IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, et al.,	)	
Plaintiffs,	)	**NO. 3:20-cv-00740**
v.	)	**JUDGE CAMPBELL**
	)	**MAGISTRATE JUDGE NEWBERN**
HERBERT H. SLATERY, et al.,	)	
Defendants.	)	

MEMORANDUM

I. Introduction

Pending before the Court are Plaintiffs' Motion for Temporary Restraining Order and/or Preliminary Injunction (Doc. No. 4),[1] Defendants' Response (Doc. No. 16),[2] Plaintiffs' Reply (Doc. No. 31)[3], and the parties' post-hearing briefs. (Doc. Nos. 82, 84). The Court issued a Temporary Restraining Order on September 29, 2020 (Doc. No. 33), which expires when the Court

[1] Plaintiffs' Motion is supported by a Complaint (Doc. No. 1), Memorandum (Doc. No. 6), and the Declarations of Courtney A. Schreiber, M.D., M.P.H. (Doc. No. 6-1), Steven Joffe, M.D., M.P.H. (Doc. No. 6-2), Melissa Grant (Doc. No. 6-3), Ashley Coffield (Doc. No. 6-4), Corinne Rovetti, FNP, APRN-BC (Doc. No. 6-5), Rebecca Terrell (Doc. No. 6-6), and Audrey Lance, M.D., M.S. (Doc. No. 6-7).

[2] Defendants' Response is supported by the Declarations of Brent Boles, M.D. (Doc. No. 16-1), Donna Harrison, M.D. (Doc. No. 16-2), Matthew Dunne (Doc. No. 16-3), George Delgado, M.D. (Doc. No. 16-4), Sarah Hurm (Doc. No. 16-6), Carrie Beth Dunavant (Doc. No. 16-7), Michael Podraza, M.D. (Doc. No. 16-8), and Martha Shuping, M.D., M.A. (Doc. No. 16-10).

All defendants except Davidson County District Attorney General Glenn Funk have also filed declarations suggesting providers would not be sanctioned or penalized for expressing disagreement with the mandated message. (Doc. Nos. 28-1 to 28-6). General Funk filed a separate declaration stating he will not enforce Section 218 because he believes it is unconstitutional. (Doc. No. 29-1).

[3] Plaintiffs' Reply is supported by the Declaration of Christine Clarke (Doc. No. 31-1), and Rebuttal Declarations of Audrey Lance, M.D., M.S. (Doc. No. 31-2), Courtney A. Schreiber, M.D., M.P.H. (Doc. No. 31-3), and Steven Joffe, M.D., M.P.H. (Doc. No. 31-4).

issues a ruling on the request for preliminary injunction (Doc. No. 38). The Court held a hearing on the request for preliminary injunction over several dates – December 1, 2, 8, and 14, 2020, and January 25, 2021. The request is now ripe for decision.

This case requires the Court to consider whether the State may, consistent with the Constitution, require abortion providers to tell their patients about a treatment Defendants' experts believe may "reverse the intended effects of a chemical abortion utilizing mifepristone." In considering the question, the Court has the language of the statute the elected legislators of the Tennessee General Assembly passed, which language the Court must accept as written and to which the plaintiffs object. It is also important for the Court to point out what is not at issue. This case is *not* about whether patients should have access to the treatment, which the Court will refer to as "progesterone therapy." Nor is this case about whether physicians should be permitted to provide progesterone therapy to patients. Indeed, physicians are currently offering progesterone therapy to patients, and information about progesterone therapy is available through the internet and other sources. Instead, this case relates only to the statutory requirement that abortion providers, under threat of criminal sanction, inform patients about progesterone therapy in language to which these providers object, and that is, for the reasons described below, untruthful and/or misleading. Because the Constitution does not permit such a requirement, the Motion for Preliminary Injunction (Doc. No. 4) is **GRANTED.**

II. The Challenged Statute and Plaintiffs' Claims

Plaintiffs request the Court issue a preliminary injunction enjoining enforcement of Tennessee Code Annotated Section 39-15-218 ("Section 218"). Section 218 prohibits a physician

from performing a chemical abortion[4] involving the use of mifepristone and misoprostol unless, at least 48 hours in advance, the physician has informed the patient of the following: "(1) It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence; and (2) Information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." Tenn. Code Ann. § 39-15-218(e). This requirement is subject to a "medical emergency" exception. *Id.*

After the mifepristone is dispensed, Section 218 also requires the physician or an agent of the physician to provide the patient with written medical discharge instructions that include the following statement:

> Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.

Tenn. Code Ann. § 39-15-218(f).

In addition to these statements, Section 218 requires a private office, ambulatory surgical treatment center, or other facility or clinic, that has performed more than 50 elective abortions during the previous calendar year to "conspicuously post a sign" that repeats the message required to be included in the discharge instructions. Tenn. Code Ann. § 39-15-218(b). This sign "must be printed with lettering that is legible and at least three quarters of an inch (0.75″) boldfaced type."

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[4] Section 218 defines a "chemical abortion" as "the use or prescription of an abortion-inducing drug dispensed with intent to cause the death of the unborn child." Tenn. Code Ann. § 39-15-218(a)(2). The statute contemplates that chemical abortions will be performed by sequentially administering two drugs: mifepristone and misoprostol. Tenn. Code Ann. § 39-15-218(a)(2).

Tenn. Code Ann. § 39-15-218(c). Private offices and ambulatory surgical treatment centers must post the sign "in each patient waiting room and patient consultation room used by patients on whom abortions are performed." Tenn. Code Ann. § 39-15-218(d). Hospitals and other facilities are required to post the sign "in each patient admission area used by patients on whom abortions are performed." *Id.*

Section 218 also requires the Tennessee Department of Health to make available on its website, and in print materials, information "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind," as well as "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion." Tenn. Code Ann. § 39-15-218(h)(i). The Department was not required to provide this information, however, until "ninety (90) days after the effective date," or until January 1, 2021. All other requirements in Section 218 were to take effect on October 1, 2020. 2020 Tenn. Pub. Acts Ch. 764, § 4.

While these proceedings were pending, the Department added the following language to its website:

> INFORMATION REGARDING CHEMICAL ABORTION
>
> As required by 2020 Public Acts C. 764, relative to abortion:
>
> The most common form of a chemical, non-surgical abortion (also called a medication abortion) typically involves administering two medications, mifepristone and misoprostol.
>
> Mifepristone temporarily blocks the hormone progesterone, which is necessary to maintain pregnancy.
>
> Mifepristone alone is not always effective in ending a pregnancy. If Misoprostol has not been taken, it may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion.

