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

BRIEF OF AMICUS CURIAE LIFE LEGAL DEFENSE FOUNDATION IN SUPPORT OF RESPONDENTS

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INTERESTS OF AMICUS CURIAE[1]

Amicus Life Legal Defense Foundation ("Life Legal") is a California non-profit 501(c)(3) public interest legal and educational organization that works to assist and support those who advocate in defense of life. Its mission is to give innocent and helpless human beings of any age, particularly unborn children, a trained and committed defense against the threat of death, and to support their advocates in the nation's courtrooms. Life Legal believes life begins at the moment of conception and should not end until natural death. It litigates cases to protect human life, from preborn babies targeted by a billion-dollar abortion industry to the elderly, disabled, and medically vulnerable denied life-sustaining care.

Amicus opposes all forms of abortion – chemical as well as medical – as a violation of the right to life of the unborn child, as well as a detriment to the health of women and girls, particularly when not accompanied by commonsense safeguards. Amicus unequivocally supports doctors' right of conscience to refuse to participate in abortion whether directly by performing them or indirectly by being complicit in them.

SUMMARY OF ARGUMENT

Respondents, as individuals and as organizations, have standing to challenge Petitioner Food and Drug Administration's (FDA) removal of

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[1] No counsel for any party authored this brief in whole or in part; no party counsel or party made a monetary contribution intended to fund its preparation or submission; and no person other than *amicus* or its counsel funded it.

safeguards accompanying the use of abortion drugs mifepristone and misoprostol. To support Article III standing, a plaintiff must show, *inter alia*, that he has sustained an injury in fact that is concrete and particularized as well as actual or imminent, not conjectural or hypothetical. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). An association may sue on behalf of its members when "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks 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." *Hunt v. Wash. State Apple Adver. Comm'n.*, 432 U.S. 333, 343 (1977).

Respondents have satisfied the first two prongs of the *Hunt* test, and the third is not necessary when an association is seeking prospective injunctive relief. *United Food & Commer. Workers Union Local 751 v. Brown Grp.*, 517 U.S. 544, 545 (1996). Respondent individual members have already sustained actual injuries because of having to treat women who are suffering from complications resulting from the taking of the abortion drugs, in violation of the doctors' moral opposition to participating in elective abortion. Also, given that it is virtually certain that women will continue to take these abortion drugs without proper safeguards and will therefore present themselves to emergency rooms needing treatment from complications, there is a "substantial risk" that the injuries will occur to these pro-life doctors again. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 fn. 5 (2013). Therefore, we urge the Court to uphold the Fifth Circuit's decision to grant standing to Respondents. Pet. App. at 34a-36a.

ARGUMENT

I. The FDA's Removal of Safety Standards for the Use of Abortion Drugs Causes an Injury in Fact to the Conscience Rights of Respondents.

To establish Article III standing, a plaintiff must show, *inter alia*, an injury in fact that is concrete and particularized as well as actual or imminent, not conjectural or hypothetical. *Lujan,* 504 U.S. at 560. Respondents claim that the FDA's approval of mifepristone and misoprostol and subsequent removal of safeguards in 2016 and 2021 has caused an injury in fact to their rights of conscience to not participate in or facilitate abortion and that this injury is sufficient to support standing.

A. Respondents Have Identified Several Members Who Have Already Been Harmed and Who Face Imminent Injury to their Consciences.

Petitioners assert that Respondents have not established injury in fact because they have not identified any member who faces an imminent conscience injury. They claim that Respondents have not explained why federal conscience provisions are not available to them, that their claim is based on statistics and a series of contingencies, that it is not an imminent future injury, and that no injuries have actually occurred. Brief for the Federal Petitioners (BFP) at 20-25; Brief for Danco Labs., LLC (BD) at 19-29.

