No. 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

AMICUS BRIEF OF THE PROLIFE CENTER AT THE UNIVERSITY OF ST. THOMAS (MN) IN SUPPORT OF RESPONDENTS

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STATEMENT OF *AMICUS* INTEREST[1]

The Prolife Center at the University of St. Thomas (MN) seeks to promote effective legal protection for human life from the moment of fertilization to natural death through scholarly research, curriculum development, and legal initiatives. Faculty associated with the Center have provided significant *pro bono* representation to government officials, organizations and individuals supporting regulation and the eventual elimination of induced abortions obtained for reasons other than threats to the mother's life.

As an academic center, faculty associated with the Prolife Center have published numerous articles regarding material cooperation with evil, as well as a broad range of issues related to abortion. The Prolife Center submits this brief to provide the Court with insight into how the Respondents' claims of conscience arise from the Petitioners' actions.

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[1] Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no person other than the *amici* and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF THE ARGUMENT

The FDA's 2016 and 2021 changes to approved conditions and distribution requirements for mifepristone, a drug primarily used to induce abortions, has eliminated the safeguards to assure that the distribution and administration of the drug minimized any adverse health effects for women obtaining chemical abortions. By permitting abortion drugs to be dispensed by non-physicians and eliminating the requirements of in-person distribution and post-administration follow up by the prescribing provider, the FDA has implicitly sanctioned mail-order abortion programs. Such programs have resulted in the need for women suffering post-drug administration to seek medical care from local physicians, many of whom have intentionally structured their professional lives to avoid participation in induced abortion – a practice they sincerely believe is contrary to the purposes of medicine and requires the taking of innocent human life, violating the most basic ethical and religious tenets governing our common life.

ARGUMENT

I. FDA's 2016 changes to mifepristone's approved conditions of use and FDA's 2021 decision to eliminate the requirement that the drug be dispensed in person have substantially increased the number of women seeking post-abortion care from emergency rooms or clinics providing care that does not include abortions.

At the heart of this case is the question of whether a federal agency can ignore the conscience rights of doctors to facilitate mail-order abortions. The lower courts in this case have correctly answered this question with a resounding "NO." Amicus urges this Court to do the same.

The conscience rights of doctors who believe that abortion takes the life of a whole, separate, unique, living human being, *see Planned Parenthood Minn. N. Dakota, S. Dakota v. Rounds*, 530 F3d 724, 735-36 (8th Cir. 2008), *rev'd en banc*, have often been a point of dispute in the national abortion debate. *See, e.g., City & Cnty. of S.F. v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019) (challenging a final Health and Human Services Department rule allowing those with religious, moral, or other conscientious

objections to refuse to provide abortions and certain other medical services on several constitutional grounds). The original FDA approval of mifepristone did not directly implicate the conscience rights of doctors because the conditions imposed on distribution of the drug appeared to limit prescribing and distribution to physicians who willingly performed or consulted on abortions.

> Mifeprex™ must be provided by or under the supervision of a physician who meets the following qualifications:
>
> 1. Ability to assess the duration of pregnancy accurately.
>
> • Ability to diagnose ectopic pregnancies.
>
> • Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding or have made plans to provide such care through other qualified physicians and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

. . . .

FDA, *Application Approval Letter for Mifepristone NDA 020687,* at 2 (Sept. 28, 2000), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf. This all began to change in 2016.

