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

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| AMERICAN MEDICAL ASSOCIATION, et al., | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | CASE NO. 1:19-cv-00125-DLH-CRH |
| | ) | |
| WAYNE STENEHJEM, et al., | ) | |
| | ) | |
| Defendants. | ) | |

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

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Nothing in the responses to Plaintiffs' motion undermines the showing that H.B. 1336 violates physicians' First Amendment rights. H.B. 1336 forces physicians to speak a message that they strongly disagree with, is unsupported by credible scientific evidence, misinforms and misleads patients, undermines informed consent, harms the patient-physician relationship, is unethical, and is irrelevant to most patients. It cannot survive *any* level of scrutiny. Defendant[1] incorrectly suggests this case is about "the conflict between two major sides of the contentious abortion debate." State of N.D.'s Mem. in Opp. to Pls.' Mot. for Prelim. Inj. ("Def.'s Resp.") at 6 [ECF 36]. It is not. This case is about the practice of medicine, not the availability of abortion. Supreme Court and Eighth Circuit precedent foreclose the State from turning physicians into mouthpieces for the State's controversial, misleading, and unethical abortion "reversal" message.

## I. Heightened Scrutiny Applies to H.B. 1336, and the Law Fails Under Such Scrutiny.

### A. Strict Scrutiny Applies Because H.B. 1336 Imposes More Than an Incidental Burden on Speech.

As Defendant does not dispute, content-based, viewpoint-based laws compelling speech on controversial topics are subject to strict scrutiny and presumptively unconstitutional. *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) ("*NIFLA*"); *see* Memo. of Law in Support of Pls.' Mot. for Prelim. Inj. ("Pls.' Mem.") at 9-10 [ECF 6-1]; Def.'s Resp. 8-9. Although Defendant tries to squeeze H.B. 1336 into an exception for regulations of professional conduct that only incidentally burden speech, H.B. 1336 cannot fit within that narrow exception.[2]

As explained in Plaintiffs' opening brief, H.B. 1336 is not an "informed consent" law. Pls.'

[1] Because Defendant Burdick relies on Defendant Stenehjem's merits arguments (Def. Birch Burdick's Resp. at 2-3 [ECF 35]), we refer herein to Mr. Stenehjem as "Defendant."

[2] While observing that strict scrutiny would apply to laws mandating "ideological" speech, Defendant argues that H.B. 1336 does not do so. Def.'s Resp. 13. Plaintiffs have not argued (for purposes of this motion) that it does.

Mem. 12-13. It "provides no information about the risks or benefits of" abortion or childbirth. *NIFLA*, 138 S. Ct. at 2373. It undermines, rather than furthers, informed consent by forcing physicians to speak, at worst, an outright lie and, at best, information about an unproven, controversial, and experimental treatment. It forces physicians to breach the ethical obligations on which informed consent is based. Decl. of Matthew Wynia ¶¶ 21-31 [ECF 18]; Decl. of James Madara ¶¶ 24-31 [ECF 6-5].

Nor is H.B. 1336 is an informed consent law just because Defendant or the State labels it as such. *See Stuart v. Camnitz*, 774 F.3d 238, 251-55 (4th Cir. 2014). Otherwise a state would be able to coopt physicians' voices and then evade heighted scrutiny by labeling forced-speech laws as "informed consent." Regardless of how Defendant characterizes H.B. 1336, it conflicts with the most basic principles of medical ethics and deviates sharply from informed consent.

Defendant's reliance (at 9-11, 20) on *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), is misplaced. Although Defendant quotes extensively from *Casey*, nearly all of his quotations—including his entire discussion of the State's purported interests—are from *Casey*'s analysis of whether the law at issue was an undue burden on patients' Fourteenth Amendment right to abortion.[3] That part of *Casey* is irrelevant here: this case involves physicians' First Amendment rights against compelled speech; it does not involve patients' rights to abortion.

