)

Table of Authorities

Page(s)

Cases

Statutes

Regulations

Other Authorities

Interest of Amici Curiae

Amici curiae[1] are a preeminent group of organizations devoted to addressing important social and medical issues—particularly healthcare decisions involving moral and bioethical concerns—and represent knowledge and experience across various disciplines:

Susan B. Anthony Pro-Life America is a "pro-life advocacy organization"[2] dedicated to ending abortion, while protecting the lives of mothers and their babies, including through advancement of pro-life laws and health-saving regulatory measures for women, girls, and the unborn through direct lobbying and grassroots campaigns.

Catholic Health Care Leadership Alliance is an alliance of Catholic organizations supporting the rights of patients and professionals to receive and provide healthcare in accordance with the moral, ethical, and social teachings of Jesus Christ and His Church.

The National Catholic Bioethics Center is a nonprofit research and educational institute committed to applying the principles of natural and moral law, con-

[1] Pursuant to Rule 29(a)(4)(E), undersigned counsel affirms that no counsel for any party authored this brief in whole or in part and that no person or entity other than amici or their counsel made a monetary contribution intended to fund the preparation and submission of this brief.

[2] *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 153 (2014) (internal quotation marks omitted).

sistent with many traditions including the teachings of the Catholic Church, to ethical issues arising in healthcare and the life sciences.

Catholic Bar Association is a community of legal professionals that educates, organizes, and inspires its members to faithfully uphold and bear witness to the Catholic faith in the study and practice of law.

Coalition for Jewish Values (CJV) is the largest Rabbinic public policy organization in America, representing over 2,000 traditional, Orthodox rabbis. The CJV Healthcare Council was formed by Torah-observant medical professionals under the auspices of the CJV Rabbinic Board to promote medical practices consonant with Jewish values and to preserve conscience rights for healthcare professionals.

Catholic Benefits Association is a nonprofit limited cooperative association committed to assisting its Catholic employer members in providing health coverage to their employees consistent with Catholic values, including protection of members' legal and conscience rights.

Christ Medicus Foundation is an organization that defends religious freedom by educating religious and lay leaders on the intersection of healthcare, the exercise of faith and religious freedom, and the right to life.

The current FDA protocol for mifepristone use has profoundly negative legal and ethical consequences because it lacks safeguards necessary to ensure informed consent. Amici are well-suited to discuss how the FDA's failure harms women who may take mifepristone to cause an abortion. The harm resulting from a lack of informed consent is relevant to the plaintiffs' arguments on standing, *see Alliance for Hippocratic Medicine v. FDA*, No. 2:22-cv-223-Z, 2023 WL 2825871, at *4 (N.D.

Tex. Apr. 7, 2023) (*AHM I*), which are in turn considered in this Court's analysis of whether the district court abused its discretion in determining that plaintiffs are likely to succeed on the merits, *Alliance for Hippocratic Medicine v. FDA*, No. 23-10362, 2023 WL 2913725, at *4 (5th Cir. Apr. 12, 2023) (per curiam) (*AHM II*). It is also relevant to this Court's review of the district court's decision on the question of irreparable harm, *see Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981) (finding irreparable harm to third-party pregnant women), and to consideration of the public's interest, *see AHM I*, 2023 WL 2825871, at *30 ("The Court . . . balances [the third and fourth preliminary-injunction factors] in favor of ensuring that women and girls are protected from unnecessary harm.").

Summary of the Argument

The requirement that a healthcare provider obtain a patient's freely given informed consent before medical treatment is firmly established in law and is a cornerstone of modern bioethics.[3] The patient's decision must be based on adequate disclosure of the diagnosis, the proposed treatment, its benefits, risks, and alternatives, and the patient must have capacity and freedom from coercion. These fundamental principles, which protect both patients and medical professionals, cannot

[3] AMA Code of Medical Ethics, Ch. 2 "Consent, Communication & Decision Making," Op. 2.1.1 (2016), https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf ("Informed consent to medical treatment is fundamental in both ethics and law.").

be met when healthcare providers prescribe mifepristone under FDA's current protocol.[4]

Because of the risks posed by taking mifepristone to cause an abortion, its availability is limited by an FDA-imposed Risk Evaluation and Mitigation Strategy (REMS) with post-marketing "elements to assure safe use" (ETASU).[5] But to the detriment of women, FDA's approval was based on studies containing safeguards not used when actually prescribing the drugs post-approval. This prevents prescribers from being able to accurately convey the true risks of the drug to patients. FDA then eroded those post-marketing requirements in 2016, 2021 and 2023. FDA's newer post-marketing restrictions do not require reporting of non-fatal adverse events to the drug's sponsors, which is critical to ensuring drugs' safety.

---

[4] Unless otherwise stated, references to mifepristone apply to both Mifeprex and its generic, which have shared a REMS since 2019. Mifeprex and generic mifepristone are sponsored and manufactured by Intervenor Danco Laboratories and GenBioPro, respectively. Unless otherwise stated, any reference to the mifepristone REMS applies to the REMS shared by Mifeprex and the generic.

