UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALL-OPTIONS, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:21-cv-01231-JPH-MJD
	)	
ATTORNEY GENERAL OF INDIANA in his official capacity, et al.,	)	
	)	
	)	
Defendants.	)	

ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs ask the Court to enter a preliminary injunction prohibiting the State of Indiana from enforcing a new law that would require qualified abortion clinic personnel to recite specific language to women seeking a medication abortion. Medication abortions involve a two-drug regimen, with the first prescription (mifepristone) taken 24 to 48 hours before the second (misoprostol).

The disclosure required by the new law (the "Required Disclosure") states:

> Some evidence suggests that the effects of Mifepristone may be avoided, ceased, or reversed if the second pill, Misoprostol, has not been taken. Immediately contact the following for more information at (insert applicable abortion inducing drug reversal Internet web site and corresponding hotline number).

The parties agree that this Required Disclosure refers to "abortion pill reversal," which is the theory that large doses of progesterone—a pregnancy-sustaining hormone—can counteract mifepristone's effects.

Plaintiffs have shown a reasonable likelihood of success on their claim that it violates the First Amendment for the State to compel abortion providers to recite the Required Disclosure. While the State may require abortion providers to give a woman seeking an abortion certain types of information as part of the informed-consent process, that information must, at a minimum, be truthful and not misleading. Plaintiffs have shown a reasonable likelihood of being able to show that the Required Disclosure is not.

In reaching this conclusion, the Court does not discredit the State's witnesses or the concept of abortion pill reversal, nor does it prevent the State from sharing information about abortion pill reversal with women who are considering medication abortions. Rather, the Court finds that because the evidence in the record does not fit with the language of the Required Disclosure, that evidence does not demonstrate that the Required Disclosure is truthful and not misleading. Therefore, Plaintiffs have shown a reasonable likelihood of success on their claim that it violates the First Amendment for the State to compel abortion providers to recite the Required Disclosure.

Plaintiffs' motion for a preliminary injunction is **GRANTED**.

I.
The Challenged Statute and Plaintiffs' Claims

Indiana law permits a woman to have a surgical or medication abortion under certain circumstances. *See* Ind. Code § 16-34-2-1. An abortion is lawful only if performed "with the voluntary and informed consent of the pregnant woman upon whom the abortion is to be performed." Ind. Code § 16-34-2-1.1.

For consent to be voluntary and informed, Indiana law requires certain conditions be met. *Id.*

Among the conditions required for informed consent, a qualified medical provider must, at least eighteen hours before the abortion, disclose certain information to the pregnant woman who is seeking the abortion, including:

- information about the physician performing the abortion;
- availability of follow-up care;
- "information concerning the abortion inducing drug";
- "[o]bjective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug";
- information about and a picture of a fetus; and
- medical risks associated with carrying a pregnancy to term.

Id.

At least eighteen hours before the abortion, the pregnant woman must also receive information orally and in writing about:

- availability of medical assistance benefits for neonatal care and childbirth;
- child-support obligations;
- availability of adoption alternatives;
- physical risks of abortion;
- emergency contact information for the facility where the abortion is performed; and
- availability of counseling.

Id.

The State of Indiana enacted Public Law No. 218-2021 on April 29, 2021, and it is scheduled to take effect on July 1, 2021. *See* dkt. 57 at 10; dkt. 53 at 7. The new law adds to the disclosures already mandated as part of the informed-consent process by requiring providers to tell a pregnant woman seeking an abortion:

> Some evidence suggests that the effects of Mifepristone may be avoided, ceased, or reversed if the second pill, Misoprostol, has not been taken. Immediately contact the following for more information at (insert applicable abortion inducing drug reversal Internet web site and corresponding hotline number).[1]

Pub. L. No. 218-2021, §§ 4(a)(1), 5(a)(1)(C), 2021 Ind. Acts ___ (to be codified at Ind. Code §§ 16-34-2-1(a)(1), 16-34-2-1.1(a)(1)(C)). The Required Disclosure must be given "orally and in writing" "[a]t least eighteen (18) hours before the abortion." § 5(a)(1), 2021 Ind. Acts ___. "A physician shall also provide" the Required Disclosure "orally and in writing" at the time of a patient's discharge from care. § 4(a)(1), 2021 Ind. Acts ___.

If the provider does not give the Required Disclosure, consent to the abortion is abrogated, thus making the abortion unlawful. § 5(a), 2021 Ind. Acts ___. Providers who violate the law by not giving the Required Disclosure, as well as clinics and hospitals that permit, aid, or abet violations, are subject to criminal penalties and disciplinary sanctions. Ind. Code §§ 16-34-2-7, 35-50-2-6(b), 34-28-5-4(a), 25-1-9-4(a)(3), 16-21-3-2(2).

[1] The website will be www.abortionpillreversal.com and the hotline telephone number will be (877) 588-0333. *See* dkt. 57-9 at 5 (Foster Decl. ¶ 12).

Plaintiffs, a group of medical clinics and physicians that provide abortions, contend that the Required Disclosure violates the First Amendment because the State is compelling them to recite a false and misleading message about using progesterone treatment to avoid a medication abortion after the woman has taken mifepristone as the first part of the regimen. They have moved for a preliminary injunction to prevent the State from enforcing the Required Disclosure before the statute's July 1, 2021 effective date. Dkt. 1; dkt. 5.