Petitioners misrepresent Respondents' conscience claim as well as the scope of the conscience

right.[2] While Respondents do claim that, at some future unspecified time, they may have to participate in the taking of an innocent human life by performing an abortion, their overall claim in fact is much broader: they assert that these medications force them to become "complicit in the elective chemical abortion" because they will be forced "to remove a baby with a beating heart *or pregnancy tissue* as the only means to save the life of the woman or girl." Joint Appendix (JA) at 87 ¶ 296 (emphasis added); Pet. App. at 119a; JA at 142-43 ¶ 26 ("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."). They are thus being forced to finish the abortion that the medications started. Contrary to Petitioners' claims (BD at 22-23, 28), several of the Declarations attached to the Complaint recount instances of Respondent doctors having had to complete unfinished abortions. JA at 163 ¶ 17 ("I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled."); *id.* at 164 ¶ 23 ("I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication."); *id.* at 153 ¶ 12 ("one of my patients . . . had obtained mifepristone and misoprostol from a

[2] "Their primary theory is that their members could be forced to violate their consciences by completing an abortion for a woman with an ongoing pregnancy." BFP at 17.

website. . . [and] required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue")[3]; *id.* at 198 ¶ 17 ("I provided her with intravenous antibiotics and performed a dilation and curettage procedure" which saved her life). As these Declarations state, these doctors already have had to complete abortions, against their own conscience, to save a woman's life or prevent her health from deteriorating further.

This case is thus unlike that of *Summers v. Earth Island Inst.*, 555 U.S. 488 (2009), relied on by Petitioners. BFP at 19-20, 22-23; BD at 19-23. In *Summers*, this Court rejected the environmental organizations' standing claim because they failed to "make specific allegations establishing that at least one identified member *had suffered* or would suffer harm" (emphasis added) and instead relied upon statistical probabilities. Here, Respondents have made specific, personal allegations of harm that have already occurred to their members, which distinguishes them from the plaintiffs in *Summers* because the latter had not suffered any identified harms as a result of the government's action. Furthermore, the plaintiffs in *Summers* failed to allege any "specific and concrete plan" to enjoy the national forests in question so they failed to establish likelihood of future harm. *Id.* at 495. In this case, Respondent doctors have maintained that they will continue to treat patients in an emergency context, thereby subjecting them to the danger of repeated conscience violations as a result of the FDA's reckless removal of safeguards. *See* Sec. I.C., *infra*.

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[3] Although the FDA has not specifically approved ordering of abortion drugs from websites, the removal of the requirement of an in-person visit in order to obtain a prescription has increased the likelihood that women will go online to obtain them.

Petitioners' objection that Respondents lack standing because the government's actions do not require them to prescribe the abortion drugs or perform abortions is also without merit. BFP at 16-17; BD at 35. This Court has long recognized that injuries to conscience encompass forced complicity, as well as direct involvement, with the objectionable conduct. For example, in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 719-26 (2014), this Court held that the Health and Human Services mandate requiring employers to cover abortifacients in their employee insurance policy placed a substantial burden upon the religious beliefs of closely held corporations. This was so even though the employers did not themselves perform abortions or directly provide the abortifacients. It was enough that the government action required them to be complicit. *Id*. at 691 ("If the owners comply with the HHS mandate, they believe they will be facilitating abortions."). As this Court later confirmed, *Hobby Lobby* held that "the [contraceptive] mandate, standing alone, violated RFRA as applied to religious entities with *complicity-based* objections." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2377 (2020) (emphasis added)*; see Cedar Park Assembly of God of Kirkland v. Kreidler,* 860 Fed. Appx. 542, 543 (9th Cir. 2021) (plaintiffs established injury in fact when, due to the enactment of a state law, its health insurer stopped offering a plan with abortion coverage restrictions and the church could not procure comparable replacement coverage); *Religious Sisters of Mercy v. Azar,* 513 F. Supp 3d 1113, 1134 (D. N.D. 2021) (plaintiffs had standing when a Health and Human Services interpretation of the Affordable Care Act forced them to choose between providing insurance coverage for gender transitions or

risk loss of federal funding and other penalties; *see also Thomas v. Review Bd. of Ind. Emp't Sec. Div.*, 450 U.S. 707, 713-18 (1981) (denial of unemployment benefits to a worker who quit his job making weapons violated his First Amendment right to free exercise; "[w]hile the compulsion may be *indirect*, the infringement upon free exercise is nonetheless substantial") (emphasis added); *Fulton v. City of Phila.,* 141 S. Ct. 1868 (2021) (holding that Catholic Social Services had the right under the Free Exercise Clause to decline to certify same-sex couples as foster parents under the City of Philadelphia's foster care program).