> If you are questioning or change your mind about your decision to terminate your pregnancy after taking mifepristone and would like further information, guidance, or assistance concerning your pregnancy, you should immediately contact a healthcare professional.
>
> The following resources are available:
>
> The Abortion Pill Reversal Hotline*: 1-877-558-0333 www.abortionpillreversal.com
>
> *The Tennessee Department of Health does not operate the hotline or website and is not affiliated with either. It does not endorse the content of either. The information provided by either does not necessarily reflect the official policy or position of the Department. The Department does not endorse or recommend medical providers. The Department encourages all patients to discuss risks and benefits of any potential medications or procedures with their medical providers.

(Doc. No. 83-1).

As for sanctions, Section 218 provides: "Any person who knowingly or recklessly performs or induces or attempts to perform or induce an abortion in violation of [the statute] commits a Class E felony." Tenn. Code Ann. § 39-15-218(j). Private offices, ambulatory surgical treatment centers, or other facilities or clinics that negligently fail to post the required sign are subject to a civil penalty of $10,000 for each day an abortion is performed there. Tenn. Code Ann. § 39-15-218(k). The statute creates a cause of action for the patient, the father, or a parent of a minor patient, to recover actual and punitive damages against a non-compliant physician. Tenn. Code Ann. § 39-15-218(l).

Plaintiffs Planned Parenthood of Tennessee and North Mississippi ("PPTNM"), Memphis Center for Reproductive Health, Knoxville Center for Reproductive Health, and carafem operate medical facilities that offer abortions to patients. (Doc. No. 1 ¶¶ 8-13). Plaintiff Audrey Lance, M.D., N.S., is an obstetrician/gynecologist ("OB-GYN"), who has provided medication abortions at PPTNM. (*Id.*) Plaintiffs have named as defendants: Herbert H. Slatery, III, the Tennessee Attorney General; Lisa Piercey, M.D., the Commissioner of the Tennessee Department of Health;

Rene Saunders, M.D., the Chair of the Board for Licensing Health Care Facilities; W. Reeves Johnson, Jr., M.D., the President of the Tennessee Board of Medical Examiners; and Amy Weirich, Glenn R. Funk, Charme P. Allen, and Tom Thompson, the District Attorneys General for the jurisdictions where Plaintiffs offer services. (*Id.* ¶¶ 14-21).

Plaintiffs argue Section 218 compels physicians and abortion providers, under threat of criminal prosecution and other sanctions, to provide their patients with inaccurate, misleading, and irrelevant information that a chemical abortion (what Plaintiffs and the witnesses call "medication abortion") can be "reversed." Plaintiffs assert such a claim is wholly unsupported by reliable scientific evidence and has been rejected by leading medical associations. The Complaint asserts that Section 218 violates: (1) the First Amendment rights of Plaintiffs, their physicians, and their staffs (Count I); (2) the substantive due process rights of Plaintiffs' patients (Count II); (3) Plaintiffs' equal protection rights (Count III); and (4) the equal protection rights of Plaintiffs' patients (Count IV). (Doc. No. 1 ¶¶ 84-92).

To support their Motion, Plaintiffs called Dr. Audrey Lance, Dr. Courtney Schreiber, and Dr. Steven Joffe to testify at the preliminary injunction hearing. Defendants called Dr. George Delgado, Dr. Brent Boles, and Dr. Donna Harrison.

III. Summary of Evidence

A. Medication Abortions

Medication abortions involve a two-drug regimen through which a patient takes 200 mg of mifepristone orally, followed within 24 to 48 hours, by 800 mcg of misoprostol buccally (in the cheek pouch).[5] Mifepristone was first approved by the Food and Drug Administration ("FDA")

[5] The current regimen was outlined by the Food and Drug Administration in 2016. (Schreiber Declaration ¶ 19).

in 2000 as part of the two-drug regimen, but the dosage and intervals between the two medications have changed over time based on subsequent research. Mifepristone terminates the pregnancy by causing the pregnancy tissue and lining of the uterus to detach from the uterine wall. More specifically, mifepristone binds to progesterone receptors in the body and blocks the hormone from activating the receptors. The second medication, misoprostol, causes uterine contractions that expel the contents of the uterus. Mifepristone is often taken at the doctor's office and misoprostol can be taken at a location of the patient's choosing. Medication abortions are generally used for patients up to 77 days gestational age. The two-drug regimen is 97% effective through 70 days gestational age and results in serious complications in less than one percent of women.

The effectiveness of the two-drug regimen decreases when mifepristone is taken alone – not followed by misoprostol. Studies conducted before FDA approval of mifepristone, most conducted during the 1980s, indicate that the rates of continued pregnancy after mifepristone *alone* (in doses generally higher than 200 mg) for up to 49 days gestational age ranged from 8 to 46%. (Plaintiffs' Hearing Exhibit 6-1, at 209, Table 1). These studies also indicate that the efficacy of the drug decreases as gestational age increases.

Approximately 30% of abortion patients undergo medication abortions. Before obtaining a medication abortion in Tennessee, according to Dr. Audrey Lance, a patient is required to provide a medical history, undergo tests, including an ultrasound to date the pregnancy, and receive counseling about the abortion process, any potential side effects, and other information. Dr. Lance testified that she also tells patients that they must be absolutely sure about this life-changing decision before they begin the abortion process. Dr. Lance said she has turned away patients who have expressed uncertainty.

B. "Reversal" Theory

The theory upon which Section 218 is predicated – that progesterone can "reverse" the effects of mifepristone – is primarily based on two papers co-authored by Dr. George Delgado.[6] Dr. Delgado is board-certified in family medicine and hospice/palliative care, and is the medical director of a family medical group and the chief medical officer of a large hospice facility. Dr. Delgado is not an OB-GYN, nor a pharmacologist.

Dr. Delgado described how he came up with the idea for the use of progesterone therapy. He testified that he received a call, in 2009, about a woman who had changed her mind about having an abortion after taking mifepristone. Based on his knowledge of mifepristone and progesterone, Dr. Delgado drew up a protocol for the administration of progesterone and provided it to another physician who agreed to prescribe the progesterone to the patient. Dr. Delgado testified that the woman later gave birth to a healthy baby. Based on subsequent interest expressed by others around the country in his progesterone therapy, in 2012, Dr. Delgado started the "Abortion Pill Reversal" website, hotline, and network of physicians who are willing to prescribe the progesterone therapy. The organization is now run by Heartbeat International and is called "Abortion Pill Rescue." Dr. Delgado is one of the organization's medical advisers. Dr. Delgado testified that progesterone has been used safely in pregnancy for over 50 years. Dr. Delgado said that he has prescribed progesterone to approximately 50 patients to counteract the effects of mifepristone, and that 30 to 35 of those women delivered babies.

[6] That Section 218 is based on Dr. Delgado's papers appears to be undisputed. Defendants rely on Dr. Delgado's papers in responding to Plaintiffs' challenge to the legislation, and Defendants have filed testimony given at a legislative committee meeting regarding Section 218 during which Dr. Delgado's papers are discussed.