In that year, the FDA removed the requirement for an in-person post-abortion follow-up examination by the provider and allowed "healthcare providers" other than physicians to dispense and administer mifepristone for abortions. *All. for Hippocratic Medicine v. U.S. Food and Drug Admin.*, 668 F. Supp. 3d 507, 532 (N.D. Tex.), *aff'd in part*, *vacated in part*, 78 F.4th 210 (5th Cir. 2023), *cert. granted, sub nom. Food and Drug Admin. v. All. for Hippocratic Medicine*, 217 L. Ed. 2d 285 (Dec. 13, 2023), *cert. granted, rev'd sub nom. Danco Labs., L.L.C. v. All. for Hippocratic Medicine*, 217 L. Ed. 2d 285 (Dec. 13, 2023), *cert. denied, rev'd sub nom. All. for Hippocratic Medicine v. Food and Drug Admin.*, 217 L. Ed. 2d 285 (Dec. 13, 2023). The elimination of the required follow-up visit increased the likelihood that women suffering from incomplete abortions or complications would seek care from physicians other than abortion providers. The expansion of prescribing privileges to include non-physician "healthcare providers" guaranteed that some

prescribers would not have the professional training and skill to "provide surgical intervention in cases of incomplete abortion or severe bleeding" as required by the original conditions in the 2000 approval letter. This change too increased the likelihood that an injured woman would seek care at an emergency room or from her primary care physician or other doctors unrelated to the initial administration of the abortion drugs.

In 2021 the FDA further attenuated any patient-abortion provider relationship with the agency's decisions to eliminate the in-person dispensing requirement and permanently allow "dispensing of mifepristone through the mail ... or through a mail-order pharmacy." 668 F. Supp. 3d at 522. These changes have resulted in abortion providers using telemedicine to prescribe abortion drugs across state lines, including providing drug deliveries to women in states restricting abortions to early stages of gestation. *See* Carrie N. Baker, *Health Care Across Borders: Funding Telemedicine Abortion for People in Abortion-Ban States*, Ms. Magazine (Feb. 22, 2024), https://msmagazine.com/2024/02/22/pay-abortion-pills-telemedicine-abortion-ban-states-shield-law/ (last viewed Feb. 25, 2024) (identifying organizations that fund telemedicine abortions and groups of abortion providers prescribing abortion

drugs to women in all states regardless of a state's local restrictions). Like the 2016 changes, the FDA's embrace of mail-order abortions expanded the number of women seeking abortion follow-up care through hospital emergency rooms or healthcare clinics offering only non-abortive services.

A. Remote and telemedicine providers often direct their patients to seek post-abortion care at emergency rooms or other medical clinics if complications arise.

The FDA's approval of mail-order abortions increased the number of women seeking post-abortion care not only because many of the healthcare providers prescribing the drugs for such abortions are not located in the same state as their patients, but also because these providers direct the women to seek any follow-up care elsewhere. The website of Aid Access, "a team of US registered abortion providers who will provide FDA registered abortion pills to people in all 50 states"[2] instructs patients who are concerned about possible complications:

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[2] Aid Access, *Who We Are*, https://aidaccess.org/en/page/561/who-are-we (last visited Feb. 25, 2024).

> If you think you might have a complication you should go to a doctor immediately. You do not have to tell the medical staff that you tried to induce an abortion; you can tell them that you had a spontaneous miscarriage. Doctors have the obligation to help in all cases and know how to handle a miscarriage.

Aid Access, *How do you know if you have abortion complications*?, (last visited Feb. 25, 2024); s*ee also* Just the Pill, *Is It Safe, How Does It Work*?, https://www.justthepill.com/faq/?gad_source=1&gclid=CjwKCAiAivGuBhBEEiwAWiFmYQaoeKH6JqcUxojGezFKjyVc2aeHUTTA0P1lv5Egh4R00AmABreE4RoCE4UQAvD_BwE (last visited Feb. 25, 2024) (patient suspecting ectopic pregnancy "will need immediate medical attention, which can be obtained at any medical facility"); and Hey Jane, *Frequently Asked Questions, What symptoms should I be concerned about after taking the abortion pills*?, https://www.heyjane.com/faqs#bm-before-during-after (last visited Feb. 25, 2024) (last visited Feb. 25, 2024) (recommending patient visit emergency room for urgent concerns after taking abortion pills).