Petitioners' nit-picking of what they perceive as deficiencies in the Respondents' injury claims (BFP at 20-25; BD at 27-29) cannot undermine those claims. This Court has stated "Courts should not undertake to dissect religious beliefs because . . . [a party's] beliefs are not articulated with the clarity and precision that a more sophisticated person might employ." *Thomas*, 450 U.S. at 716. Doctors are medical professionals, not lawyers or clergy. It is of no importance whatsoever that *Petitioners* do not believe completing an abortion procedure could or should be as morally troubling to the doctors as prescribing the abortifacient pills themselves would be—the fact remains that the doctors have asserted that it is morally objectionable *to them*. And that is enough.

The Petitioners themselves refer in their briefs to the very federal statutes that articulate and vindicate the Respondents' broad conscience claim. BFP at 22-23, BD at 28. The 1973 Church Amendments forbid requiring any recipient of Health and Human Services Grants to perform *or assist* in sterilization procedures or abortions, to make its facilities available for such procedures, or to provide

personnel for the performance *or assistance* in such procedures if that individual or entity is opposed to the procedures for religious or moral reasons. 42 U.S.C. § 300a-7. The 1996 Coates-Snowe Amendment to the Public Health Service Act prohibits any federal, state or local government which receives federal financial assistance from discriminating against any health care entity, including individuals, if, among other things, those individuals refuse to *perform, provide referrals for, or arrange for* abortions. 42 U.S.C. § 238n. These conscience protections therefore extend beyond the actual prescribing of abortion drugs or performance of abortion on a living child.

The federal government has also prohibited any federal agency or program, or state or local government which receives money from the Departments of Labor, Health and Human Services, and Education from discriminating against any individual or institutional health care entity for the refusal, not merely to perform but to *provide for, pay for, provide coverage of, or refer* for abortions.[4]

B. Federal Conscience Protections Are Inadequate to Protect the Consciences of Doctors in the Emergency Context.

While these federal protections against complicity in abortion exist on paper, the Fifth Circuit rightfully questions their true availability in light of the government's contrary position in another case.[5]

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[4] Weldon Amendment to the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 507(d)(1), 136 Stat. 4459, 4908.

[5] The FDA claims that doctors can refuse to provide abortion care while ignoring the fact that hospitals are bound by the *(continues)*

Additionally, regardless of whether doctors can in fact *legally* refuse to provide abortion-related care, there are *practical realities* of the emergency room, where prompt decisions must be made and staffing can be limited. Therefore, these federal protections are inadequate to protect respondents from the moral quandary that repeatedly ensues from the FDA's removal of safeguards.

If a woman with a life-threatening condition or serious health complication presents herself to the emergency room, a doctor can in theory conscientiously refuse to assist her and instead provide a referral. This option creates two problems. First, providing a referral is still participating in the government's elective abortion regime, to which they have stated their objection. JA at 87 ¶ 296; 42 U.S.C. § 238n. Second, and more relevant in the emergency room context, there is a risk that the woman's condition will worsen, perhaps irreversibly so, while awaiting a referral. JA at 87 ¶ 296; 173-74 ¶¶ 23-25; 198 ¶ 17. It obviously would violate the conscience of a pro-life doctor to fail to take action to save the life of his patient or to cause the patient's health to decline because of the delay caused by the referral. The only other option available to the doctor is to treat the patient, thereby participating in the elective abortion regimen. Even if the procedure were necessary at that point to save the woman's life, the necessity did not arise *as a result of the pregnancy*, which is the only reason many pro-life doctors would perform, or facilitate, a procedure which may, as an unwanted

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Emergency Medical Treatment and Active Labor Act (EMTALA). BFP at 23, fn. 3. As the Fifth Circuit noted, the government in other litigation has taken an inconsistent position on the rights of doctors to refuse participation. Pet. App. at 32a-34a

side effect, cause the untimely death of an unborn baby. Rather, the emergency at hand resulted from the woman taking the prescribed drugs without appropriate safeguards. Thus, both options available to a doctor when a woman experiences an emergency after ingesting these medications force the doctor to be complicit with elective abortion—a position which they find to be morally reprehensible.

The only scenario for which providing care would not violate these pro-life doctors' consciences is one in which the woman's life could be saved, and the baby was still alive. One doctor has averred that she provided care in just such a situation and saved the lives of both baby and mother. JA at 173-74 ¶¶ 24-25.

