# This opinion is subject to petition for rehearing Filed 10/28/14 by Clerk of Supreme Court IN THE SUPREME COURT STATE OF NORTH DAKOTA

	2014 ND 197	
MKB Management Corp, o Red River Women's Clinic		
Tammi Kromenaker, Kathryn L. Eggleston, M.D.,		Plaintiffs
MKB Management Corp, o Red River Women's Clinic Kathryn L. Eggleston, M.D.	·,	Appellees
v.		
Birch Burdick, in his officias State Attorney for Cass Terry Dwelle, M.D., in his as the chief administrator of North Dakota Department	County, official capacity of the	Defendants
Terry Dwelle, M.D., in his as the chief administrator of North Dakota Department	of the	Appellant
	No. 20130259	
Appeal from the D the Honorable Wickham C	istrict Court of Cass County, Ea	st Central Judicial District,

REVERSED.

Per Curiam.

Joseph A. Turman (appeared), Katrina A. Turman Lang (on brief), P.O. Box 110, Fargo, N.D. 58107-0110, Autumn Katz (argued), David Brown (appeared), Jennifer Sokoler (on brief), 120 Wall Street, 14th Floor, New York, N.Y. 10005, and Carmen Bremer (on brief), 200 Crescent Court, Suite 300, Dallas, TX 75201, for plaintiffs and appellees MKB Management Corp., d/b/a Red River Women's Clinic and Kathryn L. Eggleston, M.D.

Douglas A. Bahr (argued), Solicitor General, and Douglas B. Anderson (appeared), Assistant Attorney General, 500 North 9th Street, Bismarck, N.D. 58501-4509, for appellant.

Christopher T. Dodson, 103 South 3rd Street, Suite 10, Bismarck, North Dakota 58501-3800, Thomas Brejcha, 19 South LaSalle Street, Suite 603, Chicago, IL 60603, and Paul B. Linton, 921 Keystone Avenue, Northbrook, IL 60062, for amicus curiae North Dakota Catholic Conference.

Don R. Grande, 2700 12th Avenue South, Suite A, Fargo, N.D. 58103, and Mailee R. Smith, 655 15th Street NW, Suite 410, Washington, DC 20005, for amicus curiae North Dakota Legislators.

Sarah A. Herman, P.O. Box 1344, Fargo, N.D. 58107-1344, for amicus curiae North Dakota Medical Association.

LaRoy Baird III, P.O. Box 913, Bismarck, N.D. 58502-0913, for amicus curiae Steven R. Morrison, Professor of Constitutional Law, North Dakota Women's Network, and North Dakota Council on Abused Women's Services.

# MKB Management v. Burdick

### No. 20130259

## Per Curiam.

- $[\P 1]$ Article VI, § 4 of the North Dakota Constitution requires the agreement of at least four members of this Court to declare a statute unconstitutional. Justice Kapsner and Surrogate Judge Maring have concluded that H.B. 1297 is unconstitutional under the North Dakota Constitution, Chief Justice VandeWalle and Justice Sandstrom have concluded that H.B. 1297 is constitutional under the state constitution, and Justice Crothers has concluded that the state constitutional issue need not be decided. Justices Kapsner and Crothers and Surrogate Judge Maring have concluded that H.B. 1297 is unconstitutional under the federal constitution, Chief Justice VandeWalle has concluded that H.B. 1297 is constitutional under the federal constitution, and Justice Sandstrom has concluded the federal constitutional issue is not properly before this Court. Justice Kapsner and Surrogate Judge Maring have concluded that H.B. 1297 has been declared unconstitutional under the federal constitution by a sufficient majority. Chief Justice VandeWalle and Justices Sandstrom and Crothers, however, have concluded that H.B. 1297 has not been declared unconstitutional under the federal constitution by a sufficient majority. The effect of the separate opinions in this case is that H.B. 1297 is not declared unconstitutional by a sufficient majority and that the district court judgment permanently enjoining the State from enforcing H.B. 1297 is reversed.
- [¶2] Gerald W. VandeWalle, C.J.
   Carol Ronning Kapsner
   Mary Muehlen Maring, S.J.
   Daniel J. Crothers
   Dale V. Sandstrom
- [¶3] The Honorable Lisa Fair McEvers was not a member of the Court when this case was heard and did not participate in this decision. Surrogate Judge Mary Muehlen Maring, sitting.

## VandeWalle, Chief Justice.

 $\lceil \P 4 \rceil$ Terry Dwelle, M.D., in his official capacity as chief administrator of the North Dakota Department of Health, appealed from a judgment permanently enjoining the State from enforcing 2011 amendments to the North Dakota Abortion Control Act, N.D.C.C. ch. 14-02.1, regulating medication abortions ("H.B. 1297") and from an order preliminarily enjoining the State from enforcing 2013 amendments to the Abortion Control Act requiring physicians performing abortion procedures to have admitting and staffing privileges at a hospital within thirty miles of the abortion facility ("S.B. 2305"). The parties have stipulated to dismiss the claim to enjoin enforcement of S.B. 2305, and we dismiss the State's appeal from the order preliminarily enjoining enforcement of S.B. 2305. The State argues the district court erred in construing H.B. 1297 as a ban on all medication abortions and erred in determining a fundamental right to an abortion exists under the North Dakota Constitution and in applying strict scrutiny to the challenged provisions of H.B. 1297. I conclude the district court erred in determining a fundamental right to an abortion exists under the North Dakota Constitution and in applying strict scrutiny to the challenged provisions in H.B. 1297. I further conclude the court erred in construing the challenged provisions in H.B. 1297 as a ban on all medication abortions, and as construed, I conclude the challenged provisions do not constitute an undue burden on the right to an abortion under federal precedent. I would reverse the judgment permanently enjoining the State from enforcing H.B. 1297.

I

[¶5] In July 2011, MKB Management Corporation, doing business as the Red River Women's Clinic, and Kathryn L. Eggleston, a physician licensed in North Dakota and the medical director at the Clinic, sued Dwelle and Birch Burdick, in his official capacity as State's Attorney for Cass County, for a declaration that certain provisions in H.B. 1297 for medication abortions violate the North Dakota Constitution. The plaintiffs alleged the Clinic is the only abortion provider in North

Dakota and serves women residing in North Dakota, as well as women who travel to the Clinic from Minnesota and South Dakota. The plaintiffs alleged the Clinic offers both surgical and medication abortions and performed a total of about 1,300 abortions in 2010. According to Eggleston, in 2007 the Clinic began offering medication abortions using two prescription drugs, mifepristone and misoprostol, and about 20 percent of the Clinic's patients choose a medication abortion and about 80 percent of the patients choose a surgical abortion. According to Tammi Kromenaker, a director at the Clinic, the Clinic performs surgical abortions through 16 weeks of a woman's pregnancy and performs medication abortions up to 9 weeks or 63 days after a woman's last menstrual period using an "off-label" or "evidence-based" protocol rather than a "final-printed-label" protocol for administering the medication.

[¶6] To understand the issues raised in the plaintiffs' lawsuit and this appeal, I briefly describe the differences between the "final-printed-label" protocol and the "off-label" or "evidence-based" protocol for medication abortions:

Before 2000, most first-trimester abortions were surgical, performed by a procedure commonly known as vacuum aspiration or suction curettage. . . . Briefly, a surgical abortion is performed by inserting a speculum into the woman's vagina, dilating the cervix, and then inserting a tube into her uterus that empties the contents by suction. . . . .

In 2000, the Food and Drug Administration ("FDA") first approved the distribution and use of mifepristone in the United States. Mifepristone, also called RU–486, is a medication that "terminates the pregnancy by detaching the gestational sac from the uterine wall." Approximately 24 to 48 hours later, the woman takes a second medication, misoprostol, which is "a prostaglandin which induces the contractions necessary to expel the fetus and other products of conception from the uterus."...

A U.S. manufacturer first filed a New Drug Application for mifepristone in 1996. Consistent with the three clinical trials submitted in support of the application, . . . the "FDA labeling and approval letter indicated that the appropriate treatment regimen was to administer 600 mg of mifepristone orally followed by 0.4 mg of misoprostol administered orally two days later and that mifepristone was not to be administered after forty-nine days' gestation." . . .

Following FDA approval, additional clinical trials led to the development of new protocols for administering the drugs, one of which called for "200 mg of mifepristone administered orally followed one to three days later by 0.8 mg of misoprostol administered vaginally" and could be "employed up to sixty-three days' gestation." This new [off-label] protocol... changed (1) the dosage amounts of the drugs, lowering the amount of mifepristone from 600 mg to 200 mg and increasing the amount of misoprostol from .4 mg to .8 mg; (2) the number of days between the drugs, from two days to between one and three; (3) the method of administering the misoprostol, from orally at the clinic to vaginally at home; and (4) the number of days' gestation up to which the protocol could be successfully performed, from 49 to 63 days after the woman's last menstrual period ("LMP")....

In 2006, . . . a variation of the [off-label] protocol called for self-administration of the misoprostol buccally, i.e., via gum absorption. . . . By 2010, additional trials had demonstrated the safety and efficacy of buccal absorption up to 63 days LMP . . . .

Once a drug has been approved, the FDA does not ban . . . "off-label use" [] i.e., prescribing the drug for uses or in doses not identified in the approved labels.

Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 494-96 (6th Cir. 2012) (citations and footnotes omitted). See also Cline v. Oklahoma Coal. for Reprod. Justice, 2013 OK 93, ¶¶ 9-13, 313 P.3d 253 (describing FDA final-printed-label and off-label protocols for medication abortions).

[¶7] The challenged provisions for medication abortions in H.B. 1297 were scheduled to take effect on August 1, 2011, and generally regulate the use of an "abortion-inducing drug" for the purpose of inducing an "abortion" in a pregnant woman. 2011 N.D. Sess. Laws ch. 109, § 6. The legislation defines an "abortion-inducing drug" as "a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion." Id. at § 1. The legislation defines an "abortion" as "the act of using or prescribing any . . . medicine, drug, or any other substance . . . 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," and also provides

such use or prescription is not an abortion if done with the intent to save the life or preserve the health of the unborn child, to remove a dead unborn child caused by spontaneous abortion, or to treat a woman for an ectopic pregnancy. <u>Id.</u>

[9]Under those definitions, the challenged provisions in H.B. 1297 generally: (1) prohibit a physician from knowingly giving, selling, dispensing, administering, or otherwise providing or prescribing any abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion unless the person providing or prescribing the abortion-inducing drug is a physician and the provision or prescription satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug; (2) require every pregnant woman given any abortion-inducing drug to be provided with a copy of the drug's label; (3) require a physician prescribing, dispensing, or administering an abortion-inducing drug to enter a signed contract with another physician, who agrees to handle emergencies associated with the use or ingestion of the abortion-inducing drug and has active admitting privileges and gynecological and surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug; (4) require the pregnant woman 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; (5) require the proscribing or dispensing physician to produce the signed contract on demand by the patient, the health department, or a criminal justice agency; and (6) require an abortion-inducing drug used for the purpose of inducing an abortion to be administered by or in the same room and in the presence of the prescribing, dispensing, or providing physician. 2011 N.D. Sess. Laws ch. 109, § 6.

