UNITED STATES DISTRICT COURT
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.	)	

BRIEF OF THE STATE OF MISSOURI AS AMICUS CURIAE IN SUPPORT OF A PRELIMINARY INJUNCTION

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February 10, 2023

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INTEREST OF AMICUS CURIAE AND INTRODUCTION

Missouri has a strong interest in this litigation because the FDA's decision to disregard the requirements of 18 U.S.C. §§ 1461–62 and create a regime of abortion by mail imposes harms that necessarily spill over into Missouri, impeding the operation of state law and drastically increasing the risks faced by Missouri women.[1]

Missouri agrees with the analysis in the briefs filed by the State of Mississippi and the Alliance for Hippocratic Medicine. Missouri writes separately to inform the Court of specific facts Missouri recently uncovered in litigation. These facts highlight the extraordinary harms the FDA policy will impose on women across the country.

Before 2022, Missouri was one of the only states to successfully defend laws requiring abortionists[2] to undertake safety measures like maintaining admitting privileges at a nearby hospital and maintaining referral agreements with other physicians. *See Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016); *June Med. Servs., LLC v. Russo*, 591 U.S. ____ (2020). During that litigation, Missouri discovered distressing facts that reveal how distributors of abortion drugs have systemically imposed heightened risks on women.

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[1] No counsel for a party in this case authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation of this brief. No person other than amicus curiae made a monetary contribution to the preparation or submission of this brief.

[2] There is no universally agreed-upon term: "abortionist," "abortion provider," or something else. So this brief follows the convention, recently established by the Supreme Court and followed by courts of appeals, including the Fifth Circuit, of using the shorter term. *See Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2236, 2250, 2254 (2022); *E.T. v. Paxton*, 41 F.4th 709, 721 (5th Cir. 2022); *SisterSong Women of Color Reprod. Just. Collective v. Governor of Georgia*, 40 F.4th 1320, 1323–28 (11th Cir. 2022) (21 uses).

First, Missouri discovered that abortionists routinely violate the medical standard of care. In gynecological settings, the standard of care requires practitioners to prearrange for a physician to be available to treat a woman if she experiences post-procedure complications. Abortionists—not just in Missouri, but across the nation—neglect this basic duty. This neglect drastically increases the risks women face from chemical-induced abortions. And it does so in ways hard to capture by statistics.

Second, in Missouri's litigation, abortionists admitted under oath that they have long flouted their legal duty to report complications. The medical literature relies on reports about complications to study the risks of chemical-induced abortions. Because abortionists routinely fail to report complications, the authors of medical studies lack knowledge of potentially hundreds of thousands of complications.

Chemical-induced abortions already are widely known to be much riskier than surgical abortions. Missouri's experience reveals that even these higher risks are understated. This Court should keep that in mind when assessing whether the FDA's decisions were lawful.

ARGUMENT

Between 2016 and 2019, Missouri successfully defended two lawsuits brought by plaintiffs who challenged two Missouri laws intended to mitigate the harms women face from chemical-induced abortions. The laws required (1) that abortionists arrange for a physician to always be available to treat complications caused by abortion drugs, and (2) that abortionists obtain admitting privileges at a nearby

hospital. *Comprehensive Health of Planned Parenthood Great Plains v. Williams*, No. 2:17-cv-04207 (W.D. Mo. 2017); *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, No. 2:16-cv-04313 (W.D. Mo. 2016). During that litigation, Missouri uncovered distressing facts about how abortionists tend to distribute abortion drugs. Specifically, Missouri discovered,

> (1) Across the country, abortionists routinely violate the medical standard of care when issuing abortion drugs, thus increasing the risks faced by women, and
>
> (2) The medical literature substantially understates the true risk from abortion drugs because abortionists systemically fail to report complications.

I. Across the nation, those who dispense abortion drugs systemically violate the medical standard of care, thus placing women at much higher risk of harm.

1. Sworn testimony from abortionists in 2018 revealed the first distressing fact: Persons across America who distribute abortion drugs routinely depart from the medical standard of care.