II.
Preliminary Injunction Standard

A party may move under Federal Rule of Civil Procedure 65 for the issuance of a preliminary injunction. Determining whether a preliminary injunction is appropriate involves a two-step inquiry, with a threshold phase and a balancing phase. *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1044 (7th Cir. 2017). At the threshold phase, the moving party must show that: (1) without the requested relief, it will suffer irreparable harm during the pendency of its action; (2) traditional legal remedies would be inadequate; and (3) it has "a reasonable likelihood of success on the merits." *Id.* If the movant satisfies these requirements, the Court proceeds to the balancing phase "to determine whether the balance of harm favors the moving party or whether the harm to other parties or the public sufficiently outweighs the movant's interests." *Id.* This balancing process involves a 'sliding scale' approach: the more likely the plaintiff is to win

on the merits, the less the balance of harms needs to weigh in [its] favor, and vice versa." *Mays v. Dart*, 974 F.3d 810, 818 (7th Cir. 2020). To do this, "the district court equitably weighs these factors together, seeking at all times to minimize the costs of being mistaken." *Cassell v. Snyders*, 990 F.3d 539, 545 (7th Cir. 2021) (citation omitted).

III.
Summary of Evidence

A. Background on medication abortions

The U.S. Food and Drug Administration ("FDA") has approved a two-step regimen for medication abortions up to ten weeks after a woman's last menstrual period. Dkt. 53-6 at 3–4 (Schreiber[2] Decl. ¶¶ 13–14); U.S. Food & Drug Admin., Mifeprex Label 1–3 (revised Mar. 2016) (dkt. 53-6 at 51–53) (hereinafter *Mifeprex Label*). The regimen requires a patient to first take 200 milligrams of mifepristone (brand name Mifeprex). *Id.* Twenty-four to forty-eight hours later, the patient then takes 800 micrograms of misoprostol. *Id.*

Mifepristone blocks the body's receptors for progesterone, a hormone necessary to maintain a pregnancy. Dkt. 53-6 at 4–5 (Schreiber Decl. ¶ 15); *Mifeprex Label* at 10 (dkt. 53-6 at 60); dkt. 62 at 1 (Stipulation ¶ 5). This causes the tissue and lining of the uterus to detach from the uterine wall, dkt.

[2] Dr. Courtney Schreiber is a board-certified obstetrician-gynecologist, the Stuart and Emily Mudd Professor of Obstetrics and Gynecology at the University of Pennsylvania Perelman School of Medicine, Chair of the Complex Family Planning Division of the American Board of Obstetrics, and a Fellow of the American College of Obstetricians and Gynecologists. Dkt. 53-6 at 2–3 (Schreiber Decl.), 22–49 (CV). Dr. Schreiber has provided abortion care to over 5,000 patients and has published over forty peer-reviewed articles on reproductive health issues. *Id.*

53-6 at 4–5 (Schreiber Decl. ¶ 15); dkt. 57-2 at 7 (Delgado[3] Decl. ¶ 17), which renders the embryo nonviable in most cases, *see* dkt. 53-6 at 5 (Schreiber Decl. ¶ 17); dkt. 57-2 at 9 (Delgado Decl. ¶ 24). Mifepristone also softens and opens the cervix and helps trigger and strengthen uterine contractions. Dkt. 53-6 at 4–5 (Schreiber Decl. ¶ 15).

The second drug—misoprostol—causes uterine contractions that expel the contents of the uterus. *Id.* at 6 (¶ 18); dkt. 57-1 at 4–5 (Francis Decl. ¶ 6). Only 2.6 percent of patients will remain pregnant after the two-drug regimen. Dkt. 53-6 at 6 (Schreiber Decl. ¶ 18); *Mifeprex Label* at 13 (dkt. 53-6 at 63).

"Because of the risks of serious complications . . . [mifepristone] is available only through a restricted program under a Risk Evaluation and Mitigation Strategy." *Mifeprex Label* at 2 (dkt. 53-6 at 52). Under this program, "[p]atients must sign a Patient Agreement Form" and "[p]rescribers must be certified with the program by completing the Prescriber Agreement Form." *Id.* at 6 (dkt. 53-6 at 56); *see also* Ind. Code § 16-34-2-1(a)(1). The Patient Agreement Form requires a patient to certify that she "ha[s] decided to take Mifeprex and misoprostol to end [her] pregnancy and will follow [her] provider's advice about when to take each drug." U.S. Food & Drug Admin.,

[3] Dr. George Delgado is a California-licensed physician who is board-certified in family medicine and hospice and palliative medicine. *See* dkt. 57-2 at 2–3 (Delgado Decl. ¶¶ 2–3), 38–41 (CV). He is the founder of the Abortion Pill Rescue Network, the medical director of George Delgado, M.D., Inc., and the chief medical officer of The Elizabeth Hospice. *See id.* at 2–3, 4 (Delgado Decl. ¶¶ 3, 7–9), 38–41 (CV).

Mifeprex (Mifepristone) Patient Agreement Form, (revised Mar. 2016).[4] She also agrees that she "will take Mifeprex on Day 1" and take prescribed misoprostol tablets 24 to 48 hours after taking Mifeprex. *Id.* A patient can, of course, still choose to decline to follow the regimen after signing this form. The healthcare provider must also sign this form and place a copy in its medical records. *Patient Agreement Form*; *see* U.S. Food & Drug Admin., Mifeprex (Mifepristone) Prescriber Agreement Form, (revised Mar. 2016).[5]

Plaintiff abortion providers urge every woman seeking a medication abortion to be "firm" in her decision before beginning a medication abortion. *See* dkt. 53-6 at 19–20 (Schreiber Decl. ¶¶ 59–60); dkt. 53-1 at 5 (Case Decl. ¶ 20); dkt. 53-4 at 4 (Haskell Decl. ¶ 18); dkt. 53-5 at 3 (Miller Decl. ¶ 10); dkt. 53-3 at 5 (Hagstrom Miller Decl. ¶ 18); dkt. 63-1 at 5–6 (Cadwallader Decl. ¶ 14).

