Nos. 23-235, 23-236

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF *AMICUS CURIAE* OF AMERICANS UNITED FOR LIFE IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Since its founding in 1971, Americans United for Life (AUL) has represented parties or filed *amicus* briefs in virtually every abortion-related case decided by this Court. Supreme Court opinions have cited AUL briefs and scholarship in *Akron v. Akron Center for Reproductive Health*,[2] *Webster v. Reproductive Health Services*,[3] *June Medical Services, L.L.C. v. Russo*,[4] and *Dobbs v. Jackson Women's Health Organization*.[5] On February 28, 1995, Americans United for Life (AUL) filed a 100-plus page Citizen Petition (CP) on behalf of Members of Congress and doctors, urging the Food & Drug Administration (FDA) to reject any new drug application (NDA) for mifepristone "that does not contain adequate evidence that the drug has undergone nonclinical and

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[1] No party's counsel authored any part of this brief. No person other than *Amicus Curiae* and their counsel contributed any money intended to fund the preparation or submission of this brief.

[2] 462 U.S. 416, 426 n.9 (1983), *overruled by Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

[3] 492 U.S. 490, 530 (1989) (O'Connor, J., concurring in part and concurring in the judgment) (citing Br. for Am. Ass'n of Prolife Obstetricians & Gynecologists et al. as *Amici Curiae* 3), *overruled by Dobbs*, 142 S. Ct. 2228.

[4] 140 S. Ct. 2103, 2156 n.3 (2020) (Alito, J., dissenting) (citing Br. for 207 Members of Cong. as *Amici Curiae* 18–20), *overruled by Dobbs*, 142 S. Ct. 2228.

[5] 142 S. Ct. 2228 (2022) (citing Clarke D. Forsythe, *Abuse of Discretion: The Inside Story of* Roe v. Wade 127, 141 (2013)).

clinical safety and effectiveness trials."[6] The CP cited dozens of existing studies to document mifepristone's rates of incomplete abortion, infection, and complications such as pain and bleeding. *See generally* Bliley, *supra* note 6. Despite the Clinton Administration's initiative to bring mifepristone to the U.S., *see infra* note 10, the FDA responded on March 20, 1995, with a one-page letter stating that the CP was "premature" and that it constituted the "full response" of the FDA.[7] Twelve months later, the Population Council filed an NDA for mifepristone.

SUMMARY OF ARGUMENT

Respondents present claims grounded in first-party standing, since the doctor-members of the Respondent medical organizations seek redress of the FDA's direct injury to their practice of obstetrics-gynecology and their long-term medical care of women. The doctor-members of Respondent medical organizations have first-party standing due to the direct harms they have suffered from the FDA's

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[6] Thomas J. Bliley et al., Citizen Petition to Center for Drug Evaluation and Research, Food and Drug Administration (Feb. 28, 1995). The CP is available in an FDA Freedom of Information Act production. *Mifepristone (Mifeprex)*, U.S. Food & Drug Admin., at bates nos. 6,144–6,248 (June 20, 2016), http://wayback.archive-it.org/7993/20161024033540/http:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm085168.htm.

[7] Letter from Ronald Chesemore, Assoc. Comm'r for Regul. Affs., U.S. Food & Drug Admin., to Gary L. Yingling, Att'y, McKenna & Cuneo (Mar. 20, 1995), *available at Mifepristone (Mifeprex*), *supra* note 6, at bates no. 6,250.

cumulative actions promoting and deregulating chemical abortion as an *elective* procedure.

Due to the FDA's actions since 2000, women increasingly take mifepristone and misoprostol alone in their homes and as a "do-it-yourself" (DIY) option. As a result, women are increasingly separated from their doctors and their critical medical counsel which would normally involve counseling about alternatives and a discussion of the risks of the two-drug regimen involving mifepristone and misoprostol compared to existing methods of suction curettage or vacuum aspiration, including the importance of accurate gestational dating, Rh negative identification and response, confirmation of a non-ectopic pregnancy, confirmation of a completed abortion, and a follow-up examination.

Few OB/GYNs in the U.S. do abortions. Adolescents and women who have taken mifepristone and/or misoprostol—by an abortion provider or DIY—then go back for long-term care to their primary OB/GYN—including Respondents' members. These OB/GYNs are kept in the dark about the abortion by virtue of poor public health data about abortion, the woman's possibly incomplete medical history, and the unreliable data on the effect of mifepristone or misoprostol on patients. Consequently, OB/GYNs cannot offer patients reliable information to enable them to give informed consent during future medical care, including future pregnancies. An elective abortion may take days, while the care of women after *elective* abortion(s) will continue for decades.

Since 2000, the U.S. medical profession has not had accurate and reliable data about mifepristone—how many women have taken it, the number of adverse events, the complication rate, the number of ectopic pregnancies, the number of emergency room (ER) visits, the rate or effect of multiple use by women, etc. There is no accurate collection, analysis, and reporting of data in the U.S. about mifepristone's risks and complications for adolescents and women. With its 2016 action, the FDA severely reduced the already-scant data collection, reporting, and analysis. This has left obstetricians-gynecologists without essential data to care for women's health after chemical abortion and over the long-term.

Respondents' doctor-members have suffered injury-in-fact to a legally protectable interest, their ethical and effective practice of obstetrics-gynecology. The FDA's actions since 2000 have directly caused this injury, and doctor-members have a direct stake in the outcome of this litigation. *Lujan v. Defs. of Wildlife*, 504 U.S. 555 (1992); *Lexmark Int'l, Inc. v. Static Control Components, Inc.,* 572 U.S. 118 (2014); *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579 (5th Cir. 2023). *Amicus* urges the Court to affirm Respondents' first-party standing in this case.

ARGUMENT

I. MILLIONS OF ADOLESCENTS AND WOMEN WILL HAVE CHEMICAL ABORTIONS WITHOUT MEDICAL SUPERVISION AS A RESULT OF THE FDA'S RECKLESS PROMOTION OF ACCESS.