[5] Before approval, an applicant (the drug's sponsor and/or manufacturer) must demonstrate the drug's safety and efficacy "for use under the conditions prescribed, recommended, or suggested in the proposed labeling." FDCA § 505, 21 U.S.C. § 355. When FDA determines that protocols are "necessary to ensure that the benefits of the drug outweigh the risks," FDA may require a REMS. If the drug can only be approved with specific safeguards, the REMS includes ETASU. FDCA § 505-1, 21 U.S.C. § 355-1. REMS with ETASU may be weakened, strengthened, or removed following the submission of a proposal from the drug manufacturer or on the initiative of the Secretary of HHS. *Id.*

FDA also no longer requires in-person care to prescribe mifepristone.[6] But in-person care is critical. Without it, physicians are unable to adequately diagnose ectopic pregnancy, verify Rh status, or detect other contraindications. Physicians thus cannot adequately inform a woman of her personal risks related to mifepristone. Prescribers also cannot adequately determine whether patients are giving consent without coercion without in-person care. Women can only benefit from more information and more protection, especially when considering whether to take a drug that FDA acknowledges is dangerous and that has irreversible consequences. Affirming the district court's ruling would help prevent further harm to women from the lack of informed consent.

ARGUMENT

I. Informed Consent Is a Cornerstone of Modern Bioethics and Law and Is Especially Critical in the Context of Abortion.

A. Informed consent is fundamental to bodily autonomy and is firmly rooted in American law.

The principle of respect for autonomy and self-determination "predominates in modern bioethics: 'Because of the intimate and intrusive nature of biomedical decisions, a central focus of bioethics has been to respect and protect an individual's autonomy in making those decisions.'" O. Carter Snead, *The (Surprising)*

[6] *See* FDA, *Questions and Answers on Mifepristone for Termination of Pregnancy Through 10 Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

Truth About Schiavo: A Defeat for the Cause of Autonomy, 22 Const. Comment. 383, 387 (2005) (quoting John A. Robertson, *Precommitment Issues in Bioethics*, 81 Tex. L. Rev. 1849, 1849 (2003)). "The principle of informed consent—the cornerstone of modern biomedical ethics—is in large measure an extension of this general concept of personal autonomy." *Id.* at 388. According to this principle, "no medical intervention may be undertaken without the *intelligent* and *voluntary* consent of the patient." *Id.* (footnote omitted) (emphasis added).

The requirement that a healthcare provider obtain a patient's informed consent before treatment is also firmly established in law. The right to consent to or refuse medical treatment was originally established in common law, and "this notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990). Before the early 1900s, treatment was often left to the discretion of physicians with little patient involvement. Eventually, courts recognized that a patient should be able to assess a procedure's risks and consequences, and that failing to obtain a patient's consent for a medical procedure should result in legal liability. *E.g.*, *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.); *Pratt v. Davis,* 79 N.E. 562 (Ill. 1906); *Mohr v. Williams*, 104 N.W. 12 (Minn. 1905). "The informed consent doctrine has become firmly entrenched in American tort law." *Cruzan*, 497 U.S. at 269. And the Supreme Court has recognized that the principle is so fundamental that it has constitutional dimensions. *See id.* at 278–79.

According to both accepted ethical principles and the law, informed consent requires three elements: information, comprehension, and voluntariness.[7] To satisfy the first element, a physician must give a patient accurate information about the nature of the procedure, risks, benefits, and alternatives to the proposed procedure or treatment, and allow the patient to ask questions.[8] That includes the risks to the particular patient given her own circumstances and conditions.[9] It also includes informing a patient of the availability of diagnostic tests that may rule out a possible condition that would influence the patient's treatment decision.[10]

The patient must also have capacity and must make the decision freely and without coercion. *Cruzan*, 497 U.S. at 280 ("An incompetent person is not able to make an *informed* and *voluntary* choice to exercise a hypothetical right to refuse

---

[7] Part C.1, Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979), *available at* https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.

[8] *Id.*; *see also Canterbury v. Spence*, 464 F.2d 772, 787–88 (D.C. 1972); AMA Code of Medical Ethics, *supra* n. 3.

[9] Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 Am. Med. Asso. J. of Ethics 563, 564-65 (2012), *available at* https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/hlaw1-1207.pdf.

[10] *See id.*; *see also e.g. Jandre v. Physicians Ins. Co. of Wis.*, 792 N.W.2d 558, 568 (Wis. Ct. App. 2010) (noting that informed consent under Wisconsin law requires physicians to inform patients of "a test to rule out a condition [the patient] was possibly suffering from, and which [the physician] did not rule out.").

treatment or any other right." (emphasis added)). Generally, minors lack legal capacity to provide consent to medical treatment or procedures and consent must instead be obtained from the minor's parent or legal guardian.[11] In the context of abortion, most states require parental notice or consent before a minor may obtain an abortion.[12]

Aside from the obvious benefits to the patient, the doctrine of informed consent also benefits the medical profession. At minimum, it reduces the likelihood of potential legal liability.[13] Informed consent also helps physicians provide quality patient care, promotes trust and confidence, and encourages better interactions between patient and physician.[14]

B. Federal courts have long recognized that informed consent is particularly important for abortion.

The fundamental importance of informed consent is underscored in the abortion context. As the Supreme Court acknowledges, "[a]bortion is inherently differ-

---

[11] AMA Code of Medical Ethics, *supra* n. 3, at Op. 2.2.1 (noting "parents' authority as decision makers" in treatment decisions for minor children).

[12] *See, e.g.,* Guttmacher Inst., *Parental Involvement in Minors' Abortions*, https://www.guttmacher.org/state-policy/explore/parental-involvement-minors-abortions (last visited Apr. 17, 2023) (summarizing state laws; 36 states require parental involvement).

[13] *See, e.g.,* Murray, *supra* n. 9.

