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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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.

/s/ Joshua M. Divine
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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
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APPENDIX TO BRIEF OF THE STATE OF MISSOURI AS AMICUS CURIAE IN SUPPORT OF PRELIMINARY INJUNCTION

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

Comprehensive Health of Planned Parenthood Great Plains, et al. Plaintiffs, v. Joshua D. Hawley, in his official capacity as Attorney General of Missouri, et al. Defendants.	)	Case No. 2:16-cv-04313-BCW

Declaration of Randall W. Williams, MD, FACOG

1. I have been certified by the American Board of Obstetrics and Gynecology as an obstetrician/gynecologist since December 1991. I have been a fellow of the American College of Obstetrics and Gynecology ("ACOG") since December 1991. I practiced obstetrics and gynecology from 1989 until 2001, and gynecology from 2001 until 2015. I am licensed in North Carolina and Missouri, and I am a member of the Missouri State Medical Association and the North Carolina Medical Association.
2. I attended the University of North Carolina at Chapel Hill where I graduated with honors. I was a Holderness Fellow at the University of North Carolina School of Medicine, and I served as Administrative Chief Resident in Obstetrics and Gynecology at the University of North Carolina.
3. From 1993 until 1996, I served on the Wake County Board of Public Health in North Carolina. From 2004 until 2012, I served on the North Carolina Public Health Commission.

4. I have been deemed an expert witness by courts in trials in multiple states regarding the standard of care and causation involving obstetrics and gynecology. I have reviewed cases for the North Carolina Medical Board, hospitals, attorneys, and insurance companies many times since 1991 regarding the standard of care for obstetricians and gynecologists.
5. I have served overseas working with and teaching obstetricians and gynecologists, including teaching complications of laparoscopy, hysteroscopy, and dilatation and curettage in Iraq, since 2004.
6. In July 2015, I became Deputy Secretary of Health and Human Services in North Carolina, and in the fall of 2015, I became State Health Director for North Carolina. As State Health Director, I helped launch a five-year Perinatal Health Strategic Plan and served on the Maternal Mortality Review Committee.
7. In January 2017, I was appointed director of the Missouri Department of Health and Senior Services ("Department") by Governor Eric Greitens. I was confirmed unanimously to this cabinet position by the Missouri Senate in March 2017.
8. In my role as director of the Department, I lead an agency of approximately 1,750 employees with a budget of $1.4 billion. Within the Department is the Division of Regulation and Licensure, Section for Health Standards and Licensure, Bureau of Ambulatory Care, which oversees abortion facilities in Missouri.
9. My affidavit is based on my training, my clinical experience, my experience testifying to the standard of care and causation, and my review of peer-reviewed literature. I cite this literature as a board-certified obstetrician who performed surgery and delivered babies

during my clinical career, and who has experience implementing public policy to protect the public's health.

10. A true and correct copy of my curriculum vitae is attached to this affidavit as Exhibit A.

11. Physicians who agree to help patients by performing elective procedures take on a duty to care for those patients throughout the course of that care. According to Upadhyay, et al., in *Incidence of Emergency Department Visits and Complications After Abortion*, "Among all abortions (N = 54,911), 1,156 (2.1%, 95% CI 1.99 – 2.23) resulted in an abortion-related complication diagnosed or treated at any source of care, including EDs and the original abortion facility."[1]

12. After surgical abortions, some complications will be immediate and will require emergency transfer to a hospital from the abortion facility for emergency care. Some complications, both immediate and delayed, will be life-threatening and require hospitalization and/or surgical procedures in a time-sensitive manner. Patient safety is most at risk at the time of complications. Having a physician who can follow the patient from the abortion facility to a nearby hospital where the physician has privileges and can provide the life-saving treatment commonly associated with the usual major complications or timely treatment of other complications is part of the responsibility a physician undertakes when he or she agrees to provide that patient's elective care.

13. Immediate, major complications are more commonly associated with surgical abortions, especially second trimester abortions. As ACOG Practice Bulletin Number 143, *Medical Management of First Trimester Abortion* points out, surgical abortion is usually

[1]Upadhyay, Ushma D., PhD, MPH; Desai, Sheila, MPH; Zlidar, Vera, MHS; et al. Incidence of Emergency Department Visits and Complication After Abortion. Obstetrics and Gynecology. Vol. 125, No. 1, January 2015. Page 181.

completed in a predictable period of time under medical supervision, does not require follow up in most cases, and patient participation is in a single-step process.[2] When the physician performing the abortion has privileges at a nearby hospital, this provides continuity of care from that physician to whom the patient has entrusted her care, with whom she has an ongoing relationship, and who knows her best. The physician can accompany her to the hospital and be there for her with his or her expertise to immediately treat her complication. As has been said, as long as you have time, you will have opportunity to help a person, but sometimes you only have an immediate opportunity to help a person and not the luxury of time before their condition deteriorates, such as acute hemorrhage from uterine perforation or arterial laceration.

14. For delayed complications, which are associated with medical as well as surgical abortions, having hospital privileges and being available or having an established an on-call relationship with similarly trained physicians is certainly standard care and practiced by physicians throughout the United States every day in many different specialties as part of their ongoing care of patients. Medical abortion takes days to weeks to complete, has bleeding commonly not perceived as light, is unsuccessful approximately 5% of the time, requires follow-up and patient participation through a multi-step process, has higher reported rates of bleeding and cramping, and has expulsion of products of conception at home.[3] For these reasons, to ensure patient safety, a complication plan for medical abortions should provide for ongoing care of the patient, who is expected to have a higher rate of ongoing complications.

[2]ACOG Practice Bulletin No. 143, Medical Management of First-Trimester Abortion, March 2014 (Reaffirmed 2016), page 3, Box 1.
[3]ACOG Practice Bulletin No. 143, Medical Management of First-Trimester Abortion, March 2014 (Reaffirmed 2016), page 3.

15. While delayed complications cannot be predicted, the need to prearrange quality care can. As I have testified before, to argue that women receiving abortions should receive substandard care because standard care is preempted by lack of providers, scheduling issues, or distance of providers, is not consistent with patient safety. If there were a physician shortage due to absence or illness, we would not accept physicians not following sterile technique in the operating room because they were too busy to scrub. And we should not accept substandard care for women having abortions.

16. Some of the possible complications of abortion include: inability to dilate the cervix, inability to complete the abortion, uterine perforation, anaphylaxis, seizure, and embolism. The timing of each of these complications is immediate (although uterine perforation may not be recognized until later), and uterine perforation, anaphylaxis, and embolism are potentially life-threatening.[4] Because these complications occur immediately and can be life-threatening, it is imperative that the physician performing the abortion have hospital privileges so that he or she can follow the patient to the hospital and treat her complication. The attached table (Exhibit B) provides a sense of the seriousness of complications.[5]

17. Possible complications of abortion also include: cervical laceration, disseminated intravascular coagulation, uterine atony, hematometra, failed abortion, ectopic pregnancy, endometritis, incomplete abortion, postabortal triad, and septic incomplete abortion. Cervical laceration, ectopic pregnancy, and septic incomplete abortion are potentially

[4]Pearlman, Mark D.; Tintinalli, Judith E.; Dyne, Pamela L. Obstetric & Gynecologic Emergencies: Diagnosis and Management, McGraw-Hill, 2004, Table 6-2, page 70.
[5]Pearlman, Table 6-2, page 70.

life-threatening.[6] Either the physician who performed the abortion, or an on-call physician with whom he or she has a prior arrangement, should be available and have hospital privileges to treat the patient's complication. It is standard care in medicine, and post-abortion care should be no different.

18. As Upadhyay, et al., have stated, "With 1.1 million induced abortions in the United States each year, accurate estimates of abortion complications are paramount to assess and improve quality of care and determine how public policies can most effectively safeguard women's health."[7] As I have testified in another case, complications from abortions are undoubtedly under-reported. By way of illustration, since 1979, Missouri law has required abortion providers and those who treat abortion complications to report every complication to the Department of Health and Senior Services. For many years prior to my arrival at the Department, this law was not complied with in that virtually no complications were reported. As soon as I became aware of this problem, I immediately informed the public and took steps to ensure compliance going forward.[8]

19. In the textbook *Comprehensive Gynecology*, Dr. William Droegemueller, chair of the Department of Obstetrics and Gynecology at the University of North Carolina at Chapel Hill while I attended, member of ACOG, and member of the Board of Directors of the American Board of Obstetrics and Gynecology, stated, "For the patient, there are no small, insignificant or minor operations. Almost any operation is a major event in her

[6]Pearlman, Table 6-2, page 70.
[7]Upadhyay, et al., at page 175 (internal citation omitted).
[8]Statement from the Director of the Missouri Department of Health and Senior Services, May 31, 2017. https://health.mo.gov/information/news/2017/dhss-statement53117

life,"[9] and that is certainly true for abortion. For procedures such as abortion with an overall complication rate of 2.1% (according to Upadhyay, et al.), being available to patients is part of a physician's responsibility to provide continuity of care in a timely manner to prevent further morbidity or mortality when complications arise. It is not a burden but a duty that is attached to the privilege of caring for patients.

20. Abortions, like all procedures, have known risks for complications, and standard care establishes that all physicians discuss these complications with patients prior to elective procedures. Upadhyay, et al., conducted "a retrospective observational cohort study to estimate the abortion complication rate, including those diagnosed or treated at emergency departments (EDs)."[10] They distributed abortion-related complication diagnoses by type of procedure and type of treatment and listed complication diagnoses as incomplete abortion, failed abortion, hemorrhage, infection, uterine perforation, anesthesia-related and other or undertermined.[11] Major complications were defined as requiring hospital admission, surgery, or blood transfusion.[12] Their findings include the following:

> Among all abortions (N = 54,911), 1,156 (2.1%, 95% CI 1.99-2.23) resulted in an abortion-related complication diagnosed or treated at any source of care, including EDs and the original abortion facility. The unadjusted complication rate was 5.2% (n = 588) for medication abortions, 1.3% (n = 438) for first-trimester aspiration abortions, and 1.5% (n = 130) for second-trimester or later

[9]Droegemueller, William. Comprehensive Gynecology. St. Louis: Mosby. 1987. Page 643. *See also* Comprehensive Gynecology, 7th Edition, 2017. Elsevier. Lobo, Rogerio; Gershenson, David; Lentz, Gretchen; Valea, Fidel.
[10]Upadhyay, et al., at page 175.
[11]Upadhyay, et al., at page 179.
[12]Upadhyay, et al., at page 180.

procedures. Adjusted results indicate that women ages 30-39 years were 1.20 (95% CI 1.02-1.40) times as likely to have a complication compared with women ages 20-24 years, and Hispanic women were significantly less likely to have a complication compared with white women. Medication abortions were 5.96 (95% CI 5.11-6.94) times as likely to result in a complication as first-trimester aspiration abortions. Women receiving abortion care at hospitals or physician's offices or groups were significantly more likely to have a complication than women receiving care at outpatient clinics (Table 1).[13]

. . .

The rate of major complications among all 54,911 abortions was 0.23% (95% CI 0.19-0.27) (n = 126, 1/436), 0.31% (n = 35) among women who had medication abortions, 0.16% (n = 57) among women who had first-trimester aspiration abortions, and 0.41% (n = 34) among women who had second trimester or later procedures (Table 3). Among all women, 0.20% (n = 108) were admitted to hospitals, 0.02% (n = 13) had surgery, and 0.09% (n = 50) received blood transfusions (data not shown). These three categories are not mutually exclusive; some women were admitted to a hospital and had surgery, received a blood transfusion, or had surgery and a blood transfusion.[14]

. . .

We observed a 2.1% abortion-related complication rate after nearly 55,000 abortions diagnosed or treated at all sources of care."[15]

[13]Upadhyay, et al., at page 181.
[14]Upadhyay, et al., at page 181.
[15]Upadhyay, et al., at page 181.

21. A vital part of keeping patients safe and preventing complications with elective surgery is the continuity of the established physician-patient relationship before, during, and after surgery. The operating surgeon should be involved in all three facets to all reasonable degrees. Two of these facets – discussing the surgery with the patient in advance and performing the surgery – can be controlled by the surgeon. The third, the post-operative period, is more variable due to the inability to schedule unforeseen complications.

22. Abortion is a common procedure in the United States, making it even more important that it be done safely and consistently with standard practice for other elective procedures in the United States. The standard care of patients having abortions should not be different than the standard care for other surgical or elective procedures because it is an abortion.

23. As Penfield notes in *Outpatient Gynecologic Surgery*, "Abortion is often referred to as a simple procedure, particularly by those who never perform the operation. However, when the surgeon sets out to work under local anesthesia and to provide a maximum degree of safety for the patient, he or she must be prepared for a large number of variables, complicated by the fact that the procedure is a blind one that depends for its successful completion on the proper functioning of contractile and hemostatic mechanisms over which the surgeon has little control."[16]

24. Risk of death is often cited as the metric that proves abortions are safe. But depending on gestational age and type of procedure, the list of recognized common complications and their incidence is not insignificant – especially to the patients who experience them. There are those who contend that abortion complications are exceedingly rare, but this is not supported by peer-reviewed literature. Peer-reviewed literature reports that medical

[16]Penfield, A. Jefferson. Outpatient Gynecologic Surgery, 1997 Williams and Wilkins. Page 53.

abortions have a complication rate of 5.2%, which is one in twenty, and not an insignificant number.[17] Further, second-trimester medical abortions can have complication rates up to 29%, and these can lead to serious morbidity.[18]

25. There are those who contend that it is a rare event that a woman elects to or needs to have an aspiration procedure to remove retained tissue or complete an abortion. That contention is not supported by Maarit Niinimaki, MD, et al., in *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, who note, "The overall incidence of adverse events was fourfold higher in the medical compared with surgical abortion cohort (20.0% compared with 5.6%, P<.001). Hemorrhage (15.6% compared with 2.1%, P<.001) and incomplete abortion (6.7% compared with 1.6%, P<.001) were more common after medical abortion. The rate of surgical (re)evacuation was 5.9% after medical abortion and 1.8% after surgical abortion (P<.001). Although rare, injuries requiring operative treatment or operative complications occurred more often with surgical termination of pregnancy (0.6% compared with .03%, P<.001). No differences were noted in the incidence of infections (1.7% compared with 1.7%, P = .85), thromboembolic disease, psychiatric morbidity, or death."[19]

26. For those performing elective surgery or elective procedures, having an established relationship between the initial surgeon or initiator of the procedure and a prearranged (on-call) OB/GYN trained and available to handle the common complications is consistent with standard care throughout medicine. Physicians do not, as standard

[17]Upadhyay, et al., at page 175.
[18]ACOG Practice Bulletin No. 135, Second-Trimester Abortion, June 2013. (Reaffirmed 2015), page 4.
[19]Niinimaki, Maarit, MD, et al. Immediate Complications after Medical Compared with Surgical Termination of Pregnancy. Obstetrics and Gynecology. Vol. 114, No. 4, October 2009. Page 795.

practice, initiate elective procedures and then abdicate their responsibility for care when complications arise. Rather, they have in place a prearranged mechanism for patient complications to be assessed and handled before the complications become unsafe for the patients.

27. Standard care in the United States, and a vital part of keeping patients safe and preventing complications with elective procedures, is the continuity of the established physician-patient relationship before, during, and after the procedure. Care before the procedure and during the procedure can be controlled, but the post-procedure care can be variable because complications can occur at any time. This is why it is vital that a coordinated, established, and highly-communicative plan be in place when complications arise that can lead to diminished patient safety, and that the physician doing the procedure and the on-call physician both mutually agree to accept responsibility for the patient's safety. These basic principles are widely applicable to all elective procedures, including abortions.

28. There are those who contend that, if a patient experiencing a complication is brought to a hospital or subsequently seeks care at a hospital, that patient would receive the necessary care there regardless of whether the abortion facility has an agreement with an ob-gyn or ob-gyn group with privileges at the hospital. ACOG recognizes that communication between providers is vital to improve outcomes, and the nature of the handoff between providers is especially important.[20] This is why those who perform surgery or initiate procedures have, as part of standard care, a formal process to have someone on call to recognize and handle complications at all times if they are not available. Having an

[20]ACOG Committee Opinion No. 517, Communication Strategies for Patient Handoffs, February 2012. (Reaffirmed 2016).

ancillary provider or physician who, in the absence of life-threatening symptoms, tells every patient to just go to the emergency room and someone will see them does not suffice to ensure patient safety.