Since September 2000, the FDA has increasingly promoted unfettered access to *elective* chemical abortion as a lifestyle drug in the U.S. The FDA reports that "[t]he estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of December 2022 is approximately 5.9 million women."[8] It is estimated that chemical abortions make up more than half of all U.S. abortions. *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Inst. (Dec. 1, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

Progesterone is the natural hormone which enables a woman's body to sustain and nurture a pregnancy. Mifepristone is an anti-progestin, a synthetic steroid that works as a progesterone receptor antagonist. Mifepristone blocks the progesterone receptor, by binding with progesterone receptors on the nuclear membranes of cells, in the uterus and other organs. Katherine M. Scarpin et al., *Progesterone Action in Human Tissues: Regulation by*

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[8] *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022*, U.S. Food & Drug Admin. 1 (Dec. 31, 2022), https://www.fda.gov/media/164331/download.

Progesterone Receptor (PR) Isoform Expression, Nuclear Positioning and Coregulator Expression, Nuclear Receptor Signaling, Dec. 31, 2009, at 1, 1 ("Progesterone is an essential regulator of normal human female reproductive function in the uterus, ovary, mammary gland and brain, and also plays an important role in non-reproductive tissues such as the cardiovascular system, bone and the central nervous system, highlighting the widespread role of this hormone in normal physiology."). By blocking progesterone receptors in the uterus, the mother's placenta cells stop functioning, depriving nutrition to the embryonic human. This results in non-implantation to the uterine lining and thus the embryo's death, stopping the pregnancy from developing. Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to* Clostridium sordellii, 39 Annals Pharmacotherapy 1483, 1484, 1485 (2005).

Mifepristone is also an anti-glucocorticosteroid and blocks the glucocorticoid receptor. *Id*. at 1484–86. The blockage of glucocorticoid receptors also induces an immune blockade, suppressing the woman's immune system. This can result in increased susceptibility to overwhelming infection, which has resulted in deaths of young women.[9]

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[9] David M. Aronoff et al., *Misoprostol Impairs Female Reproductive Tract Innate Immunity Against* Clostridium sordellii, 180 J. Immunology 8222, 8227 (2008); Miech, *supra*, at

Researchers discovered that in a high percentage of cases, mifepristone is insufficient by itself to cause a complete abortion. So, the "FDA unlawfully mandated the unapproved use of a drug, misoprostol, as part of the RU-486 abortion regimen." Staff of Subcomm. on Crim. Just., Drug Pol'y & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong., *The FDA and RU-486: Lowering the Standard for Women's Health* 15, 23–25 (Subcomm. Print 2006) (hereafter 2006 House Subcommittee Report).[10]

Misoprostol is a prostaglandin, which is (supposed to be) administered twenty-four to forty-eight hours after mifepristone. It induces powerful uterine contractions in order to cause the expulsion of the human embryo and placenta (and fetus, with the FDA's extension to ten weeks/seventy days). The two-

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1483; Marc Fischer et al., *Fatal Toxic Shock Syndrome Associated with* Clostridium sordellii *after Medical Abortion*, 353 New Eng. J. Med. 2352 (2005); Jeanette I. Webster & Esther M. Sternberg, *Role of the Hypothalamic-pituitary-adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, 181 J. Endocrinology 207 (2004).

[10] "The Clinton administration went to great lengths to bring mifepristone into the United States. From pressuring the hesitant manufacturer to apply for approval, and utilizing a specialized review procedure normally reserved for life-saving drugs, to imposing unusual restrictions on distribution, and promising to keep the identity of the manufacturer a secret, the FDA's approval process deviated from the norm in several respects." Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 Wake Forest L. Rev. 571, 576 (2001); *see also* 2006 House Subcommittee Report, *supra*, at 15–25.

drug combination, if administered in pregnancies up to 9 weeks of gestation results in the complete expulsion of both human embryo and placenta in a high percentage of cases. Maarit J. Mentula et al., *Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 Hum. Reprod. 927, 927 (2011). However, that rate declines significantly as the gestational age lengthens, and the risk of retained fetal tissue increases with the length of pregnancy, so that by 13 weeks, approximately one out of every three women who attempt the two-drug regimen need emergency surgery for hemorrhage or retained fetal tissue. *Id*. at 931, fig. 2.

The inherent physical risks of mifepristone and misoprostol include incomplete abortion, septic infection, and hemorrhage (excessive bleeding). [11] In addition, the risks accompanying a failure to diagnose ectopic pregnancy prior to ingestion of mifepristone are real and often life-threatening. Mifepristone cannot treat or resolve ectopic pregnancies because it

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[11] In February, a new study claimed to show that telemedical chemical abortions are safe. However, two major defects in the study are that it relied on women to self-report health outcomes and twenty-four percent of the women did not respond to a follow-up survey, so the authors could not know the outcome for virtually 25%. The women who responded reported hospitalizations, infections, and complications. Michael J. New, *Mainstream Media Mislead about a New Telemed-Abortion Study*, Nat'l Rev. (Feb. 15, 2024), https://www.nationalreview.com/corner/mainstream-media-mislead-about-a-new-telemed-abortion-study/.

acts on the uterine lining, while ectopic pregnancies are outside the uterus. The effects of mifepristone and misoprostol mask the symptoms of ectopic pregnancy; the symptoms of a rupturing ectopic pregnancy—pain and bleeding—are similar to the pain and bleeding expected during the process of a mifepristone abortion.[12] One study analyzed the FDA's publication of Adverse Event Reports (FAERS) after the agency approved mifepristone, which revealed seventy-five women had received mifepristone notwithstanding their ectopic pregnancy. Twenty-six of these women had life-threatening ruptures at the time of diagnosis in the ER. Kathi Aultman et al., *Deaths and Severe Adverse Events after the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues L. & Med. 3, 4, 12, 21 (2021). Recent FAERS data report ninety-seven women with ectopic pregnancies have received mifepristone, two of whom died from a ruptured ectopic pregnancy. *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022*, *supra* note 8, at 1.