The relevant part of *Casey*—its one-paragraph discussion of the physicians' separate First Amendment claim—does not support Defendant. After emphasizing that "the physician's First Amendment rights not to speak are implicated," the *Casey* Court concluded, without further analysis: "We see no constitutional infirmity in the requirement that the physician provide the

[3] Defendants cite similar language from *Gonzales v. Carhart*, 550 U.S. 124 (2007), ignoring that there was no First Amendment claim in that case. *See* Def.'s Resp. 11-12.

information mandated by the State *here*." 505 U.S. at 884 (emphasis added). The information mandated by the law in *Casey*, however, was not at all like H.B. 1336: the law in *Casey* "required physicians to inform their patients of the nature of the procedure, the health risks of the abortion and childbirth, and the probable gestational age of the unborn child." *NIFLA*, 138 S. Ct. at 2373 (quotation marks omitted). North Dakota's *existing* informed-consent law—without H.B. 1336—already includes virtually identical requirements to those upheld in *Casey*. *Fargo Women's Health Org. v. Schafer*, 18 F.3d 526, 532 (8th Cir. 1994) ("observ[ing] the close similarity between the North Dakota statute and the Pennsylvania statute at issue in *Casey*").[4] *Casey* provides no support for H.B. 1336's additional requirement that physicians speak a controversial, government-drafted script with which they strongly disagree. *See Stuart*, 774 F.3d at 251-52.

Defendant argues that rational basis applies under *Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 530 F.3d 724, 735 (8th Cir. 2008) (en banc). Def.'s Resp. 13-14. But he offers no response to Plaintiffs' contention that *NIFLA* abrogated that decision and similar decisions that undervalued physicians' First Amendment rights and improperly conflated the analysis of *physicians'* free speech rights with the standards applicable to *patients'* abortion rights. Defendant claims that the Fifth Circuit continues to rely on *Rounds* after *NIFLA*, but the only Fifth Circuit decision he cites is from seven years before *NIFLA*. Def.'s Resp. 12 & n.1

[4] *Compare* 18 Pa. Cons. Stat. § 3205(a)(1) (requiring physician to inform woman of: "[1] The nature of the proposed procedure or treatment and of those risks and alternatives to the procedure or treatment that a reasonable patient would consider material to the decision of whether or not to undergo the abortion; [2] The probable gestational age of the unborn child at the time the abortion is to be performed; [3] The medical risks associated with carrying her child to term."), *with* N.D. Cent. Code § 14-02.1-02(11)(a)(3)-(5) (requiring physician to inform woman of: "[1] The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility; [2] The probable gestational age of the unborn child at the time the abortion is to be performed; and [3] The medical risks associated with carrying her child to term.").

(citing *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570 (5th Cir. 2012)).

The Sixth Circuit's decision in *EMW Women's Surgical Center, P.S.C. v. Beshear*, 920 F.3d 421 (6th Cir. 2019), is also unhelpful to Defendant. That decision, which is not controlling here, involved a Kentucky law requiring physicians to perform a pre-abortion ultrasound. *EMW*, 920 F.3d at 423. The Sixth Circuit saw the Kentucky law as providing details necessary to the informed-consent process. *Id.* at 432, 444. By contrast, H.B. 1336 does not inform patients about the risks and benefits of the procedure; indeed, it *mis*informs patients. Pls.' Mem. 12-13.[5]

Defendant does not even attempt to show that H.B. 1336 can survive strict scrutiny. Plaintiffs therefore have shown that H.B. 1336 is likely unconstitutional.

### B. Even If H.B. 1336 Only Incidentally Burdened Speech, H.B. 1336 Cannot Satisfy The Intermediate-Scrutiny Standard that Would Apply.

Even assuming H.B. 1336 has only an incidental effect on speech, the correct standard would be intermediate scrutiny, not rational basis. *Casey* did not specify what level of scrutiny applies to laws that only incidentally affect speech. 505 U.S. at 884. The *NIFLA* Court stated only that the standard is something less than strict scrutiny. 138 S. Ct. at 2372. Cases decided after *NIFLA*, however, describe the appropriate standard as intermediate scrutiny. *Capital Associated Indus. v. Stein*, 922 F.3d 198, 207-09 (4th Cir. 2019); *see also Otto v. City of Boca Raton*, 353 F. Supp. 3d 1237, 1256 (S.D. Fla. 2019) ("applying intermediate scrutiny to medical treatments that are effectuated through speech"), *appeal filed*, No. 19-10604 (11th Cir. Feb. 14, 2019).

