**IN THE DISTRICT COURT OF OKLAHOMA COUNTY**
**STATE OF OKLAHOMA**



TULSA WOMEN'S REPRODUCTIVE CLINIC, LLC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D.,

Plaintiffs,

v.

MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, DENNIS CARTER, in his official capacity as President of the Oklahoma State Board of Osteopathic Examiners, and GARY COX, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors

Defendants.

CASE NO. CV-2019-2176
HON. D. Andrews

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR TEMPORARY INJUNCTION**

## I. Defendants Rely on the Wrong Legal Standard

Defendants are wrong to argue that S.B. 614 may be stricken only if it is "clearly, palpably, and plainly inconsistent with the Constitution." Defs.' Resp. at 9. Where, as here, a law encroaches upon a fundamental right, such as the right to free speech, it is subject to heightened scrutiny.[1]

## II. S.B. 614 is Subject to, and Fails, Heightened Scrutiny

Defendants do not dispute that S.B. 614 is a content-based law compelling speech on a controversial topic. S.B. 614, including its publishing instructions and mandatory signage, also forces physicians to express ideological beliefs about abortion. *Cf. Am. Med. Ass'n v. Stenehjem*, 2019 WL 4280584, at *12 (D.N.D. 2019). Such laws are subject to heightened scrutiny.[2] Instead, Defendants rely on a so-called "reasonable regulation" test, based on language from *Planned Parenthood v. Casey* concerning Pennsylvania's state-mandated counseling for abortion. Defs.' Resp. at 9-10; *see Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 884 (1992).

But Defendants' reliance on *Casey* is misguided. S.B. 614 "does not facilitate informed consent" to medication abortion. *NIFLA*, 138 S. Ct. at 2373. Informed consent involves providing "information about the risks of abortion, and childbirth." *Casey*, 505 U.S. at 884; *see NIFLA*, 138 S. Ct. at 2373. However, S.B. 614 has nothing to do with the risks or benefits of medication abortion, which involves a two-drug regimen of mifepristone and misoprostol. *Existing* Oklahoma law already requires physicians to inform patients about the risks and benefits of that procedure.[3] S.B. 614 instead forces physicians to repeatedly inform patients about so called abortion "reversal"—an entirely *different*, experimental procedure involving a different combination of

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[1] *In re Initiative Petition No. 366*, 2002 OK 21, ¶ 14, 46 P.3d 123, 128 ("[A] law 'which interferes with the right to free speech' is subject to heightened scrutiny") (internal citation omitted); *see also Dani v. Miller*, 2016 OK 35, ¶ 50, 374 P.3d 779, 799 (same).
[2] *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*"); *see* Memo. of Law in Support of Pls.' Mot. for Temp. Inj. ("Pls.' Mem.") at 10-11.
[3] *See* 63 O.S. § 1-738.2.

drugs——which Plaintiffs neither offer nor provide. As the Court made clear in *NIFLA*, a state law is not part of informed consent where, as here, it requires disclosure about a procedure that is not "sought, offered, or performed" by the regulated physicians. 138 S. Ct. at 2373.

S.B. 614 *undermines* informed consent by forcing physicians to speak information about an unproven, controversial, and experimental treatment. Defendants do not meaningfully contest that S.B. 614 would force physicians to breach the ethical obligations on which informed consent is based, or address the serious ethical implications of forcing physicians to repeatedly direct their patients to APR.[4] Contrary to Defendants' speculation and anecdotes, abortion providers are trained to assess patients' decisional certainty and potential coercion.[5] Plaintiffs do not administer mifepristone to patients who are not firm in their decision to end a pregnancy. Braid Aff. ¶ 13-14.

## III. Even If S.B. 614 Were an Informed Consent Law, It Fails Intermediate Scrutiny

Even assuming S.B. 614 is an informed consent law, the applicable standard would be intermediate scrutiny. Cases decided after *NIFLA* have held that intermediate scrutiny applies to regulations of professional conduct that incidentally burden speech. *Capital Associated Indus. v. Stein*, 922 F.3d 198, 207-09 (4th Cir. 2019); *Am. Med. Ass'n v. Stenehjem*, No. 1:19-cv-125, 2019 WL 4280584, at *10 (D.N.D. Sept. 10, 2019).

