IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

American Medical Association, on behalf of itself and its members; Access Independent Health Services, Inc., d/b/a Red River Women's Clinic, on behalf of itself, its physicians, and its staff; and Kathryn L. Eggleston, M.D.; Plaintiffs, vs. Wayne Stenehjem, in his official capacity as Attorney General for the State of North Dakota; and Birch Burdick, in his official capacity as State Attorney for Cass County, as well as their employees, agents, and successors; Defendants.	**ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** Case No.: 1:19-cv-125

Before the Court is the Plaintiffs' "Motion for Preliminary Injunction" filed on June 25, 2019. See Doc. No. 6. The Plaintiffs seek a preliminary injunction, pursuant to Rule 65 of the Federal Rules of Civil Procedure, restraining the Defendants from enforcing North Dakota House Bill No. 1336. The Defendants separately filed responses to the motion for a preliminary injunction on July 19, 2019. See Doc. Nos. 35 and 36. The Plaintiffs filed a reply brief on July 31, 2019. See Doc. No. 44. For the reasons set forth below, the Court grants the Plaintiffs' motion for a preliminary injunction.

I. BACKGROUND

On June 25, 2019, the American Medical Association, Access Independent Health Services, Inc., d/b/a Red River Women's Clinic, and Kathryn L. Eggleston, M.D., filed a complaint against

North Dakota Attorney General Wayne Stenehjem (the "State") and Cass County State's Attorney Birch Burdick (the "County"), in their official capacities, challenging the constitutionality of House Bill No. 1336 ("H.B. 1336") and N.D. Cent. Code § 14-02.1-02(11)(a)(2).[1] See Doc. No. 1. North Dakota Governor Doug Burgum signed H.B. 1336 into law on March 22, 2019. See Doc. No. 36-1. Section 1 of H.B. 1336 amends and reenacts N.D. Cent. Code § 14-02.1-02(11)(b)(5) to require:

> The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:
>
> . . .
>
> (5) That it may be possible to reverse the effects of an abortion-inducing drug if she changes her mind, but time is of the essence, and information and assistance with reversing the effects of an abortion-inducing drug are available in the printed materials given to her as described in section 14-02.1-02.1.

Id. Section 2 of H.B. 1336 creates and enacts a new subdivision to subsection 1 of N.D. Cent. Code § 14-02.1-02.1, providing the state department of health shall publish:

> Materials including information it may be possible to reverse the effects of an abortion-inducing drug but time is of the essence. The materials must include information directing the patient where to obtain further information and assistance in locating a medical professional who can aid in the reversal of abortion-inducing drugs, such as mifepristone and misoprostol.

Id.

In the complaint, the Plaintiffs allege the Red River Women's Clinic (the "Clinic") "provides a range of reproductive health care to women, including medication and surgical abortions." See Doc. No. 1. The Clinic's director, Tammi Kromenaker, stated, "Of our patients who elect to

[1]N.D. Cent. Code § 14-02.1-02(11)(a)(2), which the Plaintiffs do not seek to enjoin in the instant motion, requires the physician performing an abortion (or the referring physician or physician's agent) to tell the woman receiving an abortion that "[t]he abortion will terminate the life of a whole, separate, unique, living human being."

terminate their pregnancies, approximately thirty percent (30%) of our patients receive medication abortions and the rest receive surgical abortions." See Doc. No. 6-2. According to Dr. Kathryn Eggleston, the Clinic's medical director, in the case of a medication abortion, patients take a combination of two medications orally: mifepristone at the Clinic, followed 24 to 48 hours later by misoprostol taken at the patient's home. See Doc. No. 14. The FDA has approved Mifeprex (a.k.a. mifepristone) in conjunction with misoprostol as an effective alternative to an in-clinic abortion. Id. at ¶ 6. As Dr. Eggleston explained,

> In simple terms, mifepristone stops the pregnancy from growing. My understanding from the scientific literature is that by itself, mifepristone fails to terminate a pregnancy up to 46% of the time. Misoprostol works in conjunction with mifepristone to cause uterine contractions to expel the pregnancy from the uterus. Together, the two medications are effective at terminating an early pregnancy in nearly all cases.

Id. at ¶ 7.

The State describes the procedure "to reverse the effects of an abortion-inducing drug," as provided in H.B. 1336, as taking progesterone, instead of misoprostol. The State's expert, Dr. Richard Vetter, a family physician with obstetrics at Essentia Health in Fargo, North Dakota, and the Medical Director of First Choice Clinic, explained,

> I have been involved in the use of progesterone to reverse the effects of Mifeprostone [sic] (RU486). A woman ingested Mifepristone (first step of a medication abortion) as a part of the protocol for a medication abortion which she sought. After ingesting the Mifepristone, the woman subsequently changed her mind later that day wishing to continue the pregnancy. Upon receiving a request from the woman through First Choice Clinic to assist, I prescribed progesterone to the patient to assist in reversing the effects of Mifepristone. The rationale for this treatment recommendation was that a higher level of progesterone could help by counteracting the antiprogesterone effects of Mifepristone.

See Doc. No. 36-6, ¶ 19.

