NO. 23-235, 23-236

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

On Writs to the United States Court of Appeals for the Fifth Circuit

BRIEF OF UNITED STATES MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

NATHAN W. KELLUM
Counsel of Record
CENTER FOR
RELIGIOUS EXPRESSION
699 Oakleaf Office Lane,
Suite107
Memphis, TN 38117
(901) 684-5485
nkellum@crelaw.org
Counsel for Amicus Curiae

Julio Gonzalez, M.D.
241 Nokomis Ave. S.
Venice, FL 34285
(941) 441-0310
usemdicalassn@gmail.com

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INTEREST OF AMICUS CURIAE

The United States Medical Association ("USMA" or "*amicus curiae*") is a medical society representing physicians in the United States of America, giving them a voice and to their concerns.[1] The *amicus curiae* extolls the values of compassion, self-sacrifice, dedication, and excellence in the practice of medicine ingrained in America's doctors throughout their training, and throughout the long illustrious history of this noble profession. Its core principles are:

- To strive for the continuous delivery of the most compassionate and advanced care for Americans.
- Support the equal standing of all members of society before the law without favor to any particular group, whether those individuals engage our industry as deliverers of care, or its recipients.
- Work to create a legal and administrative environment that supports America's practices and enables physicians to craft the best possible care for their patients independent of external influences.
- To ensure that, above all, the doctor-patient relationship reigns supreme, and that no policy

[1] In compliance with Supreme Court Rule 37.6, *amicus curiae* counsel represents they authored this brief in its entirety and neither the parties, nor their counsel, nor anyone other than the *amicus* and *amicus* counsel, made a monetary contribution to fund the preparation or submission of this brief.

> or rule, or law acts to interfere with the sanctity of that relationship.

USMA believes the art and science of medicine perform best when physicians are free to oversee their own practices and patients are able to independently design their care with their doctors. The *amicus curiae* strives to minimize external influences imposed on the practice of medicine and the doctor-patient relationship. Above all, USMA serves as fiduciary to the House of Medicine.

For these reasons the *amicus curiae* is keenly interested in this matter before the Court. Of particular interest to the *amicus curiae* is the question of whether Respondents, a group of medical associations and doctors, have Article III standing to challenge the wrongful actions of the Federal Drug Administration (FDA) in removing safeguards on the use of mifepristone. Some of USMA's members are obstetricians and gynecologists, others are emergency room physicians. All have apprehensions about the FDA unnecessarily and unduly interfering with patient care. The *amicus curiae* contends the FDA caused Respondents to suffer harm that can be redressed through legal remedy. USMA has encountered like harm from the FDA's actions.

INTRODUCTION AND SUMMARY OF ARGUMENT

Mifepristone is a synthetic steroid designed to induce the abortion of an unborn human when used in conjunction with misoprostol, a prostaglandin

medication that causes uterine contractions.[2] The drug's potential for harm would seemingly contemplate caution and restraint on its use. Yet, in characterizing a pregnancy as a "life threatening illness," the FDA fast tracked approval of mifepristone for new drug authorization ("NDA"). *Alliance for Hippocratic Medicine*, at 2-3.[3]

At the very least, FDA approval of mifepristone came with some common-sense safety standards ensuring medical oversight. But alas, this sense was fleeting. Over the course of just a few years, the FDA diminished the role of physicians, eventually eliminating them from the process altogether, as though medically trained physicians have nothing to offer in the administration of this patently dangerous drug. The FDA only wants physicians to stand by and ready to clean up the mess created by their exclusion.

On March 29, 2016, the FDA expanded the approval for mifepristone use by 1) increasing the maximum estimated gestational age by which mifepristone could be administered in inducing an

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[2] The term "unborn human" describes a developing human who has not yet exited the mother's womb, a term employed in deference to the district court's depiction in this case. *See Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*, 2:22-CV-223-Z, 2. n. 1 (N.D. Tex., Apr. 7, 2023).