B. Abortion pill reversal theory

Dr. George Delgado has proposed administering repeated doses of the hormone progesterone to patients who have taken only mifepristone (and not misoprostol) to "reverse" mifepristone's effects. *See* dkt. 57-2 at 3 (Delgado Decl. ¶ 6) (labeling this proposal as "APR" for "abortion pill reversal"). Dr. Delgado has explained that "progesterone and mifepristone are in direct

[4] http://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Patient_Agreement_Form.pdf [https://perma.cc/G9NS-NWCA] [hereinafter *Patient Agreement Form*].

[5] https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf [https://perma.cc/Y3T2-CU5K].

competition at the receptor level," so adding more progesterone will help it "out-compete the mifepristone" to "win the race to the receptor." *Id.* at 8, 23 (¶¶ 21–22, 63); *see* dkt. 57-5 at 6–7 (Harrison Decl. ¶ 14); dkt. 57-1 at 5 (Francis Decl. ¶ 7); dkt. 57-4 at 7–8 (Boles Decl. ¶ 12); dkt. 57-7 at 4 (Stroud Decl. ¶ 7).

At the evidentiary hearing, Dr. Delgado compared a progesterone receptor to a locked door that progesterone must open for pregnancy to continue. He testified that mifepristone fills the lock to this door, acting as a "false key" that keeps the door shut. Although it's uncontested that mifepristone binds preferentially to the receptor, Dr. Delgado explained that the false keys do not stay in the lock. Instead, they go in and out. So, he testified, it makes biologic sense that adding more "true keys" of progesterone to the body will help unlock the door enough to allow for a successful pregnancy.

Dr. Delgado has published two articles supporting this proposal. *See* George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 Annals of Pharmacotherapy (Dec. 2012) (dkt. 53-6 at 71–74); George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33(1) Issues in L. & Med. 21 (2018) (dkt. 53-6 at 76–86). In 2012, Dr. Delgado published a four-page paper describing seven patients who took mifepristone and were later administered progesterone. Dkt. 53-6 at 71–74. Four of the seven patients carried pregnancies to term. *Id.* at 72. Dr. Delgado concluded that this data "suggests that medical abortion can be arrested by progesterone injection after mifepristone ingestion prior to misoprostol due to the competitive action of

progesterone versus mifepristone." *Id.* at 73. The study also noted that it "welcome[d] further clinical trials . . . in order to have an evidence basis for the best protocol." *Id.*

In 2018, Dr. Delgado published a second, larger case-series study on the subject. *See id.* at 76–86. In this study, he performed a retrospective analysis of clinical data of "547 patients . . . who underwent progesterone therapy" after taking mifepristone without misoprostol. *Id.* at 81. Of these 547 women, 257 had confirmed successful pregnancies. *Id.* After adding four women who "were pregnant with viable fetuses but were lost to follow-up after 20 weeks gestation," the study found an "overall rate of reversal" of 48 percent. *Id.* For a group of 125 patients who received progesterone intramuscularly, the rate of successful pregnancies was 64 percent. *Id.* at 81–82. Among another group of 31 patients who received 400 milligrams of progesterone orally twice daily for three days and once daily through the end of the first trimester, the rate of successful pregnancies was 68 percent. *Id.* After comparing this data to a historical "control" group with 25 percent of patients taking mifepristone continuing their pregnancies, Dr. Delgado concluded that "[t]he reversal of the effects of mifepristone using progesterone is safe and effective" and recommended protocols for physicians to treat women seeking mifepristone reversal. *Id.* at 77, 81, 84.

Defendants also submitted declarations and testimony of several physicians who attested to their clinical experience treating women who started medication abortions by taking mifepristone but later changed their minds

about ending their pregnancies. Dr. Delgado estimated that his California office had used the protocol for 50–75 women who went on to have successful pregnancies. He also estimated that internationally there were over 2,000 documented successes with his protocol. Dr. Casey Delcoco, a board-certified family medicine physician in Indianapolis, also testified about her use of the abortion pill reversal protocol. *See* dkt. 57-3 at 2–3 (Delcoco Decl. ¶¶ 2–3), 16–17 (CV). Over her six years as the only physician providing these services in the greater Indianapolis area, Dr. Delcoco received 15 calls asking about abortion pill reversal. *See id.* at 12–14 (Delcoco Decl. ¶¶ 20–21). Ten women were either lost to follow-up or completed their abortions. The other five receiving the full abortion pill reversal protocol all went on to have successful pregnancies. *Id.* One of those patients—"Mary Roe"—testified at the evidentiary hearing, explaining the difficult decision she faced, the care she received from Dr. Delcoco, and her successful pregnancy. *See* dkt. 57-8 at 4–5 (Roe Decl.).

Defendants also designated declarations from several other physicians who have followed Dr. Delgado's recommended protocol. *See* dkt. 57-4 at 3 (Boles Decl. ¶ 3) (20 calls and 7 patients treated, with 5 having successful pregnancies); dkt. 57-7 at 3–4 (Stroud Decl. ¶ 6) (10 patients treated and 2 successful pregnancies); dkt. 57-1 at 4 (Francis Decl. ¶ 5) (one patient treated who had a successful pregnancy). And Defendants called a medical ethicist,

Dr. Farr Curlin, to testify at the evidentiary hearing about informed consent. *See* dkt. 57-6 (Curlin[6] Decl.).