For the reasons explained in Plaintiffs opening brief, H.B. 1336 fails under intermediate scrutiny. Pls.' Mem. 15. H.B. 1336 is not tailored to an important government interest. Defendant

[5] *Rounds*, *Lakey*, and *EMW* all erroneously conflated *Casey*'s discussion of patients' abortion rights with physicians' First Amendment rights not to speak. *See, e.g.*, *EMW*, 920 F.3d at 450 (Donald, J., dissenting) (criticizing the panel majority for having "focused on the wrong provision of the Constitution" by citing portions of *Casey* that are "specific to the undue burden challenge in that case" rather than the First Amendment claim).

himself recognizes that the abortion "reversal" message is irrelevant to surgical abortion patients—the overwhelming majority of North Dakota abortion patients. *See infra* p. 10. Yet H.B. 1336 forces physicians to inform all *surgical* abortion patients about *medication* abortion "reversal." That clear lack of tailoring alone invalidates the statute under intermediate scrutiny.

## II. Alternatively, H.B. 1336 Forces Physicians to Speak Information That is Untruthful, Misleading, and Irrelevant to Their Patients.

The bulk of the State's argument is that H.B. 1336 is purportedly "constitutional under the *Rounds* rational basis standard of review." Def.'s Resp. 13-24. Under *Rounds*, a law compelling physician speech about abortion is unconstitutional if "the disclosure is *either* [1] untruthful, [2] misleading *or* [3] not relevant to the patient's decision to have an abortion." *Rounds*, 530 F.3d at 735 (emphasis added). H.B. 1336 cannot survive *any* of those criteria, much less all of them.

### A. Defendant Concedes that Abortion "Reversal" Is Unsupported by Scientific Studies and Has Been Rejected by the Medical Community.

Defendant does not contest that the effects of misoprostol cannot be reversed. And the State's own expert, Dr. Obritsch, agrees with Plaintiffs that there is no credible scientific evidence that mifepristone can be reversed, stating that the mifepristone reversal "theory" "is lacking rigorous scientific studies to support its efficacy." Decl. of Jerry Obritsch ¶ 49 [ECF 36-3].

Dr. Obritsch largely agrees with Plaintiffs' experts that the two isolated papers on mifepristone "reversal" are limited and insufficient. Dr. Obritsch agrees that leading medical organizations, including the American College of Obstetricians and Gynecologists, have rejected Delgado's studies as junk science. *Id.* ¶¶ 19, 36. He does not dispute that Delgado's claimed success rate of mifepristone "reversal" was likely exaggerated or that his "success" rate is essentially the same as the expected rate of continued pregnancy after taking mifepristone alone. Pls.' Mem. 6. He agrees that the best research is a clinical study with a control group, which Delgado's papers lack. *Id.* ¶¶ 21, 35. He confirms that Delgado's 2012 paper reviewed only six

patient cases, *id.* ¶ 35, and does not dispute that such a tiny sample cannot support scientific conclusions. Pls.' Mem. 6 n.2. Dr. Obritsch also explains that Delgado's 2018 paper was "a proposed case series study," and that "the scientific community requires and demands" that case studies be followed with "more rigorous scientific studies." Obritsch Decl. ¶¶ 35, 36.

Dr. Obritsch asserts that "[t]here are approximately 200 babies born nationwide after using the Abortion Pill Reversal (APR) protocol regarding the latest data," *id.* ¶ 22, while Dr. Vetter has treated only a single patient with progesterone that, in his view, "likely was at least partly responsible in that woman continuing her pregnancy," Decl. of Richard Vetter ¶ 19 [ECF 36-6]. But Defendant's experts do not contest that these continued pregnancies can just as easily be explained by the fact that nearly half of pregnancies continue after administration of mifepristone alone. Decl. of Courtney Schreiber ¶ 25 [ECF 16]; Decl. of Kathryn Eggleston ¶¶ 7, 11 [ECF 14]; *see also In re Baycol Prods. Litig.*, 596 F.3d 884, 891 (8th Cir. 2010) (explaining that temporal relationship usually does not establish causality).

