UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*

Defendants.

Case No. 6:25-cv-01491-DCJ-DJA

Judge David C. Joseph

Magistrate Judge David J. Ayo

AMICUS BRIEF FOR CONCERNED WOMEN FOR AMERICA IN SUPPORT OF PLAINTIFFS' COMPLAINT AND THEIR MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705

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STATEMENT OF INTEREST

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 50 states and thousands in the state of Louisiana, under the leadership of CWA of Louisiana state director Laura Huber. 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 that we respectfully present this brief in support of the Plaintiffs' Complaint (Doc. 1) and Motion for Preliminary Relief (Doc. 20-26) for consideration before this honorable Court.

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

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 issued by 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]

A 2025 poll by the health nonprofit KFF found just 32% have "confidence in [agencies like the CDC and FDA] to act independently without interference from outside interests," and 34% saying the government "agencies are paying 'too much attention' to the beliefs of officials running the agencies."[2]

The Court should consider this significant breakdown in public trust 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. Only four in ten Americans being confident in the information they receive from the FDA is a disastrous development. 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.[3] Later on, the agency was 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

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[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] Alex Montero, Grace Sparks, Julian Montalvo III, Ashley Kirzinger, and Liz Hamel, *KFF Tracking Poll on Health Information and Trust: Vaccine Safety and Trust* (May 6, 2025), https://www.kff.org/health-information-trust/kff-tracking-poll-on-health-information-and-trust-vaccine-safety-and-trust/.
[3] Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty* (2021).

worked."[4] 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 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 on the effects of this heightened regimen on young women is also a worrisome aspect of public health 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

[4] 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.

and girls. Encouraging the distribution of chemical abortion through the U.S. Mail, in violation of the Comstock Act, and with some pro-abortion states seeking to shield those who distribute it from liability, is a troubling development.[5] No one knows the full ramifications of such a radical expansion of chemical abortion health policy. The FDA has not conducted a proper assessment, especially for young women.

The public deserves better than the current rush to experiment with chemical abortions on American women. The charge the public has placed on the FDA should be safeguarded by law to protect the public trust, which is crucial to the proper functioning of our public institutions. Scientific advancement and research are not driving chemical abortion policy. Politics has driven it, as laid out in the Plaintiffs' complaint, in an apparent effort to undermine the United States Supreme Court's strong acknowledgment that there is no constitutional right to an abortion.[6] 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 pro-abortion states do not like that and have therefore set out to aggressively push 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

[5] *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.
[6] *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/.

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 onto 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 reaction. About 90% of patients report adverse reactions following administration of misoprostol on day three of the treatment procedure.[7]

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.[8] A woman researching this procedure will find the following description on the reputable Mayo Clinic's website:

> Potential risks of medical abortion include:
>
> - The body not releasing all pregnancy tissue in the uterus, also called an incomplete abortion. This may require surgical abortion.
> - An ongoing pregnancy if the procedure doesn't work
> - Heavy and prolonged bleeding
> - Infection
> - Fever
> - Digestive system discomfort
>
> It's also risky to change your mind and choose to continue a pregnancy after

[7] *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.

[8] *See* MIFEPREX™ (mifepristone) Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

> taking medicine used in medical abortion. This raises the chances of having serious complications with the pregnancy.[9]

But the Mayo Clinic's explanation has also evolved following new FDA guidelines, and its changes are revealing. Back in February of 2023, those visiting the website would have seen this explanation of what your healthcare provider would do before the exam:

> 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 complications.[10]

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 today's explanation reflects the impersonal nature of the current regime:

> Before a medical abortion, your healthcare professional reviews your medical history. The healthcare professional also talks with you about how the procedure works, the side effects, and the risks and possible complications. These steps take place whether you have an in-person healthcare appointment or meet with a healthcare professional online.[11]

And, of course, with the FDA's removal of the common sense safeguards it once required when it first approved these drugs, we know a woman can obtain drugs through the mail, with

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[9] Medical Abortion About Page, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (last visited Feb. 12, 2026).
[10] Wayback Machine capture of Medical Abortion About Page, Mayo Clinic, (Feb. 27, 2023), https://web.archive.org/web/20230215232559/https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687.
[11] Medical Abortion About Page, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (last visited Feb. 12, 2026).

merely email communications. No longer are women protected through guidelines requiring doctor involvement that could verify gestational age, or rule out an ectopic pregnancy, or even ensure no remaining fetal parts endure after the procedure. The drugs have not changed. The risks have not changed. The only thing that changed were the political motivations.

CONCLUSION

The Court should grant Plaintiffs' Motion for Preliminary Relief. 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 rather than shifting the testing burden onto American women.

Respectfully submitted, this 13th day of February 2026.

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LOCAL RULE 5.7.09 CERTIFICATION

Pursuant to Local Rule 5.7.09, no certificate of service is required for this document because all parties are electronic filers and will receive notification through the Court's electronic filing system.

On this 13th day of February 2026

By: /s/ Ben E. Clayton
Ben E. Clayton