C. Plaintiffs' challenge to abortion pill reversal theory

Plaintiffs called Dr. Courtney Schreiber at the evidentiary hearing. She challenged the biologic explanation and research underlying abortion pill reversal. First, she explained that mifepristone binds tightly and preferentially to progesterone receptors and therefore "wins" out over progesterone regardless of how much progesterone is in the body. She testified that progesterone levels are already "sky high" during pregnancy, so adding more progesterone to the body would not help. As Dr. Schreiber explained it, adding more progesterone to a body already flooded with it is like rain on a swimmer in a pool—the swimmer is wet either way.

Second, Dr. Schreiber testified that Dr. Delgado's studies offer "zero scientific evidence" that adding progesterone increases the chance of carrying a pregnancy to term after a patient takes mifepristone. *See* dkt. 53-6 at 6–13 (Schreiber Decl.); dkt. 53-2 at 9–12 (Cunningham Decl.). She pointed to a systematic review published in the journal *Contraception*, which concluded that the "evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies

[6] Dr. Farr A. Curlin is the Josiah C. Trent Professor of Medical Humanities in the Duke University Trent Center for Bioethics, Humanities, and History of Medicine, a professor in Duke University's Department of Medicine, and the Co-Director of the Theology, Medicine and Culture Initiative at Duke Divinity School. *See* dkt. 57-6 at 2 (Curlin Decl. ¶¶ 2–3), 30–50 (CV). He is licensed to practice medicine in North Carolina as a general internist and is board-certified in Hospice and Palliative Medicine. *See id.*

compared to expectant management." *See* Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92(3) Contraception 206 (2015) (dkt. 53-6 at 88). She also discussed Dr. Grossman's article in the New England Journal of Medicine that briefly analyzed the 2018 Delgado study and found no indication that progesterone administration increases the likelihood of continued pregnancy. *See* Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating Without Evidence*, 379(16) N. Eng. J. Med. 1491 (2018) (dkt. 53-6 at 95–97).

Third, Dr. Schreiber testified that Dr. Delgado's research methods do not allow for broad protocol recommendations. Both of Dr. Delgado's papers are case-series studies, which "follow[] a group of patients who have a similar diagnosis or who are receiving the same treatment over a certain period of time." Dkt. 53-6 at 6–7 (Schreiber Decl. ¶ 22); dkt. 53-2 at 9 (Cunningham Decl. ¶ 24). Dr. Schreiber testified that because "[c]ase series are descriptive reports that are considered to be very low-quality evidence for drawing conclusions about a treatment's effects," The Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States 54 (2018) (Hearing Ex. 19), they are "not considered sufficient evidence to support the safety or efficacy of a new treatment," dkt. 53-6 at 6–7 (Schreiber Decl. ¶ 22); dkt. 53-2 at 9 (Cunningham Decl. ¶ 24) (noting that case-series studies are the "lowest level of clinical evidence in the hierarchy of evidence").

Fourth, Dr. Schreiber testified that Dr. Delgado's studies did not maintain an adequate control group. She described a control group as a way

for researchers to compare "apples to apples," allowing an assessment of "whether a change in a study participant's condition is due to the treatment or some other factor." *See* dkt. 62 at 2 (Stipulation ¶ 8). Neither of Dr. Delgado's studies included a concurrent control group, recorded the amount of mifepristone administered, maintained uniform routes of progesterone administration, intervals between doses, and duration of treatment, or logged standard demographic information like patient age, race, and medical history. *See* dkt. 53-6 at 9–10, 12 (Schreiber Decl. ¶¶ 29–32, 38); dkt. 53-2 at 10, 15, 17 (Cunningham Decl. ¶¶ 26, 37, 41).

And while Dr. Delgado's 2018 study included a "historical control group," Dr. Schreiber testified that the control group's members had different average gestational ages and doses of mifepristone than those women in the treatment group. *See* dkt. 53-6 at 12–13 (Schreiber Decl. ¶ 39). These differences are important, Dr. Schreiber explained, because the greater the gestational age of an embryo, the higher the likelihood for a continued pregnancy after taking mifepristone. *See, e.g.*, *Mifeprex Label* at 13 (dkt. 53-6 at 63). Dr. Schreiber also expected that a lower dose of mifepristone could result in either the same or a higher rate of continued pregnancy. Because Dr. Delgado's treatment group included patients with higher gestational ages and lower doses of mifepristone than his "control" group, she testified that it makes sense that his treatment group had lower mifepristone efficacy rates than his control group, even without any intervention. Dr. Schreiber therefore testified that it's impossible to isolate the effect of progesterone administration on members of

the treatment group without these proper standards of control. *See* dkt. 53-6 at 12–13 (Schreiber Decl. ¶ 39).

In addition, Dr. Schreiber disputed Dr. Delgado's selection of a 25-percent rate of ongoing pregnancies after mifepristone use as his "historical control group." She discussed the 2015 systematic review by Dr. Grossman cited above for support. That review identified 13 studies that met its criteria. Dkt. 53-6 at 91 (Table 1). The rates of continued pregnancies after mifepristone from those studies ranged from 8–46 percent, with a 95-percent confidence interval ranging from 3–61 percent. *See id.* Dr. Schreiber called this a "wide" range and therefore argued that Dr. Delgado's selection of a rate of 25 percent as his "control" group was arbitrary and unwarranted.

