UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, on behalf of itself, its members, and their patients; AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself, its members, and their patients; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS, on behalf of itself, its members and their patients; SHAUN JESTER, D.O., on behalf of himself and his patients; REGINA FROST-CLARK, M.D., on behalf of herself and her patients; TYLER JOHNSON, D.O., on behalf of himself and his patients; and GEORGE DELGADO, M.D., on behalf of himself and his Patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; JANET WOODCOCK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. 2:22-cv-00223-z

MOTION OF LIFE COLLECTIVE INC. SEEKING LEAVE TO FILE BRIEF AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' COMPLAINT AND MOTION FOR TEMPORARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 7(b), Life Collective, Inc. ("Life Collective") respectfully seeks the Court's leave to file the accompanying brief as an amicus curiae in support of Plaintiffs' Complaint (Doc. 1) and Plaintiffs' Motion for Preliminary Injunction (Doc. 6). Consistent with the principles set by Fed. R. App. P. 29(a)(4)(E), counsel for amicus authored its brief in whole; no counsel for a party authored this brief; and no other person or entity contributed monetarily to this brief's preparation or submission.

I. Identity and Interests of Movant

Life Collective is a non-profit corporation headquartered in Oklahoma City, Oklahoma. Life Collective educates the public and unites organizations committed to a deep respect for life, with the hope of fostering a culture that makes abortion, with all its risks, unnecessary. As part of Life Collective's mission, it seeks leave to file an amicus brief in support of Plaintiffs' Complaint (Doc. 1) and Plaintiff's Motion for Temporary Injunction (Doc. 6). Life Collective's position is that the lack of safeguards in the FDA's challenged regulations deviate from accepted ethical norms and required FDA practices meant to preserve the health and lives of patients. This departure endangers both women's health and trust in healthcare professionals.

II. Argument

This is a matter of national importance. The Court's decision will directly affect the delivery of pharmaceuticals, patients' health, and respect for the ethical underpinnings of healthcare regulation. Life Collective believes that its proposed amicus briefing will aid the Court in its review. Should this matter eventually be subjected to appellate review, the appellate court will almost certainly have the benefit of amicus curiae briefing and this Court should have no less.

Despite the lack of a specific rule addressing amicus briefs at this stage, the Court should accept this briefing as it has in other important matters. *See e.g., Kinard v. Dish Network Co.*, 228 F. Supp. 3d 771, 777 (N.D. Tex. 2017); *United States v. Texas Educ. Agency*, 138 F.R.D. 503, 508 (N.D. Tex. 1991) (allowing parties denied intervention to file amicus curiae briefing). Life Collective's briefing will provide a well-supported viewpoint concerning the importance of adhering to current FDA regulations that implement safeguards over the provision of pharmaceuticals, especially abortifacients that pose very real risks to women (particularly absent proper medical oversight), and the grave departure this would represent from established ethical standards of healthcare in the United States.

III. Conclusion

Accordingly, Life Collective respectfully requests the Court to grant its motion for leave to file the accompanying amicus curiae brief.

Respectfully submitted, this 10th day of February, 2023,

/s/ Darren McCarty

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I certify that on February 10th, 2023, I electronically filed the foregoing document with the Clerk of the Court via CM/ECF which will notify all parties in this matter who are registered with the Court's CM/ECF filing system of such filing. All other parties (if any) shall be served in accordance with the Federal Rules of Civil Procedure.

DATED this 10th day of February, 2023.

/s/ Darren McCarty
Darren McCarty

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BRIEF OF AMICUS CURIAE LIFE COLLECTIVE, INC.

The United States Food and Drug Administration (FDA) is "the oldest comprehensive consumer protection agency in the U. S. federal government."[1] One of the FDA's primary congressional mandates is to ensure that drugs "undergo a rigorous evaluation of safety, quality, and effectiveness before they can be sold."[2] The FDA is the standard bearer for all Americans in "protect[ing] the public health by ensuring the safety, efficacy, and security of human….drugs, biological products and medical devices."[3]

Women's healthcare is an area of specific concern. In 1994, Congress mandated that the FDA create an Office of Women's Health. The office is charged with a mission to "advise on scientific, ethical, and policy issues relating to women's health," and to "provide leadership regarding issues of women's health."[4]

Despite its express obligations, in 2000, the FDA first approved a chemical abortion drug regimen with significant restrictions and, by 2021, *the FDA permanently allowed the unsupervised, mail-order administration of chemical abortion drugs*[5] to women. The FDA's actions ignored its mandate to provide leadership in safeguarding women's health. These drugs

[1] U.S. Food and Drug Administration, *FDA History* (Jun, 29, 2018), https://www.fda.gov/about-fda/fda-history.
[2] U.S. Food and Drug Admin., *Promoting Safe & Effective Drugs for 100 Years* (Apr. 24, 2019), www.fda.gov/about-fda/histories-product-regulation/promoting-safe-effective-drugs-100-years.
[3] U.S. Food and Drug Admin., *What We Do*, www.fda.gov/about-fda/what-we-do; *see also* U.S. Food and Drug Admin., *FDA's Legal Authority* (Mar. 28, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/fdas-legal-authority#:~:text=The%20federal%20regulation%20of%20food,of%20the%20United%20States%20Congress.
[4] U.S. Food and Drug Admin., *Office of Women's Health* (Dec. 2, 2019), https://www.fda.gov/about-fda/office-commissioner/office-womens-health.
[5] Abortion strictly via pharmaceuticals as opposed to surgical means, often is referred to either as chemical abortion or medical abortion.

endanger women's health and depart from our country's longstanding commitment to ethical healthcare.

