IN THE UNITED STATES DISTRICT COURT
FOR THE 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,** 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.	§	CASE NO. 2:22-cv-00223-z
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,	§	
and	§	
DANCO LABORATORIES, LLC,	§	
Intervenor Defendant.	§	

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE* DOCTORS FOR AMERICA IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TO THE HONORABLE COURT:

1. Pursuant to Fed. R. Civ. P. 7 and Local Rules 7.1 and 7.2(b), Doctors for America (hereinafter "DFA") respectfully moves for leave to file the attached brief as *amicus curiae* in the above-captioned case in support of Defendants' response and opposition to Plaintiffs' motion for preliminary injunction. Defendants and Plaintiffs have stipulated that they will not oppose the filing of this or other *amicus* briefs. ECF No. 12.

2. The movant, DFA, is a 501(c)(3) non-profit, national organization of over 27,000 physicians and medical students representing all medical specialties. DFA seeks to improve the health of every American through its four guiding principles: (1) Every person in America has a fundamental right to equitable, high-quality, and affordable health care; (2) Everyone should have the opportunity to lead a healthy life; (3) Every part of society should value and promote healthy families and communities; and (4) Doctors should take a leadership role in improving health care and ending health disparities. DFA does not accept any funding from the pharmaceutical or medical device industry, which enables DFA to ensure that patients are placed before politics and profits. The issues presented in this case would limit patient access to an essential medicine, potentially impacting patients across the nation; thus, this case is of grave concern to DFA, its members, and their patients.

3. The attached brief seeks to provide the Court with first-hand accounts from physicians regarding the dangerous ramifications of enjoining access to mifepristone. These narratives by physicians highlight the importance of mifepristone in the provision of safe and effective healthcare to affected patients, the potential negative impact a removal of mifepristone

would have on those patients, and the professional difficulties such a removal would effectuate on physicians.

4. Judges in this District have broad discretion to accept *amicus* filings and have allowed *amicus* filings by interested parties in cases of significance. *See, e.g., Kinard v. Dish Network Co.*, 228 F. Supp. 3d 771, 777 (N.D. Tex. 2017); *Nat'l Fed'n of Indep. Bus. v. Perez*, No. 5:16-CV-66-C (N.D. Tex. May 2016); *Taylor v. Williams*, No. 5:14-CV-149-C (N.D. Tex. Mar. 29, 2016); *Fonovisa, Inc. v. Alvarez*, No. 1:06-CV-011-C (N.D. Tex. June 15, 2006); *Welch v. U.S. Air Force*, No. 5:00-cv-392 (N.D. Tex. Sept. 23, 2002). In addition, this Court has historically accepted *amicus* filings by interested parties. *See, e.g., State of Texas v. Becerra*, No. 2:21-cv-00229 (N.D. Tex. Nov. 15, 2021); *State of Texas v. Yellen*, No. 2:21-cv-00079 (N.D. Tex. May 3, 2021). Further, this Court has already granted leave to another *amicus curiae* in this case, the Chattanooga National Memorial for the Unborn. *See* ECF No. 30, 31.

5. Neither *amici* nor counsel received any monetary contributions to fund the preparation or submission of this brief; no party's counsel authored this brief in whole or in part; and this motion and the attached brief are timely filed. *See* ECF No. 12.

6. For all the foregoing reasons, Doctors for America respectfully requests that the Court grant it leave to participate as *amicus curiae* and accept the attached brief for filing.

Dated: February 9, 2023

Respectfully submitted,

/s/ Christopher J. Morten
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Counsel for Doctors for America

CERTIFICATE OF CONFERENCE

Plaintiffs and Defendants stipulated in their Joint Motion to Extend Deadlines not to oppose the filing of *amicus* briefs and further stipulated that any *amici* need not seek the specific consent of either Plaintiffs or Defendants before seeking leave of the Court. ECF No. 12 ¶3.