[14] *Id.*; *see also* AMA Code of Medical Ethics, *supra* n. 3, at Op. 2.1.3 ("Truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy.").

ent from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980); *accord Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022) ("[A]bortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what those decisions called 'fetal life' and what the law now before us describes as an 'unborn human being.'"); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 852 (1992), *overruled by Dobbs,* 142 S. Ct. at 2242 ("Abortion is a unique act. It is an act fraught with consequences for others: for the woman who must live with the implications of her decision . . . and, depending on one's beliefs, for the life or potential life that is aborted."). Thus, the Supreme Court has also repeatedly recognized the unique gravity of the abortion decision and the importance of ensuring it is fully informed: "The decision to abort, indeed, is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and consequences." *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 67 (1976). "Whether to have an abortion requires a difficult and painful moral decision. . . . The State has an interest in ensuring so grave a choice is well informed." *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) (citation omitted).

This Court has also repeatedly recognized the importance of ensuring a woman's decision to abort is made with full knowledge of the consequences of her decision. *See Whole Woman's Health v. Paxton*, 10 F.4th 430, 444 (5th Cir. 2021) (en banc); *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 576 (5th Cir. 2012) ("In attempting to ensure that a woman apprehends the full conse-

quences of her decision, the [State's informed consent law] furthers the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." (quoting *Casey*, 505 U.S. at 882)). And many States, including in this Circuit, have acknowledged this reality by enacting informed-consent laws for abortion that require physicians to not only disclose medical risks to the patient, but also to perform an ultrasound and allow the mother see it and to hear the baby's heartbeat, and give information about fetal development and the availability of child support and state services to support the mother and her child. *See, e.g.,* La. R.S. § 40:1061.17; Miss. Code § 41-41-33; Tex. Health & Safety Code § 171.012. Thus, it is well established that truly informed consent is even more critical in the context of abortion than it is for other types of medical procedures.

II. FDA's Pre-Approval Studies and Post-Approval Restrictions Do Not Provide Enough Information About Mifepristone's Safety, So Prescribers Cannot Adequately Inform Patients of Potential Risk.

A. Clinical trials relied on by FDA for mifepristone's initial approval provided more protection for women than has ever been required by mifepristone's label or REMS.

For a healthcare provider to adequately inform patients about risks of a treatment or procedure, those risks must be reasonably known. Applicants seeking approval for a drug must conduct "investigations, reports of which are required to be submitted to the Secretary [which] include adequate tests by all methods reasonably applicable to show whether or not such drug is *safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof*." 21 U.S.C.

§ 355(d) (emphasis added). But the "conditions" in the U.S. trial for mifepristone afforded protections to women that are not required by the drug's label or REMS.

In the U.S. clinical trial, transvaginal ultrasonography, menstrual history, and pelvic examination were used to confirm the gestational age of each pregnancy and exclude women with ectopic pregnancies.[15] The prescribers were physicians with experience in performing surgical abortions, training in the administration of the mifepristone-misoprostol procedure, and admitting privileges at medical facilities that could provide emergency care.[16] And all patients were required to be within one hour of emergency facilities or the facilities of the principal investigator, and women were monitored for four hours for adverse events after taking misoprostol.[17] None of these conditions have ever been included in the REMS since mifepristone's approval in 2000. Clinical trials used to justify mifepristone's approval that include extra safeguards cannot provide a basis to assess accurately the drug's risks *without* those safeguards. *Cf. AHM II*, 2023 WL 2913725, at *17. And a woman cannot give truly informed consent if her physician cannot inform her as to the true risks of medication abortion.

---

[15] *See* Citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists, the Christian Medical Association, and the Concerned Women for America on Aug. 2, 2002, Docket No. FDA-2002-P-0364-0001 at 75-76.

[16] *Id.*

[17] *See id.*

B. FDA's post-2016 REMS changes fail to allow for adequate post-marketing surveillance of mifepristone's safety.

If a drug is approved for use, physicians can also rely on post-marketing safety data to assess the risks when informing their patients. And from the FDA's perspective, post-marketing surveillance of adverse effects is "essential" for ensuring a drug's safety.[18] Because all possible side effects of a drug can't be anticipated based on preapproval studies involving small numbers of patients, FDA maintains a system of post-marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug-approval process.[19] Federal regulations require sponsors to report *all* adverse drug experiences to the FDA Adverse Event Reporting System (FAERS). 21 C.F.R. § 314.80(c). "Adverse drug experiences" are defined broadly and include even adverse events that occur while using the drug "whether or not considered drug related." *Id.*[20]

As a condition of mifepristone's approval in 2000, FDA required certified prescribers to report *any* serious adverse event associated with mifepristone to the

---

[18] FDA, *Postmarketing Surveillance Programs*, https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs (last visited Apr. 27, 2023).

[19] *Id.*

[20] According to 21 C.F.R. § 314.80(a), an "adverse drug experience" is "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action."

sponsor.[21] But in 2016, FDA modified the mifepristone REMS with ETASU and eliminated the reporting requirement for non-fatal adverse events.[22] As a result, the sponsors may not receive reports of non-fatal adverse events, even if they are serious. The removal of the requirement to report non-fatal adverse events causes vastly undercounted adverse event reports (AERs), skewing the safety profile of mifepristone. As the stay panel pointed out, "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision." *AHM II*, 2023 WL 2913725, at *17.

