No. 23-395

In the Supreme Court of the United States

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,
Respondents.

ON CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF *AMICI CURIAE* OF 109 MEMBERS OF CONGRESS IN SUPPORT OF CROSS-PETITIONERS AND CONDITIONAL CROSS-PETITION

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are 109 Members of the United States Congress, 17 Senators and 92 Members of the House of Representatives, representing 32 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. 21 U.S.C. § 393. 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) (citing *Mistretta v. United States*, 488 U.S. 361, 379 (1989)) (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 contravened its own regulations, and failed to follow Congress' statutorily prescribed drug approval

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[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. Cross-Petitioners and Cross-Respondents received timely notice to the filing of this brief.

process to the detriment of patient welfare. The FDA's lawless actions ultimately have endangered women and girls seeking chemical abortions.

SUMMARY OF ARGUMENT

The FDA approved mifepristone, an abortion-inducing drug, in 2000. 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, 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).

There were "approval irregularities" in the FDA's consideration of mifepristone. 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 (Subcomm. Print 2006). Relying improperly upon its Subpart H authority, the FDA misclassified pregnancy as a "life-threatening illness." *See* 21 C.F.R. § 314.500. Pregnancy is not an illness, let alone

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[2] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin. (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

a life-threatening one. Likewise, chemical abortions do not provide a "meaningful therapeutic benefit" over surgical abortions, especially considering chemical abortions pose greater health risks than surgical abortions. In approving mifepristone, the FDA also acted arbitrarily and capriciously in violation of the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 706(2)(A). The FDA subverted its obligations under the Food, Drug, and Cosmetic Act ("FDCA") to ensure new drugs are safe and effective, *see* 21 U.S.C. § 355, and failed to assess the safety and effectiveness of the drugs for pediatric use, as well as the proper dosing and administration for these young patients under the Pediatric Research Equity Act ("PREA"). *See* 21 U.S.C. § 355c.

The Fifth Circuit held it was untimely for the Cross-Petitioners to challenge the FDA's 2000 approval of mifepristone and did not have standing to challenge the 2019 generic drug approval, but correctly upheld a stay of the FDA's 2016 and 2021 actions that deregulated mifepristone. *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 222–223 (5th Cir. 2023). *Amici* support the Fifth Circuit's reinstatement of common-sense patient safeguards, which include in-person dispensing of mifepristone as well as an in-person follow-up examination to ensure a woman has not suffered complications or retained fetal tissue. Accordingly, *Amici* support Cross-Petitioners' opposition to the FDA and Danco's petitions for a writ of *certiorari*, which have asked this Court to

reconsider patient safeguards that protect women and girls seeking chemical abortion drugs.

Amici agree with Cross-Petitioners that they have a timely challenge to the FDA's unlawful approval of mifepristone in this case. *See* Conditional Cross-Pet. Writ Cert. 16–23. *Amici* write separately to contribute a federal policy perspective as to why the FDA, in approving mifepristone, (I) went beyond the scope of its Subpart H authority, and (II) acted in violation of the APA, FDCA, and PREA. Since the FDA's lawless approval of mifepristone subverts patient safeguards and contravenes federal laws, *Amici* urge the Court to grant Alliance for Hippocratic Medicine's conditional cross-petition if the Court grants the Food & Drug Administration and/or Danco's petitions for a writ of certiorari.

ARGUMENT

I. The FDA Exceeded its Subpart H Authority by Approving Mifepristone.

The FDA may apply Subpart H's accelerated approval process "to certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. In certain circumstances for drugs approved under Subpart H, the "FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product." 21 C.F.R. § 314.520. Congress codified

Subpart H's post-marketing restrictions into the FDCA in 2007 as Risk Evaluation and Mitigation Strategies ("REMS"). 21 U.S.C. § 355-1(a)(1)–(2).

The FDA used Subpart H to accelerate the approval process for the chemical abortion drug. As Professor Lars Noah detailed:

> 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). The FDA indicated in its approval letter to the Population Council in 2000 that the "FDA has determined that the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H. The meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure.*" All. for Hippocratic Med.,* 78 F.4th at 224. Yet, the FDA exceeded the scope of Subpart H's authority with this reasoning. *Amici* highlight that (A) pregnancy is not an "illness," nor "life-threatening" in normal

circumstances; and (B) chemical abortions do not provide meaningful therapeutic benefit over surgical abortions.

