Nos. 23-235, 23-236

In the Supreme Court of the United States

FOOD AND DRUG ADMINSTRATION, 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 DR. GRAZIE POZO CHRISTIE AND THE CATHOLIC ASSOCIATION FOUNDATION AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

MEGAN M. WOLD
Counsel of Record
COOPER & KIRK, PLLC
1523 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 220-9600
mwold@cooperkirk.com

Counsel for Amici Curiae

February 29, 2024

TABLE OF CONTENTS

TABLE OF AUTHORITIES

OTHER AUTHORITIES Page

INTERESTS OF AMICI CURIAE[1]

Dr. Grazie Pozo Christie is a practicing physician specializing in diagnostic radiology. Dr. Christie graduated from Columbia University and received her medical degree from the University of Miami Miller School of Medicine. She completed her residency in diagnostic radiology and a fellowship in orthopedic radiology at Jackson Memorial Hospital in Miami. She is a diplomate of the American Board of Radiology. As a practicing radiologist and physician involved in the critical care of pregnant women through ultrasound, Dr. Christie knows firsthand the importance of an in-person visit and ultrasound for women seeking FDA-approved drugs to terminate their pregnancies. She is also a Catholic physician and is familiar with the downstream effects of the FDA's deregulation of mifepristone, including the effects on Catholic health care providers and their conscience rights.

The Catholic Association Foundation (TCA) is a lay organization dedicated to providing a faithful voice for Catholics in the public square. TCA is a strong defender of religious freedom and responds to the call of the Catholic Church for the lay faithful to apply Catholic teaching, wisdom, and principles to the issues of the day. TCA has previously filed four amicus curiae briefs in this Court. *See* Brief for Montana Catholic School Parents, et al. as Amici Curiae Supporting Petitioners, *Espinoza* v. *Mont. Dept. of*

[1] Pursuant to SUP. CT. R. 37.6, amici certify that no counsel for any party authored this brief in whole or in part, no party or party's counsel made a monetary contribution to fund its preparation or submission, and no person other than amici or their counsel made such a monetary contribution.

Revenue, 140 S. Ct. 2246 (2020) (No. 18-1195); Brief for Former Foster Children & Foster Parents and The Catholic Ass'n Found. as Amici Curiae Supporting Petitioners, *Fulton* v. *City of Philadelphia*, 593 U.S. 522 (2021) (No. 19-123); Brief for The Catholic Ass'n Found., et al. as Amici Curiae Supporting Petitioners, *Little Sisters of the Poor Saints Peter and Paul Home* v. *Pennsylvania*, 140 S. Ct. 2367 (2020) (No. 19-431); Brief for Monique Chiraeu Wubbenhorst, et al. as Amici Curae Supporting Petitioners, *Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215 (2022) (No. 19-1392).

SUMMARY OF THE ARGUMENT

The FDA's 2016 and 2021 deregulatory decisions affecting mifepristone pose severe health risks to women for many reasons, including because those decisions removed the requirement of an initial in-person visit where an ultrasound would be performed to date the pregnancy and diagnose (or rule out) an ectopic pregnancy. The FDA has approved the use of the chemical abortion drug mifepristone only through the first 70 days of pregnancy. Using mifepristone after this time exposes a woman to an increased risk of severe and even life-threatening medical complications, including complications that arise when mifepristone initiates but does not complete the intended abortion. Mifepristone also risks life-threatening complications when used to terminate an embryo located outside the uterus, known as an "ectopic pregnancy." These risks are avoided when a physician uses an ultrasound to date a woman's pregnancy and determine the location of the embryo or fetus. By eliminating the requirement of an in-person visit before dispensing mifepristone, the FDA has ensured that many women will not

receive a diagnostic ultrasound and will not know the accurate date of their pregnancy or the location of their embryo or fetus before taking mifepristone. Eliminating this safeguard causes women to suffer needlessly and even face death.

