IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) SOUTH WIND WOMEN'S CENTER LLC, D/B/A TRUST WOMEN OKLAHOMA CITY, on behalf of itself, its clinicians and staff, and its patients; and (2) COLLEEN MCNICHOLAS, D.O., on behalf of herself and her patients; and (3) BRIDGET VAN TREESE, M.S.N., APRN-CNP, on behalf of herself and her patients, Plaintiffs, v. (1) MIKE HUNTER, in his official capacity as Attorney General of Oklahoma; and (2) DAVID PRATER, in his official capacity as Oklahoma County District Attorney; and (3) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and (4) G. ROBINSON STRATTON, III, in his official capacity as Executive Director of the Oklahoma State Board of Osteopathic Examiners; and (5) KIM GLAZIER, in her official capacity as the Executive Director of the Oklahoma Board of Nursing; and (6) GARY COX, in his official capacity as Oklahoma Commissioner of Health, Defendants.	Case No. CV-2019-2506 Judge Natalie Mai

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY INJUNCTION

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The State cannot show, as it must, that the special treatment imposed on abortion care by the Challenged Laws is tied to a valid legislative objective. Nor can the State demonstrate that the burdens these Laws place on women's right to access such care are justified by any safety benefit. Conspicuously absent from the State's brief is *any* explanation as to how the Physician In-Person or Physician-Only laws benefit Oklahoma patients. For good reason: the safety record of medication abortion is the same when administered via telemedicine or in person, or by an advanced practice registered nurse ("APRN") or by a physician. Grossman Aff. ¶¶ 26-28; Spetz Aff. ¶ 61. This dispositive fact is unrebutted by the State. Thus, the Challenged Laws should be temporarily enjoined pending final adjudication of this lawsuit.[1]

THE STATE'S "FACTS" ARE MISLEADING

Rather than address the essential issues at the heart of this case, the State instead launches a dubious attack on the safety of medication abortion. The State ignores that the safety and benefits of medication abortion have long been endorsed by the FDA, a wealth of scientific literature, and Oklahoma's highest court. The State's brief is riddled with false and misleading claims about medication abortion, including:[2]

- The State takes language from the FDA Mifeprex label out of context to state that "'[s]erious and sometimes fatal infections and bleeding occur' after medication abortion." Opp. Br. at 4. The full sentence *actually* reads: "Serious and sometimes fatal infections and bleeding occur ***very rarely*** following spontaneous, surgical, and medical abortions, including Mifeprex use. ***No causal relationship*** between the use of Mifeprex and misoprostol and these events has been established." U.S. Food & Drug Administration (FDA), Mifeprex Label 2016, 7 (2016).
- The State notes that there have been 1,042 hospitalizations following medication abortions, Opp. Br. at 5, but omits the key fact that these occurred over an ***18-year period*** in which approximately ***3.7 million*** women had medication abortions, resulting in a hospitalization rate of less than ***0.03%***. *See* Grossman Reply Decl. ¶ 4.

[1] Despite the State's claims to the contrary, Opp. Br. at 6, 9, these harms are redressable, as the Boards of Medicine and Nursing would be enjoined from enforcing these unconstitutional laws if the Court found for Plaintiffs.

[2] Dr. Grossman's Reply Declaration rebuts many of these claims in detail.

- The State conflates data concerning "adverse reactions" and "serious adverse reactions," and suggests that high numbers of patients experience "severe adverse reactions." Opp. Br. at 4. While "adverse reactions" such as nausea, headache, and dizziness are more commonly reported, "serious adverse reactions" (*e.g.*, hemorrhage or infection) occur in less than 0.5% of cases. *See* Grossman Reply Decl. ¶ 7.

Nor does the State address that the Oklahoma Supreme Court already rejected the State's faulty contentions on these points less than a year ago, finding medication abortion to be safe. In *Oklahoma Coalition for Reproductive Justice v. Cline*, 2019 OK 33, P31-36 ("*OCRJ*"), the parties presented substantially similar arguments regarding the safety of medication abortion through affidavits of the very same experts relied upon here—Dr. Grossman by the Plaintiffs and Dr. Harrison by the Defendants. Crediting the report of Dr. Grossman over Dr. Harrison's, the Supreme Court found medication abortion "to be safe[] with little to no significant health-related problems occurring." 2019 OK 33 at ¶ 31. Nothing has changed, and any attempts by the State to relitigate this issue here should be rejected as baseless.

THE CHALLENGED LAWS ARE IMPERMISSIBLE SPECIAL LAWS

As a threshold matter, the State's argument that laws regulating abortion cannot qualify as special laws because they are "different[] from other procedures ... due in large part to the presence of the unborn child" (Opp. Br. at 23) has already been rejected by this Court. In *Nova Health Systems v. Pruitt*, the Court held the "Ultrasound Act," which required a physician to perform a pre-abortion ultrasound and describe particular details to the patient, to be "unconstitutional as a special law." 2012 Okla. Dist. LEXIS 674, ¶¶ 2-3 (Okla. Dist. Ct. Mar. 28, 2012), *aff'd* 2012 OK 103. Accordingly, the *Reynolds* test applies, and under that test there is no question that the Challenged Laws are special laws. *See* Plaintiffs' Opening Brief (Br.) at 13-14.

The Physician-In-Person Law singles out medication abortion, physicians who provide medication abortion, and patients seeking medication abortion for disparate treatment. It does so even though a general law is clearly applicable—the Oklahoma Telemedicine Act, 36 O.S. §§

6801 *et seq.* (1997)—which states that all forms of healthcare may be provided via telemedicine to the extent consistent with a physician's professional judgment.[3] *See* Br. at 14-17.

The Physician-Only Law singles out APRNs who seek to provide medication abortion for discriminatory treatment. Qualified APRNs in Oklahoma are prohibited from providing medication abortion, even though they are authorized to prescribe the same exact medications in non-abortion contexts. The applicable general laws authorize APRNs to perform all activities within their scope of practice. 63 O.S. § 2-312; *see* Br. at 14-17.

Both Challenged Laws also fail the last prong of the *Reynolds* test because they are not reasonably or substantially related to a valid legislative purpose. *Reynolds v. Porter*, 1988 OK 88, ¶ 13, 760 P.2d at 822. There are no legislative findings justifying the laws, and the State's unsupported evocation of women's health is inadequate. Indeed, medication abortion is one of the safest treatments in contemporary medical practice, regardless of whether it is administered by a physician via telemedicine, or by a physician or APRN in person. Grossman Reply Decl. ¶ 12-16. Drugs that pose significantly greater risks than those involved in medication abortion can be prescribed via telemedicine and by APRNs. Indeed, the FDA Medical Review of Mifeprex concluded that mid-level practitioners can safely administer medication abortion.[4] The State is unable to cite a single study establishing that the Challenged Laws protect women's health. Its chief response is that the Challenged Laws regulate abortion, and therefore they are either not special laws, or they are permissible special laws. By making this argument, the State effectively concedes that the Challenged Laws are impermissible special laws, as the State can point only to an unconstitutional purpose for them—limiting access to abortion care.

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[3] The State points only to opioids as another exception. Opp. Br. at 8. But physicians can prescribe opioids via telemedicine after first establishing the patient-physician relationship in person. *See* 59 O.S. § 478.1.

[4] *See* Grossman Reply Decl. ¶ 16.

BOTH LAWS CREATE AN UNDUE BURDEN

The Challenged Laws impose an undue burden because they provide no demonstrable benefit to women's health and their purpose and effect is to create obstacles to abortion. *See OCRJ*, at P26 (Oklahoma courts "look at the burdens a law imposes on termination access together with the benefits the law confers"); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016) ("*WWH*") (courts must (i) weigh the burdens of an abortion law against its benefits; (ii) evaluate the medical justifications in the record rather than defer to the legislature; and (iii) determine if the law has a reasonable relation to a legitimate state interest).

The Oklahoma Supreme Court has already found that medication abortion is safe, and the State has offered *no* evidence—nor can it—demonstrating that medication abortion is less safe when provided via telemedicine or by an APRN. Since the Challenged Laws create no benefit, even a modest showing of burdens must mean they are unconstitutional. And here the burdens are substantial: the laws burden Oklahomans' access to abortion by limiting the number of days that patients can have a medication abortion at Trust Women, leading to delays, lengthy waiting periods, and numerous logistical barriers. Delays in accessing abortion increase health risks for pregnant women, and since medication abortion is only available to a patient for a matter of weeks after she learns of her pregnancy, delays force some patients into having a surgical abortion instead.[5] The burdens created by the Challenged Laws have been thoroughly documented and outweigh their non-existent medical benefits.

The State relies heavily on *Mazurek v. Armstrong*, 520 U.S. 968 (1997), but *Mazurek* does not contradict *Planned Parenthood v. Casey*, 505 U.S. 833 (1992) and *WWH*, which require a case-specific and evidence-based assessment of whether the Challenged Laws place burdens on

[5] Not only do some women have a strong personal preference for medication abortion (particularly survivors of sexual assault), it is also advisable for women with certain medical conditions. McNicholas Aff. ¶ 11-13.

abortion access that exceed their benefits. *See WWH*, 136 S. Ct. at 2309.[6] As *WWH* recently reaffirmed, the State must provide affirmative evidence that the Challenged Laws have a reasonable relation to a legitimate state interest and also demonstrate how that interest outweighs the burdens on women seeking abortion. The State has failed to do so here. The only question at issue in *Mazurek*, by contrast, was whether the specific physician-only law at hand had been enacted for an improper purpose, not whether the restriction had the *effect* of imposing an undue burden, as is the case here. *See* 520 U.S. at 973.[7]

A TEMPORARY INJUNCTION IS WARRANTED

Contrary to the State's assertion, when a party seeks a temporary injunction that may disrupt the status quo, "injunctive relief may also be granted when the need is urgent and the right is clear." *Waveland Drilling Partners III-B, LP v. New Dominion, LLC*, 2019 OK CIV APP 8, at P14, 435 P.3d 114, 119 (citation omitted). The "threatened deprivation" of Plaintiffs' constitutionally protected rights "is itself irreparable harm." *Nova Health Sys. v. Pruitt*, 2015 Okla. Dist. LEXIS 1045, at *10 (Okla. Dist. Ct. Oct. 28, 2015). Here, the irreparable harm to constitutional rights is imminent and ongoing. This vastly outweighs any purported threatened harm of Defendants, and the injunction would serve the public interest as it would serve women's health. *See id.* at *11.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motion for a temporary injunction of 63 O.S. § 1-729.1 and 63 O.S. § 1-731(A), and related regulations.

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[6] Contrary to the State's claim, there were no "physician-only" laws at issue in *Roe v. Wade*, 410 U.S. 113 (1973); *City of Akron v. Akron Ctr. For Reproductive Health, Inc.*, 462 U.S. 416 (1983); *Casey*; or *Gonzales v. Carhart*, 550 U.S. 124 (2007).

[7] Indeed it was undisputed in *Mazurek* that the law did not burden patients. 520 U.S. at 972. It was also decided before medication abortion was available and before the expansion of APRN practice. *See* Spetz Aff. ¶¶ 23-34.

Respectfully submitted this 30th day of January, 2020,

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IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) SOUTH WIND WOMEN'S CENTER LLC, D/B/A TRUST WOMEN OKLAHOMA CITY, on behalf of itself, its clinicians and staff, and its patients; and (2) COLLEEN MCNICHOLAS, D.O., on behalf of herself and her patients; and (3) BRIDGET VAN TREESE, M.S.N., APRN-CNP., on behalf of herself and her patients,	)	Case No. CV-2019-2506
Plaintiffs,	)	Hon. Judge N. Mai
v.	)	
(1) MIKE HUNTER, in his official capacity as Attorney General of Oklahoma; and (2) DAVID PRATER, in his official capacity as Oklahoma County District Attorney; and (3) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and (4) G. ROBINSON STRATTON, III, in his official capacity as Executive Director of the Oklahoma State Board of Osteopathic Examiners; and (5) KIM GLAZIER, in her official capacity as the Executive Director of the Oklahoma Board of Nursing; and (6) GARY COX, in his official capacity as Oklahoma Commissioner of Health,	)	
Defendants.	)	

DECLARATION OF DANIEL A. GROSSMAN, M.D. IN SUPPORT OF PLAINTIFFS' REPLY MOTION FOR A TEMPORARY INJUNCTION

DANIEL A. GROSSMAN, M.D., declares and states as follows:

1. I submit this declaration in support of Plaintiffs' Reply in Support of their Motion for a Temporary Injunction, which seeks to enjoin enforcement of 63 O.S. § 1-729.1 (the "Physician In-Person Law") and 63 O.S. § 1-731(A) (the "Physician-Only Law") (together, the "Challenged Laws"). More specifically, this declaration responds to the opinions offered by Dr. Donna Harrison in support of Defendants' opposition to the Plaintiffs' motion.

2. The opinions in this declaration are based on my education, clinical training, experience as a practicing physician over the past twenty-six years, my medical research, regular review of other medical research in my field, and attendance at professional conferences. My background is more extensively set forth in an affidavit I submitted in support of Plaintiffs' Motion for a Temporary Injunction.[1] The facts in this declaration, unless otherwise stated, are based on my personal knowledge.

Medication Abortion is Safe

3. As I discussed in my previous affidavit, under any measure of safety, medication abortion is a safe medical treatment and a safe method of abortion.[2] Numerous major, peer-reviewed studies—including several relied on by the U.S. Food and Drug Administration ("FDA") in approving an updated label for Mifeprex in 2016[3]—demonstrate the safe and effective use of mifepristone for medication abortion up to ten weeks (70 days) of gestation. As discussed in further detail below, Dr. Harrison's opinions about the safety of medication abortion are not supported by the medical literature.

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[1] *See* Grossman Aff. ¶¶ 1-4.
[2] *See* Grossman Aff. ¶ 19.
[3] U.S. Food & Drug Administration (FDA), *Mifeprex Label 2016*, 7 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [hereinafter "Mifeprex Label"].

4. Dr. Harrison's declaration selectively quotes data from the FDA's Mifepristone Adverse Events Summary ("Summary"), and, moreover, it fails to provide any context for the data.[4] The Summary reports adverse events over a period of 18 years, during which time approximately 3.7 million women have received medication abortion using mifepristone for medical termination of pregnancy. Therefore, the hospitalization rate is 0.028% (1,042/3,700,000), the blood transfusion rate is 0.016% (599/3,700,000), and the infection rate is 0.011% (412/3,700,000).[5] These numbers are consistent with those reported in peer-reviewed studies.[6] However, Dr. Harrison omits this information from her declaration, even though it is included in the FDA's Summary.

5. Moreover, Dr. Harrison's declaration focuses on the 24 deaths linked to medication abortion reported in the Summary, but omits that 11 of those 24 deaths do not appear related to medication abortion.[7] Six of the deaths were related to drug use, overdose, or intoxication, two were homicides, one was a suspected homicide, one was due to suicide, and one resulted from emphysema.[8] In addition, seven deaths were due to *C. sordellii* (Clostridium) infections,[9] but there is no causal link between medication abortion and Clostridium infection.[10] Indeed, the FDA label for Mifeprex states: "No causal relationship between the use of MIFEPREX and misoprostol and

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[4] *See* Harrison Decl. ¶ 12.
[5] U.S. Food & Drug Administration (FDA), RCM # 2007-525, Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/13/2018, at 1-2, https://www.fda.gov/media/112118/download [hereinafter "FDA Post-Marketing"].
[6] *See, e.g.*, Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTET. & GYNECOL. 166, 169 (2013); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175 (2015).
[7] FDA Post-Marketing at 1.
[8] *Id.*
[9] *Id.*
[10] American College of Obstetricians and Gynecologists, Practice Bulletin No. 143: Medical Management of First-Trimester Abortion, 8 (Mar. 2014, reaffirmed 2016) [hereinafter "AGOC Bulletin"].

[fatal infections and bleeding] has been established."[11] Further, the FDA clinical review team confirmed that "[s]ince 2009, there have been no *C. sordellii* deaths associated with medical abortion in the U.S."[12] That there are only 13 deaths cited in the Summary that are possibly related to the abortion, out of 3.7 million patients, illustrates the extremely low mortality rate resulting from medication abortions.

6. Consistent with these low rates of adverse events, a recent large-scale study that reviewed the outcomes of 233,805 medication abortions performed in the United States found that only 0.16% of patients experienced a significant adverse event (defined as hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection requiring treatment with intravenous antibiotics or admission to the hospital, or death).[13] My 2017 study of over 19,000 medication abortions in Iowa found that only 0.26% of patients experienced a clinically significant adverse event.[14] Another study that I co-authored in 2015 examined complications from approximately 55,000 abortions among California Medicaid patients and found a major complication rate of 0.31% for medication abortion patients.[15]

7. Dr. Harrison also incorrectly interprets information from the FDA Mifeprex label.[16] The label clearly states that ***serious adverse reactions***—which include transfusion, infections, and hemorrhage—occur in less than 0.5% of women.[17] However, Dr. Harrison groups the "***adverse***

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[11] Mifeprex Label at 2.
[12] U.S. Food & Drug Admin., Ctr. for Drug Evaluation and Research, No. 020687Orig1s020, Med. Rev., 83 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "FDA Med. Rev."].
[13] Cleland et al., *supra* note 6, at 168-69.
[14] Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130(4) OBSTET. & GYNECOL. 778, 781 (Oct. 2017).
[15] Upadhyay et al., *supra* note 6, at 181.
[16] *See* Harrison Decl. ¶¶ 10-11.
[17] Mifeprex Label at 7-8.

reactions" together with "***serious adverse reactions***" to incorrectly suggest that 85% of patients report "***serious adverse reactions***."[18] The most common "adverse reactions," occurring in more than 15% of patients, are "nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness."[19] The label later describes these same reactions as "side effects."[20] While these side effects may be uncomfortable, they do not suggest that mifepristone is dangerous or unsafe. Women who have decided to have a medication abortion are advised of these side effects and are instructed on how to address them.[21] They are given instructions on when to seek medical care, as with any prescription medication, and they are provided the contact information for their providers as an additional precaution.[22]

8. Dr. Harrison also mischaracterizes and omits key information when she excerpts information from the "black box warning" of the Mifeprex label.[23] Dr. Harrison quotes the label as stating: "Warning: Serious and Sometime Fatal Infections or Bleeding."[24] However, she does not fully quote the label, which goes on to read: "Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established."[25] Omission of this key information gives the false impression that infections are more common and dangerous than they actually are, and it

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[18] *See* Harrison Decl. ¶ 10 ("'About 85% of patients report at least one adverse reaction . . . .' These reactions include, but are not limited to, vomiting, headache, uterine hemorrhage, viral infections, and pelvic inflammatory disease.").
[19] Mifeprex Label at 7.
[20] *Id.* at 19.
[21] *Id.* at 18 (listing these as possible symptoms after taking Mifeprex in the "Medication Guide," which is handed to patients).
[22] *Id.* at 16.
[23] *See* Harrison Decl. ¶ 11.
[24] *Id.*
[25] Mifeprex Label at 2.

falsely insinuates that they are caused by Mifeprex—in direct contradiction to the language on the label.

9. Dr. Harrison also notes that Mifeprex has a Risk Evaluation and Mitigation Strategy ("REMS"),[26] but the presence of a REMS does not contradict or undermine the well-established safety record of medication abortion. As outlined in my 2017 article, REMS "are intended for drugs that are known or suspected to cause serious adverse effects that cannot be mitigated simply by the label instructions," but "the Mifeprex elements do not meet these specifications. Mifepristone is not inherently toxic or harmful to the woman using it."[27] Notably, other countries such as Australia and Canada have not imposed safety regulations analogous to the REMS, and have not encountered substantial safety concerns when administering mifepristone.[28] The two serious risks described on the Mifeprex label are also not unique to the drug. They occur after many other common obstetrical and gynecological procedures that are not subject to the same regulations as medication abortion.[29] The "rationale for singling out Mifeprex as needing such measures to ensure safety is lacking, and the Mifeprex elements can hardly be justified as 'commensurate' with the risks"—as the safety information included on the FDA-approved Mifeprex label itself makes clear.[30]

Medication Abortion is as Safe as Surgical Abortion

10. Dr. Harrison incorrectly asserts that medication abortions are more dangerous than surgical abortions.[31] Medication abortions have an extremely low complication rate relative to

[26] Harrison Decl. ¶ 11.
[27] Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376(8) NEW ENGL. J. MED. 790, 790-793 (2017).
[28] *Id.* at 792.
[29] *Id.*
[30] *Id.*
[31] *See* Harrison Decl. ¶¶ 15-18.

other medical procedures, including surgical abortion. While it is true that the "failure rate" for medication abortion, *i.e.*, the proportion of women who require a vacuum aspiration to complete the abortion, is higher than the proportion of women who undergo a surgical abortion and require a repeat procedure, this does not make medication more risky. In fact, it is a known feature of the method that is clearly explained to patients during the counseling process.

11. Further, as is the case in all other medical contexts, it should be up to the patient, in consultation with her medical provider, to weigh the risks and benefits of medication versus surgical abortion. As I discussed in my previous affidavit, medication abortion has certain notable advantages over surgical abortion (*e.g.*, it affords greater flexibility with respect to timing, avoids the use of anesthesia or sedation, and is less invasive and more private), and it is medically preferable for those with certain medical or anatomical conditions.[32] Moreover, the relative risk of surgical abortion is not at all relevant to the question of whether medication abortion may be safely practiced via telemedicine or by advanced practice registered nurses ("APRNs").

Medication Abortion via Telemedicine is Safe

12. As discussed at length in my prior affidavit, medication abortion can be safely provided via telemedicine.[33] Contrary to Defendants' arguments, Plaintiffs' data about the safety of medication abortion when administered by telemedicine is not based solely on data from the Planned Parenthood clinics in Iowa. The most recent telemedicine-specific study relies on data from multiple states, including Alaska, Idaho, Nevada, and Washington.[34]

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[32] *See* Grossman Aff. ¶¶ 21-23.
[33] *Id.* at ¶¶ 25-31.
[34] *Id.* at ¶ 29 (citing Julia E. Kohn & Jennifer Snow, *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 134 OBSTET. & GYNECOL. 343 (2019)).

13. Further, I disagree with Dr. Harrison's opinions about telemedicine. First, I do not believe that providing care via telemedicine "trivializes" the seriousness of that care.[35] Telemedicine is widespread around the country, and has not "trivialized" the care provided through this means. In fact, a recent systematic review found that telemedicine is used for a variety of services related to women's health.[36]

14. Secondly, I disagree with Dr. Harrison's opinion that telemedicine precludes a thorough evaluation before medication abortion.[37] An ultrasound, which I understand is part of the Trust Women protocol for medication abortion via telemedicine, permits detection of an intra-uterine pregnancy and excludes an ectopic pregnancy to the same degree as when a patient is evaluated in person. The presence of an intra-uterine device ("IUD") is generally excluded by patient history and may also be confirmed by ultrasound. Neither the ACOG Practice Bulletin nor the FDA labeling for Mifeprex requires a physical exam to provide medication abortion.[38]

15. Finally, I disagree with Dr. Harrison's concerns about complications following a medication abortion via telemedicine.[39] I understand that Trust Women, like many clinics, provides its patients with information about a follow-up appointment, a phone number for after-hours concerns, and information on potential side-effects of the procedure. Patients receive the care they need for medication abortion—whether provided via telemedicine or during an office visit. In our cohort study in Iowa, we found that patients receiving medication abortion by telemedicine were just as likely to return to the clinic for follow-up as were patients who had a

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[35] Harrison Decl. ¶ 29.
[36] Nathaniel DeNicola et al., *Telehealth Interventions to Improve Obstetric and Gynecologic Health Outcomes: A Systematic Review*. 135(2) OBSTET & GYNECOL 371 (2020).
[37] Harrison Decl. ¶¶ 30-38.
[38] *See* Mifeprex Label; ACOG Bulletin.
[39] Harrison Decl. ¶¶ 39-43.

medication abortion with an in-person visit.[40] In addition, our study of almost 20,000 patients undergoing medication abortion in Iowa used safety outcome information that all physicians are required to report to the drug's manufacturer and the FDA. Therefore, we would have captured adverse events that were detected at clinical sites other than the abortion clinic,[41] whether the treatment was provided in person or via telemedicine.[42]

APRNs Can Safely Provide Medication Abortion

16. Defendants assert that "safety and other reasons" justify preventing APRNs from performing medication abortions, without explanation or evidentiary support.[43] In fact, Defendants' position is contrary to well-accepted research and the positions of leading medical authorities. ACOG states that medication abortion "can be provided safely and effectively by nonphysician clinicians."[44] The FDA explicitly allows for non-physicians to provide medication abortions.[45] Moreover, several studies have confirmed that non-physicians can safely provide abortions.[46]

Dr. Harrison Misrepresents the Medical Literature on the Safety of Medication Abortion

17. Dr. Harrison misconstrues data from the FDA and major peer-reviewed studies, and instead relies upon outdated and unreliable studies to support her opinions. Dr. Harrison asserts that the FDA fails to adequately monitor complications.[47] She relies on a study she co-authored

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[40] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 OBSTET. & GYNECOL. 296, 302 (2011).
[41] Grossman & Grindlay, *supra* note 14, at 779.
[42] *Id.*
[43] Opp. Br. at 14.
[44] ACOG Bulletin at 11.
[45] FDA Med. Rev. at 7; Mifeprex Label (uses term "healthcare provider" rather than "physician" throughout).
[46] *See, e.g.*, Helena Kopp Kallner, et al., *The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or by Nurse-Midwives: A Randomized Controlled Equivalence Trial*, 122(4) Brit. J. OBSTET. & GYNECOL. 510, 515 (2014).
[47] Harrison Decl. ¶ 13.

that reviewed FDA Adverse Event Reports from 2000 through 2004.[48] These data are from the first four years Mifeprex was used for medication abortion in the United States and are over fifteen years old. Her study implies that the adverse event rate is underreported, but that assertion is speculative. Dr. Harrison fails to acknowledge the subsequent robust review of adverse events based not only on FDA reports, but also U.S. clinical studies published in peer-reviewed journals. Neither her article nor her declaration support the conclusion that complications are unknown or widely underreported.

18. The FDA carefully monitors reports of complications, and the agency's data are as complete for mifepristone as they are for any other FDA-approved drug. Nearly two decades of post-market experience and clinical studies have confirmed that medication abortion is safe and effective.[49]

19. Specifically, the FDA's recent review of 15 years of post-market experience and updated clinical studies highlights the overall safety and efficacy of medication abortion.[50] The FDA's efficacy review in connection with proposed changes to the Mifeprex label evaluated the quality of the studies that supported the current label, including whether the literature was an adequate primary information source to support the FDA's conclusion that the current medication abortion protocol is safe. Moreover, the FDA's medical review provides detailed information regarding the medical literature reviewed by the FDA and its reasons for approving the label

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[48] Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 ANNALS PHARMACOTHERAPY 1, 1 (2006).
[49] *See* Regina Kulier et al., *Medical Methods for First Trimester Abortion (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVS., Issue 11 (Nov. 2011).
[50] *See* FDA Med. Rev. at 47-76; *see also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation and Research, No. 020687Orig1s020, Summary Rev., 10-12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf [hereinafter "FDA Summary Rev."].

update. The 14 major studies and literature reviews relied upon by the FDA in approving the updated label are listed at Table 1 of the FDA's Medical Review.[51] The FDA's clinical review team identified key serious adverse events—including hospitalization, serious infection, bleeding requiring transfusion, and ectopic pregnancy—discussed in the medical literature.[52] The FDA team noted that, in U.S., hospitalization rates associated with medication abortion ranged from 0.04% to 0.6% (in a population of over 14,000 women); serious infection occurred in 0% to 0.2% of cases (in a population of over 12,000 women); and rates of transfusion were 0.03% to 0.5% (in a population of over 17,000 women).[53] These rates of adverse events are well within the range of an acceptable level of risk for a medical treatment.[54] The FDA noted that the regimen "has been studied extensively in the literature using U.S. and global sites"[55] and concluded that major adverse events were "exceedingly rare."[56]

20. Dr. Harrison is also wrong in her analysis of the 2015 Upadhyay study, which analyzed complication rates resulting from abortions in more than 50,000 California Medicaid patients.[57] The study, which I co-authored, reviewed billing codes to evaluate the type of medical care patients received following an abortion, both at the location where they received the abortion and at other locations, including the emergency department. Because the study's methodology captured all care women received post-abortion, it is one of the most thorough and reliable studies on abortion complications. Dr. Harrison criticizes this study by suggesting that its definition of

[51] *See* FDA Med. Rev. at 18, Table 1; *see also* FDA Med. Rev. at 91-98, App. 9.5, for the full list of references reviewed by the FDA.
[52] FDA Summary Rev. at 10.
[53] *Id.* at 10-11.
[54] FDA Med. Rev. at 47.
[55] FDA Summary Rev. at 11.
[56] FDA Med. Rev. at 47.
[57] *See* Harrison Decl. ¶ 27; Upadhyay et al., *supra* note 6.

"major" complications is unduly narrow.[58] This is not true; the study defines "major" complication broadly to include "serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion."[59] This definition is similar, if not more inclusive, than the FDA's definition of a "serious adverse event."[60]

21. Dr. Harrison suggests that "emergency room visits" should also be included in the safety assessment.[61] In our study of more than 19,000 medication abortions in Iowa, we did document the frequency of emergency department visits where treatment was given, and these visits were very rare.[62] Among 8,765 medication abortions provided by telemedicine, there were 13 cases of emergency department visits where treatment was given (0.15%).[63] Among 10,405 medication abortions provided with an in-person visit, there were 22 cases of emergency department visits where treatment was given (0.21%).[64] The prevalence of these visits was very low in both groups and did not differ to a statistically significant extent between telemedicine and in-person provision.

22. In her declaration, Dr. Harrison expresses concern that hemorrhage without transfusion is not considered a major complication. She notes that she has reviewed FDA adverse event reports where patients lost "nearly half of their blood—without [receiving] a transfusion."[65] Given that the average person has a blood volume of approximately five liters, this would mean losing approximately 2500 cc of blood. It is unfortunate that Dr. Harrison did not provide more

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[58] *See* Harrison Decl. ¶ 27.
[59] Upadhyay et al., *supra* note 6, at 176.
[60] *See* Mifeprex Label at 7-8 (defining "serious adverse event" as including transfusion, infections, and hemorrhage).
[61] *See* Harrison Decl. ¶ 27.
[62] Grossman & Grindlay, *supra* note 14.
[63] *Id.* at 781.
[64] *Id.*
[65] Harrison Decl. ¶ 27.

information about these cases, since it would be very unusual to have such a massive hemorrhage and not require a transfusion. The problem is that hemorrhage does not have a standard definition and may be interpreted to mean any degree of bleeding. Given that bleeding is an expected symptom of medication abortion, unquantified hemorrhage is not necessarily a sign of an adverse event—and certainly not a major one.

23. The study found that only 3.1 out of 1,000 patients (0.31%) in this study experienced a major complication (hospital admissions, surgery, or blood transfusion) following a medication abortion.[66] By contrast, nearly 3% (i.e., ten times higher than for medication abortions) of all women who give birth vaginally have a prolonged hospital admission or early re-admission to the hospital. For cesarean delivery (a major operation that more than 30% of American women who give birth will undergo), the figure is three times higher.[67]

24. Dr. Harrison also ignores that the study included an analysis of all "complications"—not just those defined as "major"—and employed an extremely broad definition. The study "defined a complication as any postabortion adverse event that received an abortion-related diagnosis or treatment at any source of care, including EDs [emergency departments] and the original abortion facility within 6 weeks of an abortion procedure."[68] Even following that broad definition of "complication," the study reported only a 5.2% rate of

[66] Upadhyay et al., *supra* note 6, at 175.
[67] Patricia R. Hebert et al., *Serious Maternal Morbidity After Childbirth: Prolonged Hospital Stays and Readmissions*, 94 OBSTET. & GYNECOL. 942, 944 (1999); Brady E. Hamilton et al., *Births: Preliminary Data for 2011*, 61 NAT'L VITAL STAT. REP. 1, 2 (Oct. 3, 2012), https://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_05.pdf.
[68] Upadhyay et al., *supra* note 6, at 179.

complications for medication abortions.[69] The study also posits multiple reasons why it may have *over-reported* complications.[70]

25. The studies Dr. Harrison relies on to assert that "[medication abortion] complications are common" are inferior to the studies relied upon by the FDA and by Plaintiffs.[71] Both the Mulligan study[72] and the Niinimaki study[73] have serious methodological limitations. The Mulligan study has a small sample size[74] and does not control for the route of misoprostol administration or timing of misoprostol administration.[75] The Niinimaki study does not differentiate between different medication abortion protocols.[76] The Niinimaki study also does not define how hemorrhage was quantified.[77] And in any event, the Mulligan study concludes that "the rate of any adverse outcome following early abortion is low" and that "little can be made of the likelihood of the most serious adverse outcomes of early abortion except to note that they are rare."[78] The Niinimaki study finds that there is a "low level of serious complications"[79] and medical and surgical abortion are "generally safe."[80]

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[69] *Id.* at 181.
[70] *See id.* at 182.
[71] Harrison Decl. ¶¶ 24-27.
[72] Ea Mulligan & Haley Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, 40(5) AUSTRALIAN FAMILY PHYSICIAN 342 (2011).
[73] Maarit Niinimaki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114(4) OBSTET. & GYNECOL. 795 (2009).
[74] Mulligan & Messenger, *supra* note 72, at 343 (947 medication abortion in the sample compared to 233,805 medication abortions in the sample in Cleland et al., *supra* note 6, and 11,319 medication abortion in the sample in Upadhyay et al., *supra* note 6).
[75] *Id.*
[76] Niinimaki et al., *supra* note 73, at 796.
[77] *Id.* at 799-800.
[78] Mulligan & Messenger, *supra* note 72, at 343-44.
[79] Niinimaki et al., *supra* note 73, at 803.
[80] *Id.* at 798.

26. Dr. Harrison cites to an "abortion reversal" study as part of her claim that there is a high risk of hemorrhage following medication abortions.[81] This study was designed to test a claim that medication abortions are "reversable" and was conducted by having the patient take only mifepristone, but not misoprostol, the second drug in the medication abortion regimen.[82] The higher rate of hemorrhage confirmed the importance of the two-drug regimen for medication abortion. As a result, the "reversal" study says nothing about the safety of the current protocol for medication abortion, which requires the administration of both drugs. This protocol is extremely safe, as demonstrated by the fact that serious adverse reactions, including hemorrhage, occur in less than 0.5% of women who undergo the treatment.[83]

Conclusion

27. The Challenged Laws present arbitrary, burdensome, and unreasonable restrictions on the provision of medication abortion that serve no legitimate medical purpose in light of the safety of that treatment.

28. Dr. Harrison misrepresents existing studies and relies on outdated or debunked information to suggest that medication abortion is dangerous, when—in fact—the data, research, and credible peer-reviewed studies show it is extremely safe.

29. It is my opinion that Oklahoma's prohibition on the delivery of medication abortion via telemedicine and by APRNs burdens women's access to medication abortion for no medically justifiable reason.

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[81] *See* Harrison Decl. ¶ 20.
[82] *See* Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion*, 135(1) OBSTET. & GYNECOL. 158 (2020).
[83] Mifeprex Label at 7-8.

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

Dated this 30th day of January, 2020.

Daniel A. Grossman, M.D.