A. The FDA Misclassified Pregnancy as a "Life-Threatening Illness."

Subpart H applies to drugs the FDA has "studied for their safety and effectiveness in treating serious or life-threatening illnesses." 21 C.F.R. § 314.500. Yet, in efforts to approve mifepristone, the FDA rewrote this language, indicating the "termination of an unwanted pregnancy is a serious *condition* within the scope of Subpart H." *All. for Hippocratic Med.,* 78 F.4th at 224 (emphasis added). Even with these "[l]inguistic gymnastics . . . pregnancy or the termination of pregnancy is not a 'serious or life-threatening illness,' and therefore does not fall within the defined reach of subpart H; the term 'serious condition' is not found in the Subpart H rule." Staff of Subcomm. on Crim. Just., *supra*, at 20.

Fundamentally, "pregnancy itself is not an illness." *Id*. An illness is "an unhealthy condition of body or mind." *Illness*, Merriam-Webster's Med. Dictionary https://unabridged.merriam-webster.com/medical/illness (last visited Nov. 6, 2023). Pregnancy is "the condition of being pregnant,"[3] which, in turn, means "[a body] contain[s] a developing embryo, fetus, or unborn offspring."

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[3] *Pregnancy*, Merriam-Webster's Med. Dictionary, https://unabridged.merriam-webster.com/medical/pregnancy (last visited Nov. 6, 2023).

Pregnant, Merriam-Webster's Med. Dictionary, https://unabridged.merriam-webster.com/medical/pregnant (last visited Nov. 6, 2023); *see also Pregnancy*, Taber's Med. Dictionary, https://www.tabers.com/tabersonline/view/Tabers-Dictionary/756370/all/pregnancy?q=pregnancy (last visited Nov. 6, 2023) (defining pregnancy as "[t]he condition of having a developing embryo or fetus in the body after successful conception")."Pregnancy is not a bad or unhealthy condition of the body—it's a natural consequence of a healthy and functioning reproductive system." *All. for Hippocratic Med.,* 78 F.4th at 263 (Ho, J., concurring in part and dissenting in part). Indeed, as the field of obstetrics recognizes, "ordinarily pregnancy is a normal physiological state . . . ." F. Gary Cunningham et al., *Williams Obstetrics* 12 (18th ed. 1989).

Pregnancy is not an illness, let alone a "life-threatening illness," which is what Subpart H requires. Although "[t]here are situations in which serious or life-threatening complications may arise, . . . these are atypical events." Staff of Subcomm. on Crim. Just., *supra*, at 20. The "pregnancy can sometimes *result* in illness. But that does not make the pregnancy itself an illness." *All. for Hippocratic Med.,* 78 F.4th at 263 (Ho., J., concurring in part and dissenting in part) (emphasis in original) (citation omitted).

When the FDA initially promulgated Subpart H, it indicated the agency "discussed the meaning of the terms 'serious' and 'life-threatening' in its final rules

on 'treatment IND's [investigational new drugs]' . . . and 'subpart E' procedures . . . . The use of these terms in this rule is the same as FDA defined and used the terms in those rulemakings." New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942, 58,945 (Dec. 11, 1992) (to be codified at 21 C.F.R. pts. 314, 601). In turn, the treatment INDs rule "defined an immediately life-threatening disease in the regulation as being a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466, 19,467 (May 22, 1987) (to be codified at 21 C.F.R. pt. 312). The INDs rule listed examples, such as "[a]dvanced cases of AIDs . . . [a]dvanced congestive heart failure . . . [and m]ost advanced metastatic refractory cancers." *Id*. For its part, the Subpart E rule indicated:

> A "life-threatening" disease is defined as one in which the likelihood of death is high unless the course of the disease is interrupted (e.g., progression from asymptomatic HIV infection to symptomatic HIV infection, or further progression to a later stage of AIDS; metastatic cancer; amyotrophic lateral sclerosis). This use of the term "life-threatening" plainly includes any disease whose progression is likely to lead to death, especially in a short period of time (e.g., 6 months to 1 year).

Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses, 53 Fed. Reg. 41,516, 41,518–41,519 (Oct. 21, 1988) (to be codified at 21 C.F.R. pts. 312, 314). Pregnancy, which is a normal and healthy physiological condition, cannot plausibly be compared to such life-threatening diseases.