There are other limitations on the safety data that make FDA's choice even more concerning. For example, emergency-room doctors or other non-prescribing providers handle most hemorrhages from drug-induced abortion. An analysis of AERs for mifepristone submitted to FDA from 2000 to 2019 showed that fewer than 40% of surgeries to remove retained tissue after drug-induced abortion are

---

[21] Memorandum from FDA to NDA 20-687 MIFEPREX (mifepristone) Population Council (Sept. 28, 2000), http://wayback.archive-it.org/7993/20161024033545/http:/www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf; U.S. Gov't Accountability Office, GAO-08-751, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex Appendices II and III (2008), https://www.gao.gov/products/gao-08-751.

[22] *See* U.S. Gov't Accountability Office, GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts (2018), https://www.gao.gov/products/gao-18-292; Mifepristone Shared System REMS (updated 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

done by abortion providers themselves. Yet the information in the AERs is "almost exclusively obtained from abortion providers, rather than the physician treating the complication."[23] Sponsors likely do not know about (or report to FAERS) most hemorrhages because non-prescribing doctors are not required to report them. This problem is exacerbated by the limited-to-nonexistent follow-up performed by abortion providers after chemical abortion; follow-up is now merely advised, not required, by the REMS. Patients and non-prescribing providers may choose to report adverse events to FDA through the MedWatch website.[24] But this reporting is entirely voluntary and thus incomplete.[25]

Further decreasing the likelihood that AERs are reliably reported, some prescribers encourage their patients to hide consumption of abortion-inducing drugs if

---

[23] Aultman K, et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues Law & Med. 3 (2021), https://issuesinlawandmedicine.com/wp-content/uploads/2021/01/Deaths-and-Severe-Adverse-Events-after-the-use-of-Mifepristone-as-an-Abortifacient-from-September-2000-to-February-2019-copy5.pdf.

[24] MedWatch is the FDA's medical product safety reporting program for health professionals, patients and consumers. Information submitted through MedWatch is reflected in the FAERS database. *See* https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

[25] For instance, in a study involving a similar system in Germany, 75-85% of providers had never voluntarily reported an adverse event and 20% did not even know about the voluntary reporting system. Shirley Murphy and Rosemary Roberts, *Black box 101: How the Food and Drug Administration evaluates, communicates, and manages drug benefit/risk*, 117 J. Allergy & Clinical Immunol. 34, 38 (2006); https://www.jacionline.org/action/showPdf?pii=S0091-6749%2805%2902325-0.

treated by other healthcare providers for complications. Before FDA changed the mifepristone prescribing information and Patient Agreement Form in 2023, the label instructed prescribers to "[a]dvise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe Mifeprex, so that the provider knows that she is undergoing a medical abortion." The REMS-required form also stated: "I have the MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone."[26] Yet, some prescribers, such as Aid Access, instruct their patients to lie to emergency medical personnel about having taken mifepristone.[27]

Tragically, FDA's 2023 changes further enable this deception. Prescribers are no longer directed to instruct patients to take the medication guide with them when seeking emergency treatment, and patients are no longer directed to do so in the Patient Agreement Form. This change undermines emergency healthcare providers' ability to care for patients because they will be missing critical information. It also decreases the likelihood that adverse events will be reported.

---

[26] 2016 Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_Patient_Agreement_Form.pdf.

[27] *See, e.g.,* Aid Access, *How do you know if you have complications, and what should you do?*, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do.

Ample evidence shows that adverse events are significantly underreported. In October 2021, plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) warned:

> The FDA estimates that 3.7 million medication abortions occurred between 2000 and 2018. If the rate of serious adverse events such as emergency room visits is posited to be a conservative 2%, then approximately 74,000 complications would be documented. Two analyses examined the [AERs] between 2000 to 2019 and documented 607 and 3,197 events. This total of 3,804 AERs suggests that the FDA received only 5% of an estimated 74,000 serious adverse events.[28]

Further, in a study of nearly 20 years of AERs submitted to FDA, researchers concluded:

> [FAERS] is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events. The reliance solely on interested parties to report, the large percentage of uncodable events, the redaction of critical clinical information unrelated to personally identifiable information, and the inadequacy of the reports highlight the need to overhaul the current AER system.[29]

Another study compared 2009 and 2010 AERs reported through FAERS, those provided by FDA via Freedom of Information Act request, and those identified by

---

[28] AAPLOG, *Committee Op. No. 9: Dangers of Relaxed Restrictions on Mifepristone* (Oct. 2021), https://aaplog.org/wp-content/uploads/2021/11/CO-9-Mifepristone-Restrictions-1.pdf.

[29] Aultman, *supra* n. 23.

other researchers as having occurred at Planned Parenthood.[30] While Planned Parenthood performs 37% of U.S. abortions, the study identified 1,530 mifepristone cases with AERs at Planned Parenthood alone, while FAERS only identified 664 *from all providers* and FDA released only 330 AERs through FOIA.[31] These discrepancies show that the AER reporting system is unreliable.

AERs are FDA's only objective means to obtain data on the full range of effects of the FDA-approved regimen on women. Responsible reporting is a fundamental safety mechanism that should not be sacrificed in the interest of increasing the availability of an elective drug. Yet the FDA has done just that by reducing reporting requirements and overlooking limitations with the data that is reported. As the stay panel pointed out, "[t]his ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to [FDA's] own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." *AHM II*, 2023 WL 2913725, at *17.[32] These agency actions are not only "well 'out-

[30] Cirucci, CA, et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Res. and Managerial Epidemiology 1, 5 (2021), https://journals.sagepub.com/doi/full/10.1177/23333928211068919.