29. As Pearlman, et al., note in *Obstetric and Gynecologic Emergencies*, "Abortion services are most commonly provided in free-standing specialty clinics. This pattern of care has reduced cost and made abortion services available where they would otherwise not be offered. However, when complications occur, lack of continuity of care between the clinic and the emergency department can be to the detriment of patient care.[21] Providing emergency care is more difficult if essential information from the abortion provider is not available. Management becomes simpler, and is more likely to be effective, when the abortion records can be accessed."[22]

30. In *Major complications of 20,248 consecutive first trimester abortions: problems of fragmented care,* Adv Planned Parenthood 9:52-59, Hodgson notes that "it is important to document the many and unique problems that may arise in the handling of pregnancy termination and control."[23] Hodgson continues, "Although strict adherence to technique and proper guidelines are important in the delivery of the [abortion] procedure itself, services should be available to every woman, preferably in her own community, under the direction of one competent and interested physician or family planning clinic. Formal written agreements between free-standing abortion clinics and hospitals are of little value to a patient who is met at the emergency room by an unsympathetic personnel, and whose

[21]Pearlman, Mark D.; Tintinalli, Judith E.; Dyne, Pamela L. Obstetric & Gynecologic Emergencies: Diagnosis and Management, McGraw-Hill, 2004, page 65, citing Hodgson JE: Major complications of 20,248 consecutive induced abortions: Problems of fragmented care. Adv Planned Parenthood 9:52-59, 1975.
[22]Pearlman at page 65.
[23]Adv Planned Parenthood 9:52-59, 1975. Page 58.

init[i]al operator has no further input into her subsequent care."[24] In her article, Hodgson chronicles several cases where patients endured undesirable outcomes including sterilization, multiple unnecessary surgeries, and continued pregnancy, all as a result of fragmented care and poor communication. Of these undesirable outcomes, she observed that the patients' suffering would have been greatly lessened by "continuous and concerned care throughout the entire episode" and "consultation between clinic and hospital physicians as to the proper overall treatment" of the patient.[25] Moreover, she concludes that some of the undesirable outcomes "might well have been avoided if continuous and sympathetic care had been available."[26] When physicians who perform abortions have hospital privileges, this helps ensure continuous, sympathetic, and safer care for patients.

31. "Women who have experienced complications from incomplete abortion are among the most neglected of reproductive health care patients."[27] Telling all patients experiencing abortion complications to just go to the emergency room, in the absence of life-threatening symptoms, does not meet standard care and is not consistent with ACOG principles: that a primary person or team should be identified as responsible for each patient; that the method of access to the primary contact should be clearly established; that a backup system must be identified in case the primary contact is unavailable; and that the process should be seamless.[28] Further, emergency room visit rates continue to

[24]Adv Planned Parenthood 9:52-59, 1975. Page 58.
[25]Adv Planned Parenthood 9:52-59, 1975. Page 57.
[26]Adv Planned Parenthood 9:52-59, 1975. Page 58.
[27]Dale Huntington and Nancy J. Piet-Pelon. Postabortion Care: Lessons from Operations Research. The Population Council, Inc., 1999. Page 1.
[28]ACOG Committee Opinion No. 517, Communication Strategies for Patient Handoffs, February 2012. (Reaffirmed 2016), pages 2, 3.

rise,[29] and emergency room physicians have the highest burnout rate of any medical specialty.[30]

32. ACOG Practice Bulletin Number 143 says, "Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion."[31] That provider's training does his or her patient no good if the provider is not available to provide it, and referral to an emergency room physician is not a clinician trained in surgical abortion nor with the ability to treat the number one complication: incomplete abortion. Furthermore, it is not standard care for emergency room physicians to try and find physicians to take care of patients transferred over by one physician to another similarly-trained physician in their community simply because the transferring provider has removed him or herself from caring for the patient. Of the 27 recognized specialties, emergency room physicians have the highest rate of burnout in that 60% self-report that they are burned out, and emergency room visits nationally were the highest ever recorded in 2014, the year from which we have the latest data.[32, 33] Physicians not taking care of their own patients simply adds to emergency room physicians' responsibilities, especially if the responsibility is not in their area of expertise.

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[29]Analysis of American Hospital Association Annual Survey Data, 2014, for community hospitals.
[30]Medical Specialties with the Highest Burnout Rates, "Burnout Rates by Specialty" chart, AMA Wire, January 15, 2016, citing Shanafelt, Tait D., Mayo Clinic Proceedings, Changes in Burnout and Satisfaction with Work-Life Balance in Phyicians and the General U.S. Working Population Between 2011 and 2014. December 2015, Volume 90, Issue 12.
[31]ACOG Practice Bulletin No. 143, Medical Management of First-Trimester Abortion, March 2014 (Reaffirmed 2016), page 6.
[32]Medical Specialties with the Highest Burnout Rates, "Burnout Rates by Specialty" chart.
[33]Analysis of American Hospital Association Annual Survey Data, 2014, for community hospitals.

33. Because up to 5% of patients receiving medical abortion in the first trimester may need surgical intervention, it is reasonable for patients to assess, as a condition of choosing an abortion provider, who may be providing that service. As Paul, et al., point out in *A Clinicians' Guide to Medical and Surgical Abortion*, "The skill and experience of the surgeon are important determinants of the safety of abortion. . . Surgical skills for abortion also encompass the ability to communicate effectively with the patient (Ch.3). Confidence and comfort are enhanced when the surgeon acts professionally, conveys warmth and empathy, provides useful information, and addresses the patient's questions and concerns. . . Finally, the surgeon's responsibility does not end with the completion of the abortion procedure. Diligent follow-up allows early recognition and treatment of complications, as well as ongoing support and health maintenance for the patient."[34] Given that there is a reasonable risk of surgical intervention by a gynecologist trained in treating incomplete abortion and hemorrhage after a medical abortion, it is reasonable that those physicians providing medical abortions be prepared to treat that complication – including at a hospital where the physician has privileges – or tell the patient who is having an elective procedure that a designated, similarly-trained physician whose skills have been vetted by him or her will be available in a timely fashion.

34. In my 30 years of experience taking care of patients as an obstetrician-gynecologist, I saw firsthand the importance of ensuring patient safety by taking care of my patients by having hospital privileges or prearranging to have someone with hospital privileges take care of my patients when I was not available to do so. Though I did not perform abortions, there is no reason why abortion patients should not receive the benefit of these

[34]Maureen Paul, MD, MPH, et al., A Clinician's Guide to Medical and Surgical Abortion, Churchill Livingstone. 1999. Page 111.

same types of arrangements, which are standard in the practice of medicine. This is not a burden but a responsibility that physicians dedicated to caring for their patients exercise daily to ensure their patients' safety by timely providing care at a time patients need it the most, during complications.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: September 28, 2018

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Randall W. Williams, MD, FACOG

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DIVISION OF MISSOURI
CENTRAL DIVISION
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COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,

Plaintiffs,

vs.)CASE NO.: 17-CV-04207BP

RANDALL W. WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al.,

Defendants.

DEPOSITION OF DANIEL GROSSMAN, M.D.
March 9, 2018
12:51 p.m.
220 Bush Street, Suite 1650
San Francisco, California

REPORTED BY:
HEATHER J. BAUTISTA, CSR, CRR, RPR, CLR
CSR # 11600

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Heather J. Bautista, CSR No. 11600

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Friday, March 9, 2018

Heather J. Bautista, CSR No. 11600

San Francisco, California;
MARCH 9, 2018, 12:51 .m.
DANIEL GROSSMAN, M.D.,
having been first duly sworn, was examined and testified as follows:
EXAMINATION BY MR. SAUER:

Q. Thank you, Dr. Grossman. My name is John Sauer. I'm a lawyer for the State of Missouri, as you're probably aware. You understand that you've come here today to give testimony in a case that's captioned Comprehensive Health against Williams?

A. Yes.

Q. You understand you've been noticed as an expert witness in that particular case?

A. Yes.

Q. And you understand that -- have you ever given depositions before?

A. I have.

Q. How many times?

A. I believe three.

Q. Were they all cases in which you were serving as an expert witness?

A. Two of them were.

Q. And what were those cases?

A. One was the case in Texas that became Whole

Women's Health versus Hellerstedt, and the other is for a case in Mississippi.

Q. Was that also a case that involved a constitutional challenge to an abortion regulation?

A. It's a challenge to abortion regulation.

Q. Is that a case that you listed as 2017 on your --

A. Yes.

Q. What is the nature of that case?

A. I mean, the nature of my -- my testimony is primarily related to a requirement that abortion providers be board certified obstetrician gynecologists.

Q. There were multiple claims in that case?

A. Yes.

Q. But you are providing testimony principally as one of them?

A. Yes.

Q. And you've recently given a deposition in that case?

A. It was about a year ago.

Q. Okay.

And then there's one other deposition that you've given?

A. Yes. That was in a malpractice case that was dismissed.

Q. In other words, a case against you as a defendant?

A. Correct.

Q. So you've given depositions before. Can I just go over some common ground rules for deposition?

A. Yes.

Q. First of all, let's do our best not to talk over each other. Is that okay with you?

A. Yes.

Q. And I am the worst offender on that front. Let's also try to speak slowly so that the court reporter can take down everything we're saying. Is that okay with you?

A. Yes.

Q. I am, again, the worst offender on that front. And then I ask you, as we go through this deposition, to listen carefully to the questions that I'm asking and respond to the question I'm asking, if you would. Will you be willing to do that?

A. Yes.

Q. And if at any time you don't understand a question that I'm asking, could you tell me?

A. Yes.

Q. Is there -- is there any reason you feel like you are not feeling mentally clear enough to give

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OB/GYN, as well as several residents that are providing backup for the patients that I take care of.

Q. Because you're in a large practice, it's something that happens pretty naturally and that there's coverage, so to speak?

A. Yeah, and I'm involved in a residency program, and my practice is essentially hospital-based.

Q. Outside of hospital-based practices, is it common for physicians to make prearrangements, when they're not available, with other doctors to cover complications?

A. I think it depends on the type of doctor and the type of treatment that patients -- that the physician may be doing.

Q. Let's narrow it down to OB/GYNs engaging in elective procedures that have some risk of complication, like you may have mentioned some in your affidavit -- I'm not going to try to pronounce them -- is it common for OB/GYNs in those circumstances to arrange for another physician to be physically available to treat complications when they're not available? For example, if they're traveling or taking a weekend off or whatever?

A. I think it's -- yes, I think it's common.

Q. Are you aware of any circumstances where that

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doesn't happen as a routine matter?

A. For an OB/GYN?

Q. Correct.

A. I --

Q. Outside the abortion context.

A. Yeah. I think, you know, most OB/GYN procedures are happening in a context where a physician is generally in a group practice setting where -- and particularly for OB/GYNs, because many of them are doing obstetrics as well. They are, just by the very nature of their practice, involved in a group-call situation, so yes, that is very -- that's common with OB/GYNs.

Is it -- I think your question was does it -- maybe restate your question.

Q. You've said it's common, and I wondered if there are circumstances where that routinely doesn't happen? Are there circumstances where an OB/GYN performs elective procedures that may have complications but does not make a prearrangement with another similarly qualified physician to cover potential complications when the operating physician is not available due to travel or taking time off, whatever it may be?

A. I think that that's common, and I think it's -- trying to think if there is specific scenarios.

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Particularly in -- it's hard to think of another scenario where an OB/GYN is having to travel long distances to perform a procedure that no local OB/GYN is willing to perform.

Q. So other than -- and that last thing you referred to about traveling long distances, and people not being available to perform, that's referring to an abortion context; right?

A. Correct.

Q. My question is outside of the abortion context, you believe -- your testimony is, as I understand it, is that it's common for there to be such prearrangements, and you can't think of a scenario other than the abortion context where that is not done as a routine matter?

A. Again, for OB/GYNs, I think that that's common. I can think of other examples of treatment where physicians may be providing treatment in an outpatient setting where a complication may occur at a later point that -- where you don't necessarily have prearranged backup care.

Q. Let me show you -- let's go back to the ACOG practice bulletin, Exhibit 9; right? Can you turn to Page 5. There's a paragraph that goes from Page 5 on to Page 6; correct?

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A. Yes.

Q. And the first sentence of that paragraph which is quoted by you in your declaration says "Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider." Correct?

A. Yes.

Q. And then the last sentence of that paragraph, which is quoted by Dr. Williams says "Clinicians who wish to provide medical abortion services should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion." Correct?

A. Correct.

Q. So you recall the two scenarios we were talking about. In my first scenario Dr. McNicholas is in St. Louis and the coverage doctor is in Kansas City, and the patient in Columbia experiences a complication.

Does -- would that scenario satisfy if Dr. McNicholas is referring that patient to go be treated in the emergency department, would that satisfy the principle that is stated here in the last sentence --

A. Yes.

Q. -- of this paragraph?

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.	)	
Plaintiffs,	)	Case No. 2:16-cv-04313-HFS
v.	)	
PETER LYSKOWSKI, et al.,	)	
Defendants.	)	

DECLARATION OF ANDREW STEELE, M.D.

I, Andrew Steele, declare as follows:

1. My name is Andrew Steele M.D. I am over 18 years of age and am competent to testify.

2. I am Board-Certified in Obstetrics and Gynecology as well as in the subspecialty field of Female Pelvic Medicine and Reconstructive Surgery (FPMRS). I currently serve as a Professor in the Department of Obstetrics, Gynecology and Women's Health at Saint Louis University. I also hold an appointment in the Division of Urology, Department of Surgery at Saint Louis University. I annually perform over 100 outpatient and inpatient surgical procedures as well as a large number of office-based procedures. As part of my duty functions, I also provide emergency trauma coverage for acute gynecologic conditions for a number of St. Louis area hospitals. I am a Fellow of the American College of Obstetricians and Gynecologists (ACOG). I received my Doctor of Medicine from Wayne State University and completed residency training in OB/GYN at David Grant USAF Medical Center. Following 4 years of Active Duty practice I completed a Fellowship in FPMRS at Good Samaritan Hospital, Cincinnati. I then completed 3 more years as an active-duty Air Force gynecologic surgeon, acting as residency

program director and Flight Commander / department Chair. I served as a Quality Reviewer to the Consultant for the Surgeon General of the Air Force. I have completed postgraduate training in ACOG's "Quality and Safety for Leaders in Women's Healthcare." I currently serve on the Quality Improvement committee for Saint Louis University, and Chair the joint SSM St. Mary's / Saint Louis University Quality Improvement Committee. As noted in my Curriculum Vitae (attached to this Declaration as Exhibit A), I have had the opportunity to publish extensively in my field, including peer-reviewed publications on outcomes and complications of gynecologic surgeries. I have served as invited lecturer both nationally and internationally, and have been fortunate to receive a number of national awards for teaching and practice.

3. I submit my declaration in my personal capacity alone, and do not speak for or act as an authorized representative of Saint Louis University, SSM Health, or any other entity of whom I am a member. I hold these statements to be true and accurate to a reasonable degree of medical certainty, based on: my education, training, review of published documents; and based on my extensive surgical experience including caring for post-abortal complications.

4. I do not agree with the plaintiffs' assertion that surgical abortions requiring dilation and curettage (D&C) or dilation and evacuation (D&E) are not true "surgical" procedures. The assertion that a surgical procedure requires an incision and general anesthesia is incorrect. While no scalpel may be used, several surgical instruments are utilized in D&C / D&E. A sharp instrument called a tenaculum may be used to grasp the cervix and dilators may be required to mechanically open the cervical canal. Metal instruments may be introduced blindly into the uterine cavity to remove the uterine contents. These metal instruments include sharp curettes, suction curettes of a centimeter or more in diameter, and, in the case of dilation and evacuation, crushing forceps. An evacuation of the uterus of this nature is a surgical procedure.

5. It was further asserted by the plaintiff's expert that surgical abortions do not represent real "surgeries" because general anesthesia is not used. This is a very misleading statement. The American Society of Anesthesiologists recognizes a continuum of anesthetic treatments of which the most intensive is general anesthesia.[i] However, lower levels of anesthesia are frequently used even in invasive surgical procedures; thus the requirement that a surgery must be under general anesthesia to be a true surgical procedure is incorrect.

