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.

U.S. 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,

Appeal from the United States District Court
for the Northern District of Texas, Amarillo Division, Case No. 2:22-CV-223-Z
The Honorable Matthew J. Kaczmaryk, Judge Presiding

BRIEF *AMICI CURIAE* OF 94 MEMBERS OF THE UNITED STATES CONGRESS SUPPORTING PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CERTIFICATE OF INTERESTED PERSONS

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

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94 Members of Congress (names listed in the Appendix to this brief)

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are 94 Members of the United States Congress, 18 Senators and 76 Members of the House of Representatives, representing 34 States. A complete list of *Amici* is found in the Appendix to this brief. Congress authorizes power to the U.S. Food and Drug Administration (FDA) to approve drugs and regulate their safety and efficacy. *See All. for Hippocratic Med. v. Food & Drug Admin*., No. 23-10362, slip op. at 3 (5th Cir. Apr. 12, 2023) (the FDA was given "the responsibility to ensure that 'new drugs' are 'safe and effective.'"). Congress directs administrative agencies to act within the scope of their authorized powers. 5 U.S.C. § 706; *see Skinner v. Mid-America Pipeline Co*., 490 U.S. 212, 218 (1989) (citation omitted) (There is a "longstanding principle that so long as Congress provides an administrative agency with standards guiding its actions such that a court could 'ascertain whether the will of Congress has been obeyed,' no delegation of legislative authority trenching on the principle of separation of powers has occurred.").

As pro-life elected representatives, *Amici* are committed to protecting women and girls from the harms of the abortion industry. By approving and then deregulating chemical abortion drugs, the FDA failed to follow Congress' statutorily

[1] No party's counsel authored any part of this brief. No person other than *Amici Curiae* and their counsel contributed any money intended to fund the preparation or submission of this brief. Plaintiffs-Appellees, Defendants-Appellants, and Intervenor-Appellant have granted consent to the filing of this *amici curiae* brief.

prescribed drug approval process and subverted Congress' critical public policy interests in upholding patient welfare. Moreover, the FDA in 2016 eliminated any requirement that adverse non-fatal medical events resulting from chemical abortion be reported to the FDA, then claimed in its 2021 revision that the absence of reported complications demonstrated that chemical abortion was safe. The FDA's lawless actions have endangered women and girls seeking chemical abortions, and the Court should affirm the District Court's ruling.

SUMMARY OF ARGUMENT

Congress has carefully considered the approval process for new drugs, instituting safeguards to protect patients' welfare. The Federal Food, Drug, and Cosmetic Act (FFDCA) ensures new drugs are safe and effective for patients. 21 U.S.C. § 355. The Pediatric Research Equity Act (PREA) recognizes that pediatric patients face unique challenges, and therefore requires that drug assessments include studies showing the safety and effectiveness of the drug for pediatric use, as well as the proper dosing and administration for these young patients. *Id*. at § 355c. Congress has also decreed that abortion-inducing drugs are "nonmailable matter" by the United States Postal Service and common carriers, protecting women and girls from the heightened risks of mail-order chemical abortion drugs. 18 U.S.C. §§ 1461–1462.

In spite of this, the FDA has approved and deregulated chemical abortion drugs. The "chemical abortion pill" (also known as a "medical abortion") is a regimen of two drugs, mifepristone and misoprostol.[2] "[M]ifepristone (brand name, Mifeprex), is an antiprogesterone, which starves the pregnancy. The second, misoprostol (brand name, Cytotec), a prostaglandin, causes the uterus to contract,

[2] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin. (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

which mechanically expels the fetus and placenta." Clarke D. Forsythe & Donna Harrison, *State Regulation of Chemical Abortion After* Dobbs, 16 Liberty U. L. Rev. 377, 377 (2022).

Amici agree with Appellees that the FDA's actions have contravened these federal laws, and, accordingly, have violated the Administrative Procedure Act (APA). "'[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.' When an agency exercises power beyond the bounds of its authority, it acts unlawfully." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1921 (2020) (Thomas, J., concurring in the judgment in part and dissenting in part) (alterations in original) (citations omitted). The FDA must also adhere to the APA's "arbitrary and capricious" standard, which means "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) (citation omitted).

Fundamentally, this case is about how the FDA exceeded the scope of its authorized power from Congress, which, in turn, has subverted Congress' public policy interests in patient safety. As the U.S. House Committee on Government Reform (now known as the Committee on Oversight and Accountability)'s

Subcommittee on Criminal Justice, Drug Policy and Human Resources has recognized:

> The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities. RU-486 is a hazardous drug for women, its unusual approval demonstrates a lower standard of care for women, and its withdrawal from the market is justified and necessary to protect the public's health.

