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.

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* GIANINA CAZAN-LONDON MD, MELISSA HALVORSON MD, AND WAGNER FAITH & FREEDOM CENTER IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTED

1. Whether respondents have Article III standing to challenge FDA's 2016 and 2021 actions.

2. Whether FDA's 2016 and 2021 actions were arbitrary and capricious.

3. Whether the district court properly granted preliminary relief.

This *amici curiae* brief primarily addresses the second issue.

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STATEMENT OF IDENTITYAND INTERESTS OF *AMICI CURIAE*

Pursuant to Supreme Court Rule 37, *amici curiae*, obstetricians-gynecologists Gianina Cazan-London MD and Melissa Halvorson MD, and the Wagner Faith & Freedom Center at Spring Arbor University submit this brief.[1]

Obstetricians-gynecologists Gianina Cazan-London MD (Maternal Fetal Medicine/ObGyn) and Melissa Halvorson MD, (ObGyn) are physicians who believe every human being holds the inalienable right to life from conception until natural death. They endeavor to ensure that pregnant women receive the highest quality medical care and are fully informed of the effects of abortion, including the potential long-term consequences of abortion on women's health. They hold special expertise and understanding of fetal development and abortion-related health risks helpful to this Court. Finally, these physicians educate the public truthfully about human development and the immense advancements made in their field over the last several years.

Amici Curiae physicians have special knowledge and insight that can assist this Court concerning chemical abortions.

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[1] *Amici Curiae* state that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than *amici curiae*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

Housed on the campus of Spring Arbor University, the *Wagner Faith & Freedom Center* serves as a national academic voice for faith, family, freedom, and the sanctity of human life. Working daily to secure the future for freedom of thought, conscience, and religion, the WFFC equips the next generation to be a voice for the lives of unborn children.

In public forums throughout the world the WFFC speaks on behalf of the persecuted and most vulnerable, including most especially, the unborn child. The WFFC champions the cause of the defenseless and oppressed, standing for faith, freedom, and the sanctity of life all around the world. The WFFC holds special knowledge helpful to this Court, having a significant interest in preserving constitutional good governance under the rule of law, and is a leading voice in this area.

It is through this brief that *Amici Curiae* present to this Court the life and death ethical context underlying the good governance issues before it, and especially the question of whether FDA's 2016 and 2021 actions were arbitrary and capricious.

SUMMARY OF THE ARGUMENT

The Government action at issue before this Court authorizes the telephonic dispensing of a dangerous abortion drug. Throughout its exercise of government power, the FDA acted far outside any "zone of reasonableness" and never "considered the relevant issues" or "reasonably explained" its decisions.

Not once did the FDA acknowledge that it was providing government authorization for the dispensing of a drug designed with the singular purpose of killing an innocent human life. Not once did it acknowledge the humanity of the pre-born child. And not once, in the name of political expediency, was it not willing to diminish the health and safety of pregnant mothers and the integrity of the medical profession. Whether radically weakening health and safety protections by changing the conditions of the drug's use in 2016 sans adequate study, or relying on deficient analysis to remove even the vital in-person doctor visit in 2021, the FDA placed itself and a progressive abortion agenda above the law.

Good governance, the rule of law, and humanity require more than the arbitrary and capricious exercise of power.

ARGUMENT

THE FDA ARBITRARILY AND CAPRICOUSLY AUTHORIZED THE DISPENSING OF A DANGEROUS DRUG DESIGNED WITH THE SINGULAR PURPOSE OF KILLING AN INNOCENT HUMAN LIFE

Good governance under the rule of law requires that the Food and Drug Administration (FDA) act within the scope of the rule of law. Here that legal authority is the Food, Drug, and Cosmetic Act (FDCA) Title 21 U.S.C. § 355(d), and its implementing regulation 21 C.F.R. 314.71, which mandate that the FDA ensure that the drugs it approves under its purview are "safe and effective." 21 U.S.C. § 355. Under this congressional mandate the FDA cannot give initial approval or modify a drug approval without a "sufficient" showing that the drug is safe for use as labeled.

