Nos. 23-235 and 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.

BRIEF OF *AMICUS CURIAE* THE ROBERTSON CENTER FOR CONSTITUTIONAL LAW IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[1]

For over three millennia, Jewish and Christian teaching has uplifted the sanctity of human life. This traditional understanding is firmly grounded in Scripture. See, e.g., Jeremiah 1:5 ("Before I formed you in the womb, I knew you."); Psalms 119:73 ("Thy hands made me and fashioned me."). Religious faith both convicts and inspires tens of millions of diverse Americans to advocate for protecting human life, including life in the womb.

The Robertson Center for Constitutional Law is an academic center within the Regent University School of Law. Established in 2020, the Center pairs scholarship and advocacy to advance first principles in constitutional law, including limited government, separation of powers, religious liberty, and the rule of law. The Center regularly represents organizations of various faith traditions that support religious freedom, conscience rights, and the sanctity of human life.

SUMMARY OF THE ARGUMENT

The Respondents have standing to challenge the removal of drug safety standards for mifepristone. That action harms doctors—such as OB/GYNs and

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[1] Under Rule 37.6, no counsel for a party authored this brief in whole or in part, and no person other than *amicus* or its counsel made a monetary contribution to its preparation or submission. *Amicus* notes that although counsel of record for respondents is a senior fellow with The Robertson Center, she had no role in drafting or funding this brief.

emergency-room physicians—by diverting the doctors' time and attention, exposing them to increased liability and related insurance costs, reducing pregnancies and live births, and creating unnecessary emergencies in which they are forced to act against their deeply-held beliefs. Doctors who belong to the Respondent Medical Organizations ("the Doctors") have made sworn declarations attesting to the concrete injuries they already have suffered and will continue to suffer.

Patients suffering from potentially life-threatening complications of chemical abortions present regularly to emergency rooms. Necessity requires the Doctors to focus on these emergency patients. When they do, they cannot also devote their time and critical resources to their labor-and-delivery patients.

These emergencies are high-risk events that expose the Doctors to greater malpractice liability and associated insurance costs. Loosened safety standards subject the Doctors to more high-risk situations. They must work in these emergency conditions with little or no knowledge of the patients' history. Worse yet, some patients have been instructed to provide incorrect information—deliberately telling emergency room doctors that they are experiencing a miscarriage. Moreover, the FDA's decision to lessen adverse incident reporting deprives the Doctors of critical information, increasing the risk of errors. Malpractice lawsuits inevitably will result.

The increased availability of chemical abortion also reduces the number of pregnancies and live

births. Many of the Doctors make their living delivering babies and providing pre-natal and post-natal care. When those pregnancies end early, the Doctors lose patients and suffer economic injury.

The Doctors also have suffered profound harm to their consciences and their mental and emotional wellbeing. They have moral and religious objections against participating in any stage or phase of an abortion. Yet they are also morally compelled to do what is needed to treat women in emergencies suffering catastrophic complications from mifepristone.

Conscience compels the Doctors to provide needed care in these desperate situations—just as conscience also forbids the Doctors from participating in a process that takes human life. Such catch-22 incidents undoubtedly will continue unless the FDA's decisions are reversed.

The FDA's unlawful decision to eliminate vital safety protocols on mifepristone does not harm only women and girls. The Doctors and Medical Organizations in this case also have suffered concrete harms and have standing to seek redress.

ARGUMENT

Article III standing "requires a plaintiff to demonstrate that it has '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Students for Fair Admissions, Inc.* v. *President & Fellows of Harvard*

Coll., 600 U.S. 181, 199 (2023) (quoting *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 338 (2016)). Organizations whose members have suffered concrete and redressable injuries may bring claims on behalf of their members. *Sierra Club* v. *Morton*, 405 U.S. 727, 739 (1972).

An organization may establish standing by showing that the organization itself has sustained an injury, or by "standing solely as the representative of its members." *Warth* v. *Seldin*, 422 U.S. 490, 511 (1975). The Alliance for Hippocratic Medicine, the American Association of Pro-Life Obstetricians and Gynecologists, the American College of Pediatricians, and Christian Medical & Dental Associations (collectively, "Medical Organizations") have standing under both theories. But the injuries suffered by their members most clearly establish the standing of the Medical Organizations.