Staff of Subcomm. on Crim. Just., Drug Pol'y and Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong., *The FDA and RU-486: Lowering the Standard for Women's Health* 40 (Subcomm. Print 2006). *Amici* highlight how chemical abortion drugs pose serious threats to the health and safety of women and girls, and a Section 705 stay of the FDA's approval and deregulation of chemical abortion drugs is in the interest of public policy to protect patient safety.[3]

[3] Preliminary injunctions have four factors: "(1) a substantial likelihood of prevailing on the merits; (2) a substantial threat of irreparable injury if the injunction is not granted; (3) the threatened injury outweighs any harm that will result to the non-movant if the injunction is granted; and (4) the injunction will not disserve the public interest." *Ridgely v. Fed. Emergency Mgmt. Agency*, 512 F.3d 727, 734 (5th Cir. 2008). The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). "Because the [District] Court [found] injunctive relief is generally appropriate, Section 705 plainly authorize[d] the lesser remedy of issuing 'all necessary and appropriate process' to postpone the effective date of the challenged actions." *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-223-Z, slip op. at 66 (N.D. Tex. Apr. 7, 2023).

ARGUMENT

I. THE FDA'S FAILURE TO ADHERE TO THE FFDCA'S DRUG APPROVAL PROCESS HAS CREATED GRAVE RISKS TO THE HEALTH AND SAFETY OF WOMEN AND GIRLS.

Congress places safeguards within the FFDCA to ensure new drugs are safe and efficacious for patients. 21 U.S.C. § 355. Chemical abortion drugs already pose serious threats to patient health and safety. Thus, by unlawfully approving and deregulating chemical abortion drugs, the FDA is further jeopardizing patients' welfare. As the Subcommittee on Criminal Justice, Drug Policy and Human Resources recognized in their report, *The FDA and RU-486: Lowering the Standard for Women's Health*, "the medical community knew what American women would soon learn by experience," that chemical abortion drugs pose grave risks. Staff of Subcomm. on Crim. Just., *supra*, at 13. The report detailed that "mifepristone 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. Yet the FDA has acted in an arbitrary and capricious manner in approving and deregulating chemical abortion drugs to the detriment of the health and safety of women and girls.

Contrary to its duty under the FFDCA, the FDA failed to include critical patient safeguards in its approval of chemical abortion drugs, even though the FDA

relied upon those same safeguards when regulating the drugs. As the District Court detailed:

> Here, the U.S. trials FDA relied upon when approving mifepristone required that: (1) each woman receive an ultrasound to confirm gestational age and exclude an ectopic pregnancy; (2) physicians have experience in performing surgical abortions and admitting privileges at medical facilities that provide emergency care; (3) all patients be within one hour of emergency facilities or the facilities of the principal investigator; and (4) women be monitored for four hours to check for adverse events after taking misoprostol. However, FDA included *none* of these requirements—which were explicitly stated in the clinical trial FDA relied on most—in the 2000 Approval.

All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-223-Z, slip op. at 49 (N.D. Tex. Apr. 7, 2023) (emphasis in original) (citations omitted).

The FDA perpetuated this problem by "fail[ing] to 'examine the relevant data' when it made the 2016 Major REMS changes . . . because FDA eliminated REMS safeguards based on studies that *included those very safeguards*." *All. for Hippocratic Med.*, No. 23-10362, slip op. at 34 (emphasis in original) (citation omitted). Specifically, in 2016, the FDA "omitted the requirements of the underlying tests: (1) gestational age confirmed by ultrasounds; (2) participants required to return for clinical assessment; and (3) surgical intervention if necessary." *All. for Hippocratic Med.*, No. 2:22-cv-223-Z, slip op. at 49 (citation omitted). As the Fifth Circuit stay panel analogized:

> Imagine that an agency compiles studies about how cars perform when they have passive restraint systems, like automatic seatbelts. For nearly a decade, the agency collects those studies and continues studying how

> cars perform with passive safety measures. Then one day the agency changes its mind and *eliminates* passive safety measures based only on existing data of how cars perform *with* passive safety measures. That was obviously arbitrary and capricious in *State Farm*[, 463 U.S. 29]. And so too here. The fact that mifepristone might be safe when used with the 2000 Approval's REMS (a question studied by FDA) says nothing about whether FDA can eliminate those REMS (a question not studied by FDA).