According to Dr. Delgado, the progesterone therapy he devised is supported by biologic logic, a study conducted on rats, and two human studies he conducted. As for biologic logic, Dr. Delgado explained the interaction of mifepristone and progesterone with a "lock and key" analogy. According to Dr. Delgado, mifepristone acts as a "false key" fitting into the receptor "lock," and by blocking hormones from the receptor, causes separation of the placenta from the lining of the uterus. Dr. Delgado described progesterone as the "good key," which, when it attaches to the receptor, decreases the effects of mifepristone. Biology suggests, according to Dr. Delgado, that raising the concentration of progesterone allows the progesterone molecules to "outcompete" the mifepristone molecules in attaching to the receptor.

The rat study relied on by Dr. Delgado was conducted in 1988 in Japan (Defendants' Hearing Exhibit 76), and according to Dr. Delgado, showed that rats who were given mifepristone only had pups in 33% of the cases, and the rats who were given both mifepristone and progesterone had pups in 100% of the cases. Dr. Delgado stated that he had experience with conducting scientific studies on rats because he worked in a rat laboratory as a premed student.

The two human studies on which Dr. Delgado relies as the basis for his progesterone therapy are both "case series" co-authored by him. The first case series describes the experience of six women who took progesterone after taking mifepristone in an attempt to continue their pregnancies. (Plaintiffs' Hearing Exhibit 6). The four-page paper was published in *The Annals of Pharmacotherapy,* and was co-authored by Mary L. Davenport. According to the paper, "[f]our of 6 women who took mifepristone were able to carry their pregnancies to term after receiving intramuscular progesterone 200 mg." (*Id.,* at 1). After noting certain "confounding factors" with the cases discussed, the authors state "[w]e welcome further clinical trials utilizing this protocol or others, in order to have an evidence basis for the best protocol." (*Id.*, at 3).

The other case series, published in 2018 in *Issues in Law and Medicine,* describes the experience of a larger pool of patients. (Plaintiffs' Hearing Exhibit 7). The 10-page paper, co-authored by Dr. Davenport and others, "is a retrospective analysis of clinical data of 754 patients" who took progesterone after taking mifepristone. (*Id.*, at 21). The "Results" of the paper: "Intramuscular progesterone and high dose oral progesterone were the most effective with reversal rates of 64% (P<0.001) and 68% (P< 0.001), respectively." (*Id.,* at 22). The "Conclusion:" "The reversal of the effects of mifepristone using progesterone is safe and effective." (*Id.*) The authors propose, however, that "further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed to confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient." (*Id.,* at 29).

The patients included in the case series were part of a group of women who had called an informational hotline during a four-year period (2012 to 2016), and were referred to physicians and mid-level practitioners in their respective geographic areas for treatment. (*Id.*, at 24). According to the paper, 1,668 women called the hotline and, of those, 754 women "initiated progesterone therapy." (*Id.,* at 25). Five percent of those women (38) were then excluded because they had taken mifepristone more than 72 hours earlier, and eight percent (57) were excluded because they changed their mind and decided to complete the abortion. (*Id.*) Fifteen percent (112) were excluded because they were "lost to follow-up prior to 20 weeks gestation." (*Id.*) Of the remaining 547 patients, 48% either delivered babies or kept their pregnancies for up to 20 weeks, but were then lost to follow-up. (*Id.,* at 25-26). The highest "reversal" rates were for two subgroups: 64% of 125 patients who received progesterone intramuscularly, and 68% of 31 patients who received a high dose of progesterone, taken orally. (*Id.,* at 26).

In order to make comparisons to the rate of continued pregnancies for patients who took mifepristone only, Dr. Delgado created an "historical control group" by consulting previous studies from the 1980s.[7] Based on that analysis, Dr. Delgado concluded that 25% of women who took mifepristone alone had continuing pregnancies. Dr. Delgado found the rates of continuing pregnancies in the 2018 case series "compare[d] favorably" with the 25% historical control group. (*Id.*, at 26).

Plaintiffs' experts are highly critical of using Dr. Delgado's theory and research as a basis for supporting the safety and efficacy of his progesterone therapy, as more fully discussed below. For his part, Dr. Delgado admitted that, with regard to his three bases of support for progesterone therapy, neither biologic logic nor animal studies are sufficient to prove the safety and efficacy of his progesterone therapy on humans.[8] Dr. Delgado also admitted that, in the hierarchy of medical evidence, a case series falls below a randomized controlled trial, and that while a case series can suggest causation, it cannot prove causation. Also, Dr. Delgado agreed that there is a greater possibility of bias with a case series than with a controlled trial.

As for the 2012 paper, neither Dr. Delgado nor Defendants' other experts suggest that a six-patient case series is sufficient to establish that progesterone therapy is safe and effective. Although the 2018 case series involved a larger pool of women, Dr. Delgado admitted to excluding those women whose pregnancies had terminated after mifepristone alone (as shown by ultrasound

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[7] The analysis appeared in a paper he co-authored published in *Issues in Law & Medicine* in 2017. (Plaintiffs' Hearing Exhibit 15).

[8] In addition, Plaintiffs' experts point out that the researchers conducting the 1989 rat study were not investigating whether mifepristone could be "reversed" by subsequent injections of progesterone. The rats in the study were given mifepristone and progesterone at the same time. (Doc. No. 76, at 2). Dr. Schreiber also pointed out that the researchers based their determination that a pregnancy continued on the uterine weight of a euthanized rat, rather than delivery of live pups. (Defendants' Exhibit 76, at 14).

or other test) from the 754 women who initiated progesterone therapy; nor did he count these excluded women as "reversal failures."

With regard to the "historical control group" to which he compared results, Dr. Delgado admitted the characteristics of that group did not align with those of the patients in his case series. The patients in the case series included women with a higher gestational age than the women in the control group, and Dr. Delgado agreed mifepristone becomes less effective as gestational age increases. Dr. Delgado also admitted that patients in his case series received a lower dose of mifepristone than some of the patients in the historical control group, and that a higher dose may be more effective in terminating a pregnancy. Both of these factors suggest that the rate of continuing pregnancies for women taking mifepristone alone could actually be higher than 25%, and that more than 25% of those women described in the case series could have had continued pregnancies without taking progesterone. In addition, Dr. Delgado agreed that the study on which the historical control group is based included only 30 patients, which makes the conclusions of the study less reliable. (*See* Plaintiffs' Hearing Exhibit 14, at 4 "Table 1").

As for the publication itself, Dr. Delgado conceded that *Issues in Law & Medicine* is not particularly well-known in the medical field, and that it publishes legal briefs along with medical studies. One of the entities that publishes the periodical funds pro-life research, and one of the editors is Dr. Donna Harrison, one of Defendants' other witnesses. All the other journals to which Dr. Delgado submitted the case series declined to publish it. Dr. Delgado also explained that, before the case series was published, he sought approval from the Institutional Review Board ("IRB") at the University of San Diego and received an exemption. But after the case series was published, the IRB at that university asked Dr. Delgado to withdraw the case series. Dr. Delgado then sought and obtained approval from another IRB for the withdrawn case series.