Dated: February 9, 2023

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten

CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2023, the foregoing was electronically submitted to the Clerk of Court for the U.S. District Court for the Northern District of Texas using the Court's electronic case filing system in accordance with Local Rule 5.1(e). All counsel of record will be served via the Court's CM/ECF system and via email.

Dated: February 9, 2023

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten

IN THE UNITED STATES DISTRICT COURT
FOR THE 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,** 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, and **DANCO LABORATORIES, LLC**, Intervenor Defendant.	§ §	CASE NO. 2:22-cv-00223-z

BRIEF OF *AMICUS CURIAE* DOCTORS FOR AMERICA

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TO THE HONORABLE COURT:

I. INTEREST OF AMICUS CURIAE

Doctors for America ("DFA") files this Amicus Brief in support of Defendants' Opposition To Plaintiffs' Motion For A Preliminary Injunction (ECF No. 28).[1] DFA is a nonpartisan, not-for-profit, 501(c)(3) organization of over 27,000 physician and medical student advocates in all 50 states, representing all medical specialties. DFA mobilizes doctors and medical students to be leaders in putting patients over politics to improve the health of patients, communities, and the nation. DFA takes a special interest in access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical device companies. This uniquely positions DFA as a medical organization that puts *patients over politics* and *patients over profits*.

In support of its mission, DFA formed an FDA Task Force to educate, mobilize, and empower a multispecialty group of clinicians to provide unbiased expertise in evaluating and responding to the FDA regulatory process in a way that maximizes meaningful clinical outcomes for patients. To support an FDA that puts patients first, the FDA Task Force has advocated in support of patient-centered regulatory reform through public testimony, op-eds, educational meetings with policymakers, and more. For example, DFA's FDA Task Force has written letters, testified, and met with policymakers to advocate for reforms to the Prescription Drug User Fee Act ("PDUFA") to make user fee agreements more patient-centered in order to ensure timely

[1] As noted in ECF No. 12, Plaintiffs and Defendants stipulate that they will not oppose the filing of amicus briefs, and that any amici do not need to seek the specific consent of either Plaintiffs or Defendants before seeking leave of the Court. Counsel for Amicus Curiae authored this brief in whole; no party's counsel authored, in whole or in part, this brief; and no person or entity other than amicus and their counsel contributed monetarily to preparing or submitting this brief.

access to drugs and biologic medicines proven to be effective and safe.[2] Recently, the FDA Task Force has also advocated for the addition of miscarriage management as an indication to mifepristone's label "[t]o ensure access to the safest and most effective treatments for miscarriage, and to preserve patient choice in miscarriage management."[3]

DFA submits this brief to the court to highlight the ways in which mifepristone, which has been approved for use in the United States for over twenty years,[4] impacts the practice of physicians across the United States. An injunction that withdraws or suspends approval of mifepristone would disrupt medical practice nationwide, including care for conditions beyond induced abortion, such as the management of early pregnancy loss.

II. ARGUMENT

DFA's members across the country wish to express to this Court their concerns about the potential removal of mifepristone as an approved drug, which would have grave ramifications. This amicus brief contains first-hand accounts from physicians across many practice areas about the harms that Plaintiffs' requested preliminary injunction would cause.[5] These accounts, in providers' own words, describe how an injunction ordering Defendants to withdraw approval of mifepristone would jeopardize physicians' ability to provide safe and effective healthcare, undermine the patient-physician relationship, and impose upon doctors an unacceptable choice between compliance with their ethical obligations and compliance with the law.

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[2] *Written Testimony of Reshma Ramachandran, M.D., M.P.P. at Hearing on "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics" Subcommittee on Health*, DOCTORS FOR AMERICA (2022), https://doctorsforamerica.org/written-testimony-of-reshma-ramachandran-m-d-m-p-p-athearing-on-fda-user-fee-reauthorization-ensuring-safe-and-effective-drugs-and-biologics-subcommittee-on-health/ (last visited Feb. 7, 2023).