6. Missouri's ASC requirements are not arbitrary but rather parallel recommendations by the American Society of Anesthesiologists for patients requiring levels of anesthesia deeper than local anesthesia, including what would be considered moderate or "conscious" sedation.[ii] Concerns with proper and safe anesthetic administration must be taken into account since it is evident that this is being administered for patients undergoing abortion procedures, as stated on Planned Parenthood's website.[iii]

7. Missouri's ASC requirements are not arbitrary, or imposed punitively on abortion facilities alone. Rather they also parallel the federal requirements for ambulatory surgical centers[iv] as well as guidelines from the American Association for Accreditation of Ambulatory Surgical Facilities.[v]

8. It is outside of the standard of practice for competent surgeons to lack a hospital relationship in an area where they provide surgical care for patients. The process of credentialing required by a local health care facility provides a method for ensuring that individuals meet standards for training and skill. Indeed, the American College of Surgeons, in "Patient Safety Principles for Office Based Surgery,"[vi] has delineated a number of core principles for physicians who perform surgery outside of a hospital context. Core principle #4 states, "Physicians performing office-based surgery must have admitting privileges at a nearby

hospital, or a transfer agreement with another physician who has admitting privileges at a nearby hospital, or maintain an emergency transfer agreement with a nearby hospital." Providing surgical procedures with known significant risks and without any method for collegial transfer is akin to abandonment of the patient.

9. The American College of Surgeons in Principle # 3 also speaks to outpatient surgical facilities. "Physicians who perform office-based surgery should have their facilities accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), American Association for Accreditation of Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), American Osteopathic Association (AOA), or by a state-recognized entity such as the Institute for Medical Quality (IMQ), or be state licensed and/or Medicare certified."[vii] The regulation and oversight of a surgical facility by the state is an important accepted principle intended to optimize surgical care and should only be disregarded with clear and compelling reasons. It is my opinion that facilities performing surgical abortions in the second trimester should follow guidelines expected of any ambulatory surgery center.

10. I disagree with the argument that, because the vagina has a bacterial flora in it, sterile technique is not required. In fact, we perform a number of procedures through the vagina where sterile technique and even prophylactic antibiotics are necessary. These include operative hysteroscopy, vaginal myomectomy, vaginal hysterectomy, and anti-incontinence procedures such as slings. Thus it is my opinion that for procedures used commonly but not exclusively in the 2nd trimester, such as D&C and D&E, using good aseptic surgical technique is crucial. This requires a more formal setting such as an outpatient ambulatory surgical center or hospital based OR.

11. The assertion of the plaintiffs' expert that non-gynecologic procedures such as gastrointestinal endoscopy (colonoscopy), plastic surgery and dermatologic cancer surgery are frequently performed as complex surgeries outside of the recommendations of the American College of Surgery and American Society of Anesthesiologists lacks a clear foundation. The plaintiffs' expert does not appear to be a specialist in those areas, and would not have a professional basis for giving an opinion on the standard of care. Over 30 medical societies signed off on the ACS guidelines for ambulatory surgery. While I also am not a specialist in these areas and so would not attempt to provide a definitive opinion on what the standard of care is in these disparate situations, there are some very clear statements by representative medical associations.

a. American Academy of Otolaryngology- Head and Neck Surgery: "Postoperative care should be rendered by the operating surgeon unless it is voluntarily accepted by a local otolaryngologist or another physician who is qualified to continue this essential aspect of total surgical care…It is the opinion of the American Academy of Otolaryngology- Head and Neck Surgery that itinerant surgery violates the ethical relations between surgeon and patient"[viii]

b. Joint statement of the American Society for Gastrointestinal Endoscopy, the Society of American Gastrointestinal Surgeons, and the American Society of Colorectal Surgeons: "Uniform standards should be developed that apply to all hospital staff requesting privileges to perform endoscopy, and to all areas where endoscopy is performed. Criteria must be established that are medically sound and that are applicable to all those wishing to obtain privileges in each specific endoscopic procedure. The goals must be the delivery of high-quality patient

care."[ix] Further, specific requirements for centers performing colonoscopy have been delineated which reinforce many of the requirements for ASC.[x]

12. In my experience during my 13 years of gynecologic emergency department coverage in St. Louis, I have never received a peer to peer communication from a local abortion provider directly or through an emergency department physician. I have provided emergency care for several individuals receiving abortion services in St. Louis in recent years; I am only one of many gynecologic surgeons who would be called upon to provide this emergency care for these patients. In my function providing after-hours coverage, I found that these patients were directed by their abortion facilities to go to a local emergency department due to complications arising from the procedure. Early in my practice in St. Louis I attempted to contact a local abortion facility to convey information on a patient complication, and I was not given the opportunity to speak with a health care professional.

13. I strongly disagree with the Plaintiffs' expert that the Hospital Relationship Restriction is a throwback to the "Marcus Welby" days of a general practice physician. A licensed and credentialed surgeon is more than a technician. She / he understands the nature and indications for the procedure and should have a knowledge of their management. In fact, this is all the more important since a specialization of practices means that few individuals have a breadth of knowledge to manage complications in diverse areas outside their specialty field. It's wrong to argue that an internal medicine physician or emergency room physician would understand the complexities of a post-abortal complication. The surgeon is the best one to know how the surgery progressed and which complications are likely or unlikely. For instance, a perforation at the top or fundus of the uterus could lead to bowel or bladder injury, while a perforation to the

side (lateral) would cause major blood vessel injury. The surgeon would be the one best qualified to know what happened at the procedure and what the relative risks are.

14. Even if a complication following the surgery is one that could be best managed by another physician (for instance, a post-operative myocardial infarction), the surgeon's specialized knowledge of the surgery is important in the overall team-based management of the patient. By shunning local hospital oversight and affiliation out of convenience or cost-saving, the abortion provider does a dis-service to her/his patient.

15. Simple assertions that abortion is "safe" and "low risk" may mislead policy-makers on the clinical complexity of our knowledge of the procedures. Most abortion statistics are provided by the abortion industry. There is currently no national requirement for reporting abortion complications.[xi] In contradistinction to the statistic that fewer than one-percent of women experience minor complications, a very recent peer-reviewed article presented experience with 4968 abortions in obese patients (the majority done in the 1st trimester) with a complication rate of 1.7%, including what would be considered significant complications of perforation, reoperation, and cervical laceration.[xii] Many of these complications would have required intervention best done in an ambulatory surgical or hospital setting.

16. In my opinion the attempts to compare termination of pregnancy to other medical interventions are misleading. I disagree with the numbers presented by the Plaintiffs' expert about the safety of pregnancy termination in relation to penicillin administration. The most recent data suggests a rate of anaphylactic reactions to penicillin is 1-5/ 10,000 treatments and the majority of these, while concerning, do not lead to death.[xiii] Only 35 deaths in total were attributed to penicillin anaphylaxis in the United States from 1999-2010. Given that penicillin-based antibiotics are one of the most common medications administered, the incidence of

anaphylactic deaths is microscopic.[xiv] Further, since surgical terminations of pregnancy receive prophylactic or preventive antibiotics for the procedure, the risk of medication reaction is additive to the risk of the abortion procedure itself. I also disagree with the assertion that colonoscopy complications exceed abortion complications by an appreciable amount. In data that I found from a standard textbook on gastroenterologic endoscopy, the rate of perforation and hemorrhage in colonoscopy, from multiple reports, varied from 0.11-0.42% and 0.008-2.16%.[xv] By comparison, in an article from Finland looking at over 42,000 abortions (in a country where registry data tracking is more accurate and complete than the United States), the instance of hemorrhage was 5.6% in the surgical abortion group and 20% in the medical abortion group. The instance of injury comparable in severity to bowel perforation was 1.8% and 5.9% for surgical and medical abortion respectively.[xvi]

17. Regarding the safety of Medical termination of pregnancy, the use of mifepristone does have complications. Despite the implication by the plaintiff's expert that medical abortion is safer than surgical, other data such as the study referenced above[xvii] suggest that medical termination carries higher, rather than lower complications. These include:

- Bleeding risk – patients receiving mifepristone for pregnancy termination must have access to surgeons able to perform dilation and curettage procedures under urgent or emergent conditions. As part of their Risk Evaluation and Management Strategies for this drug, the FDA requires that, prior to physicians prescribing Mifepristone, the physician must sign the manufacturer's Prescriber Agreement Form. The mifepristone provider agrees to meet the following qualification: "Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through

others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[xviii]

- Infection risk – the actual infection risk is unknown as many less severe infections may go unreported. However, the use of mifepristone has been associated with at least nine deaths due to infection with family of the bacteria Clostridia (members of this bacterial family are associated with the development of gas gangrene). Eight of those cases were associated with the bacteria Clostridium sordelli, a very uncommon pathogen. In these infections the findings are "subtle" and the patient can rapidly progress to death. Many of the usual markers for infection such as fever and abdominal pain are missing with this infection making it extremely difficult to diagnose until too late. This is not an infection that can be managed by a small community emergency room, and in fact may be missed by an emergency physician because of its unusual presentation. [xix]

  By way of comparison, in 1997 the FDA called for the voluntary withdrawal of the diet drugs fenfluramine / dexfenfluramine (key ingredient of "Fen-Phen") after reports of 82 cases of associated valvular heart disease and one (1) death. While more deaths from the medication have come to light subsequent to its removal from the market, it's clear that the number of deaths associated with mifepristone use already exceeds the threshold for FDA concern seen with other medications ultimately found to be "dangerous".[xx]

18. Current statistics for abortion morbidity and mortality as well as maternal mortality suffer from problems with data collection and reporting.

a. Patient safety data is incomplete. In the study by Weitz referenced in plaintiffs' documents, over 30% of patients were lost to follow up and no information was available on their outcomes. It is my opinion that this represents individuals who sought care elsewhere.[xxi] One of the largest data sets to date on abortion complications found an overall rate of 2.1% but recognized methodologic limitations that would likely have underreported complications.[xxii]

b. In the case of abortion, data from countries that have more advanced statistical tracking have demonstrated that up to 94% of abortion-associated deaths were not identified from death certificates or cause-of-death registries alone.[xxiii]

c. A study utilizing California Medicaid records demonstrated significantly higher mortality rates following abortion. The study linked abortion and childbirth records in 1989 with death certificates for the years 1989-97. Adjusting for age, women who had abortions were 62% more likely to die from any cause than women who gave birth.[xxiv]

d. There are issues with maternal mortality statistics, making comparisons between abortion and pregnancy safety problematic and unreliable. "It is an international embarrassment that the United States, since 2007, has not been able to provide a national maternal mortality rate to international data repositories such as those run by the OECD. This inability reflects the chronic underfunding over the past two decades of state and national vital statistics systems."[xxv]

19. A concern about breakdown in safety processes during the provision of medical services is that when adverse events do not occur the vigilance of personnel goes down, and processes ensuring patient safety are neglected or eliminated. Because of the many layers of protection

within the American medical system, most often a medical error is picked up prior to it causing injury to the patient. However, as these layers of protection are removed, the likelihood of developing problems increases. I do not feel that eliminating patient protections is in the best interest of the quality provision of care to women in Missouri.

20. It is my opinion that the current requirements in Missouri, that abortion facilities meet Ambulatory Surgical Center (ASC) specifications, and that abortion providers have Hospital Relationships, serve important medical purposes – and are in the best interests of Missouri patients. Ambulatory surgical centers are common throughout the state, including in rural areas, and physicians performing outpatient surgical procedures throughout the state are able to obtain hospital credentialing. This is consistent with the best provision of care.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 8, 2017

s/Andrew Steele
Andrew Steele MD

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[i] American Society of Anesthesiologists. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation. Accessed 1/4/2017

[ii] http://www.asahq.org/quality-and-practice-management/standards-and-guidelines. Accessed 1/4/2017.

[iii] https://plannedparenthood.org/learn/abortion/in-clinic-abortion-procedures/what-happens-during-an-in-clinic-abortion. Accessed 1/6/2017.

[iv] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html.

[v] Procedural Standards and Checklist for Accreditation of Ambulatory Facilities. Version 3, August 2011.

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,	)	No. 17-04207-CV-C-BP
Plaintiffs,	)	April 3, 2018 Jefferson City, Missouri
V.	)	CIVIL
RANDALL W. WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al.,	)	VOLUME I (Pages 1-339)
Defendants.	)	

TRANSCRIPT OF PRELIMINARY INJUNCTION HEARING

BEFORE THE HONORABLE BETH PHILLIPS
UNITED STATES DISTRICT JUDGE

Proceedings recorded by electronic stenography
Transcript produced by computer

Kathleen M. Wirt, RDR, CRR
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I N D E X

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Q. In other words, you have no firsthand knowledge of whether or not hospitals in Columbia or Springfield have OB-GYNs on staff, correct?

A. I was told this by Mr. Muniz.

Q. And, obviously, not all hospitals in Missouri have OB-GYNs on call at all times, correct?

A. That is correct.

Q. And if there was a patient experiencing medication abortion and the coverage physician was available, that coverage physician would be available to go to the hospital and assist in the treating of that patient, correct?

A. I'm sorry. Surely you're not suggesting that if there is a backup physician in Springfield that's been arranged, that that OB-GYN is going to travel to Branson if the patient goes to the emergency department. I mean, if we're talking about places -- I mean, they would be available in -- nearby to possibly --

Q. Let me ask the question this way. It guarantees the availability of an OB-GYN in the community to go to the hospital and participate in the treatment of that patient who is experiencing an emergency if the coverage physician is prearranged, correct?

A. I'm not really understanding the question because my understanding is that there are OB-GYNs on staff at the hospitals in Columbia and Springfield, so there are OB-GYNs who

are immediately available to treat complications at those facilities.

Q. If there was a community where the hospitals lacked that, an OB-GYN on call, the availability of the coverage physician would guarantee the availability of an OB-GYN to treat emergency complications, correct?

A. I don't -- again, to get back to my Branson question, you're not asking -- the regulation does not require that the OB-GYN, the backup OB-GYN be able to travel to any hospital anywhere in Missouri and provide care for that patient, correct?

I mean, we're assuming that this would be helpful locally, and I believe also part of the requirement is that the physician needs to live nearby, near the facility where he or she has privileges. So I don't know how the regulation helps us at all, that hypothetical woman who traveled to Springfield to get a medication abortion but lives in Branson, and she then goes to an emergency department there. She's going to get whatever care she can get at the emergency department there.

Q. But, of course, if she lived in Springfield and the Springfield hospitals do not, in fact, have coverage OB-GYNs available, then it would be a benefit to her to have a coverage physician available to participate in her emergency care, correct?

A. Okay. My understanding is that that is not the case

and that there are OB-GYNs available in Springfield.
Q. But you understand I asked a different question, though. I ask you to respond to my question, which is --
A. A hypothetical.
Q. Yes, a hypothetical where there is no emergency -- or there's no OB-GYN on call at the hospital, and a woman experiences a medication abortion complication in that community.
A. Okay. I'm finding this very -- I suppose there is a hypothetical other city that we could think of that's not Springfield or Columbia where that might be the case, yes.
Q. For example, Joplin, if that were to occur in Joplin. Do you know whether there are OB-GYNs on staff at the hospitals in Joplin?
A. I do not know.
Q. And if there were a provider of medication abortion in the Joplin area who had a coverage physician available, women who experience post-abortion complications in Joplin would be guaranteed the availability of an OB-GYN to participate in their emergency treatments at the hospital there, correct?
A. I suppose that is true.
Q. Could you go to Exhibit 30? This is ACOG bulletin, Practice Bulletin No. 143. If you turn to Page 6, in the first column, at the very first full sentence in that column, it says clinicians who wish to provide medical abortion services either

should be trained in surgical abortion or should be able to refer to a physician trained in surgical abortion, correct?

A. Correct.

Q. And you're actually a co-author of this, so you believe that statement, correct?

A. I do.

Q. And the reason -- I take it the reason that it's recommended that clinicians who are providing medication abortion be trained in surgical abortion is that, you know, 3 to 5 or 2 to 7 percent of the time, an aspiration has to be done to treat problems that arise after a medication abortion, correct?

A. They should either be trained or be able to refer for that service, correct.

Q. And when you say -- again, the second part says, "or should be able to refer to a clinician trained in surgical abortion." That would be an alternative way to address this based on this document, correct?

A. Correct.

Q. Do you consider sending a patient to the emergency department to be a referral to a clinician trained in surgical abortion?