Defendants suggest that Oklahoma has an interest in protecting fetal life. Defs.' Resp. at 15-16. That interest is irrelevant to physicians' free speech claim, and in any case, S.B. 614 does not further it. Defendants neither address nor dispute Plaintiffs' argument that forcing physicians to inform patients about "reversal" undermines that interest: it perversely encourages patients who

[4] Pls.' Mem., Decl. of Matthew Wynia, M.D., M.P.H. ("Wynia Decl.") ¶¶ 25-51; Pls.' Mem., Decl. of Courtney A. Schreiber, M.D., M.P.H. ("Schreiber Decl.") ¶¶ 51-58; Pls.' Mem., Decl. of Alan Braid, M.D. ("Braid Decl.") ¶¶ 22, 25-32.

[5] Supplemental Declaration of Courtney Schreiber, M.D., M.P.H. (Exhibit A) ("Supp. Schreiber Decl.") at ¶ 14.

may be undecided about abortion to take mifepristone under the mistaken belief that they can later change their minds. Pls.' Mem. at 8; Schreiber Decl. ¶ 55-57; Braid Aff. ¶ 26. Thus, S.B. 614 cannot be narrowly tailored to serve an interest in fetal life; it instead *encourages* patients to begin a medication abortion before they are firm in their decision.

Defendants also suggest that S.B. 614 furthers Oklahoma's interests in informing patients about medical procedures and protecting women's health. Defs.' Resp. at 15-16. But S.B. 614 is not narrowly tailored to serving those interests. There are other ways for Oklahoma to inform women about APR and "reversal" "without burdening [physicians] with unwanted speech." *NIFLA*, 138 S. Ct. at 2376 (citation omitted). "[M]ost obviously, [the State] could inform the women itself with a public information campaign" or "post the information on public property" near clinics that provide medication abortions. *See NIFLA* at 2376. Oklahoma "cannot co-opt" physicians who provide abortions "to deliver its message for it." *Id.*

## IV. S.B. 614 Fails Under the Test that Defendants Propose

Defendants admit that even under the so-called "reasonable regulation" analysis on which their arguments are premised, a law is unconstitutional if it requires physicians to disclose information that is (1) untruthful, (2) misleading, (3) irrelevant, *or* (4) not tied to a medical procedure. Defs.' Resp. at 10. S.B. 614 fails *all* four criteria.

S.B. 614 mandates physicians tell their patients untruthful, or at the very least, highly misleading information, and direct them to additional untruthful and misleading information on the APR website and hotline. Braid Decl. ¶¶ 27-28; Wynia Decl. ¶ 27. The sources the State relies upon as "evidence" supporting their hypothesis that medication abortion can be "reversed" include anecdotal stories and personal "belief," quotes from a magazine, general biochemistry principles, tangentially related studies, and the Delgado papers (which Plaintiffs have debunked). Schreiber Decl. ¶¶ 19-49; Supp. Schreiber Decl. ¶¶ 9-11. Defendants do not provide a basis as to why such

spurious evidence could amount to credible scientific evidence that a medical procedure is reversible (indeed, it does not). Additionally, Defendants' concession that leading medical organizations reject Delgado's studies (Defs.' Resp. at 13-14; *see also* Schreiber Decl. ¶¶ 21, 30, 38) alone makes the message untruthful or at least misleading, and thus unconstitutional.[6] *Planned Parenthood Minn., N. Dakota, S. Dakota v. Daugaard*, 799 F. Supp. 2d 1048, 1072 (D.S.D. 2011).

Implicitly conceding that no medically sound evidence supports the abortion "reversal" hypothesis, the State resorts to arguing that "ongoing debate in the medical field" supports concluding that the state-mandated information is truthful and non-misleading. Defs.' Resp. at 15. But there is "no real, serious debate within the medical profession." *Am. Med. Ass'n*, 2019 WL 4280584, at *12; *see* Schreiber Decl. ¶¶ 21, 30, 38. Defendants cite no legislative findings that abortion can be "reversed." And Defendants have no support for "the argument that, even if a medical debate exists, a state legislature is free to take sides in a medical debate and force physicians to speak to patients about a very controversial and medically-uncertain procedure." *Am. Med. Ass'n*, 2019 WL 4280584, at *12.