Fifth, Dr. Schreiber testified that no conclusion can be reached from Dr. Delgado's 2018 study because it excluded women who had taken mifepristone but did not have a viable embryo, as determined by an ultrasound. *See* dkt. 53-6 at 10, 13 (Schreiber Decl. ¶¶ 31, 40). As a result, the studies necessarily excluded women for whom mifepristone had already terminated their pregnancies. *See id.* Dr. Schreiber explained that the patients selected had therefore already withstood the initial effects of mifepristone and their pregnancies likely could have continued absent intervention. *Id.* She thus disputed Dr. Delgado's characterization of this selection method as a "confounding variable" and instead called it a confounding "outcome," comparing it to a study of cancer treatment that selected only patients whose cancer had already been cured.

Finally, Dr. Schreiber pointed to conclusions by others in the medical community on the efficacy of abortion pill reversal. *See* dkt. 53-6 at 14–15 (Schreiber Decl. ¶¶ 46–47). The American College of Obstetricians and Gynecologists ("ACOG"), the Society of Family Planning ("SFP"), and the National Abortion Federation ("NAF") have concluded that no evidence supports abortion pill reversal. *See* Am. Coll. of Obstetricians & Gynecologists and Soc'y of Family Planning, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 3 (2020) (dkt. 53-6 at 101); Nat'l Abortion Fed'n, *Clinical Policy Guidelines for Abortion Care* 18 (2020) (dkt. 53-6 at 141).

IV.
Analysis and Conclusions of Law

A. Likelihood of success on the merits

1. The First Amendment and compelled speech

The Required Disclosure alters the content of abortion providers' speech by compelling them to recite a prescribed message to women who seek an abortion. *See Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 795 (1988) ("Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech."). Because this case involves compelled speech—rather than a direct limitation on when or how an abortion may be performed—the Court begins with Plaintiffs' First Amendment claim. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*") (explaining that required notices for medical providers are "content-

based regulation[s] of speech" that implicate the First Amendment). Indeed, speech is fundamental to the physician-patient relationship because "[d]octors help patients make deeply personal decisions." *See id.* at 2374 (citation omitted).

As a general matter, government regulations of the content of speech "are presumptively unconstitutional and may be justified only if the government proves that [they are] narrowly tailored to serve compelling state interests." *Id.* at 2371 (quoting *Reed v. Town of Gilbert, Ariz.*, 576 U.S. 155, 163 (2015)). However, one "exempt[ion] . . . from the normal prohibition on content-based restrictions" is the regulation of speech "as part of the practice of medicine, subject to reasonable licensing and regulation by the State." *NIFLA*, 138 S. Ct. at 2372–73 (quoting *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 884 (1992)) (emphasis omitted).

In *Casey*, a group of abortion clinics and physicians challenged a Pennsylvania law requiring abortion providers to give certain information to women seeking an abortion. 505 U.S. at 845. That statute required abortion providers to "inform the woman of the nature of the procedure, the health risks of the abortion and of childbirth, . . . the 'probable gestational age of the unborn child,'" and "of the availability of printed materials published by the State" describing the fetus, alternatives to abortion, and certain available resources. *Id.* at 881, 902–03. The Supreme Court concluded that the required disclosures were "truthful and not misleading" and helped a woman "apprehend the full consequences of her decision." *Id.* at 882–85. Accordingly,

the Court found that the challenged informed-consent statute was "a reasonable measure to ensure an informed choice." *Id.* at 883. The information was "part of the practice of medicine," so there was "no constitutional infirmity in the requirement that the physician provide the information mandated by the State." *Id.* at 884; *see NIFLA*, 138 S. Ct. at 2373–74.

Casey therefore permits "a State to further its legitimate goal of protecting the life of the unborn by enacting legislation aimed at ensuring a decision that is mature and informed, even when in so doing the State expresses a preference for childbirth over abortion." 505 U.S. at 883. But *Casey* does not allow a State to compel abortion providers to recite anything the State chooses. *See id.* at 881–85; *Stuart v. Camnitz*, 774 F.3d 238, 249 (4th Cir. 2014) ("The single paragraph in *Casey* does not assert that physicians forfeit their First Amendment rights in the procedures surrounding abortions, . . . "). The compelled speech must, at a minimum, be "truthful and not misleading" to withstand First Amendment scrutiny. *Casey*, 505 U.S. at 882 ("If the information the State requires to be made available to the woman is truthful and not misleading, the requirement may be permissible.").

Here, the Required Disclosure is a statement about medical science—it would require abortion providers to say that "[s]ome evidence suggests" that mifepristone's effects "may be avoided, ceased, or reversed." §§ 4(a)(1), 5(a)(1)(C), 2021 Ind. Acts ___. To be truthful and not misleading, that statement must be supported by medical evidence.

2. Medical evidence analysis and factual findings

Plaintiffs argue that "no scientifically valid evidence suggests" that the Required Disclosure is true. Dkt. 53 at 22. The State contends that it has offered "ample" evidence in support, relying primarily on two published studies from Dr. Delgado. Dkt. 57 at 13–18.

a. Published studies

Dr. Delgado's research began with a 2012 case report on seven women who had taken mifepristone "and then sought assistance to block the mifepristone effects." Dkt. 53-6 at 71. One of the women did not have a live embryo documented either at the abortion clinic or at the physician's office, and four of the women eventually delivered healthy newborns. *Id.* at 72. Dr. Schreiber testified that the study followed too few pregnancies to support the effectiveness of abortion pill reversal, and Defendants have not presented contrary evidence. Indeed, a publication in the journal *Contraception* analyzed Dr. Delgado's 2012 case report and concluded that the "evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management." Dkt. 53-6 at 88.