The Aid Access webpage continues by instructing women how to avoid a physician being

able to recognize the patient's condition is due to the administration of abortion drugs:

> The symptoms of a miscarriage and an abortion with pills are exactly the same and the doctor will not be able to see or test for any evidence of an abortion, as long as the pills have completely dissolved. If you used the Misoprostol under the tongue as our protocol recommends, the pills should have dissolved within 30 minutes. If you took the pills vaginally, you must check with your finger to make sure that they are dissolved. Traces of the pills may be found in the vagina up to four days after inserting them.

Id. All of this advice, of course, is not helpful when the "complication" is an ongoing pregnancy. In those cases, the webpage informs women, "To treat an ongoing pregnancy, you must repeat a medical or surgical abortion." *Id*. This in turn creates the very harm that Respondents seek relief from – the necessity of complicity or cooperation with the taking of an innocent human life.

The referral of these providers of mail-order abortions to physicians and clinics unassociated

with the abortion industry is confirmed in the written testimony of several physicians in this case. Their declarations attest to the increased number of women seeking care for complications or continued pregnancies after taking drugs to induce an abortion.

B. The record contains sworn testimony by Respondent Physicians evidencing the post-2016 increase in numbers of women seeking care due to incomplete abortions or complications arising from attempted chemical abortions.

The lower courts correctly ruled that Respondent Physicians have established that their injuries are "fairly traceable to the defendant's allegedly unlawful conduct, and likely to be redressed by the requested relief." *Raines v. Byrd*, 521 U.S. 811, 818, 117 S. Ct. 2312, 2317, 138 L. Ed. 2d 849 (1997).

The declaration of Dr. Shaun Jester notes that abortion providers administer chemical abortion drugs from afar. *U.S. Food and Drug Admin. et al., v. Alliance for Hippocratic Medicine et al.,* 2024 WL 582361, Compl. at *85, ¶289, *id*., Decl. of Dr. Tyler Johnson at *179, ¶10, and *id*., Decl. of Dr. Shaun

Jester, at *190, ¶17. Providers often lack the ability to treat their patients in case of complication and resort to instructing women to go to the emergency department of the closest hospital for the treatment of serious complications. *See id.*, Decl. of Dr. Donna Harrison at *130, ¶19 (FDA "allowed abortion providers who lack the ability to handle complications to dispense Mifeprex;" *id.*, Decl. of Dr. Tyler Johnson at *180, ¶13 (abortion dispensing staff instructions to injured women regarding emergency room visits).

This incapacity to treat post-abortion complications and reliance upon unrelated physicians for patient care is the direct result of the FDA's 2016 changes to conditions for distribution of abortion drugs.

Dr. George Delgado, a Respondent Physician, and a board-certified physician practicing in the areas of family medicine and palliative care, confirms this result of the FDA's oversight. "I will have to treat an increased number of patients due to abortion facilities' failure to provide follow-up care to women and girls." Decl. of Dr. George Delgado, 2024 WL 582361 at *192-93, ¶18.

Commenting on the relationship between the FDA's 2016 and 2021 REMS deregulations, and his

own experience as a practicing physician, Dr. Tyler Johnson says that "these emergency situations are becoming more common as more women are turning to chemical abortion as the FDA has relaxed its regulations." *Id.*, Decl. of Dr. Tyler Johnson at *179, ¶9. His observation that "many women are told by staff at the dispensing clinics to tell emergency department doctors that they are experiencing a 'miscarriage'", *id.* at *180, ¶13, is supported by the advice on Aid Access webpage addressing complications. Aid Access, *How do you know if you have abortion complications*?, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do (last visited Feb. 25, 2024). Dr. Johnson concludes that the FDA's deregulation of abortifacient drugs "leaves emergency physicians like me to deal with preventable emergent and life-threatening situations after these women have taken these drugs." *Id.* at *180, ¶14.

This Court should affirm the lower courts' ruling that Respondents have adequately established that their injuries are traceable to the FDA's changes in its conditions for distribution of abortion drugs.