The State puts enormous emphasis on the wording of the mandatory speech—that it "*may be possible* to reverse the effects of an abortion-inducing drug." Defs.' Resp. at 1, 11-12. But stating that abortion reversal "may be possible" does not cure the misleading and untruthful nature of the message. It tells the patient that a reversal protocol exists and that the protocol works in at least some, even if not all, cases. But as Plaintiffs have already explained, there is currently no

[6] The U.S. Supreme Court has consistently relied upon ACOG for over 45 years when making decisions impacting abortion. *See, e.g., Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2313 (2016); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983); *Geduldig v. Aiello*, 417 U.S. 484, 501 n.4 (1974). ACOG has not retracted its statement opposing abortion reversal. *See* ACOG, *Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science* (Aug. 2017), available at https://tinyurl.com/y4ccqax5 (last visited Oct. 18, 2019).

credible scientific evidence that it is *ever* possible to "reverse" mifepristone. The State can no more force physicians to speak this message than it could force them to tell their patients that it "may be possible" to cure cancer through hypnotherapy. Supp. Schreiber Decl. ¶ 6.[7]

Defendants' suggestion that physicians may "cure the coercion" by denouncing the information they are unconstitutionally forced to speak is unpersuasive. *See Stuart v. Camnitz*, 774 F.3d 238, 246 (4th Cir. 2014).[8] Furthermore, forcing doctors to give patients a message, followed by an explanation that the message is incorrect, undermines physician-patient candor and trust, and would detract from the informed consent process by confusing patients.

S.B. 614 is also not "tied to" medication abortion. As noted *supra* at 1-2, so-called "reversal" is a separate medical procedure from medication abortion. S.B. 614 further forces physicians to inform all medication abortion patients about "reversal" and direct them to the APR website, even if such information is irrelevant to the patient. Moreover, S.B. 614's mandatory signage will be visible to all patients in the waiting room or shared consultation rooms—including patients receiving surgical abortion or no abortion.

## CONCLUSION

S.B. 614 should be temporarily enjoined pending final resolution of Plaintiffs' claims.

Dated: October 18, 2019

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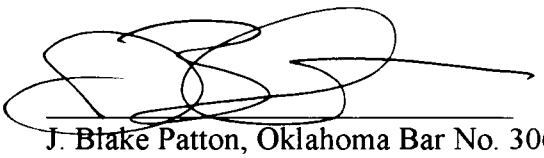
[7] The message that "time is of the essence" compounds the problems, misleading patients into believing i) that a reversal protocol exists, and ii) that its success depends on how quickly they act. Defendants provide no credible evidence showing this message is accurate.

[8] *See also Daugaard*, 799 F. Supp. 2d at 1072 (rejecting South Dakota's argument that a law mandating a misleading disclosure could be saved because the physician could denounce the disclosure).

Respectfully Submitted,



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## CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 18th day of October, 2019, a true and correct copy of the foregoing was served via U.S. Mail to the following:

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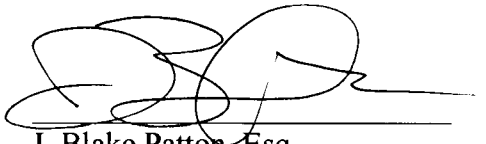

J. Blake Patton, Esq.

# EXHIBIT A

**IN THE DISTRICT COURT OF OKLAHOMA COUNTY**
**STATE OF OKLAHOMA**

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|---|---|---|
| TULSA WOMEN'S REPRODUCTIVE CLINIC, LLC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D.,<br><br>Plaintiffs,<br><br>v.<br><br>MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, DENNIS CARTER, in his official capacity as President of the Oklahoma State Board of Osteopathic Examiners, and GARY COX, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors<br><br>Defendants. | ) | CASE NO. CV-2019-2176<br>HON. D. Andrews |

**SUPPLEMENTAL DECLARATION OF COURTNEY SCHREIBER, M.D., M.P.H. IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION**

Courtney Schreiber, M.D., M.P.H., declares and states as follows:

1. I am over 18 years of age and competent to make this declaration.

2. I submit this supplemental declaration in further support of Plaintiffs' Motion for a Temporary Injunction preventing enforcement of S.B. 614.

3. I have read the State of Oklahoma's Response Motion in Opposition to Plaintiffs' Motion for Temporary Injunction and supporting exhibits, including the affidavits of Mary Martin, M.D. and Martha Shuping, M.D., and the Declaration of Donna Harrison, M.D. While the Court's

schedule did not allow for a comprehensive response, I provide the following limited responsive opinions:[1]

4. In her declaration, Dr. Harrison repeatedly acknowledges that mifepristone reversal is not a medical or scientific certainty, but instead a mere possibility. It is my opinion that the very uncertainty Dr. Harrison acknowledges makes forcing physicians to inform their patients that abortion reversal "may be possible" and repeatedly direct them to the Abortion Pill Reversal website in the manner dictated by S.B. 614 a clear deviation from the standard of care and from beneficent medical care.