Dr. Delgado next published a 2018 case-series study with "a retrospective analysis of clinical data of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone." *Id.* at 76.[7]

[7] Plaintiffs argue that Dr. Delgado's 2018 study "lacked proper IRB oversight" and "engaged in unethical experimentation." Dkt. 53 at 22–23. At the evidentiary hearing, Dr. Delgado testified about the IRB-approval process, and Plaintiffs did not rebut that

That study began with 1,668 calls to a hotline "from women who had taken mifepristone and were interested in reversal." *Id.* at 80. Of those women, 754 started progesterone therapy. *Id.* And of that number, 112 women were lost to follow-up, 57 chose to complete their abortions, and 38 had been beyond the 72-hour mark after they had taken mifepristone. *Id.* The study therefore analyzed 547 women who completed progesterone therapy. *Id.*

257 of the 547 women delivered babies, and four more were "lost to follow up" after twenty weeks gestation. *Id.* at 81–82. The study also explained how the progesterone was given. *Id.* 31 women received "High Dose Oral" progesterone with 21—or 68%—having pregnancy continue. *Id.* 125 women received intramuscular injections with 80—or 64%—having pregnancy continue. *Id.*

While this 2018 study describes relatively high rates of continuing pregnancy, two significant limitations make it unreliable as support for the "[s]ome evidence" language of the Required Disclosure. First, it excluded an unknown number of women who had nonviable embryos when progesterone therapy was being considered. Dkt. 53-6 at 84. Because the study does not disclose how many women are in that group, it could include as many as 914—the number who called the hotline but were undocumented in the study. Because the actual number is unknown, the impact cannot be calculated with certainty—but it's likely very large because the study analyzed only 547

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testimony. However, the Court makes no findings about the IRB process because Plaintiffs have not explained its relevance to whether the study qualifies as "[s]ome evidence" for abortion pill reversal. *See* dkt. 53.

women. This missing data is particularly relevant because it could help identify how many women experienced abortions after mifepristone alone before they could receive progesterone therapy. Therefore, a substantial limitation of the 2018 study is that it did not treat at least some of those cases as "failed reversals."[8]

Second, the 2018 study does not allow for an "apples to apples" comparison between the treatment and "control" groups, making it impossible to assess whether the difference in outcomes was "due to the treatment or some other factor." *See* dkt. 62 at 2 (Stipulation ¶ 8). As Dr. Delgado admitted, the treatment and "control" groups varied in gestational age and mifepristone dose. *See* dkt. 57-2 at 27, 28 (Delgado Decl. ¶¶ 74, 77–78); dkt. 53-6 at 12–13 (Schreiber Decl. ¶ 39). These differences matter because the greater the gestational age of an embryo, the higher the likelihood for a continued pregnancy after mifepristone has been taken. *See, e.g.*, *Mifeprex Label* at 13 (dkt. 53-6 at 63). And a lower dose of mifepristone could result in either the same or a higher rate of continued pregnancy. *See* dkt. 53-6 at 12–13 (Schreiber Decl. ¶ 39). Therefore, a second substantial limitation of the 2018 study is that it did not establish that the characteristics of patients in the

[8] The 2018 study identified this as a "confounding variable," *see* dkt. 53-6 at 84, but Dr. Schreiber testified that it was a confounding "outcome," likening it to a cancer study that enrolled only patients who had already been cured. Although there are too many unknowns to count every excluded case as a "failed reversal," it's enough at this stage to find that, for the reasons explained above, the exclusions make the study's outcomes unreliable.

treatment and "control" groups aligned closely enough to draw a reasonable inference of causation.

In sum, considering all evidence in the record, the Court finds that the 2018 Delgado study is not evidence of causation and does not fit or support the "[s]ome evidence" language of the Required Disclosure. Indeed, Dr. Delgado admitted that his studies "cannot prove" causation; that they are "limited" because neither was run as a randomized, controlled trial (which the parties agree is "the gold standard of scientific research"); that his 2018 study suffered from a significant "confounding variable;" and that his studies used a design that has "a greater possibility of bias" than a controlled trial. *See* dkt. 57-2 at 25, 53–54.

The parties agree that a randomized clinical trial testing the efficacy of progesterone treatment to counteract the effects of mifepristone would be meaningful. But no such clinical trial has been successfully conducted. Dr. Schreiber described a 2020 study that attempted to enroll forty patients for a randomized controlled trial studying progesterone-based abortion pill reversal. *See* Mitchell D. Creinin et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135(1) Obstetrics & Gynecology 158–65 (2020) (dkt. 53-6 at 182–89). That study was discontinued for safety reasons after enrolling only twelve patients, with ten of the patients completing the study. *Id.* at 182. Of the five patients who completed the treatment group—those receiving progesterone—four patients had continuing pregnancies. *Id.* at 184. And of the five patients who completed the control

group—those receiving a placebo—only two had continuing pregnancies. *Id.* As with Dr. Delgado's 2012 study, those numbers are too small to support any medical findings. *Id.* at 182 (explaining that because the study was discontinued with so few participants, the researchers "could not estimate the efficacy of progesterone for mifepristone antagonization").

The parties also discuss a 1988 Japanese animal study. *See* dkt. 57-2 at 8–9 (Delgado Decl. ¶ 22) (referencing Shingo Yamabe et al., *The Effect of RU486 and Progesterone on Luteal Function During Pregnancy*, 65 Folia Endocrinologica Japonica 5 (1988) (dkt. 57-2 at 58–74)); dkt. 53-6 at 78, 84. But as Dr. Schreiber testified, animal studies are "extremely preliminary" and are never alone enough to allow a clinical recommendation for a treatment's use in humans.