Dr. Delgado, and the other witnesses, discussed, at some length, a failed double-blind, placebo-controlled, randomized clinical trial conducted by Dr. Mitchell Creinin, which attempted to estimate the efficacy and safety of the progesterone therapy used by Dr. Delgado. (Plaintiffs' Hearing Exhibit 16). The paper describing the study appeared in the January 2020 issue of *Obstetrics & Gynecology*. Dr. Creinin designed the study for 40 patients to be divided into two control groups: one control group receiving mifepristone and progesterone, and the other control group receiving mifepristone and a placebo. After enrolling 12 patients, the study was discontinued for safety reasons. Two of the patients in the placebo group, and one patient in the progesterone group, had severe bleeding requiring ambulance transport to an emergency department. The progesterone patient ultimately required no intervention. Defendants' experts testified that the study results are consistent with Dr. Delgado's theory,[9] but admit the study did not have enough subjects to be statistically significant. Plaintiffs' experts testified that the results show the risk of taking mifepristone alone, with or without progesterone therapy, is potentially unsafe given the patients who experienced severe bleeding.[10]

Dr. Brent Boles testified in support of Dr. Delgado's progesterone therapy. Dr. Boles is a board-certified OB-GYN who practices in Murfreesboro, Tennessee. Dr. Boles has been a member

[9] Dr. Boles testified, however, that of the three patients who had severe bleeding, ultrasounds revealed the two patients who took mifepristone only did not have completed abortions, and the patient who had taken progesterone after mifepristone had already aborted and spontaneously passed the pregnancy tissue.

[10] The parties also discussed a study conducted by Daniel Grossman and others appearing in *Contraception* in 2015, which reviewed the literature on the effectiveness of medical abortion "reversal" treatment, including Dr. Delgado's 2012 case series. The study concluded that "evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management [doing nothing]." (Plaintiffs' Hearing Exhibit 14, at 1). In 2018, Dr. Grossman co-authored an article critical of Dr. Delgado's 2018 case series in the *New England Journal of Medicine*. (Plaintiffs' Hearing Exhibit 63).

of the Abortion Pill Rescue Network for three to four years. He is also on the medical advisory board for the network. In his role as a member of the network, Dr. Boles has prescribed progesterone therapy to patients from Tennessee and other states who have been referred to him by the network. After discussing the therapy with the patient, Dr. Boles calls in a prescription of progesterone for the patient and advises her to follow up with a local OB-GYN. Dr. Boles estimates he has prescribed this therapy for approximately 20 women, and that his success rate "is in keeping" with the 68% appearing in the Delgado study. Dr. Boles admitted, however, that he was only able to follow up with less than half of those patients, and of those, six had continuing pregnancies. Dr. Boles did not know whether the remaining patients had continuing pregnancies, or experienced adverse events.

Dr. Boles testified before a legislative committee in support of Section 218 before it was enacted. Dr. Boles told the committee the 2018 Delgado study showed there were no adverse outcomes for the mother or child with progesterone therapy; that the study involved 754 participants; and that the success rate was 68%. (Plaintiffs' Hearing Exhibit 9, at 34-35, 43). On cross examination, Dr. Boles admitted that the study did not measure adverse outcomes for the mother, and that the 68% figure only applied to a subgroup of 31 patients. Dr. Boles also told the committee the rate of continuing pregnancy for patients who took mifepristone alone was "pretty close to zero" or as low as eight percent. (*Id.*, at 34-35). But Dr. Boles agreed the study on which he relied also reflects a rate of up to 46% of continuing pregnancies with mifepristone alone.

Dr. Donna J. Harrison also testified in support of Dr. Delgado's progesterone therapy. Dr. Harrison is the Executive Director of the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"). She is board-certified in obstetrics and gynecology but has not treated patients in 20 years. Dr. Harrison testified she has followed the literature on mifepristone

since 1996 and is also familiar with Dr. Delgado's progesterone therapy and the literature addressing that topic. Dr. Harrison testified she believes Dr. Delgado's progesterone therapy is consistent with other medical literature. But she has not prescribed progesterone therapy to any patients.

According to Dr. Harrison, Dr. Delgado's theory – that progesterone competes with mifepristone to bind to the receptor – is consistent with basic biochemistry. Dr. Harrison explained that, although mifepristone binds more tightly to the receptor than progesterone, it releases after a time, and at that point, progesterone can take its place. She further explained that when progesterone attaches to the receptor, it is not "undoing" anything that has been done by mifepristone. Dr. Harrison said she would prefer not to use the term "reversal" to describe the process because it is not "precise."

Dr. Harrison is an associate editor for *Issues in Law & Medicine,* and testified that she had suggested to Dr. Delgado that he publish his papers in the journal if he were unable to publish them elsewhere. She also offered to assist Dr. Delgado in obtaining funding for his research. According to Dr. Harrison, Dr. Delgado is on the board of AAPLOG.

C. Plaintiffs' Challenge to Section 218

To support their challenge to Section 218, Plaintiffs called Dr. Courtney Schreiber, Dr. Audrey Lance, and Dr. Steven Joffe to testify at the hearing. Dr. Schreiber is a board-certified OB-GYN working at the University of Pennsylvania Health System and a Professor of Obstetrics and Gynecology at the University of Pennsylvania Perelman School of Medicine. Among her other credentials, Dr. Schreiber holds a master's degree in public health, has published over 40 peer-reviewed research articles on reproductive health issues, has been the principal investigator on approximately 45 research studies, and serves on the editorial board of the journal *Contraception.*

Dr. Audrey Lance, one of the named plaintiffs, is a board-certified OB-GYN, who is licensed in Tennessee and has provided abortions for over 10 years. In addition to her medical degree, Dr. Lance holds a master's degree in health and human research, and completed a fellowship in family planning. Dr. Joffe is a Professor of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, and has spent two decades researching medical ethics issues, including extensive research on informed consent. Dr. Joffe practiced pediatric hematology/oncology prior to his current position, and served on an Institutional Review Board for over 10 years.

These witnesses testified that requiring abortion providers to convey the mandated message about Dr. Delgado's "reversal" theory violates their ethical duties because the message is medically inaccurate, unsupported by scientific evidence, and potentially dangerous to the patient's health. "Reversal" theory, according to these witnesses, is not accepted by the mainstream medical community, and is not supported by "biologic logic" as Dr. Delgado contends. Dr. Lance testified that reversal theory does not make biological sense because mifepristone binds more strongly to the progesterone receptor than progesterone, and there is no evidence that the progesterone molecules will cause mifepristone to detach, or that it will "outcompete" mifepristone. Dr. Schreiber testified that mifepristone not only binds more tightly to the receptor than progesterone, it actually changes the shape of the receptor itself so the receptor is less hospitable to progesterone. Dr. Schreiber explained that introducing more progesterone molecules will not change that, just as adding more water to a pool does not make a submerged swimmer more wet. Mifepristone also activates cellular changes that cannot be stopped, once started, by adding more progesterone; much like a line of falling dominoes cannot be stopped, once started, by simply returning the first domino to a standing position.