A. I believe that that plan for being able to provide urgent aspiration procedures meets this criterion, yes.

Q. And you testified earlier that most ER doctors are not

trained to perform surgical aspirations, correct?
A. That is correct.
Q. And many hospitals do not have an OB-GYN on staff, correct?
A. I have to say I do not know what the proportions are -- is here in Missouri. But every hospital sees patients who are suffering complications after spontaneous miscarriage, and, as I testified earlier, the complications are really identical, as is the need for an aspiration.
Q. Can you turn to Exhibit 34? Do you recognize that document?
A. I do.
Q. What is that document?
A. This is the risk evaluation and mitigation strategy, or REMS, document for Mifeprex.
Q. And this document is cross-referenced in the FDA label, right?
A. Yes.
Q. And so these are requirements or recommendations that the FDA has approved; is that right?
A. They're requirements, yes.
Q. And turn to the second page, starting under Paragraph (A)(1), (ii)(1), it says to become specifically certified to prescribe Mifeprex, healthcare providers must have the following qualifications. And then at the top of the second

Q. And so, in other words, if a complication is defined to include the things that are called minor complications in the Upadhyay study, then you estimate the complication rate at 2 to 5 percent?

A. Correct. If you include adverse anticipated events, such as retained blood in the uterus, then the rate would be 2 to 5 percent.

Q. And that study refers to the problems of underreporting due to loss of follow-up, correct?

A. Correct.

Q. And loss of follow-up means that the clinic that performed the abortion since loses contact with the patient and, therefore, does not know whether that patient suffered a post-abortion complication, correct?

A. That's what loss of follow-up means, yes.

Q. So in certain circumstances, women who suffer post-abortion complications seek treatment from another provider who they may not even tell they've had an abortion, correct?

A. Although that's possible, that hasn't been my experience. My experience is that the patients have a trusted relationship with their abortion provider, and they call the abortion clinic when they are experiencing symptoms that they're concerned with. And so regardless of whether they achieve that secondary intervention at the clinic, the clinic

is made aware that there is a concern, and they can follow up with the patient, and I think they do that very well.

Q. But, of course, the class of women who never come back to your clinic for treatment, you just have no way of knowing how many such women exist, correct?

A. So that's a small proportion of patients for whom we can no longer -- who either don't follow up as planned or for whom we don't have telephone or other contact with.

Q. So there's some patients who you don't hear back from, and you don't know whether they -- if they suffer complication, correct?

A. Of course.

Q. And Missouri has a law that requires the filing of complication reports by any physician who is treating a post-abortion complication, correct?

A. That is correct.

Q. And as we discussed in your deposition, that law was largely ignored up until 2017, correct?

A. I can tell you that I was personally not aware of that law until 2017.

Q. And so just from your personal experience -- you've been providing abortions in Missouri for how many years?

A. Approximately seven years.

Q. For the first six years or so of that, you weren't aware that you had to file a complication report every time you

treated a post-abortion complication, correct?
A. That's correct.
Q. And you did not, in fact, do so until you became aware of that law in 2017?
A. Correct.
Q. And that applies both to post-abortion complications that you've treated when you were on call at the hospital and post-abortion complications that you've treated at the facilities -- the clinics where you provide abortion, correct?
A. So my understanding of the law is that the person responsible for filing the complication plan is the person who is treating the complication. So if the patient presents to the hospital, the treating physician at the hospital would submit that complication plan. Or I'm sorry, complication report.
Q. Turning back to the -- when you treat complication -- let me ask you this.

Under the proposed complication plan for the Columbia facility, it's my understanding that you would be personally available to treat complications in two scenarios.

First, if you were the presiding clinician two to three days a month in the Columbia facility, as you testified earlier, you would be available to treat complications of patients who came to the facility with a nonemergency complication, correct?

A. That's correct.
Q. And then if a patient who had obtained an abortion in Columbia happened to present to the emergency room at Barnes-Jewish in a week when you were the on-call physician, you might be involved in treating a post-abortion complication in those circumstances, as well, correct?
A. Or if they presented to my private clinic or to the Planned Parenthood in St. Louis or any other practicing location that I would be at, correct.
Q. But those would be the only scenarios when you would be treating post-abortion complications from people who suffered those complications in Columbia, correct?
A. So to be clear, we're talking about providing aspiration, I'm assuming.
Q. Any kind of treatment for post-abortion complication.
A. So in cases where women who are accessing abortion care at the Columbia clinic have a secondary evaluation that determines that there is something retained in the uterus, they still do have two treatment options that can be executed by the nurse practitioner. Or if she feels more comfortable, she can certainly consult me by phone to execute that plan.

If the patient requires an aspiration, a procedural intervention, or prefers a procedural intervention, then her options are when I'm at Columbia, or she can come to St. Louis in any of the clinical settings that I practice.

A. I don't know anything about the first group, so I can't compare it to anything.

Q. And you haven't attempted to quantify how many women as a proportion of all first-trimester medication -- first-trimester medication-abortion patients are delaying seeking a medication abortion as a result of the regulation, correct?

A. I can't quantify that.

Q. And you also haven't attempted or cannot quantify how many women may be prevented from obtaining an abortion at all by the regulation, correct?

A. Well, I can quantify sort of globally and say that women in mid-Missouri who desire to have a medication abortion, however, end up having a surgical abortion in Missouri, have been prevented from having a medication abortion.

Q. But my question is about how many women are prevented altogether from having an abortion, whether medication or surgical. You don't know how many women fall into that category, do you?

A. So in the Columbia -- if somebody is presenting to the Columbia facility, I have never had an experience where, if there's only one abortion mode available, patients will choose to just continue the pregnancy if it's not their preferred method.

Q. So your view would be the vast majority of patients

will either travel for a medication abortion or obtain a surgical abortion in Columbia, rather than forgo any abortion altogether.

A. Yes.

Q. Turning back to the proposed complication plan for Columbia, we had -- we have a -- when I say turning back, I didn't mean turning back to a document, I mean turning back to the topic.

Turning back to the topic of the proposed complication plan for Columbia, I think you testified earlier that you don't believe there's another doctor who provides any kind of services at the Columbia facility, correct?

A. I don't know.

Q. And so the only doctor you're aware of is yourself, correct?

A. That's correct.

Q. And the nurse practitioner at the Columbia facility cannot do aspirations, correct?

A. That's correct.

Q. And emergency room doctors are usually not trained to do aspirations, as well, correct?

A. That's correct.

Q. Under the proposed complication plan, I believe you testified that you would not go to the emergency room to treat a complication in Columbia, even if you were in Columbia as the

presiding clinician that day, correct?
A. As I don't have admitting privileges or privileges at the hospital, I would not be able to do so, whether I was willing to or not.
Q. So you would not be directly involved in the treatment of any emergency care in the Columbia facility, correct? Or, sorry.
You would not be directly -- under the proposed complication plan, you would not be directly involved in providing any kind of emergency care to patients experiencing post-abortion complications in the Columbia area, correct?
A. If a patient accessing abortion care from the Columbia facility required emergency care and presented to a hospital in Columbia, which means that that would have to be geographically the closest emergency room to her, I would not be present to participate in that care.
Q. And, in fact, you say you could not be because of the lack of privileges at that hospital, correct?
A. Correct.
Q. Sometimes -- you talked about the groups of symptoms that medication-abortion patients may experience. Is it fair to say that generally those symptoms may be symptomatic of a serious problem, or a less serious problem in certain circumstances?
A. The symptoms experienced following medication abortion

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,	)	No. 17-04207-CV-C-BP
Plaintiffs,	)	April 6, 2018
	)	Kansas City, Missouri
V.	)	CIVIL
RANDALL W. WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al.,	)	VOLUME II
	)	(Pages 340-503)
Defendants.	)	

TRANSCRIPT OF PRELIMINARY INJUNCTION HEARING

BEFORE THE HONORABLE BETH PHILLIPS
UNITED STATES DISTRICT JUDGE

Proceedings recorded by electronic stenography
Transcript produced by computer

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I N D E X

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A. Well, again, I think the biggest concern we always have if it's going to require surgical intervention, such as an aspiration or D&C, is perforation of the uterus.

Q. And so even though aspirations may be safe, in the hands of an inappropriately qualified doctor, they can be dangerous?

A. Yes.

Q. I think you testified earlier that you believe the doctor who performs the procedure has a duty to, quote, vet the credentials of a coverage physician who is going to treat the complications?

A. I do.

Q. Does the complication plan regulation in your view provide an opportunity for that vetting to occur?

A. It does. And I think, again, not only for physical and skill set expertise, but also I think it provides comfort to the patient to know -- like I said, I did this for a long time in a variety of settings, but I think it's incredibly comforting to patients to say, you know, Dr. Eisenberg is not available today, but he's asked me to fill in in his stead, and I know him, and how can I help you.

Q. Is there the same opportunity to vet the credentials of, like, the ER staff and the on-call OB-GYN at a local hospital?

A. No.

Q. So, in your view, does sending patients to the ER as the provider of first resort for emergency complications, does that satisfy the duty to vet credentials?

A. It doesn't, but I guess you could look and check the credentials of everybody on the staff at a hospital. But, again, that's not the same to me as talking with those people face-to-face and having them agree -- so you might find out they're board-certified, but that wouldn't be sufficient. I think you would have to have them agree to having that responsibility from the git-go when that patient first calls of owning the patient.

Q. Turning back to Page 111 of Exhibit 31, is that still in front of you?

A. Yes.

Q. Lower down in that first column, the very last sentence in that column, what does that say?

A. (Quoted as read.) "Confidence and comfort are enhanced when the surgeon acts professionally, conveys warmth and empathy, provides useful information, and addresses the patient's questions and concerns."

Q. Are providing comfort and confidence to the patient independently valuable things to do?

A. They are.

Q. Does the complication plan regulation, should it provide a source of comfort and confidence to patients?

A. I think it does. Again, if I could read the next paragraph. (Quoted as read.) "Finally, the surgeon's responsibility does not end with the completion of the abortion procedure" --

COURT REPORTER: I'm sorry --

THE COURT: Here's the problem. You don't have to read any slower, but you can't read faster than you talk. And so if you could read, not at a snail's pace, but at the same pace you talk, that makes it much easier for all of us.

THE WITNESS: Thank you.

A. (Quoted as read.) "Finally, the surgeon's responsibility does not end with the completion of the abortion procedure. Diligent follow-up allows early recognition and treatment of complications, as well as ongoing support and health maintenance for the patient." Thank you.

BY MR. SAUER:

Q. And how is that -- you agree with that statement?

A. I do.

Q. How does that statement inform your view of providing comfort and confidence to the patient?

A. Again, I think the key thing is that it underscores that the surgeon's responsibility is ongoing and the patient knows that.

Q. Do you believe patients would be -- would be -- would obtain reassurance if they were told going into the medication

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,

Plaintiffs,

vs.) Case No.) 2:17-cv-04207-BP

RANDALL WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al.,

Defendants.

DEPOSITION OF DAVID L. EISENBERG, M.D.
TAKEN ON BEHALF OF THE DEFENDANTS
MARCH 19, 2018

(Starting time of the deposition: 8:00 a.m.)

I N D E X

E X H I B I T S

(The original exhibits were retained by the court reporter to be attached to the original and copies of the transcript.)

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF)
PLANNED PARENTHOOD GREAT)
PLAINS, et al.,)
)
Plaintiffs,)
)
vs.) Case No.
) 2:17-cv-04207-BP
RANDALL WILLIAMS, M.D., in his)
official capacity as Director)
of the Missouri Department of)
Health and Senior Services,)
et al.,)
)
Defendants.)

DEPOSITION OF DAVID L. EISENBERG, M.D., produced, sworn and examined on MARCH 19, 2018, between the hours of eight o'clock in the forenoon and three o'clock in the afternoon of that day, at the offices of Haar & Woods LLP, 1010 Market Street, Suite 1620, St. Louis, Missouri 63101, before William L. DeVries, a Certified Court Reporter (MO) and Certified Realtime Reporter, in a certain cause now pending in the United States District Court, Western District of Missouri, Central Division, between COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al., Plaintiffs, vs. RANDALL WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al., Defendants; on behalf of the Defendants.

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IT IS HEREBY STIPULATED AND AGREED by and between counsel for the Plaintiffs and counsel for the Defendants that this deposition may be taken in shorthand by William L. DeVries, RDR/CRR, a Certified Court Reporter and Certified Shorthand Reporter, and afterwards transcribed into typewriting; and the signature of the witness is expressly reserved.

* * * * *

DAVID L. EISENBERG, M.D.,
of lawful age, produced, sworn and examined on behalf of the Defendants, deposes and says:

(Starting time of the deposition: 8:00 a.m.)

COURT REPORTER: Do you swear or affirm that the testimony you are about to give in this proceeding will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do.

EXAMINATION

QUESTIONS BY MR. SAUER:

Q. Could you please state your full name?

A. David Louis Eisenberg.

Q. And you're a medical doctor?

A. I am.

Q. Dr. Eisenberg, have you ever given a

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have to do with the frequency of office hours in Springfield and Joplin. Is that fair to say?

A. No. I think the contingencies are based on the clinical situation at hand. Yes, one of them is the availability of medical personnel, but that is not the most important one. The most important one is what's going on with the patient, what level of service does the patient need, and where can it be delivered?

Q. Suppose that office hours in Springfield are conducted only once per week and the patient calls the day after office hours, so the next office hours won't be for six days. Is there advantage to the patient to having a coverage physician available so she can be examined without having to go to the ER?

A. I just don't feel like that's a realistic scenario where we only see patients once a week.

Q. Assuming – assuming the hypothetical is true.

A. I just -- it seems ludicrous to assume the hypothetical is true. I really -- it just seems ridiculous.

Q. Just under that hypothetical would

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there be an advantage to the patient?

A. I mean, if that nurse decides the patient cannot wait till the next business day when the health center is open, it would be reasonable for her to be referred to an emergency department if that's what was available because nothing else was -- the health center wasn't open.

Q. Would it be preferable for the patient who's in this second bucket to go to the clinic during the next available office hours if they're available to being referred to the ER?

A. We would always prefer our patients to get the care that they need within our health centers because we know the kind of care that we provide. What I know is that sometimes 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, which is again one of the reasons why we have the patients go with the instructions in hand.

That includes how to contact us to talk about what's going on. We ask the patient's permission to call ahead. If the patient gives permission we do so, and we try to be a part of that care team, you know, not direct, but indirect to

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help that care provider that's there trying to assess what this patient needs to be able to, you know, do well.

Q. That's interesting. Let me ask you a follow-up about that. You referred to situations where patients are sent to the hospital and receive more interventions than necessary. What does that mean? What interventions are unnecessarily provided?

A. So my experience in taking care of women in the St. Louis metro area and far afield is that when they go somewhere postabortion, if they have bleeding of any kind they get an aspiration procedure that is unnecessary fairly often.

If they have an ultrasound that's done and that ultrasound shows anything other than a thin homogenous endometrial stripe, but might be totally within the realm of normal expectation postabortion, they get an aspiration procedure that isn't always necessary.

Q. And that's a function or result of the ER doctors at that particular hospital being less experienced in dealing with postabortion situations?

A. It might be a function of the OB/GYN on call being less experienced as well, but the fact is

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that if we can speak to that care team, whether it's the ER doctor or the OB/GYN who sees that patient or the family practice doc who's trained to do miscarriage management and abortion care and help them understand that this is actually within the realm of normal and no intervention is reasonable at this time, then we can hopefully avoid that unnecessary intervention, but sometimes that care happens without us having that conversation.

Q. And when you say we in the sense as you just said, the we you're referring to is actually you and the doctors affiliated with you who are providing apportion care in the first instance?

A. Yes, I guess that would be what I was referring to.

Q. So in other words, there's an advantage to having a communication, a direct line of communication between the doctors who provided abortion care and the ER doctors who are treating the postabortion situation in order to dissuade the ER doctors from providing unnecessary care in some situations, correct?

A. It is advantageous to have communication, but it's not necessary to have any preexisting arrangements or agreements.

Page 1

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,

Plaintiffs,

vs.) Case No.) 2:17-cv-04207-BP

RANDALL WILLIAMS, M.D., in his official capacity as Director of the Missouri Department of Health and Senior Services, et al.,

Defendants.