The ectopic pregnancy rate in the U.S. is estimated to be approximately one in fifty pregnancies. *Ectopic Pregnancy*, March of Dimes (Oct. 2017), https://www.marchofdimes.org/find-support/topics/miscarriage-loss-grief/ectopic-pregnancy. Since women have no way to determine whether or not a

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[12] *Mifeprex Prescribing Information*, U.S. Food & Drug Admin. 6 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.

pregnancy is ectopic without an ultrasound, the mail-order-availability of mifepristone without any physician interaction will likely lead to an increase in the use of mifepristone by women with ectopic pregnancies. In turn, this increases the risk of deaths from undiagnosed ruptured ectopic pregnancies. *See* Aultman, *supra*, at 9.[13]

The Fifth Circuit outlined the increased risk of complications that stems from the FDA's 2016 amendments to mifepristone's risk evaluation and mitigation strategies (REMS). These amendments included the FDA's extension of the gestational age in which mifepristone is permitted (from forty-nine to seventy days), the removal of the requirement of a

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[13] In 2018, ACOG reported that:

> According to the Centers for Disease Control and Prevention, ectopic pregnancy accounts for approximately 2% of all reported pregnancies. However, the true current incidence of ectopic pregnancy is difficult to estimate because many patients are treated in an outpatient setting where events are not tracked, and national surveillance data on ectopic pregnancy have not been updated since 1992. Despite improvements in diagnosis and management, ruptured ectopic pregnancy continues to be a significant cause of pregnancy-related mortality and morbidity. In 2011–2013, ruptured ectopic pregnancy accounted for 2.7% of all pregnancy-related deaths and was the leading cause of hemorrhage-related mortality.

Comm. on Prac. Bulls.–Gynecology, Am. Coll. of Obstetricians & Gynecologists, *Tubal Ectopic Pregnancy*, Prac. Bull. No. 193 (2018), *quoted in* Aultman, *supra*, at 20.

second or third in-person follow-up visit with a doctor, and the authorization of *non-physicians* to do chemical abortions. *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 235–37 (5th Cir. 2023) (citing the injuries Respondents have suffered from the FDA's deregulation of mifepristone as demonstrating standing). The FDA's deregulation of these drugs increases the risk of incomplete abortions, especially now that—without medical supervision—media are encouraging women to use mifepristone *or* misoprostol for abortion, not both.[14]

The FDA's 2016 amendments thus make it more likely that a woman will visit an ER for any medical problem or complication, where the chemical abortion will likely be filtered out of the public health system and never become part of a woman's medical history or public health data.[15]

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[14] *See* VICE News, *Inside Texas's Underground Abortion Pill Network*, YouTube (Feb. 9, 2022), https://www.youtube.com/watch?v=CR3uexqGgXo (discussing the use of misoprostol without physician involvement and the trafficking of misoprostol between Texas and Mexico).

[15] Abortion injuries and deaths are washed out of the U.S. public health system through a series of filters, including abortion clinic referrals to ERs, ER practices and coding procedures, cash payment for abortion, coding errors and financial disincentives, the limitations of CPT and ICD codes, unreliable death certificates, birth certificates which exclude any reference to prior abortions, and haphazard data collection by the Centers for Disease Control and Prevention (CDC). *See* John M. Thorp, *Public Health Impact of Legal Termination of Pregnancy in the*

Similar to ectopic pregnancies, the risks of inaccurate determination of gestational age are real and can be life-threatening. *Patel v. State*, 60 N.E.3d 1041, 1043 (Ind. Ct. App. 2016) (citing medical testimony that a woman "delivered a live baby of approximately twenty-five to thirty weeks gestation who died shortly after birth" after ordering mifepristone and misoprostol from a foreign pharmacy and ingesting the drugs). In fact, if mifepristone and misoprostol are not taken one after the other in a timely manner, as directed in the original labeling, the failure (incomplete abortion) rates are too high, and *neither drug can be considered effective within the meaning of* 21 U.S.C. § 355(d)(5).

These risks of elective chemical abortion are unnecessary since, as abortion advocates and researchers have documented, suction curettage or vacuum aspiration abortion pose fewer risks than mifepristone and misoprostol—less pain, less

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US: 40 Years Later, Scientifica, Dec. 13, 2012, at 1; Rachel K. Jones & Kathryn Kost, *Underreporting of Induced and Spontaneous Abortion in the United States: An Analysis of the 2002 National Survey of Family Growth*, 38 Stud. Fam. Plan. 187 (2007); Mika Gissler et al., *Methods for Identifying Pregnancy-associated Deaths: Population-based Data from Finland*, *1987–2000*, 18 Paediatric & Perinatal Epidemiology 448, 451 (2004); David C. Reardon et al., *Deaths Associated with Abortion Compared to Childbirth—A Review of New and Old Data and the Medical and Legal Implications*, 20 J. Contemp. Health L. & Pol'y 279, 286–91 (2004); Willard Cates et al., *Assessment of Surveillance and Vital Statistics Data for Monitoring Abortion Mortality*, *United States, 1972–1975*, 108 Am. J. Epidemiology 200, 204 (1978).

bleeding, and lower rates of complications and incomplete abortion. 2006 House Subcommittee Report, *supra,* at 22–23; Renate Klein et al., *RU486: Misconceptions, Myths and Morals* xviii-xix (2013 ed.). The risks for adolescent girls from chemical abortion are greater without parental involvement and without medical supervision, which the FDA's deregulations have aimed to eliminate. Yet medical personnel who are involved with chemical abortion will almost certainly not provide obstetrical-gynecological care over the course of a woman's life or for future pregnancies.

In sum, the FDA has promoted access to chemical abortion drugs without medical supervision. These actions have increased the health and safety risks to women and adolescent girls and interfered with the obstetric-gynecological care of patients.