Drugs used to treat these life-threatening illnesses contrast with mifepristone, which is intended for *elective* abortions. In the words of "William Hubbard, who served as the FDA's Associate Commissioner for Policy throughout the Clinton administration, . . . [who] remark[ed] shortly before joining the agency: 'RU-486 is intended for convenien[t] use by healthy young women rather than as a therapy for an incapacitating or life-threatening disease.'" Noah, *supra*, at 582. This means the FDA approved mifepristone for elective abortion. An "elective abortion is defined as those drugs or procedures used with the primary intent to end the life of the human being in the womb." *AAPLOG Statement: Clarification of Abortion Restrictions*, Am. Ass'n of Pro-Life Obstetricians & Gynecologists (July 14, 2022), https://aaplog.org/aaplog-statement-clarification-of-abortion-restrictions/. It is not medically required. "'Elective' . . . refers to inductions done in the absence of some condition of the mother or the fetus which requires separation of the two to protect the life of one or the other (or both)." Rsch. Comm., Am. Ass'n of Pro-Life Obstetricians & Gynecologists, *Concluding Pregnancy Ethically*, Prac.

Guideline No. 10, at 5 (Aug. 2022). This means that "by definition, there is no medical indication for elective induced abortion, since it cures no medical disease. . . . Pregnancy is not a disease, and the killing of human beings in utero is not medical care." Pro. Ethics Comm., Am. Ass'n of Pro-Life Obstetricians & Gynecologists, *Hippocratic Objection to Killing Human Beings in Medical Practice*, Comm. Op. No. 1, at 8 (May 8, 2017) (emphasis omitted). In other words, medical professionals perform elective induced abortions for *non-medical* reasons, which does not meet Subpart H's requirement that the drug treat "life-threatening illnesses." Accordingly, the FDA exceeded its Subpart H authority in approving mifepristone.

B. Chemical Abortions Do Not Provide a "Meaningful Therapeutic Benefit" Over Surgical Abortions.

For the FDA to approve a drug under Subpart H, the drug must "provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. Here, the FDA contends "[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure." *All. for Hippocratic Med.,* 78 F.4th at 224. "Clearly, this mistakes a definition for a syllogism" by saying a chemical abortion is better than a surgical abortion because, by definition, it does not involve surgery. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2268 (2022) (cleaned up). "[E]ven though some women may prefer [mifepristone] abortions over

surgical abortions, that fact does not establish the existence of a therapeutic benefit in and of itself." Staff of Subcomm. on Crim. Just., *supra*, at 22. Regardless of this logical fallacy, the FDA failed to demonstrate—contrary to its Subpart H obligations—that chemical abortion provides a meaningful therapeutic benefit over existing treatments.

As Cross-Petitioners highlight, "[m]ifepristone is not 'therapeutic.'" Conditional Cross-Pet. Writ Cert. 27. 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 recognized, "[mifepristone] was not approved for a medical indication intended for only the treatment of patients who were intolerant of surgical abortion. It was approved to treat the general population of women seeking first-trimester abortions." Staff of Subcomm. on Crim. Just., *supra*, at 22.

The FDA likewise failed to satisfy its Subpart H obligation because "it appears that no concurrently-controlled trials comparing medical and surgical abortion were required by FDA, because the Agency already knew that medical abortion—i.e., abortion by [mifepristone]—is unambiguously inferior to surgical abortion with respect to safety and effectiveness." *Id*. Comparatively, chemical abortions have greater risks

than surgical abortions.[4] In a study of 42,619 Finnish women receiving chemical abortions up to nine weeks gestational age, for example, 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.*

Likewise, "surgery is an integral part of the [mifepristone] abortion process, because a substantial proportion of women require [dilation and curettage abortions] after beginning the mifepristone regimen. Therefore, women who have [mifepristone] abortions must be able to tolerate the surgical procedure." Staff of Subcomm. on Crim. Just., *supra*, at 22. A study examining first and second trimester chemical abortions of 18,248 Finnish women highlighted

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[4] To be clear, whether chemical or surgical, abortion poses grave safety concerns. "Abortion not only poses risks to the mother, it is always lethal to an unborn child." *The Assault on Reproductive Rights in a Post-*Dobbs *America: Hearing before the S. Comm. on the Jud.*, 118th Cong. 2 (2023) (written testimony of Monique Chireau Wubbenhorst, Senior Rsch. Assoc., de Nicola Ctr. for Ethics & Culture). The abortion industry's pervasive failure to adhere to health and safety standards only exacerbates these risks to women's health. *See* Ams. United for Life, *Unsafe: America's Abortion Industry Endangers Women* (2021 ed.).

medical professionals may use surgery to complete a failed chemical abortion. 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.

In sum, chemical abortions do not provide "meaningful therapeutic benefits" to women and girls over surgical abortions, and in fact pose higher health and safety risks. The FDA improperly used its Subpart H authority to approve chemical abortion drugs.