[3] *Citizen Petition from the American College of Obstetricians and Gynecologists*, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf (last visited Feb. 7, 2023).

[4] U.S. Food & Drug Admin. Ctr. For Drug Evaluation & Rsch., Approval Letter for mifepristone (MIFEPREX) tablets (Sep. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm.

[5] The accounts presented in this amicus brief were provided directly to counsel by the doctors quoted. All the doctors quoted are members of Doctors for America.

A. Providers affirm the safety and effectiveness of mifepristone

Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.[6] The safety and effectiveness of mifepristone has been demonstrated through rigorous investigation conducted prior to the FDA's approval of mifepristone and further confirmed by a large volume of scientific literature published after its approval. Studies supplied to the FDA at the time of approval in 2000 found adverse events requiring hospitalization in less than 1% of a sample size of over 2,000 patients.[7]

Many studies have shown that serious adverse incidents occur in less than 0.5% of medication abortions in the United States.[8] Moreover, adverse events data tracked by the FDA reveals that mifepristone has a very low mortality rate of 0.65 per 100,000.[9] Mifepristone has a lower mortality rate than other common medications such as sildenafil (Viagra), which has a mortality rate more than six times greater than mifepristone, and penicillin, which has a mortality rate three times greater than mifepristone.[10] Furthermore, numerous studies have shown the combined mifepristone/misoprostol regimen to be more than 95% effective.[11] The providers' accounts presented here affirm that mifepristone has proven safe and effective in providers'

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[6] Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013).

[7] U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION & RSCH., 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 (2000), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf.

[8] *Safety and Effectiveness of First-trimester Medication Abortion in the United States*, ADVANCING NEW STANDARDS IN REPROD. HEALTH (June 2021), https://www.ansirh.org/sites/default/files/2021-06/medication-abortion-safety_2021_FINAL.pdf.

[9] Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651-52 (2022).

[10] *Id.*

[11] *See, e.g.*, Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review.*, 126 OBSTETRICS & GYNECOLOGY 12 (2015). *See also* Man-Wa Lui & Pak-Chung Ho, *First trimester termination of pregnancy,* 63 BEST PRACTICE & RESEARCH CLINICAL OBSTETRICS & GYNAECOLOGY 13, 20 2020).

practices. If mifepristone were to be made unavailable, it would not make treatment safer but would instead endanger the health of pregnant people.

Dr. Cheryl Hamlin is an obstetrician-gynecologist who now practices in Massachusetts. She attended medical school at the University of Illinois and completed her residency at Boston Medical Center. Dr. Hamlin provides a first-hand account of mifepristone's safety profile and its ability to expand access to care:

> Mifepristone is widely used both as a medication used to terminate a pregnancy as well as for medical management of a miscarriage. While misoprostol is widely available globally, the combination of mifepristone and misoprostol is more effective. Patients who wish to avoid a surgical procedure have the option for medical management for both miscarriage and termination of pregnancy or an aspiration procedure. Eliminating the option of mifepristone would significantly affect the options and therefore the health of those in need of this treatment.
>
> Patients have a wide range of reasons to choose medication management over an aspiration procedure. Some choose medication abortion because they are afraid of a surgical procedure. Others, who are driving long distances, may not be able to get a ride. They then have the option of a procedure without anesthesia.
>
> Most importantly, mifepristone means improved access to care. Outpatient offices which may not have the capability of providing aspiration procedures may be able to readily provide medication abortion.[12] Advanced practitioners and providers other than OB/GYNs may be more comfortable providing medical procedures. It can be and should be easy for providers to offer medication abortion in the office setting.
>
> As well, there is a mountain of evidence that mifepristone is extremely safe. Mifepristone has been used since 2000 in the United States and longer in Europe. The risk of serious complications is extremely rare and certainly far less likely than the risks of childbirth.[13] Most of the complications associated with medical abortions are due to the process itself, not the mifepristone. Mifepristone blocks progesterone, which disrupts the lining of the uterus. This, in fact, is what happens monthly to stimulate a menses: sudden withdrawal of progesterone. If mifepristone

[12] Lawrence Leeman et al., *Can mifepristone medication abortion be successfully integrated into medical practices that do not offer surgical abortion?*, 76 CONTRACEPTION 96 (2007).
[13] Jillian T. Henderson et al., *Safety of mifepristone abortions in clinical use*, 72 CONTRACEPTION 175 (2005).