[3] The FDA accomplished this feat under subpart H. a provision in federal law that allows for accelerated approval of a medication designed for the treatment of a "life threatening illness." 21 C.F.R. § 314.500. Subpart H was subsequently codified as Risk Evaluation and Mitigation Strategy ("REMS"). 21 U.S.C. § 355-1(a)(1)– (2).

abortion from seven weeks to ten weeks gestational age; 2) reducing the number of required in-person office visits from three to one; 3) allowing non-physicians to prescribe and administer the medication; and 4) eliminating the reporting requirements for non-fatal adverse events. *Id.* at 4. On April 12, 2021, the FDA paved the way for mail order dispensation of mifepristone during the COVID pandemic. *Id.* at 3. Then, later that year, on December 16, 2021, the FDA declared that it would permanently allow for mail dispensing of the drug. *Id.*

Following the FDA machinations, mifepristone is now a widely accessible drug with no meaningful oversight. No one needs an appointment with a doctor to obtain mifepristone. No one needs to bother with an ultrasound to order it. Consequently, recipients of mifepristone are often kept in the dark about the harms the drug may pose for them, maintaining an ignorance that could lead to various, avoidable medical complications that are urgent in nature, implicating emergency room visits with physicians who may not have the capacity or the expertise to properly handle the medical emergency, putting the physician as well as the patient in great peril.

FDA's politically driven and arbitrary actions cannot stand. The measures are injurious and challengeable, placing unlawful obstacles on physicians who earnestly wish to care for their patients.

ARGUMENT

The FDA excludes physicians from the mifepristone process when they should be involved and constrains them to participate when physicians would rather not be involved, causing substantial harm in both respects.

I. Excludes Physicians from the Process of Administering Mifepristone When They Should be Involved

A. Mifepristone use poses serious health risks

As known from the outset of FDA approval of the medicine, the use of mifepristone, either alone or coupled with other medications, is rife with physical risks and potential complications. It is common for women to experience significant hemorrhaging when taking mifepristone. *"We Celebrate Each of These Children"—APRN Marks 5K Lives Saved*, PREGNANCY HELP NEWS, (accessed Feb 18, 2024) https://pregnancyhelpnews.com/we-celebrate-each-of-these-children-aprn-marks-5k-lives-saved. Those using the drug can also present with incomplete abortions and uterine ruptures. *Id.* What's more, without medical supervision, ectopic pregnancies can be confused with intrauterine ones and induced for abortion with the medicine, which can threaten life

and necessitate timely intervention of a physician. *Id.*[4]

While the FDA claims complications with mifepristone are "rare," *U.S. Food and Drug Administration, et al. v. Alliance for Hippocratic Medicine*, et al., No. 23-235, pp. 18 & 24 (SCOTUS Petition, Sep. 8, 2023 [Petition]), even "exceedingly rare;" *id.* at 2, 5, & 12, and "extremely rare," *id.* at 14 & 24, these events are not unusual. Indeed, a Medical Officer's Review Report produced by the FDA found chemical terminations of pregnancies "had more adverse events, particularly bleeding, than did surgical abortion." FDA Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, 8 (Nov. 22, 1999) (accessed May 5, 2023), at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf.

This report is consistent with other findings on the topic. A U.S. Congressional hearing on mifepristone revealed the prevalence of health complications, noting "the deaths of six women, associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 case infections. . . added up to a

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[4] Another increasingly common complication occurs when the mother changes her mind and does not wish to proceed with the termination after taking mifepristone, generating the need to urgently reverse the effects of the medication. *Id.* The Abortion Pill Reversal Network ("APRN") reports having received over 8,300 requests of this nature. *Id.*

total of 1070 adverse reports (AERs) as of April 2006." H.R. Subcom. Crim. J., Drug. Pol., and Hum. Resources Rpt., *The FDA and RU-486: Lowering the Standard for Women's Health; Prepared for the Hon. Mark Souder Chairman, Subcommittee on Criminal Justice, Drug Policy and Human Resources*, 25 (Oct. 2006). A 2009 study out of Finland calculated the incidence of adverse events as "fourfold higher" amongst medical abortions (22,385 or 20% including 4 deaths) relative to surgical abortions (20,251 or 5.6% including 2 deaths). Maarit Niinimaki, *et al.*, *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 OBST & GYNEC, 795, Table 2 (2009).[5] Even a study by Planned Parenthood of Los Angeles drew a similar deduction, upon evaluating the experience of 30,146 women seeking terminations with estimated gestational ages of 9 weeks or less. Luu Doan Ireland, Mary Gatter, & Angela Y. Chen, *Medical Compare with Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 OBSTET & GYNECOL. 22, 22 (2015). Though 15.9% of the women receiving a medical abortion were lost to follow up, with researchers dubiously determining that all women had uncomplicated and complete abortions, *id.* at 24, the study still estimated a 0.7% serious complication rate amongst medical abortions and an overall complication rate of 21.6%, the latter being three

[5] The authors of the study dismiss the deaths, two of which were attributed to a subarachnoid hemorrhage and a traffic accident as not being related to pregnancy, but four others-three suicides and one homicide-suggest mental health issues that may have been related to the abortion. *Id.* at 796.

times higher than the overall surgical complications rate. *Id.*, Table 3.