5. A medical "theory" is very different from medical "evidence." The theory that progesterone can "reverse" mifepristone remains just that—a theory.[2] There are many medical and scientific theories that, even if they make some logical sense in theory, do not pan out in practice after they have been sufficiently studied. It is for this reason that methodical, scientific study of theories, including through clinical trials, is paramount to the safe practice of medicine. In this case, Dr. Harrison acknowledges the lack of rigorous scientific studies, Harrison Decl. ¶ 42, but nevertheless opines that it is necessary to inform patients "about the possibility of taking progesterone before and soon after taking mifepristone" in order for them to make an informed choice, Harrison Decl. ¶ 43. Dr. Martin broadly estimates that she has "worked with somewhere between 30 and 60 women in Oklahoma" over the last five to ten years who sought to reverse their medication abortion. Martin Decl. ¶ 9. Dr. Martin speculates that the "majority of [her] efforts

[1] Given the time constraints for submitting this Supplemental Declaration, I have not addressed every assertion and opinion contained in the affidavits, declarations, and other materials submitted by Defendants. The fact that I have not addressed a particular statement or assertion does not mean that I agree with the statement or assertion.

[2] Dr. Harrison indicates that mifepristone is "reversible" because it does not permanently block progesterone receptors. This is scientifically inaccurate. Mifepristone is not "reversible" simply because it temporarily (as opposed to permanently) blocks progesterone receptors.

have been successful" while admitting she does not "know the exact numbers." Martin Decl. ¶ 9. This is not sufficient evidence on which to base medical practice.

6. Similarly, ensuring that a patient is informed before consenting to a medical procedure does not include informing that patient about every single fringe medical theory that has yet to be proven by sound medical evidence. For example, some people believe, despite a lack of evidence, that hypnotherapy can cure cancer, but this does not mean that oncologists should be forced to inform all their cancer patients that it may be possible to cure cancer with hypnotherapy. In fact, doing so would be misleading. Legislating to force physicians to inform patients about unproven theories, especially when the proposed treatment may actually be harmful and costly to the patient, disrupts and impedes the patient-provider relationship and contravenes the true purpose of the informed consent process.

7. Moreover, as noted in my initial Declaration, Plaintiffs follow the FDA-approved protocol for administering mifepristone, which involves the administration of mifepristone *in combination with* misoprostol. Schreiber Decl. ¶ 13. A physician providing medication abortion must provide the patient with the information she needs to give informed consent to undergo *that procedure*. The experimental administration of a high dosage of progesterone to "reverse" the effects of mifepristone would be a distinct medical procedure, involving a different combination of medications intended to achieve an entirely different result. It is nonsensical to suggest that informing a patient about the latter procedure is necessary to obtain that patient's informed consent to the former.

8. Further, medical providers in the United States currently cannot prescribe mifepristone (marketed under the name Mifeprex) from the manufacturer unless they agree to administer mifepristone as part of a medication regimen that also involves administration of a

second medication, misoprostol.[3] Mifepristone "reversal" treatment with progesterone is not an "alternative" to the FDA-approved protocol for administering mifepristone in combination with misoprostol. There is no evidence-based protocol for administering mifepristone without also instructing patients to take the second drug, misoprostol. The medical alternatives to a medication abortion with mifepristone are, *e.g.*, a surgical abortion procedure or carrying the pregnancy to term.

9. I further disagree with Dr. Harrison's analysis of the feasibility of studying "abortion reversal." While Dr. Harrison acknowledges that randomized, prospective, placebo-controlled trials are the gold standard in research, she opines that ethical research on the use of progesterone to "reverse" mifepristone is impossible. *See* Harrison Decl. ¶ 36. Researchers could design studies where the participants properly consented to experimental treatment according to a standard progesterone protocol. Schreiber Decl. ¶ 15 n.35. Delgado's papers fail to meet even this ethical threshold.