II. THE FDA'S STATUTORY AUTHORITY DOES NOT INCLUDE USURPING THE PRACTICE OF MEDICINE.

The FDA has infringed upon obstetric-gynecological medical practice, which is traditionally within the province of State authority. As this Court said in *National Federation of Independent Business v. Department of Labor*, "[a]dministrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided." 142 S. Ct. 661, 665 (2022) (*per curiam*). This "[Court] expect[s] Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.'" *Id.* (citation omitted) That

must include issues of vast public health significance. Here, the FDA has de-medicalized chemical abortion drugs, removing health and safety safeguards that are standard in obstetrics-gynecology, and preventing primary obstetrician-gynecologists from accessing a patient's full medical history or reliable drug data. The FDA's 2016 and 2021 actions "would significantly expand" the FDA's power beyond determining safety and effectiveness "without clear congressional authorization." *Id.* Promoting medically-unsupervised access to mifepristone and misoprostol, erasing the requirement for the reporting of adverse events short of death, and expanding the indicated use to a later gestational age goes well beyond determining that the drugs are safe and effective within their labeling conditions. *See* 21 U.S.C. § 355(d).

The FDA is strictly limited from interfering with the practice of medicine. The "practice of medicine" exception is expressed in the Federal Food, Drug, and Cosmetic Act (FDCA). *See id.* at § 396. Respondents are protected by that zone of interest. *See Lexmark,* 572 U.S. 118; *see also Apter*, 80 F.4th at 592–93 (finding physicians have standing to challenge the FDA's actions interfering with the medical practice of prescribing ivermectin). Congress has never endorsed the use of elective abortion, or chemical abortion, or authorized the FDA to promote access to any form of abortion. The FDA's actions are also clearly contrary to 18 U.S.C. §§ 1461–1462, which have, for decades, prohibited the mailing or commercial delivery of abortifacients.

The safety and effectiveness standards under 21 U.S.C. § 355(d) assume a *therapeutic* use and benefit. Yet the FDA has not justified the 2016 and 2021 deregulations by "substantial evidence" of "therapeutic benefit[s]" over existing methods of suction curettage or vacuum aspiration. *See United States v. Rutherford*, 442 U.S. 544, 555–56 (1979) (stating "substantial evidence" of effectiveness necessarily entails a showing of some *therapeutic* benefit to the patient); *see also Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 629 (1973) ("[E]ffectiveness requires at least 'substantial evidence' of effectiveness for approval of an NDA.").[16]

In sum, the FDA has exceeded its authority by de-medicalizing chemical abortion drugs. In doing so, the agency has unlawfully usurped obstetric-gynecological care of patients who are considering, or have taken, mifepristone and misoprostol.

III. DOCTORS HAVE FIRST-PARTY STANDING DUE TO THE CUMULATIVE EFFECT OF THE FDA'S ACTIONS ON THE PRACTICE OF OBSTETRICS AND GYNECOLOGY.

There is no evidence that the FDA has ever considered or analyzed "the cumulative effect" of its

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[16] *Rutherford*, 442 U.S. at 555 ("A drug is effective . . . if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions."); *id*. ("In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain.").

actions since 2000 on the practice of obstetrics and gynecology and the long-term care of women, let alone evaluated the cumulative effect of these actions since 2016. *All. for Hippocratic Med.*, 78 F.4th at 246.

The FDA has progressively removed the original, 2000 labeling conditions. After a lengthy investigation and hearing, the 2006 Subcommittee Report documented the FDA's approval irregularities, the medical risks of chemical abortion, the defects of FAERS, and the lack of statutory authority. 2006 Subcommittee Report, *supra*. In 2016, the FDA entirely "[r]emov[ed] the requirement that the administration of misoprostol and the subsequent follow-up appointment be conducted in person . . . ." *All. for Hippocratic Med.*, 78 F.4th at 225. The FDA eliminated reporting of adverse events short of death. *Id.* In 2021, the FDA stopped enforcing the in-person dispensing requirement, which "allowed mifepristone to be prescribed remotely and sent via mail." *Id.* at 226. In 2023, the FDA "formalize[d] the removal of the in-person dispensing requirement." *Id.*; *see also* Aultman, *supra,* at 7, 23.

The Fifth Circuit thereby properly concluded that the FDA's 2016 and 2021 actions likely violated the Administrative Procedure Act (APA). *All. for Hippocratic Med.*, 78 F.4th at 222–23. The FDA's actions have promoted the separation and isolation of chemical abortion from a woman's complete medical history, from medical supervision, and, consequently, from a woman's long-term obstetric-gynecological

care.[17] Consequently, the FDA's actions have directly injured Respondents, and Respondents have standing to challenge the FDA's deregulation of mifepristone.

A. The FDA's Actions Have Seriously Impaired Respondents' Ability to Provide Full Informed Consent Following a Chemical Abortion.

Chemical abortions are *elective* in virtually every instance,[18] because they aim to terminate a healthy, progressing pregnancy, which does not require medical intervention. Because elective procedures do not involve disease or abnormalities requiring medical intervention, they are not medically-indicated.

Because chemical abortions are elective, a heightened standard of informed consent is ethically and legally required. The need to carefully examine all alternatives and risks is all the more imperative

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[17] Jonathan R. Nichol et al., *Medical History,* StatPearls Publ'g (Sept. 4, 2023), https://www.ncbi.nlm.nih.gov/books/NBK534249/ ("Patient medical history is often a crucial step in evaluating patients. Information gathered by doing a thorough medical history can have life or death consequences.").

[18] *See, e.g.*, *Elective Abortion*, Britannica, https://www.britannica.com/science/elective-abortion (last visited Feb. 27, 2024) ("An elective abortion is the interruption of a pregnancy before the 20th week of gestation at the woman's request for reasons other than maternal health or fetal disease. Most abortions in the United States are performed for this reason.").

with elective procedures.[19] Instead, the FDA's actions since 2000 have directly impeded fully informed consent for women.