Dr. Obritsch posits that using progesterone to prevent mifepristone's effects makes sense "[i]n theory," "is not ill-logical," and "may have merit." Obritsch Decl. ¶¶ 20, 38, 49. But that is not *evidence* that the theory is sound. Innumerable potential treatments that researchers believe may have merit in theory do not ultimately bear out as safe and effective when subjected to the rigors of clinical testing with a control group.[6]

The State argues that "[t]he clinical trials called for by the Plaintiffs simply are not realistic." Def.'s Resp. 17. To be clear, Plaintiffs are not "calling for" clinical trials. But the

[6] Supplemental Decl. of Courtney Schreiber ¶ 6 (attached hereto as Ex. A). Defendant suggests that because progesterone is a naturally occurring hormone in pregnancy, "common sense" dictates that large, artificial doses are also safe. Obritsch Decl. ¶¶ 17, 29, 31-34; Def.'s Resp. 19. But any naturally occurring compound—even water or Vitamin C—can be dangerous if administered in high enough doses. Schreiber Supp. Decl. ¶ 9.

difficulty of conducting a clinical trial is beside the point. The question under *Rounds* is whether the message is truthful, non-misleading, and relevant. *Rounds*, 530 F.3d at 735.

Implicitly conceding that no medically sound evidence supports the abortion "reversal" hypothesis, the State resorts to arguing that there is a "medical debate" and that the State gets to take sides in that debate. No such debate exists. *See* Obritsch Decl. ¶¶ 19, 36. Even if it did, the State would not get to force physicians to speak the State's preferred view. Tellingly, Defendant cites no First Amendment precedent for the proposition that a state legislature is free to take sides in a medical debate and force physicians to speak a controversial, medically uncertain message. *See* Def.'s Resp. 14-15. Even outside the First Amendment context, the Supreme Court has explained that "[t]he statement that legislatures, and not courts, must resolve questions of medical uncertainty is also inconsistent with this Court's case law." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2310 (2016). In any event, the North Dakota Legislative Assembly did not make any legislative findings about whether abortion can be "reversed."

### B. H.B. 1336 Forces Physicians to Provide Their Patients Untruthful or at Least Misleading Information.

The ability of physicians to have open, frank, and confidential communications with their patients is a fundamental tenet of medical care. Trust is foundational to the patient-physician relationship and critical to patient care. Madara Decl. ¶¶ 13, 18-19; Wynia Decl. ¶¶ 21-27. Patients rely on their physicians to give them relevant medical information and advice backed by science and tailored to the patient's unique needs. Yet H.B. 1336 forces physicians to give their patients unsound medical advice—that if the patient acts quickly, it may be possible to "reverse" a medication abortion. That is untrue and, at the very least, woefully misleading and injurious to the patient-physician relationship and to patient care. Wynia Decl. ¶¶ 23-37. H.B. 1336 thus cannot withstand even rational-basis review. *Rounds*, 530 F.3d at 735. Additionally, Defendants'

concession that leading medical organizations reject Delgado's studies (Obritsch Decl. ¶¶ 19, 36) alone makes the message untruthful or at least misleading, and thus unconstitutional. *Planned Parenthood Minn., N. Dakota, S. Dakota v. Daugaard*, 799 F. Supp. 2d 1048, 1072 (D.S.D. 2011).

Defendant's own arguments underscore the misleading nature of H.B. 1336. Dr. Obritsch openly concedes that referring to "reversal" is "somewhat *misleading* in that an abortion is not reversed but rather, abortion is prevented from occurring." Obritsch Decl. ¶ 17 (emphasis added). He explains that the progesterone treatment does not act by *reversing* the effects of mifepristone but "by *preventing* the antiprogesterone effect of mifepristone from exerting its effect upon the pregnancy." *Id.* (emphasis added). Even the State's strained explanation of H.B. 1336 is confusing: according to the State, the mandatory message "communicates that reversal of the effects of an abortion-inducing drug is not a certainty—yet, not an impossibility—while still suggesting a lack of probability." Def.'s Resp. 19 (emphasis omitted). Thus, Defendant cannot dispute that the specific language compelled by H.B. 1336 is inherently misleading.

