No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Plaintiffs-Appellees,
v.
U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendants-Appellants

On Appeal from the United States District Court
for the Northern District of Texas, No. 2:22-cv-00223-Z

BRIEF OF THE STATE OF MISSOURI AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

Under this Court's Rule 28.2.1 and Federal Rules of Appellate Procedure 26.1(a) and 29(a)(4)(A), governmental parties are not required to supply a certificate of interested persons.

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INTEREST OF AMICUS CURIAE, INTRODUCTION, AND SUMMARY OF ARGUMENT

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's abortion-by-mail policy would 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

[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. Plaintiffs and Defendants consented to the filing 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 this Court, of using the shorter term. *See Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2236, 2250,

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 abortion-drug distributors have systemically imposed heightened risks on women and how the FDA's intended abortion-by-mail regime would worsen those risks.

First, Missouri discovered that abortionists routinely violate the medical standard of care when distributing abortion drugs. 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

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).

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 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 reviewing the district court's order and assessing the FDA's request to reverse that order.

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

[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 in the district court. Because of this Court's Local Rule 31.1, the appendix is not attached to this brief, but it is available on the district court docket as Doc. 48-3 and at this URL: https://ago.mo.gov/docs/default-source/press-releases/2020-02-10-brief-of-the-state-of-missouri-and-appendix.pdf#page=18.

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 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 chemical-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

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

themselves. As an out-of-state abortionist admitted, this problem is not unique to Missouri. *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 chemical-induced abortions experience most complications at home, 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.

For example, 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 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, they may get more interventions than are necessary." *Id.* These needless interventions spur yet greater possibilities of complications.

Outside Missouri, the problem is even worse. The American

[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).

College of Obstetricians and Gynecologists says that clinicians distributing abortion drugs should, at a 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

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

drugs and by requiring physicians who perform abortions 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).

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 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 district court determined, but also 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 Missouri congresswoman was coerced into obtaining an abortion. *See Firing Line: Cori Bush* (PBS Oct. 7, 2022).[9] The ready availability of abortions by mail means that abusive boyfriends or others will 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.

The medical consensus holds that chemical-induced abortions have greater complication rates than surgical abortions. Somewhere between 5% and 20% of women who obtain a chemical-induced abortion experience complications. Mo. App. 11 (physician affidavit).[10] "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] The literature in fact *understates* the true risks from abortion drugs because—as the medical literature

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

[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.

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 in Missouri systemically violated 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. They refused because they did not expect the state to enforce the law. Mo. App. 57.[12] Colleen McNicholas, 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

[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).

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" McNicholas' staff identified as mold. Mo. App. 63.[16] A picture is included in the appendix to this amicus brief. *Id.* at 1.[17] McNicholas' staff admitted that they had "identified the problem" of 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).[18]

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[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).

[17] https://ago.mo.gov/docs/default-source/press-releases/2020-02-10-brief-of-the-state-of-missouri-and-appendix.pdf#page=18.

[18] This egregious violation is just the tip of the iceberg. As Missouri has

Given the persistent violation of the law by abortionists in Missouri—and almost assuredly elsewhere—it is 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 to affirm the district court's order.

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 increases the risks faced by women and makes it impossible to track complications. The FDA's abortion-by-mail regime only makes this problem worse because it eviscerates the medical standard of continuous care across the country.

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

elsewhere documented, abortion clinics in Missouri have a lengthy record of health and safety violations in the last decade alone. Mo. App. 87–92.

entirely fail to report—complications arising from abortion drugs. The full extent of risks women face from chemical-induced abortions thus is not sufficiently understood. Again, the FDA's abortion-by-mail regime exacerbates this problem.

The Court should affirm the district court's order.

Dated: May 12, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Joshua M. Divine, hereby certify that the foregoing brief has been filed with the Clerk of Court using the Court's electronic filing system, which sent notification of such filing to all counsel of record.

Dated: May 12, 2023

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CERTIFICATE OF COMPLIANCE

This brief complies with the word limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B)(i) because, excluding the parts of the document exempted by Fed. R. App. P. 32, it contains 2,581 words. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in proportionally spaced typeface, including serifs, using Microsoft Word 2016, in Century Schoolbook 14-point font, except for footnotes, which have been prepared the same way except in 12-point font.

Dated: May 12, 2023

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No. 23-10362 Alliance Hippocratic Medicine v. FDA
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