In addition to questionable biology, Plaintiffs' experts testified that Dr. Delgado's papers do not establish the efficacy or safety of progesterone therapy, nor does any known valid clinical data exist to support progesterone therapy. First, the nature of the papers themselves detract from their value. All the witnesses agreed the best way to test the safety and efficacy of a new treatment is with a randomized, controlled clinical trial. This type of study, as Dr. Schreiber explained, allows the researcher to isolate the effects of the new treatment on a group of patients by comparing them to an essentially identical control group of patients who are given a placebo. And the larger the sample size, the more reliable the results. The purpose of a case series, like Dr. Delgado's, on the other hand, is to share observations about the experience of certain patients as the starting point for more rigorous research. The witnesses agreed that a case series study is at the bottom of the hierarchy of medical evidence, and should not be used to draw causal conclusions.

As for specific problems with Dr. Delgado's papers, Plaintiffs' witnesses testified that the 2012 Delgado case series was not published in a journal geared to practicing physicians, involved only six patients, and did not use a control group or a uniform dosage or method of progesterone administration. As for the 2018 case series, it too was not published in a journal widely read by clinical professionals, and describes the experience of patients from multiple countries at various gestational ages, who were not given a uniform dosage of progesterone in a uniform fashion at uniform intervals. In addition, Dr. Schreiber testified that excluding patients whose ultrasound revealed fetal demise after mifepristone alone further undermines the paper's validity.[11] She explained that such "pre-selection" artificially elevates the purported success rates.

[11] In a valid study, according to Dr. Schreiber, the intervention being tested is administered before the determining the effects of the intervention on the outcome. The 2018 case series, by contrast, included patients who were already observed to have the outcome (continuing pregnancy) and were then

Another problem with the case series, according to Dr. Schreiber, is that the historical control group used by Dr. Delgado did not have the same characteristics as the patients included in the case series, so no valid comparison can be made between them. Dr. Lance pointed out that the historical control group used by Dr. Delgado involved only 30 patients whose pregnancies were seven weeks or less. Dr. Delgado's case series involved patients whose pregnancies were up to nine weeks, and mifepristone is less effective as gestational age increases. Consequently, Dr. Delgado's patients may have had a higher rate of continuing pregnancy, not because of progesterone therapy, but because they were further along in their pregnancies.

Dr. Schreiber testified that there are no studies on women taking mifepristone alone at the full range of gestational ages that would allow for comparison. The studies that do exist, conducted in the 1980s and early 1990s, reflect that the range of continuing pregnancy after mifepristone alone is between eight and 46% (and when the confidence intervals are considered, the range is between three and 61%.) (Plaintiffs' Hearing Exhibit 14). Based on this data, Dr. Schreiber opined that Dr. Delgado's 2018 case series does not show that progesterone therapy after mifepristone is more effective than simply doing nothing at all after taking mifepristone.

Finally, Dr. Schreiber pointed out that Dr. Delgado's 2018 case series does not address whether the participants experienced any adverse outcomes. And there is no data on the long-term effects of taking mifepristone and supplemental progesterone on the woman taking the drugs or on the baby. The lack of data is a problem, Dr. Schreiber testified, because "hormones are not benign." The need for testing to confirm medical treatments, Dr. Schreiber explained, is evidenced by the results of a recent clinical trial calling into question the longstanding hypothesis that progesterone

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administered the intervention (progesterone), which prevents one from drawing any conclusion about the relationship between the outcome and the intervention.

would decrease the risk of miscarriage. The clinical trial, described in a paper published in the *New England Journal of Medicine,* involved 4000 women and found that the use of progesterone does not increase the chances that a woman at risk of miscarriage will continue her pregnancy.

In addition to the potential physical harm to patients, Plaintiffs' witnesses were also concerned about the effect the mandated message may have on a patient's "life-changing" decision to have an abortion. Plaintiffs' witnesses believe that conveying the mandated message to a patient before she starts the two-step medication abortion may lead her to begin the abortion process when she is uncertain of her decision, mistakenly believing she can "reverse" the decision later. Dr. Schreiber testified that the "intended effect" of an abortion is a complete abortion, and abortions cannot be "reversed." Dr. Lance testified that patients could experience fetal demise within hours of taking mifepristone – like the patients who were excluded from Dr. Delgado's study – so it is misleading to suggest that result can be undone when it often cannot.

Dr. Schreiber disagrees with Defendants' suggestion that the ambiguity of the message tempers its import. She testified that when a physician uses the word "may" in explaining a treatment in the clinical setting, it conveys to the patient that the treatment is supported by medical evidence – not based on an unsupported theory. Dr. Joffe, an expert on informed consent, agreed. Dr. Joffe further testified that attempts by physicians to "cure" the harm caused by the mandated message by stating their disagreement with it will lead to more confusion, and undermine the relationship between physician and patient. In addition, Dr. Lance expressed concern about having to refer her patients to a website that may[12] reference the "reversal" network where she believes providers, whose identities are unknown to her, are practicing experimental medicine.

[12] At the time Dr. Lance testified, the Department of Health had not published its website reference to the "Abortion Pill Reversal Hotline."

Finally, as to the first sentence of the message on the sign and discharge papers, all the witnesses agreed that it has been established for decades that mifepristone alone is not always effective in ending a pregnancy. That research is not "recent" or "developing." Dr. Lance also testified that a sign at a healthcare facility that tells patients to consult with a healthcare professional immediately suggests the providers at the facility are not "healthcare professionals."

IV. Analysis

A. The Preliminary Injunction Factors

In determining whether to issue a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, the Court is to consider: (1) the plaintiff's likelihood of success on the merits; (2) whether the plaintiff may suffer irreparable harm absent the injunction; (3) whether granting the injunction will cause substantial harm to others; and (4) the impact of the injunction on the public interest. *See, e.g., Doe v. Univ. of Cincinnati*, 872 F.3d 393, 399 (6th Cir. 2017).

B. Standing

Defendants argue Plaintiffs lack standing to assert their patients' due process and equal protection rights for purposes of Counts II and IV. Plaintiffs contend they have standing to sue on their own behalf, and on behalf of their patients, on all of their claims.

The Supreme Court has long established that abortion providers have standing to assert their patients' rights. *See, e.g., Singleton v. Wulff,* 428 U.S. 106, 117, 96 S. Ct. 2868, 49 L. Ed. 2d 826 (1976); *see also EMW Women's Surgical Ctr., P.S.C. v. Friedlander*, 960 F.3d 785, 794 n. 2 (6th Cir. 2020); *Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1395-96 (6th Cir. 1987). In *Singleton,* the Court recognized that abortion providers are "uniquely qualified to litigate the constitutionality of the State's interference with, or discrimination against," the patient's decision to have an abortion. 428 U.S. at 117.