Several studies have found, despite the marketing of mifepristone, that women would choose surgical over chemical abortion for a second abortion. Klein, *supra*; S.C. Robson et al., *Randomised Preference Trial of Medical Versus Surgical Termination of Pregnancy Less than 14 Weeks' Gestation (TOPS)*, Health Tech. Assessment, Nov. 2009, at 1; P. Slade et al., *A Comparison of Medical and Surgical Termination of Pregnancy: Choice, Emotional Impact and Satisfaction with Care*, 105 Brit. J. Obstetric Gynaecology 1288 (1998). The reasons include: (1) chemical abortion takes longer than surgical abortion, and (2) chemical abortion involves more pain and bleeding. Some women also find it disturbing to see the human form of the embryo or fetus that emerges after contractions. Slade, *supra*.

The FDCA, Subpart H requires that the drug "provide meaningful therapeutic benefit to patients

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[19] *See*, *e.g.*, *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 359 (1987) (under the patient rule adopted for elective surgery, "the physician's duty to disclose is measured by the patient's need to have access to all information material . . . in the elective surgery situation no valid reasons existed for allowing the medical community the exclusive determination of what information would be material"); *Cowman v. Hornaday*, 329 N.W.2d 422 (Iowa 1983) (applying the patient rule in the context of elective surgery); *Small v. Gifford Mem'l Hosp.*, 349 A.2d 703, 705 (1975) ("Where the surgery is elective . . . the right of informed choice is of more significance.").

over existing treatments." 21 C.F.R. § 314.500 (1999). The "benefits" of mifepristone that the FDA identified in 2000 were avoiding surgical abortion, 2006 House Subcommittee Report, *supra*, at 21, but at least one study of women in Finland found that the "overall incidence of adverse events was fourfold higher" after chemical abortion compared to surgical abortion. Maarit Niinimäki et al., *Immediate Complications after Medical Compared to Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 795 (2009).

This contradicts the FDA's judgment in its 2021 Denial Letter that in-person dispensing in "certain healthcare settings . . . is no longer necessary to ensure that the benefits of the drug outweigh the risks." *All. for Hippocratic Med.*, 78 F.4th at 247. Eliminating in-person dispensing will not eliminate the disparity of complications between surgical and chemical abortions.

In addition, mifepristone does not provide any "therapeutic benefit," 21 C.F.R. § 314.500, because the uses of mifepristone for early abortion are virtually always *elective*, not therapeutic.[20] If a health condition necessitated separation of the mother and child, it would most likely be later in pregnancy, and

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[20] William Hubbard, who would subsequently become the FDA's Associate Commissioner for Policy during the Clinton Administration, remarked: "RU-486 is intended for convenien[t] use by healthy young women rather than as a therapy for an incapacitating or life-threatening disease." *Quoted in* Noah, *supra* note 10, at 582.

mifepristone and misoprostol would not be timely or useful, and therefore not medically-indicated.

The FDA's approval and deregulation of abortion through the actions taken since 2000 prevent fully informed consent by separating patients from doctors and putting patients into a situation—including DIY abortions—where they are unlikely to get accurate and thorough counseling and information. Isolated in their pregnancy, women and adolescents may turn to websites which provide inaccurate or incomplete information.[21] Without accurate knowledge of a woman's medical history and without access to reliable medical data, a physician cannot provide complete and accurate information to a patient to enable her, in turn, to give fully informed consent for abortion or future obstetrical-gynecological care.

The serious limitations of U.S. abortion data have been documented. John M. Thorp et al., *Long-term Physical and Psychological Health Consequences of Induced Abortion: A Review of the Evidence*, 58 Obstetrics & Gynecology Surv. 67 (2003). If the FDA does not require or maintain reliable data, or directly thwarts such data, by establishing an inadequate

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[21] Betsy Morris, *At-Home Healthcare Is Booming, but Doing It Yourself Isn't Always a Good Idea*, Wall St. J. (Feb. 22, 2022), https://www.wsj.com/articles/heathcare-at-home-cancer-tests-ear-infection-apps-monitors-11645363811 ("A flood of new health-tracking wearables, monitors, tests and apps—more than 350,000 apps, according to health research firm IQVIA—promise to help people screen, monitor or flag all sorts of maladies and conditions, with or without a doctor's orders.").

FAERS system, or depreciates the quality of the existing system, a physician has reason to doubt the reliability of the data on risks and complications.

Because of the defects in U.S. data on abortion, practicing physicians are forced to look to foreign studies, *see*, *e.g.*, Niinimäki, *supra* (using national registry data), or general health surveys to study abortion. Donald Paul Sullins, *Abortion, Substance Abuse and Mental Health in Early Adulthood: Thirteen-year Longitudinal Evidence from the United States*, SAGE Open Med., Sept. 23, 2016, at 1 (examining pregnancy history and mental health history from the National Longitudinal Study of Adolescent to Adult Health (Add Health)).

The FDA's deregulation of mifepristone since 2016 directly affects the informed consent process after abortion with a woman's primary obstetrician-gynecologist. "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972). However, the FDA's actions have diminished the already-minimal data on chemical abortion complications. In turn, OB/GYNs do not have the necessary information to provide informed consent counseling to women immediately following a chemical abortion or in their long-term care.

1. The FAERS System Cannot Accurately Track Complications or Yield Reliable Data for Doctors to Treat Patients after Chemical Abortion or Long-term.

Few American obstetrician-gynecologists do elective abortions.[22] American women have a chemical abortion by an abortion provider or by DIY. Thereafter, women return to their primary obstetrician-gynecologist for regular care, typically without informing their primary obstetrician-gynecologist of the abortion or any complications. Notice of Intervention Below, & Mot. of Mo., Idaho, & Kan. to Intervene 3 ("The Federal Government admits that 5 to 8 percent of these women [returning to Missouri] experience significant complications after returning home . . . Many are forced to seek emergency medical care in Missouri."). Few if any chemical abortions are recorded or made part of a woman's medical history. Yet, many women who seek an abortion desire a future pregnancy.[23] Doctors need

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[22] *See*, *e.g.*, Debra B. Stulberg et al., *Abortion Provision Among Practicing Obstetrician-Gynecologists*, 118 Obstetrics & Gynecology 609, 609 (2011) ("Among practicing obstetrician–gynecologists . . . 14% performed them.").