B. Discounting doctor care causes harm

In the face of all the obvious health risks surrounding mifepristone usage, the FDA did not see fit to pursue more extensive regulations or physician guidance. Rather, to allow for greater, easier access to the drug, the FDA purged physicians from the process altogether. But while the FDA achieved its goal – removing the barrier to mifepristone access it perceives physicians to be – the agency sacrificed much, namely, the health and welfare of women taking the drug.

The FDA's elimination of physician participation in mifepristone usage was systematic and relatively swift work. In 2016, the FDA authorized non-physicians to prescribe the medicine. It also reduced the number of requisite in-person visits. Then, in 2021, the FDA executed a *coup de grâce* on physician care, permitting mail order of mifepristone, initially, on a temporary basis, and later making the change permanent, to keep physicians out of the loop.

These changes were (unsurprisingly) impactful. By 2020, medicine induced abortion became the most common form of aborting an unborn human. *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INSTITUTE, (accessed Feb 17, 2024) https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

According to the Center for Disease Control and Prevention ("CDC"), "early medication abortion[s]" accounted for 53% of those reported abortions in 2021, representing an increase of 137% since 2012. *CDCs Abortion Surveillance System FAQs*, CDC, (accessed Feb 17, 2024) https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm. And the increased usage of mifepristone correspondingly increased the associated health risks. Compounding the risks even more, the FDA allows women to obtain the medicine without an in-person doctor office visit or a screening—or staging—pre-use ultrasound. *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG,* FOOD AND DRUG ADMINISTRATION (Most Recent Modification May 2021) (accessed Feb 18, 2024) https://www.fda.gov/media/164651/download?attachment.

Without physician consult or ultrasound, women lack adequate information about mifepristone, unaware of latent dangers with the ingestion. Moreover, the dropping of physician safeguards works to extend the gestational age of pregnancies in women taking the drug, to their detriment. The indication for a mail order is a desire to undergo a medical termination of an intrauterine pregnancy through ten weeks (70 days) gestational age as measured from the first day of the patient's last menstrual period. *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FOOD AND DRUG ADMINISTRATION, (accessed Feb 17, 2024)

https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation. While an ultrasound is now deemed superfluous and no longer required for this assessment, *id.,* studies on safe mifepristone use anticipate ultrasound staging of the patient's pregnancy to ensure proper gestational age. Isabelle Carlsson, Karin Breding, and P.G. Larson, *Complications Related to Induced Abortion: A Combined Retrospective and Longitudinal Follow-Up Sturdy,* 18 BMC WOMEN'S HEALTH (2018), at 3; Elizabeth G. Raymond, *et. al.*, *TelAbortion*; *Evaluation of Direct to Patient Telemedicine Abortion Service in the United States*, 100 CONTRACEPTION (May 24, 2009), at 174*:* According to a white paper by the APRN, the percentage of women seeking their services who reported having an ultrasound prior to taking the abortifacient has steadily diminished from 100% in 2017 to 62% in 2023. *The Changing Face of Abortion Today; Abortion Trends Following the Overturn of Roe*, HEARTBEAT INTERNATIONAL, Figure at 11 (accessed Feb 17, 2024) https://www.heartbeatinternational.org/images/HeartbeatServices/WhitePapers/WhitePaperTheChangingFaceofAbortionToday.pdf. As a consequence, between 2019 and 2023, the APRN noted a 35% increase in clients who were beyond ten weeks of gestation when taking mifepristone. *Id.,* Figure at 7.[6] And as a recent study out of England confirms, there is a direct

[6] APRN routinely deals with patients who present requests for reversal of their chemical abortion with gestational ages far beyond those recommended by the FDA at the time they given mifepristone.

correlation between increasing gestational age and complication rates (~1 per thousand for those under 9 weeks estimated gestational age and ~48 per thousand in those with estimated gestational ages of twenty weeks or greater). *Complications from Abortions in England: Comparison of Abortion Notification System Data and Hospital Episode Statistics 2017 to 2021*, OFFICE OF HEALTH IMPROVEMENT AND DISPARITIES, Fig. 3 (Nov. 23, 2023) (accessed Feb 17, 2024) https://www.gov.uk/government/statistics/complications-from-abortions-in-england-2017-to-2021/complications-from-abortions-in-england-comparison-of-abortion-notification-system-data-and-hospital-episode-statistics-2017-to-2021#:~:text=Table%201%3A%20complication%20type%20using%20the%20ANS%2C%20England%2C%202021.

