NOS. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

and

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 OF *AMICI CURIAE* FAMILY POLICY ALLIANCE AND STATE FAMILY POLICY COUNCILS IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF AMICI CURIAE 1

CONCISE STATEMENT OF THE CASE..... 2

SUMMARY OF ARGUMENT 4

ARGUMENT 5

I. Principles of Federalism Require FDA Adherence to Federal Law 6

II. Chemical Abortions are Inherently Dangerous..... 7

A. There is a Double Standard in the Treatment of Pregnant Women..... 7

B. The FDA's New Approach is Particularly Dangerous for Women with Ectopic Pregnancies..... 8

C. Gestational Age is Inaccurately Calculated in the Absence of In-Person Visits..... 9

D. Lack of Physician After-Care Increases the Risk of Serious Infection..... 10

E. Medical Emergencies Caused by Mifepristone are Increasing..... 10

F. Mifepristone Complications are Being Miscoded as Miscarriage Complications Because of the Lack of Continuity of Care Resulting from the FDA's Actions..... 12

G. Chemical Abortion Failure Means Some Women Will Require Two Abortions Instead of One..... 13

H. Women can Experience Psychological Trauma from Encountering the Remains of Their Aborted Children, a Significant Adverse Effect the FDA has not Addressed..... 13

III. The FDA is Not Listening Resulting in Arbitrary and Capricious Decisions..... 15

CONCLUSION 16

TABLE OF AUTHORITIES

Cases

Alliance for Hippocratic Med. v. *FDA,* 2023 U.S. App. LEXIS 8898 (5th Cir. Apr. 12, 2023) 15
Alliance for Hippocratic Med. v. *United States FDA*, 2023 U.S. Dist. LEXIS 61474 (N.D. Tex. Apr. 7, 2023) 12, 15
Dobbs v. *Jackson Women's Health Org.*, 597 U.S. 215 (2022) 5, 6, 7
Motor Vehicle Mfrs. Ass'n v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983) 15, 16

Statutes

5 U.S.C. 706(2)(A) 15
21 U.S.C. 321(p) and 355 2
21 U.S.C. 355-1(a)(1)-(2) 3
21 U.S.C. 393(b)(2)(B) 2

Regulations

21 C.F.R. 314.500 2

Other Authorities

Caroline Kitchener, *Covert network provides pills for thousands of abortions in U.S. post Roe*, Wash. Post (Oct. 18, 2022) 14
Caroline S. Hoffman et al., Comparison of gestational age at birth based on last menstrual period and ultrasound during the first trimester, 22 PAEDIATRIC & PERINATAL EPIDEMIOLOGY 587 (2008) 9
David A. Savitz et al., Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination,

187 AM. J. OBSTETRICS GYN. 1660 (2002)..... 9
James Studnicki et al., A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015, 8 HEALTH SERV. RSCH. MGMT. EPIDEMIOLOGY 8 (2021)..... 12
Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives, 36 HEALTH COMMC'N. 1485 (2021)..... 12
Richard C. Henshaw, et al., Comparison of medical abortion with surgical vacuum aspiration. Women's preferences and acceptability of treatment, 307 BRIT. MED. J. 714 (1993)..... 14
The Federalist No. 39, at 192 (James Madison) (Lawrence Goldman, ed., 2008)..... 7
Tyler Mummert & David M. Gnugnoli, *Ectopic Pregnancy* (2024) 8

INTEREST OF AMICI CURIAE[1]

Amici curiae Family Policy Alliance and state family policy councils[2] joining in this brief are organizations that advocate for strong families and communities. Amici support laws, regulations, and policies that protect the health and safety of women, and oppose any double standard that exempts abortion medications from the same rigorous safety criteria applied to other drugs. Additionally, as organizations with a special focus on state law, amici value the benefits of federalism and wish to address the flawed argument that requiring the U.S. Food and Drug Administration ("FDA") to adhere to the

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[1] No party's counsel authored any part of this brief. No person other than *amici* and their counsel contributed any money intended to fund the preparation or submission of this brief. Counsel for all parties received timely notice of the intent to file this brief.