[31] *Id.*

[32] A "Black Box" warning means that there is "reasonable evidence of an association of a serious hazard with the drug" and "the adverse reaction may lead to death or serious injury." Murphy & Roberts, *supra* n. 25, at 36-39; *accord* 21 C.F.R. § 201.57(e).

side the zone of reasonableness.'" *Id.* (citation omitted). Because FDA's REMS does not require comprehensive reporting of adverse events, it is impossible for FDA to provide accurate and complete information to prescribers. In turn, prescribers cannot fully inform their patients of the risks caused by or associated with mifepristone, robbing women of their right to make well-informed decisions about their care.

III. Without Providing In-Person Care, Mifepristone Prescribers Cannot Adequately Inform a Patient of Her Personal Risks.

To obtain genuine informed consent, a physician must inform the patient of the medical condition requiring the proposed treatment, and must explain any risks, including contraindications that increase the patient's risk. But FDA's post-approval changes to the mifepristone label and REMS do not require certified prescribers of mifepristone to adequately screen their patients for potential risks. A prescriber who merely consults with a patient through video, phone, or email—which is now explicitly permitted by FDA—cannot accurately assess the duration of a patient's pregnancy or diagnose ectopic pregnancy.

The existing REMS acknowledges the importance of a healthcare provider's *ability* to identify increased risks, like the presence of an ectopic pregnancy, because it requires sponsors to ensure that "healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described [in the REMS] and de-certify healthcare providers who do not maintain compliance

with certification requirements."[33] In turn, the REMS requires healthcare providers who wish to be certified to sign a Prescriber Agreement Form stating that "you agree that you meet the qualifications [] and will follow the guidelines for use." [34] The qualifications of prescribers and guidelines for use are also listed on the form:

> Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:
>
> - Ability to assess the duration of pregnancy accurately.
> - Ability to diagnose ectopic pregnancies.
> - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary. . . .
>
> In addition to meeting these qualifications, you also agree to follow these guidelines for use:
>
> - Ensure that the Patient Agreement Form is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.

---

[33] Mifepristone Tablets, 200 mg Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg, 2 (most recent modification 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

[34] Prescriber Agreement Form (updated Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf.

- Ensure that the healthcare provider and patient sign the Patient Agreement Form.
- Ensure that the patient is provided with a copy of the Patient Agreement Form and the Medication Guide. . . . [35]

But the prescriber qualification requirements and guidelines regarding a provider's *abilities* in the REMS are meaningless if a prescriber does not actually *use* these skills in caring for a patient. What good is a healthcare provider's ability to diagnose an ectopic pregnancy, for example, if the provider does not perform the diagnostic tests to determine whether the patient has an ectopic pregnancy? A prescriber cannot obtain true informed consent without adequately screening the patient for contraindications. *See, e.g., Jandre*, 792 N.W.2d at 568.

FDA claims that it is inappropriate to mandate how providers assess women for gestational age or ectopic pregnancy, and that certified prescribers do not have to be physically present with the patient.[36] These assertions ignore the best practices necessary to protect women's health and ensure informed consent. The REMS requires that certified prescribers be qualified to "assess" the duration of pregnancy and "diagnose" ectopic pregnancy—not simply confirm a patient's opinion, or the opinion of another provider, that the patient's pregnancy is 10 weeks or less

[35] *Id.*

[36] FDA's citizen petition response dated Dec. 16, 2021, to the citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians on Mar. 29, 2019, Docket No. FDA-2019-P-1534 at 25.

and that it is an intrauterine pregnancy.[37] In a joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG), the American Institute of Ultrasound in Medicine, and the Society for Maternal-Fetal Medicine agree that "[u]ltrasound measurement of the embryo or fetus in the first trimester . . . is the most accurate method to establish or confirm gestational age."[38] Women often underestimate gestational age.[39] And mifepristone's failures (requiring surgery) and complications indisputably increase as gestational age advances, which is why mifepristone is only approved for use in early pregnancy.[40]

The possibility that women receiving remote "care" may take mifepristone with an ectopic or extrauterine pregnancy is extremely troubling. An ectopic pregnancy can rupture the fallopian tube as the pregnancy progresses, causing major internal bleeding, severe pain, and possibly death if emergency surgical intervention

---

[37] Prescriber Agreement Form, *supra* n. 34.

[38] ACOG Committee Op. No. 700, *Methods for Estimating the Due Date,* 129 Obstet. & Gynecol. 1, 3 (2017), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.pdf.

[39] *See, e.g.,* Ellertson C., et al., *Accuracy of assessment of pregnancy duration by women seeking early abortions*, 355 Lancet 877, 879 (2000), *abstract available at* https://pubmed.ncbi.nlm.nih.gov/10752703/ (finding that almost 15% of Atlanta women were in error by more than two weeks when calculating gestation based on LMP).

[40] *See* AAPLOG Committee Op. No. 9, *supra* n. 28 (citing Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download).

is unavailable.[41] Half of women who experience ectopic pregnancy do not have any risk factors.[42] As noted above, ectopic pregnancies can only be reliably diagnosed through an ultrasound evaluation and confirmation of the location of the pregnancy. If a woman with an extrauterine pregnancy is given mifepristone, she may believe her symptoms are simply the effects of drug-induced abortion because they are similar, and may delay obtaining immediate medical care at great risk to her safety.[43] As of June 30, 2021, at least 97 women with ectopic pregnancies in the United States had been given mifepristone.[44] At least two of these women bled to death from an undiagnosed ectopic pregnancy.[45] They likely did not recognize that their abdominal pain and bleeding were indications of a life-threatening ectopic pregnancy, not expected effects of a chemical abortion. A woman is 30% more likely

---

[41] "What is ectopic pregnancy?," ACOG, *FAQ: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

[42] *Id.* at "What are the risk factors for ectopic pregnancy?"