To be clear, the Court does not find that the medical studies in the record have shown that abortion pill reversal does not or cannot work. As Dr. Creinin's study concluded, "we should not dismiss mifepristone antagonization [with progesterone] as impossible." Dkt. 53-6 at 188. The lack of evidence on causation goes to the question that is key for First Amendment purposes—whether the medical evidence in the record sufficiently fits the Required Disclosure as to make the statement "[s]ome evidence suggests" that mifepristone's effects "may be avoided, ceased, or reversed" truthful and not misleading. *See* §§ 4(a)(1), 5(a)(1)(C), 2021 Ind. Acts ___. The medical studies in the record do not justify that statement because those studies do not support causation.

b. Biological principles

Progesterone is an essential hormone for a healthy pregnancy, and progesterone levels are typically far higher for pregnant women than for those who are not pregnant. Mifepristone is a progesterone receptor antagonist that binds preferentially to progesterone receptors within a few hours of the patient taking it. In short, mifepristone blocks progesterone.

The State argues that biological principles regarding how mifepristone and progesterone work "provide good reason to think that taking progesterone will decrease the odds that mifepristone will successfully terminate the pregnancy." Dkt. 57 at 13.

At the evidentiary hearing, Dr. Delgado analogized mifepristone to a "false key" that enters the lock but will not "turn" to cause the hormone effect. He testified that mifepristone does not stay in the lock but goes in and out. Therefore, he testified, "if you flood the system with extra good keys" of progesterone, "then the odds are that the progesterone is going to . . . have the good hormone effect." Other State experts testified "that administering progesterone can inhibit the effects of mifepristone and prevent fetal death." Dkt. 57 at 11 (citing declarations).

Dr. Schreiber, however, testified that mifepristone binds preferentially and very tightly to the receptors, so "the progesterone can't seem to get in." Dr. Schreiber also testified that, regardless of mifepristone's effectiveness, adding progesterone is "entirely unlikely" to prevent an abortion. She explained that

progesterone levels are already very high in pregnancy, so adding more is like rain on a swimmer in a pool—the swimmer cannot get more wet.

The conflicting testimony does not resolve whether biological principles may provide "good reason to think" that progesterone treatment is efficacious, but that question does not need to be resolved in this case. The question is whether "[s]ome evidence suggests" that abortion pill reversal may have the effect of avoiding, ceasing, or reversing the effects of mifepristone. In other words, is there evidence of causation? The biological principle relied upon by the State is not "[s]ome evidence" of causation; instead, it merely supports what the medical research in the record has concluded—that further research is required. *See* dkt. 53-6 at 188.

c. Clinical experience

There's no dispute that there are some cases where women who have taken mifepristone have continued their pregnancies to term and delivered healthy babies. It is similarly uncontested that in some of those cases, the women had received progesterone therapy after having taken mifepristone. But those cases do not show a causal relationship between the treatment (progesterone therapy) and the outcome (the survival and delivery of a healthy baby). In other words, those cases do not show that the progesterone treatment was the reason for the survival and delivery of the healthy babies.

Dr. Delcoco, for example, agreed that her patients who had delivered babies after having taken mifepristone followed by progesterone therapy "may have had continuing pregnancies without any treatment at all." Neither Dr.

Delcoco nor the other clinical physicians in the record offered evidence of causation between the progesterone therapy and the outcome of continued pregnancies. These outcomes do not qualify as "[s]ome evidence" that progesterone therapy can counteract the effects of mifepristone because they do not support the inference of causation.

3. First Amendment protection against untrue or misleading compelled speech

The State has an "important and legitimate interest" in "protecting the life of the unborn." *Casey*, 505 at 883, 945–46. And the Supreme Court "has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007). Indeed, Indiana law already requires many other informed-consent disclosures, including disclosure of "information concerning the abortion inducing drug"; "[o]bjective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug"; and the availability of medical assistance benefits for neonatal care and childbirth, child support obligations, availability of adoption alternatives, physical risks of abortion, and the availability of counseling. Ind. Code § 16-34-2-1.1. None of those requirements are challenged here.

Instead, this case involves the State compelling content-based speech. *See NIFLA*, 138 S. Ct. at 2371 ("By compelling individuals to speak a particular message, such notices alter the content of their speech." (citation and alterations omitted)). And because the Required Disclosure mandates specific language, it does not regulate "conduct [that] incidentally involves speech." *Id.*

at 2372 (citing *Casey*, 505 U.S. at 884). It instead "regulates speech as speech." *Id.* at 2374.[9]

To satisfy the First Amendment's standards, therefore, the Required Disclosure must, at a minimum, be truthful and not misleading. The Required Disclosure expressly relies on medical evidence—"[s]ome evidence suggests"—so, for it to be truthful and not misleading, the language of the Required Disclosure must fit with the medical evidence. The State's evidence includes medical studies, testimony about biological principles, and physicians' clinical experiences.[10] This evidence does not establish causation. There is therefore no medical evidence in the record supporting the Required Disclosure, which expressly requires "[s]ome evidence" for it to be "truthful and not misleading." *Casey*, 505 U.S. at 882.

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[9] The Court does not resolve whether strict scrutiny or a lower level of scrutiny applies. Generally, strict scrutiny applies to content-based regulations of speech. *See NIFLA*, 138 S. Ct. at 2371, 2374. While this case implicates the "exempt[ion]" for informed-consent requirements, that exemption generally applies to conduct regulations that only incidentally burden speech rather than direct regulations on speech. *Id.* at 2373–74. The Court need not resolve this question because even the lower level of scrutiny requires compelled speech to be truthful and not misleading, which is not satisfied here.

