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 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

AMICUS **BRIEF FOR CONCERNED WOMEN FOR AMERICA IN SUPPORT OF PLAINTIFFS' COMPLAINT AND MOTION FOR PRELIMINARY INJUNCTION**

Amicus, Concerned Women for America (CWA) is the largest public policy organization for women in the nation with hundreds of thousands of members in all fifty states and thousands in the state of Texas. CWA women uphold the sanctity of every human life and want to defend and affirm the dignity and safety of every woman, including unborn women, in federal and state public policy laws. Contrary to the popular narrative, women are not a monolithic group represented by the most vocal pro-abortion supporters. The pro-life movement, representing millions of voices around the country, is led by women for women, and it is in that spirit, we respectfully present this brief in support of the Plaintiffs' Complaint (Doc. 1) and Motion for Preliminary Injunction (Doc. 6) for consideration before this honorable Court.

PUBLIC INTEREST CONSIDERATIONS WEIGH HEAVILY IN FAVOR OF PLAINTIFFS AND GRANTING OF MOTION FOR PRELIMINARY INJUNCTION

Public trust in our institutions is in a precarious state in our country. In the area of public health, especially, trust is essential to effective public policy. The success of a government agency's response to a public health challenge depends in no small part on citizens heeding and trusting the advice and regulations it receives from the experts entrusted with their welfare and safety. A May 2021 survey published by the Robert Wood Johnson Foundation and the Harvard T.H. Chan School of Public Health asked, "In terms of recommendations made to improve health, how much do you trust the recommendations of each of the following groups? Do you trust them a great deal, quite a lot, somewhat, not very much, or not at all for recommendations they make to improve health?" According to the report,

> Fewer than four in ten adults report ha[d] a great deal or quite a lot of trust in the National Institutes of Health (37%), the Food and Drug Administration (37%), the National Academy of Medicine (34%), and the federal Department of Health and

Human Services (33%), when it comes to recommendations made to improve health.[1]

The Court should consider this significant breakdown as it weighs the U.S. Food and Drug Administration's (FDA) numerous irregular actions in its approval of chemical abortion drugs as outlined in the Plaintiffs' Complaint. For comparison, the Center for Disease Control and Prevention (CDC) had a 52% approval rating in the same survey. Only four in ten Americans being confident of the information they receive from the FDA is a disastrous development, and it is decisions such as this one relating to the approval and promotion of chemical abortion drugs that appear to be driven by politics rather than scientific advancement that contribute to this state and further aggravate the distrust. It ultimately puts women's lives at greater risk.

To be sure, multiple factors contribute to these misgivings. Patrick Radden Keefe's book *Empire of Pain* chronicles the numerous breakdowns with the FDA's approval process of the dangerous drug OxyContin, for example.[2] More recently, the agency has been entangled in a scandal involving the approval of aducanumab, an unproven Alzheimer's drug it approved, even though "a council of senior agency officials resoundingly agreed that there wasn't enough evidence it worked."[3] The FDA's rush to approve dangerous drugs while under pressure from political activists and pharmaceutical manufacturers without proper supporting results from studies and trials, as we see in this case with the hasty approval of the mifepristone, misoprostol chemical abortion regimen, seems to be a common denominator.

By removing the most basic standards of care, as it increased the gestational age for which

[1] Robert Wood Johnson Foundation and the Harvard T.H. Chan School of Public Health, *The Public's Perspective on the United States Public Health System*, 5 (2021), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf.
[2] Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty* (2021).
[3] Pam Belluck, Sheila Kaplan and Rebecca Robbins, *How an Unproven Alzheimer's Drug Got Approved*, N.Y. Times, July 19, 2021, https://www.nytimes.com/2021/07/19/health/alzheimers-drug-aduhelm-fda.html.

a pregnant woman can take chemical abortion drugs, changed the dosage, significantly reduced the number of required in-person visits, and even allowed non-doctors to prescribe and administer chemical abortions, the FDA effectively introduced a "new drug" with significant heightened risks under 21 C.F.R. § 310.3(h)(5). Moreover, it approved it despite the fact that there are no clinical studies of the adverse effects of using these chemical abortion drugs under this riskier recommended regimen. Worse yet, the FDA also eliminated the requirement to report nonfatal adverse effects of these drugs. The lack of interest and regard for women's safety should be scrutinized. Not only was the data not available for a proper risk assessment before the drug was put on the market under this new regimen, but now the FDA is hindering the collection of crucial data after the fact. This is highly concerning as a matter of public interest.