[¶9] The plaintiffs alleged H.B. 1297 violates the Clinic's patients' rights under N.D. Const. art. I, §§ 1 and 12 by: (1) banning all medication abortions; (2) banning medication abortions for women between 50 and 63 days of pregnancy; (3) banning safer and more effective "off-label" medication abortions; (4) banning medication abortions when a surgical abortion would threaten a woman's health; and (5)

requiring women receiving a medication abortion to be provided with misleading information about emergency treatment.

In July 2011, the district court restrained enforcement of H.B. 1297 pending resolution of the plaintiffs' motion for a preliminary restraining order. In February 2012, the court preliminarily enjoined enforcement of H.B. 1297 during the lawsuit, concluding the plaintiffs were likely to prevail on their state constitutional challenge. The court described the existing undue burden standard for reviewing abortion legislation under the due process clause of the Fourteenth Amendment of the United States Constitution from the plurality opinion in Planned Parenthood of Se. Penn. v. Casey, 505 U.S. 833, 876-78 (1992). In granting the preliminary injunction, the court said the language in N.D. Const. art. I, § 1, is more expansive than the due process language in the federal constitution and cited Hoff v. Berg, 1999 ND 115, 595 N.W.2d 285 and State v. Cromwell, 72 N.D. 565, 9 N.W.2d 914 (N.D. 1943) for its determination that a woman's liberty right under the state constitution is fundamental and includes the freedom to have an abortion during the early stages of a pregnancy, which the court explained was subject to review under strict scrutiny. The court construed H.B. 1297 to prohibit all medication abortions after determining misoprostol, the second drug used in the FDA final-printed-label protocol for mifepristone, is an "abortion-inducing drug" and has not received separate FDA approval for use in abortions. The court construed the language requiring a physician providing abortions to enter an emergency services contract with another physician to require the other physician to provide exclusive coverage on an emergency basis and effectively banned all medication abortions because the court said the requirement for an exclusive emergency services contract was impossible to satisfy. The court also said the language requiring administration of an abortion-inducing drug in the physical presence and same room as the prescribing physician made it impossible to perform medication abortions because of staffing concerns and costs associated with a return trip to an abortion facility for administering misoprostol. As construed, the court concluded H.B. 1297 failed to withstand strict scrutiny under the state constitution and the plaintiffs were likely to prevail on their state constitutional claims. The court also determined the regulations in H.B. 1297 constituted an undue burden on a woman's right to an abortion under the federal constitution because the amendments prohibited a method for performing an abortion before viability.

[¶11]After an April 2012 trial on the merits, the district court permanently enjoined the State from enforcing the challenged provisions in H.B. 1297. The court reiterated its earlier determination that a woman's right to an abortion is a fundamental liberty right under N.D. Const. art. I, §§ 1 and 12 and restrictions on that right were subject to strict scrutiny, which required the challenged legislation be narrowly drawn and necessary to address a compelling need. The court again construed the amendments in H.B. 1297 to ban all medication abortions after concluding misoprostol is an abortion-inducing drug and the final-printed-label protocol for misoprostol is not separately approved by the FDA for medication abortions. The court concluded the ban on all medication abortions was unconstitutional under the state constitution and was also an undue burden on a woman's right to an abortion before viability under the federal constitution. The court further ruled the state and federal constitutional provisions were violated by: (1) the requirement for dispensing or administering misoprostol in the same room and physical presence of the prescribing physician; (2) the 14-day difference in gestational limits for performing medication abortions under the FDA final-printed-label protocol and the off-label protocol; (3) the requirement for an exclusive emergency services contract; and (4) the lack of exceptions for a woman's health, for victims of rape and abuse, and for physical abnormalities. The court permanently enjoined enforcement of the challenged provisions in H.B. 1297.

[¶12] Meanwhile, in June 2013, the district court granted the plaintiffs' motion to supplement its complaint to add Kromenaker as a plaintiff and to raise a state constitutional challenge to 2013 legislation in S.B. 2305 requiring physicians performing abortion procedures to have admitting and staffing privileges at a hospital within thirty miles of the abortion facility. See 2013 N.D. Sess. Laws ch. 118, §1.

On July 31, 2013, the court preliminarily enjoined the State from enforcing S.B. 2305 pending trial. The State appealed from the judgment permanently enjoining enforcement of the 2011 amendments in H.B. 1297 and from the order preliminarily enjoining enforcement of the 2013 amendments in S.B. 2305.

II

[¶13] While the appeal was pending, the parties stipulated to dismiss the plaintiffs' claim to enjoin enforcement of the 2013 amendments in S.B. 2305, and the district court dismissed that claim and vacated the order preliminarily enjoining enforcement of S.B. 2305. We therefore dismiss the State's appeal from the order preliminarily enjoining enforcement of S.B. 2305 and consider the parties' arguments about the judgment permanently enjoining enforcement of the challenged provisions in H.B. 1297.

Ш

[¶14] The State argues the plaintiffs failed to establish the challenged provisions in H.B. 1297 violate N.D. Const. art. I, §§ 1 and 12. The State contends the district court erred in determining a fundamental right to abortion exists under the North Dakota Constitution and in applying strict scrutiny to H.B. 1297. The State also asserts the court erred in interpreting the language in H.B. 1297 to ban all medication abortions.

A

[¶15] Before addressing the state constitutional arguments, I describe the current contours of federal law involving abortion. In 1973, in Roe v. Wade, 410 U.S. 113, 117-18 (1973), the United States Supreme Court considered a federal constitutional challenge to Texas statutes prohibiting abortions except for the purpose of saving the mother's life. The Court surveyed the history of abortion and what the Court described as the "relatively recent vintage" of statutory proscriptions of abortion. Id.

at 129-52. The Court concluded an individual's right to privacy under the Fourteenth Amendment's concept of personal liberty was broad enough to cover the abortion decision. <u>Id.</u> at 152-55. The Court concluded, however, an individual's right to an abortion was not absolute and was subject to some limitations, and at some point, the state's interest in the protection of a woman's health, medical standards, and the potential for prenatal life became dominant. <u>Id.</u> The Court explained "[w]here certain 'fundamental rights' are involved, . . . regulation[s] limiting these rights may be justified only by a 'compelling state interest,' and that legislative enactments [regulating those fundamental rights] must be narrowly drawn to express only the legitimate state interests at stake." <u>Id.</u> at 155 (citations omitted). The Court balanced the respective interests and announced a trimester framework for evaluating abortion regulations:

- 1. A state criminal abortion statute . . . that excepts from criminality only a <u>life-saving</u> procedure on behalf of the mother, without regard to pregnancy stage and without recognition of the other interests involved, is violative of the Due Process Clause of the Fourteenth Amendment.
- (a) For the stage prior to approximately the end of the first trimester, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician.
- (b) For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health.
- (c) For the stage subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.

. . . .

This holding, we feel, is consistent with the relative weights of the respective interests involved, with the lessons and examples of medical and legal history, with the lenity of the common law, and with the demands of the profound problems of the present day. The decision leaves the State free to place increasing restrictions on abortion as the period of pregnancy lengthens, so long as those restrictions are tailored to the recognized state interests. The decision vindicates the right of the physician to administer medical treatment according to his professional judgment up to the points where important state interests provide compelling justifications for intervention. Up to those points, the abortion decision in all its aspects is inherently, and primarily, a medical decision, and basic responsibility for it must rest with the physician.

Roe, 410 U.S. at 164-66.

[¶16] In 1992, in <u>Casey</u>, 505 U.S. at 844, the Supreme Court considered a federal constitutional challenge to several provisions of the Pennsylvania Abortion Control Act of 1982, including language: (1) defining a "medical emergency" for purposes of certain exemptions from the requirements of the Act; (2) requiring informed consent and a twenty-four hour waiting period for a woman seeking an abortion; (3) requiring informed parental consent with a judicial bypass option for a minor seeking an abortion; and (4) requiring a married woman's signed statement that she had notified her husband of her intended abortion. In <u>Casey</u>, at 846, a plurality of the Supreme Court reaffirmed the "essential holding" in <u>Roe</u> that the right to terminate a pregnancy before viability is a liberty interest under the Fourteenth Amendment's due process clause:

First is a recognition of the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State. Before viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure. Second is a confirmation of the State's power to restrict abortions after fetal viability, if the law contains exceptions for pregnancies which endanger the woman's life or health. And third is the principle that the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child.

[¶17] In <u>Casey</u>, 505 U.S. at 852, 871-72, the plurality decision recognized "[a]bortion is a unique act . . . fraught with consequences for others" for purposes of constitutional analysis and discussed the practical difficulty in applying strict scrutiny to abortion regulations because of a state's important and legitimate interests in a

woman's health and in potential life. The plurality opinion abandoned the trimester framework from <u>Roe</u> as a rigid prohibition on all previability regulation aimed at the protection of fetal life. <u>Id.</u> at 873. The plurality decision explained that not every law that makes a right more difficult to exercise is an infringement of that right and applied an "undue burden" standard under the federal constitution to evaluate the constitutionality of abortion regulations before viability. <u>Id.</u> at 869-79. The plurality decision described the undue burden standard:

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 of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends. . . . Understood another way, we answer the question, left open in previous opinions discussing the undue burden formulation, whether a law designed to further the State's interest in fetal life which imposes an undue burden on the woman's decision before fetal viability could be constitutional. The answer is no.

Some guiding principles should emerge. What is at stake, is the woman's right to make the ultimate decision, not a right to be insulated from all others in doing so. Regulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose. See [505 U.S.] at [899-900] (addressing Pennsylvania's parental consent requirement). Unless it has that effect on her right of choice, a state measure designed to persuade her to choose childbirth over abortion will be upheld if reasonably related to that goal. Regulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden.

- .... We give this summary:
- (a) To protect the central right recognized by <u>Roe v. Wade</u> while at the same time accommodating the State's profound interest in potential life, we will employ the undue burden analysis as

explained in this opinion. An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.