When a physician agrees to perform an elective gynecological procedure, the physician becomes responsible for that patient "throughout the course of that care." Mo. App. 4 (physician affidavit).[3] The standard of care requires more than just performing the gynecological procedure; it also means being ready and willing to treat a patient if she experiences post-procedure complications. *Id.* A physician who cannot treat a patient personally must arrange for another to do so. Where a procedure can involve delayed complications, "being available or having established

[3] Williams Decl., Doc. 141-2, No. 2:16-cv-04313 (W.D. Mo. 2018). Documents from Missouri's litigation also appear in an appendix filed with this brief.

an on-call relationship with similarly trained physicians is certainly standard care and practiced by physicians throughout the United States every day." *Id.* at 5.

At least when it comes to every other gynecological procedure, abortionists agree with this standard. Daniel Grossman, a California abortionist who presented testimony in 2018, conceded that the standard of care in every other elective gynecological context includes arranging for backup physicians if there is a risk of complications. Indeed, when asked under oath whether, other than abortion, he was "aware of any circumstances where that doesn't happen as a routine matter," he admitted that it was "hard to think of another scenario." *Id.* at 20.[4]

But when it comes to chemically induced abortion, these physicians create an ad hoc exception. They do not ensure that women can access a physician who can treat complications. They leave women to fend for themselves. And the problem is not unique to Missouri. No doubt some abortionists comply with the medical standard of care, but in Missouri's litigation, an out-of-state abortionist conceded that abortionists across the nation routinely do not. *See id.*

2. This systemic neglect of the medical standard of care puts women who obtain abortion drugs at substantially heightened risk.

First, when abortionists fail to prearrange care, a woman experiencing serious complications is usually forced to see a physician who knows nothing about what is causing her emergency. Unlike women who obtain surgical abortions, women who have obtained chemically induced abortions experience most complications at home,

[4] Grossman Dep., Doc. 91-18, No. 2:17-cv-04207 (W.D. Mo. 2018).

away from medical help. Some may be too embarrassed to tell a stranger that they are in the emergency room because of an abortion. Unless the treating physician has a prearranged relationship with the abortionist, the treating physician often will not learn the cause of the emergency. That impedes proper care and makes it impossible for treating physicians to accurately report the abortion complications they treat.

Abortionists in Missouri made it especially difficult for treating physicians. One doctor who treated post-abortion complications in St. Louis for 13 years testified that no abortionist in the area *ever* informed him that the cause of his patient's emergency was an abortion. *Id.* at 26.[5] On his own initiative, this physician tried to contact abortionists about necessary patient information, but they would not speak with him. *Id.* at 26. Missouri has no reason to believe that that the experience for treating physicians in other states has been different.

Second, even when the treating physician knows that the patient's emergency condition is due to abortion, the physician typically is not adequately trained to handle those complications. In 2018, abortionists in Missouri conceded that emergency room doctors generally are not trained to address abortion complications. *Id.* at 45.[6] David Eisenberg, then an abortionist in Missouri, admitted that women "fairly often" receive unnecessary medical interventions when seeking care for abortion complications in emergency rooms. *Id.* at 55.[7] In his words, "when a patient shows up to another hospital that isn't familiar with the care of abortion patients,

[5] Steele Decl., Doc. 28-4, No. 2:16-cv-04313 (W.D. Mo. 2017).
[6] Tr. Prelim. Inj. Hr'g., Doc. 115, No. 2:17-cv-04207 (W.D. Mo. 2018).
[7] Eisenberg Dep., Doc. 122-1, No. 2:17-cv-04207 (W.D. Mo. 2018).

they may get more interventions than are necessary." *Id.* These needless interventions spur yet greater possibilities of complications. At least in Missouri's experience, abortionists have systemically subjected women to this heightened risk by refusing to abide by the medical standard of care.