[23] *See*, *e.g.*, Yvonne Butler Tobah, *Could an Elective Abortion Increase the Risk of Problems in a Subsequent Pregnancy?*, Mayo Clinic (Aug. 3, 2022), https://www.mayoclinic.org/healthy-lifestyle/getting-pregnant/expert-answers/abortion/faq-20058551; Lawrence B. Finer et al., *Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives*, 37 Persps. Sexual & Reprod. Health 110, 114 (2005) ("Most framed their decision in terms of the desire to have children later, when they could better provide for them.").

to know their patients' medical history to adequately care for them in their long-term gynecological care, and through future pregnancies and births.

The U.S. public health system does not require by law the collection and reporting of abortion data and does not thoroughly or reliably track abortions or abortion complications. There are only two entities in the U.S. which collect national abortion data, the Guttmacher Institute and the Centers for Disease Control & Prevention (CDC). Reporting to both is *voluntary*.[24] This is contrary to medical practice in other nations, where abortions are recorded as part of a national registry. *See* Mentula, *supra* (analyzing data from Finland).

Into that uncertain and unreliable public health context, the FDA introduced chemical abortion in 2000. The FDA created an ineffective reporting system, FAERS. Christina A. Cirucci 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*, Health Servs. Rsch. & Managerial Epidemiology, Dec. 21, 2021, at 1. FAERS is "a voluntary reporting website." *All. for Hippocratic Med.*, 78 F.4th at 247. It is virtually certain that the FDA's data is incomplete, as the 2006 House Subcommittee hearings and report documented. 2006 House Subcommittee Report,

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[24] Thorp, *Public Health Impact of Legal Termination of Pregnancy in the US*, *supra* note 15, at 2.

supra, at 27. "Common estimates of the proportion of adverse events actually captured by FDA in AERS are from one to ten percent." *Id*.

In addition, the FDA demanded post-marketing studies on the effect of mifepristone on women, a common practice of the FDA.[25] But neither the Population Council or Danco ever completed them. 2006 House Subcommittee Report, *supra*, at 21. The FDA cannot have reasonably assumed that "the risks associated with mifepristone were well known." *All. for Hippocratic Med.*, 78 F.4th at 246.[26]

Notably, the FAERs system, though incomplete, showed significant complications from adverse event reports (AERs). The first independent analysis of AERs was not published until 2006, which detailed the weakness of FAERS reporting. Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 Annals Pharmacotherapy 191 (2006).

The FDA's 2016 elimination of non-fatal adverse event reporting has only limited the meager U.S. data

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[25] *See* Off. of Tech. Assessment, *Postmarketing Surveillance of Prescription Drugs* (1982), *available at* https://ota.fas.org/reports/8220.pdf.

[26] *See also* Byron C. Calhoun & Donna J. Harrison, *Challenges to the FDA Approval of Mifepristone*, 38 Annals Pharmacotherapy 163 (2004); Noah, *supra* note 10, at 573 (evaluating "a number of peculiar aspects of the approval process" that were "truly unprecedented").

on chemical abortion drugs. This data limitation harms doctors in their treatment of patients suffering chemical abortion complications and long-term care of post-abortive women and adolescents.

2. Complications from Ectopic Pregnancy Masked by Mifepristone Are Not Recorded, Analyzed, or Reported.

The FDA originally put a premium on the significance of ruling out an ectopic pregnancy by ultrasound. This is imperative because mifepristone can mask the symptoms of ectopic pregnancy and mifepristone cannot treat or terminate a pregnancy that is outside the uterus (ectopic). Discussed in Section I, *supra*. Ultrasound is the only reliable method of ruling out an ectopic pregnancy. The serious complications arising when a women with an ectopic pregnancy takes mifepristone and/or misoprostol will almost certainly affect her future health and pregnancies.

The removal of the in-person dispensing requirement significantly raises the risk that a woman with an ectopic pregnancy will end up taking mifepristone. If a woman is diagnosed with an ectopic pregnancy by ultrasound prior to rupture, there are non-invasive treatments like methotrexate, which may be able to resolve the ectopic pregnancy without surgery. Even if surgery is required to resolve the ectopic pregnancy, it is much more likely to be able to save a woman's fallopian tube if the surgery is done under non-emergency circumstances. However, if the

diagnosis of ectopic pregnancy is made after rupture, it is almost impossible to spare her fallopian tube and she will lose that organ with resultant decrease in her ability to be able to become pregnant in the future. This damage is completely unnecessary and could be prevented with a simple in-person visit with ultrasound. FDA is well aware of this reality, and the risk is part of the "Black Box warning" on the mifepristone label that mifepristone should not be administered to women with known or suspected ectopic pregnancy.[27]

As recently as its "Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2022," the FDA affirmed that "[a]dministration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus),"[28] though the FDA rescinded the requirement of an ultrasound, *the only reliable tool* to diagnose or rule out an ectopic pregnancy. Thus, the FDA has interfered with obstetric-gynecological care of women with ectopic pregnancies.

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[27] *Mifeprex Prescribing Information*, *supra* note 12, at 1 ("Warnings and Precautions . . . Ectopic pregnancy: Exclude before treatment.").

[28] *Supra* note 8, at 1.

3. The Complications to Women Who End up in Emergency Rooms after Chemical Abortion Are Not Tracked, Recorded or Reported.

If a woman has any complications, it is the standard of abortion practice in the U.S. to instruct the woman not to return to the abortion clinic but to go to the nearest ER.[29] The abortion providers' instructions mean they do not see, record, or report their own patient's complications. And ER doctors may have no reason to identify that abortion was the cause of complications or hemorrhage. In addition, ER doctors may miscode complications as spontaneous miscarriage and never record them as related to abortion. The FDA's actions, along with coding problems in the medical system, filter abortions, including chemical abortions, out of the U.S. public health system. *See supra* note 15.

In addition, the AERs submitted to the FDA from 2000 to 2019 demonstrated that over half of the emergency care after a mifepristone abortion is given in the ER by someone other than the abortion prescriber. Aultman, *supra*, at 4. This means that in treating the one in twenty women who need surgical completion of a mifepristone abortion, Respondents

[29] A woman in the American trial reported to an emergency room after having "lost between one-half to two-thirds of her blood volume." Reprod. Health Drugs Advisory Comm., Ctr. for Drug Evaluation & Rsch., *Hearings on New Drug Application for the Use of Mifepristone for Interruption of Early Pregnancy* 223–25 (1996) (testimony of an emergency room physician).

will be diverted from their normal medical duties to handle the complications of an elective procedure. In a busy labor and delivery unit, this means decreased ability to care for patients with unavoidable complications. It also increases the stress on the healthcare delivery system which often rests on the obstetrician-gynecologist or ER physicians staffing the units. This also raises the risk of liability for the obstetrician-gynecologists who care for these patients without access to the abortion provider's records and who may be unaware of the history of mifepristone abortion, which increases the risks of misdiagnosis. Consequently, the FDA's actions have harmed emergency room doctors caring for post-chemical-abortive patients.

B. The FDA's Actions Have Seriously Impaired Respondents' Ability to Practice According to the Established Standard of Care.

1. Isolating Women in their Pregnancy Increases the Risk of Coerced Abortion and of Future Mental Trauma.

The FDA's deregulation of mifepristone has served to separate women from their doctors and adolescent patients from parents and doctors. Women are isolated and more susceptible to coercion from numerous sources, including trafficking, uncommitted men, or parents.

Coerced abortion is a significant problem. Some studies have found that a majority of abortions in a

particular cohort are coerced.[30] The American College of Obstetricians and Gynecologists (ACOG) reported that "[i]n 2007, the prevalence of IPV [intimate partner violence] was nearly three times greater for women seeking an abortion compared with women who were continuing their pregnancies . . . ."[31] Another group of researchers found "[h]igh rates of physical, sexual, and emotional IPV . . . across six continents among women seeking a TOP [termination of pregnancy]." Megan Hall et al., *Associations between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis*, PLOS Med., Jan. 7, 2014, at 1, 15.

Coercion comes in many different forms, including force, abandonment, and offering to pay for the abortion. *See*, *e.g.*, Sam Rowlands & Susan Walker, *Reproductive Control by Others: Means, Perpetrators and Effects*, 45 BMJ Sexual & Reprod. Health 61, 62 (2019). Coerced abortion heightens the risk of future mental trauma.[32] Coerced abortion is so prevalent

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[30] David C. Reardon et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, Cureus, May 11, 2023, at 1.

[31] Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Reproductive and Sexual Coercion*, Comm. Op. No. 554, at 2 (reaffirmed 2022).

[32] *See*, *e.g.*, Donald Paul Sullins, *Affective and Substance Abuse Disorders Following Abortion by Pregnancy Intention in the United States: A Longitudinal Cohort Study*, 55 Medicina 741 (2019) (examining the National Longitudinal Survey of Adolescent to Adult Health (Add Health) and reporting that at least one in seven abortions in the cohort (14.7%) were of

that numerous states have passed legislation to address the problem, including outright prohibitions of coerced abortion or including warnings to women as part of informed consent requirements.[33]

Neither the CDC or the Guttmacher Institute record or report coerced abortions, and coerced chemical abortions are not reported or recorded in FAERS. When a woman has a chemical abortion and then returns, her primary obstetrician-gynecologist has no way of knowing whether her abortion was coerced, nor the risk of future mental trauma.

The FDA has never considered the risk of coerced abortion in its 2000 approval or actions since then, let

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pregnancies that the woman reported were wanted, and finding that "abortions of wanted pregnancies are associated with a greater risk of negative psychological affect").

[33] At least 25 states currently have some form of law to protect women from coerced abortion: Ala. Code § 26-23A-4(b)(7) (2014); Ariz. Rev. Stat. § 36-2153(A)(2)(d) (2021); Ark. Code § 20-16-1705 (2015); Conn. Gen. Stat. § 19a-601(a)(1) (1990); Del. Code tit. 24 § 1786 (1995); Idaho Code § 18-615 (2008); Ind. Code § 16-34-6-5 (2022); Kan. Stat. § 65-6709(k) (2017); La. Stat. § 40:1061.17(C)(1)(j) (2022); Me. Stat. tit. 22 § 1599-A(1) (2019); Mich. Comp. Laws § 333.17015 (2013); Mo. Rev. Stat. § 188.027(4) (2019); Mont. Code § 50-20-106(7) (2009); Neb. Rev. Stat. §§ 28-327(1)(d), (4)(a) (2022); N.C. Gen. Stat. § 90-21.91 (2023); N.D. Cent. Code § 14-02.1-02.1(1)(a) (2023); Ohio Rev. Code Ann. §§ 2317.56(B)(4)(b) (2021), 3701.791(C) (2009); Okla. Stat. tit. 63 § 1-757.7 (2021); 18 Pa. Cons. Stat. § 3206(g) (1992); S.D. Codified Laws §§ 22-17-14 (2021), 34-23A-56 (2015); Tenn. Code Ann. § 39-15-202(i)(1)(A) (2018); Tex. Health & Safety Code Ann. § 171.012 (2021); Utah Code Ann. § 76-7-312 (1974); W. Va. Code § 16-2I-2 (2021); Wis. Stat. §§ 253.10(3)(b), (3)(c) (2023).

alone the implications of requiring no physician involvement. Without a woman's full medical history, the FDA's actions have harmed obstetrician-gynecologists' care of women suffering from coerced abortions.

2. The Increased Risk of Sepsis from Eliminating the Requirement of an In-person Follow-up Appointment Will Not Be Recorded or Reported.

An inherent risk of mifepristone, by virtue of its effect in blocking the glucocorticoid receptor, is to lower the effectiveness of a woman's immune system. This has been observed in many cases, including the death of young women. Fischer, *supra* note 9. To prevent septic infection, the FDA originally put a premium on multiple physician visits to monitor the woman for complications. The FDA's minimal regulations in the 2000 approval and subsequent deregulations have isolated women, downgraded in-person visits, and separated women from doctors.