The current FDA-approved regimen is especially troubling to *amicus* as a women's organization seeking to empower the next generation through CWA's Young Women for America chapters. The lack of FDA guidelines or interest in the research of the effects of this heightened regimen on young women is also a worrisome aspect in terms of the public's general welfare that warrants the Court's attention. The women we represent respectfully submit that this weighs heavily in favor of stopping the rush to promote these chemicals using accelerated methods that shortchange women and girls. Recently the U.S. Department of Justice has come out encouraging the distribution of chemical abortion through the U.S. Mail in a troubling legal opinion by the Office of Legal Counsel applying the Comstock Act to the mailing of chemical abortion drugs.[4] No one knows the full ramifications of such a radical expansion of chemical abortion health policy. A proper assessment has not been made by the FDA, especially for young women.

[4] *See* Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. (Dec. 23, 2022), https://www.justice.gov/olc/opinion/file/1560596/download.

The public deserve better than the current rush to experiment with chemical abortions on American women. The charge the public has placed on the FDA should be guarded in law to protect the public trust that is crucial to the proper function of our public institutions. Scientific advancement and research are not driving chemical abortion policy. Politics drives it. An apparent effort to undermine the United State Supreme Court's recent acknowledgment that there is no constitutional right to an abortion is driving it.[5] The U.S. Supreme Court's determination in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), has allowed states to enact laws protecting the unborn at different stages of development. The Biden Administration and its supporters do not like that and have therefore been aggressively pushing to promulgate abortifacients to circumvent these duly enacted state laws. Lost in that urge though are the seriously increased risks for women utilizing these drugs under waning supervision.

PUBLIC INTEREST DEMANDS THE FDA, NOT WOMEN, BEAR THE BURDEN OF ENSURING THE SAFETY OF CHEMICAL ABORTION DRUGS

Any reasonable person reading the Mifeprex' (mifepristone) approved labels would be alarmed at the risks associated with using this drug. It is scary for women to go through this without the continuous involvement of a doctor. Yet this is precisely what is being promoted. It is unreasonable for the FDA to shift the burden that comes with chemical abortion drugs unto individual pregnant women without proper evidence and protocols ensuring their safety. With minimal consultation, the FDA wants women, who are often in distress, to bear the burden of the serious risks that come with the use of a dangerous drug when, as the agency itself has acknowledged:

> Nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such

[5] *See* E.O. No. 14076, 87 Fed. Reg. 42053 (Jul 8, 2022), https://www.whitehouse.gov/briefing-room/presidential-actions/2022/07/08/executive-order-on-protecting-access-to-reproductive-healthcare-services/.

reaction. About 90% of patients report adverse reactions following administration of misoprostol on day three of the treatment procedure.[6]

With just one consultation over the web or phone, women are supposed to handle the possible severe adverse reactions, which include cramping, heavy bleeding, and severe pain. Other common side effects acknowledged in the drug's label are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.[7] A woman researching this procedure will find the following description on the reputable Mayo Clinic's website:

> Potential risks of medical abortion include:
>
> - Incomplete abortion, which may need to be followed by surgical abortion
> - An ongoing pregnancy if the procedure doesn't work
> - Heavy and prolonged bleeding
> - Infection
> - Fever
> - Digestive system discomfort
>
> If you decide to continue the pregnancy after taking medicine used in medical abortion, your pregnancy may be at risk of major complications.[8]

The Mayo Clinic's explanation of the procedure understandably states:

> Before a medical abortion, your health care provider will likely:
>
> - Evaluate your medical history and overall health
> - Confirm your pregnancy with a physical exam
> - Do an ultrasound exam to date the pregnancy and check that it's not outside the uterus (ectopic pregnancy) and not a tumor that developed in the uterus (molar pregnancy)
> - Do blood and urine tests
> - Explain how the procedure works, the side effects, and possible risks and

[6] *See* MIFEPREX™ (mifepristone) Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm; Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, 30 (2006), http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.
[7] *See* MIFEPREX™ (mifepristone) Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[8] Medical Abortion About Page, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (last visited Feb. 10, 2023).

complications.[9]

That, of course, would be more than reasonable given the seriousness of the chemical abortion procedure approved by the FDA, as we have discussed. But the reality is that the FDA has removed the safeguards it once required when it first approved these drugs. Things like doctor involvement that could verify gestational age, or rule out an ectopic pregnancy, or even make sure no remaining fetal parts endure after the procedure. The drugs have not changed. The risks have not changed. The only thing that has changed is the administrative political climate.

CONCLUSION

The Court should grant Plaintiffs' Motion for Preliminary Injunction. Such intervention on behalf of women is necessary and legally justified in this case. Rather than making an ultimate determination as to the risks and safety associated with these drugs, the Court would be holding the FDA to the high standards of care required by law and acting in the public's best interest. The burden should be on the FDA. It should be directed to go through the full process of ensuring the safety of women using these drugs before it releases and significantly expands their availability to the public. It should be required to conduct proper trials instead of shifting the testing burden to American women.

Respectfully submitted, this 10th day of February 2023.

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[9] *Id.*

CERTIFICATE OF SERVICE

I certify that this document will be served on all defendants via ECF and via first class United States mail and email to:

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On this 10th day of February 2023

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