The resulting medical complications for women will be handled in emergency rooms. Without the critical information that an in-person visit and ultrasound provides, women are more likely to take mifepristone in riskier circumstances, including when the gestational age of a pregnancy is greater than 70 days or when the woman is experiencing an ectopic pregnancy. The FDA's own label for mifepristone admits that the drug will result in emergency room care for roughly one in 25 women who take it. J.A.533. Emergency room treatment after mifepristone may include taking medical action to complete an incomplete abortion.

The FDA's unlawful deregulation of mifepristone will lead to a predictable rise in avoidable emergency room visits, which will in turn have a significant impact on Catholic hospitals and healthcare providers. Catholic hospitals and healthcare providers have a long history of providing care for the sick and the needy regardless of their patients' background or beliefs, and of doing so in a way that honors Catholic teaching, wisdom, and principles on the dignity of life, from conception to natural death. The FDA's endorsement of unsupervised mifepristone use will send more women to emergency rooms with medical complications from mifepristone, including women seeking to complete incomplete abortions. In these circumstances, Catholic hospitals and healthcare providers could be forced to engage in practices that violate their

deeply held religious beliefs and rights of conscience. The rise of avoidable emergency room visits due to mifepristone will also divert Catholic hospitals and healthcare providers from the life-saving care they provide to other patients. Catholic hospitals and healthcare providers want nothing more than to continue to provide their vital services.

BACKGROUND

In 2016, the Food and Drug Administration (FDA) made changes to the "risk evaluation and mitigation strategies" (REMS) for mifepristone that had been in place since 2000. The relevant 2000 REMS required in-person consultations and limited the drug's approved use to 49 days' gestational age or less to mitigate maternal morbidity and mortality—that is, significant medical complications and death. J.A. 226–34. The 2016 changes permitted non-physicians to prescribe the drug, eliminated some previously required in-person visits, and increased the maximum gestational age from 49 to 70 days (seven to ten weeks). J.A. 295, 318–19. In 2021, citing the Covid-19 pandemic as the justification, the FDA announced it would no longer enforce the in-person dispensing requirement that had been in effect since 2000 (the only remaining in-person requirement at that time). J.A. 365, 378. Later that year, the agency permanently removed the in-person dispensing requirement. The FDA has made other major and interrelated changes since 2016. All have resulted in further deregulation of mifepristone so that it can be prescribed remotely, without a physician's examination or supervision, and distributed via mail.

By relaxing the mifepristone REMS in these ways, the FDA effectively jettisoned an ultrasound examination for women seeking this chemical abortion drug. Ultrasound is a radiologic examination that is commonly used when planning a chemical abortion—and for good reason. An ultrasound is used to determine both the gestational age of the embryo or fetus and to rule out an ectopic pregnancy. An ultrasound examination is thus one of the most vital steps to ensuring the health and safety of a pregnant woman contemplating a chemical abortion.

For decades, pregnancy care in developed countries has included ultrasonography. It is a painless exam that utilizes sound waves to generate images. An ultrasound is completely safe for both the pregnant woman and her fetus, and is also inexpensive and easy to use. An ultrasound examination of the woman and her fetus delivers crucial information that affects maternal and fetal care throughout a pregnancy. For expectant parents and physicians planning for a successful birth, an ultrasound provides critical medical information. For a mother seeking and a physician prescribing a chemical abortion, an ultrasound provides two essential pieces of data that cannot be confidently determined any other way: the embryo's gestational age and its location.

ARGUMENT

A woman who learns she is unexpectedly pregnant faces one of the most fraught crises of her life. In some instances, a woman in this situation may decide to terminate her pregnancy, and the FDA has approved mifepristone for that purpose. But mifepristone must be taken in precise circumstances to avoid

or minimize the risk of severe and even life-threatening complications. Specifically, mifepristone complications are more likely where a pregnancy is greater than 70 days long or is ectopic.

Ultrasound is an inexpensive, noninvasive, and highly effective way of dating a pregnancy and ruling out (or diagnosing) an ectopic pregnancy. In its effort to deregulate mifepristone, the FDA has eliminated the requirements that ensured women received an ultrasound through an in-person visit with a physician before taking mifepristone. The predictable result is a greater incidence of avoidable complications for women taking mifepristone and a consequent increase in emergency room visits due to mifepristone use and misuse.

I. AN IN-PERSON PHYSICIAN VISIT AND ULTRASOUND PROTECTS WOMEN FROM AVOIDABLE HEALTH RISKS CAUSED BY MIFEPRISTONE.

An in-person physician visit, where an ultrasound would likely be performed, is an important protection for women seeking to use mifepristone to terminate a pregnancy. Mifepristone poses life-threatening risks when used beyond 70 days' gestation or in an ectopic pregnancy. An ultrasound is the only effective way to date a pregnancy, and an ultrasound will also diagnose or rule out an ectopic pregnancy. Women who take mifepristone without first obtaining an ultrasound face substantial but avoidable health risks, and the FDA's deregulation of mifepristone has made these avoidable health risks more likely.

A. An Ultrasound Is the Most Accurate Way to Date a Pregnancy and Diagnose an Ectopic Pregnancy.

An ultrasound is the most accurate method to determine gestational age and diagnose an ectopic pregnancy.

Obstetric ultrasound was introduced by Stuart Campbell in 1969. S. Campbell, *A Short History of Sonography and Obstetrics and Gynaecology,* 5 FACTS, VIEWS & VISION IN OBGYN 213 (2013), https://bit.ly/3T60kir. Today, determination of gestational age by ultrasound is considered an essential and basic part of pregnancy care in the developed world. Eric O. Ohuma, et al., *Estimation of Gestational Age In Early Pregnancy From Crown-rump Length When Gestational Age Range is Truncated: The Case Study of the INTERGROWTH-21st Project*, 13 BMC MED. RSCH. METHODOLOGY 151 (2013), https://bit.ly/3I4n7oy. Ultrasound uses the size of the fetus to determine gestational age by correlating the size with established fetal growth standards in which the fetus is measured from the crown of the head to the rump. In the first trimester these measurements are extremely consistent, regardless of fetal sex, race, and even the mother and father's height and weight.

The American College of Obstetricians and Gynecologists recommends ultrasound as the most accurate method to determine gestational age. *Comm. Op. No. 700: Methods for Estimating the Due Date* at 4, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (May 2017), https://bit.ly/49M9EO9. In choosing to deregulate mifepristone, the studies the FDA has relied on required participants to use ultrasound to confirm

gestational age—an important safeguard that the FDA has nonetheless chosen to eliminate. J.A. 292–320; *see* Resp.Br. at 6–7.

Other methods of dating a pregnancy outside of ultrasound are not accurate or reliable.

Physical exam. In the first trimester (the only time that the FDA has approved mifepristone use), a physical exam is not available to diagnose a pregnancy. At this stage of pregnancy, the uterus is simply too small for a physician to feel (palpate) in an exam.

Menstrual History. Menstrual history alone is not a reliable or accurate way to date a pregnancy. Menstrual history is often used to estimate the age of an embryo by assuming that ovulation, and therefore conception, occurred on the 14th day of the woman's cycle or on the 14th day *after* the start of her last menstrual period (LMP). *Comm. Op. No. 700*, *supra*, at 2. Many women, however, have irregular periods (whether due to breastfeeding, recent cessation of oral contraception, or other causes) or cannot accurately remember the date of their LMP. *See* Ganesa Wegienka & Donna D. Baird, *A Comparison of Recalled Date of Last Menstrual Period with Prospectively Recorded Dates*, 14 J. WOMEN'S HEALTH 248 (2005), https://bit.ly/48oh4FZ Estimating based on LMP, then, "does not account for inaccurate recall of the LMP, irregularities in cycle length, or variability in the timing of ovulation." *Comm. Op. No. 700*, *supra*, at 2. Studies have shown that half of women do not remember their LMP, and that 40% of pregnant women who receive a first-trimester ultrasound will have the age of their pregnancy adjusted because of a

discrepancy of more than five days between the ultrasound dating and LMP dating methods. *Id.*

Even if a woman has regular cycles and ovulates on the 14th day of her cycle, confusion regarding the LMP date can still result from "implantation bleeding," which occurs when the early embryo migrates into the uterus and implants itself into the uterine wall, disrupting blood vessels in the uterine lining and causing bleeding. Susan B. Promes, *Pitfalls in First-Trimester Bleeding*, 28 EMERGENCY MED. CLINICS N. AM. 219, 220 (2010). An implantation bleed can occur weeks after a woman's ovulation and be easily mistaken for another period. In that scenario, the embryo can easily be two weeks older than the woman estimates based on what she (incorrectly) believes to be her LMP.

The risk of unintentional misdating of a pregnancy is substantial. One peer-reviewed analysis shows that 14.8 percent of women underestimate the age of their embryo. Dana Schonberg, et al., *The Accuracy of Using Last Menstrual Period to Determine gestational Age for First Trimester Medication Abortion: A Systematic Review*, 90 CONTRACEPTION J. 480 (2014), https://bit.ly/42JbM6Z. This means that a woman who thinks she is nine weeks pregnant can easily be 11 weeks pregnant. This kind of underestimation could lead a woman to take mifepristone beyond the FDA's 70-day threshold, placing her at risk for severe and even life-threatening complications. Indeed, studies show that up to 11.8 percent of women who had a chemical abortion were actually ineligible to use the drugs—and at serious health risk as a result—because of the advanced age and size of their fetus. *Id.*

Additionally, many patients are what doctors call "unreliable historians." A woman may not be confident in the date of her LMP or may feel confident but simply misremember. In the case of over-the-internet prescribing of mifepristone, a woman may experience pressure to misdate her last period, whether consciously or unconsciously. For example, she may have heard that chemical abortions are physically easier and less expensive than surgical abortions, so she may not share her doubts about her LMP with the telehealth provider because doing so could require her to undergo a surgical abortion. As a result, she may be prescribed mifepristone even though her fetus is well beyond the FDA's 70-day maximum—and her chemical abortion would be far riskier and traumatic as a result.

Because of the menstrual-history method's inherent inaccuracies, the American College of Obstetricians and Gynecologists recommends ultrasound as the most reliable method to determine gestational age. If an ultrasound is not performed, the American College of Obstetricians and Gynecologists considers the pregnancy "suboptimally dated". *Comm. Op. No. 700*, *supra*, at 4.

Ectopic pregnancies. In addition to accurately determining the age of the embryo or fetus, ultrasound pinpoints the exact location of the pregnancy. Most pregnancies occur, properly, within the uterine cavity. However, one in 50 pregnancies are "ectopic." Promes, *supra*, at 220. That is, they are situated outside the uterus. Failure to detect these ectopic pregnancies is life-threatening. Ectopic pregnancies account for nine percent of all pregnancy-related deaths. *Id*. An

ultrasound is the only way to accurately diagnose or rule out an ectopic pregnancy.

B. Women Taking Mifepristone Face Life-Threatening Dangers If the Gestational Age of Their Pregnancy Is Not Accurately Determined.

When a pregnant woman takes mifepristone based on an inaccurate belief in her embryo's age, she faces a grave risk of serious complications—including risk of maternal death. That is because the likelihood of an "incomplete abortion" following mifepristone use increases with the growth of the fetus and placenta. An "incomplete abortion" occurs when the embryo or fetus, the placenta, and other products of conception do not fully evacuate the uterus during the cramping and expulsion phase of a chemical abortion.

An incomplete abortion can lead to serious complications. Retained tissue in the uterus causes persistent bleeding and cramping, which can lead to hemorrhaging, infection, sepsis (inflammation throughout the body trigged by infection), and maternal death. Treatment for these complications requires surgical abortion to manually empty the uterus, antibiotics in the case of infection or sepsis, and transfusion in the case of severe blood loss. Notably, the third in-person visit (the follow-up) with a physician that the FDA required before 2016 was intended to diagnose and treat these complications. Without the third in-person visit, women must rely on their own self-diagnosis of symptoms and resulting emergency room care. A woman may wait too long to go to the emergency room, mistaking the symptoms of her complication as the symptoms of a normal chemical abortion. When a woman

does arrive in an emergency room, she will depend on doctors who are unfamiliar with her case.

The likelihood of incomplete abortion increases with the growth of the fetus and placenta: the larger the fetus and placenta, the more likely that mifepristone use will not lead to a complete abortion. J.A. 381, 538. That is why the FDA has limited the use of mifepristone based on gestational age: originally up to 49 days' gestation, and expanded to 70 days' gestation in 2016. This change in itself increased the risk of incomplete abortions and associated complications for women who take mifepristone. For the same reasons, the risks of mifepristone use increase significantly as a fetus and placenta grow beyond 70 days' gestation.

Specifically, at less than 49 days' gestation, the mifepristone/misoprostol regimen failed to work 1.9% of the time. Between 49 and 56 days, the failure rate increased to 3.3%; between 56 and 63 days, it increased to 4.8%; and between 63 and 70 days, it jumped to 6.9%. After 84 days, 38.5% of all chemical abortions required follow-up surgery, and 4% resulted in infection. *See* Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 OBSTETRICS & GYNECOLOGY 12 (2015), https://bit.ly/3OMtroz; *see also* J.A. 542 (FDA label: "About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.").

This last, catastrophic increase occurs only *14 days* beyond the FDA's limitation on the use of mifepristone and misoprostol—yet the FDA now allows women to determine gestational age *on their own*

using the most unreliable dating procedure (a self-estimation of her LMP) and to convey this critical determination over the phone or internet. This deregulation represents the FDA's retreat from necessary protections and safeguards for pregnant women seeking to terminate their pregnancies with mifepristone.

C. Women Taking Mifepristone Face Life-Threatening Dangers If the Location of the Embryo Is Not Known.

In an ectopic pregnancy the embryo implants in the fallopian tube, the abdominal cavity, or the cesarean scar on the outside of the uterus. These pregnancies are extremely dangerous for the mother. If undetected and untreated, they may rupture, causing extreme blood loss, pain, and even maternal death. A ruptured ectopic pregnancy is a medical emergency requiring immediate surgery.

Although two percent of all pregnancies are ectopic, they account for 13 percent of all maternal deaths. Laura L. Marion & George R. Meeks, *Ectopic pregnancy: History, incidence, epidemiology, and risk factors*, 55 CLINICAL OBSTETRICS & GYNECOLOGY 376 (2012), https://bit.ly/49JHGlR. They are more common in women who have had prior pelvic surgery, sexually transmitted diseases, pelvic inflammatory disease, a history of smoking, and in women who are over 35-years old. Physicians are especially careful when evaluating pregnant women with these risk factors. But the lack of risk factors is not dispositive: half of women who have ectopic pregnancies have none of these risk factors. *Ectopic Pregnancy*, ACOG, https://bit.ly/49J9B5M (last updated July 2022).

Patient history simply cannot rule out an ectopic pregnancy. Instead, only an ultrasound can, and it can do so with complete certainty and reliability.

It is inevitable that pregnant women who obtain mifepristone in mail-order, over-the-internet, or telehealth settings will not undergo the only testing that can diagnose or rule out an ectopic pregnancy: ultrasound. Omitting this critical step places expectant mothers at unnecessary and grave risk. The fact that only two percent of all pregnancies are ectopic may strike some as insignificant, but that number is very significant when coupled with the reality that chemical abortion drugs are dispensed to millions of women. Jeff Diamant & Besheer Mohamed, *What the data says about abortion in the U.S.*, PEW RSCH. CTR. (Jan. 11, 2023), https://pewrsr.ch/3uCHtSR.

Chemical abortion drugs are "not effective for terminating ectopic pregnancies," but the symptoms of an ectopic-pregnancy rupture can be indistinguishable from those of a chemical abortion, including dizziness, faintness, bleeding, and abdominal and pelvic pain. J.A. 531. For that reason, the FDA's current approved label for mifepristone states that a prescriber must "[e]xclude [ectopic pregnancy] before treatment," J.A. 526, "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." J.A. 531.

A woman who has been told to expect these symptoms in a chemical abortion using mifepristone and misoprostol may not initially seek medical help in the case of a ruptured ectopic pregnancy, but she will ultimately need emergency care. By removing the

regulation requiring mifepristone to be dispensed in-person—and therefore without an ultrasound—the FDA has made it more likely that women seeking a chemical abortion will need emergency services afterwards. This abandons many American women to face an avoidable and highly dangerous condition on their own, forced to seek emergency room care if they are able to spot the signs of a life-threatening complication in time.

II. THE FDA'S DEREGULATION OF MIFEPRISTONE IMPAIRS CATHOLIC HOSPITALS AND HEALTHCARE PROVIDERS.

The Catholic Church pioneered our modern-day hospital system and remains an essential pillar of modern medical care. As the American Medical Association notes in its *Journal of Ethics*, the "tradition of Catholic hospitals is a long one, stretching back to medieval Europe and beyond." Marcy Doderer, *Catholic Hospitals and the Safety Net*, 13 AMA J. OF ETHICS 569 (2011), https://bit.ly/48qO1lp. "Hospitals run by religious orders were among the first in the United States." *Id.* And now, "Catholic hospitals, because of their mission and their preferential treatment of the poor, are a significant, even essential part of today's health care safety net." *Id.*

In its "Ethical and Religious Directives for Catholic Health Care Services," the U.S. Conference of Catholic Bishops states that, despite "the ever-changing circumstances of health care and its delivery," the prioritization of the poor remains a core principle "that guide[s] the Church's vision of healthcare." *Ethical & Religious Directives for Catholic Health Care Services: Sixth Edition* at 4, U.S. CONF. OF CATHOLIC

BISHOPS (June 2018), https://bit.ly/48oaNdB. This document, which is authoritative for the nation's Catholic hospitals and affiliated institutions, goes on to say: "In Catholic institutions, particular attention should be given to the health care needs of the poor, the uninsured, and the underinsured." *Id.* at 8. This core commitment "flow[s] from the Church's teaching about the dignity of the human person[.]" *Id.* at 4. Catholic hospitals and health care workers serve this mission precisely *because of* their religious identity and deeply held beliefs.

As a result of its longstanding commitment rooted in religious belief, the Catholic Church is today the largest non-governmental provider of healthcare services to the poor in the United States. It stands in the breach in a healthcare system where non-profit options are quickly disappearing. Every day, more than one in seven patients in the United States is cared for in a Catholic hospital. *U.S. Catholic Health Care*, CHA, https://bit.ly/3SXAdZH (last updated Apr. 2023). The more than 650 Catholic hospitals in this country serve 5 million hospital admissions each year. *Id*. They provide 101 million outpatient visits, 17.5 emergency room visits, and deliver 500,000 babies. *Id*. They serve 87 million patients annually, and employ approximately 750,000 full- and part-time employees. *Catholic Health Care, Social Services and Humanitarian Aid*, U.S. CONF. OF CATHOLIC BISHOPS (2014), https://bit.ly/3uxYnlE.

The presence of Catholic hospitals is particularly pronounced in rural areas, where profit-seeking private hospitals are closing, exacerbating an already acute shortage of healthcare for lower-income Americans. While the number of U.S. hospitals is declining,

the percentage of Catholic hospitals nationwide has increased by 22 percent in recent years. Anna M. Barry-Jester & Amelia Thomson-DeVeaux, *How Catholic Bishops Are Shaping Health Care In Rural America*, ABC NEWS (July 25, 2018), https://bit.ly/3I7PfHt. According to a 2020 tax filing, Catholic hospitals spent more than $6 billion on charity care and costs of services that are not fully paid by Medicaid and other means-tested programs and invested an additional $3.5 billion in community health improvement and subsidized health services. Mary Haddad, *Guest View: Correcting the Record on the Value Catholic Hospitals Deliver*, OA ONLINE (November 26, 2023), https://bit.ly/3Tjfrp6.

Because Catholic hospitals are uniquely prevalent, they are also uniquely impacted by the FDA's 2016 and 2021 regulatory changes. Emergency rooms and emergency-room personnel at Catholic hospitals are forced to deal with the dire—and, again, needless—consequences of failing to accurately determine gestational age or detect ectopic pregnancies before administering mifepristone to perform a chemical abortion. This means that Catholic hospitals and Catholic emergency-room doctors, nurses, and other healthcare providers can be conscripted into completing attempted abortions, or otherwise participating in medical treatment that facilitates an abortion, in violation of their conscience. The same risk applies to Catholic OB-GYN hospitalists and Catholic on-call OB-GYNs, who also respond to obstetrical emergencies, including those caused by chemical abortions.

The belief in the human dignity of every patient shapes the pro-life ethic of Catholic hospitals and healthcare providers. Catholic hospitals will always

provide life-saving care to a woman in a medical emergency.

But two consequences follow from the FDA's deregulation of mifepristone, which increases the likelihood of women seeking emergency room care related to chemical abortions.

First, Catholic hospitals and healthcare providers may be asked or compelled to assist a woman to complete an attempted chemical abortion in violation of their conscience and religious beliefs. Catholic teaching "affirm[s] the moral evil of every procured abortion." *Respect for Unborn Human Life: The Church's Constant Teaching*, U.S. CONF. OF CATHOLIC BISHOPS, https://bit.ly/3OZL7NC. And the Catechism of the Catholic Church forbids cooperation in the evil act of another, whether through formal cooperation or lending material support. THE ROMAN CATHOLIC CHURCH, CATECHISM OF THE CATHOLIC CHURCH 1868–69 (2000); *see also Moral Cooperation in the Evil of Another*, EWTN, https://bit.ly/48yjJgz. A Catholic healthcare provider will be complicit in the evil of abortion if required to end the life of a still-living fetus when a chemical abortion has failed. It is not far-fetched to expect that women will present to emergency rooms in such a condition: according to the FDA's own label, even when properly prescribed, mifepristone will not cause a complete abortion for up to seven percent of women who take it. J.A. 542.

Second, the increase in avoidable emergency room visits caused by women taking mifepristone without a physician visit or ultrasound will divert emergency room resources away from providing life-saving care to other patients, especially the many millions for

whom a Catholic hospital is the only affordable or physically available option.

The FDA's multi-year retreat from the regulation of the chemical abortion drug mifepristone not only jeopardizes women's health, but also substantially increases the likelihood that Catholic hospitals and healthcare providers are conscripted into procedures that violate their consciences and are diverted from their faith-based mission to ensure care is available for the most vulnerable members of society—a mission foundational to Catholic hospitals since their inception. Catholic hospitals, emergency-room physicians, and other healthcare providers want nothing more than to continue to pursue their foundational mission now and in the future. The FDA's deregulation of mifepristone impairs their ability to do so consistently with their deeply held religious beliefs and faith-based mission.

CONCLUSION

The FDA's step-by-step deregulation of the abortion drug mifepristone and the all-too-predictable rise in emergency room visits that it will cause is a threat to the health and safety of American women and to the conscience rights of Catholic hospitals and healthcare providers. The judgment of the court of appeals should be upheld.

February 29, 2024

Respectfully submitted,

MEGAN M. WOLD
Counsel of Record
COOPER & KIRK, PLLC
1523 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 220-9600
mwold@cooperkirk.com

Counsel for Amici Curiae