DEPOSITION OF DAVID L. EISENBERG, M.D.
TAKEN ON BEHALF OF THE DEFENDANTS
MARCH 19, 2018

(Starting time of the deposition: 8:00 a.m.)

Page 2

I N D E X

E X H I B I T S

Page 3

Page 4

(The original exhibits were retained by the court reporter to be attached to the original and copies of the transcript.)

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A. I -- yes.
Q. Okay. I mean, you don't dispute that RHS did not file a single abortion complication report in 15 years for postabortion complications with DHSS, correct?
A. In the time that I've been at RHS as their medical director my understanding is that we've been -- that we have not and that was not in effect.
Q. So your understanding is that you were not legally required to file abortion complication reports with DHSS while you have been medical director of RHS?
A. As you described, that came up during the other case, and there was a memo published by the director of DHSS on May 31st that made it clear that that law is in effect, but prior to that time I was told that that was not an enforced area of the law.
Q. You were told by whom?
A. The folks at Planned Parenthood.
Q. The folks at Planned Parenthood?
A. At Planned Parenthood.
Q. Who in particular told you that that law was not in effect?

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A. I don't remember, but I -- as I said, I've been medical director since August 2009. I've read the statutes covering abortion care in my physician's training reading law and asked the regulatory folks at RHS and the higher-ups throughout the organization and was told that it wasn't required, and that was true of other healthcare facilities where I had provided postabortion care, and there have been a number of conversations as you've pointed out about this issue that resulted in the Dr. Williams memo May 31st, and since that time we have been reporting those.
Q. So you have taken steps since May 31st of 2017 to ensure that the RHS facility is filing postabortion complication reports?
A. Yes.
Q. You referred in your answer a moment ago to higher-ups and regulatory personnel who advised you that it was not required to file those reports. Who are those human beings?
A. Our previous CEO, Paula Gianino. Our current CEO, Mary Kogut. Our lead clinician Suzy Bender and our quality assurance person Caroline Spencer are at least four of them.
There may have been others, but all of whom had participated in annual inspections from the health department, all of whom had been involved in ensuring the induced termination of pregnancy reports are reported, and so I had no reason to question their understanding because they've been through these state-level inspections and other things and it has never been discussed or brought up as an area of concern.

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Q. So do you specifically recollect having conversations with all four of those individuals?
A. No. You asked me who are the human beings. I said that's probably who it would be plus a few others.
Q. Do you remember any specific conversation with another human being where that person advised you that it was not required to file complication reports?
THE WITNESS: Can I ask you a question?
MR. SAUER: That's fine with us.
THE WITNESS: I know he has a question on the table, but can I ask you a question?
MR. HAAR: Sure.
(WHEREIN, a recess was taken from 2:11 p.m. to 2:25 p.m.)
Q. (By Mr. Sauer) When before we broke for you to talk with counsel --

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MR. HAAR: Yeah.
Q. (By Mr. Sauer) -- my understanding was I had asked you about with whom you had discussed the conclusion that RHS was not required to file abortion complication reports with DHSS. You recall that?
A. Yes.
Q. And I understand from an off-the-record conversation with your attorney that there's going to be an assertion of attorney-client privilege as to those conversations?
MR. HAAR: Let me state that it was clear after discussing this issue with Mr. Eisenberg -- Dr. Eisenberg that these conversations in large part, in totality again were in the context of soliciting advice, collecting information, consultation with counsel, and therefore under the circumstances I believe I'm going to have to instruct him not to answer.
Q. (By Mr. Sauer) So following up on what your attorney stated, is it your testimony that all the conversations you had on this topic were either conversations with counsel or conversations that you had for the purpose of seeking advice of counsel?

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

Comprehensive Health of Planned Parenthood Great Plains, et al. Plaintiffs, v. Joshua D. Hawley, in his official capacity as Attorney General of Missouri, et al. Defendants.	)	Case No. 2:16-cv-04313-BCW

Declaration of William Koebel

1. My name is William Koebel. I am the Section Administrator for the Section for Health Standards and Licensure within the Division of Regulation and Licensure of the Missouri Department of Health and Senior Services (Department), which is responsible for inspecting and licensing abortion facilities in Missouri.
2. Attached hereto as Exhibit A is a copy of the Statement of Deficiencies issued by the Department on September 28, 2018, regarding a licensure inspection revisit conducted on September 26, 2018, of the Planned Parenthood licensed abortion facility located at 711 North Providence Road, Columbia, Missouri 65203 (Facility). Exhibit A is a true and accurate copy of the original Statement of Deficiencies issued to the Facility and a true and accurate report of what was observed during the September 26, 2018, licensure inspection revisit of the Facility.
3. Attached hereto as Exhibit B is a copy of the Facility's current abortion facility license which reflects that the license expires on October 2, 2018.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 9-28-18

William Koebel
Section Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services

Exhibit A

PRINTED: 09/28/2018
FORM APPROVED

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases.	{L1084}		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services

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{L1084}	Continued From page 1 Findings included: 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. - Recommendation III.c. * Operating and procedure rooms must be cleaned after each patient. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas and sterile storage areas. 2. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control and Prevention (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC);	{L1084}		

Missouri Department of Health and Senior Services

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{L1084}	Continued From page 2 - Association for the Advancement of Medical Instrumentation (AAMI); and - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Review of the facility's "Infection Prevention Manual" policy titled, "Directions for Cleaning and Disinfection - Abortion Procedure Suction Tubing," dated 08/15, showed: - Single-use suction tubing must be disposed of as an infectious waste after each patient use. - Multi-use suction tubing is first cleaned by running water through the tube, removing all blood and bioburden immediately after the procedure. Then soak tubing in chemical disinfectant ad per manufacturer's instructions for semi-critical devices. 5. Observation on 09/26/18 at 9:40 AM of the procedure room showed: - The metal suction machine cabinet had numerous rusted areas (uncleanable surface); - There was a used, single-use suction tubing connected to a plastic suction canister. The single-use tubing contained reddish colored fluid; - A reusable series connecting hose on the top of the machine had a blackish-gray substance on the inside the length of the tubing; and - The reusable series connecting hose was connected to a reusable glass suction bottle. There was a layer of dried black substance in the bottom of the bottle.	{L1084}		

Missouri Department of Health and Senior Services

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{L1084}	Continued From page 3 During an interview upon the observation Staff C, Health Center Manager, stated that the replacement reusable series connecting hose was on back order. 6. Observation on 09/26/18 at 9:50 AM of the storage room showed the metal cabinet of a second suction machine had numerous rusted areas, old peeling tape, dried adhesive residue on the front surface, (uncleanable surfaces) and a dried brown spill down the side of the machine that was approximately six-inches long. 7. During an interview on 09/26/18 at 9:55 AM, Staff C stated that: - The substance in the single-use suction tubing was most likely bodily fluid; - Their last procedure had been the previous Friday (09/21/18); - She did not think they had used the suction machine that day; and - The blackish gray substance in the secondary reusable series connecting hose was mold. 8. During an interview on 09/26/18 at 12:00 PM, Staff I, Maintenance, stated that the replacement for the reusable series connecting hose was located inside the suction machine cabinet. Staff C stated that she was not aware that the secondary replacement reusable series connecting hose was inside the suction cabinet. 9. During an interview on 09/26/18 at 2:10 PM, Staff C stated that: - She identified the problem (blackish gray residue) inside the reusable series connecting hose a couple of months previously (probably July) and began trying to find replacement tubing; - They continued to use the machine (with the	{L1084}		

Missouri Department of Health and Senior Services

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{L1084}	Continued From page 4 reusable series connecting hose that had blackish gray residue inside) on patients after they identified the issue; and - She had talked with other people about the issue with the reusable series connecting hose and it was not an infection control issue. 10. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 2017, showed: - 3.3.6.4 Sterile storage: * Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. * Storage areas should be designed to protect sterile items and their packaging from damage. - 11.1.1 Storage Facilities: * The bottom shelf of storage carts or shelving should be solid. 11. Observation on 09/26/18 at 10:00 AM of the recovery room medication supply room showed a metal storage shelving unit. There was no bottom barrier on the bottom shelf. The shelf was placed over a submersible sump pump (used to remove water that has accumulated in a water-collecting sump basin) installed in the floor. 12. Observation on 09/26/18 from 10:05 AM to 10:10 AM of exam room #1 and #2 showed each room contained a pressed wood table with chipped paint exposing the pressed wood (uncleanable surface). 13. Observation on 09/26/18 at 10:10 AM of the soiled room showed the cabinet under the sink	{L1084}		

Missouri Department of Health and Senior Services

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{L1084}	Continued From page 5 had a large area of dried white residue and an area of dried yellowish brown residue. During an interview upon the observation, Staff C stated that housekeeping staff were responsible to clean and confirmed the cabinet was not clean.	{L1084}		
L1113	19 CSR 30-30.060(2)(K) The facility shall ensure, each patient prep The facility shall ensure that each patient is prepared for the abortion in a manner that facilitates her safety and comfort. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included: 1. Review of the FDA/Consumer Product Safety Commission (CPSC) document titled, "FDA/CPSC Public Health Advisory - Hazards Associated with the Use of Electric Heating Pads", dated 12/12/95, showed: - The FDA and CPSC have received many reports of injury and death from burns, electric shock and fires associated with the use of electric heating pads. - An electric heating pad can be dangerous for patients with decreased temperature sensation and patients taking medication for pain.	L1113		

Missouri Department of Health and Senior Services

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L1113	Continued From page 6 - Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads: - Never [partial list]: * Use on a person who has skin that is not sensitive to temperature changes (e.g. sedated or medicated for pain). * Use in an oxygen enriched environment or near equipment that stores or emits oxygen. 2. Observation 09/26/18 at 9:30 AM in the recovery room showed: - Four recovery chairs with heating pads draped across the backs. - Three of the four heating pads were labeled "For Household Use Only" and the fourth heating pad was not labeled. - The fourth heating pad cover showed a one inch streak of clear, hard surface matter with a small circular bead of clear material at the top on the heating pad cover. 3. During an interview on 09/26/18 at 1:45 PM, Staff C, Health Center Manager, stated that: - The heating pads were for household use and needed to be removed. - She did not believe the facility had a policy for the use of heating pads.	L1113		

ABORTION FACILITY LICENSE

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

Comprehensive Health of Planned Parenthood Great Plains, Inc.

711 N. Providence Road
Columbia MO 65203

IS GRANTED THIS LICENSE PURSUANT TO SECTIONS 197.200 THROUGH 197.240, RSMo TO OPERATE AN ABORTION FACILITY

Issue Date: October 3, 2017

Expiration Date: October 2, 2018

Administrator
Bureau of Ambulatory Care

LICENSE NO. 16-3

DHSS Complaint Number: 1-573-751-6083

MO 580-0015 (7-03) 0069

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al. Plaintiffs, v. DR. RANDALL WILLIAMS, et al., Defendants.	)	Case No. 2:16-cv-04313-HFS

STATE DEFENDANT'S SUGGESTIONS IN OPPOSITION TO PLAINTIFFS' THIRD MOTION FOR PRELIMINARY INJUNCTION

Table of Contents

INTRODUCTION

Plaintiffs' third motion for preliminary injunction, Doc. 152, should be denied. Plaintiffs' claim for relief at the Columbia facility fails as a matter of law for several reasons. First, Plaintiffs cannot establish that the hospital-privileges requirement imposes a substantial obstacle on a "large fraction" of affected Missouri women. The fraction that Plaintiffs themselves provide—22 percent—is not a "large fraction" under controlling case law. Second, Plaintiffs rely solely on increased driving distances to posit a "substantial obstacle," but the Supreme Court's case make clear that increased travel distances alone do not constitute a "substantial obstacle." Third, the hospital-privileges requirement is not unduly difficult to satisfy in Columbia, Missouri, which has many OB/GYNs and multiple hospitals. If Plaintiffs cannot satisfy the requirement, that is because of the refusal or unwillingness of doctors with hospital privileges to perform abortions, and it is not due to any action of the State. As the Jackson County Circuit Court recently held, "the issue of abortion provider scarcity is not one of the state's making and, therefore, should not be considered by this Court in consideration of the undue-burden analysis." Fourth, Plaintiffs lack standing and their claim is unripe because they have presented no evidence of any recent efforts to comply with the hospital-privileges requirement in Columbia—their only evidence is two years old. Fifth, Plaintiffs gravely underestimate the health risks of abortion in Missouri, and abundant evidence in the record demonstrates that those risks are far greater than Plaintiffs' expert predicts. Sixth, Plaintiffs ignore or mischaracterize the evident health benefits of the requirement, which include ensuring continuity of care for patients and ensuring that a qualified physician takes responsibility for patients experiencing post-abortion complications. Seventh, Plaintiffs greatly exaggerate the supposed burdens on women from the hospital-privileges requirement, and their methodologically flawed analysis overestimates the number of women impacted.

The State Defendants hereby incorporate by reference the evidence and arguments in their prior filings in this case, including but not limited to their Response in Opposition to Plaintiffs' Second Motion for Temporary Restraining Order, ECF No. 141, and Exhibits thereto.

ARGUMENT

Preliminary injunctive relief is "an extraordinary remedy," and "the burden of establishing the propriety of an injunction is on the movant." *Watkins Inc. v. Lewis*, 346 F.3d 841, 44 (8th Cir. 2003). The Court considers four factors in determining whether to grant a temporary injunction: "(1) the likelihood of the movant's success on the merits; (2) the threat of irreparable harm to the movant in the absence of relief; (3) the balance between that harm and the harm that the relief would cause to other litigants; and (4) the public interest." *Id.* (citing *Dataphase Sys., Inc. v. C.L. Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc)).

I. Plaintiffs Are Not Likely to Succeed on the Merits.

Plaintiffs are not likely to succeed on the merits because their claim of an undue burden for women seeking abortions at the Columbia facility suffers from numerous fatal deficiencies.

A. Plaintiffs' claim fails because 22 percent is not a "large fraction."

First, Plaintiffs' claims fail as a matter of law because 22 percent is not a "large fraction" of Missouri women seeking abortions for whom the Columbia clinic is the closest clinic. Thus, even if Plaintiffs' predictions of impact on the abortion rate were correct (which they are not, *see infra*), and even if Plaintiffs had identified the correct denominator (which they have not),[1] their claims would still fail as a matter of law.

[1] As the State Defendants previously argued, Doc. 141, at 20-21, the correct denominator is not the number of women seeking abortions for whom the Columbia facility is the closest, but the number of women seeking abortions throughout Missouri, because the regulation affects all Missouri abortion facilities and it is thus "relevant" for all Missouri women. *See* Doc. 141, at 20-21; *Planned Parenthood of Arkansas & E. Oklahoma v. Jegley*, 864 F.3d 953, 953 (8th Cir. 2017)

The Supreme Court in *Casey* identified two threshold elements for any undue-burden challenge to an abortion regulation: the challenged regulation must impose (1) a "substantial obstacle" to (2) a "large fraction" of women for whom the restriction is relevant. *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 894-95 (1992) (holding that an abortion regulation is invalid if, "in a *large fraction* of the cases in which [the statute] is relevant, it will operate as a *substantial obstacle* to a woman's choice to undergo an abortion") (emphases added); *see also June Med. Servs. L.L.C. v. Gee*, 905 F.3d 787, 803 (5th Cir. 2018) ("[W]e must weigh the benefits and burdens of [the statute] to determine whether it places a *substantial obstacle* in the path of a *large fraction* of women seeking abortions in Louisiana") (emphases added).

Here, Plaintiffs purport to seek relief on behalf of all Missouri women "for whom the Columbia health center is the closest [abortion] provider." Doc. 153, at 25; *see also id.* at 17, 18, 23 n.23, 24. They predict that the hospital-privileges requirement will prevent 22 percent of those women, for whom the Columbia facility is the closest in-state abortion facility, from obtaining an abortion who otherwise would have obtained one. *Id.* at 3, 17, 19, 20; *see also* Doc. 133-3 (Lindo Declaration).