[43] *Compare id.* at "What are the symptoms of ectopic pregnancy?" (symptoms include vaginal bleeding, abdominal pain, dizziness, weakness, and fainting) *with* Planned Parenthood, *How does the abortion pill work?*, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-does-the-abortion-pill-work (last accessed May 9, 2022) (symptoms related to a medication abortion include heavy vaginal bleeding, abdominal pain, dizziness, vomiting, and weakness).

[44] Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021, RCM # 2007-525, NDA 020687, ANDA 091178, https://www.fda.gov/media/154941/download.

[45] *Id.*

to die from an ectopic pregnancy while undergoing an abortion than if she had an ectopic pregnancy but had not sought an abortion.[46]

There are other contraindications that must also be investigated before administering mifepristone: presence of an intrauterine device (IUD), undiagnosed adnexal mass, chronic adrenal failure, concurrent long-term corticosteroid therapy, history of allergy to mifepristone, misoprostol, or other prostaglandins, hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding), or inherited porphyrias.[47]

Along with the danger of contraindications, a patient's Rh status is another concern not adequately addressed by FDA's current REMS, despite its importance in protecting a patient's future fertility. The Rh factor is a protein found on the surface of red blood cells.[48] If a mother's cells have this protein, she is Rh-positive.[49] But if a mother is Rh-negative and her unborn child is Rh-positive, when the baby's blood gets into the mother's bloodstream, her body will recognize that the Rh-

---

[46] Atrash H.K., et al., *Ectopic pregnancy concurrent with induced abortion: Incidence and mortality*, 162 Am. J. of Obstet. & Gynecol. 726, 727 (1990), *abstract available at* https://pubmed.ncbi.nlm.nih.gov/2316578/.

[47] *See* Highlights of Prescribing Information 4-5, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (mifepristone prescribing information approved by FDA for Danco).

[48] ACOG, *The RH Factor: How it Can Affect Your Pregnancy*, https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy#:~:text=The%20Rh%20factor%20is%20a,refers%20to%20your%20Rh%20status.

[49] *Id.*

positive blood is not hers and produce anti-Rh antibodies. These antibodies can cross the placenta in future pregnancies and lead to serious health problems, or even death, for the unborn child or newborn.[50] A woman's body can still produce these antibodies even if the first pregnancy is not carried to term because of abortion.[51] Thus, Rh-negative patients who have been pregnant before must be administered Rhogam to avoid miscarriage or severe injury to their future unborn children.[52] But Rh-negative women who are not tested before a chemical abortion may not know that they need treatment.

FDA's elimination of follow-up care also increases risks of post-abortion complications. The 2000 regimen's requirement that women return fourteen days after ingesting mifepristone and misoprostol was necessary to ensure that the unborn child and all pregnancy tissue had been expelled from the woman's body.[53] Retained tissue can lead to continued bleeding and serious intrauterine infections.[54] A

---

[50] *Id.*

[51] *Id.*

[52] *Id.*; *see also* ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, 130 Obstet. & Gyncol. E57 (2017), https://journals.lww.com/greenjournal/Fulltext/2017/08000/Practice_Bulletin_No__181__Prevention_of_Rh_D.54.aspx.

[53] Mifeprex 2000 label, Day 14: Post-Treatment Examination, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[54] Citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians on Mar. 29, 2019, Docket No. FDA-2019-P-1534 at 10.

return visit permits the healthcare provider to ensure that the patient is not experiencing complications and to administer Rhogam to Rh-negative women.[55] FDA's current framework does not require this visit, which means women may not recognize complications until they become more severe, resulting in greater harm.

The inadequacy of telemedicine is buttressed by the fact that twenty-nine states permit only physicians to prescribe mifepristone, with eighteen states requiring the provider to be physically present with the patient—and for good reason.[56] A call to a hotline or remote prescriber will not help a hemorrhaging woman reach an emergency room quickly. It is nonsensical for FDA to acknowledge that the dangers posed to women from mifepristone require ETASU[57] yet also refuse to require prescribers to perform the most accurate assessments of women who wish to use the drug. Without these patient-specific determinations, certified prescribers cannot obtain truly informed consent.[58] A woman cannot properly consent to a chemical abortion without knowing the specific risks that mifepristone poses to *her* life, health, and fertility.

---

[55] *Id.*

[56] *See* Guttmacher Inst., *Medication Abortion*, https://www.guttmacher.org/state-policy/explore/medication-abortion (last updated Apr. 13, 2023).

[57] See Questions and Answers on Mifepristone, *supra* n. 6.

[58] *See Canterbury*, 464 F.2d at 787.

IV. Without Providing In-Person Care, Mifepristone Prescribers Cannot Adequately Screen for Coercion.

Voluntariness is essential to informed consent. Coerced consent is no consent at all, and there is an increased risk of coercion and abuse in the context of abortion drugs if the prescriber does not thoroughly screen the patient. Abortion-inducing drugs are thus also inherently different from other prescribed drugs in this respect. This risk is increased by FDA's removal of the in-person dispensing requirement—an important safeguard to ensure that physicians can directly see and evaluate the voluntariness of the patient's consent. FDA's post-marketing restrictions thus fail to protect women from coercive partners and predators.