In a more recent case, the Supreme Court reaffirmed this principle. In *June Med. Servs. L.L.C. v. Russo,* ___ U.S. ___, 140 S. Ct. 2103, 2118, 207 L. Ed. 2d 566 (2020), five of nine justices agreed that abortion providers have standing to assert the constitutional rights of their patients. ("We have long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations."); 140 S. Ct. at 2139 n.4 (Roberts, C.J., concurring in judgment) ("For the reasons the plurality explains, *ante,* at 11-16, I agree that the abortion providers in this case have standing to assert the constitutional rights of their patients.") In addition, the Court pointed out that plaintiffs have also been permitted to assert third-party rights in cases where enforcement of the challenged restriction "against the litigant" would also result in indirect violation of the third party's rights. *Id.,* at 2118-19.

Defendants argue this authority does not apply here because the challenged law does not interfere with a patient's right to obtain an abortion; rather, it provides them with additional information about the abortion procedure. Defendants suggest that a patient's interest in receiving the mandated message may potentially diverge from the physician's interest in challenging the requirement.

But this argument has been considered and rejected by the Supreme Court and the Sixth Circuit. *June Med. Servs. L. L. C. v. Russo*, 140 S. Ct. at 2119 ("Our dissenting colleagues suggest that this case is different because the plaintiffs have challenged a law ostensibly enacted to protect the women whose rights they are asserting . . . But that is a common feature of cases in which we have found third-party standing."); *EMW Women's Surgical Ctr., P.S.C. v. Friedlander*, 960 F.3d 785, 794 n.2 (6th Cir. 2020) (" Even if Plaintiffs were not directly regulated by H.B. 454 and only asserted their patients' rights, the Supreme Court has long since determined that abortion providers have standing to do so . . . And it has found that providers have standing even when their interests

are arguably in potential conflict with patients'—as when regulations assertedly protect the health and safety of patients. *See, e.g.*, *City of Akron*, 462 U.S. at 440 n.30, 103 S. Ct. 2481; *Danforth*, 428 U.S. at 62, 96 S. Ct. 2831; *Doe v. Bolton*, 410 U.S. at 188, 93 S. Ct. 739.") Based on this line of cases, the Court concludes Defendants' standing argument is without merit.

C. Plaintiffs' First Amendment Claim

Plaintiffs argue Section 218 violates their First Amendment rights by compelling them to engage in speech that is untruthful and misleading.[13] In *National Institute of Family and Life Advocates v. Becerra,* ___ U.S. ___, 138 S. Ct. 2361, 2371, 201 L. Ed. 2d 835 (2018), the Supreme Court explained that legislation compelling an individual to speak a particular message is content-based and generally subject to strict scrutiny under the First Amendment. But less protection has been afforded to compelled speech, according to *Becerra,* where the legislation regulates professional conduct that incidentally involves speech. 138 S. Ct. at 2372. Citing *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 884, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992), the *Becerra* Court reasoned that informed consent laws are an example of such legislation. In *Casey,* the challenged statute required physicians, before performing an abortion, to convey to the patient: "the nature of the procedure, the health risks of the abortion and childbirth, and the 'probable gestational age of the unborn child.'" 138 S. Ct. at 2373. The law also required physicians to inform patients of the availability of printed materials provided by the State relating to adoption and various forms of assistance. *Id.* The *Becerra* Court ultimately determined that the legislation at issue in that case, which required crisis pregnancy centers to disclose to patients that

[13] Plaintiffs also argue Section 218 violates their patients' substantive due process rights under the Fourteenth Amendment by forcing them to receive information that is untruthful, misleading, and/or irrelevant. Plaintiffs have not separately addressed this claim in their briefs, and therefore, the Court does not separately address it herein.

the State offered abortion services, was *not* an informed consent law, and therefore, greater scrutiny was required under the First Amendment. 138 S. Ct. 2368-75.

Relying on *Becerra* and *Casey,* the Sixth Circuit recently addressed a First Amendment challenge to a law requiring a physician, before performing an abortion, to make audible the fetal heartbeat, perform an ultrasound, and display and describe the ultrasound images to the patient. *EMW Women's Surgical Center, P.S.C. v. Beshear,* 920 F.3d 421, 424 (6th Cir. 2019). Concluding that the law involved informed consent, the court held it was not required to "highly scrutinize" the statute, as long as it met three requirements: "(1) it must relate to a medical procedure; (2) it must be truthful and not misleading; and (3) it must be relevant to the patient's decision whether to undertake the procedure, which may include, in the abortion context, information relevant to the woman's health risks, as well as the impact on the unborn life." 920 F.3d at 428-29.[14]

A North Dakota District Court recently sustained a First Amendment challenge to a statute similar to Section 218, and preliminarily enjoined enforcement of the statute. In *American Medical Association v. Stenehjem,* 412 F. Supp. 3d 1134 (D.N.D. 2019), the court concluded the statute was likely unconstitutional "because it requires physicians to disclose information which is either untruthful, misleading, and/or irrelevant to the patient's decision to have an abortion." *Id.,* at 1149. The court found that the law "interferes with the doctor-patient relationship; forces the attending physician to convey to his/her patient a state-mandated message that is devoid of credible scientific evidence; misinforms and misleads the patient; undermines informed consent and the standard of

[14] Plaintiffs initially argue Section 218 is not an informed consent law because it relates to a procedure they do not provide, and goes beyond the information discussed before an abortion procedure. The Court is persuaded, however, that the message conveyed by Section 218, if true, could be relevant to the abortion procedure.

care; and is arguably unethical." *Id.,* at 1151. The court went on to consider and reject the defendants' argument that the equivocal nature of the statutory language cured any defects:

> H.B. 1336 forces physicians to give their patients unsound and unproven medical advice—that if the woman acts quickly it 'may be possible' to reverse a medication abortion. The evidence in the record does not support that theory. The wording of the statute—that it '*may be possible'* to reverse the effects of an abortion-inducing drug—also fails to cure the misleading nature of the message. Legislation which forces physicians to tell their patients, as part of informed consent, that 'it may be possible' to reverse or cure an ailment, disease, illness, surgical procedure, or the effects of any medication—in the absence of any medical or scientific evidence to support such a message—is unsound, misplaced, and would not survive a constitutional challenge under any level of scrutiny. State legislatures should not be mandating unproven medical treatments, or requiring physicians to provide patients with misleading and inaccurate information. The provisions of H.B. 1336 violate a physician's right not to speak and go far beyond any informed consent laws addressed by the United States Supreme Court, the Eighth Circuit Court of Appeals, or other courts to date.

Id.