As the State Defendants have previously argued, Doc. 141, at 5-8, the law is clear that 22 percent is not a "large fraction" under *Casey*. Just a few months ago, the Fifth Circuit held that 30 percent is not a "large fraction." *June Medical*, 905 F.3d at 814 (holding that the large-fraction requirement was not met where "only 30% (or, less than one-third) of women seeking an abortion

("Because the [challenged] requirement only applies to medication-abortion providers, the 'relevant denominator' here is women seeking abortions in Arkansas."); *June Medical*, 905 F.3d at 802 ("Here, too, the relevant denominator to determine a "large fraction" is all women seeking abortions in Louisiana, as [the statute] applies to providers of both medication and surgical abortions."); *Whole Woman's Health v. Lakey*, 769 F.3d 285, 299 (5th Cir. 2014) ("*Casey* itself counsels that the denominator should encompass all women 'for whom the law is a restriction.'").

would face even a potential burden of increased wait times"); *id.* at 815 ("Bearing a burden of 30% compared to the typical burden of 100% is not large. To conclude otherwise eviscerates the restrictions on a successful facial challenge."). The Fifth Circuit had already held that 17 percent is "nowhere near a 'large fraction.'" *Whole Women's Health v. Lakey*, 769 F.3d 285, 298 (5th Cir. 2014) (holding that 16.7 percent is "nowhere near a 'large fraction' . . . We decline to interpret *Casey* as changing the threshold for facial challenges from 100% to 17%."). Last year, the Eighth Circuit stated in *Jegley* that 12 percent is not a "large fraction." *Planned Parenthood of Arkansas & E. Oklahoma v. Jegley*, 864 F.3d 953, 959 n.8 (8th Cir. 2017) (citing with approval the Sixth Circuit's holding that "12 percent does not constitute a 'large fraction'"). Both the Eighth Circuit and the Fifth Circuit cited with approval the Sixth Circuit case holding that 12 percent is not a "large fraction." *Cincinnati Women's Services, Inc. v. Taft*, 468 F.3d 361, 374 (6th Cir. 2006) ("[T]he term 'large fraction' . . . envisions something more than the 12 out of 100 women identified here").[2]

[2] Plaintiffs argue in a footnote that the Eighth Circuit has suggested that 18 percent is a "large fraction," Doc. 153, at 26 n.27 (citing *Planned Parenthood, Sioux Falls Clinic v. Miller*, 63 F.3d 1452, 1462 n.10 (1995)), but they plainly misconstrue that case. *Miller* held that a parental-notice statute that lacked a judicial-bypass provision was unconstitutional. *Miller* explicitly stated that "requiring parental notice . . . is *not* an undue burden on immature minors who cannot show that an abortion would be in their best interests." *Miller*, 63 F.3d at 1459. *Miller* held that: "The State runs afoul of the Constitution, however, when it attempts to give that same power to parents of mature daughters capable of making their own informed choices." *Id.* at 1460. In other words, *Miller* concluded that the parental notice-requirement constituted a substantial obstacle for all the minors for whom it was relevant—*i.e.* those who were sufficiently mature to make their own decision or for whom an abortion was in the best interest. *Id.* The "large fraction" in *Miller* was thus 100 percent, not 18 percent. *See id.* (holding that the "requirement . . . places a substantial obstacle in the way of a mature or best-interests minor's right to choose"). *Miller* referred to the 18 percent figure only in a footnote, in rejecting the argument that South Dakota's alternative abuse-and-neglect bypass procedure was insufficient. That footnote stated in passing: "Roughly eighteen per cent. of South Dakota's minors live in single-parent homes; many of them, as a practical matter, have only one parent to notify." *Id.* at 1462. Nothing in the reasoning or holding of *Miller*, therefore, even remotely suggests that 18 percent is a "large fraction" under *Casey*.

Moreover, the Sixth Circuit case, which both the Eighth Circuit and the Fifth Circuit cited with approval, holds that a "large fraction" must be substantially more than 50 percent, and likely much closer to 100 percent—*i.e.*, "practically all of the affected women." *Id.* at 373 ("Other circuits that have applied the large fraction test to facial challenges to abortion regulations have, likewise, only found a large fraction when *practically all* of the affected women would face a substantial obstacle in obtaining an abortion.") (emphasis added). The Fifth Circuit, likewise, has held that a "large fraction" must comprise the "vast majority" of women affected by the regulation. *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 748 F.3d 583, 600 (5th Cir. 2014) (holding that the "large fraction" test was not met because "the burden does not fall on the *vast majority* of Texas women seeking abortions") (emphasis added).

This holding that a "large fraction" is much closer to 100 percent than 50 percent follows directly from the reasoning of the Supreme Court's abortion decisions. Outside of the abortion context, the default rule for facial challenges is that 100 percent of the challenged statute's applications have to be invalid. *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449 (2008); *United States v. Salerno*, 481 U.S. 739, 745 (1987). In adopting the "large fraction" test in *Casey*, the Supreme Court relaxed the *Salerno* standard somewhat, but did not purport to abolish it entirely. *See June Medical*, 905 F.3d at 815 ("The shift from the usual [*Salerno*] standard to the large-fraction standard was intended to ease the burden on abortion plaintiffs relative to plaintiffs who bring challenges to other sorts of laws. There is a difference, however, between cracking the door and holding it wide open."). For this reason, the Supreme Court has explicitly stated that the "large fraction" test is *more* exacting, and thus requires a *bigger* fraction, than the "substantial overbreadth" test of the First Amendment, which requires something more than 50 percent. *See Gonzales v. Carhart*, 550 U.S. 124, 167 (2007) ("The latitude given

facial challenges in the First Amendment context [substantial overbreadth] is inapplicable here. Broad challenges of this type impose 'a heavy burden' upon the parties maintaining the suit."). To argue that 22 percent is a "large fraction" directly contradicts the reasoning and holding of *Gonzales*.

Plaintiffs' arguments to the contrary have no merit. First, Plaintiffs argue that the "large fraction" test does not apply *at all*, because they claim they have asserted an "as-applied" challenge. This argument is plainly meritless. As the State Defendants have previously pointed out, Doc. 141, at 4-5, the "large fraction" test does not apply to "as applied" challenges only when the challenge is brought *on behalf of a single, individual woman seeking an abortion*. This is because the "large fraction" test makes no sense to apply to a challenge brought by a single individual—the numerator and denominator are both one, leading to a fraction of 100 percent in every case where a substantial obstacle is found (or zero percent if one is not found). But Plaintiffs do not seek relief on behalf of an individual patient. Rather, their motion seeks sweeping relief on behalf of all women for whom the Columbia facility is the closest in-state abortion facility, which includes many thousands of Missouri women of reproductive age in much of central and Western Missouri—in fact, because Plaintiffs discount out-state facilities, it may include more than half of Missouri's female population, including the entire western half of the State. As the State Defendants have previously argued, this is not an "as applied" challenge at all, but a modified facial challenge. Doc. 141, at 4-5. The Supreme Court has clearly held that an "as applied" challenge, in the abortion context, relates to the "discrete case" of an individual patient seeking an abortion. *Gonzales*, 550 U.S. at 168 (describing "as applied" challenges, in the abortion context, as one which presents "a discrete case" of an individual woman's personal health risk, and holding

that "for this reason, as-applied challenges are the basic building blocks of constitutional adjudication"). There is nothing "discrete" about the sweeping relief sought here.

In any event, regardless of whether the relief sought in Plaintiffs' motion is described as "facial" or "as-applied," they seek relief that would prevent enforcement of the law on behalf of a large geographical and demographic swath of Missouri. By Plaintiffs' logic, they would be entitled to an injunction against enforcement of the law at the Columbia facility if they could demonstrate that it imposed a substantial obstacle on *a single woman* in mid-Missouri, which is directly contrary to the reasoning and holding of both *Casey* and *Gonzales*. *Casey*, 550 U.S. at 894-95; *Gonzales*, 550 U.S. at 168. Plaintiffs cite no authority that supports this counterintuitive and absurd conclusion.

Plaintiffs also argue that their estimate of 22 percent is less than the total fraction of women facing a substantial obstacle, because that number reflects the women who are prevented from having an abortion, while an indeterminate number of additional women are *delayed* before having an abortion. Even if a mere delay of indeterminate length could constitute a "substantial obstacle," which it does not, the Eighth Circuit's opinion in *Jegley* forecloses this argument. In *Jegley*, the Eighth Circuit held that a plaintiff who argues that women will experience delay before having an abortion must provide evidence supporting an estimate of "the number of women who would postpone their abortions," to allow for meaningful application of the "large fraction" test. *Jegley*, 864 F.3d at 959-60. Here, Plaintiffs provide no numerical evidence of "the number of women who would postpone their abortions," other than vague speculation. *Id.* Because the "large fraction" test is "not entirely freewheeling," *id.* at 960, this speculation is insufficient to carry their burden.

B. Increased driving distances alone do not constitute a "substantial obstacle."

Second, Plaintiffs' claims fail as a matter of law because the only increased burden on women that they identify is increased driving distances (and the incidental burdens that necessarily follow from travel, such as transportation costs, costs of child care while traveling, and costs of taking time off work to travel). Such increased travel distances do not constitute a "substantial obstacle" under the holding of *Casey*, because *Casey* itself held that increased driving distances very similar to those asserted here—up to three hours of travel for 42 percent of women in Pennsylvania—did not constitute a substantial obstacle. *Casey*, 505 U.S. at 886-87; *see also Planned Parenthood of Southeastern Pa. v. Casey*, 744 F. Supp. 1323, 1352 (E.D. Pa 1990).

Because of *Casey*'s holding that such increased driving distances did not constitute a substantial obstacle, subsequent cases have carefully specified that other burdens in addition to and independent of increased driving distances must be included as well to constitute a undue burden. For example, *Whole Woman's Health v. Hellerstedt* explicitly "recognize[d] that increased distances do not always constitute an 'undue burden,'" and treated them as "one additional burden" to be "taken together with others that the closings brought about," such as massive congestion at Texas abortion facilities, long waiting periods before obtaining an abortion, and similar burdens. 136 S. Ct. 2292, 2313 (2016). In *Hellerstedt*, "the Court identified four obstacles erected by Texas's requirement of admitting privileges: closure of facilities, difficulty in obtaining privileges, driving distances, and clinic capacities. The Court decided not that any burden individually was sufficient but that the four dominoed to constitute a substantial burden." *June Medical*, 905 F.3d at 807. *Hellerstedt* thus concluded that there was a substantial obstacle only by "stacking that burden [of driving distances] on top of the others." *Id.* at 804.

Here, by contrast, Plaintiffs do not identify any burdens other than increased driving distances and inconveniences that flow directly from increased driving distances, and they provide no evidence of increased congestion or long wait times at Missouri clinics. "The Court in [*Hellerstedt*] found unduly burdensome the expectation that 8 clinics could absorb the work of 40. Each remaining Texas abortion provider would have had to increase his capacity by a factor of 5." *June Medical*, 905 F.3d at 812 (citing *Hellerstedt*, 136 S. Ct. at 2317). In Missouri, the St. Louis facility is much larger and performs many times more procedures than the Columbia facility. The operation of the Columbia facility will have no discernible impact on congestion at the St. Louis facility—and Plaintiffs have submitted no evidence to suggest otherwise. Accordingly, this case differs starkly from *Hellerstedt*, and *Casey*'s holding directly controls.

C. Plaintiffs' claims fail because they incorrectly attribute to the State burdens that are attributable to third parties outside the State's control.

In addition, Plaintiffs' claim fails as a matter of law because they repeatedly, and erroneously, attribute to the State alleged burdens on access to abortion that are caused by the independent actions of third parties outside the State's control.

As the Supreme Court has repeatedly held, "[a]lthough government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles not of its own creation." *Harris v. McRae*, 448 U.S. 297, 316 (1980); *see also Maher v. Roe*, 432 U.S. 464, 474 (1977). Despite this holding, Plaintiffs repeatedly attribute to the State issues relating to abortion access that are caused by the actions of third parties outside the State's control. For example, Plaintiffs repeatedly complain that Missouri's informed-consent law requires women to travel to the abortion facility "twice," supposedly doubling the requisite driving distance. Doc. 153, at 2, 4, 17, 18, 21, 23, 24. But Missouri's informed-consent law does not

require two trips to the abortion facility to complete the informed-consent process. The informed consent may occur at another facility, such as the Columbia facility, regardless of whether the abortion is performed there. The reason the informed-consent process does not happen in Columbia is that Plaintiffs' physicians are unwilling to travel to Columbia to meet women before they have abortions, because they contend that they are simply too busy with other matters, and/or that there are too few physicians willing to perform this role. The Jackson County Circuit Court, in denying a TRO to these same plaintiffs in a recent case challenging this very aspect of the informed-consent law, held as follows: "the issue of abortion provider scarcity is not one of the state's making and, therefore, should not be considered by this Court in consideration of the undue-burden analysis." *See* Judgment/Order Denying TRO, *Comprehensive Health of Planned Parenthood Great Plains, et al. v. Hawley*, No. 1716-CV24109 (Jackson Cty. Cir. Ct.) (Oct. 23, 2017), at 8 (filed as Doc. 141-5).

The same reasoning undermines Plaintiffs' entire theory of undue burden in this case. Plaintiffs contend that the hospital-privileges requirement prevents the Columbia facility from performing abortions, because the sole doctor willing to perform abortions there is based in St. Louis and cannot obtain hospital privileges in Columbia. But there are many OB/GYNs in the Columbia area who are able to obtain hospital privileges in the area, which contains at least two major hospitals. Unlike the situation in Texas, *see June Medical*, 905 F.3d at 804, there is no evidence that it is unduly difficult for doctors who reside and practice in the Columbia area to obtain hospital privileges in Columbia. Rather, Plaintiffs' difficulty is that, for reasons entirely outside the State's control, they have failed to recruit any of the many qualified OB/GYNs or other physicians with hospital privileges in the Columbia area to perform abortions at their Columbia facility. If it is true that no qualified physicians in the Columbia area are willing to perform

abortions at the Columbia facility, *but see infra* Part I.D, that fact is not caused by the State, but it is caused by the independent choices and actions of parties outside the State's control. The Constitution simply does not obligate the State to recruit and produce willing abortion providers for the Columbia facility.[3] As the Fifth Circuit squarely held in *June Medical*, the "inaction" and "personal choice" of abortion providers not to perform abortions "cannot be legally attributed to" the challenged statute. *June Medical*, 905 F.3d at 811. And as Judge Burnett held, "the issue of abortion provider scarcity is not one of the state's making and . . . should not be considered by this Court in consideration of the undue-burden analysis." Doc. 141-5, at 8.

D. Plaintiffs have not submitted sufficient evidence to establish standing and ripeness for their claim.

For related reasons, Plaintiffs have not submitted evidence to establish standing and ripeness for their current request for relief. Obviously, the hospital-privileges requirement imposes no obstacle to women in the Columbia area if Plaintiffs can comply with it—*i.e.*, if they can recruit a physician with hospital privileges who is willing to perform abortions at the Columbia facility. Over two years ago, in late 2016, Plaintiffs presented evidence that they were unable either to recruit a physician with such privileges or to obtain privileges for the physician(s) who are willing to perform abortions there. *See* Doc. 15-1. But Plaintiffs have submitted no evidence of any efforts to recruit a physician with privileges in Columbia, or to obtain privileges for their physicians in Columbia, in the intervening two years. Neither the motion they filed in September 2018, nor their current renewed motion filed in December 2018, cited or provided any such evidence. In fact,

[3] For the same reason, Plaintiffs' argument that the undue-burden analysis should not take into account abortion facilities in neighboring States that Missouri women frequently use—such as the facility in Overland Park, Kansas, which is in the Kansas City metropolitan area—is meritless. The Supreme Court's abortion cases do not require the States to take affirmative steps to guarantee the existence of abortion providers within their borders. Those cases only prohibit the States from imposing undue burdens on access to the abortion providers who are available.

Plaintiffs are currently refusing to respond to the State Defendants' preliminary-injunction-related discovery requests, which ask for this very information. *See, e.g.,* Doc. 155-4, at 6 (Interrogatories 1 and 2).