- (b) We reject the rigid trimester framework of <u>Roe v. Wade</u>. To promote the State's profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and measures designed to advance this interest will not be invalidated as long as their purpose is to persuade the woman to choose childbirth over abortion. These measures must not be an undue burden on the right.
- (c) As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.
- (d) Our adoption of the undue burden analysis does not disturb the central holding of <u>Roe v. Wade</u>, and we reaffirm that holding. Regardless of whether exceptions are made for particular circumstances, a State may not prohibit any woman from making the ultimate decision to terminate her pregnancy before viability.
- (e) We also reaffirm <u>Roe's</u> holding that "subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."

Casey, at 877-79 (citations omitted).

[¶18] In <u>Casey</u>, 505 U.S. at 879-901, the plurality decision considered whether certain regulations in Pennsylvania's Abortion Control Act constituted an undue burden on a woman's right to an abortion before viability. The decision construed the exemptions from the Act's regulations under the definition of a "medical emergency" in a manner to avoid a constitutional infirmity so as to not constitute an undue burden on a woman's right to an abortion before viability. <u>Id.</u> at 879-80. The decision explained the requirement for informed consent and a twenty-four hour waiting period for a woman seeking an abortion was a reasonable measure to ensure an informed choice. <u>Id.</u> at 881-83. The decision determined the requirement for informed consent and a waiting period did not constitute an undue burden even though it may require

at least two visits to a physician and increase the cost of an abortion. <u>Id.</u> at 883-87. The decision determined the requirement that, except in a medical emergency, a married woman obtain consent from her spouse constituted an undue burden because the spousal notification requirement was a substantial obstacle for a woman for whom the restriction was relevant. <u>Id.</u> at 887-98. The decision ruled the requirement that, except for a medical emergency, a minor child obtain parental consent for an abortion, with a judicial bypass option, did not constitute an undue burden. <u>Id.</u> at 899-900. Finally, the decision said the requirement for record keeping and reporting by an abortion facility, except reporting relating to spousal notification, did not constitute an undue burden on a woman's right to an abortion before viability. <u>Id.</u> at 900-01. [¶19] In <u>Gonzales v. Carhart</u>, 550 U.S. 124, 132-33 (2007), the Supreme Court considered the validity of the Partial-Birth Abortion Act of 2003, 18 U.S.C. § 1531, a federal statute regulating certain partial-birth abortion procedures in the second trimester of a pregnancy and upheld the Act against a facial attack. The Court described "assume[d]" principles from <u>Casey</u> for purposes of its decision:

Before viability, a State "may not prohibit any woman from making the ultimate decision to terminate her pregnancy." 505 U.S., at 879 (plurality opinion). It also may not impose upon this right an undue burden, which exists if a regulation's "purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability." Id., at 878. On the other hand, "[r]egulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose." Id., at 877. Casey, in short, struck a balance.

# Gonzales, at 146.

[¶20] In <u>Gonzales</u>, the Court construed the Partial-Birth Abortion Act and concluded it prohibited intentionally performing one type of abortion procedure described as an "intact" dilation and evacuation procedure, but did not prohibit a standard dilation and evacuation procedure in which the fetus was removed in parts. 550 U.S. at 150-67. The Court described the congressional history supporting the

regulation and held the regulation on its face did not have the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion before viability. Id. at 141-43, 156-67. The Court explained the purpose of regulating the procedure for abortions by intact dilation and evacuation expressed respect for the legitimate governmental interests in the dignity of human life and recognition of the State's interest in regulating the medical profession and potential life. Id. at 158. The Court said "[w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in the furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn." Id. at 158. The Court also explained the effect of the legislation did not impose an undue burden on a woman's abortion right for purposes of a facial attack on the legislation because there was a documented medical disagreement whether the prohibition of this specific procedure imposed significant health risks on women. Id. at 161-67. In Gonzales, at 166-67, the Court further explained its determination the Act did not require a health exception and did not impose an undue burden on a woman's right to an abortion was supported by the existence of alternatives to the prohibited procedure:

Considerations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends. When standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not follow that the State is altogether barred from imposing reasonable regulations. The Act is not invalid on its face where there is uncertainty over whether the barred procedure is ever necessary to preserve a woman's health, given the availability of other abortion procedures that are considered to be safe alternatives.

In <u>Gonzales</u>, at 167-68, the Court also determined the facial attack should not have been entertained in the first instance because as-applied challenges provided the

proper manner to protect the health of a woman and assess medical risks and the regulations were not unconstitutional even in a large fraction of relevant cases.

[¶21] Under Supreme Court precedent, a state may not prohibit a woman from making the ultimate decision to terminate a pregnancy before viability, and the undue burden standard governs the analysis of abortion regulations under federal law. See Gonzalez, 550 U.S. at 146; Casey, 505 U.S. at 877-79. As Gonzales, at 158, explains, where a state has a rational basis to act and does not impose an undue burden on a woman's right to an abortion before viability, a state may use its regulatory powers to bar certain procedures and substitute others in the furtherance of legitimate interests in regulating the medical profession to promote respect for human life, including the life of the unborn.

В

[¶22] Against the background of federal precedent describing a woman's fundamental right to an abortion before viability under the federal constitution, I consider the parties' arguments under N.D. Const. art. I, §§ 1 and 12, which provide:

Section 1. 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; acquiring, possessing and protecting property and reputation; pursuing and obtaining safety and happiness; and to keep and bear arms for the defense of their person, family, property, and the state, and for lawful hunting, recreational, and other lawful purposes, which shall not be infringed.

. . . .

Section 12. In criminal prosecutions in any court whatever, the party accused shall have the right to a speedy and public trial; to have the process of the court to compel the attendance of witnesses in his behalf; and to appear and defend in person and with counsel. No person shall be twice put in jeopardy for the same offense, nor be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty or property without due process of law.

[¶23] The State argues the district court erred in determining a fundamental right to abortion exists under those state constitutional provisions and in applying strict scrutiny to the challenged provisions in H.B. 1297. The State contends those constitutional provisions must be interpreted to ascertain the framers' intent, which the State claims is evidenced by statutes continuously prohibiting abortions in the Dakota Territory and in North Dakota through the United States Supreme Court's decision in Roe in 1973.

[924]The plaintiffs respond the district court correctly decided a woman's right to terminate a pregnancy is an inalienable and fundamental liberty right protected by the state constitution, which protects individual liberties to the same or greater extent than the federal constitution and must be interpreted in light of changed circumstances. [925]In interpreting constitutional provisions, we apply general principles of statutory construction. Thompson v. Jaeger, 2010 ND 174, ¶7, 788 N.W.2d 586. Our overriding objective is to give effect to the intent and purpose of the people adopting the constitutional provision. City of Bismarck v. Fettig, 1999 ND 193, ¶ 8, 601 N.W.2d 247. The intent and purpose of constitutional provisions are to be determined, if possible, from the language itself. Thompson, at ¶ 7. In construing constitutional provisions, we ascribe to the words the meaning the framers understood the provisions to have when adopted. Kadrmas v. Dickinson Pub. Schs., 402 N.W.2d 897, 899 (N.D. 1987). We may consider contemporary legal practices and laws in effect when the people adopted the constitutional provisions. See State v. Orr, 375 N.W.2d 171, 177-78 (N.D. 1985) (interpreting right to counsel provision of state constitution in view of statutes in effect when constitution adopted); City of Bismarck v. Altevogt, 353 N.W.2d 760, 764-65 (N.D. 1984) (interpreting right to jury trial under state constitution in view of territorial statutes defining right to jury trial). This Court has recognized the due process language in N.D. Const. art I, § [926]12 "protects and insures the use and enjoinment of the rights declared" by N.D. Const. art. I, § 1. Cromwell, 72 N.D. at 574-75, 9 N.W.2d at 919. In different contexts, this Court has discussed issues about the rights secured by N.D. Const. art. I, §§ 1 and 12.

See Hoff, 1999 ND 115, ¶ 8-18, 595 N.W.2d 285 (holding grandparent visitation statute unconstitutional under due process clause of state and federal constitutions; stating parents have fundamental right to parent children and only compelling state interest justifies burdening parent's fundamental right); Continental Res., Inc. v. Farrar Oil, Co., 1997 ND 31, ¶ 15-18, 559 N.W.2d 841 (discussing property rights protected by state constitution in context of compulsory pooling order for horizontal oil and gas well; recognizing property is subject to police power to impose restrictions as practically necessary for general welfare of all); State ex rel. Schuetzle v. Vogel, 537 N.W.2d 358, 360-64 (N.D. 1995) (recognizing person's constitutionally protected liberty interest to refuse unwanted medical treatment and balancing liberty interest against relevant state penological interest); In re K.A.S., 499 N.W.2d 558, 560-68 (N.D. 1993) (discussing due process in context of statute for court-appointed counsel for indigent parent in termination and adoption proceeding; construing statute to require court-appointed counsel for indigent parent in termination and adoption proceedings to avoid equal protection infirmity); Johnson v. Elkin, 263 N.W.2d 123, 128-130 (N.D. 1978) (identifying liberty right to engage in ordinary occupation without state regulation; recognizing police power to impose restrictions on right for general welfare of all); Bob Rosen Water Conditioning Co. v. City of Bismarck, 181 N.W.2d 722, 724 (N.D. 1970) (upholding requirement for plumbing license to install water softener; stating police power is not absolute and individual liberty may be restrained or abridged to benefit public welfare); State v. Odegaard, 165 N.W.2d 677, 680 (N.D. 1969) (holding statute requiring motorcycle operator to wear crash helmet was legitimate exercise of police power and did not violate state or federal constitutions); Cromwell, 72 N.D. at 581, 9 N.W.2d at 922 (holding statute requiring license to engage in business of photography violated due process clause of state constitution).

[¶27] In <u>Cromwell</u>, 72 N.D. at 573-74, 9 N.W.2d at 918-19, this Court broadly described the "inherent rights" protected by the language in N.D. Const. art. I, §§ 1 and 12, in the context of addressing a challenge to statutes prohibiting the practice of

professional photography without a license. This Court said the language in N.D. Const. art. I, § 1, embodies the essence of "self-evident truths," and the term "liberty" includes "in general, the opportunity to do those things which are ordinarily done by free men." Id. at 573, 9 N.W.2d at 918. This Court explained the pursuit of happiness was not capable of specific definitions or limitation but was the aggregate of many rights included in the guaranty of liberty. Id. at 574, 9 N.W.2d at 918. This Court recognized, however, a state's police power authorized a state to impose restrictions on private rights as practically necessary for the general public welfare and health and comfort of all. Id. at 575-78, 9 N.W.2d at 919-21. This Court held the business of photography was not of such a character as to warrant the restraint imposed by licensing statutes and the regulations were not reasonably required and appropriate for the protection of the public. Id. at 578-81, 9 N.W.2d at 921-22. This Court held the statute requiring professional photographers to be licensed was unconstitutional under the language of N.D. Const. art. I, §§ 1 and 12. Cromwell, at 581, 9 N.W.2d at 922.

[¶28] In Johnson, 263 N.W.2d at 128-29 (citing David L. Chambers, Alternatives to Civil Commitment of the Mentally III: Practical Guides and Constitutional Imperatives, 70 Mich. L. Rev. 1107, 1157 (1972)), in the context of considering a state constitutional challenge to regulations governing house movers, this Court identified what had been called an "expansive" reading of the language in N.D. Const. art. I, § 1, in Cromwell. This Court explained the expansive rights in that provision were modified and limited by the police power to impose such restrictions upon private rights as are practically necessary for the general welfare of all. Johnson, at 129. This Court concluded "there is no general constitutional prohibition against legislation limiting entry into occupations or professions," and "[t]he only question is whether the regulation, as to entry into the occupation or profession or otherwise, is reasonable and, within constitutional limits, promotes the order, safety, health, morals and general welfare of society." Id. at 130.

[¶29] In Hoff, 1999 ND 115, ¶¶8-18, 595 N.W.2d 285, in the context of addressing state and federal constitutional challenges to a grandparent visitation statute, this Court generally outlined the levels of scrutiny applicable to liberty claims under the due process clause:

"[T]he Fourteenth Amendment 'forbids the government to infringe . . . "fundamental" liberty interests . . . unless the infringement is narrowly tailored to serve a compelling state interest." If a fundamental liberty interest is not involved, a statute need only "be rationally related to legitimate government interests." "[N]arrow tailoring is required only when fundamental rights are involved. The impairment of a lesser interest . . . demands no more than a 'reasonable fit' between governmental purpose . . . and the means chosen to advance that purpose." The level of scrutiny employed in analyzing due process claims has been recently summarized:

Where fundamental rights or interests are involved, a state regulation limiting these fundamental rights can be justified only by a compelling state interest and legislative enactments must be narrowly drawn to express only the legitimate state interests at stake. Therefore, state limitations on a fundamental right such as the right of privacy are permissible only if they survive strict constitutional scrutiny. However, where fundamental rights or interests are not implicated or infringed, state statutes are reviewed under the rational basis test . . . . Under rational basis review, "a statute withstands a substantive due process challenge if the state identifies a legitimate state interest that the legislature could rationally conclude was served by the statute."

<u>Hoff</u>, at  $\P$  13 (citations omitted).

[¶30] In Hoff, 1999 ND 115, ¶ 18, 595 N.W.2d 285, we recognized parents have a fundamental right to parent children and to decide when, under what conditions, and with whom their children may associate. We concluded the version of the grandparent visitation statute at issue in that case failed to withstand strict scrutiny and was unconstitutional under the due process clause of the state and federal constitutions. Id. at ¶ 18.

[¶31] A common thread in this Court's precedent construing the language in N.D. Const. art. I, §§ 1 and 12 in the context of individual liberty and the state's

countervailing interests recognizes application of the state's police power, which is not always compatible with applying strict scrutiny to challenged regulations. The United States Supreme Court recognized as much in Casey, 505 U.S. at 852, 871-72, when it said "abortion is a unique act" and described the practical difficulties in applying the exacting standard of strict scrutiny to abortion regulations because of a state's important and legitimate interests in a woman's health and in potential life. I acknowledge that some state courts have recognized a woman's [¶32]fundamental state constitutional liberty or privacy right to terminate a pregnancy, which is subject to judicial review under strict scrutiny. See Valley Hosp. Assoc., Inc. v. Mat-Su Coal. for Choice, 948 P.2d 963, 966-69 (Alaska 1997); People v. Belous, 458 P.2d 194, 199-200 (Cal. 1969); North Florida Women's Health & Counseling Servs., Inc. v. State, 866 So.2d 612, 634-35 (Fla. 2003); Women of Minnesota v. Gomez, 542 N.W.2d 17, 27-31 (Minn. 1995); Armstrong v. State, 1999 MT 261, ¶41, 989 P.2d 364; Planned Parenthood of Middle Tennessee v. Sundquist, 38 S.W.3d 1, 14-17 (Tenn. 2000).

[¶33] Because of the difficulty in applying strict scrutiny to the competing state and individual interests involved with abortion regulations, however, some state courts have recognized their state constitutions do not guarantee a right to abortion separate and distinct from the federal constitution. See Mahaffey v. Attorney General, 564 N.W.2d 104, 111 (Mich. Ct. App. 1997) (holding Michigan Constitution does not guarantee right to abortion separate and distinct from federal right); Preterm Cleveland v. Voinovich, 627 N.E.2d 570, 577 (Ohio Ct. App. 1993) (stating nothing justified utilizing compelling state interest test for analyzing abortion regulation under Ohio Constitution and applying undue burden standard under federal law).

[¶34] In Mahaffey, 564 N.W.2d at 109-10, the Michigan Court of Appeals said that when the relevant state constitutional provisions for a right to privacy were adopted, abortion was a criminal offense in Michigan, and it was presumed the drafters of the Michigan Constitution were aware of the statutory prohibition. The court explained the state constitution and the debates of the constitutional convention were silent

about abortion, evidencing no intent to alter the existing law, and the court concluded the people adopting the constitution did not intend the right to privacy to include a state constitutional right to abortion. <u>Id.</u> at 110-14. The court emphasized its decision had no effect on the right of Michigan women to obtain an abortion under the federal constitution and held that the Michigan Constitution did not guarantee a right to abortion separate and distinct from the federal right. <u>Id.</u> at 111. In addressing the constitutionality of an informed consent statute under the Michigan Constitution, the court explained the stated purposes of the statute were legitimate legislative objectives and the law was reasonably related to the achievement of those objectives. <u>Id.</u> at 113-14.

[¶35] In <u>Preterm Cleveland</u>, 627 N.E.2d at 575-76, the Ohio Court of Appeals discussed <u>Roe</u> and <u>Casey</u> and said a right to bear a child was one of the liberties guaranteed by the Ohio Constitution, but was not absolute or unqualified and must be balanced against important state interests in regulation. In considering those interests, the court explained there was "nothing demonstrated to justify utilization of a compelling-state-interest test" for abortion regulations and applied the federal undue burden standard to Ohio abortion regulations. <u>Id.</u> at 577. The court found no basis for concluding the Ohio Constitution imposed greater restrictions upon states than the federal constitution and held the trial court erred in applying strict scrutiny to the abortion regulations. <u>Id.</u> at 577-78.

[¶36] Before the United States Supreme Court decided Roe in 1973, North Dakota had a long history of prohibiting abortions except to preserve a woman's life. See Penal Code, Dakota Territory §§ 337, 338 (1877); Compiled Laws of the Territory of Dakota §§ 6538, 6539 (1887); N.D.R.C. §§ 7177, 7178 (1895); N.D.R.C. §§ 8912, 8913 (1905); N.D. Compiled Laws §§ 9604, 9605 (1913); N.D.R.C. ch. 12-25 (1943); N.D.C.C. ch. 12-25 (1960). After Roe was decided, the 1973 legislature enacted provisions continuing to prohibit abortions as part of a comprehensive enactment of the criminal code in N.D.C.C. tit. 12.1. See 1973 N.D. Sess. Laws § 19 (enacting N.D.C.C. ch. 12.1-19) and § 41 (repealing N.D.C.C. ch. 12-25). The provisions in

N.D.C.C. ch. 12.1-19 were repealed by the adoption of the Abortion Control Act in 1975. See 1975 N.D. Sess. Laws ch. 124 (adopting N.D.C.C. ch. 14-02.1).

[¶37] The provisions prohibiting abortions were continuously in effect before statehood, at statehood, and after statehood, and I have found no contrary reference to abortions in the North Dakota Constitution, nor in the 1889 debates of the North Dakota Constitutional Convention. See Official Report of the Proceedings and Debates of the First State Constitutional Convention of North Dakota (1889). Our state constitution is silent about creating a state constitutional right to abortion, and the prevailing practice in the Dakota Territory and when the relevant constitutional provisions were adopted prohibited abortions except to preserve a woman's life. The laws of the Dakota Territory and this State thus provide no long-standing tradition recognizing a separate state right to an abortion, and the drafters of our constitution are presumed to know the existing laws and to have drafted the state constitution accordingly. See Orr, 375 N.W.2d at 177-78; Altevogt, 353 N.W.2d 764-65. See also Mahaffey, 564 N.W.2d at 109-10.

[¶38] In some contexts, this Court has recognized our state constitution may be interpreted in light of changed circumstances. See Johnson v. Hasset, 217 N.W.2d 771, 779 (N.D. 1974) (construing constitutionality of guest statute and stating in matters of constitutional law, as in other matters, times change and doctrine changes with the times); Ferch v. Housing Auth., 79 N.D. 764, 772, 59 N.W.2d 849, 856 (N.D. 1953) (stating views as to what constitutes a public use vary with changing conceptions of scope and functions of government); State v. Norton, 64 N.D. 675, 686, 255 N.W. 787, 792 (1934) (stating constitution is living, breathing vital instrument, adaptable to the needs of the day as was so intended by the people when adopted). In view of the laws affirmatively prohibiting abortion in the Dakota Territory and North Dakota when the relevant constitutional provisions were adopted and the absence of a reference to abortion during proceedings leading up to adoption of the state constitution, however, I decline to hold the people of North Dakota intended to create a liberty right to abortion under the state constitution. See

Mahaffey, 564 N.W.2d at 109-11. I discern no basis for concluding the North Dakota Constitution imposes greater restrictions upon the State than the federal constitution. In view of the competing state interests involved in the "unique act of abortion" recognized in <u>Casey</u>, 505 U.S. at 842, 871-72, I agree with the rationale of the Michigan Court of Appeals that our state constitutional provisions were not intended to encompass a fundamental right to abortion justifying review under strict scrutiny and the compelling state interest test. I therefore conclude the district court erred in applying strict scrutiny to the challenged amendments in H.B. 1297.

 $\mathbf{C}$ 

[¶39] The district court's analysis was primarily under the state constitution, but the court also described case law analyzing the right to abortion under the federal constitution and said the challenged provisions also were unconstitutional under federal precedent prohibiting regulations placing an undue burden on a woman's right to an abortion before viability.

1

[¶40] The State argues the district court exceeded its jurisdiction by deciding the federal constitutional issue, which the State claims was not raised in the complaint or tried by consent. The State argues a decision on the federal constitutional issue was not required to resolve this case.

[¶41] As a rule of construction, we independently interpret our state constitution in light of the text and history of that document, but as a practical matter we may not deny a person a right secured by the federal constitution. See, e.g., Southeast Cass Water Res. Dist. v. Burlington N. R.R. Co., 527 N.W.2d 884, 890 (N.D. 1995) (recognizing state constitution may not grant narrower rights than guaranteed by federal constitution). Our state constitutional analysis of the right to an abortion under the state constitution has no effect on the right to obtain an abortion under the federal constitution. See Mahaffey, 564 N.W.2d at 111; Preterm Cleveland, 627

N.E.2d at 577. I therefore consider the challenged provisions in H.B. 1297 under the undue burden standard of the federal constitution. See Preterm Cleveland, at 577.

2

[¶42] Under the undue burden standard, I consider the district court's interpretation of the specific language at issue in H.B. 1297, which defines an "abortion-inducing drug" as a "medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion." 2011 N.D. Sess. Laws ch. 109, § 1. The legislation defines an "abortion" as the "act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means 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," but provides such use or prescription is not an abortion if done with the intent to save the life or preserve the health of the unborn child, to remove a dead unborn child caused by a spontaneous abortion, or to treat a woman for an ectopic pregnancy. Id.

[¶43] In the context of those definitions, the challenged language pertaining to the use of an "abortion-inducing drug" for a medication "abortion" provides:

- 1. For purposes of this chapter, an abortion accomplished by the use of an abortion-inducing drug is deemed to occur when the drug is prescribed, in the case of a prescription, or when the drug is administered directly to the woman by the physician.
- 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.

- 3. Every pregnant woman to whom a physician gives, sells, dispenses, administers, otherwise provides, or prescribes any abortion-inducing drug must be provided with a copy of the drug's label.
- Any physician who gives, sells, dispenses, administers, 4. 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 abortioninducing drug must be provided the name and telephone number of the physician whom will be handling emergencies and the hospital at which any emergences 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 emergences 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.

2011 N.D. Sess. Laws ch. 109, § 6.

[¶44] Statutory interpretation is a question of law, fully reviewable on appeal. In re P.F., 2008 ND 37, ¶11, 744 N.W.2d 724. In enacting a statute, it is presumed the legislation is intended to comply with the state and federal constitutions, the entire statute is intended to be effective, a just and reasonable result is intended, a result feasible of execution is intended, and public interest is favored over any private interest. N.D.C.C. § 1-02-38. Words in a statute are given their plain, ordinary, and commonly understood meaning unless defined by statute or unless a contrary intention plainly appears. N.D.C.C. § 1-02-02. Statutes are construed as a whole and are harmonized to give meaning to related provisions. N.D.C.C. § 1-02-07. If the language of a statute is clear and unambiguous, the letter of the statute must not to be

disregarded under the pretext of pursuing its spirit. N.D.C.C. § 1-02-05. If the language of a statute is ambiguous, however, a court may resort to extrinsic aids to determine the intention of the legislation, including the object sought to be attained, the circumstances under which the legislation was enacted, and the legislative history. N.D.C.C. § 1-02-39. A statute is ambiguous if it is susceptible to different, rational meanings. State v. Meador, 2010 ND 139, ¶ 11, 785 N.W.2d 886.

[¶45] The determination whether a statute is constitutional is a question of law, which is fully reviewable on appeal. State v. Holbach, 2009 ND 37, ¶ 23, 763 N.W.2d 761. All regularly enacted statutes carry a strong presumption of constitutionality, which is conclusive unless the party challenging the statute clearly demonstrates it contravenes the state or federal constitution. Teigen v. State, 2008 ND 88, ¶ 7, 749 N.W.2d 505. Any doubt about a statute's constitutionality must, when possible, be resolved in favor of its validity. State v. M.B., 2010 ND 57, ¶ 4, 780 N.W.2d 663. The power to declare a legislative act unconstitutional is one of the highest functions of the courts, and that power must be exercised with great restraint. Teigen, at ¶ 7. The presumption of constitutionality is so strong that a statute will not be declared unconstitutional unless its invalidity is, in the court's judgment, beyond a reasonable doubt. In re Craig, 545 N.W.2d 764, 766 (N.D. 1996). The party challenging the constitutionality of a statute has the burden of proving its constitutional infirmity. State v. Brown, 2009 ND 150, ¶ 30, 771 N.W.2d 267.

[¶46] In considering the challenged language in H.B. 1297, the State argues the district court erred in construing the legislation to ban all medication abortions. The State argues the language in H.B. 1297, when construed together to give meaning to each word and phrase, requires adherence to the FDA final-printed-label protocol for medication abortions.

[¶47] The protocol for mifepristone's FDA final-printed-label regimen and the off-label use for mifepristone for medication abortions require mifepristone to be used in conjunction with misoprostol. The parties do not dispute misoprostol has not been separately approved by the FDA for use in abortions and the FDA final-printed-label

protocol for misoprostol authorizes use of misoprostol to treat ulcers but is silent on abortion-related uses. The medical evidence in this record reflects mifepristone by itself, completes a medication abortion in about seven percent of cases, and misoprostol is necessary to complete the medication abortion in the remainder of cases. As construed in conjunction with the FDA final-printed-label protocol, those definitions suggest a complete prohibition of medication abortions using misoprostol. See Cline, 2013 OK 93, ¶¶ 15-17, 313 P.3d 253 (construing abortion-inducing drug under Oklahoma statute to include misoprostol; citing statutory definition of abortioninducing drug as including misoprostol). Unlike the statutory definition of abortioninducing drug at issue in Cline, however, H.B. 1297 does not specifically define abortion-inducing drug to include misoprostol, and other provisions in H.B. 1297 require that medication abortions follow the FDA final-printed-label protocol for the abortion-inducing drug. Mifepristone is an abortion-inducing drug and incorporates the use of misoprostol in that regimen. When read together, the amendments are not clear about whether H.B. 1297 was intended to include misoprostol as an abortion inducing drug and to prohibit all medication abortions or to require medication abortions to follow the FDA final-printed-label protocol for mifepristone. I therefore consider extrinsic aids in construing H.B. 1297, including the legislative history.

[¶48] The legislative history for H.B. 1297 does not include any references to a total ban on all medication abortions; rather, the legislative history manifests that the legislation was intended to permit medication abortions under the protocol tested and authorized by the FDA final-printed-label protocol. See Hearing on H.B. 1297 Before House Human Servs. Comm., 62nd N.D. Legis. Sess (Jan. 31, 2011) (testimony of Representative Betty Grande that legislation uses FDA guidelines for definitions and safe practices; written testimony of Christopher T. Dodson, Executive Director of North Dakota Catholic Conference that use of abortion-inducing drug is in manner authorized by FDA in accordance with manufacturer's instructions; and written testimony of Amy Jacobson, North Dakota Public Affairs Manager for Planned Parenthood of Minnesota, North Dakota, and South Dakota that bill would require

physicians to follow outdated protocol for medication abortion instead of best standard available). Nothing in the legislative history indicates H.B. 1297 was intended to prohibit all medication abortions and the history of the legislation supports an interpretation that H.B. 1297 requires adherence to the FDA final-printed-label protocol, which authorizes the use of mifepristone and incorporates the use of misoprostol for medication abortions according to the FDA final-printed-label protocol for mifepristone. I construe H.B. 1297 to permit medication abortions under the FDA final-printed-label protocol for mifepristone, which employs the administration of mifepristone and misoprostol up to 49 days after a woman's last menstrual period and requires the misoprostol to be administered orally at the clinic. I conclude the district court erred in interpreting H.B. 1297 to ban all medication abortions.

[¶49] I also construe the plain language of H.B. 1297 to require a physician prescribing, giving, administering, or otherwise providing an abortion-inducing drug to enter a signed contract with another physician for emergencies associated with the use or ingestion of the abortion-inducing drug and to require the pregnant woman be provided with the name and telephone number of the other physician who will be handling emergencies and the hospital at which any emergencies will be handled. Moreover, the plain language of the amendments requires the other physician to have admitting privileges and gynecological and surgical privileges at the designated hospital. The district court construed the provisions for the emergency services contract to require the prescribing or providing physician to enter an "exclusive" contract with another physician. Although the language of H.B. 1297 requires a physician prescribing or providing an abortion-inducing drug to enter a written contract with another physician for emergency services, the plain language does not require an exclusive contract and does not preclude the prescribing or providing physician from giving a pregnant woman other additional information for dealing with emergencies, such as going to the nearest available hospital for an emergency. Moreover, I also note the plain language about the emergency services contract does

not include any geographical limitations like the admitting and staffing privileges requirement in the 2013 amendments in S.B. 2305.

[¶50] Finally, the plain language of H.B. 1297 requires an abortion-inducing drug used for the purpose of inducing an abortion to be administered in the same room and in the physical presence of the prescribing or dispensing physician. The State contends misoprostol, the second drug employed in the off-label protocol and the FDA final-printed-label protocol for medication abortions, is not an "abortion-inducing drug" prescribed or dispensed with the intent of causing an "abortion" when used after mifepristone because misoprostol expels the contents of the uterus and does not cause or induce the death of an unborn child, as those terms are defined in the legislation. I agree with the State's interpretation of H.B. 1297 that misoprostol is not an abortion-inducing drug under the language in H.B. 1297, but I nevertheless recognize the FDA final-printed-label protocol requires misoprostol to be administered orally at the clinic two days after mifepristone.

3

[¶51] Having construed the challenged provisions in H.B. 1297, I consider that legislation under the undue burden standard. The federal courts that have considered challenges to state laws regulating medication abortions have reached varying results under the undue burden standard. See DeWine, 696 F.3d at 513-18; Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott, 748 F.3d 583, 600-05 (5th Cir. 2014); Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 911-18 (9th Cir. 2014).

[¶52] In <u>DeWine</u>, 696 F.3d at 513-18 (opinion by McKeague, J.), the Sixth Circuit Court of Appeals, in a 2-1 decision, affirmed a summary judgment dismissing a challenge to an Ohio statute requiring adherence to the dosage requirements and gestational time limits in the FDA final-printed-label protocol for medication abortions. The court held the statute did not have the effect of creating a substantial obstacle to a woman's right to an abortion and did not impose an undue burden on a

woman's ability to make the decision to have an abortion. Id. The court explained the ban on medication abortions from 50 to 63 days after a woman's last menstrual period was not an undue burden because the ban on that method of abortion for that time frame did not preclude a surgical abortion, which was the most common method of abortion for that time period. Id. at 514-16. The court said a woman's right to choose an abortion did not encompass the right to choose a particular method of abortion. Id. The court explained the right to abortion under federal jurisprudence protects the freedom to decide whether to terminate a pregnancy, but has not been extended to a woman's preferred method of terminating a pregnancy. Id. at 516. The court concluded in the absence of any evidence the statute created a substantial obstacle to the ultimate abortion decision, any conclusion about what a woman might prefer did not create a disputed issue of material fact. Id. The court also determined the increased costs associated with increased or different dosages of medication under the FDA final-printed-label protocol did not create an undue burden on a woman's right to an abortion. Id. at 516. The court cited Casey for the proposition that although at some point increased costs could become a substantial obstacle to a woman's right to obtain an abortion, increased costs associated with additional trips to an abortion clinic did not constitute an undue burden on a woman's right to an abortion for a large fraction of affected women. 696 F.3d at 517. The court concluded the provisions for medication abortions at issue in that case did not constitute an undue burden on a woman's right to an abortion before viability. Id. at 514-17.

[¶53] In <u>Abbott</u>, 748 F.3d at 600-05, the Fifth Circuit Court of Appeals considered a facial challenge to a Texas statute requiring medication abortions follow the FDA final-printed-label protocol for mifepristone and concluded the statute was constitutional. In the context of that facial challenge, the court applied <u>Gonzales</u> to analyze whether restrictions on medication abortions from 50 to 63 days after a woman's last menstrual period facially imposed an undue burden on the abortion right of women who, because of gynecological abnormalities, cannot safely undergo a

surgical abortion during that time period. Abbott, at 600-05. The court concluded the Texas statute's requirement for adherence to the FDA final-printed-label protocol for medication abortions did not facially require a court imposed exception for the life or health of a woman. Id. The court explained the Texas statute did not ban an entire abortion method; rather, it shortened the window during which a woman may elect to have a medication abortion. Id. The court held the statute, on its face, did not impose an undue burden on the life and health of a woman and explained that its decision did not detract from the requirement in Casey regarding abortion restrictions where the abortion is necessary to preserve the life of the mother. Id.

In Humble, 753 F.3d at 907, 911-18, the Ninth Circuit Court of Appeals [954]reversed a federal district court decision denying a motion to preliminarily enjoin enforcement of Arizona regulations restricting medication abortions to the FDA finalprinted-label protocol. The Ninth Circuit Court of Appeals concluded Abbott and DeWine were inconsistent with the undue burden test articulated in Casey and Gonzales, stating the Fifth and Sixth Circuits' approach failed to recognize the undue burden test is context-specific and both the severity of a burden and the strength of the state's justification can vary depending on the circumstances. Humble, at 914-15. The Ninth Circuit Court of Appeals adhered to its approach in Tucson Woman's Clinic v. Eden, 379 F.3d 531, 539 (9th Cir. 2004), which the court explained required weighing the extent of the burden against the strength of the state's justification in the context of each individual state regulation. Humble, at 914-15. The court concluded the Arizona regulation, on the record before the court for the preliminary injunction, appeared wholly unnecessary for a woman's health. Id. In reversing the denial of a preliminary injunction, the court said the plaintiffs had provided uncontroverted evidence Arizona's regulation of medication abortions substantially burdens a woman's access to abortion services and Arizona provided no evidence the law advances its interest in a woman's health. Id. at 916-17.

[¶55] I recognize the split in the federal circuits on issues relating to medication abortions, which ultimately may require resolution by the United States Supreme

Court. I agree, however, with the application of the undue burden standard by the Fifth and Sixth Circuits because I conclude those decisions reflect the proper deference to a state's interest in a woman's health and in potential life under <u>Gonzales</u> and <u>Casey</u>.

[¶56] During the legislative process, the proponents of H.B. 1297 provided the legislature with information describing dangers of abortion-inducing drugs and the need for regulation. See Hearings on H.B. 1297 Before House and Senate Human Servs. Comms., 62nd N.D. Legis. Sess. (Jan. 31, 2011 and March 14, 2011) (prepared testimony of Christopher T. Dodson, Executive Director of North Dakota Catholic Conference with attached exhibit). The legislature was also provided with contrary information describing the efficacy of a medication abortion at the Clinic under the off-label protocol. See Hearing on H.B. 1297 Before Senate Human Servs. Comm, 62nd N.D. Legis. Sess. (March 14, 2011) (testimony of Tammi Kromenaker, Director of Red River Woman's Clinic).

[¶57] On its face, H.B. 1297 reflects a legitimate purpose to protect women from asserted dangers of off-label use of an abortion-inducing drug for a medication abortion while permitting surgical abortions and medication abortions using the FDA final-printed-label protocol. "Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn." Gonzales, 550 U.S. at 158. The plaintiffs have presented evidence reflecting medication abortion is extremely safe and the off-label protocol used by the Clinic has advantages over the FDA final-printed-label protocol. I am not persuaded, however, that the evidence suggests there is no basis for the regulations in H.B. 1297. A legislature need not legislate the best means to achieve a goal and it is not for this Court to "improve" or "cleanse" the legislative process. See Abbott, 748 F.3d at 594. [¶58] I have construed H.B. 1297 to permit medication abortions under the FDA final-printed-label protocol for mifepristone and to not require an exclusive contract with another physician for emergency services. As I have construed H.B. 1297, I am not persuaded the purpose or effect of the legislation imposes a substantial obstacle on a woman's right to an abortion before viability under federal precedent. To the extent the district court made contrary determinations about the effect of H.B. 1297, the court's findings were based on its erroneous interpretation of the language of H.B. 1297 and the court's erroneous application of strict scrutiny to the legislation. We have often said findings of fact based on an erroneous conception of the law are not entitled to deference under the clearly erroneous standard of review. See, e.g., MayPort Farmers Coop. v. St. Hilaire Seed Co., Inc., 2012 ND 257, ¶ 4, 825 N.W.2d 883.

[¶59] I agree with the ultimate conclusions in <u>DeWine</u> and <u>Abbott</u> that statutes requiring adherence to the FDA final-printed-label protocol for medication abortions are rational regulations related to the regulation of the medical profession to promote a woman's health and respect for life, including the life of the unborn, and do not constitute an undue burden on a woman's right to an abortion before viability. I conclude the rationale of <u>DeWine</u> and <u>Abbott</u> is persuasive for assessing H.B. 1297 under applicable federal precedent. I conclude the challenged provisions of H.B. 1297, on their face and as I have construed them, do not constitute an undue burden on a woman's right to abortion before viability under applicable federal precedent.

IV

[¶60] Under N.D. Const. art. VI, § 4, the concurrence of four members of this Court is required to declare a statute unconstitutional. Only two members of this Court would hold the provisions of H.B. 1297 regulating medication abortions unconstitutional under the state constitution. Three members of this Court would hold those statutory provisions unconstitutional under the federal constitution but neither is that a sufficient majority under N.D. Const. art. VI, § 4. See State ex rel. Olson v. Maxwell, 259 N.W.2d 621, 629 (N.D. 1977) (holding by three justices of this Court that statute as written and as applied to female prisoners transferred outside State

failed to comply with procedural due process standards required under both federal and state constitutions and stating that because concurrence of four members of this Court is required to declare statute unconstitutional under language currently found in N.D. Const. art. VI, § 4, the statute was not declared unconstitutional by a sufficient majority). I would reverse the judgment declaring H.B. 1297 unconstitutional and permanently enjoining the State from enforcing H.B. 1297.

[¶61] Gerald W. VandeWalle, C.J.

#### Kapsner, Justice.

[¶62] Terry Dwelle, M.D., in his official capacity as chief administrator of the North Dakota Department of Health, appealed from a judgment permanently enjoining the State from enforcing 2011 amendments to the North Dakota Abortion Control Act, N.D.C.C. ch. 14-02.1, regulating medication abortions ("H.B. 1297") and from an order preliminarily enjoining the State from enforcing 2013 amendments to the Abortion Control Act requiring physicians performing abortion procedures to have admitting and staffing privileges at a hospital within thirty miles of the abortion facility ("S.B. 2305"). The parties have stipulated to dismiss the claim to enjoin enforcement of S.B. 2305, and we dismiss the State's appeal from the order preliminarily enjoining enforcement of S.B. 2305.

[¶63] The State argues the district court erred in construing H.B. 1297 as a ban on all medication abortions, in determining a fundamental right to an abortion exists under the North Dakota Constitution, and in applying strict scrutiny to the challenged provisions of H.B. 1297. We conclude the district court did not err in applying strict scrutiny to the challenged provisions in H.B. 1297 under our state constitution. We conclude the district court did not err in construing the challenged provisions in H.B. 1297 as a de facto ban on all medication abortions. Furthermore, we conclude that, even under the more lenient undue burden standard, the challenged provisions in H.B. 1297 are unconstitutional. The district court judgment permanently enjoining the State from enforcing H.B. 1297 should be affirmed.

### I. Background

[964]This case is not directly about the right to an abortion. A right to abortion exists under federal law. Roe v. Wade, 410 U.S. 113, 153 (1973) (concluding the Fourteenth Amendment's concept of personal liberties and restrictions on state action is broad enough to encompass a woman's decision to terminate her pregnancy). Abortion is permitted under state law. N.D.C.C. § 14-02.1-04. The legislation at issue did not explicitly ban medication abortions. (This opinion refers to "medication" abortions." The district court referred to "medical abortions." Both refer to the same procedure.). Had the legislation at issue taken effect, abortion still would have been legal in the state of North Dakota. Instead, the legislation at issue in this case regulated abortions. Thus, this case should not be viewed in the controversial light surrounding abortion, but should be viewed as a case involving the legislature's regulation of medical practices and pharmaceutical drugs. At issue is a woman's liberty interest in making fundamental, appropriate, and informed medical decisions in consultation with her doctor. As the evidence shows, however, in some instances, for medical reasons, a woman is unable to have a surgical abortion. In those cases, the legislation is an obstacle to a safe and appropriate form of abortion and does reach the woman's right to have an abortion in any form. The case also touches on a doctor's right to practice good medicine without fear of prosecution.

[¶65] In July 2011, MKB Management Corporation ("MKB"), doing business as the Red River Women's Clinic (the "Clinic"), and Kathryn L. Eggleston, M.D., a physician licensed in North Dakota and the medical director at the Clinic, sued Dr. Dwelle and Birch Burdick, in his official capacity as State's Attorney for Cass County, for a declaration that certain provisions in H.B. 1297 for medication abortions violate the North Dakota Constitution. The plaintiffs allege the Clinic is the only abortion provider in North Dakota and serves women residing in North Dakota, as well as women who travel to the Clinic from Minnesota and South Dakota. The plaintiffs allege the Clinic offers both surgical and medication abortions and performed a total of about 1,300 abortions in 2010. According to Dr. Eggleston, in

2007 the Clinic began offering medication abortions using two prescription drugs, mifepristone and misoprostol, and typically about 20 percent of the Clinic's patients choose a medication abortion and about 80 percent of the patients choose a surgical abortion. According to Tammi Kromenaker, a director at the Clinic, the Clinic performs surgical abortions through 16 weeks of a woman's pregnancy and performs medication abortions up to 9 weeks or 63 days after a woman's last menstrual period using an "off-label" or "evidence-based" protocol rather than a "final-printed-label" protocol for administering the medication.

[¶66] A medication abortion is one that is brought about by taking medications that will end a pregnancy. Two medications are used as part of the medication abortion: mifepristone and misoprostol. Mifepristone works by blocking the hormone progesterone, which is necessary to sustain pregnancy. Without this hormone, the lining of the uterus breaks down, the cervix softens, and bleeding begins. Misoprostol causes the uterus to contract and empty. (Trial Exhibit 30). This case centers, in part, around the difference between the FDA label protocol and the "off-label" or "evidence-based" protocol for administering medication abortions.

[¶67] Under the FDA label protocol, the patient takes 3 mifepristone tablets (600 mg) at the Clinic. The patient must then return to the Clinic two days later to take 2 misoprostol tablets (400 mg) orally. The patient must then return to the Clinic a third time on or about day 14 for an ultrasound to confirm that the pregnancy has been terminated. (Trial Exhibit 3).

[¶68] Under the evidence-based protocol, the patient takes 1 mifepristone tablet (200 mg) at the Clinic. The patient then takes 4 misoprostol tablets (800 mg) buccally at home 24-48 hours later. The patient returns for a second visit in 1-3 weeks to confirm that the pregnancy has been terminated. (Trial Exhibit 12).

[¶69] The challenged provisions for medication abortions in H.B. 1297 were scheduled to take effect on August 1, 2011, and generally regulate the use of an "abortion-inducing drug" for the purpose of inducing an "abortion" in a pregnant woman. 2011 N.D. Sess. Laws ch. 109, § 6. The plaintiffs allege H.B. 1297 violates

the Clinic's patients' rights under N.D. Const. art. I, §§ 1 and 12 by: (1) banning all medication abortions; (2) banning medication abortions for women between 50 and 63 days of pregnancy; (3) banning safer and more effective "off-label" medication abortions; (4) banning medication abortions when a surgical abortion would threaten a woman's health; and (5) requiring women receiving a medication abortion to be provided with misleading information about emergency treatment.

In July 2011, the district court restrained enforcement of H.B. 1297 pending  $[\P 70]$ resolution of the plaintiffs' motion for a preliminary restraining order. In February 2012, the court preliminarily enjoined enforcement of H.B. 1297 during the lawsuit, concluding the plaintiffs were likely to prevail on their state constitutional challenge. The court described the existing undue burden standard for reviewing abortion legislation under the due process clause of the Fourteenth Amendment of the United States Constitution from the plurality opinion in <u>Planned Parenthood of Se. Penn. v.</u> Casey, 505 U.S. 833, 876-78 (1992). In granting the preliminary injunction, the court said the language in N.D. Const. art. I, § 1, is more expansive than the due process language in the federal constitution and cited Hoff v. Berg, 1999 ND 115, 595 N.W.2d 285, and State v. Cromwell, 72 N.D. 565, 9 N.W.2d 914 (N.D. 1943), for its determination that a woman's liberty right under the state constitution is fundamental and includes the freedom to have an abortion during the early stages of a pregnancy, which the court explained was subject to review under strict scrutiny. The court construed H.B. 1297 to prohibit all medication abortions after determining misoprostol, the second drug used in the FDA final-printed-label protocol for mifepristone, is an "abortion-inducing drug" and has not received separate FDA approval for use in abortions. The court construed the language requiring a physician providing abortions to enter an emergency services contract with another physician to require the other physician to provide exclusive coverage on an emergency basis, effectively banned all medication abortions, because the court said the requirement for an exclusive emergency services contract was impossible to satisfy. The court also said the language requiring administration of an abortion-inducing drug in the physical presence and same room as the prescribing physician made it impossible to perform medication abortions because of staffing concerns and costs associated with a return trip to an abortion facility for administering misoprostol. As construed, the court concluded H.B. 1297 failed to withstand strict scrutiny under the state constitution and the plaintiffs were likely to prevail on their state constitutional claims. The court also determined the requirements in H.B. 1297 constituted an undue burden on a woman's right to an abortion under the federal constitution because the amendments prohibited a method for performing an abortion before viability.

After an April 2012 trial on the merits, the district court permanently [¶71] enjoined the State from enforcing the challenged provisions in H.B. 1297. The court reiterated its earlier determination that a woman's right to an abortion is a fundamental liberty right under N.D. Const. art. I, §§ 1 and 12 and restrictions on that right were subject to strict scrutiny, which required the challenged legislation be narrowly drawn and necessary to address a compelling need. The court again construed the amendments in H.B. 1297 as banning all medication abortions after concluding misoprostol is an abortion-inducing drug and the final-printed-label protocol for misoprostol is not separately approved by the FDA for medication The court concluded the ban on all medication abortions was abortions. unconstitutional under the state constitution and was also an undue burden on a woman's right to an abortion before viability under the federal constitution. The court further ruled the state and federal constitutional provisions were violated by: (1) the requirement for dispensing or administering misoprostol in the same room and physical presence of the prescribing physician; (2) the 14-day difference in gestational limits for performing medication abortions under the FDA final-printed-label protocol and the off-label protocol; (3) the requirement for an exclusive emergency services contract; and (4) the lack of exceptions for a woman's health, for victims of rape and abuse, and for physical abnormalities. The court permanently enjoined enforcement of the challenged provisions in H.B. 1297.

[¶72] In June 2013, the district court granted the plaintiffs' motion to supplement its complaint to add Kromenaker as a plaintiff and to raise a state constitutional challenge to 2013 legislation in S.B. 2305 requiring physicians performing abortion procedures to have admitting and staffing privileges at a hospital within thirty miles of the abortion facility. See 2013 N.D. Sess. Laws ch. 118, §1. On July 31, 2013, the court preliminarily enjoined the State from enforcing S.B. 2305 pending trial. The State appealed from the judgment permanently enjoining enforcement of the 2011 amendments in H.B. 1297 and from the order preliminarily enjoining enforcement of the 2013 amendments in S.B. 2305.

#### II. Dismissal of 2013 Amendment Claims

[¶73] While the appeal was pending, the parties stipulated to dismiss the plaintiffs' claim to enjoin enforcement of the 2013 amendments in S.B. 2305. The district court dismissed that claim and vacated the order preliminarily enjoining enforcement of S.B. 2305. We therefore dismiss the State's appeal from the order preliminarily enjoining enforcement of S.B. 2305.

# III. Interpretation of Statutory Provisions

[¶74] The State argues the district court erred in interpreting the language in H.B. 1297. The State argues H.B. 1297 does not create a de facto ban on medication abortions, H.B. 1297 does not require physicians to direct patients to go to a specific physician and hospital if they have complications, H.B. 1297 does not require public disclosure of the contract, and H.B. 1297 does not impose criminal liability on physicians if a patient does not attend an appointment.

[¶75] Statutory interpretation is a question of law, fully reviewable on appeal. In re P.F., 2008 ND 37, ¶ 11, 744 N.W.2d 724.

Our primary objective in construing a statute is to ascertain the intent of the Legislature by looking at the language of the statute itself and giving it its plain, ordinary, and commonly understood meaning. State ex rel. Heitkamp v. Family Life Services, Inc., 2000 ND 166, ¶ 7, 616 N.W.2d 826. Although courts may resort to extrinsic aids to interpret a statute if it is ambiguous, we look first to the statutory language, and if the language is clear and

unambiguous, the legislative intent is presumed clear from the face of the statute. Overboe v. Farm Credit Services, 2001 ND 58, ¶ 9, 623 N.W.2d 372. In interpreting a statute, we presume the Legislature did not intend an absurd or ludicrous result or unjust consequences. Fleck v. ANG Coal Gasification Co., 522 N.W.2d 445, 454 (N.D. 1994). Rather, statutes are to be construed in a practical manner. Huber v. Oliver County, 1999 ND 220, ¶ 16, 602 N.W.2d 710. We give consideration to the context of the statutes and the purposes for which they were enacted. Falcon v. State, 1997 ND 200, ¶ 9, 570 N.W.2d 719.

McDowell v. Gillie, 2001 ND 91, ¶ 11, 626 N.W.2d 666. In enacting a statute, it is presumed the legislation is intended to comply with the state and federal constitutions, the entire statute is intended to be effective, a just and reasonable result is intended, a result feasible of execution is intended, and public interest is favored over any private interest. N.D.C.C. § 1-02-38. Words in a statute are given their plain, ordinary, and commonly understood meaning unless defined by statute or unless a contrary intention plainly appears. N.D.C.C. § 1-02-02. Statutes are construed as a whole and are harmonized to give meaning to related provisions. N.D.C.C. § 1-02-07. If the language of a statute is clear and unambiguous, the letter of the statute must not be disregarded under the pretext of pursuing its spirit. N.D.C.C. § 1-02-05. If the language of a statute is ambiguous, however, a court may resort to extrinsic aids to determine the intention of the legislation, including the object sought to be attained, the circumstances under which the legislation was enacted, and the legislative history. N.D.C.C. § 1-02-39. A statute is ambiguous if it is susceptible to different, rational meanings. State v. Meador, 2010 ND 139, ¶ 11, 785 N.W.2d 886.

[¶76] H.B. 1297 defines an "abortion-inducing drug" as a "medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion." 2011 N.D. Sess. Laws ch. 109, § 1. The legislation defines an "abortion" as the "act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means 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," but provides such use or

prescription is not an abortion if done (a) with the intent to save the life or preserve the health of the unborn child, (b) to remove a dead unborn child caused by a spontaneous abortion, or (c) to treat a woman for an ectopic pregnancy. <u>Id.</u> In the context of those definitions, the challenged language pertaining to the use of an "abortion-inducing drug" for a medication "abortion" provides:

- 1. For purposes of this chapter, an abortion accomplished by the use of an abortion-inducing drug is deemed to occur when the drug is prescribed, in the case of a prescription, or when the drug is administered directly to the woman by the physician.
- 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.
- 3. Every pregnant woman to whom a physician gives, sells, dispenses, administers, otherwise provides, or prescribes any abortion-inducing drug must be provided with a copy of the drug's label.
- 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 abortioninducing drug must be provided the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergences 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.