In addition to the requirements of Section 218, healthcare providers in Tennessee are required to comply with other statutes regulating informed consent before performing abortions. Before providing medical treatment generally, physicians are required to obtain voluntary and informed consent, consistent with recognized practice standards in the relevant medical specialty, in order to avoid civil liability. Tenn. Code Ann. § 29-26-118. In order to avoid criminal liability in the abortion context, another statute requires that physicians obtain "written consent" from the patient at least 48 hours before a procedure, after informing the patient of the following:

> (1) That according to the best judgment of her attending physician or referring physician she is pregnant;
>
> (2)(A) The probable gestational age of the unborn child at the time the abortion is to be performed, based upon the information provided by her as to the time of her last menstrual period or after a history, physical examination, and appropriate laboratory tests;
>
> (B) If an ultrasound is performed as part of the examination prior to performing the

> abortion, the person who performs the ultrasound shall offer the woman the opportunity to learn the results of the ultrasound. If the woman elects to learn the results of the ultrasound, the person who performs the ultrasound or a qualified healthcare provider in the facility performing the ultrasound shall, in addition to any other information provided, inform the woman of the presence or absence of a fetal heartbeat and document the patient has been informed;
>
> (3) That if twenty-four (24) or more weeks have elapsed from the first day of her last menstrual period or twenty-two (22) or more weeks have elapsed from the time of conception, her unborn child may be viable, that is, capable of sustained survival outside of the womb, with or without medical assistance, and that if a viable child is prematurely born alive in the course of an abortion, the physician performing the abortion has a legal obligation to take steps to preserve the life and health of the child;
>
> (4) That numerous public and private agencies and services are available to assist her during her pregnancy and after the birth of her child, if she chooses not to have the abortion, whether she wishes to keep her child or place the child for adoption, and that her attending physician or referring physician will provide her with a list of the agencies and the services available if she so requests; and
>
> (5) The normal and reasonably foreseeable medical benefits, risks, or both of undergoing an abortion or continuing the pregnancy to term.

Tenn. Code Ann. § 39-15-202(b), (d). The physician must also inform the patient of "the particular risks associated with her pregnancy and continuing the pregnancy to term, based upon the information known to the physician, as well as the risks of undergoing an abortion, along with a general description of the method of abortion to be used and the medical instructions to be followed subsequent to the abortion." Tenn. Code Ann. § 39-15-202(c).

In a recent opinion, Judge Bernard A. Friedman enjoined enforcement of Section 39-15-202's 48-hour waiting period but declined to enjoin enforcement of the requirement that the listed information be provided by a physician before performing an abortion. *Adams & Boyle, P.C. v. Slatery*, __ F. Supp. 3d ___, 2020 WL 6063778, at *1 (M.D. Tenn. Oct. 14, 2020).

With this background, the Court considers the specific additional messages mandated by Section 218. As noted above, the language of the sign and discharge instructions states:

> Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.

Tenn. Code Ann. § 39-15-218(b).

The witnesses essentially agree the first sentence of the mandated message is inaccurate as stated because research indicating "mifepristone alone is not always effective in ending a pregnancy" is neither "recent" nor "developing." Indeed, the research is approximately 30 years old. Although Defendants suggest the words "recent" and "developing" somehow modify the entire paragraph, the average patient would not reach the same conclusion, and Defendants' own witness, Dr. Boles, disagreed with this suggestion.

The next sentence is more problematic, however, primarily because the word "reverse" does not accurately describe to patients the medical research on progesterone therapy. The plain and ordinary meaning of the word "reverse" is "to turn completely about in position or direction" or "to undo or negate the effect of (something, such as a condition or surgical operation)." https://www.Merriam-Webster.com/dictionary/reverse (last visited Dec. 30, 2020). Thus, to the average patient reading this sentence, the message conveyed is that, if the patient has taken the first pill and not the second, there is a treatment that may undo or negate her abortion. But neither Dr. Delgado's research nor his biological explanation supports the idea that an abortion can be undone or negated. Indeed, Dr. Delgado admitted that the progesterone therapy rates of success and failure described in his 2018 case series did not include those patients whose pregnancies had already terminated after taking mifepristone alone. Progesterone therapy was not even attempted on those patients, Dr. Delgado said, because doing so would have been futile. The pool of women reading the mandated message, however, will undoubtedly include patients whose pregnancies

will terminate after taking the first pill, and it is undisputed that progesterone therapy will not "reverse" the abortions of those patients.[15] The word "reversal" makes the mandated message untruthful and/or misleading because it promises more than progesterone therapy has even attempted to deliver.

Additionally, the term "reverse" does not accurately describe the theory underlying Dr. Delgado's progesterone therapy. In explaining the theory's "biologic logic," Dr. Delgado does not suggest supplemental progesterone completely neutralizes – or "reverses" – the effects of mifepristone; he describes a type of competition between the supplemental progesterone molecules and the mifepristone molecules in binding to the receptor.[16] But the word "reverse" suggests more – that supplemental progesterone acts as a kind of anecdote to mifepristone. *See Stenehjem,* 412 F. Supp. 3d at 1149 (noting defendants' own expert admits the term "abortion reversal" "is somewhat *misleading* in that an abortion is not reversed but rather, abortion is prevented from occurring . . .") Simply put, Defendants' argument is hoist on Dr. Degado's petard.

Finally, the mandated "reversal" message is misleading because it suggests progesterone therapy has reached a level of safety and efficacy that is not supported by medical evidence. Dr. Delgado's research has numerous flaws, as outlined above, and requiring a physician to discuss his theory as part of an informed consent discussion with a patient elevates the theory to a level of scientific certainty it has not achieved to date. *See Stenehjem,* 412 F. Supp. 3d at 1150-51

[15] The message also fails to convey the time limit Dr. Delgado has placed on the effectiveness of his progesterone therapy. Patients who had taken mifepristone more than 72 hours earlier were also excluded from the 2018 case series, *i.e.*, progesterone therapy was not attempted on these patients.

[16] As noted above, Dr. Schreiber disagrees with the "competition" description, pointing out that mifepristone binds more tightly to the receptor and actually changes the shape of the receptor to make it less hospitable to progesterone. It also begins a process of cellular changes that cannot be stopped by adding more progesterone.

(describing reversal theory as "devoid of scientific support," "an unproven medical and scientific theory," and "a very controversial and medically-uncertain procedure.") Despite Defendants' argument to the contrary, use of the word "may" does not adequately address this concern. As Drs. Schreiber and Joffe explained, the word "may," when it is used by a healthcare professional to describe a particular treatment, suggests to patients that the treatment has a certain level of scientific research to support it.[17] And Defendants' other suggestion – that physicians simply convey information about "reversal" treatment, then explain why the treatment is unproven and possibly unsafe – is likely to be thoroughly confusing to patients. Neither suggestion ameliorates the misleading nature of the mandated "reversal" message.[18]

The last sentence of the message on the sign and discharge instructions – "Please consult with a healthcare professional immediately" – appears to be benign when used in the discharge instructions, but is, at best, confusing when appearing on a sign in a physician's office, suggesting those practicing medicine there are not actually "healthcare professionals." But, standing alone, the Court does not consider the sentence to be untruthful.