Another District Judge in this Circuit recently denied temporary injunctive relief to these same Plaintiffs, raising similar claims, for exactly the same reason. In *Comprehensive Health of Planned Parenthood Great Plains v. Williams*, No. 17-4207-CV-C-BP, Judge Phillips denied Plaintiffs' request for a temporary restraining order against Missouri's complication-plan requirement because Plaintiffs had not "identified efforts made to comply with the regulation." Order and Opinion Denying Plaintiffs' Motion for Temporary Restraining Order, *Comprehensive Health of Planned Parenthood Great Plains v. Williams*, No. 17-4207-CV-C-BP, Doc. 26, at 6 (Nov. 3, 2017) (attached as Exhibit 1). This Court held that Plaintiffs had not submitted evidence to show that they were unable to recruit a backup physician with admitting privileges in the Columbia area, because their only efforts to do so were two years old: "Moreover, even if admitting privileges are required, Plaintiffs have not attempted to find a qualifying OB/GYN who will contract with the Columbia clinic. They last sought doctors to contract with in 2015, which was two years ago. This does not establish that Plaintiffs could not *today* find an OB/GYN who will satisfy the regulation's requirements." *Id.* at 7 (emphasis in original). For this reason, the Court concluded that "[a]t present, Plaintiffs have not demonstrated that they cannot comply with the regulation." *Id.*

So also here, Plaintiffs have not submitted evidence to demonstrate their inability to recruit a doctor with hospital privileges to perform abortions at the Columbia facility since late 2016, "which was two years ago." *Id.* "This does not establish that Plaintiffs could not *today* find an OB/GYN who will satisfy the [statute's] requirements." *Id.* (emphasis in original).

In the absence of current evidence demonstrating that they cannot satisfy the hospital-privileges requirement through reasonable efforts, Plaintiffs lack Article III standing and their claims are unripe. Standing requires "that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Article III standing is lacking where "the dispute is purely hypothetical and the injury is speculative." *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1137 (9th Cir. 2000) (en banc).

The ripeness doctrine "prevent[s] courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Thus, "the ripeness doctrine is 'drawn from both Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.'" *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (quoting *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993)).

The burden is on the party invoking the court's jurisdiction to prove that its injuries are not speculative and hypothetical, and that its claims are ripe. *Nebraska Pub. Power Dist. v. MidAmerican Energy Co*., 234 F.3d 1032, 1039 (8th Cir. 2000). This burden requires a showing both that the issues have crystallized to the point of being fit for review, and that there would be hardship to the parties from withholding court consideration. *Parrish v. Dayton*, 761 F.3d 873, 875 (8th Cir. 2014). Because Plaintiffs have submitted no evidence in over two years to

demonstrate that they are not currently able to satisfy the hospital-privileges requirement at the Columbia facility, they lack standing and their claim is unripe.

E. Plaintiffs gravely underestimate the health risks of abortion in Missouri.

In addition, Plaintiffs gravely underestimate the health risks of abortion in Missouri. As the State Defendants have established through previous filings, the record demonstrates that abortion complications are far more frequent and more severe than Plaintiffs predict.

1. Plaintiffs ignore strong evidence of systematic underreporting of abortion complications.

The evidence in the record indicates that there are four "layers," so to speak, of abortion complications. First, there are the abortion complications that are known to the abortion providers and reported to the States. Plaintiffs' predictions of abortion complication rates are entirely rooted in this first "layer," and they ignore the impact of the other three layers of complications. And even relying on this first "layer" alone, Plaintiffs gravely underestimate the frequency and severity of complications. *See* Coleman Decl., Ex. 2, ¶¶ 55-61. The abortion complication reports filed with the State since May 2017 indicate that this first "layer" alone is far more severe than Plaintiffs admit, for the reasons discussed below. *See infra* Part I.E.2.

Second, there are complications that are known to abortion providers but that they fail to report to the States. For decades prior to 2017, this "layer" comprised virtually *all* complications in Missouri, as Plaintiffs and other abortion providers systematically ignored their legal obligation to provide abortion-complication reports, as mandated by Mo. Rev. Stat. § 188.052.2. Plaintiffs do not dispute that they never filed any mandatory abortion complication reports at any time prior to May 2017, though the statutory obligation has been in effect for decades.

Third, there are the abortion complications that neither the abortion providers nor the State ever know about, because the patients seek treatment elsewhere, do not notify the health care

provider that the complications arose from an abortion, and/or the patient is "lost to follow-up" for any number of other reasons. These are major issues leading to significant underreporting of abortion complications, as Plaintiffs have effectively conceded in a related case. *See, e.g.,* Eisenberg Dep. 235-36 (attached as Exhibit 3) (testifying that "it's a regular occurrence" that women seeking post-abortion treatment fail to disclose to doctors that they had an abortion); McNicholas Testimony Tr. 265 (attached as Exhibit 4) (agreeing that "many women who seek treatment for post-abortion complications may not tell the [provider treating the complication] that they had an abortion"). And a practice bulletin of the American College of Obstetricians and Gynecologists reports "loss-to-follow rates as high as 45% in clinical settings" for post-abortion treatment of medication abortion patients. ACOG Practice Bulletin No. 143, at 9 (2014).

Fourth, there are the abortion complications that would have occurred but did not, because since 2007 Missouri has imposed reasonable regulations on abortion facilities designed to promote women's health and safety. In claiming that the St. Louis facility has a strong safety record (which it does not), Plaintiffs overlook that, for the entire relevant time period, the St. Louis facility complied with both the ASC requirements and the hospital-privileges requirement that have been challenged in this case. Even more complications, and more severe complications, would undoubtedly have occurred if abortion facilities had been radically deregulated as Plaintiffs wish. This point is especially important because the hospital-privileges requirement and other regulations are not directed only to Plaintiffs, or only to the Columbia facility. Rather, they are *statewide* requirements that prevent abuses and promote safety not just at Plaintiffs' facilities, but also for "the shoddiest operators" and "the worst providers." Doc. 84, at 1 (quoting Megan Twohey, *State Abortion Records Full of Gaps*, CHICAGO TRIBUNE, at 5 (June 16, 2011) (filed as Doc. 84-1)).

2. Complication reports filed since May 2017 reflect a much higher complication rate than Plaintiffs contend.

Plaintiffs contend that "the record shows that abortion complication rates in Missouri are entirely consistent with the rates reported in the national literature." Doc. 153, at 5. On the contrary, the existing evidence from recent complication reports suggests that abortion complication rates in Missouri are much higher than the national rates predicted by Dr. Eisenberg and the Upadhyay study on which he relies. *See* Doc. 153, at 5 n.4. As discussed in the State Defendants' motion for preliminary-injunction-related discovery, Doc. 155, at 6-7, "the complication reports filed since May 2017 directly undermine the Plaintiffs' contentions regarding the safety of abortion procedures in Missouri." *Id.* at 6. Between June 2017 and October 2018, the Department received 193 complication reports and 4,669 abortion reports, implying an overall complication rate of 4.13 percent (193/4,669).[4] *See* Affidavit of Lori Brenneke, attached as Exhibit 5 & atts. (attachments to be filed separately as an Exhibit under seal upon leave of Court). Again, this ratio is almost double the national complication rate of 2.1 percent predicted by Plaintiffs' expert and the Upadhyay study. *See* Doc. 153, at 5. Those 193 complication reports reflect 28 incidents that Plaintiffs and Upadhyay et al. would classify as "major" complications, involving hospital treatment, blood transfusions, and problems of similar severity. *See, e.g.,* Ex. 5 & att. at 29, 30, 32, 47-52, 54, 83, 84, 92, 102, 103, 105, 107, 123, 143, 149, 150, 157, 159, 160, 161, 162, 169, 172, 175, 178, 180, 182, 194 (complication reports reflecting major complications). This implies an overall rate of major complications of 0.60 percent (28/4,669)—again, much higher

[4] These numbers are updated from the numbers reported in the State Defendants' Motion for Preliminary-Injunction-Related Discovery, Doc. 155, at 5-7, because the Department received additional complication reports and abortion reports for October 2018 since that filing on December 28, 2018. As they did previously, the State Defendants are filing with this response a motion for leave to file the additional complication reports under seal and to disclose them to Plaintiff's counsel pursuant to the protective order.

than the major-complication rate predicted for Missouri by Dr. Eisenberg. These major complications include grave and life-threatening scenarios such as septic abortion, cervical laceration, uterine perforation, significant hemorrhages, pyrexia, and other conditions. *See id.*

To be sure, any complication rate drawn from the complication reports is inexact because (1) the complication reports include many cases of treatment in Missouri for abortions performed outside Missouri, and (2) they do not include cases for treatment provided outside Missouri for abortions performed in Missouri. *Id.* Also, the complication reports are almost certainly greatly underinclusive. Given that health care providers failed to file such reports for decades, failing to file such reports almost certainly continues. Furthermore, the complication reports cannot capture instances where women sought treatment for complications without telling the physician that the complications resulted from an abortion, which Plaintiffs' physicians have admitted in another case is a significant source of underreporting. *See* Eisenberg Dep. 235-236 (Ex. 3); McNicholas Tr. 265 (Ex. 4); ACOG Practice Bulletin No. 143, at 9.[5]

Plaintiffs repeatedly contend that "DHSS did not *request or collect* complication reports from abortion providers or any other medical providers" prior to May 2017. Doc. 153, at 7 (emphasis added); *see also* Doc. 153-2, ¶ 7. But the statute does not require the Department to "request or collect" complication reports. The statute places the affirmative duty on *the providers* to file the reports: "An individual abortion complication report for any post-abortion care performed upon a woman shall be completed *by the physician* providing such post-abortion care."

[5] Plaintiffs contend that the complication reports filed since May 2017 provide no evidence of poor communication between abortion providers and physicians treating complications from the abortions. On the contrary, numerous complication reports indicate that the doctor treating the complication did not even know where the abortion was performed. *See, e.g.*, Ex. 5 & att. at 49, 79, 80, 83, 91, 95, 100, 156, 174. In some cases, there had obviously been no communication *at all* between the abortion provider and the physician treating the complication. *See also* Doc. 28-4, at 6.

Mo. Rev. Stat. § 188.052.2. "All complication reports shall be signed by the physician providing the post-abortion care and submitted to the department of health and senior services within forty-five days from the date of the post-abortion care." Mo. Rev. Stat. § 188.052.3. Moreover, the very same statutory section requires the filing of abortion reports, *see id.*, and Plaintiffs filed many thousands of abortion reports during the same time period. Plaintiffs have never explained why they complied with the requirement of filing abortion reports while systematically ignoring the requirement of filing complication reports, which is found in the very same statutory section—and again, they are currently refusing to respond to the State Defendants' discovery requests, which ask these very questions.[6] Docs. 155-3, 155-4 (Interrogatories 5, 6, 7).

Plaintiffs contend that their failure to file mandatory complication reports for decades should be excused because they were supposedly "complying with the state-mandated quality assurance process overseen by DHSS." Doc. 153, at 7. On the contrary, Plaintiffs' facilities were frequently cited for failing to comply with quality-assurance procedures during this period. *See infra* Part I.E.3. In any event, establishing a quality-assurance process is not a substitute for filing complication reports, because it does not create reliable statistical data for abortion complications in Missouri, and does not allow off-site scrutiny of the health-and-safety records of the facilities.

3. Plaintiffs' own facilities have a troubling history of substandard health-and-safety practices.

Moreover, the health-and-safety records of Plaintiffs' own abortion facilities highlight the problems in abortion safety in Missouri. Most recently, on September 26, 2018, black mold and bodily fluid were discovered in the tubing of the suction aspiration machine used on patients in the

[6] Plaintiffs also claim that the Department failed to publish complication data in annual reports. Doc. 153, at 7. Because Plaintiffs and other providers were not filing complication reports, it is hard to see what data Plaintiffs think the Department should have been publishing, but was not.

Columbia facility at issue here. *See* Doc. 141-1 (Declaration of William Koebel); *see also* Declaration of William Koebel ¶¶ 2-8 (attached as Exhibit 6). Plaintiffs argue that the State's claim that black mold and bodily fluid were discovered in the suction aspiration machine is "inflammatory and false," but Plaintiffs never actually dispute any of the critical facts: (1) a black substance was clearly visible in one portion of tubing, and a reddish fluid was clearly visible in another portion of tubing; (2) Plaintiff's own Health Center Manager identified the substances and mold and bodily fluid during the inspection; and (3) the machine had been used on at least one patient while it was in that unsanitary, substandard condition. *See id.*

While it is particularly shocking, this most recent health-and-safety violation at the Columbia facility is only the tip of the iceberg. The Columbia facility has a history of troubling inspection deficiencies regarding cleanliness, treatment, and reporting. In 2013, the facility was found deficient because it failed to ensure clean linens were stored separately from soiled linens. *See* Ex. A to Affidavit of William Koebel (attached as Exhibit 7), Statement (June 11, 2013). In 2015, the facility was cited for failing to demonstrate compliance with its own infection prevention program, including failing to maintain a sterilization log and failing to stock the supplies necessary to disinfect its vaginal ultrasound probes properly. *See* Ex. B to Ex. 7, Findings Letter (Apr. 3, 2015). In addition, the Department has repeatedly cited the facility for not having a properly equipped emergency tray. For instance, its Automated External Defibrillator did not have working batteries in 2013. *See* Ex. A to Ex. 7. In 2016, the facility lacked medications and supplies that state law says must be "immediately available" to a physician on the emergency tray. *See* Ex. C to Ex. 7, Statement (Nov. 2, 2016). In 2013, 2015, and 2016, the facility did not have certifications to administer controlled substances from the Drug Enforcement Administration and Bureau of Narcotics and Dangerous Drugs (although it was not licensed at all for some or all of this time).

See Exs. A, B, C to Ex. 7. In 2016, the program was cited for a deficient quality assurance program. *See* Ex. C to Ex. 7.

The August 2018 report found that the facility had failed to maintain an adequate infection control program, including proper hand hygiene practices. *See* Ex. D to Ex 7, Statement (Aug. 14, 2018). The suction machine cabinet had numerous spots of rust. *See id.* The exam rooms were not clean or sanitary. *Id*. Patient medical records were incomplete: they did not include discharge instructions; they showed that medication orders were not properly marked with the date and time or were not signed by medical staff; and several files did not include physician notes documenting abortion counseling. *Id*.

As noted above, the September 26, 2018 inspection noted several significant deficiencies. *See* Ex. E to Ex. 7, Statement (Sept. 26, 2018). The facility had failed to dispose of used, soiled single-use suction tubing filled with "reddish fluid," which (as noted above) was identified as human bodily fluid. *Id.* A reusable glass suction bottle had "a layer of dried black substance in the bottom." *Id.* The suction machine had a "dried brown spill" down one side. *Id.* A reusable series of connecting hose had a "blackish-gray substance on the inside of the length of the tubing," which (as noted above) was identified as mold. *Id*. Staff said they had identified this mold problem "a couple of months previously" but had "continued to use the machine" with the hose anyway. *Id*.

Plaintiffs' St. Louis facility has a troubled history of health-and-safety violations as well. Inspection reports show that the St. Louis facility has a longstanding problem of not complying with regulations designed to prevent infections and maintain a clean environment. *See* Ex. F. to Ex. 7, Statement (Apr. 5, 2001). A 2013 inspection found rust in what were supposed to be sanitary environments—including a rusted stool, oxygen tank, suction machine, and the base of a procedure

table. *See* Ex. G to Ex. 7, Statement (Jan. 31, 2013). In 2015, the facility was cited for an examination table with multiple tears in the pad, exposing the uncleanable, non-sterile foam underneath. *See* Ex. H to Ex. 7, Statement (Mar. 31, 2015). The same 2015 report noted a "layer of dust" on shelving where IV tubing was stored and on the frame of an "often" used wheelchair. *Id*. A "[b]rownish residue" was found in a cabinet and on the floor in the sterilization room. *Id*. Dust and strands of hair were found in the laboratory refrigerator. *Id*. In 2016, the facility was cited for failing to clean its sterilizer machines. *See* Ex. I to Ex. 7, Statement (Mar. 16, 2016). The manual cautioned that "dirt and debris will build up and clog the tubing" if not cleaned, and the inspection in fact showed discoloring "with shades of brown spots." *Id*. The 2016 inspection also found "white flecks" and dust in the sterilization room on the peel pouches used to store instruments after sterilization. *Id*. The facility was also cited in 2016 for failing to provide ongoing staff education regarding infection control. *Id*. Both the 2017 and 2018 inspection reports noted that staff followed poor hand hygiene practices. *See* Ex. J to Ex. 7, Statement (May 25, 2017); Ex. K to Ex. 7, Statement (Mar. 7, 2018). The 2017 inspector noted that the oxygen tanks in the procedure rooms "were soiled" and dirt was actually "stuck on the tanks." *See* Ex. J to Ex. 7.