As a result of the FDA's removal of proper safeguards for the administering of the abortion drugs in question, all the options (except the unusual scenario directly above) presented to the doctors in the emergency room require them to violate their consciences. Therefore, the FDA's actions have placed a "substantial burden" on the Respondent doctors and organizations.

In *Hobby Lobby*, the only alternatives available to the corporations besides paying for insurance coverage that would cover abortifacients was to incur large penalties for not providing the coverage or forego providing insurance to their employees at all. This latter option would cause them to incur other penalties and also would violate their religious beliefs. This Court held that both options still represented a substantial burden on the corporations. *Hobby Lobby*, 573 U.S. at at 720-23.

Like the plaintiffs in *Hobby Lobby*, the Respondent doctors have been cornered by the FDA's actions. In all but the rarest situations, every available option presents them with a moral dilemma

requiring them to compromise their consciences. The FDA's actions therefore have already caused actual, concrete and particularized injury to the Respondents' consciences. This satisfies the first prong of the standing requirements. *Lujan*, 504 U.S. 560 ("'injury in fact' . . . which is (a) concrete and particularized. . . and (b) 'actual or imminent, not conjectural or hypothetical'").

C. The Ongoing Adverse Effect of the FDA's Decision to Remove Safeguards Means the Harm to Respondents is Not Speculative.

The circumstances that gave rise to the injury—the FDA's current reckless chemical abortion policy and its stated reliance on emergency rooms to make up for the lack of required follow-up care and in person pre-screening[6]—constitute "continuing, present adverse effects" that establish a present case or controversy. *O'Shea v. Littleton*, 414 U.S. 488, 495-96 (1974) (denying standing where "past exposure" to constitutional violations was "unaccompanied by any continuing, present adverse effects" and future injury would rest on likelihood that respondents would again be arrested). In *City of Los Angeles v. Lyons*, 461 U.S. 95 (1983), the petitioner claimed to have been subjected to a choke hold by police officers although he had offered no resistance. He was seeking injunctive relief barring the use of choke holds except

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[6] *See* Brief for the Respondents (BFR) at 8-9, 24-26, 40; JA at 384; Respondent's Brief in Opposition (RBO) at 25. There is a "Black Box" warning on the packaging to "[e]nsure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable." Pet. App. at 219a.

in situations where the proposed victim reasonably appeared to be threatening the immediate use of deadly force. This Court held that there was no case or controversy because "[i]t was to be assumed that '[plaintiffs] will conduct their activities within the law and so avoid prosecution and conviction as well as exposure to the challenged course of conduct.'" *Id*. at 103 (quoting *O'Shea*, 414 U.S. 488*)*. Here, the assumptions implicit in the evidence run counter to the Petitioners' position that the claim of future harm is speculative and counterintuitive.

Petitioners argue six separate, attenuated steps must happen before Respondents will be harmed.[7] But their steps do not properly represent the situations.

First, contrary to Federal Petitioner's claim, it is not "speculative" that "(i) a woman [will] choose[] to take mifepristone after consultation with another provider." (BFP at 21) Rather, it is virtually certain that this will occur to women all over the United States—because abortion providers are prescribing these medicines daily nationwide. There is no reason to believe the use of chemical abortion drugs by women seeking to destroy their unborn children will stop; rather it will likely increase, as it has every year

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[7] "(i) a woman chooses to take mifepristone after consultation with another provider; (ii) the woman suffers an exceedingly rare serious adverse event requiring emergency care; (iii) rather than returning to the prescribing provider, the woman seeks care from one of respondents' members or presents in an emergency room where a member is working; (iv) when the woman does so, her pregnancy is still ongoing; (v) it would violate the member's conscience to complete an abortion in such urgent circumstances; and (vi) the member is unable to seek assistance from another doctor or invoke federal conscience protections and is instead forced to complete an abortion." BFP at 21; *see* BD at 25-26.

since 2000.[8] The Guttmacher Institute estimates that, in 2020, over 492,200 pregnancies were ended via chemical abortion.[9] Petitioner Danco asserts that the only group of women who are relevant to the question of whether any doctor faces injury are the ones who were prescribed the abortion drugs after 2016 or 2021 *and* who would not have otherwise been prescribed the drug, noting that that this number is not in the record. BD at 24-25. This assertion is not true. All women who were prescribed the drugs after 2016 and 2021 did so under the FDA's riskier protocols, so that entire group of women is relevant to the question of injury since all of them would be endangered by the lack of proper safeguards.