The Government action at issue before this Court authorizes the telephonic dispensing of a dangerous drug designed with the singular purpose of killing an innocent human life. It is that government action with which we begin.

Ultimately, this Court must decide whether the FDA's 2016 and 2021 actions were arbitrary and capricious. In *Federal Communications Commission v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021) this Court held that the Administrative Procedure Act's "arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained" citing, *FCC v. Fox Television Stations, Inc.*,

556 U.S. 502, 513–514 (2009); *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) and *FCC v. WNCN Listeners Guild*, 450 U.S. 582, 596 (1981). Under this standard the FDA was required to act "within a zone of reasonableness." *Id.* Specifically, the FDA was required to "reasonably" consider the relevant issues and "reasonably" explain its decisions. *Id.* The FDA failed miserably.

In 2000, the U.S. Food and Drug Administration (FDA) approved the abortion drug RU486 (brand name Mifeprex, also known as mifepristone). J.A. 18, 39. Although promoted as a private way to abort a child up to 7 weeks gestation, J.A. 234, the FDA understood that without extra precautions use of the drug was not safe. J.A.230. The regulation, therefore, required physicians prescribing the drug to: 1) be licensed; 2) be capable of correctly determining gestational age; and 3) be capable of diagnosing ectopic pregnancies. *Id.* Additionally, to protect the health and safety of the mother from the danger posed by the drug, the FDA mandated treating physicians provide continuing in-person physician-patient care. J.A. 226-27, 230.

A 2007 act of Congress mandated a "Risk Evaluation and Mitigation Strategy" (REMS) by the FDA because of its "potential harmfulness" and connection with a "serious adverse drug experience." Food and Drug Administration Amendments Act of 2007, Pub.L. No. 110-85, tit. IX § 909(b)(1), 121 Stat. 823, 950. Because, with added safety considerations, the FDA had previously approved the dangerous abortion drug, the new congressional mandate here

considered the drug to provisionally hold an approved REMS. 21 U.S.C. § 355-1(f)(1); Pub. L. No. 110-85 at § 909(b)(1).

Thereafter, FDA approval of a REMS for RU-486 occurred in 2011. ROA 671-75; JA 296. At this time the FDA reaffirmed the necessity of the in-person physician-patient meetings, (i.e., physical exam, counselling, etc), and reiterated the health and safety concern of gestational age determinations and ectopic pregnancies dangers. J.A. 276; 296. Only 62 drugs with such potentially serious side effects require a REMS— and the drug at issue before this Court is one of them. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

The FDA, in 2016, profoundly changed the conditions of the drug's use, radically diminishing previous safety standards such as lengthening permissible use of the drug for up to 10 weeks gestation, J.A. 295, and removing any requirement to report serious adverse events to the FDA. J.A. 318. The government in doing so neither conducted any analysis that examined the changes made as considered all together, nor did it describe why it declared cumulative studies unnecessary here. See e.g., J.A. 549

Then, in 2021, the FDA relied on untrustworthy information and deficient analysis to modify its approval by additionally removing even the vital in-person doctor visit originally required by the rule. J.A.365; 378; Pet. App. 59a; 61a. This was so even though two national physician associations had previously warned the FDA of the extreme danger in doing so. J.S. 321-47. This was so even though the

FDA in 2020 represented to this Court that an in-person physician-patient meeting was "necessary" to for the safety of the women and girls taking the drug. Appl. For. Stay, *FDA v. ACOG*, No. 20A34 (U.S. Aug. 26, 2020).

Again, it is important to understand what the government authorized here: *The dispensing of a drug designed with the singular purpose of killing an innocent human life.* The chemical killing regimen here includes two steps:

> 1) depriving the unborn human baby of necessary nutrients to survive and weakening the connection between the mother and baby - (via an initial dose of RU-486 which blocks the vital pregnancy hormone progesterone); and
>
> 2) expelling the baby after it is killed -(via the ulcer medicine misoprostol taken 24 to 48 hours later, causing the uterus to contract)

Mifeprex Medication Guide, U.S. Food and Drug Administration, accessed December 28, 2021, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

Amici curiae believe that human life is made in the image of God, and that therefore every human life holds positive value worthy of protection and dignity. *Genesis* 1:26 (NIV). Underlying the government's action here is a rejection of this inviolable standard present in the natural law, divine law, and positive law, in favor of an arbitrary and capricious morally relative standard where a government regime

authorizes absent doctors to decide when and whether a human life has positive value.

Ultimately, allowing the telephonic dispensing of federally controlled drugs to kill an innocent unborn child proceeds from the fundamentally erroneous premise that human life in certain conditions has no positive value. That premise has incalculably grave implications for all of us. When we abandon medical moral absolutes today, it becomes easy tomorrow to choose death in other ways, for other people, in other situations, since the positive value of life has become an immorally relative individual choice.

The Hippocratic Oath written during the fifth to fourth centuries B.C. declares, "… I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art." Hippocratic Oath, *available at* https://biotech.law.lsu.edu/cases/research/hippocratic-oath.htm (last visited February 26, 2024). For most of world history this standard was a cornerstone of medical ethics.

Physicians treating a pregnant mother have two patients, the mother and the unborn child. In the context of chemical abortion, a treating doctor cannot help one patient without endangering the other. And, absent an in-person physical examination, could endanger both the mother and child. Abortion of pre-born children is, and always has been, fundamentally incompatible with the physician's role as healer. Cf. Brief of the American Medical Assn., American Nurses Assn., American Psychiatric Assn., et al., as Amicus Curiae in Support of Petitioners at 5, *Glucksberg* (No. 96-110), available in 1996 WL 656263.

The government's conduct in the case at bar rejects this position and the fundamental inviolable standard which serves as its foundation. Underlying its action instead is a morally relative medical foundation, where politically driven regimes and doctors choose when and whether a human life has positive value, completely ignoring the health and safety of the physician's patients.

For example, it is undisputed that the presence of an ectopic pregnancy affects the health and safety of pregnant women. Ectopic pregnancies occur in 1-2% of all pregnancies and cause 2.7% of pregnancy related deaths. https://www.aafp.org/pubs/afp/ issues/2020/ 0515/p599.html (last visited February 26, 2024)

Undiagnosed ectopic pregnancies are particularly dangerous; the side effects of Mifepristone are similar to symptoms of a potentially fatal ruptured ectopic pregnancy. Even the FDA acknowledges that doctors should not prescribe Mifepristone to "patients with a confirmed or suspected ectopic pregnancy" and that an ectopic pregnancy cannot be diagnosed without a physical examination.[2]

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[2] The FDA medication guide for Mifepristone provides that

> MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies [see Contraindications (4)]. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The

The FDA's actions in the case at bar nonetheless enabled the dispensing of Mifepristone via the U.S. mail without a physician conducting a physical examination. Instead, a physician merely has an electronic "patient consultation" (e.g., via phone or video). The physician dispenses the death drug through the mail without any follow-up medical care. The FDA promulgated this policy knowing abortionists had previously violated FDA guidelines by using telemedicine procedures to bypass the initial in-person distribution safety requirement. Carole Novielli, "Increasing Number of Abortion Pill Expansion Schemes Flout FDA Safety Regulations," Live Action News, November 7, 2021, https://www.liveaction.org/news/increasingabortion-pill-expansion-flout-fda/. Moreover, the FDA enacted this change notwithstanding the very real-life scenario where a despicable third person could trick or coerce a pregnant mother with an undiagnosed ectopic pregnancy into taking the death drug at issue here - with no physical exam by a physician to save her.

> presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX. Patients who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

Mifeprex medication guide, U.S. Food and Drug Administration, 5.4 Ectopic Pregnancy, accessed December 28, 2021, https://www.accessdata.fda.gov/scripts/cder/daf/ index.cfm

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf

Likewise, correct gestational age affects the health and safety of pregnant women. The FDA's action nonetheless enabled the dispensing of chemical abortion drugs via the U.S. mail without a physician conducting a physical examination to determine gestational age. This is so even though abortion providers continually violated the FDA guidelines by prescribing RU-486 to women beyond the permitted gestation time. Ben Johnson, "Supreme Court Allows Abortionists to Violate FDA Guidelines When Using RU-486," LifeSiteNews.com, December 15, 2014, https://www.lifesitenews.com/news/supreme-court-allows-abortionists-to-violate-fda-guidelines-when-using-ru-4/ (last accessed February 26, 2024)

Moreover, the FDA's action endangers the mother's health and safety in additional ways. A review of the FDA's own data shows that 85% of women report at least one or more of the following adverse reactions after taking the death drug regimen:

- bleeding
- nausea
- weakness
- fever/chills
- vomiting
- headache
- diarrhea
- dizziness

Women bled or spotted for an average of 9 to 16 days. Between 2% and 7% of the abortions failed, meaning women needed follow-up surgical abortions. Moreover, the FDA received reports of the deaths of women associated with RU-486. *Mifeprex Medication Guide,* U.S. Food and Drug Administration, accessed December 28, 2021, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Even today the FDA acknowledges that up to 4.6 percent of pregnant mothers who use the prescription will go to an emergency room afterwards. J.A. 533

The grave implications for our nation of a government authorizing doctors to dispense poison designed with the sole purpose of efficiently killing an innocent human life should cause pause, especially given the historical proficiency with which other governments, like the Third Reich, arbitrarily and capriciously authorized doctors to dispense poison designed with the sole purpose of efficiently killing "unworthy" innocent human life. Foundations do matter. Every human life holds inherent value as a moral absolute, and is worthy, therefore, of being treated with dignity and respect. No government regime and no doctor should hold the power to decide that someone else's life is not worthy. Innocent human life must be protected and promoted by the law if order and liberty are to flourish. There is no state or medical interest greater than the protection of human life. And there is no life more in need of state and medical protection than those most vulnerable, such as a pre-born child.

Human life holds inherent value and merits protection when it is human, and every human life

begins at conception.[3] As Professor Francis Beckwith cogently explains:

> Only artifacts, such as clocks and spaceships, come into existence part by part. Living beings come into existence all at once and then gradually unfold to themselves and to the world what they already *are*, but only incipiently are. Because one can only develop certain functions by nature (i.e., a result of basic, intrinsic capacities) a human being at every stage of development is *never* a potential person, she is *always* a person with potential even if that potential is never actualized due to premature death or the result of the absence or deformity of a physical state necessary to actualize that potential.[4]

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[3] *See, e.g.,* Scott Klusendorf, *The Case for Life* (2009) at 36, 44 (citing numerous embryological experts and texts and noting that even rabid abortion advocates such as Peter Singer admit an embryo is a human being at conception); Dianne N. Irving, *When do human beings begin? Scientific myths and scientific facts*, International Journal of Sociology and Social Policy, Vol. 19 No. 3/4 (1999) at 22-46, *available at* https://doi.org/10.1108/01443339910788730 (last visited 7/24/21); Charles I. Lugosi, *Conforming to the Rule of Law: When Person and Human Being Finally Mean the Same Thing in Fourteenth Amendment Jurisprudence*, 4 GEOJLPP 361, 362, n.2 (2006) (citing a variety of authoritative sources).

[4] Francis J. Beckwith, Defending Life: A Moral and Legal Case Against Abortion Choice (2007) at 34 (emphasis in original; internal citation omitted).

Again, what this means as practical matter is that all human life has dignity and is worthy of protection.

Significantly, scientists no longer disagree on when human life begins. The consensus among scientists is that it begins at conception.[5]

Any decision involving the government authorization of chemical abortion presupposes a decision about when one becomes a person, because a person cannot be killed lawfully——except in cases of self-defense or a state-administered sentence after a fair trial and exhaustion of all appeals -- but not by a mail order death drug pursuant to a progressive abortion agenda.

If a government decides a baby at a certain stage of development can, in ordinary circumstances, be killed, it has decided that that baby is not a person. If it decides that baby cannot be killed, it has decided that that baby is a person. What a government purports to be doing when it makes those decisions is immaterial; it is unquestionably defining our humanity. The only question is how it will do so. Conceived by a human father and a human mother, are we to be recognized as human beings, whole and equal by nature?

Why, exactly, does the state have an interest in the lives of pre-born human beings? It is because they are human beings – not only as a matter of morality, but of biological science as well. If the state has an interest in preserving human life (which it does), then

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[5] *See* fn. 3, *supra*.

it has an interest in human life; and that interest begins when human life begins.

Our humanity is a constant. It does not vary over time under different circumstances. It is our nature, not a feature of our environment or our accomplishment. It does not vacillate based on the state of our technology, including even the technology that lets a baby live outside the mother's womb. Just a few centuries ago, a child typically couldn't live outside the womb before it reached near full gestation, which is thirty-seven to forty weeks. You and your baby at 37 weeks pregnant, *available at* https://www.nhs.uk/pregnancy/week-by-week/28-to-40-plus/37-weeks/ (last visited February 26, 2024). When *Roe* was decided, just fifty years ago, viability—and hence personhood in the *Roe* Court's eyes—was gained at about twenty-eight weeks.[6] Now in the post-*Dobbs* era, it is about twenty-three weeks.[7] One can imagine a time when our technology advances to the point that an embryo at conception could be placed into a technological or bionic "mother" of some sort and be viable. Any conception of our humanity as a technologically determined variables is utterly dehumanizing.

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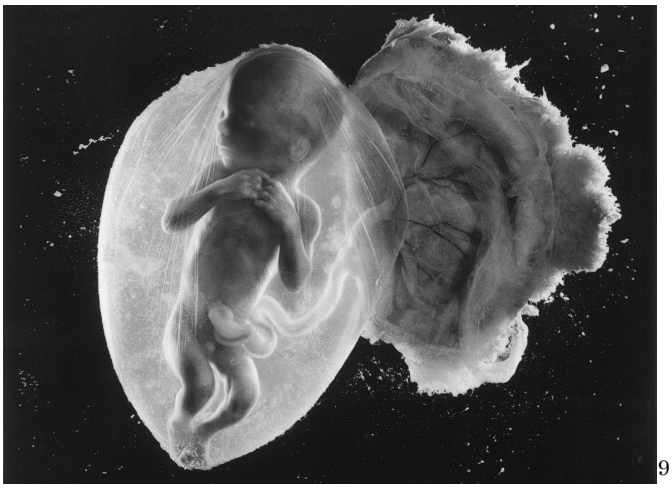
[6] Hollowell, K. J., *Defining a Person Under the Fourteenth Amendment: A Constitutionally and Scientifically Based Analysis*, 14 Regent UL Rev. 67, 83-86 (2001); *see also* Bonnie Rochman, *A 21-Week-Old Baby Survives and Doctors Ask, How Young is Too Young to Save?* Time Magazine (May 27, 2011), available at https://healthland.time.com/2011/05/27/baby-born-at-21-weeks-survives-how-young-is-too-young-to-save/ (last visited July 27, 2021).

[7] *Id*. at 84.

Advances in science now reveal the remarkable development of a pre-born child from the moment of fertilization. Gone are the days when society can question whether such a pre-born child is merely a "clump of cells."[8] Actual video of children in the womb reveals the completeness of development of a fetus. *See* https://www.ehd.org/your-life-before-birth-video/ (last visited February 26, 2024) (displaying pieces of actual video footage of a child's development in utero).

 [9]

At twenty-two days, the child's heart begins to beat. https://www.ehd.org/your-life-before-birth-video/ (last visited July 15, 2020).

At six weeks, the child begins moving. *Id.*

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[8] *See* Klusendorf, *supra*, at 38-39 (dispelling "clump of cells" argument).

[9] Photograph of a human fetus at eighteen weeks of gestational development. Lennart Nilsson, Foetus 18 weeks, http://100photos.time.com/photos/lennart-nilsson-fetus (last visited July 14, 2020).

At seven weeks, scientists can detect a child's brainwaves, and the child can move his or her own head and hands. *Id.* The child also displays leg movements and the startle response by that time. *Id.*

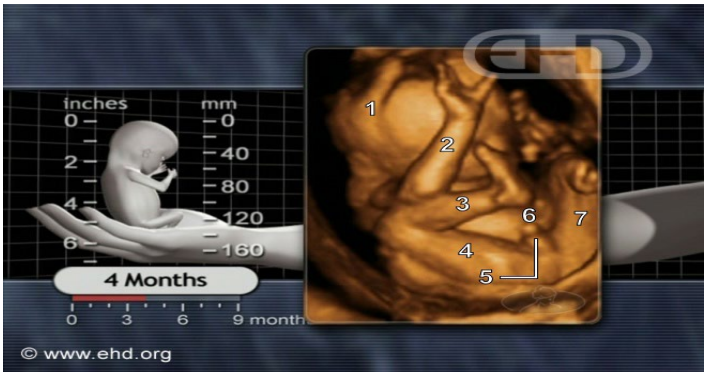
At eight weeks, the child's brain exhibits complex development. *Id.* The child also then begins breathing movements and shows preference for either his or her left or right hand. *Id.* At nine weeks, the child sucks his or her thumb, swallows, and responds to light touch. *Id.*

At ten weeks, the child's unique fingerprints are formed on his or her fingers. *Id.*

At twelve weeks, the child opens and closes his or her mouth and moves his or her tongue. *Id.* The child's fingers and hands are also fully formed by twelve weeks' gestation. *Id.*

https://www.ehd.org/movies/231/Responds-to-Touch (last visited February 26, 2024) (displaying video of baby at fifteen weeks responding to touch).

By sixteen weeks, the child's gender is easily detectable, and the child looks undeniably human:



https://www.ehd.org/gallery/436/Hiding-the-Face#content (last visited February 26, 2024) (showing photographic still of sixteen-week ultrasound video of a male fetus hiding his head away from the touch of the ultrasound transducer).

By nineteen weeks, the child hears and responds to noises, even making different facial expressions when listening to music. *See, e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4616906/ (last visited February 26, 2024) (finding that neural pathways participating in the auditory–motor system may be developed as early as the gestational age of sixteen weeks).

The humanity of the pre-born child is even more apparent today than ever before.

Throughout its exercise of government power, the FDA acted far outside any "zone of reasonableness" and never "considered the relevant issues" or "reasonably explained" its decisions. Not once did the FDA acknowledge that it was providing government authorization for the dispensing of a drug designed with the singular purpose of killing an innocent human life. Not once did it acknowledge the humanity of the pre-born child. And not once, in the name of political expediency, was it not willing to diminish the health and safety of pregnant mothers and the integrity of the medical profession. Whether radically weakening health and safety protections by changing the conditions of the drug's use in 2016 sans adequate study, or relying on deficient analysis to remove even the necessary in-person doctor visit in 2021, the FDA placed itself and its progressive abortion agenda above the law.

Good governance, the rule of law, and humanity require more than the arbitrary and capricious exercise of power.

CONCLUSION

For the foregoing reasons, *Amici Curiae* urge this Court to affirm the Fifth Circuit's order and remand for further proceedings.

Respectfully submitted,

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