> were inadvertently given to a non-menstruating person, it would likely have no effect.
>
> Not having the full range of options to offer my patients would adversely affect my patients, potentially delaying care, causing them to require more invasive procedures and subjecting them to the associated risks. Mifepristone must remain readily available to those for whom the best option is a medication procedure.

As Dr. Hamlin described, the safety and effectiveness of mifepristone is substantiated by scientific evidence showing that complications are extremely rare. An injunction withdrawing or suspending approval of mifepristone would endanger the health of patients by removing the availability of a safe and effective treatment option.

B. Providers underscore that mifepristone is a standard treatment option not only for abortion, but also for early pregnancy loss

The most effective treatment option for medication management of early pregnancy loss includes mifepristone taken in combination with misoprostol.[14] For successful management of early pregnancy loss, mifepristone followed by treatment with misoprostol is over 83% effective and results in complications requiring blood transfusion in only 2% of women.[15] An injunction reversing the approval of mifepristone would remove the availability of an evidence-based treatment that is the safest and best option for many patients. As physicians describe *infra*, the removal of mifepristone would undermine their ability to provide safe and effective management of early pregnancy loss.

Dr. Cynthia Davis is an obstetrician-gynecologist in South Dakota. She attended medical School at the University of Florida and completed her residency at the University of Colorado. Dr.

[14] Honor Macnaughton, Melissa Nothnagle & Jessica Early, *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473 (2021).
[15] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEW ENG. J. MED. 2161 (2018).

Davis conveys the importance of mifepristone for treating early pregnancy loss and the significant health and ethical harms that would occur were mifepristone to be removed as an option for treatment:

> I speak from the experience of an obstetrician-gynecologist in a state where it has always been very difficult to obtain mifepristone. I am not an abortion provider, but I can tell you that the difficulty of obtaining this drug in treating pregnancy loss has significantly harmed many of my patients. When it is clear that a woman has lost her pregnancy but has not passed the tissue, the use of mifepristone combined with misoprostol is over 90% effective in resolving the missed pregnancy loss, compared to the 75% success of misoprostol alone. Given how common first-trimester pregnancy loss is, this treatment delay, often resulting in significant bleeding, infection, and psychological trauma, is devastating. I have seen this result in women requiring blood transfusions and surgeries they otherwise would not have needed. I have seen women avoid any future pregnancies for fear of this situation's recurring trauma.
>
> Of course, other options exist to treat the clinical situations mentioned above. However, expectant management can result in acute bleeding episodes, increased risk of infection, anxiety, and depression, which I have witnessed in multiple patients over the years. Surgical management is often more expedient for clinical management. Still, there are risks, including bleeding, infection, uterine scarring resulting in infertility, and uterine perforation with possible damage to the bowel, bladder, or blood vessels. In addition, the costs associated with surgical management are often more than the family can absorb.
>
> And although there can be complications related to any medication, I have found mifepristone to be effective and safe in my many years of experience (over 30 years). It is heartbreaking to watch a family go through the difficulties related to pregnancy loss and, more so, to watch harm come to our women patients. Interference in the doctor-patient relationship by removing mifepristone as an approved drug disrespects a woman's autonomy and the sacred relationship between doctor and patient, much less the expertise in a physician's medical training.