ACOG recognizes that "reproductive coercion," which "involves behavior intended to maintain power and control in a relationship related to reproductive health by someone who is, was, or wishes to be involved in an intimate or dating relationship with an adult or adolescent," includes "pregnancy pressure."[59] Pregnancy pressure includes "forcing a female partner to terminate a pregnancy when she does not want to [] or injuring a female partner in a way that may cause a miscarriage."[60] ACOG advises that because violence is often linked to reproductive coercion, "providers should screen women and adolescent girls for . . . reproductive [] coercion at periodic intervals such as annual examinations, new patient vis-

[59] ACOG Committee Op. No. 554, *Reproductive and Sexual Coercion* (February 2013; Reaffirmed 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/02/reproductive-and-sexual-coercion.

[60] *Id.*

its, and during obstetric care (at the first prenatal visit, at least once per trimester, and at the postpartum checkup)."[61] In 2007, the prevalence of intimate partner violence was nearly three times greater for women seeking abortions than for women who continued their pregnancies.[62]

With no in-person contact, prescribers lose the ability to ensure that abusers are not just out of the frame of a video conference pressuring their victims into requesting abortion-inducing drugs or ordering the drugs themselves to lace their victims' food or beverages. AAPLOG writes:

> Intimate partner violence is associated with abortion and with repeat abortions, and this is particularly true of adolescents and women being trafficked for sex. . . . Interaction with the health care system is an opportunity for these women to be identified and helped, but availability of medication abortion to abusers removes this opportunity.[63]

To find out how common sexual coercion is, the BBC commissioned a survey of one thousand women aged 18-44 and found that *half* said they had experienced at least one type of reproductive coercion.[64] Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their

---

[61] *Id*.

[62] *Id*.

[63] AAPLOG Committee Op. No. 9, *supra* n. 28.

[64] Alys Harte and Rachel Stonehouse, *Reproductive coercion: 'I wasn't allowed to take my pill*,' BBC News (Mar. 13, 2022), https://www.bbc.com/news/newsbeat-60646285; *Reproductive Coercion Poll – BBC Radio 4 – 8 March 2022*, Savanta ComRes, https://comresglobal.com/polls/reproductive-coercion-poll-bbc-radio-4-8-march-2022.

will.[65] Three percent were given a substance to cause an abortion without their knowledge or consent.[66] Five percent experienced physical violence with the intention to end their pregnancies.[67]

Tragically, most instances of coerced abortion are never publicly known, and there is no justice for the victims. In-person dispensing requirements provided a line of defense—though an imperfect one—against coerced abortion. By failing to require in-person contact between prescribers and patients, FDA's post-marketing restrictions cannot ensure that women and girls are protected from coercive partners and predators—further eroding the ability of women to make independent, voluntary decisions to use mifepristone.

[65] *Id.*

[66] *Id.*

[67] *Id.*

CONCLUSION

The district court's order should be affirmed.

Respectfully submitted.

/s/Heather Gebelin Hacker
Heather Gebelin Hacker
HACKER STEPHENS LLP
108 Wild Basin Road South
Suite 250
Austin, Texas 78746
(512) 399-3022 (phone)
heather@hackerstephens.com

Counsel for Amici Curiae

Certificate of Service

On May 11, 2023, this brief was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court. Counsel further certifies that: (1) any required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; and (2) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1.

/s/ Heather Gebelin Hacker
Heather Gebelin Hacker

Certificate of Compliance

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 6489 words, excluding the parts exempted by Rule 32(f); and (2) the typeface and type style requirements of Rule 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the program used for the word count).

/s/ Heather Gebelin Hacker
Heather Gebelin Hacker

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

May 13, 2023

Mr. Ben E. Clayton
Clayton Law Firm, L.L.C.
893 Brownswitch Road
Suite 101
Slidell, LA 70458

Ms. Heather Gebelin Hacker
Hacker Stephens, L.L.P.
108 Wild Basin Road, S.
Suite 250
Austin, TX 78746

No. 23-10362 Alliance Hippocratic Medicine v. FDA
USDC No. 2:22-CV-223

Dear Counsel,

The following pertains to your brief electronically filed on May 13, 2023.

You must electronically file a "Form for Appearance of Counsel" within **5** days from this date. You must name each party you represent, see **FED. R. APP. P.** 12(b) and **5TH CIR. R.** 12 & 46.3. The form is available from the Fifth Circuit's website, www.ca5.uscourts.gov. If you fail to electronically file the form, the brief will be stricken and returned unfiled.

Sincerely,

LYLE W. CAYCE, Clerk

Shea E. Pertuit

By: _____
Shea E. Pertuit, Deputy Clerk
504-310-7666

cc:
Mr. Steven H. Aden
Ms. Jessica Ring Amunson
Mr. Adam B. Aukland-Peck

Ms. Charlotte Baigent
Mr. Erik Baptist
Ms. Cynthia Barmore
Mr. Cody S. Barnett
Ms. Amanda Beane
Mr. Boris Bershteyn
Ms. Julie Marie Blake
Mr. Matthew Scott Bowman
Ms. Beth S. Brinkmann
Mr. John J. Bursch
Ms. Elizabeth A. Charles
Mr. Anthony Scott Chinn
Mr. Joshua Paul Clayton
Mr. Richard Dearing
Mr. Joshua M. Divine
Ms. Margaret Dotzel
Ms. Jessica Lynn Ellsworth
Mr. John Patrick Elwood
Mr. Charles William Fillmore
Ms. Emily Gerry
Ms. Kaitlyn Golden
Mr. Marlan Golden
Ms. Elissa Graves
Ms. Stephanie L. Gutwein
Ms. Denise Harle
Ms. Sarah Elaine Harrington
Ms. Erin Morrow Hawley
Ms. Alyssa Howard
Mrs. Jayme Alyse Jonat
Mr. Robert J. Katerberg
Mr. Philip Katz
Mr. Thomas S. Leatherbury
Mr. David Lehn
Mr. Peter Dominick Lepiscopo
Mr. Robert Allen Long Jr.
Ms. Janice Mac Avoy
Mr. Justin Lee Matheny
Ms. Megan McGuiggan
Ms. Lynn Whipkey Mehler
Mr. Paul Alessio Mezzina
Mr. Christopher Morten
Ms. Ester Murdukhayeva
Ms. Rachel Neil
Mr. Warren Norred
Mr. Allan Edward Parker Jr.
Mr. Hugh Carleton Phillips
Ms. Rona Proper
Mr. Michael S. Raab
Mr. Joshua Rosenthal
Mr. Nicolas Sansone
Mr. Dean John Sauer
Mr. Gene C. Schaerr
Ms. Eva Marie Schifini
Mr. Andrew Layton Schlafly
Mr. William B. Schultz
Mr. Daniel Schwei
Ms. Delia Scoville
Mr. Jordan Dentler Segall
Ms. Shannon Rose Selden

Mr. Michael Francis Smith
Mr. Samuel Spital
Ms. Danielle Desaulniers Stempel
Ms. Catherine Emily Stetson
Mr. Christian D. Stewart
Ms. Simona Strauss
Ms. Eva Temkin
Mr. John F. Walsh III
Mr. John Marc Wheat
Mr. Edward Lawrence White
Ms. Grace Zhou
Ms. Allison M. Zieve

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

May 13, 2023

Mr. Joshua Paul Clayton
Clayton Law Firm, L.L.C.
893 Brownswitch Road
Suite 101
Slidell, LA 70458

Ms. Heather Gebelin Hacker
Hacker Stephens, L.L.P.
108 Wild Basin Road, S.
Suite 250
Austin, TX 78746

No. 23-10362 Alliance Hippocratic Medicine v. FDA
USDC No. 2:22-CV-223

Dear Counsel,

You must submit the 7 paper copies of your brief required by 5th Cir. R. 31.1 **by Monday, May 15, 2023,** pursuant to 5th Cir. ECF Filing Standard E.1. Failure to timely provide the appropriate number of copies may result in the dismissal of your appeal pursuant to 5th Cir. R. 42.3. Exception: As of July 2, 2018, Anders briefs only require 2 paper copies.

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

Due to the expedited nature of this case, please submit the paper copies of this document by Monday, May 15, 2023.

The covers of your documents must be the following colors: Amici briefs must be green. **DO NOT INCLUDE ANY DEFICIENCY NOTICES WITHIN THE PAPER COPIES.**

Sincerely,

LYLE W. CAYCE, Clerk

Shea E. Pertuit

By: _____
Shea E. Pertuit, Deputy Clerk
504-310-7666

cc:
Mr. Steven H. Aden
Ms. Jessica Ring Amunson
Mr. Adam B. Aukland-Peck
Ms. Charlotte Baigent
Mr. Erik Baptist
Ms. Cynthia Barmore
Mr. Cody S. Barnett
Ms. Amanda Beane
Mr. Boris Bershteyn
Ms. Julie Marie Blake
Mr. Matthew Scott Bowman
Ms. Beth S. Brinkmann
Mr. John J. Bursch
Ms. Elizabeth A. Charles
Mr. Anthony Scott Chinn
Mr. Ben E. Clayton
Mr. Richard Dearing
Mr. Joshua M. Divine
Ms. Margaret Dotzel
Ms. Jessica Lynn Ellsworth
Mr. John Patrick Elwood
Mr. Charles William Fillmore
Ms. Emily Gerry
Ms. Kaitlyn Golden
Mr. Marlan Golden
Ms. Elissa Graves
Ms. Stephanie L. Gutwein
Ms. Denise Harle
Ms. Sarah Elaine Harrington
Ms. Erin Morrow Hawley
Ms. Alyssa Howard
Mrs. Jayme Alyse Jonat
Mr. Robert J. Katerberg
Mr. Philip Katz
Mr. Thomas S. Leatherbury
Mr. David Lehn
Mr. Peter Dominick Lepiscopo
Mr. Robert Allen Long Jr.
Ms. Janice Mac Avoy
Mr. Justin Lee Matheny
Ms. Megan McGuiggan
Ms. Lynn Whipkey Mehler
Mr. Paul Alessio Mezzina
Mr. Christopher Morten
Ms. Ester Murdukhayeva
Ms. Rachel Neil
Mr. Warren Norred
Mr. Allan Edward Parker Jr.
Mr. Hugh Carleton Phillips

Ms. Rona Proper
Mr. Michael S. Raab
Mr. Joshua Rosenthal
Mr. Nicolas Sansone
Mr. Dean John Sauer
Mr. Gene C. Schaerr
Ms. Eva Marie Schifini
Mr. Andrew Layton Schlafly
Mr. William B. Schultz
Mr. Daniel Schwei
Ms. Delia Scoville
Mr. Jordan Dentler Segall
Ms. Shannon Rose Selden
Mr. Michael Francis Smith
Mr. Samuel Spital
Ms. Danielle Desaulniers Stempel
Ms. Catherine Emily Stetson
Mr. Christian D. Stewart
Ms. Simona Strauss
Ms. Eva Temkin
Mr. John F. Walsh III
Mr. John Marc Wheat
Mr. Edward Lawrence White
Ms. Grace Zhou
Ms. Allison M. Zieve