10. In response to Dr. Harrison's claims as to whether the 2018 Delgado case series received IRB approval that was subsequently withdrawn or removed, the information in my Declaration provides my opinions on that matter based on the currently available information. All

[3] U.S. Federal Food and Drug Administration, Approved Risk Evaluation and Mitigation Strategies for Mifeprex and mifepristone, Summary, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last visited Oct. 18, 2019); Provider Agreement Form for Danco Laboratories, available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf (last visited Oct. 18, 2019); Prescriber Information for GenBio Pro, Inc., available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_Prescriber_Agreement_Form_for_GenBioPro_Inc.pdf (last visited Oct. 18, 2019).

human subject research, including case studies,[4] should be approved by an IRB to ensure that such research is ethical. Offering experimental care without proper institutional oversight, as Delgado appears to have done, is not only unethical research on human subjects but it undermines researchers' ability to perform ethical research, as patients will be less inclined to enroll in data-generating studies if they can obtain the same experimental treatment outside the research setting.

11. I disagree with Dr. Harrison's opinion that Delgado's 2018 case series has scientific merit because he used a "historic control group" derived from a 2017 literature review. Neither of Dr. Delgado's abortion reversal papers had a scientifically valid control group. Historic control groups may be a legitimate means of comparing a study with no control group to literature or a similar cohort study in similar circumstances to get preliminary hint at increased efficacy of intervention. But comparison to an historic control group is far weaker evidence than comparison to a concurrent control group. An appropriate historic control group for the case study Delgado was conducting is described in my Declaration, along with my opinions on the multiple flaws in Delgado's study design and the reasons the Davenport literature review is not a scientifically appropriate historical control.[5] The assertion that using a concurrent control group is impossible is false.

12. Dr. Harrison incorrectly claims that based on animal studies, anecdotal and/or scientifically invalid evidence of mifepristone "reversal" with progesterone, and that progesterone is commonly prescribed to women early in pregnancy, it is "scientifically proper" to administer patients with high doses of exogenous progesterone. Harrison Decl. ¶ 28–30. It is common

[4] As I explained in my original declaration, Delgado's papers did not use an accepted or valid study design and cannot even fairly be categories as scientifically valid "case series." Schreiber Decl. ¶ 33.

[5] Schreiber Decl. ¶ 35–40.

knowledge within the medical profession that too large exogenous doses of any naturally occurring hormone or chemical, including water and Vitamin C, can be risky or even dangerous. Indeed, I cite studies in my original declaration documenting the potential risks from progesterone treatment. *See* Schreiber Decl. ¶ 42.[6] Because the use of progesterone to "reverse" abortion has not been proven safe, and because there is an absence of data on its efficacy for this purpose, it is my opinion that exposing patients to this treatment as a matter of course is unethical.

13. Dr. Harrison mischaracterizes the discussion in my Declaration about studies that raised concerns regarding certain exogenous progesterone preparations. Discussing these risks in the abortion "reversal" context is not misleading. It is my understanding that S.B. 614 requires physicians to repeatedly direct patients to the Abortion Pill Reversal hotline. To my knowledge, APR has never publicized the delivery system or name of the compound they recommend for "reversal" treatment with progesterone. There is an extensive range of natural and synthetic progesterone compounds available on the market; this could be confusing to a provider administering progesterone treatments without an evidence-based protocol to follow (and to my knowledge, no such protocol currently exists). Given the ready availability of both natural and synthetic progesterone, and the lack of information about the manner in which APR-affiliated individuals are providing "reversal" treatment, I believe there is a potential for harm and that studies on the potential risks of both natural and synthetic progesterone are relevant at this time. Only further studies could clarify the safest, most effective regimen.

14. Abortion providers are very familiar with the issues around coercion. In my role at the University of Pennsylvania, I train physicians and healthcare professionals in informed consent

[6] One of these studies found an increase in the rate of miscarriages and stillbirths in the group of patients that received progesterone. Paul J. Meiss et al., *Prevention of Recurrent Preterm Delivery by 17 Alpha- Hydroxyprogesterone Caproate*, 348 N. Eng. J. Med. 2379, 2382 (2003).

counseling for patients considering or seeking abortion care. Abortion providers receive specific training to assess the context in which the decision is being made andensure that before initiating the abortion procedure that it is the best decision for the *patient*. Anything that undermines that process, such as coercion, or requiring by law that the physician provide information that muddles and confuses the informed consent process, undermines the value of informed consent and deconstructs the process of informed consent counseling and good medicine.

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

Executed on October 18, 2019.

Courtney A. Schreiber, M.D., M.P.H.