Section 218 mandates that a somewhat different message be conveyed by physicians, and it requires the message be conveyed at least 48 hours before performing a medication abortion. As noted above, the physician must state:

(1) It may be possible to reverse the intended effects of a chemical abortion utilizing

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[17] In the Court's view, Dr. Harrison's suggestion that the message simply conveys the treatment "might, may, perhaps" save the pregnancy, not that "there's a miracle going to happen," is not likely how the message will be received by patients.

[18] Furthermore, Defendants' argument that a patient has a "right to try" experimental treatments has nothing to do with the issue before the Court (as Dr. Joffe explained). Dr. Delgado and other physicians are free to offer progesterone therapy to patients who desire to receive it. They are also free to publicize and advertise the availability of the treatment. The issue here, however, is whether abortion providers must convey messages about the treatment under threat of criminal sanction.

mifepristone if the woman changes her mind, but that time is of the essence; and

(2) Information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website.

Tenn. Code Ann. § 39-15-218(e).

For the reasons stated above in connection with the message on the sign and discharge instructions, the terms "reverse" and "reversing" in this mandated message render it untruthful and/or misleading. Furthermore, the second part of the mandated message requires the physician to refer patients to information on a website that also uses the term, and identifies a "resource" that uses the term: "The Abortion Pill Reversal Hotline" and www.abortionpillreversal.com.[19] Consequently, the misleading use of the term "reverse" or "reversal" is reinforced by appearing in website information published by the State's own Department of Health. In addition, there is no information about the identity and/or qualifications of those providers who will be administering "reversal" treatment.[20] Requiring a physician to refer patients to such an information source is likely to further mislead, and confuse patients.

Finally, the timing of this message – requiring that it be conveyed *before* the patient makes the decision to begin the procedure – contributes to its misleading nature.[21] As part of the informed consent process, the patient will presumably be told that medication abortions are a *two-step* procedure. Indeed, patients are apparently required to sign paperwork stating they have decided to

[19] Although the Department disclaims "endorsement" of the "Abortion Pill Reversal" network, reference to the network is the only "information" and "assistance" resource, *see* Tenn. Code Ann. § 39-15-218(h)(i), listed on the website.

[20] Not even Dr. Boles, who serves on the Medical Advisory Board of the network, can identify the other providers in Tennessee. (Plaintiffs' Hearing Exhibit 93, at 336).

[21] The parties have not addressed whether the 48-hour requirement is subject to challenge in light of Judge Friedman's decision in *Adams v. Boyle, P.C. v. Slatery, supra.* Therefore, the Court finds it unnecessary to address the issue here.

take *both* drugs and will follow their provider's advice about when to do so. (*See* "Patient Agreement Form" (Defendants' Hearing Exhibit 51)). According to undisputed testimony, patients are also told they should be sure of their decision before they begin the process. In the midst of this information, however, Section 218 requires they be told that "it may be possible to reverse" the abortion if they do not follow the two-pill regimen they have agreed to follow. As Dr. Lance and Dr. Schreiber testified, this "reversal" message is likely to mislead patients into believing they can begin the two-step process, and still save their pregnancies if they change their mind later. But it is undisputed that a portion of patients who change their mind will *not* be able to save their pregnancies. In the Court's view, misleading an undecided patient into beginning a procedure that may have unalterable consequences by suggesting she can "reverse" it later is not a result desired by either side.

For these reasons, the Court concludes Plaintiffs have shown a likelihood of success on the merits in establishing that the messages mandated by Section 218 violate the First Amendment because they are untruthful and/or misleading.

D. Equal Protection

In Counts III and IV, Plaintiffs allege Section 218 violates their equal protection rights, and their patients' equal protection rights, under the Fourteenth Amendment. Plaintiffs contend Section 218 imposes a requirement – state-compelled provision of inaccurate information – that is not imposed on providers and patients in any other medical contexts. According to Plaintiffs, Tennessee does not require physicians providing sterilization procedures to inform their patients the procedure "may be reversible" as part of obtaining informed consent for the procedure. Defendants argue that providing patients with information about all their options is a legitimate interest furthered by the legislation, and does not present an undue burden on a woman seeking an

abortion. In light of the Court's determination that Section 218 likely violates the First Amendment, the Court finds it unnecessary to address the equal protection claim at this time.

E. Other Rule 65 Factors

Plaintiffs have demonstrated they and their patients will suffer immediate and irreparable injury, harm, loss, or damage if injunctive relief is not granted pending trial. Section 218 imposes criminal penalties and other sanctions on abortion providers who fail to comply with its provisions. *Overstreet v. Lexington-Fayette Urban Cty. Gov't*, 305 F.3d 566, 578 (6th Cir. 2002) ("A plaintiff's harm from the denial of a preliminary injunction is irreparable if it is not fully compensable by monetary damages.") In addition, the deprivation of First Amendment rights constitutes irreparable injury. *Libertarian Party of Ohio v. Husted*, 751 F.3d 403, 412 (6th Cir. 2014) (recognizing that even minimal infringement upon First Amendment values constitutes irreparable injury sufficient to justify injunctive relief.); *see also Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1400 (6th Cir. 1987) (finding irreparable harm based on a violation of constitutional rights.)

The balance of relative harms among the parties weighs in favor of Plaintiffs and against Defendants. Enjoining enforcement of Section 218 will preserve the status quo pending trial, and the public interest will not be harmed by preserving the status quo. *See Husted,* 751 F.3d at 412 ("[I]t is always in the public interest to prevent the violation of a party's constitutional rights.") In addition, the public interest is served when the legislature acts within its constitutional limits, as set forth in the Bill of Rights. *See Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, ___ U.S. ___, 138 S. Ct. 2448, 2486 n.28, 201 L. Ed. 2d 924 (2018) ("In holding that these laws violate the Constitution, we are simply enforcing the First Amendment as properly understood, '[t]he very purpose of [which] was to withdraw certain subjects from the vicissitudes

of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts.' W*est Virginia Bd of Ed. v. Barnette,* 319 U.S. 624, 638, 63 S. Ct. 1178, 87 L. Ed. 1628 (1943)").

It is, therefore, ORDERED that, pursuant to Federal Rule of Civil Procedure 65: Defendants, their officers, agents, employees, servants, attorneys, and all persons in active concert or participation with them, are hereby enjoined and restrained from enforcing Section 39-15-218, pending further order of the Court.

Given that Defendants are unlikely to incur damages or costs from this injunctive relief, Plaintiffs are excused from posting security as a condition of obtaining injunctive relief.

It is so **ORDERED**.

WILLIAM L. CAMPBELL, JR.
UNITED STATES DISTRICT JUDGE