During a woman's pregnancy, two patients are at stake—the child in the womb and the pregnant mother. The government itself acknowledges this dual relationship. The Centers for Disease Control and Prevention (CDC) maintain a program called *Treating for Two*,[6] that focuses on the choices pregnant women face when taking medications because of the potential effects on the unborn child. Of course, abortion entirely dispenses with the rights and wellbeing of the unborn child. But the FDA's new approach to chemical abortion makes even a mother's health secondary to promoting abortion. This approach is a significant and dangerous departure from the statutorily required recognition of the rights, care, and dignity of the woman as a patient and as a healthcare recipient.

The FDA's regulatory devolution over chemical abortion is extraordinary. Attempting to mitigate the dangers of chemical abortion, for years after the FDA initially approved the chemical abortion regimen, it was subject to an FDA drug safety program called "Risk Evaluation and Mitigation Strategy" (REMS). The FDA uses REMS to "focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."[7] As part of the REMS, chemical abortion drugs could only be dispensed in-person. But in April 2021, the FDA stated that it would temporarily cease the in-person dispensing requirement.[8] Then in December 2021, the

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[6] Centers for Disease Control and Prevention, *Treating for Two: Medicine and Pregnancy* (Sep. 20, 2022), https://www.cdc.gov/pregnancy/meds/treatingfortwo/index.html.
[7] U.S. Food and Drug Admin, *Risk Evaluation and Mitigation Strategies | REMS* (Dec. 17, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.
[8] Pam Belluck, *F.D.A. will allow abortion pills by mail during the pandemic*, N.Y. Times (Apr. 13, 2021), https://www.nytimes.com/2021/04/13/health/covid-abortion-pills-mailed.html.

FDA permanently lifted the in-person dispensing REMS, making chemical abortion drugs available without any in-person encounter with a healthcare professional. These drugs that at the outset were considered too risky for anything but in-person dispensing, have now become, in the judgment of the FDA, so trivial as to be available via mail-order.

Yet multiple studies on the effects of chemical abortions on women have proven that these abortions pose serious risk of harm. Medical abortions are four times more dangerous than surgical abortions.[9] Infections increased significantly among women who had chemical abortions.[10] The Cleveland Clinic noted that typical side effects of chemical abortions include "heavy bleeding that can last for weeks, cramping, nausea and vomiting, fever and chills, diarrhea, and severe headaches."[11] Additionally, the Clinic noted that medical abortions place women at a higher risk of incomplete abortions that require emergency surgery.[12] "[T]he rate of emergency room visits related to medical abortions increased by 500% from 2002 to 2015, far outpacing already high surgical abortion rates."[13]

One particular concern is ectopic pregnancy, which occurs in approximately one out of every fifty pregnancies.[14] The FDA acknowledges that women should not undergo chemical

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[9] Maarit Niinimäki , Anneli Pouta, Aini Bloigu, Mika Gissler, Elina Hemminki, Satu Suhonen, Oskari Heikinheimo, *Immediate complications after medical compared with surgical termination of pregnancy*, 4 Obstet Gynecol., 2009, https://pubmed.ncbi.nlm.nih.gov/19888037/.
[10] Isabelle Carlsson, Karin Breding & P.-G. Larsson, *Complications related to induced abortion: a combined retrospective and longitudinal follow-up study* (2018), https://doi.org/10.1186/s12905-018-0645-6.
[11] Cleveland Clinic, *Medical Abortion* (Oct. 21, 2021), https://my.clevelandclinic.org/health/treatments/21899-medical-abortion.
[12] *See id.*
[13] James Studnicki , Donna J. Harrison, Tessa Longbons, Ingrid Skop, David C. Reardon, John W. Fisher, Maka Tsulukidze, Christopher Craver, *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015* (Nov. 9, 2021), https://pubmed.ncbi.nlm.nih.gov/34778493/.
[14] Healthline, *Ectopic Pregnancy* (Jan. 8, 2018), https://www.healthline.com/health/pregnancy/ectopic-pregnancy.

abortion when a pregnancy is ectopic.[15] The FDA's own data reported the deaths of multiple women who had ectopic pregnancies and proceeded with chemical abortions.[16] Yet the FDA's current approach not only allows these dangerous chemical abortion drugs, but disregards any safeguards—such as in-person evaluation and ultrasound—that would diagnose an ectopic pregnancy beforehand.

These concrete risks to women's health also risks compromising healthcare providers. The American Medical Association, which was founded in 1847 that convenes over 190 state and specialty medical societies and stakeholders, has developed a code of ethics to which its members must adhere. Among its ethical principles is that each physician must be "dedicated to providing competent medical care, with compassion and respect for human dignity and rights."[17] The medical ethics code also requires a physician to "respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."[18] Poor patient outcomes because of the FDA's failure to prioritize women's health and safety will undoubtedly cause an erosion of trust in the FDA by medical providers seeking to ethically practice and provide care to their patients.

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[15] U.S. Food and Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[16] U.S. Food and Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[17] American Medical Association, *AMA Code of Medical Ethics*, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf

[18] *Id.*

Unfortunately, the FDA has proven reckless in its duty to uphold the safety and dignity of women by loosening its restrictions on such a harmful drug. In doing so, it has compromised its purpose and sacred trust with the medical practitioners it exists to benefit, and the public which it is to serve. Women are now left alone before, during, and after an abortion, fending for themselves while enduring the difficult, yet common and traumatizing side-effects—and the quite serious risks—of chemical abortion. At a minimum, women deserve to receive medical supervision and care by trustworthy healthcare practitioners. The FDA has made an egregious error and violated its own stated principles and public mandates.

With deep concern for the health of both women and unborn children, Life Collective firmly supports the Plaintiffs' position in this case.

Respectfully submitted, this 10th day of February, 2023,

/s/ Darren McCarty

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