[2] Alabama Policy Institute, Alaska Family Council, Center for Arizona Policy, California Family Council, Family Institute of Connecticut, Delaware Family Policy Council, Florida Family Policy Council, Frontline Policy Council (Georgia), Hawaii Family Forum, Indiana Family Institute, The FAMiLY Leader (Iowa), Kanas Family Voice, The Family Foundation (KY), Louisiana Family Forum, Christian Civic League of Maine, Maryland Family Institute, Michigan Family Forum, Minnesota Family Council, Montana Family Foundation, Nebraska Family Alliance, Cornerstone Action (New Hampshire), New Jersey Family Policy Center, New Mexico Family Action Movement, New Yorkers Family Research Foundation, North Carolina Family Policy Council, North Dakota Family Alliance, Center for Christian Virtue (Ohio), Oklahoma Council for Public Affairs, Pennsylvania Family Institute, Rhode Island Family Institute, Palmetto Family Council (South Carolina), Family Voice (South Dakota), Alliance for Law & Liberty (Tennessee), Texas Values, Family Policy Institute of Washington, Wisconsin Family Council, and Wyoming Family Alliance.

standards applicable under federal law undermines the principles of federalism.

CONCISE STATEMENT OF THE CASE

The FDA is responsible for ensuring that new drugs are "safe and effective." 21 U.S.C. 321(p) and 355; see also 21 U.S.C. 393(b)(2)(B). In 2000, the FDA approved the drugs mifepristone and misoprostol for inducing chemical abortion in early pregnancy.

Chemical abortion involves using these two drugs together. Mifepristone is a synthetic steroid that blocks progesterone, causing the death of the unborn child. Misoprostol induces cramping and contractions so the woman expels the dead unborn child and other pregnancy tissue through the birth canal.

The FDA approved these drugs under "Subpart H" because the FDA determined that pregnancy is a "serious or life-threatening illness" and that these chemical abortion-inducing drugs provided "meaningful therapeutic benefit to patients over existing treatments," namely surgical abortion. FDA Approval Mem., Mifeprex (Sep. 28, 2000)[3]; 21 C.F.R. 314.500.

To protect women's health, the FDA imposed certain safety requirements, now known as "risk evaluation and mitigation strategies" ("REMS"). 21

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[3] Gov't C.A. Add. to Emergency Motion for Stay ("C.A. Add.") at 186, *Alliance for Hippocratic Med.* v. *FDA*, 2023 U.S. App. LEXIS 8898 (5th Cir. Apr. 10, 2023) (No. 23-10362).

U.S.C. 355-1(a)(1)-(2). The FDA safety requirements for chemical abortion in 2000 included:

- Pregnancies must be less than 50 days gestation (7 weeks)
- Three in-person office visits required
- Supervision by a qualified physician
- All adverse events must be reported

See FDA Approval Mem., Mifeprex; FDA Approval Letter, Mifeprex (Sept. 28, 2000).[4]

In 2016, the FDA began relaxing its safety requirements for chemical abortion in the following ways:

- Maximum gestational age increased to 70 days (10 weeks)
- Only one in-person office visit required
- Non-doctors can prescribe and administer abortion drugs
- Only fatalities must be reported

See FDA Summary Review, Mifeprex REMS Changes (Mar. 29, 2016).[5] In 2021 during the COVID-19 pandemic, the FDA used "enforcement discretion" to allow women to mail-order chemical abortion drugs. 2021 Mail-Order Decision.[6] In 2023, the FDA decided to make its pandemic-related approach permanent.

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[4] C.A. Add. 181-91.

[5] C.A. Add. 777-802.

[6] Alliance for Hippocratic Med., et al. Appendix in Support of Motion for Preliminary Injunction ("PI App."), at 713-15, *Alliance for Hippocratic Med.* v. *United States FDA*, 2023 U.S. Dist. LEXIS 61474 (N.D. Tex. Nov. 18, 2022) *(*No. 2:22-CV-223-Z).

