STATE OF NORTH DAKOTA
COUNTY OF CASS

IN DISTRICT COURT
EAST CENTRAL JUDICIAL
DISTRICT

MKB MANAGEMENT CORP, d/b/a RED RIVER WOMEN'S CLINIC, et al., Plaintiffs, vs. BIRCH BURDICK, in his official capacity as State Attorney for Cass County, et al., Defendants.	Civil No. 09-2011-CV-02205

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION

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INTRODUCTION

Currently, women seeking early abortions in North Dakota have two options. They can undergo a surgical abortion procedure or they can terminate the pregnancy by taking certain prescribed medications. Medication abortion is a safe, effective and common method of abortion used through nine weeks of pregnancy. The development and availability of medication abortion represents an advance in medical care for women.

During the 2011 session, the North Dakota Legislature enacted House Bill 1297 ("HB 1297" or "the Act") which, if allowed to take effect, will ban the provision of medication abortion. Under the Act it is illegal, upon pain of criminal punishment, to prescribe an "abortion-inducing drug" unless several conditions are met, including a requirement that the drug be prescribed in accordance with the "protocol tested and authorized by the federal food and drug administration." The language of HB 1297 demonstrates a fundamental lack of understanding on the part of the Legislature as to the FDA's role in approving prescription drugs for distribution in the United States. The result of that misunderstanding is that no abortion-inducing drug can meet the conditions imposed by the Act, and all medication abortions are therefore prohibited. The ban on medication abortions imposed by HB 1297 violates the rights of women to terminate a pregnancy, protected under the North Dakota Constitution. Even if the Act did not completely ban medication abortions, the requirements of HB 1297 are incomprehensible and the Act is hopelessly vague. In addition to these already fatal flaws, in passing the Act, the North Dakota legislature improperly ceded its constitutional responsibility to make the law, and created an impermissible special law.

HB 1297 serves no legitimate purpose. It will not advance the state's interest in protecting the health of women seeking abortions. Rather, it will foreclose the safe and effective option that medication abortion offers to North Dakota women, including women for whom medication abortion will better protect their health. No other North Dakota citizens are denied access to FDA-approved medications that their physicians believe are safe and effective. As a result, both Plaintiffs and their patients will suffer irreparable harm if the challenged provisions of HB 1297 are allowed to take effect. For all of the above reasons, this Court should preserve the status quo under which women can access medication abortions by issuing a temporary injunction pending final resolution of the serious constitutional issues raised by HB 1297.

STATEMENT OF FACTS

Plaintiff Red River Women's Clinic, ("the Clinic") located in Fargo, is the only abortion provider in the State of North Dakota. Kromenaker Aff. ¶ 4. Plaintiff Dr. Kathryn Eggleston, M.D., is the Clinic's medical director. Eggleston Aff. ¶ 3. The Clinic serves women who reside throughout North Dakota as well as women who travel from South Dakota and Minnesota. Kromenaker Aff. ¶ 4. Abortions are provided at the Clinic approximately four to six days per month. *Id.* at ¶ 5. Approximately 70% of the Clinic's abortion patients travel from more than two hours away and approximately 40-50% of the Clinic's abortion patients travel from at least four hours away. *Id.* at ¶ 4. The Clinic provides abortions through 16 weeks of pregnancy. *Id.* at ¶ 6.

Between the time that a pregnancy can be confirmed -- around four to five weeks-- and the ninth week, the Clinic offers women seeking abortions the option of a surgical procedure or a termination that is accomplished solely through the ingestion of prescribed

medication. *See id.* at ¶ 6. Both options are safe and effective, Eggleston Aff. ¶ 6, and the price for a surgical or medication abortion is the same. Kromenaker Aff. ¶ 8. Approximately 20% of the Clinic's abortion patients choose medication abortions. *Id.* at ¶ 7. Given the qualitative difference between surgical and medication abortion, a number of factors may come in to play for women deciding between the two. Some women prefer to avoid surgical abortion because they fear invasive procedures in general. *See id.* at ¶ 12; Eggleston Aff. ¶ 21. Some feel that medication abortion is more natural or more private. Kromenaker Aff. ¶ 12; Grossman Aff. ¶ 10.[1]

For women with certain medical conditions, surgical, as compared to medication, abortion may be more difficult and carry greater risk of both complications and failure. Eggleston Aff. ¶ 21; Grossman Aff. ¶ 10. For example, it is more difficult to adequately dilate the cervix to allow the passage of instruments used in surgical abortions in women with tightly closed or blocked cervixes. Eggleston Aff. ¶ 21. The size and body shape of severely obese women can also make surgical abortion difficult. *Id.* In these circumstances, medication abortion may be the safer and more effective option. If medication abortion were not available, the only option for some of the Clinic's patients would be a referral out of state for a more risky and expensive in-patient procedure. Eggleston Aff. ¶ 21.

The most commonly used means of inducing abortion using medication in the United States, and the one used by the Clinic, is the provision of the prescription drug

[1] Daniel A. Grossman, M.D., is an assistant Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. Grossman Aff. ¶¶ 1-2. He is also a Senior Associate with Ibis Reproductive Health, a nonprofit organization that conducts clinical and social science research concerning sexual and reproductive health.

mifepristone, in conjunction with another prescription medication, misoprostol. Grossman Aff. ¶ 11; Eggleston Aff. ¶ 8. Mifepristone, which is sold in the United States under the brand name Mifeprex, works by blocking the hormone progesterone, which is needed to maintain a pregnancy. Grossman Aff. ¶ 13. Misoprostol, which is sold in the United States under the brand name Cytotec, is a prostaglandin analogue that causes the cervix to open and the uterus to contract and expel its contents. *Id.* at ¶ 14. The availability of Mifeprex has resulted in a greater proportion of abortions taking place earlier in pregnancy than was the case previously. Eggleston Aff. ¶ 7.

Drug companies must obtain Food and Drug Administration ("FDA") approval to market a new prescription drug in the United States. The FDA does not itself test protocols or conduct clinical trials for new drugs, but rather reviews reports of studies submitted by drug manufacturers. Grossman Aff. ¶ 4. Nor does the FDA create the information that accompanies prescription drugs on the packaging or as a separate document. That information is drafted by the drug's manufacturer, who bears responsibility for it at all times. Rarick Aff. ¶ 11. When the FDA approves a drug for marketing, it also approves this Final Printed Labeling ("FPL"), which is an informational document that provides physicians with guidance about how to use a drug in accordance with how the drug sponsor requested and received FDA approval for its use. *See id.* ¶¶ 10-11; Grossman Aff. ¶ 4.

Neither the FPL nor any regulation of the FDA makes it illegal for a physician to prescribe approved drugs using other dosage and administration regimens or to use drugs for wholly different purposes than that for which a drug is labeled and marketed. Rarick

Aff. ¶ 14;[2] Eggleston Aff. ¶ 14. Indeed, this practice, known as "off-label" use, is not only common throughout the United States, but is part of responsible medical practice. Eggleston Aff. ¶¶ 14-18. The FDA has repeatedly acknowledged that off-label use is common and is sometimes required by good medical practice. *See* Rarick Aff. ¶¶ 14-17.

The FDA approved the marketing of Mifeprex for use to terminate a pregnancy in September 2000. Rarick Aff. ¶¶ 5, 8. Mifeprex is the only medication in the United States that has received FDA approval for marketing for the purposes of inducing first trimester abortions. *Id.* at ¶ 5. The FDA's approval was based on the agency's review of three clinical trials demonstrating the safety and efficacy of mifepristone, used in combination with misoprostol. *Id.* at ¶ 7. Misoprostol was already available as a prescription drug when the manufacturer of Mifeprex submitted its application, but it has never been labeled for use in medication abortions. Eggleston Aff. ¶ 39.

The Dosage and Administration information in the FPL for Mifeprex reflects the regimen used during the clinical trials for termination of pregnancy through 49 days: Day One, the patient reads the Medication Guide, signs the Patient Agreement, and receives three 200 mg tables of Mifeprex, taken orally at the health care facility; Day Three, the patient returns to the health care facility and, unless the abortion has already occurred, receives two 200 mg of misoprostol taken orally; Day 14, approximately fourteen days after the mifepristone was administered, the patient returns to the health

[2] Lisa D. Rarick, M.D., formerly worked at the FDA as the Director of the Division of Reproductive and Urologic Drug Products.

facility to confirm "that a complete termination of pregnancy has occurred." Long Aff. Ex. A (current Mifeprex FPL).[3]

Clinical studies conducted after the FDA approved Mifeprex have shown that other protocols ("evidence-based protocols"), including the one used by the Clinic, are superior to the Dosage and Administration information in the FPL. *See* Grossman Aff. ¶¶ 18-29. Studies specifically support the safety and efficacy of the protocol utilized by the Clinic, through 63 days of pregnancy, under which patients take 200 mg of Mifeprex at the Clinic, and self-administers 800 ug of misoprostol bucally (dissolving the pill against the gum) at a location of their choosing approximately 48 hours later. Grossman Aff. ¶¶ 19-24; Eggleston Aff. ¶¶ 8-10. As a result of the medical evidence, leading health organizations, including the American College of Obstetricians and Gynecologists and the World Health Organization, have recognized that evidence-based regimens for Mifeprex and misoprostol are safe and effective, are less expensive than the regimen in the Mifeprex FPL, and can have fewer side effects. Grossman Aff. ¶¶ 21-22.

All of the Clinic's abortion patients, whether surgical or medication, are given both oral and written aftercare instructions, and a follow-up appointment scheduled. Kromenaker Aff. ¶¶ 10, 13. Included in those instructions is a telephone number for patients to use 24 hours a day, seven days a week, if they have questions or concerns. *Id.* at ¶ 13; Eggleston Aff. ¶ 29. Complications from medication abortions are not common, and complications requiring emergency medical treatment are rare. Eggleston Aff. at ¶ 30; Grossman ¶ 30. Nevertheless, if a woman believes she needs emergency treatment or when she is advised by a health care professional to seek such treatment, she should

[3] Abigail A. Long is the Director of Marketing and Public Affairs for Danco Laboratories, LLC.

immediately proceed to a hospital that is nearby. The Clinic advises its patients accordingly. Eggleston Aff. ¶¶ 31-32; Kromenaker Aff. ¶ 16.

Until the enactment of HB 1297 singling out abortion, no off-label use of any drug was prohibited under North Dakota law, not even for medications that pose greater risks than Mifeprex. *See* Eggleston Aff. ¶ 13; *see also* Rarick Aff. ¶ 19. In fact, other provisions of North Dakota law seek to protect access to off-label use of medication. *See* N.D. CENT. CODE ANN. § 26.1-36-06.1 (2) (limiting the exclusion of insurance coverage for medications prescribed off-label).

THE MEDICATION ABORTION PROVISIONS OF HB 1297

House Bill 1297 consists of fourteen separate sections, which both amend and create new sections of the Abortion Control Act found within the North Dakota Century Code at § 14-02.1-01, *et seq*. House Bill 1297 completely bans the provision of medication abortions in North Dakota and its provisions are hopelessly vague. It also imposes unnecessary requirements that will undermine the ability of patients experiencing medical emergencies to access care. Violation of any these provisions of HB 1297 is a class A misdemeanor offense. N.D. CENT. CODE ANN. § 14-02.1-11.

Section 6 of HB 1297 provides, in relevant part:

> (2) It is unlawful to knowingly give, sell, dispense, administer, otherwise provide, or prescribe any abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in that pregnant woman, or enabling another person to induce an abortion in a pregnant woman, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician, and the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug.
>
> (4) Any physician who gives, sells, dispenses, administers, prescribes, or otherwise provides an abortion-inducing drug shall enter a signed contract

with another physician who agrees to handle emergencies associated with the use or ingestion of the abortion-inducing drug. The physician shall produce the signed contract on demand by the patient, the department of health, or a criminal justice agency. Every pregnant woman to whom a physician gives, sells, dispenses, administers, prescribes, or otherwise provides any abortion-inducing drug must be provided the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled. The physician who contracts to handle emergencies must have active admitting privileges and gynecological and surgical privileges at the hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

(5) When an abortion-inducing drug or chemical is used for the purpose of inducing an abortion, the drug or chemical must be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient.

HB 1297, Section 6 (creating a new section within N.D. CENT. CODE ANN. § 14-02.1).

House Bill 1297 provides the following definitions, in relevant part:

"Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion.

"Drug label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as "final printing labeling instructions", drug label is the federal food and drug administration document that delineates how a drug is to be used according to the federal food and drug administration approval.

HB 1297, Section 1 (amending N.D. CENT. CODE ANN. § 14-02.1-02).

ARGUMENT

North Dakota trial courts assess the following four factors when considering temporary injunctions: (1) substantial probability of succeeding on the merits; (2) irreparable injury; (3) harm to other interested parties; and (4) effect on the public interest. *Eberts v. Billings Cnty. Bd. Of Comm'r*, 2005 ND 85, ¶ 8, 695 N.W. 2d 691

(citations omitted). One purpose of a temporary injunction is to maintain the status quo until trial. *State v. Holecek*, 545 N.W. 2d 800, 804 (N.D. 1996); *see also Vorachek v. Citizen's State Bank of Lankin*, 461 N.W. 2d 580, 585 (1990) (in considering a preliminary injunction, a "court's discretion is exercised in light of preserving the status quo and protecting the rights of the applicant . . . .) (citation omitted).

A temporary injunction against enforcement of HB 1297 should issue in this case because Plaintiffs have a substantial probability of success on the merits of their claims and will suffer irreparable injury if the Act is not enjoined. In addition, an injunction would benefit the public interest and would not harm Defendants. Moreover, a temporary injunction will preserve the status quo, ensuring that women can receive safe and effective medication abortions through 63 days of pregnancy in North Dakota.

I. PLAINTIFFS HAVE A SUBSTANTIAL PROBABILITY OF SUCCESS ON THE MERITS OF THEIR CLAIMS AGAINST HB 1297.

A. HB 1297 VIOLATES THE RIGHTS OF WOMEN SEEKING MEDICATION ABORTIONS UNDER ARTICLE I, §§ 1 AND 12 OF THE NORTH DAKOTA CONSTITUTION

As the United States Supreme Court has repeatedly explained, central to the concept of the fundamental liberty right protected by the due process clause, and central to a woman's personal dignity and autonomy, is the freedom to choose whether to continue or terminate a pregnancy. *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 859, (1992) (included within the "fundamental rights comprised within the term liberty" is "the interest in independence in making certain kinds of important decisions" such as whether to choose an abortion) (citations omitted); *see also id.* at 847, 851-53, 857-860, 869, 871; *Stenberg v. Carhart* ("*Carhart I*"), 530 U.S. 914, 921 (2000)

("considering the matter in light of the Constitution's guarantees of fundamental individual liberty, this Court, in the course of a generation, has determined and then redetermined that the Constitution offers basic protection to the woman's right to choose") (citations omitted); *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) ("In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the "liberty" specially protected by the Due Process Clause includes the right[] to . . . abortion.") (citations omitted).

Like the federal constitution, the North Dakota Constitution contains a due process clause guaranteeing liberty. *See* N.D. Const. art. I, § 12. But the North Dakota Constitution also provides an additional, explicit and more expansive guarantee of the fundamental rights of liberty and personal freedom:

> All individuals are by nature equally free and independent and have certain inalienable rights, among which are those of enjoying and defending life and liberty; ... pursuing and obtaining safety and happiness....

N.D. Const. art. I, § 1. Thus, some rights protected by the guarantees of due process are additionally protected by Article I, § 1. *See, e.g., Hoff v. Berg*, 1999 ND 115, 595 N.W.2d 285 (explaining how parental rights to raise children found in due process clause of federal constitution can also be found in Article I, § 1 of North Dakota Constitution).

The North Dakota Supreme Court's discussion of Article I, § 1 reveals that a woman's fundamental right to choose falls under the guarantees it is designed to protect. As the court has explained, the right of pursuit of happiness:

> is not capable of specific definition or limitation, but is really the aggregate of many particular rights, some of which are enumerated in the constitutions, and others included in the general guaranty of liberty. . . . [I]t is clear that it must comprise personal freedom . . . 'liberty' of

> conscience, and the right to enjoy the domestic relations and the privileges of the family and the home.

State v. Cromwell, 9 N.W.2d 914, 918-19 (1943) (citation omitted);[4] *see also id.* at 918 (explaining that liberty includes "the opportunity to do those things which are ordinarily done by free men") (citation omitted).

Choosing whether to terminate a pregnancy implicates rights affecting personal freedom, familial decisions, conscience, and the opportunity to choose how to participate in society. *See Casey,* at 851 (right to choose abortion "involv[es] the most intimate and personal choices a person may make in a lifetime"); *id.* at 860 (describing the "concept of liberty" as "defining the capacity of women to act in society"); *id.* at 869 (explaining that the right of a woman to "retain the ultimate control over her destiny and her body" is "implicit in the meaning of liberty"). Indeed, a provision in the New Jersey Constitution virtually identical in relevant part to Article I, § 1, has been interpreted to protect the right to terminate a pregnancy. *See Right to Choose v. Byrne*, 450 A.2d 925, 934 (N.J. 1982) ("the right to choose whether to have an abortion . . . is a fundamental right of all pregnant women").

Although the North Dakota Supreme Court has not addressed the issue, given this expansive language, it logically follows that Article I provides even greater protection to the right to terminate a pregnancy than the federal constitution. As the North Dakota Supreme Court has explained, "[t]he history of our state constitution shows that the framers and the people of North Dakota intended to grant an array of basic individual rights broader than that guaranteed by the federal constitution." *State v. Herrick*, 1999

[4] The due process clause within Article I, § 12, protects and insures the exercise and enjoyment of rights defined and declared by Article I, § 1. *Cromwell*, 9 N.W.2d at 919. (At the time of *Cromwell*, the due process clause was § 13.).

ND 1, ¶ 51, 588 N.W.2d 847 (citation omitted). Indeed, North Dakota courts have so held. *See id.* (listing cases in which broader rights were found in the following categories: protection from takings for public use; right to counsel; jury trial rights; grand jury protections; right to appeal; protection from illegal searches; right to uniform application of laws; standing to challenge illegal searches). Notably, a determination of broader protection under the state constitution has often been based on more expansive state constitutional language, *see, e.g., Grand Forks-Traill Water Users, Inc. v. Hjelle*, 413 N.W.2d 344, 346 (N.D. 1987), thus supporting a determination that greater protection for a woman's right to choose is warranted under the state constitution. *See Right to Choose*, 450 A.2d at 933-34 (highlighting expansive language of provision virtually identical in relevant part to Article I, § 1 and declaring abortion restriction unconstitutional under state constitution despite United States Supreme Court authority to the contrary).

1. HB 1297 Unconstitutionally Bans All Medication Abortions

House Bill 1297 makes it unlawful to knowingly provide "any abortion-inducing drug . . . for the purpose of inducing an abortion" unless, *inter alia*, "the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug." HB 1297, Section 6. House Bill 1297 defines abortion-inducing drug as "a medicine, drug or any other substance prescribed or dispensed with the intent of causing an abortion." HB 1297, Section 1. The Act also changes the definition of abortion to mean "the act of using or prescribing any . . . drug . . . with the intent to terminate the clinically diagnosable intrauterine pregnancy of a woman . . . with

knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. . . ." HB 1297, Section 1.1 (amending N.D. CENT. CODE ANN. § 14-02.1-02).

Under these definitions, both Mifeprex and misoprostol are "abortion-inducing drugs." But while the Mifeprex Final Printed Labeling or FPL contains a regimen for use to induce abortion, the FPL for misoprostol does *not* contain a regimen for its use in inducing abortions. Eggleston Aff. ¶ 39. Yet all accepted regimens for the use of Mifeprex, the only drug that has been approved for marketing for first trimester medication abortion in the United States, *see* Rarick ¶ 5, include the use of misoprostol,[5] Eggleston Aff. ¶ 12. Thus, HB 1297 on its face prohibits all medication abortions because it would be illegal to use misoprostol and Mifeprex cannot be used without it.[6]

The test of the validity of a state law "is whether it violates any of the express or implied restrictions of the state or federal Constitutions." *Cromwell*, 9 N.W.2d at 918. House Bill 1297 bans all medication abortions. It therefore impermissibly interferes with a woman's right to terminate a pregnancy by denying access to a safe, effective, and common method of early abortion that is qualitatively different than the alternative of

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[5] Indeed, rather than delineating a protocol for use to induce abortion, the FPL for Cytotec repeatedly *warns* that its use may cause an abortion. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory.

[6] If HB 1297 does not ban the use of misoprostol, then the definition of "abortion-inducing drug" and all operative provisions that use that term fail to give adequate notice to Plaintiffs regarding what conduct is prohibited, further supporting Plaintiffs' argument that the Act is unconstitutionally vague. *See infra* Argument Section B; *See* Eggleston Aff. ¶ 38.

surgical abortion. This burden on the constitutional right to terminate a pregnancy guaranteed by Article I, §§ 1 and 12, *see supra* section A, is unconstitutional.

When a statute interferes with fundamental rights guaranteed by Article I, §§ 1 and 12, it is reviewed under the strict scrutiny standard. *See Hoff*, 1999 ND 115, ¶ 9-10, 595 N.W.2d 285; *B.H. v. K.D.*, 506 N.W.2d 368, 375 (N.D. 1993). In order to survive strict scrutiny, the state must demonstrate both that there is a compelling interest justifying the restriction and the restriction is necessary to accomplish the legitimate purpose. *B.H.*, 506 N.W.2d at 375.

There is no compelling reason—and no justification whatsoever—for banning medication abortions in North Dakota. Medication abortions are a safe, effective and common method for women to exercise their right to choose an abortion. Eggleston Aff. ¶ 6. The development and availability of medication abortion represents an advance in the provision of abortion services in this country by providing a safe alternative to surgical abortion. *See* Eggleston Aff. ¶¶ 6-7. No conceivable state interest, and particularly not an asserted interest in women's health, supports denying women in North Dakota access to medication abortion. Accordingly, Plaintiffs are likely to succeed on the merits of their claim that HB 1297 is unconstitutional for banning all medication abortions.

While restrictions on abortion are reviewed under the federal constitution applying an "undue burden" standard, that standard should not supplant the strict scrutiny standard employed under Article I, §§ 1 and 12. Given Article I, § 1's explicit and more expansive protection of fundamental liberties compared to the federal constitution, a more stringent, yet unexceptional, standard for review of a burden on a woman's right to

choose is warranted under the North Dakota constitution, with the result being that the ban on medication abortion is unconstitutional.

Even under the federal undue burden test, however, HB 1297 is unconstitutional. As the Supreme Court explained in *Casey*, "[a] finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion . . . ." 505 U.S. at 877. Here, the effect of HB 1297 is to deny access to a common, safe and effective means of terminating a pregnancy in the first trimester.

In *Carhart I*, the Supreme Court struck down a Nebraska abortion restriction, holding that because the law at issue effectively prohibited one of the most common pre-viability abortion methods, the statute unduly burdened "the right to choose abortion itself." 530 U.S. at 930 (quoting *Casey*, 505 U.S. at 874); *see also Gonzales v. Carhart* ("*Carhart II*"), 550 U.S. 124, 147 (2007) (explaining that defendant did "not dispute that the Act would impose an undue burden if it covered standard D & E," the most common second trimester abortion method).

Here, HB 1297 bans the provision of a medication abortion, which accounts for approximately 20% of the abortions performed by the Clinic.[7] Kromenaker Aff. ¶ 7. Denying women access to common, safe, and effective medical care that provides them with a non-surgical option not only poses a substantial obstacle, it is irrational. Women seeking to effectuate their decision to terminate a pregnancy cannot be arbitrarily denied access to the medical care that best meets their medical and personal needs. Thus, even

[7] *See also,* Jones, RK, Abortion Incidence and Access to Services in the United States, 2008, *Perspectives on Sexual and Reproductive Health*, 2011, 43(1):41-50 (first trimester medication abortions accounted for approximately 17% of all abortions in the United States in 2008).

applying the undue burden test, Plaintiffs have shown a substantial likelihood of success on their claim that the Act violates the constitutional rights of their patients seeking medication abortions.

2. Even If Construed to Permit Some Medication Abortions, HB 1297 Would Still Violate Article I, §§ 1 and 12.

On its face, HB 1297 bans all medication abortions. Defendants may nonetheless assert (albeit without textual support) that HB 1297 can be interpreted to allow some medication abortions – those provided in compliance with the FPL for Mifeprex.[8] Under such an interpretation, however, the Act still would violate Plaintiffs' and their patients' constitutional rights and must fall.

a. HB 1297 would ban safer and more effective regimens for the provision of medication abortion

Even if HB 1297 could be construed to permit medication abortions that followed the Mifeprex FPL, which it cannot be, the Act would prohibit well-tested evidence-based protocols, including the one used by the Clinic, that are safer, more effective, and less burdensome than that indicated on the Mifeprex FPL. Eggleston Aff. ¶¶ 9-10. Thus, HB 1297 would still create an unconstitutional burden on the right to choose an abortion.

The Mifeprex FPL directs that: 1) Mifeprex may be used to terminate a pregnancy only up to 49 days; 2) 600 mg of mifepristone is to be administered; and 3) 400 micrograms of misoprostol is to be administered orally at the health facility two days later. Grossman Aff. ¶ 16. Under the Clinic's protocol, medication abortions are available through 63 days, women are required to take only 200 mg of mifepristone, and women

[8]An interpretation that HB 1297 permits medication abortions that are provided by following the Dosage and Administration information in the FPL for Mifeprex would necessarily explicitly or implicitly include a finding that misoprostol is not an abortion inducing drug for purposes of the Act when taken after Mifeprex.

are allowed to self-administer 800 micrograms of misoprostol bucally at a location of their choosing. Eggleston Aff. ¶ 8.

Scientific evidence supports the use of the clinic's protocol as safer and more effective—and thus superior to—the one listed in Mifeprex's FPL. Eggleston Aff. ¶ 10; Grossman Aff. ¶¶ 18-29.[9] Not surprisingly then, the off-label evidence-based protocols for Mifeprex such as the one used by the Clinic, are used in the vast majority of medication abortions performed in the United States. Grossman Aff. ¶ 26.

The practice of prescribing medication off-label is an extremely common and accepted practice in the United States. Eggleston Aff. ¶¶ 14, 16; Rarick Aff. ¶ 14; Grossman Aff. ¶¶ 6-8. Indeed, the FDA itself has specifically stated that good medicine sometimes *requires* off-label use. For example, one FDA Guidance document notes that:

> Good medical practice and the best interests of the patient *require* that physicians use legally available drugs . . . according to their best knowledge and judgement (sic). If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, [and] to base its use on firm scientific rationale and on sound medical evidence . . . .

Rarick Aff. ¶ 17. Another states that:

> Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens . . . that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature. . . . [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling.

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[9] In addition to these benefits, the evidence-based protocol requires one fewer visit to the Clinic than the FPL for Mifeprex, which eliminates unnecessary burden and expense, particularly for women for whom an extra trip to the Clinic is particularly onerous—those who are in abusive relationships, who must travel a long distance to the Clinic, or who have very limited financial resources. Eggleston Aff. ¶ 24; Kromenaker Aff. ¶ 21. Moreover, the costs associated with the provision of two additional tablets of Mifeprex, as indicated in the FPL, is approximately $200. Kromenaker Aff. ¶ 23.

Rarick Aff. ¶ 15, Ex. B. Indeed, the FPLs for both Mifeprex and Cytotec recognize that both drugs are used off-label. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory (stating that "[v]aginal administration of Cytotec, outside of its approved indication, has been used as a cervical ripening agent, for the induction of labor and for treatment of serious postpartum hemorrhage in the presence of uterine atony"); Long Aff., Ex. A (Mifeprex Medication Guide p. 29) ("Medicines are sometimes prescribed for purposes other than those listed in a MEDICATION GUIDE.") And the North Dakota legislature itself has recognized the legitimacy of off-label use by, for instance, prohibiting insurance companies from denying coverage for off-label uses of prescription drugs where the off-label use is recognized by standard medical literature. N.D. CENT. CODE ANN. § 26.1-36-06.1.

Under HB 1297, however, doctors in North Dakota are prohibited from utilizing evidence-based protocols, thus denying women seeking medication abortions the benefits of these advances in medical care. Because there is no compelling or other justification for permitting one regimen for medication abortion, but banning *safer, more effective and more common regimens*, HB 1297 is an unconstitutional violation of a woman's right to choose an abortion, and Plaintiffs are likely to succeed on the merits of that claim.

b. HB 1297 is unconstitutional because it bans medication abortion for women between 50 and 63 days.

Studies have demonstrated that the evidence-based protocol used by the Clinic is safe and effective through 63 days of pregnancy. Eggleston Aff. ¶ 10; Grossman Aff. ¶

27. Approximately 40-50% of the Clinic's medication abortion patients seek medication abortions during that time. Kromenaker Aff. ¶ 7. The FPL for Mifeprex, however, refers to use of the drug for medication abortions only up to 49 days. Grossman Aff. ¶ 16. Accordingly, HB 1297 bans medication abortions between 50 and 63 days. Because such a ban significantly burdens a woman's right to terminate her pregnancy and there is no compelling (or any other) reason justifying such a restriction, Plaintiffs have shown a substantial likelihood of success on their claim that the Act violates their constitutional right to choose an abortion.

c. HB 1297 imposes an unconstitutional burden on women with certain medical conditions.

House Bill 1297 will prohibit all or some medication abortions in North Dakota. The Act makes no exception for circumstances in which a physician believes that medication abortion is a safer and more effective option than surgical abortion for a particular woman in order to avoid significant threats to the woman's health. This burden on women seeking abortions is impermissible under Article I, §§ 1 and 12.

Surgical abortions are accomplished by dilating, or opening the cervix, and passing instruments through the vagina and cervix and into the uterus. For women with certain medical conditions, insertion of instruments is more difficult and inherently more dangerous. In these situations, medication abortion is both safer and more effective. Eggleston Aff. ¶¶ 20, 21.

For example, female genital cutting, a cultural practice in some African, Asian and Middle Eastern cultures, can involve procedures that narrow the vaginal opening. In some instances, as a result of FGC, the vaginal opening is so small that a speculum used to open the vagina cannot even fit into the vagina to allow the insertion of dilators or

instruments. Eggleston Aff. ¶ 21. Similarly, if the opening to the cervix is small, narrow or scarred for other reasons, it prevents or complicates the passage of surgical instruments. *Id.* (explaining that this condition can be present with very young patients or patients who have been treated for precancerous and cancerous lesions on the cervix).

There are several other conditions that make medication abortion a safer and more effective option. For some women with abnormal uterine structures, a surgical abortion would require more time and additional insertion of instruments than for a woman with a normal uterus. If the uterus is tipped too far forward (severe antiflexion) or too far back (severe retroversion) it may be difficult or impossible for instruments to reach the uterus. For some obese women, longer and larger speculums may be needed which make the procedure more difficult and less successful. And for patients with conditions such as a severe seizure disorder or allergy to lidocaine, it may not be possible to perform a surgical abortion in an outpatient setting. *Id.*

For other women, medication abortion is preferred because the prospect of surgical abortion causes significant fear or anxiety. Victims of rape or sexual abuse may be unable to tolerate the examination and insertion of instruments into the vagina associated with surgical abortions. *Id.*

The possibility that women seeking abortions at the Clinic may have one of these conditions is not hypothetical. Dr. Eggleston has seen many of these conditions in her practice at the Clinic or other facilities. *Id.*

If HB 1297 bans all or some medication abortions, the alternatives for women for whom medication abortion is preferable—or necessary—due to a medical condition are not at all comparable. They can travel out of state to obtain a medication abortion, but

only if they are able to make arrangements to do so within the window when medication abortions are available. They can agree to undergo a more risky surgical procedure at the Clinic, if that is possible. If their conditions require a surgical abortion to be performed in a hospital, they would be forced to travel out of state and that procedure, which would involve higher levels of sedation and more instrumentation of the uterus, would pose higher risks of complications than a medication abortion. Eggleston Aff. ¶ 21. For some women, it is likely that none of these options will be available and they will be forced to carry the pregnancy to term.

The burden on women's health that will result if HB 1297 bans all or some medication abortions fails to meet the constitutional requirements of Article I, § 12, and also the applicable federal standard. There is no compelling reason or justification whatsoever for the State to endanger women's health. Moreover, federal courts have consistently held that laws that restrict access to abortion are unconstitutional unless they contain adequate exceptions to protect women's health. *Casey*, 505 U.S. at 846, 879-80. As the Supreme Court recently reiterated in reviewing a ban on so-called partial-birth abortions, "[t]he prohibition in the Act would be unconstitutional, under precedents we here assume to be controlling, if it "subject[ed] [women] to significant health risks."

Carhart II, 550 U.S. at 161 (quoting *Ayotte v. Planned Parenthood of Northern New. Eng.*, 546 U.S. 320, 328 (2006)) (further citations omitted).[10]

Accordingly, Plaintiffs have shown that they are substantially likely to succeed on the merits of their claim that HB 1297 violates a woman's right to terminate her pregnancy by prohibiting medication abortions even in situations where Dr. Eggleston or other physicians at the Clinic believe it would pose significantly less risk to the woman. *See also Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 511-12 (6th Cir. 2006) (affirming in part issuance of a preliminary injunction against restrictions on the use of mifepristone for medication abortion for failing to adequately protect women's health).

3. HB 1297's Back-Up Agreement Provision Is an Effective Ban on All Medication Abortions.

House Bill 1297 requires that physicians providing medication abortions "enter a signed contract with another physician who agrees to handle emergencies associated with the use or ingestion of the abortion-inducing drug," and that all medication abortion patients "must be provided the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled." HB

[10] The Supreme Court's ultimate determination that the federal statute at issue was not unconstitutional for lack of a health exception has little or no bearing on the issues before this court. The *Carhart II* Court made clear that its holding was based on the fact that plaintiffs had brought a facial challenge to the law. The Court noted that a "preenforcement, as-applied challenge[] to the Act can be maintained," and that "[t]his is the proper manner to protect the health of the woman if it can be shown that in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used." 550 U.S. at 167. Here, plaintiffs bring such as an-applied, preenforcement challenge, and moreover, have established that conditions that make the provision of medication abortion necessary to avoid significant health risks have and are likely to occur among the Clinic's patients.

1297, Section 6.4. The contract must be made available to the Department of Health and criminal justice agencies upon request. *Id.*

If allowed to take effect, this provision will act as a de facto ban on medication abortions because Plaintiffs cannot find a physician willing to enter into the required contract. Eggleston Aff. ¶¶ 34-36; Kromenaker Aff. ¶ ¶ 24-25. Plaintiffs have contacted several physicians, who have indicated that although they would otherwise likely be willing to enter into the required contract, they are not willing to do so because HB 1297 requires that their name and telephone number be provided to every medication abortion patient. Eggleston Aff. ¶ 35. The physicians have expressed concerns that they will face harassment, retaliation, or even violence from abortion opponents if their names and telephone numbers are distributed. *Id.* Such fears are well founded, as the Clinic and its staff, have endured threats, picketing and harassment from abortion opponents, and abortion providers in other states have likewise been subject to violent attacks and even killed. Kromenaker Aff. ¶ 26. In spite of their efforts to do so, as of the filing of this motion, the Plaintiffs have been unable to find a physician willing to enter into the contract required by HB 1297. Eggleston Aff. ¶¶ 35-36.

There is no legitimate reason for the State to institute this *de facto* ban. Patients are instructed how to reach Clinic staff 24 hours a day, seven days a week. Kromenaker Aff. ¶ 13; Eggleston Aff. ¶ 29. In the rare case of an emergency following a medication abortion, patients should immediately proceed to a hospital near them, Eggleston Aff. ¶¶ 31-32, where they will be treated as all emergency patients are, regardless of the existence of a back-up agreement. *See* 42 U.S.C. § 1395dd (popularly known as EMTALA) (requiring hospitals to provide a medical screening and stabilizing treatment

if necessary to all patients seeking care for emergency medical conditions); Grossman Aff. ¶ 30. Accordingly, requiring a back-up agreement with a physician (who could be located several hours away from the Clinic and/or the patient) serves no purpose. Plaintiffs have therefore shown a likelihood of success on the merits of their claim that Section 6.4 of HB 1297 violates the right of a woman to terminate her pregnancy under Article I, §§ 1 and 12.

4. HB 1297 Impermissibly Burdens the Right to Terminate a Pregnancy by Requiring Women to Receive Misleading Information.

As noted, HB 1297 requires that all medication abortion patients "be provided the name and telephone number of *the* physician who *will be* handling emergencies and *the* hospital at which any emergencies *will be* handled." HB 1297, Section 6.4 (emphases added); *see also id.*(referring to "*the* hospital designated to handle any emergencies associated with" medication abortion). This requirement is likely to result in patients receiving confusing and contradictory information concerning the handling of emergencies that could potentially endanger, not protect, their health and safety. Eggleston Aff. ¶¶ 28, 33.

All Clinic patients are provided both oral and written after-care instructions, including a telephone number for patients to use 24 hours a day if they have questions or concerns. Kromenaker Aff. ¶ 13; Eggleston Aff. ¶ 29. Medication abortion patients are instructed to call the Clinic if they experience an emergency or any of several listed symptoms. Kromenaker Aff. ¶ 14. In the rare instance that a true emergency arises, patients are instructed to immediately proceed to the closest health care facility. *Id.*at ¶ 17; Eggleston Aff. ¶ 29.

But HB 1297 requires the Clinic to tell patients that any emergency is to be handled by a specific physician and at a specific hospital irrespective of where the patient lives or is otherwise located when an emergency arises. This information contradicts the Clinic's current and medically appropriate instructions. If provided the information required under HB 1297, a patient experiencing an emergency may not immediately proceed to the nearest health care facility as is medically appropriate, but rather may travel to the hospital "designated" to treat such emergencies as required under HB 1297. Because the Clinic sees women from all over the State and from other states, Kromenaker Aff. ¶ 4, the designated hospital will not be the nearest health care facility for a significant number of the Clinic's patients. Accordingly, this provision requires that women receive misleading and potentially dangerous information about their options for emergency medical care.

The requirement that women receive misleading information that could undermine their health in medical emergencies violates the protections afforded to women seeking to terminate their pregnancies under Article I, §§ 1 and 12. Like its failure to provide an exception to the medication abortion ban for women whose health is threatened if they are denied such access, *see supra* Argument Section A.2.c., here again the State is imposing burdens on women's health with no compelling or even rational justification. Plaintiffs have therefore shown a likelihood of success on the merits of their claim that the Act violates §§ 1 and 12 of Article I of the North Dakota Constitution.

B. HB 1297 IS VOID FOR VAGUENESS.

The language of HB 1297 demonstrates a fundamental lack of understanding on the part of the legislature as to the FDA's role in approving prescription drugs for

distribution in the United States. The result of that misunderstanding is a law that is hopelessly vague.

The Supreme Court of North Dakota recently reiterated the due process standards applicable when a law is challenged on vagueness grounds:

> All laws must meet two requirements to survive a void-for-vagueness challenge: (1) the law must create minimum guidelines for the reasonable police officer, judge, or jury charged with enforcement of the statute; and (2) the law must provide a reasonable person with adequate and fair warning of the proscribed conduct. . . . A law is void for vagueness if "it either forbids or requires 'the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.' "

In re Maedche, 2010 ND 171, ¶ 14, 788 N.W.2d 331 (quoting *City of Fargo v. Salsman*, 2009 ND 15, ¶ 21, 760 N.W.2d 123 (additional citations omitted). "The degree of vagueness that the Constitution tolerates … depends in part on the nature of the enactment." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). Statutes that impose criminal penalties are subjected to a higher standard of certainty in their language than is applicable to other statutes. *See City of Belfield v. Kilkenny*, 2007 ND 44, ¶ 11, 729 N.W.2d 120 ("[T]he standard of certainty required in criminal statutes is more exacting than in noncriminal statutes.") (quoting *Barenblatt v. United States*, 360 U.S. 109, 137 (1959)). Moreover, the Constitution demands the greatest clarity from a statute where, as here, the "uncertainty induced by the statute threatens to inhibit the exercise of constitutionally protected rights." *Colautti v. Franklin*, 439 U.S. 379, 391 (1979) (citations omitted).

Here, the definitions and operative language of HB 1297 wholly fail to meet these standards, both in numerous particular aspects and taken as a whole. HB 1297 prohibits the use of abortion inducing drugs unless "the provision or prescription of the abortion-

inducing drug satisfies the protocol *tested and authorized* by the federal food and drug administration *and as outlined in the label* for the abortion-inducing drug." HB 1297, Section 6.2 (emphasis added). But these conditions make no sense, making it impossible for a reasonable person to know what conduct is prohibited under HB 1297.

1. HB 1297 Is Impermissibly Vague Because the FDA Does Not Test or Authorize Drug Protocols.

a. The FDA does not test drug protocols.

Although HB 1297 makes it unlawful for a physician to provide a medication abortion unless the prescription "satisfies the protocol tested" by the FDA, the FDA does not, in fact, test drug protocols. Rarick Aff. ¶ 8; Grossman Aff. ¶ 4. When a drug manufacturer seeks to market a prescription drug, it submits a new drug application ("NDA"), test results and proposed product labeling to the FDA. The FDA reviews those submissions and if it determines that the drug's benefits outweigh its known risks, the drug is approved for marketing. *See* U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, (Feb. 22, 2010), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm.

Thus, taken literally, HB 1297's requirement that medication abortions be provided under the protocol "tested . . . by the federal food and drug administration" is a complete prohibition on medication abortions. If HB 1297 is not intended to be read literally, then the criminal act proscribed is not definite, and HB 1297 does not give physicians adequate and fair notice of which acts are prohibited.

b. The FDA does not authorize protocols.

Similarly, HB 1297 makes it unlawful for a physician to prescribe an abortion-inducing drug unless the "protocol" has been "authorized" by the FDA. HB 1297,

Section 6.2. Just as the FDA does not test drug protocols, it does not "authorize" protocols for prescribing medications. Rarick Aff. ¶ 8. As discussed above, the FDA will approve an NDA if the application demonstrates that the drug is safe and effective for its proposed use and its benefits outweigh its risks. Approval of a new drug application simply permits the drug sponsor *to advertise and promote* the drug for the use and in the way that the sponsor sought approval. *Id.*; *see also Grossman* ¶ 4.

FDA approval of an NDA regarding how a drug can be marketed cannot be equated with "authorizing" a protocol. Not only does the FDA lack authority to authorize uses, it has repeatedly recognized the importance of drugs being used in ways that differ from and go beyond the use for which marketing permission was sought and received. Rarick Aff. ¶¶ 14-17.

Indeed, rather than authorizing any particular use of a drug, the FDA has repeatedly recognized the benefits of off-label use of drugs, even stating that good medical practice sometimes *requires* the use of a drug off-label. *See supra* Argument Section I.A.2.a. Such recognition by the FDA signifies that its approval to market a drug in a certain way according to the FPL submitted by the drug sponsor should *not* be interpreted as the FDA authorizing any particular use or dosage of a drug. Indeed, the FDA lacks the authority to "authorize" any particular use of or protocol for a drug, for such an act would be regulating the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) (explaining that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, and that off-label use is generally accepted) (citation omitted); *see also U.S. v. Evers*, 643 F.2d 1043, 1049 (5th Cir. 1981) (federal government, agreeing with defendant physician, that the FDA does

not have the authority to prevent a physician from prescribing approved drugs for unapproved uses). As the agency itself has explained:

> Once (an approved) new drug is in a local pharmacy . . . , the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.

Id. at 1048 (quoting 37 Fed.Reg. 16503 (1972)).

House Bill 1297's requirement that medication abortions be provided under the protocol "authorized . . . by the federal food and drug administration" appears to be a complete prohibition on medication abortions. If HB 1297 is not intended to be read literally, then it is impermissibly vague, as it does not provide adequate notice as to what conduct is permissible and what conduct is prohibited.

2. HB 1297's Requirement That Abortion-Inducing Drugs Be Prescribed Only As "Outlined in the Label" Is an Incomprehensible Condition.

House Bill 1297 prohibits the use of abortion inducing drugs unless the physician "satisfies the protocol … outlined in the label for the abortion-inducing drug." HB 1297, Section 6.2. But this condition makes no sense. HB 1297 defines "drug label" as:

> the *pamphlet* accompanying an abortion-inducing drug which outlines *the protocol tested and authorized* by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as *"final printing labeling instructions,"* drug label is the *federal food and drug administration document* that delineates how a drug is to be used according to the federal food and drug administration approval.

HB 1297, Section 1 (amending N.D. CENT. CODE ANN. § 14-02.1-02). As with other provisions in HB 1297, this language demonstrates the Legislature's unfamiliarity with the role and processes of the FDA, and, as a result, HB 1297 is impermissibly vague.

The definition of "drug label" refers to the "the pamphlet accompanying an abortion-inducing drug." There is, however, no document named or even commonly known as a "pamphlet" that accompanies Mifeprex or Cytotec. Eggleston Aff. ¶ 40; Rarick Aff. ¶ 12.

Similarly, it is not clear what the definition of drug label is referring to by "final print*ing* labeling *instructions*"—there is no such document. Eggleston Aff. ¶ 40; Rarick Aff. ¶ 12. The final printed labeling ("FPL") for Mifeprex, for example, consists of four distinct parts: Prescribing Information, Medication Guide, Patient Agreement, and Prescriber's Agreement. Long Aff. ¶ 3. The document, however, is not called the "final printing labeling instructions," nor is any subpart of that document identified as "instructions." Similarly, the Cytotec FPL does not contain the word "instructions." *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory.

Further, HB 1297 defines "drug label" as "the federal food and drug administration document." But neither a drug's FPL, nor any subpart of it, is an FDA document. As noted, the drug sponsor bears responsibility for creating the FPL and submitting it to the FDA for approval. Rarick Aff. ¶ 11. The scope of the uses and dosage and administration regimens submitted for approval are determined by the manufacturer. The FDA is not mentioned anywhere within the labeling.

Individually and taken together, these provisions again demonstrate that HB 1297 operates either as a complete ban on abortion or that its provisions fail to provide the required guidance to health care providers and enforcement officers of what is prohibited by the Act.

3. HB 1297 Is Impermissibly Vague Because FPLs Are Not Drafted with the Precision Required of Criminal Statutes.

Even if the language of HB 1297 could be interpreted to refer to the FPL or parts of the FPL for any abortion-inducing drug, the Act as-applied to Mifeprex and misoprostol is impermissibly vague because the FPLs for those drugs lack the precision required of a criminal statute.

As noted, drug labeling is not created by a government agency, but by private entities that bear responsibility for the content. They are drafted for the purpose of providing a range of information to the public. *See* Rarick Aff. ¶ 11. They are not intended to function as laws or regulations, *see id.* ¶ 13, and even a cursory review demonstrates that the content of FPLs for drugs that may come within the definition of "abortion-inducing drugs" lack the necessary clarity required of criminal statutes.

For example, a provision within the section of the Mifeprex FPL entitled "Prescribing Information" states that the physician must "be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary." Long Aff., Ex. A. It is not clear how a physician could "assure" patient access, which is governed by third parties, including medical facilities and the patient herself, while a medication abortion is occurring. Even if a physician does attempt to determine how far a woman lives from a hospital, her access to transportation, and other factors, such as winter weather, in order to determine whether the patient has access,

there is no way for the physician to know whether that assessment will be adequate in the eyes of prosecutorial authorities.

The Dosage and Administration section for Mifeprex is also ambiguous in that it states: "Day 14: Post-Treatment Examination. Patients *will return* for a follow-up visit *approximately* 14 days after the administration of Mifeprex." *Id.* (emphasis added). The Clinic instructs all patients to return for a follow-up visit. While many patients do return, the show rate is less than one-hundred percent, Eggleston Aff. ¶41, which is common nationwide. Grossman Aff. ¶¶ 32-33. Under this statute, a physician could be held criminally liable for the inaction of a patient even if the physician takes all possible steps to inform the patient of the obligation to return.

That language also fails to give adequate guidance about what would be an acceptable time range to meet the requirement of having the follow-up visit "approximately" 14 days after mifepristone is administered. Is three days to 21 days acceptable, or only 13 to 15? Terms like "approximately" illustrate why it is not only inappropriate—but a violation of due process—to attempt to define criminal conduct by reference to a privately controlled document written for a wholly different purpose.

In sum, HB 1297 is riddled with flaws that render it either a complete ban on medication abortion or virtually incomprehensible. Plaintiffs have therefore established a substantial likelihood of success on their claim that HB 1297 is impermissibly vague.

C. HB 1297 IS AN UNCONSTITUTIONAL DELEGATION OF LEGISLATIVE AUTHORITY.

The Legislature has authority to delegate certain functions to administrative agencies and other bodies, but it cannot delegate its power to make a law. *North Dakota Council of School Adm'rs v. Sinner*, 458 N.W.2d 280, 286 (N.D. 1990). "The true

distinction between the powers which the Legislature may delegate and those which it may not is to be determined by ascertaining whether the power granted gives authority to make a law or whether the power pertains only to the execution of the law which was enacted by the Legislative Assembly." *Ralston Purina Co. v. Hagemeister*, 188 N.W.2d 405, 411 (N.D. 1971). In passing the provision criminalizing provision of abortion-inducing drugs unless, among other things, "the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration," the Legislature impermissibly delegated its authority to make law to the FDA and, more accurately, to private parties. The law is therefore unconstitutional and its enforcement should be enjoined.

As set forth above, approval to market a new drug in the United States starts with the filing of a new drug application or NDA by a drug manufacturer. If the NDA is approved, the product label submitted by the drug manufacturer to the FDA is also reviewed and approved, and then becomes the FPL. By its wholesale incorporation of the current and any future FPL for abortion-inducing drugs to define the scope of criminal conduct, the Legislature has delegated to the FDA the power to make the law concerning the permissible regimen for providing medication abortions, not merely the power to execute the law. Indeed, because an FPL is a document drafted and submitted by drug manufacturers, for which the drug company bears responsibility, Rarick Aff. ¶ 11, the conduct to be criminalized will be determined largely by private companies. HB 1297 thus impermissibly delegates legislative authority not really to the FDA, but to the private companies that control the FPLs for abortion-inducing drugs.

Further, for a law that delegates legislative authority to meet the requirements of the North Dakota Constitution, and the law must "set forth reasonably clear guidelines" concerning how the authority is to be exercised, *Sinner*, 458 N.W.2d at 286. *See also Trinity Medical Ctr. v. North Dakota Bd. of Nursing*, 399 N.W.2d 835, 843 (N.D. 1987) ("[T]he vesting in other bodies of some powers ordinarily exercised by the Legislature is not unconstitutional *so long as the Legislature itself fixes the guidelines within which such powers will be exercised.*") (emphasis added). The delegated authority must also be subject to "adequate standards and procedural safeguards" so that they are not given uncontrolled discretion. *See Sinner*, 458 N.W.2d at 285; *Trinity Medical Ctr.*, 399 N.W.2d at 844.

Here, HB 1297 delegates authority to make *criminal* law to the FDA and to drug manufacturers without setting forth *any* standards or guidelines as to how the delegated authority is to be executed. Nor are there procedural safeguards in place. The process leading to approval of the FPL for an abortion-inducing drug involves communication between the drug sponsor and the FDA; it does not provide for public participation. *C.f. Trinity Medical Ctr.*, 399 N.W.2d at 844 (statute was not an unconstitutional impermissible delegation of legislative authority because public hearings were required before rules, regulations or standards were adopted).[11] Accordingly, Plaintiffs have shown a likelihood of success on the merits of their claim that HB 1297 should be invalidated as an unconstitutional delegation of legislative authority to the FDA and private companies.

[11] The absence of adequate standards and procedural safeguards is particularly troubling in the context of a criminal law, where there should be a heightened concern for impermissible delegation of the Legislature's authority to define criminal conduct.

D. HB 1297 IS AN UNCONSTITUTIONAL SPECIAL LAW.

The North Dakota Constitution prohibits the Legislature from enacting "special laws." N.D. Const. art. IV, § 13. A law that relates to "particular persons or things" within a class is a special law. *Teigen v. State*, 2008 ND 88, ¶ 12, 749 N.W.2d 505. By contrast, "a statute is not special, but general, if . . . [i]t operates alike on all persons and property similarly situated . . . . In other words, it operates alike in all cases where the facts are substantially the same." *Id.* (quoting *Bellemare v. Gateway Builders, Inc.*, 420 N.W.2d 733, 739 (N.D. 1988)) (internal quotation marks and further citations omitted).

The standard used to review statutory classifications under the special law provision is "reasonableness." *Id.* at 510 (citing *Best Products Co.*, 461 N.W.2d at 99). The North Dakota Supreme Court has invalidated laws under the special laws provision where it determines that the legislature has created arbitrary classifications that do not serve the purposes of the statute. *See Angell v. Cass County*, 91 N.W. 72, 74 (N.D. 1902) (striking down law that gave certain tax enforcement powers to officials in only some counties); *In re Connolly*, 117 N.W. 946 (N.D. 1908) (striking law that placed different rules regarding elections on counties with populations of more than 6,500 inhabitants and those with fewer).

House Bill 1297's classification scheme, under which medication abortions are singled out for restriction, is not reasonable. HB 1297 classifies on the basis of whether a drug is used to induce an abortion; it requires physicians to use a certain protocol and enter into a back-up agreement with another physician for the handling of emergencies when drugs are used to induce an abortion. HB 1297, Section 1(2), (4), Section 6. It does not, however, place those requirements on physicians using the *same drugs* for

different purposes. Eggleston Aff. ¶ 26. There is no reasonable basis for this distinction. Indeed, the only governmental purpose for which that classification *would not* be arbitrary would be for the goal of targeting and reducing access to medication abortion.

That the classification that HB 1297 creates does not "stand[] on reasons related to the character of the legislation challenged," *MCI Telecomm. Corp. v. Heitkamp*, 523 N.W.2d. 548, 554 (N.D. 1994), is further demonstrated by the safety and effectiveness of medication abortion. Presumably the purpose of the Act is to protect patient health. The abortion-inducing drugs used by the Clinic, and the protocol it employs, are common, safe and effective. Eggleston Aff. ¶¶ 6, 8; Grossman Aff. ¶ 20. In addition, the use of other drugs with similar risk profiles that are used off-label —and even ones that are *more dangerous*— Rarick Aff. ¶ 19—are not subject to such restrictions. Because there is no "substantial distinction, having reference to the subject-matter of the proposed legislation, between the objects or places embraced in such legislation and the objects or places excluded," HB 1297 is an impermissible special law. *See In re Connolly*, 117 N.W. at 948.

In addition to treating physicians' prescription of these medications, only for the purpose of inducing abortion, differently from other procedures, HB 1297 treats women seeking medication abortions differently from patients receiving other medications. This classification reduces health care choices, and therefore burdens access, only for women seeking a particular treatment. The Act's creation of these differing burdens, *see Angell*, 91 N.W.2d at 74, further demonstrate that HB 1297 is an unconstitutional special law and that Plaintiffs have established a probability of success on this claim.

II. PLAINTIFFS AND THEIR PATIENTS WILL SUFFER IRREPARABLE HARM IF HB 1297 GOES INTO EFFECT.

Plaintiffs have demonstrated that enforcement of the challenged provisions of HB 1297 will result in multiple violations of their constitutional rights and those of their patients. A temporary injunction "is designed to protect people by preventing unlawful acts which are against public policy and cause irreparable injury to civil or property rights or privileges of the people." *State ex rel. Holloway v. First Am. Bank & Trust Co.*, 186 N.W. 2d 573, 576 (N.D. 1971), (citing *State ex rel. Burgum v. Hooker*, 87 N.W.2d 337 (N.D.1957)). Here, a temporary injunction is necessary to protect plaintiffs and their patients from the irreparable injury they will suffer from the denial of their civil rights if the medication abortion provisions of HB 1297 take effect.

It is well established that in cases involving deprivation of constitutional rights, no further showing of irreparable injury is necessary. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976) (loss of constitutional "freedoms . . . unquestionably constitutes irreparable injury"); *Planned Parenthood of Minn., Inc. v. Citizens for Cnty. Action*, 558 F.2d 861, 867 (8th Cir. 1977) (plaintiff's showing of interference "with the exercise of its constitutional rights and the rights of its patients supports a finding of irreparable injury"); 11A Charles Alan Wright, Arthur R. Miller, Mary Kay Kane & Richard L. Marcus, *Federal Practice and Procedure* § 2948.1 (2d ed. 1995) ("When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary."). Moreover, a threatened violation of a woman's constitutional right to have an abortion "mandates" a finding of irreparable injury because "once an infringement has occurred it cannot be undone by monetary relief." *Deerfield*

Med. Ctr v. City of Deerfield Beach, 661 F.2d 328, 338 (5th Cir. Unit B 1981) (citing *Planned Parenthood of Minn.*, 558 F.2d at 867) (further citation omitted).

In addition to the deprivation of constitutional rights that will ensue should the challenged provisions be allowed to take effect, Plaintiffs' patients seeking medication abortions will be denied access to medical care that is safe and effective. These patients will be forced to forego their preferred method of abortion or forced to accept medical care that their physician does not believe is in their best medical interests. Eggleston Aff. ¶ 19. This deprivation will have a particularly harsh impact on women with medical conditions that make surgical abortion significantly more risky. *See id.* at ¶¶ 19-21. This additional irreparable injury further supports the issuance of a temporary injunction.

III. DEFENDANTS WILL NOT BE HARMED AND THE PUBLIC INTEREST WILL BE SERVED IF THE MEDICATION ABORTION PROVISIONS OF HB 1297 ARE ENJOINED.

Defendants will suffer no harm if a temporary injunction is granted. The only possible disadvantage to Defendants would be delayed enforcement of the challenged provisions, while Plaintiffs continue to provide safe and effective medication abortions. Delayed enforcement of HB 1297 will do nothing more than preserve the status quo, an important purpose of temporary injunctive relief. *See Holecek*, 545 N.W.2d at 804 (quoting *Gunsch v. Gunsch*, 69 N.W.2d 739, 745 (N.D. 1954)).

Moreover, the public interest will be served by the issuance of a temporary injunction. Protection of constitutional rights is always in the public interest. *See Phelps-Roper v. Nixon*, 509 F.3d 480, 485 (8th Cir. 2007). Therefore, the public interest is served when an injunction that prevents violations of constitutional rights is granted.

CONCLUSION

For the foregoing reasons, the Plaintiffs respectfully request that this Court temporarily enjoin enforcement of the medication provisions of HB 1297 pending final adjudication.

Dated this 15th day of July 2011.

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