[10] At the evidentiary hearing, the State argued, for the first time, that the Required Disclosure is truthful and not misleading, regardless of the merits of abortion pill reversal, because it states only that mifepristone alone is not extremely effective at causing abortion. While the Required Disclosure does not mention progesterone treatment, it directs women to "[i]mmediately contact" Heartbeat International's website and hotline for "Abortion Pill Reversal." *See* §§ 4(a)(1), 5(a)(1)(C), 2021 Ind. Acts ___; dkt. 57-9 at 5 (Foster Decl. ¶ 12). Both resources are dedicated to using progesterone to counter or mitigate the effects of mifepristone. *See id.* Moreover, the parties have otherwise presented evidence and argument focused solely on whether the Required Disclosure is true and not misleading in the context of undergoing progesterone treatment. The Court accordingly evaluates the issue as framed and presented by the parties through the briefing and evidence.

This is not to say that the State has no way to provide information about abortion pill reversal to pregnant women. The State could give information about abortion pill reversal on the Indiana Department of Health's website. Abortion providers are already required to inform each woman about that website before she undergoes an abortion. *See* Ind. Code § 16-34-2-1.1(a)(2)(F). The State could also itself inform women about the 24/7 hotline referenced in the Required Disclosure. *See* dkt. 57-9 at 5 (Foster Decl. ¶ 12). That type of government speech does not implicate the First Amendment. *See Walker v. Texas Div., Sons of Confederate Vets., Inc.*, 576 U.S. 200, 207 (2015) ("When government speaks, it is not barred by the Free Speech Clause from determining the content of what it says."). But the First Amendment is directly implicated when the State takes the same message and forces medical providers to recite it. *See NIFLA*, 138 S. Ct. at 2376 ("The First Amendment does not permit the State to sacrifice speech for efficiency.") (citation omitted); *see Cedar Point Nursery v. Hassid,* --- S. Ct. ----, 2021 WL 2557070, at *6 (U.S. June 23, 2021) ("The Constitution . . . is concerned with means as well as ends.") (citation omitted).

In sum, because the evidence in the record does not show that the Required Disclosure is "truthful and not misleading," it is not a "reasonable" regulation of "the practice of medicine," *Casey*, 505 U.S. at 884, that is categorically "exempt . . . from the normal prohibition on content-based restrictions," *NIFLA*, 138 S. Ct. at 2372. Instead, it "regulates speech as speech" without an adequate medical basis. *NIFLA*, 138 S. Ct. at 2374.

Plaintiffs have thus shown a reasonable likelihood of success on the merits of their First Amendment claim.[11]

B. Irreparable harm with no adequate remedy at law

"[V]iolations of First Amendment rights are presumed to constitute irreparable injuries." *Christian Legal Soc'y v. Walker*, 453 F.3d 853, 867 (7th Cir. 2006); *see* 11A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2948.1 (3d ed. Apr. 2021 Update) ("When an alleged deprivation of a constitutional right is involved, such as the right to free speech or freedom of religion, most courts hold that no further showing of irreparable injury is necessary."). Plaintiffs have demonstrated a reasonable likelihood of success on the merits of their First Amendment claim, so they have shown irreparable injury without an adequate remedy at law absent a preliminary injunction.

C. Balancing

Because Plaintiffs are reasonably likely to succeed on the merits of their First Amendment claim, their action is in the public interest. *See Whole Woman's Health All. v. Hill*, 937 F.3d 864, 875 (7th Cir. 2019) ("Enforcing a constitutional right is in the public interest."). Although Hoosiers have a strong interest in protecting democratically enacted laws, "the public interest is not harmed by preliminarily enjoining the enforcement of a statute that is probably

[11] Plaintiffs also argue that the Required Disclosure places an undue burden on the rights of women who seek an abortion. *See* dkt. 53 at 22–24. Because the Court finds that Plaintiffs are reasonably likely to succeed on the merits of their First Amendment claim, the Court need not address their Due Process claim.

unconstitutional." *Higher Soc'y of Ind. v. Tippecanoe Cty.*, 858 F.3d 1113, 1116 (7th Cir. 2017) (citation omitted).

And for the reasons explained above, "it is beyond dispute that the plaintiffs face greater harm irreparable by the entry of a final judgment in their favor than the irreparable harm that the state faces if the implementation of its statute is delayed." *Planned Parenthood of Wisconsin, Inc. v. Van Hollen*, 738 F.3d 786, 795 (7th Cir. 2013). Indeed, the Seventh Circuit has held that state actors experience "no harm at all" when prevented from violating constitutional rights. *See Christian Legal Soc'y*, 453 F.3d at 867. As a result, the balance of harms favors granting a preliminary injunction.

D. Bond requirement

Finally, Plaintiffs request a waiver of Federal Rule of Civil Procedure 65(c)'s bond requirement. Dkt. 53 at 32. "There is no reason to require a bond" in a case in which "the court is satisfied that there's no danger that the opposing party will incur any damages from the injunction." *Habitat Educ. Ctr. v. U.S. Forest Serv.*, 607 F.3d 453, 458 (7th Cir. 2010). Here, Defendants have not argued a likelihood of damages, and the Court discerns no danger of damages from granting the injunction. As a result, the Court excuses the requirement for bond. *See BankDirect Cap. Fin., LLC v. Cap. Premium Fin., Inc.*, 912 F.3d 1054, 1058 (7th Cir. 2019).

V.
Conclusion

Plaintiffs' motion for a preliminary injunction is **GRANTED**. Dkt. [5]. Pursuant to Federal Rule of Civil Procedure 65, a separate order consisting of the preliminary injunction shall issue contemporaneously with this Order.

SO ORDERED.

Date: 6/30/2021

James Patrick Hanlon

James Patrick Hanlon
United States District Judge
Southern District of Indiana

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