Next, contrary to Petitioners' claims, it is not "speculative" that "(ii) the woman suffers an exceedingly rare serious adverse event requiring emergency care" or that "(iii) rather than returning to the prescribing provider, the woman seeks care from one of respondents' members or presents in an emergency room where a member is working." (BFP at 21). To the contrary, Danco itself admits—and the FDA has acknowledged—that 2.9 to 4.6% of women

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[8] Medication abortions have continued to increase as a percentage of all abortions since first approved for use in 2000. They accounted for 53% of abortions in 2020, up from 39% of abortions in 2017 and 6% of abortions in 2001. Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin, Marielle Kirstein, *Medication Abortion Now Accounts for More than Half of All US Abortion,* Guttmacher Institute (February 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[9] Rachel K. Jones, Marielle Kirstein, Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, Guttmacher Institute (November 2022), https://www.guttmacher.org/article/2022/11/abortion-incidence-and-service-availability-united-states-2020.

will require a visit to the emergency room after ingesting mifepristone (Pet. App. at 18a). That is over 14,000 women per year in the emergency room due solely to this drug.

These are not "unsupportable" assumptions as Petitioner Danco claims (BD at 24) but are easily verified facts, admitted by Petitioners. (Pet. App. at 18a).

It is highly likely that some of these thousands of women will continue to encounter one of the Respondent doctors—or one of the doctors in the Alliance for Hippocratic Medicine. There is no reason to believe these doctors will cease to be confronted with women seeking emergency care from taking the abortion drugs who have retained pregnancy tissue. The doctors have, in fact, stated that they expect to or already are experiencing an increasing number of women who need emergency care since the FDA removed the safeguards to the dispensing of these abortion drugs. JA at 120 ¶¶ 11-12; 131-32 ¶¶ 26-31; 148 ¶ 16; 153-55 ¶¶ 10-14; 163 ¶¶ 20-22; 164-65 ¶¶ 25-28; 166-67 ¶ 32; 171-72 ¶¶ 14-18; 175 ¶ 29; 181 ¶ 18; 185 ¶ 12; 186 ¶ 18; 192 -93 ¶ 18; 197 ¶12; 198-99 ¶ 20.

Federal Petitioners' fourth assertion is that it is speculative that a woman will present to the emergency room with an "ongoing pregnancy." (BFP at 21). The Respondents' conscience concerns are not limited to the situation where the abortion drugs failed to end to the life of the child. *See* Sec. I.A, *supra*. Nevertheless, this contingency is not speculative because it has already occurred to one Respondent. Though her partner was the one who ultimately completed the abortion on the live child, the patient was hers also. JA at 154 ¶ 13.

The FDA's final two "speculative" contingencies (i.e., "(v) it would violate the member's conscience to complete an abortion in such urgent circumstances; and (vi) the member is unable to seek assistance from another doctor or invoke federal conscience protections and is instead forced to complete an abortion") were addressed in Sections I.A and I.B, *supra*. Given the urgency of patients receiving timely medical care in the emergency context, the doctors are forced into being complicit in the FDA's abortion regimen and exercising their federal conscience rights could place their patients' lives or health in jeopardy.

Unless the Petitioners can show an intervening cause that would significantly decrease the current numbers of chemical abortions, there is no reason to believe that the threat to Respondents posed by the FDA's actions will not continue. Petitioner Danco's claim that state laws banning abortion or regulating medication abortions will "shrink the already tiny fraction" of women who will seek emergency room treatment (BD at 23) fails to take into account the availability of the telehealth and remote access options specifically created by the FDA. Women can also travel out of state to obtain their prescriptions. As one article noted: "It's likely that many women will be able to continue to access medication abortion in states with abortion bans, although they may face risks, experts say."[10] Danco's argument also ignores that there are two ongoing court cases filed by pro-abortion advocates for the sole purpose of overriding state laws regulating and restricting the use of

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[10] Aimee Picchi, *Abortion Pill: Will Women in States with Abortion Bans Still Have Access?*, CBS News (June 29, 2022, 6:21 PM), https://www.cbsnews.com/news/abortion-pill-mifepristone-access-in-states-with-abortion-bans/.

mifepristone[11] as well as the fact that President Biden issued a Presidential Memorandum that directs the Secretary of the Department of Health and Human Services to consider new guidance to support patients, providers, and pharmacies who wish to legally access, prescribe, or provide mifepristone—"*no matter where they live*."[12] Given these ongoing battles, there is no reason to assume that the numbers of women seeking medication abortion and who will need care in the emergency room will decrease.

Predicting the continuation of the current trend does not "require guesswork as to how independent decisionmakers will exercise their judgment." *Clapper,* 568 U.S. at 413 (denying standing to attorneys and human rights organizations who had no *actual knowledge* of the Government's surveillance targeting practices and could not possibly know if the Foreign Intelligence Surveillance Court would grant authorization to surveil their foreign contacts). This is because, as previously stated, Petitioners have made clear that a percentage of women will of necessity seek out emergency care after taking Mifeprex, and we know with reasonable certainty how many women have and will continue to seek out medical abortions. *See* fns. 8-9, *supra*. Therefore, the prospect of

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[11] *GenBioPro, Inc. v. Raynes, et al.,* No. 3:23-cv-0058, 2023 U.S. Dist. LEXIS 149195 (S.D. W. Va. Aug. 24, 2023) (appeal pending); *Bryant v. Stein*, No. 1:23-cv-00077 (M.D. N.C. filed Jan. 25, 2023).

[12] *FACT SHEET: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion*, The White House (January 22, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/01/22/fact-sheet-president-biden-to-sign-presidential-memorandum-on-ensuring-safe-access-to-medication-abortion/ (emphasis added).

Respondents suffering future injury is not speculative at all.

Petitioner's long list of statistical facts that they claim Respondents need to show in order to establish standing (BD at 24-27) contradicts the holding of *Clapper*, which clearly stated "Our cases do not uniformly require plaintiffs to demonstrate that it is *literally certain* that the harms they identify will come about. In some instances, we have found standing based on a *'substantial risk'* that the harm will occur." *Id.* at 414, fn. 5 (emphasis added) (citations omitted). Therefore, Respondents have established injury in fact because the FDA's actions pose a "substantial risk" of future harm, injuries have clearly already occurred, and future injury is not based on a chain of speculative contingencies as Petitioners claim.

II. Granting Standing to Respondents Will Not Result in an "Endless Parade of Suits".

The FDA argues that Respondents have put forth a "novel theory" of injury based on "stress and pressure" that would invite a "parade of suits" based on presumptively spurious claims, at least in the mind of the FDA. BFP at 26-27. However, as the Fifth Circuit noted, the stress and pressure are "best understood as additional to the Doctors' conscience injuries, not independent from them." Pet. App. at 34a-35a. The FDA's straw man argument depends on ignoring the parts of the Respondents' conscience claim they disagree with. *See* Sec. I, *supra*. None of the FDA's hypotheticals featuring plaintiffs (i.e. doctors, lawyers and other professionals) who supposedly would be unleashed to challenge policies

for no reason other than that those policies cause them stress includes sufficient details upon which to determine standing. In particular, the examples do not indicate that the offensive policy might have been adopted illegitimately, as Respondents in this case are alleging. JA at 4-8. Nor do the "parade" examples indicate that the policymaker has specifically provided that the victims of its bad decision can go to any of the hypothetical plaintiffs to redress the effects of the challenged policy, as is the case in this lawsuit. *See* BFR at 8-9, 24-26, 40; JA at 384. And the FDA also fails to address that some circuits have acknowledged standing based on "emotional or psychological harm." Pet. App. at 34a-35a.[13]

Similarly, Danco argues that granting Respondents standing would "bless any suit by an association of healthcare providers challenging any agency decision that might affect a potential patient." BD at 34. Danco argues that Respondents are merely challenging the FDA because they "dislike" the drugs which have side effects that require treatment, just like any other drug. *Id*. But Respondents have not alleged that they merely "dislike" chemical abortion drugs or abortion. And they are not challenging the

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[13] *Maddox v. Bank of N.Y. Mellon Tr. Co.*, 19 F.4th 58, 65 (2d Cir. 2021) (quoting *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2211 n.7 (2021)) ("great stress, mental anguish, anxiety, and distress . . . . are of the sort that *TransUnion* contemplated might form the basis for Article III standing"); *Clemens v. ExecuPharm Inc.,* 48 F.4th 146, 156 (3d Cir. 2022) (present experience of "emotional distress" sufficient to allege a concrete injury in identity theft case); *see also Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006) ("An injury-in-fact may simply be the fear or anxiety of future harm" in a case involving improper and fraudulent tax counseling); *Hedges v. Obama*, 724 F.3d 170, 195 (2d Cir. 2013) (fear of future harm that is imminent may support standing).

removal of safeguards because of the dangers side effects pose *to the patients who take them* but rather because of the fact that they will be forced to provide morally objectionable treatment due to the side effects of the drugs. In other words, Danco ignores the legally cognizable *conscience* claim that Respondents assert regarding these drugs and elective abortion. And while it is true that any drug has side effects, Respondents are alleging that the FDA's actions in removing safeguards have *increased the incidence* of women experiencing complications who then show up in the emergency room rather than being treated by the doctor's office that initially prescribed the mediation. Pet. App. at 10A. Like the FDA's parade list, Danco's hypotheticals prove nothing because they lack factual context, let alone any facts that are analogous to Respondents' allegations.

III. Aesthetic Harm Is an Additional Basis for Granting Standing to Respondents.

There are numerous cases in which associational standing has been granted to organizations whose members have experienced aesthetic harm due to governmental or private action affecting the environment or animals. Moreover, several of these courts have recognized emotional harm as indicative of aesthetic injury. *Animal Legal Def. Fund v. Glickman,* 154 F.3d 426, 430 (D.C. Cir. 1998) (granting standing on the basis of aesthetic injury when plaintiff experienced "extreme aesthetic harm and emotional and physical distress" when viewing primates subjected to inhumane treatment); *A.S.P.C.A. v. Ringling Bros. & Barnum & Bailey Circus*, 317 F.3d 334 (D.C. Cir. 2003) (plaintiff had standing based on "aesthetic and emotional injury"

from viewing elephants who had suffered mistreatment); *Ohio Valley Env't. Coal., Inc. v. Hobet Mining, LLC,* 702 F. Supp. 2d 644, 648 (S.D. W. Va. 2010) (standing granted on basis of aesthetic injury when stream pollution deprived plaintiff of "emotional and spiritual well-being" and "joy" from her outdoor activities).

Aesthetic injury has been found to exist when plaintiffs were forced to view dead animals; were deprived of viewing animal, insect or plant species in which they had an interest; or experienced reduced enjoyment of the environment due to governmental action. *Humane Soc'y. of U.S. v. Hodel,* 840 F.2d 45, 52 (D.C. Cir. 1988) (granting standing for aesthetic injuries to organization because "the existence of hunting on wildlife refuges forces Society members to witness *animal corpses* and environmental degradation, in addition to depleting the supply of animals and birds that refuge visitors seek to view.") (emphasis added); *Am. Bottom Conservancy v. U.S. Army Corps of Eng'rs*, 650 F.3d 652, 657-58 (7th Cir. 2011) (standing granted to birdwatchers to challenge agency permit that would allow development and thus "diminish the wildlife population visible to them" and therefore reduce their pleasure); *Ctr. for Biological Diversity v. Env't. Prot. Agency*, 861 F.3d 174, 183 (D.C. Cir. 2017) (standing where agency authorization to use pesticide created "demonstrable risk" to beetles and butterflies that plaintiffs intended to view); *Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc,* 528 U.S. 167, 182-83 (2000), *remanded to* 2000 U.S. App. LEXIS 3705 (environmental groups had standing because emissions from a wastewater treatment plant prevented them from fishing, camping, swimming, canoeing, birdwatching, and picnicking in affected areas); *Sierra Club v. U.S.*

Env't. Prot. Agency, 964 F.3d 882, 888 (10th Cir. 2020) (the Sierra Club had standing partly because its members experienced diminished visibility of nearby national parks and wilderness areas because of the operations of a nearby industrial plant); *Clean Wis. v. Env't. Prot. Agency,* 964 F.3d 1145 (D.C. Cir. 2020) (environmental group had standing because the EPA's challenged rule resulted in an increase in ozone levels, thereby affecting their ability to engage in healthy outdoor recreational activities); *Port Arthur Cmty. Action Network v. Tex. Comm'n. On Env't. Quality*, 86 F.4th 653, 659 (5th Cir. 2023) (environmental group had standing because of the negative effect of air pollution on recreational activities).

If a party's desire to enjoy nature and to avoid merely *viewing* dead or mistreated animals are cognizable aesthetic interests for environmentalists, how much more so is the pro-life Respondents' desire to avoid complicity in killing preborn children a cognizable injury, especially if that involves directly *participating in* the destruction of unborn life? JA at 154 ¶ 13. Respondent doctors believe in defending "the sacredness and dignity of human life at all stages." JA at 119 ¶ 6; *see id.* at 134 ¶ 40. Consistent with "sacred scripture," they affirm "respect for the sanctity of human life." *Id.* at139 ¶ 6; *see id.* at 157 ¶ 21. They are "committed to the care and well-being of their patients including both pregnant women and their unborn children . . . [and] are concerned about the adverse impacts of chemical abortion on their practice of medicine." *Id.* at 126 ¶ 8; 127 ¶ 13. Their deep spiritual and emotional regard for human life as inherently valuable is no less important to them and their medical practices than the environmentalist's love of nature. They experience deep spiritual and

emotional anguish when they are confronted with women harmed by chemical abortion and subsequently have to participate in completing those abortions: "This causes CMA's member physicians much stress and grief, while impeding their ability to perform their practice of medicine in the manner that they desire." *Id.* at 120-21 ¶ 14; 87 ¶ 296; 142-43 ¶¶ 26-27; 167 ¶ 33 ("Unsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care."); *id.* at 191 ¶ 14 ("They are distressed, sad, and feel terrible about what they have done. While it is rewarding to offer these women a chance at reversing chemical abortion, this is some of the most emotionally taxing work I have done in my career."); *id.* at 198 ¶ 19 ("When my patients have chemical abortions, I lose the opportunity to provide these obstetrical and medical services to care for the woman and child through pregnancy and bring about a successful delivery of a new life."); *id.* at 200 ¶ 27 ("[I]t disturbed me that [my patient] was not informed that it was not normal to bleed for multiple weeks and that if she had a routine follow-up visit, as required by past REMS, this situation could have been avoided before requiring overnight hospitalization.").

The loss of aesthetic enjoyment and diminishment of pleasure in the environment due to having to view dead or mistreated animals, being unable to view birds and insects, or having to reduce or eliminate recreational activities cannot be more constitutionally significant than the emotional distress and "heartbreak" experienced by Respondents, who have had to view similar harms to *human women and babies* and who do not wish to be complicit in those harms any more.

IV. Respondents Have Established Associational Standing.

This Court has held that an association may sue on behalf of its members when "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks 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." *Hunt,* 432 U.S. at 343. This Court has also held that the third prong is more a matter of "administrative convenience and efficiency" rather than a necessary element of "case or controversy within the meaning of the Constitution." *United Food,* 517 U.S. at 556. It would not be required when, as in the present case, an association seeks only prospective or injunctive relief. *Id*. at 545.

Respondents have satisfied the first prong, based on their conscience injury (Section I, *supra)* and aesthetic injury (Section III, *supra*). Since, as Petitioners note, Respondent pro-life organizations oppose elective surgical or chemical abortion (JA at 9-12; BFP at 2; BD at 1), the second prong of associational standing is satisfied as well. Therefore, Respondent organizations have established that they have standing to pursue their suit against the FDA.

CONCLUSION

Respondent doctors have established injury in fact because they have been forced to be complicit in the FDA's regimen of elective abortion as a result of the latter's relaxation of safeguards in the administering of the dangerous drugs mifepristone and misoprostol. The pro-life organizations to which they belong, and

which share the doctors' conscience concerns, therefore also have standing. Additionally, the doctors have sustained aesthetic injuries by having to participate in the taking of human life, which is of much greater weight than the aesthetic injuries asserted by environmentalist groups, and on the basis of which standing is routinely granted to those groups. There is a substantial risk that these injuries will recur because the under-regulated use of these drugs to end human lives creates a continuous and present threat that women will continue to arrive at emergency rooms seeking assistance from pro-life doctors in finishing the job. Federal conscience protections are inadequate to address the moral dilemma faced by emergency room doctors in time-sensitive emergency situations. Therefore, this Court should grant standing to the Respondents, and affirm the Fifth Circuit opinion.

Respectfully Submitted,

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