Following the FDA's efforts to excise physicians from mifepristone usage, Petitioners boast that "millions of women have taken mifepristone;" Petition, at 15. But if true, and the complication rate lies somewhere between 2% and 20% of cases, as studies confirm, even with a minimum volume of two million women their needs – the smallest number that would earn "millions" a plural designation – between 40,000 and 400,000 cases of mifepristone complications have taken place. Alternatively, using CDC's estimate of 368,868 early chemical abortions in 2021, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, the estimated number of complications range from 7,377 cases to 73,773 cases in one year. Anecdotally, according to one

obstetrician, he has personally cared for over twenty patients suffering from serious mifepristone complications necessitating hospitalizations over a two-year period, as one of seven doctors rotating coverage in the emergency room in his hospital. Conversation with Dr. Brent Boles (Feb. 16, 2024). Additionally, Dr. Ingrid Skop testified that she has "often treat[ed] patients who [were] admitted through the hospital's emergency room with complications from chemical abortions." Declaration of Dr. Ingrid Skop, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.,* at 4 (N.D. Tex., Nov. 11, 2022).

Abortion advocates are also encouraging women to stock up on mifepristone, not only so they may have it for later use, but also to give the drug to others. *A Guide to Surviving in a Post-Roe World; How to Have a Medication Abortion*. The opportunity for stocking up is available only because of the FDA's mail order decision. As one advocate put it "[f]or now, abortion pills via telemedicine are accessible and legal;" *A Guide to Surviving in a Post Roe World*.

In effect, the FDA's procedurally unsubstantiated decisions have wrought a perilous, wild-west type of system conducive to unsupervised chemical abortions and other abuses. An alarming number of women have received mifepristone without a pre-dispensing ultrasound to ascertain the baby's gestational age and to determine whether the patient's pregnancy is ectopic or intrauterine. In the face of this health crisis, it bears remembering: Physicians play a key role in the health and well-being of individuals taking dangerous drugs like

mifepristone. They should not be removed from the process.

II. Constrains Physicians to Participate in Chemical Abortions When They Would Rather Not Be Involved

Neither should physicians be forced to manage a health crisis created by the FDA's marginalization of them.

A. Sets physicians up for failure and deleterious repercussions

The emergency room setting can be arduous for physicians – even under the best of circumstances – due to the urgency of the care, the undifferentiated patient population, the absence of an established relationship with most patients, the unstable conditions that patients present, and the limited time and resources available to manage the acutely ill and injured. Jestin N. Carlson, *et. al*, *Provider and Practice Factors Associated with Emergency Physicians Being Named in a Malpractice Claim*, 71 ANN. EMERG. MED., 71, 158 (Feb 2018) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5785561/. The FDA's dictates on mifepristone have made this challenging context considerably more difficult for physicians, constraining them to work under intolerable conditions.

The FDA's reckless actions in 2016 and 2021 sanctioned virtually uninhibited access to mifepristone, leading to increasing frequency and numbers of chemical abortions conducted in the

United States, elevating the drug to the abortion method of choice for most women. This newfound popularity, in turn, has led to a far greater need for physicians trained in obstetrics and gynecology to emergently respond to complications that come with mifepristone. The increased need is not only due to the greater number of chemical abortions, but also to the cavalier way by which this method is carried out. In the absence of a directive to do otherwise, women are prone to take mifepristone without consulting a physician or having an ultrasound. Moreover, chemical abortion proponents are encouraging women to undergo "self-managed abortions" without the support or supervision of a physician. Rebecca Grant & Elizabeth Isadora Gold, *How to Have a Medication Abortion Where to Find the Pill and What to Expect.*, NEW YORK, (updated Jun 28,2022) (accessed Feb 18, 2022) https://www.thecut.com/article/find-abortion-pill-what-to-expect.html?utm_source=Sailthru&utm_medium=email&utm_campaign=Cover%20Drop%205/23&utm_term=NYMag%20-%20Paywall.[7]