The Plaintiffs contend that a "so-called abortion 'reversal' [is] based on controversial, unproven theories rejected by major medical organizations." See Doc. No. 6-1. For support, the Plaintiffs submit the declarations of several medical experts. Dr. Brian Wildey, an obstetrician/gynecologist at Altru Health System in Grand Forks, North Dakota, states,

> First, I practice evidence-based medicine, meaning that I endeavor to base recommendations and decisions about patient care on the most credible scientific information. I am not aware of any credible medical evidence supporting the notion that the effects of mifepristone or misoprostol can be reversed.
>
> I have read the papers about so-called abortion "reversal" published by Dr. George Delgado and Dr. Mary Davenport in 2012 and 2018 in *Annals of Pharmacotherapy* and *Issues of Law and Medicine*. The data in Dr. Delgado's and Dr. Davenport's papers do not support their claims that administering progesterone to patients may reverse the effects of mifepristone. In fact, the papers do not show that progesterone has any effect on patients who have taken mifepristone.
>
> The 2012 published paper had a sample size of seven patients, and results were available for only six of the seven. This sample size is far too small to rely on as evidence for making any changes in clinical practice.
>
> Most concerning, neither paper appears to have employed a control group. Randomized, double-blind, placebo control studies are the gold standard for clinical studies, and I consider results from those studies to be of the highest value to my medical practice. I generally would not make medical decisions or recommendations based on studies that did not have a control group because it is usually difficult or impossible to draw any inferences about causation from them. Studies without a control group are among the weakest forms of medical evidence. A control group would be especially important to a study about medication-abortion "reversal" because it is known that taking mifepristone without misoprostol does not have a high success rate for terminating a pregnancy. So before believing that progesterone can reverse the effects of mifepristone, I would need to see a randomized trial with a control group comparing statistically viable groups of patients receiving mifepristone alone against patients receiving mifepristone and progesterone.
>
> . . .
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> Second, because there is no credible medical evidence behind it, I consider administering progesterone to try to "reverse" an abortion to be unethical experimentation on patients. There is no dose and method of administering

progesterone that has been shown to be both safe and effective to "reverse" a medication abortion. So giving a patient progesterone for that purpose is pure experimentation. It would be unethical for me, as a physician, to experiment on my patients outside the context of controlled research monitored and approved by an institutional review board.

. . .

I have read H.B. 1336. In my opinion, H.B. 1336 is an unwarranted and inappropriate intrusion on the practice of evidence-based medicine. By forcing physicians to speak a message with which they disagree, it improperly interferes with the ability of physicians to practice medicine ethically. It is also dangerous for patients because it misleads them into believing an unproven, unsupported theory, introduces needless health risks, and has the potential to stigmatize physicians.

As an OB/GYN, I am not aware of any other medical procedure where I would be required to discuss with my patients purported results of controversial or experimental papers. I would object to any such imposition on my ability to speak freely and honestly with my patients.

Having to tell patients that an irreversible procedure may nevertheless be reversed interferes with and is completely contrary to the physician's ethical and legal obligation to obtain informed consent for a medical procedure. Before beginning a medical procedure, I make sure the patient has provided her informed consent; my staff or I discuss the procedure with the patient, explain its risks and benefits and the risks and benefits of alternative procedures, and explain what she should expect during and after the procedure. I am ethically bound to provide my patients with only information that is true, relevant, not misleading, and based on my professional medical judgment.

Even if it were true that progesterone can theoretically "reverse" mifepristone, of which there is no credible evidence, that does not mean that medication abortion is "reversible" and telling patients otherwise will not aid in their ability to consent to abortion. For example, I would only perform a sterilization procedure such as a tubal ligation for a patient who wants a permanent sterilization. I would not, as part of the consenting process, tell the patient that some clinics have had limited success in bypassing or reversing a tubal ligation in some, but not all, cases, as that does not mean the procedure is "reversible," is not relevant to the patient's ability to provide informed consent, and would serve only to confuse patients. In fact, if the patient expressed an interest in being able to later have a tubal ligation reversal, I would direct the patient away from having a tubal ligation and toward using a long-lasting, reversible contraceptive instead. For similar reasons, before performing a hysterectomy, I would not inform a patient that a handful of physicians have had

> isolated success with uterine transplant after a hysterectomy. Where a drug or procedure is not reliably reversible, understanding the permanent nature of the procedure is critical to ensuring that the patient's consent to the procedure is truly informed and voluntary, and telling patients otherwise would only serve to confuse patients and impede their ability to consent.
>
> H.B. 1336 disrupts medical practice by encouraging patients to participate in unmonitored and experimental research. Even Dr. Delgado and Dr. Davenport acknowledge that further research is needed to determine "which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient."
>
> I am also concerned that H.B. 1336 will lead to stigmatization of physicians who refuse to administer progesterone to try to "reverse" an abortion. In North Dakota, abortion providers and women who exercise their constitutional right to have an abortion are often stigmatized by those who are opposed to abortion. I am concerned that physicians like myself who practice evidence-based medicine and thus would refuse to try to "reverse" a medication abortion would be accused of facilitating abortion and consequently be exposed to anti-abortion stigma.

See Doc. No. 19, ¶¶ 8-11, 13, 18-23. Dr. Eggleston also commented on the flaws of these papers and stated:

> There is no medically acceptable or reliable evidence proving that progesterone can reverse the effects of any abortion-inducing drugs, including mifepristone and misoprostol. I am familiar with the literature on so-called mifepristone "reversal," including two papers authored by Dr. George Delgado together with co-authors. The Delgado papers claim that progesterone can counteract the effects of mifepristone to "reverse" an abortion. These papers are flawed and do not represent ethical, evidence-based medicine. The flaws in these papers include: lack of a control group, meaning it is very possible that the studied pregnancies would have continued regardless of the administration of progesterone; flawed statistical analysis because the authors excluded from their calculations patients whose ultrasounds confirmed embryonic death; failure to separate patients based on gestational age, which effects the success of mifepristone; and lack of proof that the authors complied with standards for clinical research and rather instead were experimenting on patients with treatments that are not evidence-based. For these reasons, the Delgado papers do not provide information that is relevant to my patients.
>
> Because there are no evidence-based studies on the "reversal" of mifepristone, I cannot ethically recommend this treatment to my patients. For one

> thing, the impact on patients of mifepristone combined with high doses of progesterone is virtually unstudied. Scientists thus do not know what impact, including potential birth defects, the administration of these drugs could have on the children born to patients following Delgado's proposed protocols.
>
> Additionally, the protocol for mifepristone "reversal" does not appear to be legally permitted under North Dakota law. The FDA label for mifepristone does not provide for a dose of progesterone, nor does it allow for mifepristone to be taken alone without misoprostol. I personally would not administer progesterone to attempt to reverse mifepristone, as this practice appears to be inconsistent with North Dakota law.
>
> I am not aware of any studies, let alone evidence-based studies, that support the conclusion that the effects of misoprostol can be "reversed." Thus, there is no medically sound evidence that it is possible to "reverse" an abortion, whether through the use of progesterone or otherwise.
>
> I am aware that the American Congress of Obstetricians and Gynecologists ("ACOG") has released a public statement regarding medication abortion "reversal" and that the North Dakota Section of ACOG submitted a similar statement to the legislature opposing HB 1336 . . . . I agree with their conclusions that so-called abortion "reversal" procedures are not based in science and are unethical. I find ACOG to be a reliable, well-respected, source on best practices in obstetric and gynecological care that has an obligation to support evidence-based reproductive health care.

See Doc. No. 14, ¶¶ 11-15.

Dr. Courtney Schreiber, an obstetrician/gynecologist at the University of Pennsylvania Health System—Penn Medicine, declares:

> I understand that the Act requires physicians (or agents acting on their behalf), at least twenty-four hours before an abortion, to inform every patient, regardless of how far along she is in the pregnancy and whether or not she is considering or is eligible for medication abortion, "[t]hat it may be possible to reverse the effects of an abortion-inducing drug if she changes her mind, but time is of the essence." I am aware of a similar law that passed in Arizona several years ago but was later repealed. Until the law in Arizona passed, I had never heard or read of "reversing" any abortion-inducing drugs, and as an abortion provider and professor, I keep up to date with new research about medication abortion.
>
> I am aware of a proposal by two physicians based in California, Dr. George Delgado and Dr. Mary Davenport, that physicians administer progesterone to reverse

the effects of mifepristone in women who started the early medication abortion regimen but did not take the misoprostol. Delgado and Davenport have published two papers that they claim support their proposal regarding the use of progesterone. . . .

In my medical opinion, the administration of progesterone, which only addresses the potential to reverse mifepristone, not misoprostol or any other abortion-inducing drugs, is experimental and unsupported by scientific evidence. Thus, requiring physicians to tell women that there is "assistance" available to reverse the effects of abortion-inducing drugs generally, including mifepristone and misoprostol, could easily mislead patients into wrongly assuming that there are reliable data to support this practice. Doing so on the bases of the published papers, which provide no scientific support for this practice, is unethical.

ACOG [the American College of Obstetricians and Gynecologists] has issued a statement to this effect, explaining that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards," and that requiring that physicians inform patients about so-called "reversal" and make referrals for such treatments "compromise patient care and safety." . . . I agree with ACOG's determinations completely.

. . .

In short, no responsible physician would suggest, based on this paper, that "reversal" of mifepristone is possible. As ACOG has explained, Dr. Delgado's claims of "reversing" mifepristone "are unproven and unethical," and his study does not amount to valid "scientific evidence that progesterone" can be used for these purposes.

. . .

For all these reasons, the two flawed Delgado papers do not provide evidence upon which to base a treatment regimen. At a very practical level, progesterone injections are painful and *expensive*; it is unethical to recommend a treatment that causes pain and potential economic hardship when there is insufficient evidence of benefit to patients.

Moreover, although progesterone is considered a low-risk medication, it does carry risks. Progesterone has been associated with maternal complications such as depression, cholestatic jaundice, and hypertension. And while some data support the general safety of progesterone in pregnancy, there are also some studies that have raised concerns about a possible association with second trimester miscarriage and stillbirth in pregnancies exposed to certain exogenous progesterone preparations. Investigators also have reported associations with hypospadias, a defect in the male

infant's genitalia, occurring in the male infants born to women who used progestins (synthetic or pharmacologic progesterones) during pregnancy. While none of these data are conclusive, they are enough to raise concern in the absence of proven benefit.

. . .

For all the reasons above, in my opinion, the research that Dr. Delgado and his colleagues are conducting is highly unethical and unprofessional. Likewise, it would be unprofessional for a physician to recommend to a patient that she undergo an experimental protocol (outside of an IRB approved research protocol). As a physician, I would never recommend this treatment to a patient nor would I refer a patient for such care given the current state of the evidence. I also would not suggest to a patient that she visit abortionpillreversal.com to learn more about this treatment. In the unlikely event that a patient came to me seeking to interrupt the medication abortion regimen after she had ingested the mifepristone, I would initiate comprehensive pregnancy options counseling and probe as to what had motivated the patient's change of heart; if I confirmed that she carried an ongoing pregnancy and wished to continue to term, I would then refer her for prenatal care.

. . .

Even apart from the fact that the administration of progesterone to reverse the effects of mifepristone is not supported by medical evidence and that there are concerns that Dr. Delgado's research is not being conducted ethically, it is my opinion that requiring physicians to inform patients about the possibility of medication abortion reversal is in and of itself harmful to physicians and patients in a variety of ways.

. . .

For patients having a medication abortion with the standard mifepristone and misoprostol regimen, the Act's requirement is confusing and misleading. Under the Act, patients must hear from their physician, or their agent, that reversal "may be possible" and that the state offers assistance with obtaining this treatment. In this situation, patients are likely to conclude that this treatment is established as safe and effective, which as explained above, is far from true. In effect, the Act forces physicians and their agents to endorse experimental medical treatment and refer patients for that treatment, despite the fact that the physicians do not think this treatment is in their patients' best interests.

The Act's specific requirement that physicians or their agents provide patients with information about reversal of abortion-inducing drugs such as "mifepristone *and misoprostol*" is even more troubling. I am not aware of any research claiming that

> there is an effective reversal treatment for misoprostol, but that may not be clear to the patient given this confusing and irrelevant legislative mandate.
>
> In my opinion, these problems cannot be solved by physicians providing further explanation. If a physicians tried to explain that what she had just been required to tell the patient was untrue, misleading, and/or not relevant at all to the patient, that would increase patient confusion and make it harder for the physician to ensure that the patient understood all the relevant facts she needed to make an informed decision about whether or not to proceed with an abortion in the first place. It could also lead a patient not to trust any of the information the physician gave her. It could even lead a patient to seek a malpractice action against her physician for providing information and advice that deviates from the standard of care.
>
> Finally, I am concerned that the Act's state-mandated advisory might distort the patient's decision-making and create a risk that she would begin the abortion procedure before she was fully prepared to do so. Worse still, the Act's reference to misoprostol as well as mifepristone could lead patients to think that the abortion is reversible after it has already been completed. During the informed consent discussion with my abortion patients, I stress that they should not begin the procedure until they are resolved to terminate their pregnancy.

See Doc. No. 16, ¶¶ 16-19, 28, 38-39, 47, 48, 52-55.

Dr. Schreiber also submitted a supplemental affidavit which addresses the theories of the State's medical expert, Dr. Jerry Obritsch, an obstetrician/gynecologist at the Center for Women, Mid Dakota Clinic, in Bismarck, North Dakota:

> My opinions diverge from Dr. Obritsch, however, because it is the very uncertainty he acknowledges that, in my opinion, makes forcing physicians to inform their patients that abortion reversal "may be possible" a clear deviation from the standard of care and from beneficent medical care.
>
> A medical "theory" is very different from medical "evidence." The theory that progesterone can "reverse" mifepristone remains just that—a theory. There are many medical and scientific theories that, even if they make some logical sense in theory, do not pan out in practice after they have been sufficiently studied. It is for this reason that methodical, scientific study of theories, including through clinical trials, is paramount to the safe practice of medicine. In this case, Dr. Obritsch acknowledges the lack of rigorous scientific studies, Obritsch Decl. ¶ 49, and the most Dr. Vetter can muster, based on his experience with a *single* patient, is that progesterone "intervention *likely* was at least *partially* responsible" for the patient carrying her pregnancy to term, Vetter Decl. ¶ 19. This is not sufficient evidence on

which to base medical practice.

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

I also disagree with Dr. Obritsch and Dr. Vetter's analysis of the feasibility of studying "abortion reversal." While Dr. Obritsch correctly acknowledges that randomized, prospective, placebo-controlled trials are the gold standard in research, he implies both that such trials are the only ones that require Institutional Review Board (IRB) approval, and that such trials are impossible in this context. *See* Obritsch Decl. ¶¶ 21, 49. Neither contention is correct. All human subject research, including case studies, should be approved by an IRB to ensure that such research is ethical. Offering experimental care without proper institutional oversight, as Delgado appears to have done, is not only unethical research on human subjects but it undermines researchers' ability to perform ethical research, as patients will be less inclined to enroll in data-generating studies if they can obtain the same experimental treatment outside the research setting. Similarly, Dr. Obritsch and Dr. Vetter are wrong to suggest that ethical, IRB-approved research on the use of progesterone to "reverse" mifepristone is impossible. Researchers could design studies where the participants properly consented to experimental treatment according to a standard progesterone protocol. Delgado's papers fail to meet even this ethical threshold.

Finally, Dr. Vetter and Dr. Obritsch incorrectly claim that because progesterone is "naturally occurring in pregnancy," there are no risks to administering patients with high doses of exogenous progesterone throughout pregnancy. It is common knowledge within the medical profession that too large exogenous doses of any naturally occurring hormone or chemical, including water and Vitamin C, can be risky or even dangerous. Indeed, I cite studies in my original declaration documenting the potential risks from progesterone treatment. *See* [Doc.] No. 16, Schreiber Decl. ¶ 39. Because the use of progesterone to "reverse" abortion has not been proven safe, and because there is an absence of data on its efficacy for this purpose, it is my opinion that exposing patients to this treatment as a matter of course is unethical.

See Doc. No. 44-1, ¶¶ 5-9.

Dr. Matthew Wynia, the Director of the Center for Bioethics and Humanities at the University of Colorado, states that the provisions of H.B. 1336 are contrary to the core principles of medical ethics:

> Because there is no accepted scientific evidence that administration of progesterone safely and effectively "reverses" medication abortion, ingesting this drug in an attempt to do so is unproven and therefore effectively experimental.
>
> For use of an experimental treatment to meet the ethical foundations of the Belmont Report and regulations of the Common Rule, health professionals must ensure, for example, that the protocol for using the experimental treatment has been approved by an institutional review board (IRB). Health professionals engaged in research on human beings must also obtain informed consent from each patient specific to participation in the experiment, ensuring that participating patients understand the full extent of the experiment, their rights to withdraw from the experiment without penalty, and so on. Progesterone treatment to "reverse" abortion does not meet these minimal requirements to protect human subjects of medical experimentation.
>
> H.B. 1336 specifically hides the fact that this treatment is poorly studied and understood, as it forces physicians to present and presumably deliver progesterone treatment without any of the benefits or protections of an ethically-conducted medical experiment. Fundamentally, this misrepresentation will serve to mislead or coerce patients who want to "undo" a medication abortion to participate in an unethical experiment without their knowledge. For physicians who are forced to deliver a misleading and inaccurate message that might cause their patients to enroll in an experiment without their full knowledge, doing so is highly unethical. In sum, H.B. 1336 compels health care professionals, contrary to the principles of medical ethics, to be complicit in unethical experimentation on their patients.
>
> For all of the foregoing reasons, it is my opinion that the requirements of H.B. 1336 are contrary to the core principles of medical ethics. H.B. 1336 damages the patient-physician relationship, undermines patient autonomy generally as well as the informed consent process, forces physicians to do harm to their patients without countervailing benefit, and violates principles of medical research ethics.

See Doc. No. 18, ¶¶ 40-43.

Finally, the American College of Obstetricians and Gynecologists (ACOG) has released a public statement opposing medication abortion "reversal." See Doc. No. 16-4. ACOG is the

nation's leading group of physicians providing health care for women. The North Dakota Section of ACOG submitted a statement to the North Dakota legislature opposing H.B. 1336 and expressly stated as follows:

> The North Dakota Section of the American College of Obstetricians and Gynecologists (ACOG) opposes HB 1336 which would require ND physicians to inform patients that their medical abortion may be reversed if she acts quickly and where to seek treatment if they want to reverse the abortion.
>
> Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence and does not support prescribing progesterone to stop a medical abortion. Politicians who push legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care represents dangerous political interference in patient care and compromises patient safety.
>
> ACOG firmly believes that science must be at the core of public health policies and medical decision-making. HB 1336 would insert the government into those personal medical decisions.
>
> The American College of Obstetricians and Gynecologists is the nation's leading group of physicians providing health care for women. The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists is its companion organization.
>
> ACOG supports guaranteed access to the full array of clinical and reproductive services appropriate to each individual woman's needs throughout her life and recognizes that patients and families with input from their doctors should make decisions regarding each person's unique healthcare needs, not the government.

See Doc. No. 14-2.

The Plaintiffs move the Court for a preliminary injunction that would restrain the Defendants from enforcing H.B. 1336, arguing "[t]he First Amendment protects physicians against laws that compel them to speak against their will." See Doc. No. 6-1. H.B. 1336 went into effect on August

1, 2019; however, the Court adopted the joint stipulation of the parties, which provides the Defendants will not take any legal action to enforce H.B. 1336 prior to the Court ruling on the motion for a preliminary injunction. See Doc. No. 34. The motion for a preliminary injunction is now ripe for consideration.

II. LEGAL DISCUSSION

The Plaintiffs seek a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure. The primary purpose of a preliminary injunction is to preserve the status quo until a court can grant full, effective relief upon a final hearing. Ferry-Morse Seed Co. v. Food Corn, Inc., 729 F.2d 589, 593 (8th Cir. 1984). A preliminary injunction is an extraordinary remedy, with the burden of establishing the necessity of a preliminary injunction placed on the movant. Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003); Baker Elec. Coop., Inc. v. Chaske, 28 F.3d 1466, 1472 (8th Cir. 1994); Modern Computer Sys., Inc. v. Modern Banking Sys., Inc., 871 F.2d 734, 737 (8th Cir. 1989). The court determines whether the movant has met its burden of proof by weighing the factors set forth in Dataphase Systems, Inc. v. C L Systems, Inc., 640 F.2d 109, 114 (8th Cir. 1981).

The *Dataphase* factors include "(1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." Id. "No single factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance they weigh towards granting the injunction." Baker Elec. Coop., Inc., 28 F.3d at 1472 (quoting Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500, 503 (8th Cir. 1987)); see also CDI Energy Servs., Inc. v. W. River Pumps, Inc., 567 F.3d 398, 401-03 (8th

Cir. 2009). The Eighth Circuit has held that of the four factors to be considered by the district court in considering preliminary injunctive relief, the likelihood of success on the merits is "most significant." S & M Constructors, Inc. v. Foley Co., 959 F.2d 97, 98 (8th Cir. 1992).

A. PROBABILITY OF SUCCESS ON THE MERITS

"The First Amendment, applicable to the States through the Fourteenth Amendment, prohibits laws that abridge the freedom of speech." Nat'l Inst. of Family and Life Advocates v. Becerra, 138 S.Ct. 2361, 2371 (2018) ("NIFLA"). The right to free speech "includes both the right to speak freely and the right to refrain from speaking at all." Wooley v. Maynard, 430 U.S. 705, 714 (1977). Informed consent statutes implicate a physician's First Amendment right not to speak. However, the right to speak or to refrain from speaking is not absolute. Physicians have First Amendment rights not to be compelled to speak by the state, but those rights may be limited by "reasonable licensing and regulation." Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 884 (1992) (a woman has a right to an abortion before viability without undue interference from the state). A state may require physicians to provide objectively truthful and non-misleading information before obtaining a patient's informed consent to an abortion. Id. at 882. However, if "the State's interest is to disseminate an ideology, no matter how acceptable to some, such interest cannot outweigh an individual's First Amendment right to avoid becoming the courier for such message." Wooley, 430 U.S. at 717. Thus, informed consent statutes may violate the First Amendment rights of physicians if the state requires the doctor to communicate its ideology. See Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds, 530 F.3d 724, 734-35 (8th Cir. 2008).

Courts distinguish between content-based and content-neutral regulations of speech. NIFLA, 138 S.Ct. at 2371. "Content-based regulations 'target speech based on its communicative content'" and are "presumptively unconstitutional." Reed v. Town of Gilbert, 135 S.Ct. 2218, 2226 (2015). Generally, a content-based regulation cannot withstand a challenge unless the government proves the law is narrowly tailored to serve a compelling state interest. NIFLA, 138 S.Ct. at 2371. "This stringent standard reflects the fundamental principle that governments have no power to restrict expression because of its message, its ideas, its subject matter, or its content." Id. (internal quotes omitted). The parties agree that H.B. 1336 is a content-based regulation on speech.

In *NIFLA*, the Supreme Court of the United States noted it has afforded less protection for professional speech in two circumstances. First, it has applied a more deferential review to laws that require professionals to disclose "factual, noncontroversial information in their 'commercial speech.'" Id. at 2372. Second, less protection is afforded for regulations of professional conduct that incidentally burden speech. Id. at 2373. The first exception—not advanced by the State—is inapplicable because H.B. 1336 does not involve non-controversial commercial speech. Instead, the State argues that H.B. 1336 regulates professional conduct that incidentally burdens speech. Without deciding, the Court will assume this exception applies.

The question thus becomes, which level of scrutiny applies: intermediate review or rational basis review. The *NIFLA* Court did not decide the level of scrutiny. In a post-*NIFLA* decision, the Fourth Circuit Court of Appeals concluded intermediate review applies to regulations of professional conduct that incidentally burden speech:

> [W]e hold that intermediate scrutiny is the appropriate standard for reviewing conduct regulations that incidentally impact speech. We think this a sensible result, as it fits neatly with the broad leeway that states have to regulate professions. For laws with only an incidental impact on speech, intermediate scrutiny strikes the

appropriate balance between the states' police powers and individual rights.

Capital Associated Indus. v. Stein, 922 F.3d 198, 209 (4th Cir. 2019); see also Otto v. City of Boca Raton, 353 F. Supp. 3d 1237, 1256 (S.D. Fla. 2019) (stating that the application of "intermediate scrutiny to medical treatments that are effectuated through speech would strike the appropriate balance between recognizing that doctors maintain some freedom of speech within their offices, and acknowledging that treatments may be subject to significant regulation under the government's police powers."), appeal filed, No. 19-10604 (11th Cir. Feb. 14, 2019). The Court agrees—assuming H.B. 1336 regulates professional conduct that incidentally burdens speech—intermediate review is the more appropriate standard of review to apply.

Under intermediate review, the government must establish that the law furthers a substantial government interest and is sufficiently tailored to further that interest. See NIFLA, 138 S.Ct. at 2375. The State contends it has a substantial interest in preserving and promoting fetal life. However, given this interest, the Defendants cannot show H.B. 1336 is sufficiently tailored to serving that interest. The Defendants have not disputed the fact the alleged "abortion reversal" procedure described in H.B. 1336 is irrelevant to surgical abortion patients because a surgical abortion cannot be reversed. According to the Clinic's director, approximately 70% of the patients who decide to pursue an abortion receive surgical abortions. Because H.B. 1336 requires physicians to inform every abortion patient that "it may be possible to reverse the effects of an abortion-inducing drug," regardless of the type of abortion she is receiving (medication or surgical), H.B. 1336 is not sufficiently tailored to serve a substantial government interest.

The State argues the *Rounds* test applies, not intermediate review. In *Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 530 F.3d 724 (8th Cir. 2008), the Eighth Circuit

Court of Appeals articulated a standard that applied to government efforts to compel speech by abortion providers. Under that abortion-specific standard, a government-compelled speech requirement "violates a physician's right not to speak" if "the disclosure is either untruthful, misleading or not relevant to the patient's decision to have an abortion." Id. at 735. In the recent *NIFLA* decision, the Supreme Court rejected special rules for separate categories of speech. See NIFLA, 138 S.Ct. at 2371-72 (stating that it "has not recognized 'professional speech' as a separate category of speech" and has "been reluctant to mark off new categories of speech for diminished constitutional protection."). However, even if the *Rounds* test applies, H.B. 1336 is 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.

First, the statement that "it may be possible to reverse the effects of an abortion-inducing drug" is misleading at best. The State's own expert, Dr. Obritsch, admits that: "The term 'abortion reversal' is somewhat *misleading* in that an abortion is not reversed but rather, abortion is prevented from occurring . . . by preventing the antiprogesterone effect of mifepristone from exerting its effect upon the pregnancy." See Doc. No. 36-3, ¶ 17 (emphasis added). Dr. Obritsch concludes, "The Abortion Pill Reversal (APR) protocol is lacking rigorous scientific studies to support its efficacy." Id. at ¶ 49. Dr. Obritsch also agreed that the American College of Obstetricians and Gynecologists have expressly rejected Delgado's studies as "junk science." Id. at ¶ 19.

The affidavits submitted by the Plaintiffs' expert witnesses further support the fact the "abortion reversal" protocol is devoid of scientific support, misleading, and untrue. Dr. Wildey states, "I am not aware of any credible medical evidence supporting the notion that the effects of mifepristone or misoprostol can be reversed." See Doc. No. 19, ¶ 8. Dr. Schreiber asserts "the

administration of progesterone . . . is experimental and unsupported by scientific evidence. Thus, requiring physicians to tell women that there is 'assistance' available to reverse the effects of abortion-inducing drugs generally, including mifepristone and misoprostol, could easily mislead patients into wrongly assuming that there are reliable data to support this practice." See Doc. No. 16, ¶ 18; see also Doc. No. 14, ¶ 11 (Dr. Eggleston discussing the flaws of the studies supporting the "abortion reversal" protocol); Doc. No. 19, ¶ 11 (Dr. Wildey discussing the lack of a control group). The American College of Obstetricians and Gynecologists declared, "Claims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards." See Doc. No. 16-4.

Second, as stated above, the "abortion reversal" information required under H.B. 1336 must be provided to every patient, including those receiving a surgical abortion (seventy percent of the Clinic's patients). The State does not dispute this information is irrelevant to those patients. See Doc. No. 36, p. 23 ("Those patients who undergo a surgical abortion, one can reasonably assume, will deduce that the abortion reversal medical information is not applicable to them and merely discard the information."). Thus, even if the *Rounds* test applies, H.B. 1336 is likely unconstitutional.

In *Casey*, the United States Supreme Court upheld provisions of a Pennsylvania abortion statute that prohibited abortions in the absence of informed consent. In Pennsylvania, consent to an abortion was voluntary and informed only if, at least 24 hours prior to the abortion, the physician had orally informed the woman of the nature of the procedure, and of the risks and alternatives to the procedure that a reasonable patient would consider material in deciding whether to undergo an abortion. Casey, 505 U.S. at 902. The physician was required to describe the "probable gestational age of the unborn child at the time [of] the abortion" and the "medical risks associated with carrying

her child to term." Id. The patient was also required to be informed of certain state published printed materials describing the unborn child and listing agencies that offer alternatives to abortion. Id. at 902-903. The Supreme Court found "no constitutional infirmity in the requirement that the physician provide the information mandated by the State here." Id. at 884.

The new amendment to North Dakota's informed consent statute (H.B. 1336) goes far beyond the informed consent statute upheld in *Casey* and other cases reviewing similar statutes. The Court finds that the mandate of H.B. 1336 violates the First Amendment rights of physicians. Rather than focus on relevant medical information designed to assist a woman in making a free choice, H.B. 1336 expresses ideological beliefs essentially designed to make it more difficult for women to choose an abortion. The North Dakota law requires abortion providers to enunciate the State's viewpoint on an unproven medical and scientific theory, namely whether a chemical abortion can be reversed. North Dakota may not violate the First Amendment rights of physicians by compelling them to espouse the State's ideology. The law also clearly 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 care; and is arguably unethical. A law which mandates that physicians become mouthpieces for a false, misleading, and controversial "abortion reversal" message would not survive any level of constitutional scrutiny. The Court believes H.B. 1336 violates a physician's First Amendment protection against compelled speech.

The State contends there is an ongoing medical debate about whether a chemical abortion can be reversed. However, the record reveals no real, serious debate within the medical profession at the current time. ACOG, the nation's leading group of physicians providing health care to women,

and the North Dakota Section of ACOG, have denounced claims of abortion "reversal" treatment. ACOG has publically announced that claims of abortion "reversal" are not based on science and do not meet current clinical standards of medical care. ACOG does not support prescribing progesterone to stop a medical abortion, and has stated that politicians "should never mandate treatments or require that physicians tell patients inaccurate information." See Doc. No. 16-4. The Court is unaware of any federal case that supports the argument that, even if a medical debate exists, a state legislature is free to take sides in a medical debate and force physicians to speak to patients about a very controversial and medically-uncertain procedure. More important, the North Dakota Legislative Assembly ignored the ACOG pronouncements and failed to make any legislative findings as to whether an abortion can indeed ever be "reversed."

The State contends that H.B. 1336 is constitutional under the *Rounds* rational basis standard of review. Under *Rounds*, a law compelling physician speech in the abortion context is unconstitutional if the disclosure is untruthful, misleading, or not relevant to the patient's decision to have an abortion. Rounds, 530 F.3d at 735. 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. Accordingly, the Plaintiffs have shown they are likely to prevail on the merits of their compelled speech claim. This *Dataphase* factor weighs in favor of the Plaintiffs.

B. THREAT OF IRREPARABLE HARM

It is well-established in the Eighth Circuit that the "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Johnson v. Minneapolis Park & Recreation Bd., 729 F.3d 1094, 1101-02 (8th Cir. 2013) (quoting Elrod v. Burns, 427 U.S. 347, 373 (1976)). Because H.B. 1336 likely violates the First Amendment rights of physicians who choose to provide abortions, the Plaintiffs will suffer an irreparable harm if an injunction is not granted. This *Dataphase* factor weighs in favor of the Plaintiffs.

C. BALANCE OF THE HARMS

The Plaintiffs contend the Defendants will suffer no harm if the statute is enjoined, and the Court agrees. North Dakota's current informed consent laws require physicians to advise women of the medical risks associated with an abortion. See N.D. Cent. Code ch. 14-02.1 and specifically N.D. Cent. Code §§ 14-02.1-02(11) and 14-02.1-03. These North Dakota laws will remain in effect if the Court enjoins the amended version, H.B. 1336. Thus, women seeking abortions will continue to be advised of the relevant risks and alternatives to an abortion whether or not the Court issues an

injunction. The denial of the motion for a preliminary injunction would likely result in irreparable harm to the Plaintiffs' First Amendment rights and the threat of criminal prosecution. The Court finds that the balancing of the equities weighs in favor of the Plaintiffs.

D. PUBLIC INTEREST

The public interest is always served by free expression on issues of public concern and the protection of constitutional rights. Kirkeby v. Furness, 52 F.3d 772, 775 (8th Cir. 1995). Although the public has an interest in the freedom of state legislatures to act without interference from the judicial branch, the Bill of Rights was designed to place certain subjects beyond the reach of public officials and to establish them as legal principles to be applied by the courts. West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 639 (1943). The public interest is served when the legislature acts within its constitutional limits. The Court finds this *Dataphase* factor weighs in favor of granting a preliminary injunction.

III. CONCLUSION

After a careful review of the entire record and consideration of the *Dataphase* factors, the Court finds all of the *Dataphase* factors weigh in favor of the issuance of a preliminary injunction. The Plaintiffs have met their burden of establishing the necessity of a preliminary injunction. Accordingly, the Plaintiffs' motion for a preliminary injunction (Doc. No. 6) is **GRANTED**. As previously noted, this preliminary injunction only addresses the provisions of H.B. 1336 that mandate a discussion about the possibility of reversing the effects of an abortion-inducing drug. The Plaintiffs in this motion are not seeking to enjoin the other informed consent state law at issue in this

litigation which requires a physician performing an abortion to tell the woman that the abortion will terminate the life of a "whole, separate, unique, living human being." See N.D. Cent. Code § 14-02.1-02(11)(a)(2). To preserve the status quo during the pendency of this case, the Defendants are enjoined from enforcing H.B. 1336 until final resolution of the Plaintiffs' claims or until further order of the Court. The security bond required under Fed. R. Civ. P. 65(c) is waived.

IT IS SO ORDERED.

Dated this 10th day of September, 2019.

/s/ Daniel L. Hovland
Daniel L. Hovland, Chief Judge
United States District Court