All. for Hippocratic Med., No. 23-10362, slip op. at at 34–35 (emphasis in original) (citations omitted).

Since 2016, the FDA has only required adverse events reporting for deaths resulting from chemical abortion drugs; reporting is otherwise voluntary. As the Fifth Circuit stay panel described:

> After eliminating that adverse-event reporting requirement, FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is "safe." This ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to applicants' own documents, necessitates a REMS program, a "Patient Agreement Form," and a "Black Box" warning. It'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.

Id. at 35 (citations omitted). Besides the unreasonableness of this action, there are safety concerns. As one study concludes, "FAERS [the FDA Adverse Event Reporting System] is inadequate to evaluate the safety of mifepristone" due to reporting discrepancies, and the fact that the FDA no longer mandates reporting of non-lethal adverse events. Christina A. Circucci 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, 4. Even so, the FDA has received FAERS Mifeprex reports through June 30, 2022 documenting 28 deaths, 4,213 adverse events, 1,048 hospitalizations (excluding deaths), 604 blood loss incidents requiring transfusions, 414 infections, and 71 severe infections. *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 06/30/2022*, U.S. Food & Drug Admin. 1, 1–2 (June 30, 2022), https://www.fda.gov/media/164331/download.

Fundamentally, chemical abortion drugs pose serious health and safety risks to women and girls. The FDA's arbitrary and capricious actions in approving and deregulating the drugs only exacerbates those risks. A 2021 peer-reviewed study showed alarming results; chemical-abortion related emergency room visits (*i.e.*, visits medically coded as chemical abortion complications) per 1,000 abortions "went from 8.5 to 51.7, an increase of 507%" over thirteen years. James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, Health Servs. Rsch. & Managerial Epidemiology, Nov. 9, 2021, at 1, 5. By 2015, the rate of emergency room visits within 30 days for any cause (*i.e.*, any emergency room visit regardless of how it was medically coded) per 1000 chemical abortions was 354.8. *Id*. at 4–5. This means 35.48% of women ended up in the emergency room within thirty days

of taking chemical abortion drugs. *Id*. The study found that "[emergency room] visits following [a chemical abortion] grew from 3.6% of all postabortion visits in 2002 to 33.9% of all postabortion visits in 2015." *Id*. at 8. During the same period, chemical abortions "increased from 4.4% of total abortions in 2002 to 34.1% in 2015." *Id*.

The actual number of adverse effects is likely much higher due to emergency room miscoding. As compared to miscoding of surgical abortion-related treatment, 2015 data showed emergency rooms were four times as likely to miscode chemical abortion-related treatment as miscarriage-related treatment. *Id*. at 1. Between 2013 and 2015, emergency rooms miscoded up to 60.9% of chemical abortion-related visits as miscarriage-related visits. *Id*. at 4. This means that U.S. data are severely incomplete, and studies have understated the risks chemical abortion drugs pose to women and girls, which include hemorrhaging and infection due to retained pregnancy tissue.

Previously, U.S. abortion studies have reported lower chemical abortion complication rates than statistics found in international scientific studies. *Id*. at 7. For example, studies from Scandinavian countries, which record pregnancy and medical events more accurately than the United States, give a better picture of chemical abortion complications than U.S. data. In a study of 42,619 Finnish women receiving chemical abortions up to nine weeks gestational age, the overall adverse events were almost fourfold higher in chemical (20.0%) versus surgical abortions

(5.6%). Maarit Niinimaki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 795 (2009). Women hemorrhaged more commonly after chemical abortion (15.6% compared with 2.1%). *Id*. They also had incomplete abortions more often in chemical abortions (6.7% versus 1.6%). *Id*. The rate of surgical (re)evacuation was higher after chemical abortions (5.9%) than surgical abortions (1.8%). *Id*.

Another study examined first and second trimester chemical abortions of 18,248 Finnish women. 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). Women undergoing first and second trimester chemical abortions needed surgical evacuation in 9.9% of cases. *Id*. at 929. Women specifically undergoing second trimester chemical abortions needed surgical evacuation in 39% of cases. *Id*. at 931. Later in pregnancy, the likelihood of serious complications significantly increases, something that cannot be controlled for when drugs are sent through the mail and taken at the woman's discretion.