Organizations may bring suit on behalf of their members when "(a) [their] members would otherwise have standing to sue in their own right; (b) the interests [they] seek[] to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit."[2]

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[2] This Court held that the third prong for associational standing is not required by Article III but is rather a prudential factor applied at a court's discretion. *United Food & Com. Workers Union Loc. 751* v. *Brown Grp., Inc.*, 517 U.S. 544, 555 (1996).

Hunt v. *Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977).

To show that their members would have standing in their own rights, the Medical Organizations must "make specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 498 (2009). There must be a showing, by affidavit, "that one or more of respondents' members would thereby be 'directly' affected . . . ." *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 563 (1992) (quoting *Sierra Club,* 405 U.S., at 735). Doctors Mario Dickerson, Donna Harrison, Jeffrey Barrows, Christina Francis, Ingrid Skop, Nancy Wozniak, Tyler Johnson, Shaun Jester, and George Delgado each have provided supporting declarations that explain the harms they have suffered or will suffer as a result of the FDA's unlawful actions. See generally Joint Appendix ("J.A.") Vol. 1. Many of the Doctors are not traditional emergency room physicians. Rather, they are OB/GYNs or OB/GYN hospitalists who are pulled by necessity into the medical emergencies created by mifepristone deregulation. J.A. 152–54, 161–62, 170–73, 184, 195–96.

Reducing the dangerous impact of chemical abortion drugs on patients and member physicians is unquestionably "germane to" each Respondent Medical Organization's purpose. *Hunt*, 432 U.S. at 343. The Medical Organizations exist to promote Hippocratic medicine. J.A. 127. They oppose abortion as destructive to human life and harmful to women and girls. J.A. 120, 127, 139. They encourage their members to apply these ideals in their everyday

practices. J.A. 119–20. They seek to protect patient wellbeing and human life at all stages of development. And the Doctors conscientiously object to performing or facilitating abortions of any kind. J.A. 120, 127, 139.

I. Mifepristone Deregulation Harms The Doctors Economically By Diverting Resources, Increasing Costs, And Reducing Live Births.

Economic injuries create Article III standing. See *Sierra Club*, 405 U.S. at 737. The FDA's 2016 and 2021 actions harm the Doctors economically by diverting resources, increasing costs, and reducing the number of pregnant women and live births.

A. Mifepristone patients with complications divert resources from the Doctors' bread-and-butter practices.

The FDA's 2016 and 2021 actions "astronomical[ly]" increased the number of women and girls coming into the Doctors' practices with complications from chemical abortions. J.A. 132; see also J.A. 172, 192. As a result, the Doctors must reallocate finite resources—time, medical expertise, office space, and medical supplies—to the detriment of their core practices.

The Doctors must treat chemical abortion patients in emergency situations instead of caring for labor-and-delivery patients who need them. J.A. 120, 153–54, 174, 192–93. As Dr. Ingrid Skop declared, "When

I am called to the operating room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients." J.A. 166–67. And Dr. Tyler Johnson explained that "[b]ecause more women are unnecessarily presenting in the emergency department, more of my time and attention is taken away from other patients who need it."). J.A. 180–81.

Emergency mifepristone treatments consume scarce medical resources, including medicines and blood for transfusions. J.A. 131. Women and girls suffering needless complications from chemical abortions occupy beds in hospitals and clinics and use equipment that could be used otherwise. J.A. 131. Some women seek emergency care when they are experiencing the typical—but still terrible—side effects of mifepristone, including "cramping, heavy bleeding, and severe pain." J.A. 132; see also J.A. 179, 180–81. These visits also consume emergency resources.

Patients suffering needless complications divert the Doctors' time from women giving birth and those to whom the Doctors are providing pre-natal care. J.A. 153–54, 166–67. The Doctors have worked willingly in these difficult situations. J.A. 174. They will continue to do so. But they cannot be in two places at once. The FDA's decisions come at a cost—to women and their doctors.