The "self-managed abortion" approach is a recipe for a health disaster. Without doctor care, more and more women are taking mifepristone at a later gestational stage or when its consumption would

[7] The full extent of the harm caused by this unsavory advice cannot be ascertained because patients are often not forthcoming about their mifepristone use and there are no billing codes differentiating between medication induced abortions and miscarriage related conditions. (Conversation with Dr. William Lile, Feb. 16, 2024). Dr. Lile is a board-certified obstetrician and gynecologist practicing in Florida and a member of the Abortion Pill Rescue Network.

otherwise be harmful, prompting mifepristone complications that tend to overwhelm the capacity of emergency rooms and their physicians. The predicament is further exacerbated by the predatorial market for mifepristone, with advocates of the drug telling women to keep their use of mifepristone under wraps. There are numerous reports of women falsely denying use of mifepristone when presenting in the emergency room. (Conversations with Dr. DM,[8] Dr. HB,[9] and Dr. Brent Boles.[10]) In an environment where the medication is taken in a manner inconsistent with medical recommendations (as well as FDA's own procedural policies), and this misuse is concealed by the patient, the physician is put at a great disadvantage to provide appropriate care.

This situation is even more dire for numerous emergency rooms across the country that have no access to trained obstetricians and gynecologists, "healthcare deserts" that must rely on physicians who practice outside of the OB/GYN specialty to treat patients with emergent mifepristone complications. March of Dimes, *Maternity Cares Desert Report. No*

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[8] Dr. DM is a board-certified, obstetrician and gynecologist practicing in Florida. The doctor requested to remain anonymous because of concerns regarding negative professional standing repercussion as a result of the views expressed in this document.

[9] Dr. HB is a board-certified, obstetrician and gynecologist practicing in Florida. The doctor requested to remain anonymous because of concerns regarding negative professional standing repercussion as a result of the views expressed in this document. Dr. HB is also a member in good standing of the USMA.

[10] Dr. Brent Boles is a board-certified obstetrician and gynecologist practicing in Florida. He is the Medical Director of Heartbeat International.

where to go: Maternity Care Deserts Across the US. (2022 Report) (accessed February 27, 2024) https://www.marchofdimes.org/maternity-care-deserts-report. Andrea Sonenberg and Diana J. Mason, *Maternity Care Deserts in the US*, (January 12, 2023) (accessed February 27, 2024) https://jamanetwork.com/journals/jama-health-forum/fullarticle/2800629. These emergency rooms are not equipped to handle the medical traumas caused by the drug. But, for that matter, no emergency room is truly equipped to deal with the dilemma perpetuated by the FDA's abandonment of much-needed regulations on mifepristone usage. Emergency room physicians treating patients who have taken the drug, covertly or otherwise, are thrust into an uncontrollable, unpredictable environment fraught with peril.

And this peril goes beyond the patient. Though the impact of FDA's actions on pregnant women taking mifepristone is profound, it is not isolated. The FDA's actions adversely affect emergency room physicians as well (who are represented by Respondents and *amicus curiae*).

Petitioners suggest the emergency room conditions triggered by the FDA do not negatively impact physicians because they are not required to receive or prescribe mifepristone. Petition, at 13. This view is myopic. FDA actions produce a highly stressful emergency room environment that places undue burdens on the doctors working in these facilities. Physicians aim to successfully treat their patients and the complications caused by mifepristone intake without medical oversight sets

them up for failure, in situations where they may not be able to bring their patients back to full health. Aside from the harm to the patients, these bad results harm the physicians too, subjecting them to malpractice claims and costly litigation.

Also, as explained in Respondents' Brief, the FDA's de-regulation of mifepristone can cause some physicians to go through internal dilemmas, pitting their profession against their morality in urgent situations, obliging these doctors to violate their conscience. *See* Resp. Brief, pp. 18-21.

These resultant harms to physicians are real, a by-product of the FDA's arbitrary and capricious 2016 and 2021 actions.

B. Without any means for avoiding the unconscionable dilemmas caused by the FDA

Despite emergency room physicians being placed in unbearable conditions – not of their own or any other physician's making – they are not afforded an opportunity to opt out. They are forced to proceed with medical treatment, regardless of their capacity, competence, and conscience.