One particularly concerning aspect of the initial drug approval is that the FDA had no evidence of the drugs' psychological or long-term physical effects. As FDA Commissioner Jane Henney testified before Congress in February 2000 regarding the FDA's review of chemical abortion drugs:

> 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.[4]

Abortion poses mental health risks for women and girls. "Pregnancy loss (natural or induced) is associated with an increased risk of mental health problems." David C. Reardon & Christopher Craver, *Effects of Pregnancy Loss on Subsequent Postpartum Mental Health: A Prospective Longitudinal Cohort Study*, Int'l J. Env't Rsch. & Pub. Health, Feb. 23, 2021, at 1, 1. "Research on mental health subsequent to early pregnancy loss as a result of elective induced abortions has historically been polarized, but recent research indicates an increased correlation to the genesis or exacerbation of substance abuse and affective disorders including suicidal ideation." Kathryn R. Grauerholz et al., *Uncovering Prolonged Grief Reactions Subsequent to a Reproductive Loss: Implications for the Primary Care Provider*, Frontiers Psych., May 12, 2021, at 1, 2. Scholarship shows "that the emotional reaction or grief experience related to miscarriage and abortion can be prolonged, afflict mental health, and/or impact intimate or parental relationships." *Id*. Similarly, "[s]everal recent international studies have demonstrated that repetitive early pregnancy loss,

[4] *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) (emphasis added). The testimony is available at https://www.govinfo.gov/content/pkg/CHRG-106hhrg63888/html/CHRG-106hhrg63888.htm.

including both miscarriage and induced abortions, is associated with increased levels of distress, depression, anxiety, and reduced quality of life scores in social and mental health categories." *Id*.; *see, e.g.*, Louis Jacob et al., *Association Between Induced Abortion, Spontaneous Abortion, and Infertility Respectively and the Risk of Psychiatric Disorders in 57,770 Women Followed in Gynecological Practices in Germany*, 251 J. Affective Disorders 107, 111 (2019) (finding "a positive relationship between induced abortion . . . and psychiatric disorders in gynecological practices in Germany").

"In the case of medical abortion, consideration needs to be given to the pharmacological effects of mifepristone (RU486), in addition to any procedural consequences." Christina Camilleri et al., *Biological, Behavioral and Physiological Consequences of Drug-Induced Pregnancy Termination at First-Trimester Human Equivalent in an Animal Model*, Frontiers NeuroSci., May 29, 2019, at 1, 2. One study examined the "biological, behavioral and physiological consequences of pharmacologically terminating a pregnancy at mid-term (first-trimester human equivalent) in an animal model." *Id*. at 13. The researchers concluded, "[t]aken together, our analyses appear to indicate a significant effect of pregnancy termination on the biological (rat weight, food intake, vaginal impedance), physiological (oxidative balance) and most especially, behavioral parameters (sucrose consumption, rearings, distance active, percentage time active, overall

speed) measured." *Id*. The study suggested further research regarding chemical abortion's impact on physiology and neurophysiology to help understand chemical abortion's impact on humans. *Id*. at 16.

In sum, chemical abortion drugs already pose serious threats to patient welfare. Under the Administrative Procedure Act, "[n]ot only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Allentown Mack Sales & Serv., Inc. v. Nat'l Labor Rels. Bd.*, 522 U.S. 359, 374 (1998). It is arbitrary and capricious for the FDA to rely on studies with patient safeguards but fail to include those patient safeguards when approving and deregulating chemical abortion drugs. Similarly, it is illogical for the FDA to claim that chemical abortion drugs are safe and effective when, since 2016, the FDA has made non-lethal adverse event reporting voluntary. By subverting the FFDCA's patient safeguards to ensure new drugs are safe and efficacious, the FDA has acted beyond its congressionally authorized power, and is playing a dangerous game with the health and safety of women and girls. Accordingly, the Court should affirm the District Court's Section 705 stay of the FDA's approval and deregulation of chemical abortion drugs.

II. THE FDA ENDANGERS PREGNANT ADOLESCENTS SEEKING CHEMICAL ABORTION DRUGS BY UNLAWFULLY SUBVERTING THE PEDIATRIC STUDY REQUIREMENT.

Under the Pediatric Research Equity Act (PREA), assessments of new drugs must include studies showing the safety and effectiveness of the drug for pediatric use, as well as the proper dosing and administration for adolescent patients. 21 U.S.C. § 355c. The FDA can waive the pediatric rule "[i]f the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients . . . ." *Id.* at § 355c(a)(2)(B)(i). Again,

> Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers. Congress may limit an agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue.

Heckler v. Chaney, 470 U.S. 821, 833 (1985). Accordingly, the FDA must adhere to the pediatric rule before approving or deregulating drugs for adolescent patients because they face unique challenges when experiencing pregnancy.