The St. Louis facility has also been found deficient for its poor handling of controlled substances and medical supplies. A 2013 report found the facility did not dispose of single-use medication vials, including the dangerous opioid Fentanyl, but instead used the open vial for multiple patients. *See* Ex. G to Ex. 7. The same inspection found a range of expired medication and products, including valium, that had not been discarded. *Id*. A 2015 inspection again found expired medications that had not been discarded, this time including Fentanyl. *See* Ex. H to Ex. 7. In 2016, the facility was again cited for administering single-dose vials to multiple patients, and again cited for not disposing of expired medical supplies. *See* Ex. I to Ex. 7. The facility had also

failed to ensure the temperature of its medication refrigerator was stable. *Id.* The log showed unsafe temperatures on 15 of 27 recorded days, including seven days below freezing, and showed no one had recorded the temperature at all on many other days. *Id*. The facility was also cited for using a single-patient blood glucose monitoring system on multiple patients even thought it was not approved for such use. *Id*. And heating pads were used by recovering patients that were marked "household use only" and specifically not recommended for those sedated or medicated because of burn risks. *Id*.

The facility's "quality assurance" (QA) program has also consistently been deficient. The 2001 report noted the facility's QA program did not measure up to regulatory requirements. *See* Ex. F to Ex. 7. The 2013 licensing report found the facility failed to maintain an adequate quality assurance program that correctly tracked cases and documented the responsive actions taken. *See* Ex. G to Ex. 7. The facility also did not inform patients in writing that complaints could be reported directly to DHSS. *Id*. A 2016 inspection report found the facility failed to follow its own protocols for post-operative patient monitoring to track stability and vital signs during recovery. *See* Ex. I to Ex. 7. The same report noted that patient medical records were often incomplete. *Id.* In 2017, the facility was cited for failing to submit complication reports after a review of an internal log showed complications that had not been reported to the Department. *See* Ex. J to Ex. 7. The facility's Quality Assurance Manual showed it had "no policy specific to the submission of post-abortion complication reports." *Id*. Staff acknowledged that they had known for "several months" that complication reports need to be made but still "had not sent in any." *Id.* The quality assurance program had still not been corrected by March 2018. *See* Ex. K to Ex. 7. For example, the facility had no method to track length of stay, and the facility did not review results on a quarterly basis as required. *Id*. Finally, the facility gave inadequate warnings about short and long-term risks,

telling patients there was "no medical evidence" to support the statement of risks required by state law. *Id.*

The troubled health-and-safety histories of Plaintiffs' own facilities contradict their arguments that abortion is supposedly "safe" and that abortion facilities should be radically deregulated. Requirements like the hospital-privileges requirement work to prevent such problems by ensuring that a qualified physician with ties to the local medical community is present and has ultimate responsibility for the quality of care provided by the facility. As Dr. Steele opined, "itinerant surgery violates the ethical relations between surgeon and patient." Doc. 28-4, at 5. And as Dr. Williams has frequently opined, requirements like the hospital-privileges requirement ensure that a qualified physician "owns" both the patient and the abortion facility, taking ultimate responsibility for the quality of care provided. *See* Doc. 141-2. The fact that Plaintiffs have frequently fallen short in their responsibility to maintain clean, safe facilities for providing medical care is not an argument that they should be protected from further regulation—quite the contrary, the opposite is true.

4. Published literature does not support Plaintiffs' conclusions regarding the safety of abortion procedures.

As the State Defendants have previously discussed at great length, the published literature on abortion complications does not support Plaintiffs' sweeping claims regarding the "safety" of abortion. *See, e.g.,* Doc. 54-2. Plaintiffs' most recent submissions do not cure this deficiency. Dr. Eisenberg engages in selective overview of literature that lacks a critical review of study methodology. Coleman Decl., Ex. 2, ¶ 55-61. Studies employing rigorous methodologies and more complete follow-up rates with patients reflect complication rates that are much higher than predicted by Plaintiffs. *See id.* ¶ 58. As a result, "abortion-related morbidity and mortality [are] far greater than the estimates provided by the Plaintiffs' experts." *Id.* ¶ 61. "A careful examination

of the data . . . relying on the most complete data sources with the most reliable diagnostic information, suggested that abortion-related physical complication rates [are] considerably greater than Plaintiffs' experts contend." *Id.*

Plaintiffs argue that statistics regarding medication-abortion complications are irrelevant because "the Columbia health center does not seek to provide medication abortions at this time." Doc. 153, at 6. This is incorrect. The hospital-privileges requirement, which applies to providers of both surgical and medication abortion, is a statewide policy that addresses a statewide problem with a statewide justification. Moreover, the fact that the Columbia facility is not *currently* providing medication abortion does not mean it will not attempt to do so in the future. As the Eighth Circuit stated in *Jegley*, "Planned Parenthood could unilaterally decide" to change its practices, so the State has an interest in establishing standards of care irrespective of their current practices. *Jegley*, 864 F.3d at 860 n.9. "While we elect not to quantify it at this time, we certainly see some benefit for patients where the State mandates continuity-of-care standards—especially in the face of known complications and where there previously had been no state requirements." *Id.* In any event, the safety problems are much greater than predicted by Plaintiffs even if one focuses solely on risks from surgical abortion. *See, e.g.,* Coleman Decl., Ex. 2, ¶¶ 55-61.

F. Plaintiffs misconstrue and ignore the significant health benefits of the hospital-privileges requirement.

Plaintiffs alternatively mischaracterize and ignore the significant health benefits from the hospital-privileges requirement. The State Defendants previously demonstrated that the regulation provides significant benefits to women's health. *See* Doc. 141, at 13-17; Doc. 141-2 (Declaration of Randall Williams). These benefits include (1) ensuring continuity of care for abortion patients; (2) ensuring that each patient has greater access to a physician qualified to treat her; (3) ensuring that the patient experiencing a complication has greater access to the physician with knowledge of

the procedure; (4) reducing the likelihood that abortion patients receive unnecessary treatment; (5) fostering effective communication between the physician who performed the abortion and the treating physician; (6) ensuring that physicians performing abortions are well-credentialed and "meet standards for training and skill," Steele Decl., Doc. 28-4, at 3; and (7) improving the tracking and accurate reporting of abortion complications. Doc. 141, at 13-17.

Plaintiffs fail to meaningfully address or undermine these benefits of the hospital-privileges requirement. Most fundamentally, "it is the Department's contention that there should not be two standards of care applied just because a surgical or medical procedure is deemed 'safe' when physicians have a duty to provide standard care for their patients in the event that complications arise from elective procedures." Rebuttal Declaration of Randall W. Williams, MD, FACOG, ¶ 15 (attached as Exhibit 8). It is consistent with standard care for other elective procedures with similar risks of complications to provide continuous coverage by a physician with hospital privileges in the community. *Id.* ¶ 16. "For elective gynecological procedures, the standard by which physicians are trained and then held to is that they have a duty to provide care for elective procedures prior, during and after procedures as a component of providing standard care." *Id.* ¶ 16. The hospital-privileges requirement directly implements and advances this fundamental principle of standard care. *Id.* ¶ 23. "It is not standard practice to have a consulting OB-GYN from another practice who is covering unassigned call for the Emergency Room to see a patient of another physician who had hospital privileges who has performed an elective procedure on the patient and chooses not to follow their patient into the Emergency Room because he or she deemed the procedure 'safe' and therefore thought that somebody else should be responsible." *Id.* ¶ 23. In fact, Missouri imposes similar regulatory requirements on many similar facilities and procedures.

In the unique context of abortion, however, the State is aware of a push by providers to address the issue of provider scarcity by attempting to dilute the standard of care. Ex. 8 (Williams Rebuttal Decl.) ¶ 19 ("[P]laintiffs have held themselves out to a different standard because of their perceived safety of the procedure."); *id.* ("In my years of practice and review, I am unaware of a similar procedure in gynecology in which physicians have stated that due to the argument that the procedure is 'safe' they are not responsible for being able to treat complications."). Indeed, Dr. Eisenberg's "admission that abortion care sees itself as 'set aside' lends credence to a concern that abortion providers in their view do not have to follow those same standards." *Id.* ¶ 24. "In my 30 years of experience taking care of patients as an obstetrician-gynecologist, I saw firsthand the importance of ensuring patient safety by taking care of my patients by having hospital privileges or prearranging to have someone with hospital privileges to take care of my patients when I was not available to do so." *Id.* "[T]here is no reason why abortion patients should not receive the benefit of these same types of arrangements, which are standard in the practice of medicine." *Id.*

The hospital-privileges requirement is part of a comprehensive regulatory scheme designed to address this unique problem of attempts to "dilute" the standard of care in the abortion context, and to ensure that abortion patients are not provided substandard care just because fewer physicians are willing to perform abortions than other elective procedures, or because abortion providers think abortion is so "safe" that standard care should not apply. *Id.* ¶¶ 16, 23.

G. Plaintiffs greatly overstate the burdens on abortion access from the hospital-privileges requirement.

To draw their conclusion that 22 percent of women in the Columbia area will be prevented from having an abortion, Plaintiffs rely heavily on the analysis of Dr. Lindo, which relies heavily on the analysis of abortion rates in Texas in the unpublished "LMSC" study. *See* Lindo Decl. (citing Lindo, Myers, Schlosser, and Cunningham, *How Far Is Too Far? New Evidence on*

Abortion Clinic Closures, Access, and Abortions?). But Dr. Lindo's analysis suffers from several fatal deficiencies. *See* Coleman Decl., Ex. 2, ¶¶ 8-29; Solanky Decl., Ex. 9, ¶¶ 4-18, 20-22. The LMSC study is unpublished and has never been peer-reviewed. Coleman Decl., Ex. 2, ¶ 9. Dr. Lindo's analysis overlooks the significant limitations of his "differences-in-differences" methodology, which are well-established in the peer-reviewed literature. *Id.* ¶¶ 10-17. The LMSC study fails adequately to account for the effects of several empirical factors that undermine confidence in its results. Solanky Decl., Ex. 9, ¶ 7(a)-(d). Properly controlling for these empirical factors would demonstrate that the impact of abortion-facility restrictions on the abortion rate was much smaller in Texas than the LMSC study concludes. *Id.* ¶ 8.

Two critical problems with Dr. Lindo's analysis vividly illustrate this problem, and they are merely illustrative of other deficiencies that wholly undermine his conclusions. *See* Solanky Decl., Ex. 9, ¶¶ 4-18, 20-22. First, as Dr. Coleman points out, "Dr. Lindo struggled to understand why his observed reduction in abortion rates was not mirrored by an increase in births. Clearly the methodology was flawed, rendering the quantitative estimates unreliable and/or unmeasured variables were the sources of the differences." Coleman Decl., Ex. 2, ¶ 17. Though the LMSC study concluded that there were "missing abortions" after Texas passed restrictions that limited the number of abortions, the LMSC study did *not* find a corresponding increase in live births that reflected the "missing" abortions. *Id.* ¶¶ 22-23. The study speculated that, among other possibilities, "some women responded to the reduction in access to abortion facilities by decreasing risky sexual behaviors and, as a result, unintended pregnancies." *Id.* ¶ 23. This concession undermines Plaintiffs' entire theory of undue burden in this case. If women respond to clinic closures by decreasing risky behaviors that lead to unintended pregnancy, and thus *never have any reason to seek an abortion*, the clinic closures impose no possible "undue burden" on

those women's right to abortion—they never need to have one. *See id.* Dr. Lindo concedes that this is a significant likelihood, but he makes no attempt to quantify it. *Id.*

Second, Dr. Lindo's attempt to extrapolate from Texas to Missouri's unique situation is similarly flawed and unconvincing. Coleman Decl., Ex. 2, ¶ 27-28. Dr. Lindo attempts to extrapolate from the observed differences in abortion rates in Texas counties to draw conclusions regarding abortion rates in Missouri, yet his own analysis in the LMSC paper (of which he is the lead author) states: "Introducing additional data from other states where abortion rates are evolving differently over time would invalidate the study." Solanky Decl., Ex. 9, at 9 (quoting Lindo Supp. Decl. ¶ 9). Dr. Lindo's extrapolation from the Texas data to mid-Missouri is based on other unjustified or faulty assumptions as well. *Id.* ¶¶ 12-16.

In short, Dr. Lindo's reliance on Texas to draw causal conclusions about Missouri is deeply flawed. As Dr. Solanky notes, "Texas is a rather unique state which shares borders with Mexico and two states, Louisiana and New Mexico, which changed their out-of-state abortion reporting starting in 2013. . . . [T]he counties which are impacted by these missing/unreliable reporting of abortions have impacted the conclusions derived by the LMSC study." *Id.* ¶ 22. "Also, the Texas counties which account for the vast majority of abortions in Texas, over 90%, who have complete/reliable data, merely saw a 3% additional drop in abortions over a two-year period after [Texas's] HB2." *Id.* "Apart from the inaccuracies of the LMSC model, the applicability of the Texas based study in predicting abortions in Missouri is scientifically incorrect." *Id.*

Independent peer-reviewed research that uses more rigorous methodology and examines larger trends also contradicts Dr. Lindo's conclusions. According to the "largest, most comprehensive and sophisticated analysis" of the impact of health-and-safety regulations of abortion facilities on abortion rates, Coleman Decl., Ex. 2, ¶ 34, such regulations "failed to show

a discernible impact on the abortion rate." *Id.* ¶ 36. Other peer-reviewed studies came to similar conclusions. *Id.* ¶¶ 38-39, 41-46. Perhaps most notably, during the period from 2011 to 2014, Missouri had one of the two largest proportional reductions of the number of abortion facilities of any State in the nation, yet during that time period, Missouri "experienced declines in the abortion rate that were comparable to the national average." *Id.* ¶ 42 (quoting Jones and Jerman (2017)). Dr. Solanky likewise notes recent research that has "analyzed abortion data from all 50 states and the District of Columbia" and has concluded that "the evidence suggests that contraception and fewer unintended pregnancies played a larger role in these most recent declines than new abortion restrictions." Solanky Decl., Ex. 9, ¶ 19. Thus, "the relationship between abortion access, as measured by the number of clinics, and abortion rates is not straightforward." *Id.*

II. The Other Three Dataphase Factors Weigh Heavily Against Granting a Preliminary Injunction.

The remaining *Dataphase* factors include "(2) the threat of irreparable harm to the movant in the absence of relief; (3) the balance between that harm and the harm that the relief would cause to the other litigants; and (4) the public interest." *Watkins*, 346 F.3d at 844 (citing *Dataphase*, 640 F.2d at 114). All these factors weigh against Plaintiffs' request for relief.

First, as many courts have recognized, an order that prevents the State from enforcing its duly enacted laws is heavily disfavored and inflicts *per se* irreparable injury on the State. *See, e.g., 1-800-411-Pain Referral Service, LLC v. Otto*, 744 F.3d 1045, 1053-54 (8th Cir. 2014) (holding that, "because Plaintiffs seek to enjoin enforcement of a validly enacted statute," they must meet "a more rigorous threshold showing than th[e] ordinary preliminary injunction test"). "Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted). "When a statute is enjoined, the State necessarily suffers the

irreparable harm of denying the public interest in the enforcement of its law." *Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013). Thus, "a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined." *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997).

Second, for the reasons discussed in detail above, an order blocking enforcement of the Privileges Requirement will impose significant irreparable harm on women seeking abortions by permitting Plaintiffs to pursue substandard practices. *See supra* Part I.

Third, in assessing the public interest, the actions of Missouri's legislature, Governor, and state officials provide decisive evidence of where the public interest lies. Where the party opposing equitable relief is the government, consideration of the public interest "merge[s]" with consideration of harm to the government. *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also, e.g.*, *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). A statute "is in itself a declaration of public interest and policy." *Virginian Ry. Co. v. Sys. Fed'n No. 40*, 300 U.S. 515, 552 (1937). Thus, the public has a strong interest in the enforcement of duly enacted laws and validly promulgated regulations. *Peterson v. Village of Downers Grove*, No. 14-C-09851, 2016 WL 427566, at *5 (N.D. Ill. Feb. 4, 2016); *Abbott*, 734 F.3d at 419. Courts should not "ignore the judgment" of the legislature "deliberately expressed in legislation," and "override [the legislature's] policy choice, articulated in a statute, as to what behavior should be prohibited." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001).

CONCLUSION

Plaintiffs third motion for preliminary injunction, Doc. 152, should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent electronic notification to all counsel of record.

/s/ D. John Sauer