II. The FDA changes imminently threaten the conscience rights of Respondents.

Petitioners FDA and Danco persistently mischaracterize the threat to Respondent Physicians' consciences. "Respondents oppose abortion and therefore oppose the use of mifepristone. But respondents "are not required to receive" or prescribe mifepristone . . ." *U.S. Food and Drug Administration, et al., v. All. for Hippocratic Medicine, et al.*, Pet. For Cert., 2023 WL 5979790, at *13. Appellant-Intervenor Danco's characterization of Respondents' injuries is equally inaccurate.

> The individual Plaintiff-physicians oppose abortion. They do not prescribe medication abortion, consult on elective abortions, or perform surgical abortions as part of their regular practice. Nor are they required to do so by any FDA action challenged in this case or by any other federal law. No Plaintiff-physician seeks to treat patients who have had medication abortions-the opposite appears to be true. In the world of physicians who could or would possibly treat a woman for any medical reason associated with a medication abortion, these doctors are among the very last to be considered.

U.S. Food and Drug Administration, et al., v. All. for Hippocratic Medicine, et al., Opening Brief for Intervenor-Appellate Danco Laboratories, Inc., 2023 WL 3273781 at *21. None of respondents have ever claimed that they, individually or organizationally, are" required to receive or prescribe mifepristone" or to "prescribe medication abortion" or "perform surgical abortions as part of their regular practice."

Respondents' injuries to their consciences arise from the need to provide abortion-related care when a woman seeks Respondent Physicians' assistance in treating complications after initiating a chemical abortion. Such assistance may require completing the abortion, whether surgically, or through addition administration of the abortion drugs. *E.g., U.S. Food and Drug Admin. et al., v. Alliance for Hippocratic Medicine et al.,* 2024 WL 582361, Decl. of Mario Dickerson at *121, ¶16; *id.* Decl. of Dr. Donna Harrison at *136, ¶44 (members of the Alliance for Hippocratic Medicine and the Association of Prolife Obstetricians and Gynecologists may be required to end the life of an unborn child to treat complications).

Prior to the 2016 and 2021 changes to FDA and Danco policies, such follow-up care would have been provided from the abortion provider or "other qualified physicians" with whom the provider has

arranged to provide all necessary follow-up care. *All. for Hippocratic Medicine v. U.S. Food and Drug Admin.*, 668 F. Supp. 3d at 532.

A. Providing emergent follow-up care for women who have ingested abortion drugs is a form of cooperation with the act of abortion.

None of the parties in this case argue that Respondent Physicians and members of Respondent Organizations are insincere in their claims that they or their members believe that induced abortion is a grave moral wrong. For some Respondents, that belief is based, at least in part, on their understanding of the purposes of medicine.

> The members of Plaintiff medical associations oppose being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location.

U.S. Food and Drug Administration, et al., v. All. for Hippocratic Medicine, et al., Compl. at ¶289, 2022 WL 17091784 (N.D. Tex.).

For some, their beliefs are based, at least in part, on their understanding of their religious obligations. This is true both of some Respondent Physicians and some Respondent Organizations.

Two examples from Respondent Organizations illustrate this point.

The Christian Medical and Dental Association (CMDA) is an organizational plaintiff in this case. *U.S. Food and Drug Administration, et al., v. All. for Hippocratic Medicine, et al.*, Compl. at ¶36, 2022 WL 17091784 (N.D. Tex.). The CMDA statement on moral complicity with evil specifically notes: "Moral complicity may involve enabling or facilitating future immoral actions of patients or professionals", giving "referral for or assisting in abortion" as an example of such forbidden complicity. CMDA, *Position Statement on Moral Complicity with Evil, unanimously approved by the CMDA House of Delegates on June 11, 2004,* https://cmda.org/policy-issues-home/position-statements/ (last modified Feb. 26, 2024). Moral complicity with evil is not permissible based on the Biblical command that

Christians "must avoid every kind of evil, (I Thessalonians 5:22)," and they "may never do evil that good may come." (Romans 3:8)." *id.* Thus, assisting in an induced abortion, whether as part of the initial administration of abortion drugs, or after such drugs are taken and complications ensue, is prohibited as complicity with the evil of abortion.