The FDA subverted PREA and exceeded the scope of its authorized power. In the initial drug approval of chemical abortion drugs in 2000, the FDA waived the pediatric rule, incorrectly stating "there is no biological reason to expect menstruating females under age 18 to have a different physiological outcome with the regimen." Compl. Ex. 24, Dist. Ct. ECF No. 1-25 at 8; *All. for Hippocratic Med.*, No. 2:22-cv-223-Z, slip op. at 51 (during the 2000 approval, "[n]or was the drug

tested for under-18 girls undergoing reproductive development").[5] As discussed below, this contention is flatly incorrect and endangers girls seeking chemical abortion drugs.

The 2016 Major REMS changes only exacerbated the problem. As Appellees detailed:

> The FDA did not require Danco to submit an assessment on the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, nor did the FDA require Danco to submit an assessment that supported the dosing and administration for each pediatric subpopulation for which the drug is safe and effective.

Compl. ¶ 207, Dist. Ct. ECF No. 1 at 57 (citation omitted). The FDA cited three studies which presented issues of whether the FDA could safely extrapolate the data to meet its duty to ensure the drugs are safe for pediatric use. Compl. ¶¶ 208–215, Dist. Ct. ECF No. 1 at 57–60 (citations omitted). For example, the primary study included an ultrasound examination on all patients prior to chemical abortions and the provision of "routine antibiotic coverage" during the chemical abortion. Compl. ¶ 212, Dist. Ct. ECF No. 1 at 58–59 (citation omitted). "But the FDA did not require any of these safeguards for women and girls under the 2016 Major Changes." Compl. ¶ 212, Dist. Ct. ECF No. 1 at 59.

[5] References to "Dist. Ct. ECF" are to the District Court docket, No. 2:22-cv-223-Z (N.D. Tex.). All ECF page numbers reference the blue ECF headers.

Adolescent patients seeking chemical abortions face unique challenges that place them in dissimilar conditions to adult women. Thus, it is imperative that the FDA fulfills its statutory duty to ensure the drugs, dosages, and administration are safe and effective for girls seeking chemical abortion drugs.

Adolescents do not have fully developed decision-making capabilities. As the Supreme Court acknowledged in *H.L. v. Matheson*, "[t]he medical, emotional, and psychological consequences of an abortion are serious and can be lasting; this is particularly so when the patient is immature." 450 U.S. 398, 411 (1981), *overruled on other grounds by Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). Generally, "[a]ppropriate decisional capacity and legal empowerment are the determinants of decision-making authority in medicine." Aviva L. Katz et al., *Informed Consent in Decision-Making in Pediatric Practice*, Pediatrics, Aug. 2016, at e1, e2. Nevertheless, "[a] reliance on individual liberties and autonomy in the pediatric patient is not realistic or legally accepted, so parents or other surrogates provide 'informed permission' for diagnosis and treatment, with the assent of the child as developmentally appropriate." *Id*. Consequently, parental guidance is instrumental for an adolescent patient's informed consent.[6] Parental involvement

[6] The FDA's approval and deregulation of chemical abortion drugs also blatantly ignores parents' constitutional rights to the care and upbringing of their minor pregnant daughters. *See Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972) ("The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition.").

helps an adolescent patient select a competent healthcare professional who prioritizes her health. *Child Interstate Abortion Notification Act: Hearing on H.R. 2299 Before the Subcomm. on the Const. of the H. Comm. on the Judiciary*, 112th Cong. 19 (2012) (statement of Teresa Stanton Collett, Professor of Law, University of St. Thomas School of Law). Parents may "provide additional medical history and information [regarding their minor daughter] to abortion providers prior to [the] performance of the abortion," safeguard that an adolescent girl understands the medical risks of the procedure, and give her advice during the informed consent process. *Id*. at 26–27. Moreover, parental involvement "ensures that the parents have the ability to monitor for post-abortion complications." *Id*. at 19.