The State puts enormous emphasis on the wording of the mandatory speech—that it "*may be possible* to reverse the effects of an abortion-inducing drug." *Id.* at 18-19. That does not cure the misleading and untruthful nature of the message. As the State concedes, "may be possible" communicates to the patient that reversing the effects of an abortion-inducing drug is "*not an impossibility*." *Id.* at 19. It tells the patient that a reversal protocol exists and that the protocol works in at least some, even if not all, cases. But as explained, there is no credible evidence that reversing an abortion-inducing drug is *ever* possible in *any* circumstance. The State can no more force physicians to speak this message than it could force them to tell their patients that it "may be possible" to cure cancer through hypnotherapy. *See* Schreiber Supp. Decl. ¶ 7.

The message that "time is of the essence" compounds the problems. Telling patients that "time is of the essence" misinforms them that an abortion-reversal protocol exists *and* that whether it will succeed depends on how quickly the patient acts. No part of that message is accurate. The message would mislead patients into believing they must decide quickly after taking mifepristone whether to try to reverse it, despite the absence of any supporting evidence.

Contrary to the State's suggestion (Def.'s Resp. 21-22), a physician's ability to inform her patient that she disagrees with the government-scripted message does not cure H.B. 1336's constitutional infirmity. H.B. 1336 does not expressly provide for physician disavowal, but even if disavowal is permitted, it would only further mislead patients. Being forced to give patients a message, followed by an explanation that the message is incorrect, is confusing and undermines physician candor and patient trust. Wynia Decl. ¶ 27. Even setting all that aside, the ability to disassociate from the message is not "relevant to the compelled speech analysis." *Rounds*, 530 F.3d at 737; *see Daugaard*, 799 F. Supp. 2d at 1072 (rejecting South Dakota's argument that a law mandating a misleading disclosure could be saved because "the physician is free to explain to the patient that this type of forced disclosure is untruthful or misleading").

Nor can H.B. 1336 be saved under rational-basis review by Defendant's assertion of the State's interest in protecting fetal life. Defs.' Resp. 10. That interest is irrelevant to physicians' free speech claim. *See supra* p. 2. Even if such an interest were relevant, H.B. 1336 does not further it. Defendant does not even address, let alone dispute, Plaintiffs' argument that forcing physicians to give their patients a government-scripted message about "reversal" will have the perverse effect of encouraging patients who may be on the fence about abortion to choose to take mifepristone under the mistaken belief that they can later change their minds. Pls.' Mem. 18; Eggleston Decl. ¶¶ 16-17.

### C. H.B. 1336 Forces Physicians to Speak an Irrelevant Message.

Finally, Defendant concedes that for the vast majority of patients—70% of which receive surgical abortions rather than medication abortions (Decl. of Tammi Kromenaker ¶ 5 [ECF 6-2])—H.B. 1336 forces physicians to give their patients irrelevant information. Defendant acknowledges that "[t]hose patients who undergo a surgical abortion . . . will deduce that the abortion reversal medical information *is not applicable to them* and merely discard the information." Def.'s Resp. 23 (emphasis added). That alone makes the statute unconstitutional under *Rounds*.

Defendant's response, that "it is not the intent of the State to know which patient will undergo a medical versus surgical abortion (nor is it the State's business to know)," Def.'s Resp. 22-23, is neither relevant nor credible. The State does not need to know which procedure a patient will receive in order to avoid forcing speech in categories of cases in which the speech is completely irrelevant. In any event, North Dakota law undermines this argument, as it prohibits patients beyond 10 weeks of pregnancy (measured from the first day of the woman's last menstrual period) from having medication abortions and also prohibits surgical abortions performed using a particular method. *See* N.D. Cent. Code Ann. § 14-02.1-03.5(2); H.B. 1546, 66th Leg. Assemb., Reg. Sess. (N.D. 2019). The State has thus made it very much "the State's business to know" what type of procedure an abortion patient receives.

## CONCLUSION

For the foregoing reasons and those in Plaintiff's opening brief, H.B. 1336 is likely unconstitutional. Defendant does not dispute that, once Plaintiffs show likelihood of success on the merits, Plaintiffs have also shown irreparable harm, that the equities favor injunctive relief, and that no bond should be required. Plaintiffs thus request that the Court preliminarily enjoin enforcement of H.B. 1336 pending final resolution of Plaintiffs' claims.

Dated: July 31, 2019

Respectfully submitted,

*/s/ Thomas A. Dickson*

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**CERTIFICATE OF SERVICE**

I certify that on this 31st day of July 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*
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