Outside Missouri, the problem is even worse. The American College of Obstetricians and Gynecologists says that clinicians who distribute abortion drugs should, at the very minimum, be "trained in surgical abortion or should be able to refer to a physician trained in surgical abortion." *Id.* at 37–38.[8] That is because a common complication from abortion drugs is an incomplete abortion, where the child dies but is not fully expelled. That complication often requires an aspiration procedure performed just like a surgical abortion. But some states allow non-physicians to distribute abortion drugs. These persons neither are "trained in surgical abortion" nor have a referral relationship with a physician. In these states, women fall into a catch-22: If they go to an emergency room, nobody may be available who is adequately trained. And if they go to the non-physician who gave them chemical abortion drugs, that person typically will be unable to assist and will not have prearranged a relationship with an OB-GYN.

3. In the narrow circumstances where abortion is permitted in Missouri (*i.e.*, to save the life of the mother), state law ensures that women benefit from the medical standard of continuous care. Missouri law does this both by requiring in-person administration of abortion drugs and by requiring physicians who perform abortions

[8] Tr. Prelim. Inj. Hr'g., Doc. 115, No. 2:17-cv-04207 (W.D. Mo. 2018).

to prearrange for backup physicians to address complications if needed. Mo. Rev. Stat. § 188.021.1–2; 19 C.S.R. 10-15.050. The in-person dispensing requirement ensures that physicians "shall make all reasonable efforts" to ensure patient follow-up, decreasing the chance that a woman will find herself in an emergency room with a doctor who has no idea what happened. Mo. Rev. Stat. § 188.021.1. Other states have similar requirements. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 467 F. Supp. 3d 282, 286–87 (D. Md. 2020) (collecting laws from nine states, including Missouri).

The FDA policy harms women because it does the opposite. By purporting to create a nationwide license to distribute chemical abortion drugs by mail, the FDA threatens to permanently sever women from the physician relationships that are critical to properly resolve complications that inevitably occur. The FDA's new rule not only violates 18 U.S.C. § 1461, as the plaintiffs correctly contend. But it is also unlawful because it fails to consider how eviscerating the medical standard of care will harm women.

The FDA policy similarly fails to seriously assess the increased risk of coerced abortion created by the FDA's abortion-by-mail regime. Last year, people across the state and nation were saddened to hear that a sitting congresswoman was coerced into obtaining an abortion. *See Firing Line: Cori Bush* (PBS Oct. 7, 2022).[9] Sadly, that horror is guaranteed to increase under the FDA's abortion-by-mail plan. The ready availability of abortions by mail means that abusive boyfriends or others will

[9] https://www.pbs.org/video/cori-bush-fzpcjd.

more easily be able to coerce women (by force, pressure, or deception) to obtain abortions.

II. Abortionists systemically underreport complications from abortion drugs, artificially making those drugs appear less risky.

According to the medical literature consensus, chemically induced abortions have much greater complication rates than surgical abortions. Somewhere between 5% and 20% of women who obtain a chemically induced abortion experience complications. Mo. App. 11 (physician affidavit).[10] That is substantially worse than for aspiration abortions. "Medication abortions were 5.96 times as likely to result in a complication as first-trimester aspiration abortions." Ushma D. Upadhyay, et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (Jan. 2015) (parenthetical omitted).[11] These numbers in fact *understate* the true risks from abortion drugs because—as the medical literature recognizes—many women never report their complications. *Id.* at 175 ("[C]omplication rates are underestimated by low follow-up rates.").

In litigation, Missouri discovered a second reason why the medical literature underestimates the complication rates: Abortionists systemically violate their duty to report these complications. For at least 15 years, abortionists in Missouri violated a law requiring them to report complications to the state. In sworn testimony, Eisenberg admitted that he and other abortionists at his St. Louis clinic refused to file these reports even though they *knew* about the state law requiring the reports.

[10] Williams Decl., Doc. 141-2, No. 2:16-cv-04313 (W.D. Mo. 2018).

[11] https://www.ansirh.org/sites/default/files/publications/files/upadhyay-jan15-incidence_of_emergency_department_visits.pdf.

They refused because they did not expect the state to enforce the law. Mo. App. 57.[12] Colleen McNicholas, another person who until recently performed abortions in Missouri, likewise admitted under oath that she violated this law for years. *Id.* at 41.[13]

There is no reason to think that this systemic failure to file lawfully required complication reports is limited to Missouri. Those who performed abortions in Missouri also perform them elsewhere. Indeed, Eisenberg admitted he did not file these reports at "other healthcare facilities" where he worked. *Id.* at 57.[14] And a recent news story describes McNicholas as an abortionist who "zig-zags across the Midwest," performing abortions in many different states. *On the Front Lines of the Abortion Wars*, Marie Claire (Oct. 12, 2021).[15]

McNicholas in particular has a pattern of not complying with state law. In September 2018, health inspectors were forced to shut down her clinic in Columbia, Missouri, because she had been inserting moldy equipment into women's wombs for months. The equipment contained a substance that her staff said was "most likely bodily fluid," as well as a separate "blackish gray substance" that McNicholas' staff identified as mold. Mo. App. 63.[16] A picture is included in the appendix to this amicus brief. *Id.* at 1. McNicholas' staff admitted that they had "identified the problem" of

[12] Eisenberg Dep., Doc. 141-4, No. 2:16-cv-04313 (W.D. Mo. 2018).
[13] Tr. Prelim. Inj. Hr'g., Doc. 115, No. 2:17-cv-04207 (W.D. Mo. 2018).
[14] Eisenberg Dep., Doc. 141-4, No. 2:16-cv-04313 (W.D. Mo. 2018).
[15] https://www.marieclaire.com/culture/a20565/mission-critical-abortion-rights-midwest/.
[16] Statement of Deficiencies, Doc. 141-1, No. 2:16-cv-04313 (W.D. Mo. 2018).

mold "a couple of months previously" but that they had "*continued* to use the machine on patients *after* they identified the issue." *Id.* at 63–64 (emphasis added) (parenthetical omitted).[17]

Given the persistent violation of the law by abortionists in Missouri—and almost assuredly elsewhere—it is highly likely that the actual complication rate from abortion drugs is much higher than the rate printed in established medical literature.

CONCLUSION

What Missouri discovered provides at least two further reasons that support a preliminary injunction.

First, chemical-induced abortions are much riskier than surgical abortions. This fact is well known in the literature, but Missouri learned that the risks are in fact higher than reported because abortionists systemically fail to comply with the medical standard of care. This failure both increases the risks faced by women and makes it difficult or impossible to track complications. And the FDA's approval of abortion by mail only makes this problem worse because it eviscerates the medical standard of continuous care across the country. The plaintiffs are therefore correct to argue that the FDA failed to establish that abortion drugs "provide meaningful therapeutic benefit" compared to surgical abortion. *See* Doc. 7 at 21; 21 C.F.R. § 314.500. Because abortion drugs are far riskier (and their full risks are unknown), they do not provide any meaningful therapeutic benefit.

[17] This egregious violation is just the tip of the iceberg. As Missouri has elsewhere documented, abortion clinics in Missouri have a lengthy record of health and safety violations in the last decade alone. Mo. App. 87–92.

Second, "there is a lack of substantial information that the drugs will have the effect they purport." Doc. 7 at 27. Missouri's litigation revealed that providers of abortion drugs systemically underreport—or entirely fail to report—complications arising from abortion drugs. The full extent of risks women face from chemically induced abortions thus is not sufficiently understood. And again, the FDA's approval of abortion by mail makes this problem worse.

This Court should consider this context when determining whether the FDA's decision to eviscerate the medical standard of continuous care—by purporting to allow abortions by mail—was arbitrary and capricious or otherwise unlawful.

For the reasons stated in this brief, the plaintiffs' brief, and the brief by the State of Mississippi, the Court should grant a preliminary injunction.

Dated: February 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 10, 2023, a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) and served on all counsel of record.

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