Similarly, the Catholic Medical Association ("CMA") is a member of the Alliance for Hippocratic Medicine. *U.S. Food and Drug Administration, et al., v. All. for Hippocratic Medicine, et al*., Compl. at ¶¶33, 319, 2022 WL 17091784 (N.D. Tex.). As an organization CMA adheres to Catholic teaching regarding abortion. *U.S. Food and Drug Admin. et al., v. Alliance for Hippocratic Medicine et al.,* 2024 WL 582361, Decl. of Mario Dickerson at *119-120, ¶¶8-9.

The Catholic Church teaches that abortion is an "unspeakable crime," Vatican Council II, *Gaudium et Spes*: *Pastoral Constitution on the Church in the Modern World*, §51 (1965), https://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_cons_19651207_gaudium-et-spes_en.html, and procuring or assisting in the procurement of an abortion is a sin. Congregation for the Doctrine of the Faith, *Clarification on Procured Abortion* (2009),

https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20090711_aborto-procurato_en.html.

A detailed explanation of the Catholic position on abortion is containing in the papal encyclical, *Evangelium Vitae* (Gospel of Life) authored by St. John Paul, II in 1995. The encyclical provides guidance regarding the obligations of healthcare providers within a legal regime that, like the current U.S. administration, endorses abortion:

> Christians, like all people of good will, are called upon under grave obligation of conscience not to cooperate formally in practices which, even if permitted by civil legislation, are contrary to God's law. Indeed, from the moral standpoint, it is never licit to cooperate formally in evil. Such cooperation occurs when an action, either by its very nature or by the form it takes in a concrete situation, can be defined as a direct participation in an act against innocent human life or a sharing in the immoral intention of the person committing it. This cooperation can never be justified either by invoking respect for the freedom of others or by appealing to the fact that civil law permits it or requires it.

Pope John Paul, II, *Evangelium Vitae (The Gospel of Life)*, §74 (1995), https://www.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html.

By eliminating the requirement that follow-up care be provided by the physicians initiating the chemical abortion, and subsequently authorizing distribution of abortion drugs by mail, the FDA radically diluted the responsibility of abortion providers for the well-being of their patients, while dramatically increasing the burdens for post-abortion care on physicians serving in emergency rooms and clinics that do not provide abortions. Among these burdens is the burden imposed on Respondents of deciding whether the physician's duty to provide post-abortion care for prospective patient outweighs the duty to God to avoid being a part of taking the unborn child's life.

This burden represents a unique and unnecessary Hobson's choice. Nowhere else in America – not even in the military or law enforcement – is the right to practice one's lawful profession conditioned on willing participation in the killing of an *innocent* person.

This choice has been thrust upon Respondents, not because participation in induced abortions must be required of all physicians to assure the health and safety of women. In fact, there is strong evidence that mail-order abortions undermine that goal. Rather, mail-order abortions have been made available because Danco Laboratories, manufacturer of Mifepristone, and the FDA, the federal agency charged with ensuring the safety of drugs marketed and distributed in this country, wanted to expand access, and reduce costs of this elective procedure – and did so at the cost of women's safety and many physicians' consciences.

These injuries are "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021) (*citing Monsanto Co. v. Geertson Seed Farms,* 561 U.S. 139,130 S.Ct. 2743, 2752, 177 L.Ed.2d 461 (2010)).

The standing of the Respondents to pursue relief for their injuries should be affirmed, and the rulings of the lower courts affirmed.

CONCLUSION

For the reasons set forth above, we urge this Court to affirm the judgment of the U.S. Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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