See REMS Single Shared System for Mifepristone 200 mg (Jan. 2023) (the "2023 Mail Order Decision").[7]

In November 2022, Respondents (physicians and physician organizations) sued in the U.S. District Court for the Northern District of Texas and moved for a preliminary injunction. The Fifth Circuit found that Respondents were likely to succeed on the merits regarding the FDA's actions in 2016 and subsequent years.

In summary, the FDA believes that pregnancy is a "serious or life-threatening illness" that can be treated by chemical-inducing abortion drugs prescribed by someone who is not a doctor, to a woman who has never been seen by a doctor, up to 10 weeks of pregnancy, shipped to a woman in the mail, and the FDA only wants to hear from medical personnel about adverse events when patients are dead. For all non-fatal adverse consequences, the FDA is content only to receive reports from the manufacturers profiting off of the sale of these drugs. See FDA Summary Review, Mifeprex.[8] This is a women's health nightmare.

SUMMARY OF ARGUMENT

The FDA has turned chemical abortion into self-managed abortion, which is dangerous for women. Under the FDA's anemic safety standards, women are expected to accurately diagnose the gestational age of unexpected pregnancies with woefully inadequate

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[7]Available at https://perma.cc/MJT5-35LF.
[8] C.A. Add. 802.

tools, self-administer abortion-inducing drugs, dispose of fetal remains themselves, and go to the emergency room when foreseeable and fully preventable serious medical complications occur. The removal of doctors from the chemical abortion process, the increasing span of gestational age for prescription, and the removal of key adverse event reporting requirements only serve two objectives – maximum abortion access and pharmaceutical profit – at the expense of women's health.

Respondents have demonstrated before the district court and the court of appeals that the FDA's relaxation of its own safety requirements for mifepristone use is arbitrary and capricious, sending vulnerable women to the emergency room, and causing other significant adverse effects. This gross disregard for women's health must stop.

Nevertheless, 640 state legislators filed an amicus brief justifying the FDA's violations of federal law on federalism grounds. They argue that post-*Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215 (2022), federal courts cannot hold the FDA accountable because court action violates federalism. This is an "abortion access" argument in disguise. The FDA as a federal agency can and should be held accountable by federal courts for violations of federal law.

ARGUMENT

The court opinions below recount many harrowing stories of doctors and medical professionals who have been personally impacted,

and have seen their patients' lives threatened, by the reckless posture of the FDA.

I. Principles of Federalism Require FDA Adherence to Federal Law.

The state legislators' brief argues that the Fifth Circuit's decision undermines states' longstanding authority over public health matters in violation of the federalism principles in *Dobbs*. This is an "abortion access" argument dressed up like federalism, except that the federalism dress does not match or fit at all.

The FDA is a federal agency being held accountable by federal courts to follow federal law. Taking legislators' argument to its logical conclusion would mean dissolving the FDA entirely because only states may regulate matters of public health. Of course, the legislators do not want to do that because, as they say in their brief, they "depend on FDA's science-based processes to approve medications as safe and effective for distribution." Br. of Amici Over 640 State Legislators, at 10. Instead, legislators' desire to allow a federal agency to do whatever it wants turns federalism on its head by encouraging federal overreach. The FDA has a role to play, and states have a role to play. These roles existed pre-*Dobbs* and they exist post-*Dobbs*. *Dobbs* removed constitutional barriers to abortion regulation; *Dobbs* did not change the role of the FDA, standards set forth in the Administrative Procedure Act ("APA"), or the ability of federal courts to hold the FDA accountable for violations of federal law.

In Federalist Paper 39, James Madison recognized a key principle of federalism – that while certain powers belong to the federal government, federalism leaves "to the several states a residuary and inviolable sovereignty over all other objects." The Federalist No. 39, at 192 (James Madison) (Lawrence Goldman, ed., 2008). Yet, in no way did the *Dobbs* decision give states exclusive jurisdiction on all things that affect abortion. If it did, states would not only be the sole regulator of medication used in chemical abortion, but the sole regulator of all medical devices used in surgical abortion as well. In summary, the legislators' arguments fall apart on many levels – causing us to acknowledge that their brief is really about abortion access at the expense of women's health, which is where we turn next.

II. Chemical Abortions are Inherently Dangerous.

A. There is a Double Standard in the Treatment of Pregnant Women.

During the pandemic, we witnessed a two-tiered system of pregnancy-related healthcare. For women carrying children to term, in-person pregnancy care continued, albeit with masks, temperature checks, and leaving partners at home. For women seeking abortion, the FDA mailed it in. What was "essential" for one became "unessential" for the other. Women carrying children to term continued to receive ultrasounds – which properly diagnose gestational age and medically confirm that embryos are implanted in the uterus. This information is critical – regardless of whether a woman decides to abort or

give birth. Failure to provide this care to women seeking chemical abortion can have devastating consequences.

B. The FDA's New Approach is Particularly Dangerous for Women with Ectopic Pregnancies.

When embryos implant outside the uterus, the child cannot survive and the woman's life is in danger. This is ectopic pregnancy, which remains a silent killer under the FDA's prescribing regimen.

One to two percent of pregnancies are ectopic. Tyler Mummert & David M. Gnugnoli, *Ectopic Pregnancy* (2024).[9] Not only do mifepristone and misoprostol not work in ending ectopic pregnancies, they also leave women "at risk of severe harm from hemorrhage due to tubal rupture," which can be life-threatening. Decl. of Dr. Ingrid Skop at 29 (Nov. 11, 2022).[10] By removing doctors from the prescription and administration of these drugs, chemical abortions become a blind game of "point and shoot" – where we know with statistical certainty that we are going to miss in a number of cases. When that happens, emergency rooms become the default health care provider because those who provide mifepristone are incapable of handling these types of medical emergencies.

The complications surrounding ectopic pregnancy are common enough and sufficiently recurrent that

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[9]Available at https://www.ncbi.nlm.nih.gov/books/NBK539860/.
[10] PI App. at 208.

they are noted on the FDA "Patient Agreement Form" that the manufacturer requires every mifepristone user to sign. 2023 Mail-Order Decision at 10. However, signing a form does nothing to alleviate these risks and complications because medical professionals are prescribing these drugs blindfolded.

C. Gestational Age is Inaccurately Calculated in the Absence of In-Person Visits.

Without an in-person doctor visit, a woman is left to diagnose gestational age on her own. She has a "yes/no" at-home pregnancy test – where the same pink lines appear whether she has just missed a period or is about to give birth. She also has her menstrual cycle history to draw from, which can be highly variable and misleading. A woman can have irregular cycles, mistake blood spotting during pregnancy for a period, or in the busyness of life lose track of the date of the start of her last menstrual period – these are unexpected pregnancies after all. This is why medical professionals don't rely on at-home pregnancy tests or cycle history when assessing gestational age for women carrying children to term – they perform ultrasounds. If women *trying* and *wanting* to get pregnant get gestational age wrong,[11] how much more likely is it that women who find

[11] Caroline S. Hoffman et al., Comparison of gestational age at birth based on last menstrual period and ultrasound during the first trimester, 22 PAEDIATRIC & PERINATAL EPIDEMIOLOGY 587-596 (2008).; David A. Savitz et al., Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination, 187 AM. J. OBSTETRICS GYN. 1660 (2002).

themselves pregnant *unexpectedly* get gestational age wrong.

D. Lack of Physician After-Care Increases the Risk of Serious Infection.

The FDA no longer requires a third in-person office visit to assess complications and ensure no fetal tissue remains in the womb. This lack of care means that women have to wait for a serious infection or life-threatening sepsis to take hold before starting treatment. The FDA knows this is a common enough problem that "serious infection" is mentioned on the FDA "Patient Agreement Form" that mifepristone users sign. Signing a form does nothing to prevent an infection that is otherwise medically preventable with proper after-care. Signing a form is no substitute for an examination by a doctor. The FDA cannot call pregnancy a "serious or life-threatening illness" and then be lax about medical care.

E. Medical Emergencies Caused by Mifepristone are Increasing.

The Fifth Circuit noted, "[m]ifepristone users who present themselves to [Respondents] have required blood transfusions, overnight hospitalization, intensive care, and even surgical abortions." Decl. of Dr. Ingrid Skop at 10.[12] Sepsis, intravenous antibiotics, heavy bleeding, abdominal pain, fever, endometritis, infection of the uterine lining, acute kidney injury, elevated creatinine, intravenous

[12] PI App. 205-06.

hydration, tubal rupture, and unstable vital signs are all serious medical consequences noted by the Court of Appeals. "[T]he risk of severe bleeding with chemical abortion is five times higher than from surgical abortion." Decl. of Dr. George Delgado at 11 (Nov. 14, 2022).[13] As one would expect, the frequency of emergencies involving chemical abortion is only increasing. See Decl. of Dr. Christina Francis (Nov. 11, 2022); Decl. of Dr. Ingrid Skop; Decl. of Dr. Nancy Wozniak (Nov. 11, 2022); Decl. of Dr. Tyler Johnson (Nov. 11, 2022).[14]

These emergencies impact doctors beyond the emergency room. One doctor quoted in the Fifth Circuit opinion was kept from performing his or her primary duties in the hospital labor and delivery unit because of necessary emergency care following chemical abortion. Decl. of Dr. Christina Francis at 12.[15] Given the nature of abortion, it makes sense that doctors from the labor and delivery unit, outside the emergency room, would sometimes need to intervene in a reproductive health emergency. Unfortunately, women in active labor cannot wait either – so one can see how the tradeoffs are real.

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[13] PI App. 879.
[14] PI App. 194, 205, 215, 865-66.
[15] PI App. 194-95.

F. Mifepristone Complications are Being Miscoded as Miscarriage Complications Because of the Lack of Continuity of Care Resulting from the FDA's Actions.

Mifepristone complications are being miscoded in the emergency room as complications relating to miscarriage because there is no continuity of care for patients.[16] This phenomenon further undermines the FDA's data pool and allows the FDA to turn a blind eye to the full spectrum of adverse effects women are experiencing from mifepristone and misoprostol. Lack of proper reporting means patients remain unaware of the true health risks and are unable to give truly informed consent[17] and make informed healthcare decisions.

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[16] "Studies support this conclusion by finding over sixty percent of women and girls' emergency room visits after chemical abortions are miscoded as 'miscarriages' rather than adverse effects to mifepristone." *Alliance for Hippocratic Med.*, 2023 U.S. Dist. LEXIS 61474, (N.D. Tex. Apr. 7, 2023) at *68 (citing James Studnicki et al., A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015, 8 HEALTH SERV. RSCH. MGMT. EPIDEMIOLOGY 8 (2021)).

[17] "In one study, fourteen percent of women and girls reported having received insufficient information about (1) side effects, (2) the intensity of the cramping and bleeding, (3) the next steps after expelling the aborted human, and (4) potential negative emotional reactions like fear, uncertainty, sadness, regret, and pain." *Alliance for Hippocratic Med.* v. *United States FDA*, 2023 U.S. Dist. LEXIS 61474, at *13 (citing Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives, 36 HEALTH COMMC'N. 1485, 1485-94 (2021)).

G. Chemical Abortion Failure Means Some Women Will Require Two Abortions Instead of One.

The FDA "Patient Acknowledgement Form" acknowledges a two-percent to seven-percent chemical abortion fail rate. When a chemical abortion fails and part of the unborn child or pregnancy tissue remains – the woman must undergo a second abortion surgically. This means a woman undergoes two abortions instead of just one – a chemical abortion and a surgical abortion – which can in no way be considered a meaningful therapeutic benefit. Blind "point-and-shoot" prescribing has many negative consequences.

H. Women can Experience Psychological Trauma from Encountering the Remains of Their Aborted Children, a Significant Adverse Effect the FDA has not Addressed.

There is one psychological harm that is unique to chemical abortion vis-à-vis surgical abortion that the FDA failed to address. In chemical abortion, the woman is responsible for disposing of her own dead unborn child. This adverse effect does not appear on the "Patient Authorization Form" and to our knowledge, the FDA has not addressed this in any meaningful way. As the age of gestation increases, the images become more and more graphic. Images of an unborn child at ten weeks gestation are different from images weeks earlier. It does not appear that when the FDA increased permissible gestational age from

seven to ten weeks it took increased psychological trauma into account, making the FDA's decision to increase permissible gestational age to ten weeks squarely "arbitrary and capricious."

As one study describes, it "appears to be a difficult aspect of the medical termination process [chemical abortion] which can be distressing, bring home the reality of the event and may influence later emotional adaptation." Richard C. Henshaw, et al., Comparison of medical abortion with surgical vacuum aspiration. Women's preferences and acceptability of treatment, 307 BRIT. MED. J. 714-717 (1993). Many women are shocked when they encounter the development of the unborn child. One woman describes getting in the bath during a chemical abortion and screaming when she saw it "floating in the water. Slightly smaller than her palm, the fetus had a head, hands, and legs, she said. Defined fingers and toes." Caroline Kitchener, *Covert network provides pills for thousands of abortions in U.S. post Roe*, Wash. Post (Oct. 18, 2022).

We cannot ignore this psychological component of a woman's health. These are mental images of a woman's own children. Whether a woman miscarries naturally or terminates pregnancy through chemical abortion, mental images can live on forever, carried in silence, like a scar that never really goes away.

III. The FDA is Not Listening, Resulting in Arbitrary and Capricious Decisions.

The FDA beats the drum of "abortion access" to the detriment of women's health. The drumbeat is so loud that the FDA is unable to listen to the reports of those on the frontlines being directly impacted by the FDA's abandonment of its own safety standards. When an agency stops listening, "arbitrary and capricious" decisions are bound to follow. Challenges to the 2000 drug approval are not before this Court, but when an agency takes 16 years to respond to a citizen petition, it is not listening. See *Alliance for Hippocratic Med.*, 2023 U.S. Dist. LEXIS 61474, at *3. In fact, the Court of Appeals notes "as far as the record before us reveals, FDA has not structured the distribution of any comparable drug in this way." *Alliance for Hippocratic Med.* v. *FDA,* 2023 U.S. App. LEXIS 8898, (5th Cir. Apr. 12, 2023) at *27. It is truly an anomaly in need of judicial accountability.

The "FDA's actions are constrained by the APA's arbitrary-and-capricious standard." See 5 U.S.C. 706(2)(A); *Alliance for Hippocratic Med.*, 2023 U.S. App. LEXIS 8898, at *44. Courts must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency's action is "arbitrary and capricious" if it "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a

difference in view or the product of agency expertise." *Ibid.*

The record before the Court in this case is clear – the FDA's actions in 2016 and 2021 were arbitrary and capricious.

CONCLUSION

The FDA has become so lax toward chemical abortion that mail-order abortion is on the cusp of becoming the new "back alley" – where women are left to self-diagnose, self-induce, self-treat, and dispose of fetal remains themselves – and when something goes wrong, which it will with statistical certainty, women must be admitted to the emergency room before it is too late.

It is time for the loud drumbeat of "abortion access" to stop because it is undermining women's health and patient safety. The FDA is ignoring its duties – both to protect women's health and to adhere to federal law. Any argument that federalism dictates this unethical and lawless action is severely misplaced.

Therefore, amici asks this Court to affirm the Court of Appeals.

Respectfully submitted,

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