Petitioners claim the FDA's actions do not harm physicians because they do not require physicians to treat patients. Petition, at 18. But physicians are nevertheless required to do their job. Petitioners ignore state regulations and hospital rules obliging physicians to treat anyone in need. An emergency room physician has a duty to care for a

patient whose life is in danger regardless of how he or she got there or the physician's beliefs about the appropriateness of the patients' actions.

Additionally, emergency room physicians are not well positioned to better their situation in the current political climate. Physicians who call attention to the concerns surrounding FDA's policies on mifepristone are subject to harassment, particularly within their own professional communities. Illustrative of this concern, last year in 2023, American College of Obstetrics and Gynecologist (herein "ACOG") kept the nation's premiere pro-life obstetrics and gynecology organization, the American Association of Pro-Life Obstetricians and Gynecologists (herein "AAPLOG")—a respondent in this case— from having a booth at a meeting, despite their having a booth for fifteen years. In explaining the sudden departure from practice, ACOG denigrated the organization for its views, claiming AAPLOG no longer "align[s] with ACOG's and APGO's[11] commitment to the advancement of evidence-based, scientific information." Rachel Kingery in Jordan Boyd, *American College of OB-GYNs Bans Pro-Life Doctors From Conference After they Show Up,* THE FEDERALIST, (Feb 28, 2023) (accessed Feb 18, 2023) https://thefederalist.com/2023/02/28/american-college-of-ob-gyns-bans-pro-life-doctors-from-conference-after-they-show-up/; Joel Silverstein, *American College of OB-GYNs Bans Pro-Life Doctors From Conference; 'Vague Explanation',* FOX NEWS,

[11] APGO is the Association of Professors of Obstetrics and Gynecology.

(Mar 1, 2023) (accessed Feb 18, 2023) https://www.foxnews.com/media/american-college-ob-gyns-bans-pro-life-doctors-conference-vague-explanation.

Another professional espousing an anti-mifepristone position was censored for espousing these views, resulting in retractions of scientific articles demonstrating higher hospitalization and complication rates with medical abortions as compared to surgical abortions. Brittany Bernstein, *Researcher Decries 'Increasingly Politicized Environment' after Journal Retracts Pro-Life Studies*, (Feb 8, 2024) (accessed Feb 18, 2024) https://www.nationalreview.com/news/researcher-decries-increasingly-politicized-environment-after-journal-retracts-pro-life-studies/. The publisher alleged that the reason for the retraction was the absence of a declaration of conflict of interests, but the conflicts were clearly mentioned on the first page of each study. Michael J, New, *A Journal Retracts Three Studies Showing Health Risks of Chemical Abortions*, (Feb 8, 2024) (accessed Feb 18, 2024) https://www.nationalreview.com/corner/a-journal-retracts-three-studies-showing-health-risks-of-chemical-abortions/. Short of any allegation of researcher misconduct, the retractions appear more politically motivated than scientifically based. *Researcher Decries 'Increasingly Politicized Environment'*. Also peculiar is the delayed timing of the retractions, as they were announced on February 5, 2024, in the midst of the present appellate process, for studies published in 2019, 2021, and 2022. Sage Retraction Notice, SAGE JOURNALS, (February 5,

2024) (accessed February 19, 2024) https://journals.sagepub.com/doi/10.1177/23333928231216699.

In line with this professional bullying, most of the doctors with whom we spoke about the mifepristone issue for the purpose of this brief did not wish to have their names published in the record for fear of negative repercussions to their career. Only those physicians who were already openly involved in advocacy efforts agreed to be named in this amicus brief.

CONCLUSION

The FDA's 2016 and 2021 actions egregiously interfere with the doctor-patient relationship, divorcing the two, depriving the patient of a doctor, doing serious harm to both.

Consisting of organizations and physicians directly and adversely affected by the FDA's actions, Respondents demonstrate requisite harm for standing to challenge them. Similarly affected, sharing the same concerns, and having a vested interest in the outcome of this case, *amicus curiae* joins Respondents in asking this Court to affirm the Fifth Circuit's Order.

Respectfully Submitted,

NATHAN W. KELLUM
Counsel of Record
CENTER FOR RELIGIOUS EXPRESSION
699 Oakleaf Office Lane
Suite 107
Memphis, TN 38117
(901) 684-5485
nkellum@crelaw.org
Counsel for Amicus Curiae

Julio Gonzalez, M.D.
241 Nokomis Ave. S.
Venice, FL 34285
(941) 441-0310
usemdicalassn@gmail.com