Adolescents have high risk pregnancies and often delay prenatal care. "Adolescence is a critical period marking phenomenal changes including rapid physical, psychosocial, sexual and cognitive maturation, and nutrient needs of adolescents are higher than at any other stage in the lifecycle." Nadia Akseer et al., *Characteristics and Birth Outcomes of Pregnant Adolescents Compared to Older Women: An Analysis of Individual Level Data from 140,000 Mothers from 20 RCTs*, eClinicalMed., Feb. 26, 2022, at 1, 3. During pregnancy, "adolescent girls are a particularly vulnerable group since the demands of regular growth and development are augmented by the heightened nutritional requirements of supporting a fetus." *Id*. Due to adolescent patients' developing bodies, they have a "biological

predisposition for high-risk pregnancies." *Id*. at 12. The high-risk nature of adolescent pregnancy is compounded by the fact that pregnant adolescent patients often delay care. Nathalie Fleming et al., *Adolescent Pregnancy Guidelines*, 37 J. Obstetrics & Gynaecology Can. 740, 743 (2015). There are multiple reasons adolescent patients delay care, including:

> lack of knowledge about the importance of prenatal care and lack of understanding of the consequences of its absence; history as a victim of violence, desire to hide pregnancy, fear of potential apprehension of the baby, contemplation of abortion services; concerns about lack of privacy or judgemental attitudes from health care providers or adults; and financial barriers.

Id. Unfortunately, "[l]ack of, or delayed, adolescent prenatal care is associated with adverse maternal, obstetrical, and neonatal outcomes." *Id*.

The FDA approved and deregulated chemical abortion drugs without knowing the drugs' impact on adolescent development, especially its effect on girls' immune systems. *See* Subcomm. on Crim. Just., *supra*, at 12 (recognizing medical concerns about mifepristone's immune system inhibition); Compl. ¶ 216, Dist. Ct. ECF No. 1 at 60 (During the 2016 Major REMS changes, "[t]he FDA did not require any studies on the long-term effects of chemical abortion drugs in pediatric populations with developing reproductive systems."). Mifepristone, an anti-progestin, interferes with the immune system "by binding with a woman's progesterone receptors on the nuclear membranes of cells in the uterus, ovary, brain, breast, and immune system." Forsythe, *supra*, at 388. Since mifepristone has blocked uterine progesterone

receptors, "the mother's cells in the placenta stop functioning, which eventually leads to the death of the embryo through, in essence, starvation," and at a certain point, the mother loses her unborn child. *Id*. at 388–389. However, mifepristone has another effect upon the body: "the blockade of glucocorticoid receptors also induces an unexpected immune blockade, suppressing the immune system, which can result in increased susceptibility to overwhelming infection" throughout the body. *Id*. at 389; *see also* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to* Clostridium Sordellii, 39 Annals Pharmacotherapy 1483, 1483 (2005) ("[I]t appears that the mechanisms of mifepristone action favor the development of infection that leads to septic shock and intensifies the actions of multiple inflammatory cytokines, resulting in fulminant, lethal septic shock.").

Thus, adolescent patients seeking chemical abortion drugs face unique challenges compared to their adult counterparts. The FDA had no authority to waive the pediatric study in the initial 2000 drug approval. In its deregulation of the drugs, the FDA did not adhere to its legal obligation to ensure the chemical abortion drugs, dosages, and administration are safe and effective for adolescent patients. *See* 21 U.S.C. § 355c. Accordingly, the FDA acted outside the scope of its authorized power under PREA, and risked the health and safety of adolescent patients.

III. THE FDA HAS CREATED SERIOUS HAZARDS FOR WOMEN'S HEALTH AND SAFETY BY PERMITTING MAIL-ORDER CHEMICAL ABORTION DRUGS IN VIOLATION OF FEDERAL LAW.

Federal law bars the use of the United States Postal Service and common carriers from mailing abortion-inducing drugs, including the chemical abortion regimen of mifepristone and misoprostol. 18 U.S.C. §§ 1461–1462.[7] As the Fifth Circuit has recognized, "[i]t is of highest public importance that federal agencies follow the law." *R.J. Reynolds Vapor Co. v. Food & Drug Admin.*, No. 23-60037, slip op. at 16 (5th Cir. Mar. 23, 2023) (citation omitted). *Amici* agree with Appellees that the FDA's actions permit distribution of these drugs through means prohibited under 18 U.S.C. §§ 1461–1462. Pls.' Br. In Supp. of Their Mot. for Prelim. Inj. 20–21, Dist. Ct. ECF No. 7 at 25–26. And as the Fifth Circuit stay panel held,

> [T]he Comstock Act nevertheless undermines applicants' showing on the final three [preliminary injunction] factors. For example, if the Comstock Act is construed in-line with its literal terms, then Danco cannot say it is irreparably harmed by the district court's order, because Danco has no interest in continuing to violate the law, which (under a plain view of the Act) it does every time it ships mifepristone. For further example, if the Comstock Act is strictly understood, then applicants may lose the public interest prong entirely, because there is no public interest in the perpetuation of illegality.

[7] Members of Congress recently expressed their opposition to the FDA's decision to eliminate the in-person dispensing requirement for chemical abortion drugs, recognizing the dangers the drugs pose to women and girls, and how the FDA's actions violate federal criminal law. Letter from Cindy Hyde-Smith, Senator, U.S. Cong., et al., to Robert Califf, Comm'r, U.S. Food & Drug Admin. (Jan. 26, 2023), https://www.hydesmith.senate.gov/sites/default/files/2023-01/012623%20Bicameral%20Letter%20to%20FDA%20re%20Abortion%20Drugs.pdf.

All. for Hippocratic Med., No. 23-10362, slip op. at 41 (citation omitted). The Fifth Circuit stay panel similarly, and rightfully, rejected Appellants' arguments that Congress *sub silentio* repealed the Comstock Act, or, "[f]ailing all else, . . . the Comstock Act does not mean what it says it means." *Id*. at 42.[8]

By contravening federal law to allow telemedicine and mail-order chemical abortion drugs, the FDA is endangering women's health and safety. In-person visits are necessary for chemical abortions. The Mayo Clinic states that: "Medical abortion isn't an option if you . . . *[c]an't make follow-up visits to your doctor* or don't have access to emergency care." *Medical Abortion*, Mayo Clinic (July 29, 2022), https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (emphasis in original). Medical institutions are in agreement about this, as "[a] medical abortion involves at least two visits to a doctor's office or clinic." *Medical Abortion*, Univ. of Cal. San Francisco Health, www.ucsfhealth.org/treatments/medical-abortion (last visited May 11, 2023). Follow-up visits and reporting are critical to ensure that if a woman has retained tissue, she receives essential follow-up care.

[8] In response to the Department of Justice Office of Legal Counsel's recent memo contending federal laws do not prohibit the mailing of chemical abortion drugs, Members of Congress wrote to Attorney General Merrick Garland, reminding him that the "plain text and clear meaning of the law" prohibit the mailing of chemical abortion drugs. Letter from James Lankford, Senator, U.S. Cong., et al., to Merrick B. Garland, Att'y Gen., U.S. Dep't of Just. 1 (Jan. 25, 2023), https://www.lankford.senate.gov/imo/media/doc/dojletterabortionmail.pdf.

But even before a chemical abortion, healthcare providers must confirm a woman is a medically appropriate candidate for chemical abortion. In most states, this consultation is with a physician. In a few states, like California, it can be done by a midlevel provider, such as a nurse practitioner, certified nurse-midwife, or physician assistant. Cal. Bus. & Prof. Code § 2253(b) (2022). A number of medical conditions make a woman ineligible to take chemical abortion drugs, including having a potentially dangerous ectopic pregnancy (a pregnancy outside of the uterus) or having an intrauterine device (IUD) in place. *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra*. Chemical abortion cannot terminate an ectopic pregnancy and should not be used after the first seventy days of pregnancy due to heightened risk to the woman's health. *Id*. A physician can only diagnose an ectopic pregnancy by blood tests and an ultrasound, which means a physician cannot determine via telemedicine whether a pregnancy is ectopic. *Ectopic Pregnancy*, Mayo Clinic (Mar. 12, 2022), https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis-treatment/drc-20372093.

Determining gestational age usually is done in person by ultrasound. Ultrasound is the most accurate method to establish or confirm gestational age in the first trimester. Comm. on Obstetric Practice, Am. Coll. of Obstetricians & Gynecologists et al., *Methods for Estimating the Due Date*, Comm. Op. No. 700, at 1

(reaffirmed 2022). Dating a pregnancy by using a woman's last menstrual period (LMP) is far less accurate. The American College of Obstetricians and Gynecologists (ACOG) indicates only one half of women accurately recall their LMP. *Id*. at 2. In one study, forty percent of women had more than a five-day discrepancy between their LMP dating and the ultrasound dating. *Id*. In this regard, LMP dating is not nearly as precise as an ultrasound. But an accurate measurement of gestational age is required to show that a woman is even a candidate for a chemical abortion.