The lack of medical supervision increases the risk of incomplete abortions, which raises the risk of septic infection. Yet in 2021, the FDA eliminated in-person visits, which helped physicians monitor the mifepristone process, confirm a completed abortion, and monitor hemorrhage.

The Americans Association of Pro-life Obstetricians and Gynecologists reports that "[m]isoprostol is part of the protocol because

mifepristone alone has an incomplete abortion rate of 20-40%, defined as incomplete expulsion of the uterine contents."[34] The FDA's rescission of in-person follow-up medical consultations and oversight increases the risk of incomplete abortion when women take mifepristone without misoprostol. Incomplete chemical abortion will likely result in surgical abortion.

The complication rate (both hemorrhage and incomplete abortion) is higher with chemical than surgical (suction) abortion. Niinimäki, *supra*. The FDA knew this before the 2000 approval. *See* 2006 House Subcommittee Report, *supra*, at 29–30. As the Report detailed:

> [M]ifepristone interferes with the body's immune response . . . is more inconvenient than surgical abortion . . . is more painful . . . is less effective . . . is associated with more adverse events . . . [and] causes more frequent and more severe hemorrhage than its surgical counterpart.

Id. at 13–14.

Reliable confirmation of an incomplete abortion requires ultrasound. A review of sixteen studies found that four studies which did not use ultrasound "did not clearly distinguish between an incomplete

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[34] Rsch. Comm., Am. Ass'n Pro-life Obstetricians & Gynecologists, *The Reversal of the Effects of Mifepristone by Progesterone*, Prac. Guideline No. 6, at 1 (2022).

abortion and continuing pregnancy." The other twelve studies used ultrasound and were able to "determine the presence of a living embryo" and "differentiate between an incomplete abortion and a continuing pregnancy." Paul L. C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, 90 Linacre Quarterly 395, 397 (2023).

Septic infection will not be diagnosed or treated or recorded and reported. Accurate public health information will be undermined and accurate knowledge of the rate of complications will be obstructed. This undermines physician care and a patient's informed consent to an elective procedure.

3. Pregnant Women Who Are Rh Negative Will Not Be Identified or Treated.

In 2017, ACOG recommended "that healthcare providers administer Rh D immune globulin to Rh D-negative women who have a medication abortion." *Id.* at 376.[35] Women with Rh *negative* blood need to have that diagnosed early in a first pregnancy. If the blood of their child who is Rh *positive* mingles with theirs,

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[35] *See The Rh Factor: How It Can Affect Your Pregnancy, Am. Coll. of Obstetricians & Gynecologists* (June 2022), https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy#:~:text=Most%20people%20are%20Rh%20positive,it%20is%20called%20Rh%20incompatibility; Comm. on Prac. Bulls.–Obstetrics, Am. Coll. of Obstetricians & Gynecologists, *Prevention of Rh D Alloimmunization*, Prac. Bull. No. 181 (2017).

it could have a devastating effect on all future pregnancies. If they have Rh negative blood, they should be treated with Rh D immune globulin (brandnameRhoGAM). *See* Athina L. Yoham & Damian Casadesus, *Rho(D) Immune Globulin*, StatPearls Publ'g (May 22, 2023), https://www.ncbi.nlm.nih.gov/books/NBK557884/. Women are entitled to be informed of this risk and its implications for their future health and pregnancies.

As a consequence of the FDA's countenancing mail-order mifepristone, health care providers are less able to inquire and administer Rh immune globulin to Rh-negative women. Rh negative women will not be informed of their condition, the risks to their future pregnancies, or their need for therapy. Physicians will not know whether women have Rh negative or have received Rh therapy. That too will be excluded from a woman's medical history and negatively impact an obstetrician-gynecologist's long-term care of the patient.

4. Obstetricians-Gynecologists Will Not Have a Complete Medical History or Know the Complications that Impact Long-term Care of Future Pregnancies and Deliveries.

In February 2000, FDA Commissioner Jane Henney testified before Congress, regarding the FDA's review of chemical abortion, that:

> The primary clinical trials conducted by the sponsor to support the safety and efficacy of

> mifepristone—RU-486—were discussed before the Reproductive Health Advisory Committee in July 1996. These clinical studies did not include an evaluation of the psychological effects of the drug in women or an evaluation of the long-term medical consequences of the drug in women. FDA is unaware of any published studies on the psychological effects or the long-term medical consequences of mifepristone in women.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2001: Part 2 of Hearings Before the Subcomm. of the Comm. on Appropriations, 106th Cong. (2000).[36]

After abortion, women need vigilant medical monitoring, especially during future pregnancies. The FDA's actions have interfered with this long-term obstetric-gynecological care.

The FDA's actions since 2000 have had a cumulative effect. Each action builds on the previous one, usurping obstetric-gynecological care. By de-medicalizing mifepristone and misoprostol, the FDA is steering patients away from any medical counseling, and preventing doctors from having reliable medical information to effectively counsel patients in the immediate situation and in their long-term care. Without a complete and accurate medical

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[36] The testimony is available at https://www.govinfo.gov/content/pkg/CHRG-106hhrg63888/html/CHRG-106hhrg63888.htm.

history, physicians cannot accurately and reliably address short-term or long-term post-abortive complications, or accurately treat patients during future pregnancies.

The FDA's actions have injured Respondents in their care of their patients, now and in the future. They have a personal stake in the outcome of the FDA deregulation of mifepristone and in the outcome of this case. *Biden v. Nebraska*, 143 S. Ct. 2355, 2365 (2023); *Lujan*, 504 U.S. at 560–61; *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157–58 (2014); *Hunt v. Wash. State Apple Ad. Com.*, 432 U.S. 333 (1977); *Apter*, 80 F.4th 579 (holding medical doctors had standing to challenge the FDA's actions interfering with the medical practice of prescribing ivermectin).

CONCLUSION

The doctors have first-party standing to challenge the FDA's actions. For the reasons set forth above, *Amicus* urges the Court to affirm.

Respectfully submitted,

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