B. Removal of safeguards exposes the Doctors to greater malpractice liability and insurance costs.

"The risk of complications from chemical abortions is four to seven times greater than from surgical abortions." J.A. 172. Treating women suffering complications from chemical abortions is risky business. That risk creates liability exposure—and results in increased insurance premiums. J.A. 142, 173, 198–99.

The Doctors regularly treat women who are experiencing severe abnormal bleeding, severe pain, hemorrhage, sepsis, fever, endometritis, uterine lining infections, and acute kidney injury. J.A. 120, 153–54, 184. They typically do so with little to no information about the women's medical history because the women are not their regular patients and present in emergency rooms in urgent situations. J.A. 172–73. Doctor Jeffrey Barrows noted the clinical importance of the relationship between a patient and her doctor: "The best way to prevent malpractice is for physicians to establish relationships with patients who they can treat over time." He continued: "By doing away with the necessary medical supervision, the FDA will cause more women and girls to present in life-threatening circumstances [to] . . . emergency department physicians who have no prior history with these patients." J.A. 142. Often the Doctors don't know the gestational age of the fetus and don't know the "medications that the patient[s] may have been prescribed." J.A. 172–73; see J.A. 121.

Deceptive tactics by FDA-authorized mifepristone dispensers exacerbate that risk, creating a "culture of chaos" for the Doctors. J.A. 180. Many who seek the Doctors' help do not understand the effects of mifepristone or do "not even know what drugs they consume[]." J.A. 121, 185–86. Some do not understand that complications are possible. J.A. 162–63. These patients "usually" do not understand "their follow-up instructions." J.A. 185–86. Worse, some dispensers encourage patients to deceive emergency room doctors by telling them they are experiencing a miscarriage.[3] See also J.A. 121, 180. Many women follow this advice. J.A. 174, 180.

Moreover, the FDA's deregulation did away with adverse event reporting coincident with dispensing mifepristone. J.A. 141, 187. Thus, the Doctors can no longer rely on that data when making treatment decisions. J.A. 187.

The Doctors must make critical medical decisions blind to significant information. J.A. 166, 172, 180, 181, 187. And they must make those decisions more often and in "higher-risk situations" because of the removal of mifepristone safeguards. J.A. 173. Treating more patients under such circumstances increases the Doctors' exposure to malpractice claims.

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[3] See, e.g., *Will a Doctor Be Able to Tell If You've Taken Abortion Pills?*, Women Help Women (Sept. 23, 2019), https://womenhelp.org/en/page/1093/will-a-doctor-be-able-to-tell-if-you-ve-taken-abortion-pills; *How Do You Know If You Have Complications and What Should You Do?*, AidAccess, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do (last visited Feb. 27, 2024).

J.A. 142, 166, 172, 181, 187. In fact, the claims have already started. See Complaint, *Dixon v. Dignity Health*, No. A-23-877731-C (Nev. Dist. Ct., Clark Cnty., Sept. 13, 2023) (suing hospital and healthcare professionals for malpractice over the abortion-drug death of a twenty-four-year-old woman).

C. The FDA has imposed competitive injury on the Doctors by lifting regulatory restrictions on an alternative to live birth.

When chemical abortions become easier to access, fewer babies are born, and fewer women require pre- or post-natal care. As Dr. George Delgado explained "When my patients have chemical abortions, there is a tangible financial loss to my practice in losing the opportunity to render professional prenatal care for the mother or to care for babies who are never born." J.A. 192. Likewise, Dr. Shaun Jester explains, "[M]y hospital will bill for the cost of obstetrical and medical services rendered. When my patients have chemical abortions, I lose the opportunity to provide these . . . services to care for the woman and child through pregnancy and bring about a successful delivery of a new life." J.A. 198.

The doctrine of competitive injury standing recognizes that "economic actors 'suffer [an] injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition' against them." *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010) (quoting *La. Energy & Power Auth. v. FERC,* 141 F.3d 364, 367 (D.C. Cir. 1998)) (alterations in original). "The form of that injury may

vary; for example, a seller facing increased competition may lose sales to rivals . . . to the detriment of its bottom line." *Id.* "[A]ccounting for additional *rivals* constitutes injury in fact." *Shays v. FEC*, 414 F.3d 76, 86 (D.C. Cir. 2005).

This Court has found that increased competition resulting from government action to be an injury in fact to a private competitor. See *Ass'n of Data Processing Serv. Orgs., Inc.* v. *Camp*, 397 U.S. 150, 151–52 (1970) (finding that sellers of data processing services had standing to challenge the Comptroller of the Currency's ruling that national banks could provide data processing services to other banks and bank customers "as an incident to their banking services" under the APA); see also *Bennett* v. *Spear*, 520 U.S. 154, 157, 167–68 (1997) (holding that parties with "competing economic and other interests" in a particular water supply had standing to challenge federal agency action reducing that supply in the aggregate); *Singleton* v. *Wulff*, 428 U.S. 106, 112–13 (1976) (finding physicians had alleged an injury in fact when the government further limited the types of procedures it would cover under Medicaid).

Following this principle, in *Cooper v. Texas Alcoholic Beverage Commission*, the Fifth Circuit found that "[i]t is a 'basic law of economics' that increased competition leads to actual economic injury." 820 F.3d 730, 738 (5th Cir. 2016) (quoting *New World Radio, Inc. v. F.C.C.*, 294 F.3d 164, 172 (D.C. Cir. 2002)). The FDA's rule changes have increased the number of competitors in the pre-natal care market. As a result, doctors like Dr. Delgado and Dr. Jester have been harmed. See J.A. 192, 198.

II. The Doctors' Conscience, Mental, And Emotional Injuries Also Provide Standing.

Injuries need not be tangible to be concrete. *Spokeo*, 578 U.S. at 340 ("[W]e have confirmed in many of our previous cases that intangible injuries can nevertheless be concrete."). Injury to one's conscience is no less concrete than economic injury. *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 425 (2021) (noting concrete, intangible harms such as free speech and free exercise violations). And here, the Doctors' conscience-based objections are strikingly similar to those recognized by this Court in *Burwell* v. *Hobby Lobby Stores, Inc.*. See 573 U.S. 682, 701–03, 736 (2014) (holding for litigants whose consciences would suffer injury if forced to provide insurance coverage for abortion-inducing drugs). Here, the Doctors have suffered grave injuries to their consciences and their mental and emotional wellbeing.

A. The Doctors suffer conscience injuries when they are morally complicit in ending human life.

The FDA's mifepristone deregulation directly causes women to seek emergency care for chemical abortion complications. J.A. 135–36. Caring for these women necessarily implicates the Doctors in the termination of human life. And that is deeply troubling to any doctor who believes that life begins at conception.

The Doctors cannot in good conscience have any part in the termination of a human life. "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." J.A. 155. As Dr. Skop explained, "[M]y moral and ethical obligation to my patients is to promote human life and health. But the FDA's actions may force me to end the life of a human being in the womb for no medical reason." J.A. 167. Dr. Jester expressed similar concerns about problems that may arise from a lack of information: "The elimination of REMS [Risk Evaluation and Management Strategies] . . . prevents doctors from fulfilling their oath to 'do no harm' by permitting the administration of abortifacient drugs to patients without full knowledge or appreciation for the impact those drugs would have on them." J.A. 200.

Sometimes caring for women in the emergency room because of mifepristone complications requires the attending doctor to complete the abortion. J.A. 121. As Dr. Barrows described: "I am also concerned that the FDA's actions will force CMDA members to complete an unfinished elective abortion in an emergency situation, causing immediate emotional and moral distress for our members who are opposed to elective abortion and do not want to feel complicit in an immoral, unnecessary procedure." J.A. 142–43; see also J.A. 121.

These concerns are more than conjectural or hypothetical. They have happened and will happen again. Dr. Christina Francis told the following story:

> [A] partner of mine and I cared for another patient who also suffered complications from

> chemical abortion. I had taken care of her when she was hospitalized for hyperemesis gravidarum at 9 weeks 5 days gestation. . . . Approximately one week after her discharge, the patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs. One of my partners was able to detect a fetal heartbeat. Due to the amount of bleeding that she was experiencing and evidence of hemodynamic instability, however, my partner had no choice but to perform an emergency D&C. . . . [B]ecause the preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion.

J.A. 154.

Dr. Shaun Jester described a similar event. J.A. 198. After taking mifepristone, a woman bled for two weeks and developed a uterine infection. *Id.* At the hospital, Dr. Jester treated the woman and performed an emergency surgical abortion, a D&C. *Id.* A D&C, or dilation and curettage, requires the physician to widen the woman's cervix and then scrape the remains of her unborn child out of her uterus.[4] If the

[4] *Dilation and Curettage (D&C)*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/dilation-and-curettage/about/pac-20384910 (last visited Feb. 27, 2024).

woman "had waited a few more days before receiving care, she could have been septic and died." *Id.*

Being forced to violate a deeply-held conviction causes the Doctors mental and emotional harm. When they must facilitate or complete an abortion, the Doctors understand that they are taking life. This leads to "immediate emotional and moral distress" because they "feel complicit in an immoral, unnecessary procedure." J.A. 142–43. They also experience "grief" and "enormous stress and pressure" from participating, under emergency conditions, in the process of removing fetal parts, treating severe infections, and stopping heavy bleeding. J.A. 120, 172; see also J.A. 163.

The Doctors also suffer emotional harm from watching their patients suffer. Dr. Skop described having cared for "several dozen" women who were totally unprepared for the pain, bleeding, and other effects of a chemical abortion, or who were traumatized by the sight of the body of their unborn child in the toilet after a chemical abortion. J.A. 162. She also described caring for many women with life-threatening side effects they did not anticipate because they were not given complete information and "likely did not have sufficient informed consent to proceed with chemical abortion." J.A. 163. Dr. Skop found it "heartbreaking" to watch her patients endure this needless suffering. J.A. 167.

In *Lujan*, this Court recognized that "the desire to use or observe an animal species, even for purely esthetic purposes, is undeniably a cognizable interest for purpose of standing." 504 U.S. at 562–63.

Similarly, in *Summers*, this Court recognized that an organization's member had an interest in "viewing the flora and fauna of [an] area." 555 U.S. at 494. If individuals suffer concrete injuries when they experience emotional and mental distress caused by the inability to access wildlife and vegetation, then the Doctors certainly suffer concrete injuries too. They experience emotional and mental distress caused by seeing their patients suffer needlessly in horrific emergencies and, perhaps worst of all, being complicit—against their will—in the taking of innocent life.

B. The FDA's unlawful actions force the Doctors into an impossible dilemma of conscience.

Conscience compels the Doctors to provide needed care to women experiencing such desperate situations—just as conscience also forbids the Doctors from completing a process that takes human life.

No exemption will solve the dilemma foisted upon the Doctors. Most of the Doctors are OB/GYN hospitalists called into emergency situations, and one is an emergency-room doctor. J.A. 152–54, 161–62, 170–74, 178, 184, 196. Emergency room doctors are in short supply, and hospitals legally cannot turn away patients in emergency situations. For the hospitalists, the FDA is counting on them to provide a response to abortion-drug complications. J.A. 227, 229–30. Many of these emergencies could have been avoided if not for the FDA's removal of mifepristone safeguards. J.A. 120. Exigency and the FDA's unlawful actions now conscript the Doctors into abortion care.

The Doctors have served bravely during emergencies, treating every patient at great personal cost. They face an impossible choice: Violate their consciences by playing a part in an abortion or violate their Hippocratic Oath by refusing to treat patients in dire distress. The Doctors should not be forced to make this choice—or choose between their calling and their conscience.

CONCLUSION

The Doctors and Medical Organizations have standing to challenge the FDA's unlawful actions. This Court should affirm the order of the Fifth Circuit and remand for further proceedings.

Respectfully submitted,

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