Without an in-person evaluation, abortion providers also cannot test for Rh negative blood type. During pregnancy, if a woman has Rh negative blood while her fetus is Rh positive, the woman's body may produce antibodies after exposure to fetal red blood cells. *Rh Factor Blood Test*, Mayo Clinic (July 29, 2022), https://www.mayoclinic.org/tests-procedures/rh-factor/about/pac-20394960. Abortion can cause maternal exposure to fetal blood, even in the first trimester. *Id*. Therefore, if indicated, a healthcare provider must give a woman with Rh negative blood an Rh immuneglobulin injection. Without the injection, antibodies can damage future pregnancies by creating life-threatening anemia in fetal red blood cells. *Id*. ACOG describes that "Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated." Comm. On Practice Bulletins—Gynecology and the Soc'y of Family Planning, Am. Coll. of Obstetricians & Gynecologists, *Medication*

Abortion Up to 70 Days of Gestation, Comm. Op. 225, at 40 (reaffirmed 2023). Rh negative blood typing is thus a medically necessary test, but it cannot occur during chemical abortions consultations that are done entirely via telemedicine.

A woman seeking an abortion may be facing intimate partner violence (IPV). There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]." 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. For women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy. Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Reproductive and Sexual Coercion*, Comm. Op. No. 554, at 2 (reaffirmed 2022). Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression . . . , suicidal ideation . . . , stress . . . , and disturbing thoughts." Hall, *supra*, at 11.

Similarly, intimate partners, family members, and sex traffickers may be asserting reproductive control over the woman, which are "actions that interfere with a woman's reproductive intentions." Sam Rowlands & Susan Walker, *Reproductive Control by Others: Means, Perpetrators and Effects*, 45 BMJ Sexual & Reprod. Health 61, 62, 65 (2019). In the context of abortion, reproductive control not only produces coerced abortions or continued pregnancies, but it also affects whether the

pregnancy was intended in the first place. *Id*. at 62–63. Reproductive control is a prevalent issue for women. "As many as one-quarter of women of reproductive age attending for sexual and reproductive health services give a history of ever having suffered [reproductive control]." *Id*. at 62.

Medical professionals must "[s]creen for IPV in a private and safe setting with the woman alone and not with her partner, friends, family, or caregiver." Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Intimate Partner Violence*, Comm. Op. No. 518, at 3 (reaffirmed 2022). Yet, telemedicine cannot ensure that a coercive partner, friend, family member, or caregiver is not in the room with a woman seeking a chemical abortion. In a telehealth setting, ACOG recommends healthcare providers screen patients multiple times because patients may not be able to disclose abuse each time they are screened. *COVID-19 FAQs for Obstetricians-Gynecologists, Obstetrics*, Am. Coll. of Obstetricians & Gynecologists (rev. July 1, 2021), https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics; *see also Intimate Partner Violence*, *supra*, at 3 (noting IPV screening should occur periodically and "at various times . . . because some women do not disclose abuse the first time they are asked"). In other words, domestic violence screening by telehealth "may not allow individuals the privacy or safety needed to disclose abuse." *Id*. Thus, telehealth ineffectively screens women seeking chemical abortions for domestic violence or

coercion. If she changes her mind, no medical professional is there to help her. She is left alone to care for her physiological and psychological health, as well as her safety if complications or IPV arise.

Accordingly, by openly disregarding federal restrictions on the mailing of chemical abortion drugs, the FDA has exacerbated the health risks of chemical abortion drugs, and reduced safeguards against domestic violence.

CONCLUSION

The FDA's unlawful approval and deregulation of chemical abortion drugs subverts Congress' public policy considerations and safeguards for patient safety. The FDA's "power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is ultra vires." *City of Arlington v. Fed. Commc'ns Comm'n*, 569 U.S. 290, 297 (2013). *Amici* respectfully urge this Court to affirm the District Court's order because the FDA exceeded the scope of its authorized power, and endangered the health and safety of women and girls seeking chemical abortion drugs.

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CERTIFICATE OF COMPLIANCE

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Typeface Requirements, and Type-Style Requirements

A. I hereby certify, pursuant to Federal Rule of Appellate Procedure 32(g), that this brief complies with the type-volume limit of Fed. R. App. P. 29(a)(5) because it contains 6338 words, excluding the parts exempted by Fed. R. App. P. 32(f).

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CERTIFICATE OF SERVICE

I certify that on May 12, 2023, I electronically filed the foregoing brief with the Clerk of Court throughout the CM/ECF system, which shall send notification of such filing to any CM/ECF participants.

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Kevin Cramer (ND)

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Steve Daines (MT)

John Hoeven (ND)

James Lankford (OK)

Roger Marshall (KS)

James Risch (ID)

Marco Rubio (FL)

Rick Scott (FL)

John Thune (SD)

Tommy Tuberville (AL)

Roger Wicker (MS)

United States House of Representatives

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