II. The FDA's Approval of Mifepristone Subverted Patient Health and Safety Safeguards Within Federal Laws.

Amici agree with Cross-Petitioners that the FDA's actions have contravened the APA and FDCA. Conditional Cross-Pet. Writ Cert. 28–31.[5] *Amici* add

[5] *Amici* also note the FDA's 2021 actions, which eliminated in-person dispensing of chemical abortion drugs, contradicted the "plain text and clear meaning of the [Comstock Act]." 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. Members of Congress recently expressed their opposition to the FDA's 2021 actions, recognizing the dangers

that the FDA's actions also have subverted PREA, discussed below. "'[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 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) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

The FDA acted arbitrarily and capriciously in approving mifepristone. As the U.S. House Committee on Government Reform's Subcommittee on Criminal Justice, Drug Policy and Human Resources recognized:

> The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this

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mail-order chemical abortions pose to women and girls. 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.

> 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., *supra*, at 40. In approving mifepristone, the FDA did not act "in accordance" with patient safeguards within the FDCA and PREA, and approved mifepristone in excess of its statutory authority. *See* 5 U.S.C. § 706(2)(A).

A. The FDA's Failure to Adhere to the FDCA's Drug Approval Process Has Created Significant Health and Safety Risks to Women and Girls.

Congress places safeguards within the FDCA to ensure new drugs are safe and efficacious for patients. 21 U.S.C. § 355. As Cross-Petitioners note, the FDA failed to include critical patient safeguards in its approval of chemical abortion drugs, even though the FDA approved mifepristone by relying upon studies that used those safeguards. Conditional Cross-Pet. Writ Cert. 30. Namely, the clinical trials required medical professionals to perform "an ultrasound to confirm gestational age and to exclude an ectopic pregnancy," as well as monitor the woman for a period of three to five hours after she took misoprostol. *Id*. Removing these conditions of use, even after relying

upon them in the approval of mifepristone, is contrary to the FDCA's requirements. *See* 21 U.S.C. § 355(d).

By subverting these patient safeguards, the ultimate victims of the FDA's lawless actions have been women and girls seeking these drugs. Unfortunately, "the medical community knew what American women would soon learn by experience," that chemical abortion drugs pose significant risks. Staff of Subcomm. on Crim. Just., *supra*, at 13. "[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.

Fundamentally, chemical abortion drugs pose serious health and safety risks to women and girls. There is an "assumption that [a chemical abortion] is more natural, private and safer than a surgical procedure, but physicians and patients alike may be unaware that it takes much longer, involves far more bleeding and pain, and complications occur four times more frequently from medical as compared to surgical abortions." Rsch. Comm., Am. Ass'n Pro-Life Obstetricians & Gynecologists, *Medication Abortion*, Prac. Guideline No. 8, at 3 (Feb. 2020). After taking chemical abortion drugs, [t]he average woman bleeds for 9–16 days and eight percent will bleed longer than a month." *Id*. Unfortunately, "[t]he side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever/chills, vomiting, headache, diarrhea,

and dizziness occur in almost all women." *Id*. As the gestational age increases, so too will the complication rates for women taking chemical abortion drugs. *Id*.

Since 2016, the FDA has only required adverse events reporting for deaths resulting from chemical abortion drugs; reporting is otherwise voluntary.[6] Even so, the FDA has received FAERS Mifeprex reports through December 31, 2022 documenting 32 deaths (regardless of causality), 4,218 adverse events, 1,049 hospitalizations (excluding deaths), 604 blood loss incidents requiring transfusions, 418 infections, and 75 severe infections. *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, U.S. Food & Drug Admin. 1, 1–2 (Dec. 31, 2022), https://www.fda.gov/media/164331/download.

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*

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[6] 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.

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 mifepristone 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 events 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 3. 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.

One concerning aspect of the initial drug approval is that the FDA "entirely failed to consider an

important aspect of the problem," *State Farm*, 463 U.S. at 43, namely, the 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.[7]

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,

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[7] *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.

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, 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 sum, the FDA failed to follow FDCA patient safety requirements, which is to the detriment of the health and safety of women and girls seeking chemical abortion drugs.

B. The FDA Endangers Pregnant Adolescents Seeking Chemical Abortion Drugs by Subverting the Pediatric Study Requirement.

Under 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(a)(2)(A).[8] The FDA can waive the pediatric study "[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 PREA before approving or deregulating drugs for adolescent patients because they face unique challenges when experiencing pregnancy.

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[8] For background on the FDA's pediatric rule and Congress' codification of the regulation into PREA, *see All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, slip op. at 51 n.49 (N.D. Tex. Apr. 7, 2023); Compl. ¶¶ 89–96, Dist. Ct. ECF No. 1 at 26–28.