Dr. Amy Kaleka is a family medicine provider in Wisconsin. She attended medical school at Central America Health Sciences University and completed her residency in family medicine at Virginia Tech Carilion School of Medicine. Dr. Kaleka explains the harms that withdrawing or

suspending FDA approval of mifepristone would have on the management of early miscarriage, for which a standard treatment involves mifepristone:

> I am a family medicine and obstetrics provider in a state where an abortion ban already exists and has resulted in unsafe care for pregnant patients as it is, but a ban on mifepristone would prevent me from being able to safely manage miscarriages in early pregnancy without hospitalizations. Having to stop providing abortion care to patients in Wisconsin for the past six months has revealed further difficulties for patients in rural settings, which are the same settings where no maternity wards exist in the hospital. These patients are now being forced to birth, so the risks of bleeding and poor fetal and maternal outcomes have significantly risen. Mifepristone is vital to providing safe care for early pregnancy loss.
>
> Increasing restrictions on medications that can improve safety outcomes of pregnant patients will inevitably lead to worse maternal outcomes. As providers, we do our best to perform safe and high quality care to prevent complications. The availability of mifepristone allows me to provide safe and high quality miscarriage management care to patients, reducing their likelihood of complications which ultimately reduces health care costs by avoiding hospitalizations. The use of this medicine is vital for medication management of miscarriages per the latest medical guidelines.[16] I hope to continue to provide safe obstetric care, which involves mifepristone as an option for pregnant patients for both miscarriage and abortion care.

As Dr. Davis and Dr. Kaleka highlight, mifepristone is critical for managing early pregnancy loss. The withdrawal or suspension of FDA approval of mifepristone would result in misoprostol being the only option for management of early pregnancy by medication. Medicine is practiced as a shared decision-making process between the physician and patient. For certain patients, mifepristone and misoprostol in combination may be the best option based on their individual therapeutic and psychological needs. For other patients, offering misoprostol alone or pursuing expectant or surgical management might be the indicated course of care that a physician and their patient agree upon. An injunction withdrawing or suspending FDA approval of

[16] *Id.*

mifepristone would limit providers' ability to provide the evidence-based care that is best for individual patients, worsening maternal outcomes.

C. Providers emphasize that the availability of mifepristone is essential to protect patient autonomy

Respect for patient autonomy is a core tenet of physicians' professional ethics. The principle of respect for patient autonomy "acknowledges an individual's right to hold views, to make choices, and to take actions based on her own personal values and beliefs."[17] Respect for patient autonomy requires respect for the right of patients to make their own health care choices. It is therefore critical, and central to medical ethics, that patients have the option to choose the treatment that best suits them.

For many patients, a combined mifepristone/misoprostol regimen is the best option. Patients may prefer or require medication abortion over surgical abortion for a variety of reasons, including pre-existing medical conditions, privacy, time constraints, transportation, the desire to avoid an invasive procedure, or other practical concerns. For instance, patients who are victims of abuse, including rape or incest, may prefer medication abortion to avoid retraumatization. *See* Glaser Decl. Ex. 7, at 6, ECF No. 29.

Dr. Andrea Palmer is an obstetrician-gynecologist who lives and practices in Texas. She attended medical school at the University of Oklahoma College of Medicine and completed her residency at the University of Oklahoma Health Sciences Center. Dr. Palmer wishes to share with the court an example of how withdrawing or suspending FDA approval of mifepristone would

[17] American College of Obstetricians and Gynecology, *ACOG Committee Opinion No. 390, December 2007. Ethical decision making in obstetrics and gynecology*, 110 OBSTETRICS & GYNECOLOGY 1479, 1481 (Dec. 2007, reaff'd 2016).

provide women with even fewer options following sexual assault or rape, restricting patient autonomy[18]:

> As I glanced at my schedule, I noticed with delight a familiar patient, Josie,[19] scheduled for a new OB appointment. However, the moment I walked in the room, I knew this was not a typical new pregnancy visit. Josie's appointment brought unexpected and devastating news. Two weeks ago, she had joined a group of girlfriends for a night out to celebrate a coworker's birthday. Like any dedicated infertility couple, she and her husband had been timing their intercourse around her ovulation time and had sex that day. Tragically, that night of celebration ended with her as a victim of the most personally violating crime. That night she was drugged and raped.
>
> Like most rape victims, Josie had stayed silent about her assault. Now two weeks after living with the shame, guilt, and pain of her attack she found out she was pregnant. Months and months of trying, years of hoping, and dozens of negative pregnancy tests later, and this was the one that was positive. Josie could not know who the father of this pregnancy was—her husband or the rapist. Obviously if this pregnancy were conceived with her husband, this would be the beginning of the next phase of their life together. But there was an unfortunate chance that this pregnancy was a product of rape. Understandably, she could not bear the thought of carrying that pregnancy to term.
>
> The soonest paternity could have been established was 7 weeks gestation. However, Josie lives, and I practice, in Texas. This was November 2021, just a few months after passage of SB8 which banned abortion in the state of Texas after 6 weeks. As Josie and I cried together, we reviewed her options. She could choose to terminate now, but time was running out. At this point, she was just over 4 weeks gestation. She could choose to wait and determine paternity, but if she were pregnant as a product of her rape, she would need to travel out of state for termination. This was not something that she had the resources to do. She could not afford the time off work interstate travel would have required, and the waitlist for appointments in surrounding states was growing daily. Waiting was not an option for her. Carrying a pregnancy and raising a baby that was a product of rape from a random stranger was not an option for her. Josie sought out medication abortion before her sixth week.

[18] A version of Dr. Palmer's account was originally published on Medpage Today: Andrea Palmer, *Abortion Restrictions Rob Our Patients of Self-Determination*, MEDPAGE TODAY (2022), https://www.medpagetoday.com/opinion/second-opinions/98103 (last visited Feb 7, 2023).

[19] Patient names have been changed to protect their privacy.

> Josie barely had time to begin to process the trauma of her attack before she had to make an unwinnable, unfathomable choice. Her most precious dreams were stolen by a rapist, and her agency and options for self-determination were stolen by a legislature out to limit access to reproductive care without thought of the innumerable consequences they could not fathom, because they do not have to. Without access to mifepristone, more women may be forced to make unwinnable, unfathomable choices of their own.
>
> The millions of nuanced reasons that women seek and consider abortion, sometimes ending very desired pregnancies, should be considered. The decision about pregnancy should be left to women and the doctors who counsel them, care for them, cry with them, celebrate and mourn with them.

As Dr. Palmer describes, respect for patient autonomy requires respect for the right of patients to make the difficult and nuanced choice to obtain a medication abortion. An injunction withdrawing or suspending FDA approval of mifepristone would intrude into the patient-physician relationship and deny patients the ability to make autonomous medical choices.

III. CONCLUSION

For the foregoing reasons, DFA respectfully asks the Court to deny Plaintiffs' Motion for a Preliminary Injunction and to refrain from withdrawing or suspending FDA approval of mifepristone.

Dated: February 9, 2023

Respectfully submitted,[20]

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[20] Counsel thanks Columbia Law students Emily M. Davidson, Jae Hyun Lee, and Matthew R. Tracy for their many contributions to this brief and associated papers.

CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2023, the foregoing was electronically submitted to the Clerk of Court for the U.S. District Court for the Northern District of Texas using the Court's electronic case filing system in accordance with Local Rule 5.1(e). All counsel of record will be served via the Court's CM/ECF system and via email.

Dated: February 9, 2023

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,	§	
Plaintiffs,	§	
v.	§	CASE NO. 2:22-cv-00223-z
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	§	
Defendants.	§	

[PROPOSED] ORDER

Before the Court is Motion of Doctors for America for Leave to File a Brief as *Amicus Curiae* in Support of Defendants' Opposition for Temporary Injunction ("Motion") (ECF No. __), filed on February 9, 2023. The Court **GRANTS** the Motion and **ORDERS** that the brief be filed.

SO ORDERED.

February ___, 2023

_____
MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE