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

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,	)	CIVIL ACTION
v.	)	CASE NO. 1:19-cv-00125-DLH-CRH
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.	)	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Other References

INTRODUCTION

The First Amendment protects physicians against laws that compel them to speak against their will, particularly when the government seeks to compel controversial speech that threatens the public's health. In direct contravention of the First Amendment and physicians' legal and ethical duties to their patients, North Dakota House Bill 1336 ("H.B. 1336") forces physicians to act as the mouthpiece for a government-scripted message endorsing so-called abortion "reversal" based on controversial, unproven theories rejected by major medical organizations. H.B. 1336 also forces physicians to distribute government-created materials touting these untruths and referring patients for treatments that are at best, experimental, and at worst, detrimental to their health.

The American Medical Association, Red River Women's Clinic, and Dr. Kathryn Eggleston, (collectively, "Plaintiffs" or "Physicians") represent abortion providers who strongly object to H.B. 1336 because it compels them to speak controversial messages with which they disagree, forces them to violate their ethical obligations to their patients, and makes them expose their patients to potential harm. In particular, H.B. 1336 violates the *Code of Medical Ethics of the American Medical Association*, the most comprehensive and well-respected code for physicians worldwide, which has been published by the American Medical Association since 1847.

Plaintiffs seek a preliminary injunction to preserve the status quo and prevent irreparable harm to their constitutional rights. **Plaintiffs respectfully request the Court to act by H.B. 1336's effective date of August 1, 2019.**

STATEMENT OF FACTS

I. Plaintiffs' Provision of Abortion Services in North Dakota.

The American Medical Association ("AMA") is the largest professional medical association in the United States, with members in North Dakota as well as every other state in the country. Red River Women's Clinic (the "Clinic") is the only clinic providing outpatient abortion

services in North Dakota, and Dr. Kathryn Eggleston is the Clinic's medical director. The Clinic provides family-planning services and high-quality abortion care to patients primarily from North Dakota, South Dakota, and Minnesota. Decl. of Tammi Kromenaker (attached hereto as Ex. 1) ("Kromenaker Decl.") ¶ 4; Decl. of Kathryn L. Eggleston, M.D. (attached hereto as Ex. 2) ("Eggleston Decl.") ¶ 2. Approximately 70% of the Clinic's abortion patients receive surgical abortions (i.e. abortions that involve the introduction of instruments into the patient's uterus) while 30% receive medication abortions (i.e. abortions that only involve administration of oral medications). Kromenaker Decl. ¶ 5.

The Clinic uses an evidence-based regimen approved by the Food and Drug Administration ("FDA") for medication abortion up to 10 weeks' pregnancy (measured from the first day of a woman's last menstrual period). Under this regimen, patients take a combination of two medications orally: mifepristone at the Clinic, followed 24 to 48 hours later by misoprostol taken at a location of the patient's choosing, usually the patient's home. Eggleston Decl. ¶ 6. Mifepristone typically stops the pregnancy from progressing by blocking progesterone receptors, but if taken alone, it fails to terminate a pregnancy up to 46% of the time. Eggleston Decl. ¶ 7; Declaration of Courtney A. Schreiber, M.D., M.P.H. (attached hereto as Ex. 3) ("Schreiber Decl.") ¶ 14. Misoprostol works in conjunction with mifepristone to cause uterine contractions to expel the pregnancy from the uterus. Eggleston Decl. ¶ 7; Schreiber Decl. ¶ 13. When the two drugs are used together, as outlined by the FDA label, the success rate in the United States for medication abortion is 97.4%. Schreiber Decl. ¶ 10.

The staff and physicians at the Clinic have decades of experience counseling women seeking abortion care. Kromenaker Decl. ¶ 3; Eggleston Decl. ¶ 4. The Clinic currently provides abortions one day per week and does not accept walk-ins for abortion services. Eggleston Decl.

¶ 6; Kromenaker Decl. ¶ 4. As required by North Dakota law, the Clinic provides patients with both the information currently required under state law and a variety of other resources and information at least 24 hours before their abortion procedures. Kromenaker Decl. ¶ 7; Eggleston Decl. ¶ 8. On the day of a patient's procedure, before moving forward with any abortion services, each physician ensures that each patient is confident in her decision to have an abortion. Kromenaker Decl. ¶ 8; Eggleston Decl. ¶ 16. While the vast majority of patients are sure of their decision before receiving counseling, in the rare instance that a patient is unsure, the Clinic will not provide an abortion (including administering mifepristone), until she is confident in her decision. Kromenaker Decl. ¶ 8; Eggleston Decl. ¶ 16.

II. Medical Ethics and Current North Dakota Law Already Impose Stringent Requirements on Abortion Provider Speech.

Physicians' obligations to patients are regulated by applicable state law but are also grounded in the tenets of medical ethics that guide the medical profession. These tenets mandate not only that patients provide informed consent to a medical procedure—by discussing the details, risks, and benefits of the patient's chosen procedure and alternatives—but also that physicians are able to build a relationship of trust with their patients. Decl. of James L. Madara, M.D. (attached hereto as Ex. 4) ("Madara Decl.") ¶¶ 18, 19, 24-31; Decl. of Matthew K. Wynia, M.D., M.P.H., F.A.C.P. (attached hereto as Ex. 5) ("Wynia Decl.") ¶ 22; Decl. of Brian M. Wildey, M.D. (attached hereto as Ex. 6) ("Wildey Dec.") ¶ 20. It is imperative to patient care at the Clinic that the physicians and staff provide truthful, comprehensive, relevant, and evidence-based information to their patients about their chosen abortion procedure before the patient begins that procedure. Forcing physicians to provide patients with unproven, untruthful, misleading, and/or irrelevant information prevents physicians from building trust with their patients and actively undermines

their ability to ensure that patients are providing informed consent. Eggleston Decl. ¶ 18; Wynia Decl. ¶¶ 4, 23-33.

North Dakota law imposes specific speech requirements on physicians who provide abortions. Under North Dakota's statutory definition of "informed consent," the physician or her agent must discuss certain information with patients at least 24 hours beforehand, including not only the information necessary for the patient to provide informed consent under the tenets of medical ethics, but also information unrelated to the process of consenting to the procedure—such as that the "abortion will terminate the life of a whole, separate, unique, living human being." N.D. Cent. Code § 14-02.1-02(11)(a)(2). The Clinic also must provide the patient with materials published by the North Dakota State Department of Health ("DOH") that includes information and resources, much of which is similarly unrelated to the informed consent process. Violation of these laws subjects physicians to criminal penalties and allows patients to seek civil damages against physicians for failing to provide "informed consent." N.D. Cent. Code §§ 14-2.1-11, 14-02.1-03.2.

North Dakota law also provides that a physician may only administer "abortion-inducing drugs" (i.e. medication abortion) if she does so consistent with "the protocol tested and authorized by the [FDA] and as outlined in the label for the abortion-inducing drug." N.D. Cent. Code § 14-02.1-03.5(2). The Clinic complies with the FDA label protocol. Eggleston Decl. ¶ 6.

III. H.B. 1336 and Its Amendment of Existing North Dakota Law.

H.B. 1336 changes this existing scheme by compelling physicians or their agents to orally tell women seeking an abortion 24 hours before their procedure 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 that "information and assistance with reversing the effects of an abortion-inducting drug are available in the printed materials" that the physician gives them. H.B. 1336, 1.11(b)(5). This applies even when patients are seeking surgical abortion. H.B. 1336 neither references nor amends

the North Dakota law requiring administration of medication abortion according to the FDA label protocol but instead requires physicians to tell patients about an unproven, experimental treatment, wherein the patient (1) takes mifepristone and (2) instead of taking misoprostol, takes large doses of progesterone in ways inconsistent with the FDA label protocol. *See infra* at 5-7.

H.B. 1336 also adds a new subdivision to the statute detailing the DOH-created, printed materials that abortion providers must give their patients that repeats the falsehood that abortion can be "reversed" and effectively requires physicians to *refer* patients for this highly controversial care. The materials "direct[] 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.*[1] H.B. 1336 does not provide a corresponding deadline to update the materials, and as of the date of this filing, DOH has not yet done so.

IV. The Scientifically Unsupported Abortion "Reversal" Theory.

Two physicians from southern California, George Delgado and Mary Davenport, have theorized that administering high doses of progesterone after the patient has taken mifepristone, but before she has taken misoprostol, can counteract mifepristone's effects and stop the medication abortion. As explained fully in the attached declaration from Dr. Courtney Schreiber, medication abortion cannot be "reversed," as no credible, scientific evidence supports the theory that mifepristone, misoprostol, or any abortion-inducing drugs can be "reversed." Schreiber Decl. ¶ 18; *see also* Eggleston Decl. ¶ 11; Wildey Decl. ¶ 8. Further, there is no credible, scientific evidence that if a patient takes mifepristone alone, progesterone treatments leads to a higher rate of continued pregnancy than simply doing nothing.

[1] Although H.B. 1336 refers to misoprostol as an abortion-inducing drug, the North Dakota Supreme Court has explicitly found that "misoprostol is not an abortion inducing drug." *MKB Mgmt. Corp. v. Burdick*, 855 NW 2d 31, 49 (2014).

Delgado and Davenport's theory of "reversal" is described in two flawed and ethically problematic papers they published in 2012 and 2018. Delgado and Davenport's 2012 paper describes seven patients and their 2018 paper discusses 754 patients who took mifepristone (but not misoprostol) and were then administered progesterone by a variety of providers. Serious methodological problems abound in both papers. Schreiber Decl. ¶ 36. Neither was published in a respected, peer-reviewed journal, and neither appears to have obtained the proper vetting for ethical research. Critically, neither paper used a control group comparing progesterone treatment against mifepristone alone—a fatal flaw given that mifepristone (without misoprostol) is known to have a high failure rate. Schreiber Decl. ¶¶ 14, 22, 31-32; Eggleston Decl. ¶ 11.

The 2012 paper claims that four of seven patients carried pregnancies to terms,[2] while the 2018 paper claims a "reversal" rate of 48%—a figure not significantly different from the 46% expected continued pregnancy rate after taking mifepristone alone. Schreiber Decl. ¶ 25; Eggleston Decl. ¶¶ 7, 11. Even this "success rate" was likely exaggerated because the papers lacked a control group and most patients were administered progesterone only after an ultrasound already confirmed ongoing fetal cardiac activity, meaning that the pregnancies were already predisposed to continue. Schreiber Decl. ¶ 26. Indeed, the authors admit that these pregnancies "may have survived without progesterone therapy." Schreiber Decl. ¶¶ 26, 33; Ex. C to Schreiber Decl. at 29. Additionally, the patients in the 2018 paper received progesterone according to ten different regimens, further limiting any interpretation of the results. Schreiber Decl. ¶ 34. The authors

[2] This tiny sample size alone precludes physicians from drawing any generally applicable conclusions from its results. The paper was also never reviewed and approved by an institutional review board—a formal group that monitors human research to protect the subjects' rights and welfare. Schreiber Decl. ¶ 24; Eggleston Decl. ¶ 11; Wildey Decl. ¶ 10.

themselves acknowledge that "further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed." Schreiber Decl. ¶ 42.[3]

Major medical organizations reject this supposed evidence that mifepristone can be "reversed." The American College of Obstetricians and Gynecologists ("ACOG")—the premier professional organization of women's health providers—has explained that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards," and that papers "with no control groups are among the weakest forms of medical evidence." Schreiber Decl. ¶¶ 19, 28. Indeed, the North Dakota chapter of ACOG opposed H.B. 1336 for this very reason. Ex. B. to Eggleston Decl. ¶ 15. Moreover, studies and editorials published in the last several years in highly respected journals, including a systematic review of the research on mifepristone "reversal," conclude there is insufficient evidence to determine if treatment with progesterone after mifepristone results in a higher rate of continued pregnancy. Schreiber Decl. ¶ 36.

V. Ethical Implications of H.B. 1336.

H.B. 1336 forces Physicians to violate the basic tenets of medical ethics, as well as the medical profession's cardinal treatise, the *Code of Medical Ethics of the American Medical Association*. *See* Wynia Decl. ¶¶ 3, 24-44; Madara Decl. ¶¶ 8, 12-34. Primarily, H.B. 1336 forces Physicians to breach their fundamental ethical duties to patients, including respect for patient autonomy and the duty to do no harm. Wynia Decl. ¶¶ 29-38. By forcing Physicians to tell their patients about an unproven, experimental medical treatment, H.B. 1336 undermines the basis of the doctor-patient relationship of trust and impedes patients' ability to make informed healthcare decisions. Wynia Decl. ¶¶ 24-28.

[3] The authors were forced to withdraw the 2018 paper after its initial publication. When the article was republished, the authors had rewritten the research methods to describe a fundamentally different research protocol from the original paper yet did nothing to change their methodology. Such a bait and switch is unheard of in reputable scientific publications. Schreiber Decl. ¶ 30.

H.B. 1336 also forces Physicians to provide information to their patients that is irrelevant and even potentially damaging to their patients. It requires Physicians to provide information about medication abortion "reversal" to *all* patients seeking abortion, even those who are not eligible for medication abortion or who have chosen to receive a surgical abortion. Wynia Decl. ¶ 34; Schreiber Decl. ¶¶ 9, 16, 49-51. Even for patients seeking medication abortion, H.B. 1336 actively undermines the informed consent process for abortion. Indeed, it may have the perverse effect of encouraging patients who may still be unsure of their decision to nonetheless consent and take mifepristone, under the mistaken belief that they can later change their minds. Wynia Decl. ¶ 33; Schreiber Decl. ¶¶ 56, 57; Madara Decl. ¶¶ 24-31.

Indeed, H.B. 1336 goes further and forces Physicians to actively refer their patients to providers who are willing to prescribe experimentally high doses of progesterone to reverse mifepristone. Eggleston Decl. ¶¶ 20, 21; Wildey Decl. ¶¶ 13-17, 22. Ethical principles of experimentation on human subjects, as well as federal law, require physicians to ensure that patients consent to and understand the full extent of a medical experiment. Wynia Decl. ¶¶ 40, 42; 45 C.F.R. § 46.201-207. Yet H.B. 1336 forces physicians to endorse and even refer their patients for care that amounts to ethical experimentation, giving the treatment a false air of legal and medical legitimacy. Wynia Decl. ¶¶ 39-43; Schreiber Decl. ¶¶ 18, 45, 52.

Finally, H.B. 1336 violates various central provisions of the *Code of Medical Ethics of the American Medical Association*. As explained in the attached declaration from Dr. James Madara, Chief Executive Officer and Executive Vice President of the AMA, H.B. 1336 violates numerous principles from the *Code of Medical Ethics*, including Physicians' obligations to: uphold fidelity to patients' welfare; build a relationship of trust with patients; maintain truthful and honest communication with patients; honor patients' requests not to receive information; further, rather

than undermine, patients' ability to provide informed consent; and prevent political matters from interfering with the delivery of professional care. Madara Decl. ¶¶ 12-34.

ARGUMENT

"The primary function of a preliminary injunction is to preserve the *status quo* until, upon final hearing, a court may grant full, effective relief." *Kan. City S. Transp. Co. v. Teamsters Local Union No. 41*, 126 F.3d 1059, 1066 (8th Cir. 1997) (quotation omitted). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *accord Sierra Club v. U.S. Army Corps of Eng'rs*, 645 F.3d 978, 989-98 (8th Cir. 2011). Plaintiffs meet this standard.

I. Plaintiffs are Likely to Succeed on the Merits of Their First Amendment Claim.

First Amendment free speech protections are at their zenith where, as here, the government controls the content of speech. *See Nat'l Inst. Of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) ("*NIFLA*"). H.B. 1336 violates Plaintiffs' free speech rights by forcing them to speak the government's message, with which they disagree, on a controversial topic, in violation of their professional judgment and ethical obligations to their patients.

A. Compelled Speech Regulations Like H.B. 1336 are Presumptively Unconstitutional and Subject to Heightened Scrutiny.

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). In recent years, the Court has further emphasized the "damage" done when "individuals are coerced into betraying their convictions." *Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, 138 S. Ct. 2448, 2464 (2018). Compelled speech forces individuals to tailor the *content* of their speech to the whims

of the government. *See NIFLA*, 138 S. Ct. at 2371 ("By compelling individuals to speak a particular message, such notices 'alte[r] the content of [their] speech.'" (quoting *Riley v. Nat'l Fed. of Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988))). Regulations that force speakers to alter the content of their speech are inherently dangerous and "presumptively unconstitutional." *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226-28 (2015).

Just last year, the Supreme Court held that these principles apply with full force to physician speech. In *NIFLA*, the Court considered a state law requiring, among other things, that licensed pregnancy centers "disseminate a government-drafted notice on site" by posting a notice in the waiting room and on materials provided to clients that the state offers eligible women free or low-cost access to family-planning services, including abortion. 138 S. Ct. at 2369. The Court made clear that "[s]peech is not unprotected merely because it is uttered by professionals," emphasizing the threat "of content-based regulations 'in the fields of medicine and public health, where information can save lives.'" *Id*. at 2371-74 (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011)). *NIFLA* clarified that because "[d]octors help patients make deeply personal decisions, and their candor is crucial," regulating the content of medical professionals' speech "pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information." *Id*. at 2374.

As in *NIFLA*, various courts of appeals have recognized that regulations constituting government "attempts to compel physicians to deliver its message, especially when that message runs counter to the physician's professional judgment and the patient's autonomous decision about what information she wants," violate the First Amendment. *Stuart v. Camnitz*, 774 F.3d 238, 255 (4th Cir. 2014) (invalidating North Carolina law compelling abortion providers to speak government message about pregnancy); *see also Wollschlaeger v. Governor of Fla.*, 848 F.3d

1293, 1311 (11th Cir. 2017) (en banc) (invalidating Florida law that prevented physicians from discussing gun ownership and safety with patients) (quoted in *NIFLA*, 138 S. Ct. at 2374); *Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002) (enjoining federal law that prohibited physicians from communicating with their patients about medical marijuana).

Here, H.B. 1336 compels physicians to speak in ways that are far more troubling and intrusive than the speech at issue in *NIFLA*. Primarily, it compels speech that is not only content-based but also speaker- and viewpoint-based. Indeed, it forces physicians providing abortions, and only those physicians, to adopt and disseminate a controversial government-approved message that abortion may be "reversible," contrary to their views and the consensus of the medical community. *See NIFLA*, 138 S. Ct. at 2378 ("Speaker-based laws run the risk that 'the State has left unburdened those speakers whose messages are in accord with its own views.'" (quoting *Sorrell*, 564 U.S. at 580))); *id.* at 2379 (Kennedy, J., concurring) (Viewpoint discrimination occurs when the "government seeks to impose its own message in the place of individual speech, thought, and expression."). Additionally, H.B. 1336 forces physicians to *orally speak* this controversial, government-scripted message (as opposed to passively posting a sign, as in *NIFLA*) during a process otherwise geared towards providing patients with informed consent. *See Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 457 (1978) (observing difference between written advertisements which "leave[] the recipient free to act . . . or not" and "in-person solicitation" which "may exert pressure and often demand[] an immediate response"). H.B. 1336 goes even further, forcing physicians to convey the government's message orally *and* through mandatory distribution of

state-created materials containing referrals to providers "who can aid in [abortion] reversal," H.B. 1336, § 2, despite Plaintiffs' belief that such care is unethical and harmful to patients.[4]

B. None of the Exceptions to Heightened Scrutiny Apply to H.B. 1336.

The Court in *NIFLA* noted it "has afforded less protection for professional speech in two circumstances," (1) for "regulations of professional conduct that incidentally burden speech," and (2) for uncontroversial commercial speech. 138 S. Ct. at 2372-73. Neither applies here.

First, the Court in NIFLA noted that "[l]ongstanding torts for professional malpractice . . . 'fall within the traditional purview of state regulation of professional conduct,'" *id.* at 2373 (quoting *NAACP v. Button*, 371 U.S. 415, 438 (1963)), as do some informed consent laws, *id.* (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992)). In *NIFLA*, the state law requiring pregnancy centers to disclose the availability of abortion did not fit within this exception because the mandatory "notice provide[d] no information about the risks or benefits of [medical] procedures." *NIFLA*, 138 S. Ct. at 2373. Likewise, H.B. 1336 is not a regulation of professional conduct. In *Casey*, the Court found that informing women twenty-four hours before the abortion of the "nature" and "risks" of the abortion procedure, the "probable gestational age" of the pregnancy, and the "medical risks associated with carrying her child to term" furthered the informed consent process. *See Casey*, 505 U.S. at 881-82; 18 Pa. Cons. Stat. § 3205(a)(1). Critically, this finding was supported by the fact that the plaintiffs' physicians were *already*

[4] Physicians' ability to disassociate themselves from the government's compelled message does not cure the constitutional violation. When the government compels speech by private actors—as opposed to forcing private actors to provide a space for government speech to occur—the ability to disassociate is, if anything, more evidence of harm, not less. *See, e.g.*, *Pacific Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 15-16 (1986) (forcing speaker to disassociate from government-mandated speech with which the speaker disagreed "is antithetical to the free discussion that the First Amendment seeks to foster"). Indeed, in *NIFLA*, the Court held the forced speech unconstitutional over the state's argument that the challenged law "leaves clinics entirely free to expressly disavow the notice." Br. for State Respondents at 43, *NIFLA v. Becerra*, 138 S. Ct. 2361 (2018) (No. 16-1140), 2018 WL 1027815.

providing this information to their patients as part of the informed consent process, even before the Pennsylvania law was enacted, and that the Pennsylvania law preserved room for physician judgment not to provide information if it would harm the patient. *See Casey*, 505 U.S. at 967.

By contrast, H.B. 1336 is entirely unrelated to "facilitat[ing] informed consent to a medical procedure," *see NIFLA*, 138 S. Ct. at 2373, and in fact *undermines* informed consent, as it forces physicians to convey a government-scripted message to their patients about a separate, unproven, controversial, and effectively experimental treatment. Compelling physicians to deliver such a message falls far outside *Casey*'s narrow definition of informed consent to an abortion procedure.

H.B. 1336 is also unrelated to informed consent for a more fundamental reason: Mainstream medical ethics, not state-specific legal definitions, define the contours of informed consent. *See* Madara Decl. ¶¶ 24-31; Wynia Decl. ¶¶ 22, 23, 31-34. H.B. 1336 not only requires physicians to breach the very ethical obligations towards patients on which informed consent is based, but it actually *undermines* physicians' ability to obtain informed consent from their patients. *See supra* at 8. A physician's ethical duty to ensure that patients provide "informed consent to a [specific] medical procedure," *NIFLA*, 138 S. Ct. at 2373, cannot be served by government-mandated disclosures that violate both the fundamental tenets of medical ethics (patient autonomy, beneficence, non-malfeasance, and justice) and the *AMA Code of Medical Ethics*, *see* Madara Decl. ¶¶ 12-31; Wynia Decl. ¶¶ 3, 29-38, 44.

Second, H.B. 1336 falls far outside the exception identified in *NIFLA* for commercial speech related to "purely factual and uncontroversial information." *See NIFLA*, 138 S. Ct. at 2372 (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985)). H.B. 1336 does not regulate commercial speech—e.g. speech related to solicitations for business or advertisements—but in any event, a lower level of scrutiny only applies to commercial

speech restrictions that involve "factual, noncontroversial" disclosures. *See id.; see also Am. Beverage Ass'n v. City & Cty. of S.F.*, 916 F.3d 749, 755 (9th Cir. 2019) (discussing application of lower level of scrutiny to commercial speech post-*NIFLA*). As discussed *supra* at 5-9, 11, H.B. 1336 is nothing if not controversial.

Indeed, far from purely factual and uncontroversial information, H.B. 1336 compels speech that, at worst, is an outright lie and, at best, is highly controversial. The consensus in the medical community, including from the country's leading medical organizations such as the AMA and ACOG, is that there is no evidence-based medicine supporting abortion "reversal." *See* Madara Decl. ¶ 4; Schreiber Decl. ¶¶ 16-47; Eggleston Decl. ¶¶ 14, 15; *supra* at 5-7. The controversial nature of the unproven theory of abortion "reversal" alone justifies heightened scrutiny. *See NIFLA*, 136 S. Ct. at 2372; *Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 249-50 (2d Cir. 2014) (striking down requirement to "address abortion, emergency contraception, or prenatal care at the beginning of their contact with potential clients" because it "alters the [speakers'] political speech" and "mandates discussion of controversial political topics").

C. Even if H.B. 1336 Were Understood as a Professional Regulation That Only Incidentally Affects Speech, It Would Still Fail Constitutional Review.

The Court in *NIFLA* declined to decide whether intermediate or strict scrutiny applied to compelled speech of medical professionals because the law at issue could not survive even intermediate scrutiny. *NIFLA*, 138 S. Ct. at 2375. Indeed, even assuming H.B. 1336 is a law incidentally affecting speech, courts after *NIFLA* have held that intermediate scrutiny applies. *Capital Associated Indus. v. Stein*, 922 F.3d 198, 207-09 (4th Cir. 2019) (explaining, post-*NIFLA*, "[f]or laws with only an incidental impact on speech, intermediate scrutiny strikes the appropriate balance between the states' police powers and individual rights."); *Otto v. City of Boca Raton*, 353 F. Supp. 3d 1237 (S.D. Fla. 2019) (same), *appeal filed*, No. 19-10604 (11th Cir. Feb. 14, 2019).

For the same reasons identified in *NIFLA*, this Court should apply at least intermediate scrutiny here. Under intermediate scrutiny, the government must prove that the law furthers an important government interest and is substantially tailored to furthering that interest. *See, e.g.*, *United States v. O'Brien*, 391 U.S. 367, 377 (1968) (applying intermediate scrutiny to law with incidental effect on speech). H.B. 1336 cannot meet even this standard.

First, the State cannot show an important, let alone compelling, reason why *all* patients seeking abortion must be informed by their physicians of an unproven procedure for "reversing" medication abortion. Rather than furthering a legitimate public health goal, information about "reversal" is misleading and irrelevant for most, if not all, patients. *See infra* at 5-8. While the state may have an important interest in ensuring that patients provide informed consent before a medical procedure, no such interest is present here, where the law undermines a physician's ability to obtain such consent and violates physicians' ethical obligations to their patients.

Second, even assuming the State could demonstrate an important interest in informing patients about "reversal," the State cannot show that H.B. 1336 is sufficiently tailored to serving that interest. As explained in *NIFLA*, the State could easily inform women about "reversal" "without burdening a speaker with unwanted speech," as "[most] obviously, it could inform women itself with a public-information campaign" or by "post[ing] the information on public property" near the Clinic. 138 S. Ct. at 2376 (citation omitted). Instead, the State chose to force physicians and their agents to *orally speak* the government message themselves and *actively facilitate* the provision of state materials and state-endorsed referrals. Such lack of tailoring is wholly deficient, particularly since "'[p]recision . . . must be the touchstone' when it comes to regulations of speech, which 'so closely touc[h] our most precious freedoms.'" *Id.* (quoting *NAACP v. Button*, 371 U.S. at 438 (alterations in original)).

D. In the Alternative, H.B. 1336 is Likely Unconstitutional Because It Forces Physicians to Speak Information That is Untruthful, Misleading, and Irrelevant to Their Patients.

Before the Supreme Court's decision in *NIFLA*, the Eighth Circuit had articulated a different standard that applied only 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 [1] untruthful, [2] misleading or [3] not relevant to the patient's decision to have an abortion." *Planned Parenthood Minn., N.D., & S.D. v. Rounds*, 530 F.3d 724, 735 (8th Cir. 2008) (en banc). That standard, however, is inconsistent with and implicitly abrogated by *NIFLA*, which rejected special rules for separate categories of speech. *NIFLA*, 138 S. Ct. at 2371-72. *NIFLA* makes clear that physicians do not lose their free speech rights just because they are speaking in a physician office or about abortion; to the contrary, the First Amendment applies with full force to speech by medical professionals, particularly on controversial topics. Plaintiffs thus need not meet the *Rounds* test. But even if *NIFLA* did not change the constitutional standard for compelled physician speech in this Circuit, H.B. 1336 is still unconstitutional under *Rounds*.

1. H.B. 1336 Forces Physicians to Speak a Government Message That is Untruthful.

As discussed *supra* at 5-7, H.B. 1336's message is untruthful. It is uncontested that no known protocol exists to reverse the effects of misoprostol. As to mifepristone, H.B. 1336 is premised on the unproven and, at best, experimental theory that an extended course of high doses of progesterone may reverse its effects—a theory rejected by every leading medical organization.

As an initial matter, the FDA—the national authority on the safety and efficacy of drugs—has not found that large doses of progesterone are either (1) safe to give to women after taking mifepristone or (2) effective at reversing mifepristone's effects to *any* degree. The FDA typically requires a series of clinical trials—usually with a control group to limit research bias—and the

trials usually must be supervised and approved by an institutional review board to protect the rights and welfare of the human subjects. Nothing remotely like that type of research has been done with progesterone to "reverse" mifepristone. Wynia Decl. ¶ 42. This is particularly troubling given North Dakota's requirement that physicians follow the FDA's protocol for the administration of medication abortion. *See* N.D. Cent. Code Ann. § 14-02.1-03.5(2).

Further, no credible scientific evidence supports the truthfulness of abortion "reversal." The theory that progesterone can potentially reverse mifepristone's effects is based on two isolated papers, neither of which establishes that administering progesterone after taking mifepristone is any more successful at continuing a pregnancy than simply taking mifepristone alone and which are both ethically and scientifically flawed. *See supra* at 5-7; *see also* Schreiber Decl. ¶ 25.

Finally, leading medical organizations and researchers agree that the two Delgado papers are methodologically and ethically flawed, meaning they cannot be relied upon to support the truthfulness of "reversal." Schreiber Decl. ¶¶ 22-38; Wynia Decl. ¶¶ 19, 42-43. In a similar case involving South Dakota's state-mandated message about a supposed link between abortion and breast cancer, a district court found the message untruthful and thus likely unconstitutional under *Rounds* because "national organizations with specialized expertise in cancer and reproductive health such as . . . the American College of Obstetricians and Gynecologists[] have reached a consensus that having an abortion does *not* increase patients' risk of breast cancer." *Planned Parenthood v. Daugaard*, 799 F. Supp. 2d 1048, 1072 (D.S.D. 2011).

So too here. Various properly controlled studies confirm that the theory of abortion "reversal" is just that—an unproven theory. *See supra* at 7. ACOG's view is that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards." Schreiber Decl. ¶ 19. The fact that the AMA, the largest professional association of

physicians, residents, and medical students in the United States, has not only taken a position on the issue but is a plaintiff in this case, speaks for itself. *See* Madara Decl. ¶¶ 5-7.[5]

2. H.B. 1336 Forces Physicians to Mislead Their Patients.

H.B. 1336 is also "misleading," *Rounds*, 530 F.3d at 735, because it misleads women into believing there is a medically sound protocol for reversing a medication abortion when no such protocol exists. Before taking mifepristone to begin an abortion, patients should understand the truth: That taking mifepristone and misoprostol will end their pregnancy, and that mifepristone can terminate the pregnancy on its own. Schreiber Decl. ¶ 13; Eggleston Decl. ¶¶ 11, 14. For this reason, physicians, including the Plaintiffs, do not provide patients with mifepristone unless and until their patients are confident in their decision to obtain an abortion. Eggleston Decl. ¶ 17; Kromenaker Decl. ¶¶ 8, 13. Yet, forcing physicians to give their patients a government-scripted message about "reversal" interferes with physicians' ability to obtain informed consent from their patients because it will have the perverse effect of encouraging patients to "consent" to abortion before they are ready, under the mistaken belief that they can later change their minds.[6]

3. H.B. 1336 Forces Physicians to Speak a Message That is Irrelevant to Their Patients.

Finally, H.B. 1336 forces physicians to speak a message that is not "relevant to the patient's decision to have an abortion." *Rounds*, 530 F.3d at 734. First, H.B. 1336 broadly applies to *all*

[5] The message's untruthfulness is in no way mitigated by the wording that it "*may* be possible" to reverse mifepristone. The phrase "may be possible," implies the existence of a protocol that is effective in some but not all cases, but as explained *supra* at 5-7, no such protocol exists. Moreover, patients will reasonably construe "possible" to mean "significantly probable" because they will assume their physicians are imparting meaningful information, rather than theoretical abstractions.

[6] Thus, to the extent the State may justify infringements on physician speech under the theory that it may use its regulatory authority to "encourage the patient to choose childbirth over abortion," *Rounds*, 530 F.3d at 735, by encouraging more women to start medication abortions, H.B. 1336 actually *undermines* this goal rather than furthers it.

abortion patients, even those who are not receiving a medication abortion. *See* Eggleston Decl. ¶ 9. For the 70% of the Clinic's patients receiving surgical abortions, Kromenaker Decl. ¶ 5, there is no logical reason to receive any information about "reversing" a treatment that they are not seeking in the first place. Second, H.B. 1336 is irrelevant even for patients seeking medication abortions. The vast majority of the Clinic's patients are sure of their decision, so information about so-called "reversal" is not relevant to them. Eggleston Decl. ¶ 16. Even for the small subset of women who are unsure of their decision, information about "reversal" cannot meaningfully aid in her decision-making because, as explained *supra* at 5-7, it is untruthful and misleading. *See* Wildey Decl. ¶ 21 (explaining that he would not counsel a patient having a tubal ligation or a hysterectomy of the remote possibility of reversing either procedure).

II. Physicians Will Suffer Irreparable Harm if H.B. 1336 is not Enjoined.

If the Act is not enjoined, Plaintiffs will suffer irreparable harm to their rights of free speech and will be forced to inflict harm on their patients in violation of their ethical obligations as physicians. It is well established by both the Eighth Circuit and the Supreme Court that a "'loss of [constitutional] freedoms . . . 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)). In violation of Plaintiffs' First Amendment rights, the Act will compel them to speak a government-mandated message with which they disagree, misinform their patients, and diminish the integrity of the medical field and physician-patient relationship. *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action*, 558 F.2d 861, 867 (8th Cir. 1977) ("Planned Parenthood's showing that the ordinance interfered with the exercise of its constitutional rights and the rights of its patients supports a finding of irreparable injury.").

Beyond the constitutional violation, H.B. 1336 will also irreparably harm physicians by forcing them to impose immediate harm on their patients. By providing their patients false and

misleading information, physicians will undermine, rather than further, their patients' ability to provide informed consent to abortion. *See supra* at 7-8.

III. The Balance of Equities and the Public Interest Favor an Injunction.

The balance of equities, as well as public interest, also weigh in favor of an injunction. As set forth above, absent an injunction, Plaintiffs will suffer irreparable harm to their constitutional rights and be forced to impose additional harms on their patients. Conversely, Defendants will not suffer any losses if H.B. 1336 is enjoined. "The primary function of a preliminary injunction is to preserve the status quo," which is precisely the result that would be achieved through an injunction in this case. *Ferry-Morse Seed Co. v. Food Corn, Inc.*, 729 F.2d 589, 593 (8th Cir. 1984).

Lastly, granting an injunction would be in the public's best interest because it "'is always in the public interest to prevent the violation of a party's constitutional rights.'" *D.M. by Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1004 (8th Cir. 2019) (quoting *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)). Protecting First Amendment rights is especially important to the public as they have the right to be informed, and particularly, not to be misinformed. *See ACLU v. Reno*, 929 F. Supp. 824, 851 (E.D. Pa. 1996) ("No long string of citations is necessary to find that the public interest weighs in favor of having access to a free flow of constitutionally protected speech.").

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court issue a preliminary injunction preventing enforcement by Defendants of H.B. 1336 pending final resolution of Plaintiffs' claims or further order of the Court, and further request that bond be waived.

Dated: June 25, 2019

Respectfully submitted,

/s/ Thomas A. Dickson

Thomas A. Dickson
DICKSON LAW OFFICE
P.O. Box 1896
Bismarck, North Dakota 58502
tdickson@dicksonlaw.com
(701) 222-4400

Brian D. Vandenberg*
Leonard A. Nelson*
Erin G. Sutton*
AMERICAN MEDICAL ASSOCIATION
Office of General Counsel
330 N. Wabash Avenue
Chicago, IL 60611
brian.vandenberg@ama-assn.org
leonard.nelson@ama-assn.org
erin.sutton@ama-assn.org

Counsel for Plaintiff American Medical Association

Molly Duane*
Marc Hearron*
Autumn Katz*
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, New York 10038
mduane@reprorights.org
mhearron@reprorights.org
akatz@reprorights.org
(917) 637-3631

Benjamin E. Marks
Steven A. Reiss
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
benjamin.marks@weil.com
steven.reiss@weil.com

Lauren Alexander
WEIL, GOTSHAL & MANGES LLP
1395 Brickell Avenue, Suite 1200
Miami, Florida 33131
lauren.alexander@weil.com

Counsel for All Plaintiffs

*Application for admission *pro hac vice* pending

CERTIFICATE OF SERVICE

I certify that on this 25th day of June 2019, I electronically filed a copy of the above document with the Clerk of the Court using the CM/ECF system, and personally served all Defendants.

/s/ Thomas A. Dickson
Thomas A. Dickson