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 study, 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. v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, slip op. at 51 (N.D. Tex. Apr. 7, 2023) (during the 2000 approval, "[n]or was the drug tested for under-18 girls undergoing reproductive development").[9] This contention "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," *State Farm*, 463 U.S. at 43, and endangers girls seeking chemical abortion drugs.[10]

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,

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[9] 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.

[10] The FDA likewise failed to meet its PREA obligations during the 2016 Major REMS changes. *See* Compl. ¶¶ 206–216, Dist. Ct. ECF No. 1 at 57–60.

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*, 142 S. Ct. 2228. 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.[11] Parental involvement 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

[11] 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.").

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 their effects on girls' immune systems. *See* Staff of 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, and did not 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.

In sum, "the political motivations for bringing [mifepristone] to the U.S. market overwhelmed considerations of women's health and safety." Staff of Subcomm. on Crim. Just., *supra*, at 9. The FDA

subverted patient safeguards when it violated the APA, FDCA, and PREA's requirements.

CONCLUSION

If the Court grants the FDA and/or Danco's petitions for a writ of certiorari, then *Amici* urge the Court to grant Alliance for Hippocratic Medicine's conditional cross-petition. The FDA unlawfully approved mifepristone as a "life-threatening illness" under Subpart H, and subverted patient safeguards within federal laws. The FDA's actions have endangered women and girls seeking these dangerous drugs.

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November 15, 2023

APPENDIX

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LIST OF *AMICI CURIAE*

U.S. Senate

Lead Senator: Cindy Hyde-Smith (MS)

John Barrasso (WY)	John Hoeven (ND)
Mike Braun (IN)	James Lankford (OK)
Katie Britt (AL)	Roger Marshall (KS)
Ted Budd (NC)	Markwayne Mullin (OK)
Bill Cassidy (LA)	James Risch (ID)
Kevin Cramer (ND)	Marco Rubio (FL)
Mike Crapo (ID)	Rick Scott (FL)
Steve Daines (MT)	Roger Wicker (MS)

U.S. House of Representatives

Lead Representative: August Pfluger (TX–11)

Robert Aderholt (AL–04)

Mark Alford (MO–04)

Rick Allen (GA–12)

Jodey Arrington (TX–19)

Brian Babin (TX–36)

Don Bacon (NE–02)

James Baird (IN–04)

Troy Balderson (OH–12)

Jim Banks (IN–03)

Aaron Bean (FL–04)

Cliff Bentz (OR–02)

Andy Biggs (AZ–05)

Gus Bilirakis (FL–12)

Lauren Boebert (CO–03)

Mike Bost (IL–12)

Josh Brecheen (OK–02)

Tim Burchett (TN–02)

Michael Burgess, M.D. (TX–26)

Eric Burlison (MO–07)

Kat Cammack (FL–03)

Jerry Carl (AL–01)

Earl L. "Buddy" Carter (GA–01)

Ben Cline (VA–06)

Michael Cloud (TX–27)

Andrew S. Clyde (GA–09)

Mike Collins (GA–10)

Dan Crenshaw (TX–02)

Warren Davidson (OH–08)

Jeff Duncan (SC–03)

Dr. Neal Dunn (FL–02)

Jake Ellzey (TX–06)

Ron Estes (KS–04)

Mike Ezell (MS–04)

Scott Fitzgerald (WI–05)

Virginia Foxx (NC–05)

Russ Fulcher (ID–01)

Bob Good (VA–05)

Lance Gooden (TX–05)

Paul A. Gosar, D.D.S. (AZ–09)

Garrett Graves (LA–06)

Mark Green (TN–07)

Marjorie Taylor Greene (GA–14)

Michael Guest (MS–03)

Harriet Hageman (WY)

Andy Harris, M.D. (MD–01)

Diana Harshbarger (TN–01)

Kevin Hern (OK–01)

Clay Higgins (LA–03)

Ashley Hinson (IA–02)

Erin Houchin (IN–09)

Richard Hudson (NC–09)

Bill Johnson (OH–06)

Jim Jordan (OH–04)

Mike Kelly (PA–16)

Trent Kelly (MS–01)

Doug Lamborn (CO–05)

Jake LaTurner (KS–02)

Debbie Lesko (AZ–08)

Barry Loudermilk (GA–11)

Lisa McClain (MI–09)

Dr. Richard McCormick (GA–06)

Carol Miller (WV–01)

Mary Miller (IL–15)

John Moolenaar (MI–02)

Alex X. Mooney (WV–02)

Barry Moore (AL–02)

Nathaniel Moran (TX–01)

Ralph Norman (SC–05)

Andrew Ogles (TN–05)

Gary Palmer (AL–06)

Bill Posey (FL–08)

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