2011 N.D. Sess. Laws ch. 109, § 6.

#### A. FDA Label Provision

[¶77] The State argues H.B. 1297 does not create a de facto ban on medication abortions. This argument is based upon the State's proposition that the plain language of H.B. 1297's definitions of "abortion" and "abortion-inducing drug" allow for a reading under which mifepristone is classified as an abortion-inducing drug and misoprostol is not. This scenario could exist if "abortion" meant only the detachment of the fetus from the uterine lining, and not the expulsion of the fetus from the uterus. However, the definition of abortion includes the prescription of medicine, drug, or any other substance with the intent to terminate the intrauterine pregnancy of a woman. Section 1 of H.B. 1297 specifically excludes from the definition of abortion the use or prescription when the intent is to "[r]emove a dead unborn child caused by spontaneous abortion." This exclusion would not be necessary if the expulsion of an already detached fetus were not included in the statutory definition of abortion.

[¶78] Section 6 of H.B. 1297 requires that an "abortion-inducing drug" be administered in a manner that "satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug." Misoprostol has not been separately approved by the FDA for use in medication abortion procedures. However, the FDA label protocol specifies the use of misoprostol in conjunction with mifepristone. The evidence in this case is that mifepristone alone accomplishes an abortion, including the expulsion of the fetus from the uterus, in only about seven percent of the cases. Misoprostol is necessary to complete the abortion process in about ninety-three percent of the cases. Thus, under our reading of the definitions of "abortion" and "abortion-inducing drug," the

FDA label provision of H.B. 1297 necessarily operates as a de facto ban on medication abortions under current medical practices, at least until such a time as misoprostol is separately approved by the FDA for use in abortions or our statute is amended.

[¶79] For those women for whom a surgical abortion is not a possibility and for those women who are between 49 and 63 days past their last menstrual period, H.B. 1297 also operates as a complete ban despite the evidence presented at trial that the protocol developed using mifepristone and misoprostol is a safe and effective option for terminating an early pregnancy.

[¶80] When H.B. 1297 requires that medication abortions follow the FDA label protocol and that protocol includes the use of both mifepristone and misoprostol, it is unclear from the legislation whether both were intended as abortion-inducing drugs. It is, however, clear that any use of misoprostol that varies from the FDA label would subject a physician to criminal liability. Since the evidence establishes that the current standard of care for medication abortion varies from the FDA label, the legislation operates as a de facto ban as found by the district court.

#### B. Emergency Contract Provision and Public Disclosure

[¶81] The State argues H.B. 1297 does not require physicians to direct patients to go to a specific physician and hospital if they have complications and does not require public disclosure of the signed contract for emergency services beyond the identified statutory requirements. We assume, without deciding, for purposes of this opinion, the State is correct in this interpretation. As discussed below under the undue burden test, this interpretation does not assist in preserving the constitutionality of the challenged legislation.

### C. Criminal Liability on Physicians

[¶82] The State argues H.B. 1297 does not impose criminal liability on physicians if a patient does not attend an appointment. Section 6 of H.B. 1297 states:

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.

We assume that the limited interpretation of the State is correct. However, it begs the question. The district court concluded the plain language of this provision would impose criminal liability on a physician who provides abortion services under the evidence-based methods which the testimony indicates is the current standard of medical care. A physician who did not schedule three separate appointments, but who provided misoprostol to be taken buccally at home, would not satisfy the protocol of the FDA label. Such care would therefore be unlawful. The State's interpretation could only apply to appointments scheduled under the FDA label protocol.

# IV. Strict Scrutiny Analysis

[¶83] The district court analyzed the challenged legislation under strict scrutiny and under the undue burden test. We hold the district court properly applied both tests under our state constitution, and we discuss each separately.

[¶84] The State argues the district court erred in finding a right to abortion exists under the North Dakota Constitution and in applying strict scrutiny to the analysis of whether the challenged portion of H.B. 1297 is unconstitutional. One of this Court's highest powers is the authority to hold that a statute passed by our legislature violates the constitution of this state. Because of the gravity of such a ruling, we view statutes as presumptively constitutional, and we exercise our power with "restraint, caution, and reluctance," and only where "constitutional infirmity" has been demonstrated. Hoff v. Berg, 1999 ND 115, ¶ 7, 595 N.W.2d 285 (citations omitted). The party challenging the constitutionality of a statute has the burden of proving its constitutional infirmity. State v. Brown, 2009 ND 150, ¶ 30, 771 N.W.2d 267. The

determination whether a statute is constitutional is a question of law, which is fully reviewable on appeal. <u>State v. Holbach</u>, 2009 ND 37, ¶ 23, 763 N.W.2d 761.

# A. Fundamental Right

### [¶85] Pursuant to N.D. Const. art. I, §§ 1, 12:

Section 1. 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; acquiring, possessing and protecting property and reputation; pursuing and obtaining safety and happiness; and to keep and bear arms for the defense of their person, family, property, and the state, and for lawful hunting, recreational, and other lawful purposes, which shall not be infringed.

. . . .

Section 12. In criminal prosecutions in any court whatever, the party accused shall have the right to a speedy and public trial; to have the process of the court to compel the attendance of witnesses in his behalf; and to appear and defend in person and with counsel. No person shall be twice put in jeopardy for the same offense, nor be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty or property without due process of law.

[¶86] The preambles to the constitutions of the United States and the state of North Dakota celebrate liberty as a fundamental interest to be fostered and protected by these two forms of government. Other than Article I, Sections 9 and 10, the federal constitution said little about personal liberty until the addition of its amendments. Article I, Declaration of Rights, in our state constitution articulates those rights its framers considered fundamental. The "liberty" language of the 5th Amendment of the United States Constitution—"nor shall any person be . . . deprived of life, liberty, or property, without due process of law"—and the 14th Amendment—"nor shall any state deprive any person of life, liberty or property, without due process of law"—is mirrored in section 12 of the North Dakota state constitution: "No person shall be . . . deprived of life, liberty or property without due process of law." But article I, section 1 of the North Dakota state constitution has articulated a liberty interest that is more expansive and without parallel in the federal constitution. Like the Supreme

Court of Tennessee, we are "not free to discount the fact that the framers of our state constitution used language different from that used by the framers of the United States Constitution. No words in our constitution can properly be said to be surplusage." Planned Parenthood of Middle Tennessee v. Sundquist, 38 S.W.3d 1, 14 (Tenn. 2000).

[¶87] In interpreting constitutional provisions, we apply general principles of statutory construction. Thompson v. Jaeger, 2010 ND 174, ¶7, 788 N.W.2d 586. Our overriding objective is to give effect to the intent and purpose of the people adopting the constitutional provision. City of Bismarck v. Fettig, 1999 ND 193, ¶8, 601 N.W.2d 247. The intent and purpose of constitutional provisions are to be determined, if possible, from the language itself. Thompson, at ¶7. In construing constitutional provisions, we ascribe to the words the meaning the framers understood the provisions to have when adopted. Kadrmas v. Dickinson Pub. Schs., 402 N.W.2d 897, 899 (N.D. 1987).

The Journal of the Constitutional Convention shows that the language [¶88] originally proposed for article III, section 1 was: "All men are born equally free and independent, and have certain inherent, inalienable and indefeasible rights, among which are those of enjoying and defending life and liberty, of acquiring, possessing and protecting property and reputation, and of pursuing their own happiness." Journal of the Constitutional Convention for North Dakota 66 (1889). By the time of the first reading on July 31, 1889, the language was amended to read: "All men are by nature equally free and independent, and have certain inalienable rights, among which are those of enjoying and defending life and liberty; acquiring, possessing and protecting property and reputation, and pursuing and obtaining safety and happiness." Id. at 157. The Debates of the Convention indicate virtually no discussion about Section I. See Official Report of the Proceedings and Debates of the First Constitutional Convention of North Dakota 361 (1889). This language was adopted unanimously on August 13, 1889 by the framers of our state constitution. Thus, we are left with the plain meaning of the language.

[¶89] On November 6, 1984, an initiated measure was approved by the electorate of the state to make section I gender-neutral. 1985 N.D. Sess. Laws ch. 702, § 1. It now states, "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; acquiring, possessing and protecting property and reputation; pursuing and obtaining safety and happiness . . . ." N.D. Const. art. I, § 1. A woman has, under our state constitution, an inalienable right to enjoy and defend her liberty.

[¶90] This Court has recognized the due process language in N.D. Const. art I, § 12 "protects and insures the use and enjoinment of the rights declared" by N.D. Const. art. I, § 1. Cromwell, 72 N.D. at 574-75, 9 N.W.2d at 919. In different contexts, this Court has discussed issues about the rights secured by N.D. Const. art. I, §§ 1, 12. See Hoff, 1999 ND 115, ¶ 8-18, 595 N.W.2d 285 (holding grandparent visitation statute unconstitutional under due process clause of state and federal constitutions; stating parents have fundamental right to parent children and only compelling state interest justifies burdening parents' fundamental right); Cont'l Res., Inc. v. Farrar Oil Co., 1997 ND 31, ¶ 15-18, 559 N.W.2d 841 (discussing property rights protected by state constitution in context of compulsory pooling order for horizontal oil and gas well; recognizing property is subject to police power to impose restrictions as practically necessary for general welfare of all); State ex rel. Schuetzle v. Vogel, 537 N.W.2d 358, 360-64 (N.D. 1995) (recognizing person's constitutionally protected liberty interest to refuse unwanted medical treatment and balancing liberty interest against relevant state penological interest); Matter of K.A.S., 499 N.W.2d 558, 560-68 (N.D. 1993) (discussing due process in context of statute for court-appointed counsel for indigent parent in termination and adoption proceeding; construing statute to require court-appointed counsel for indigent parent in termination and adoption proceedings to avoid equal protection infirmity); Johnson v. Elkin, 263 N.W.2d 123, 128-30 (N.D. 1978) (identifying liberty right to engage in ordinary occupation without state regulation; recognizing police power to impose restrictions on right for general welfare of all); Bob Rosen Water Conditioning Co. v. City of Bismarck, 181 N.W.2d 722, 724 (N.D. 1970) (upholding requirement for plumbing license to install water softener; stating police power is not absolute and individual liberty may be restrained or abridged to benefit public welfare); <a href="State v. Odegaard">State v. Odegaard</a>, 165 N.W.2d 677, 680 (N.D. 1969) (holding statute requiring motorcycle operator to wear crash helmet was legitimate exercise of police power and did not violate state or federal constitutions); <a href="Cromwell">Cromwell</a>, 72 N.D. at 581, 9 N.W.2d at 922 (holding statute requiring license to engage in business of photography violated due process clause of state constitution). <a href="¶91">¶91</a>] In <a href="Cromwell">Cromwell</a>, 72 N.D. at 573-74, 9 N.W.2d at 918-19, this Court broadly described the "inherent rights" protected by the language in N.D. Const. art. I, §§ 1, 12, in the context of addressing a challenge to statutes prohibiting the practice of professional photography without a license. This Court explained:

This section [of the North Dakota Constitution] embodies the essence of the statement of the "self-evident truths" set forth in the Declaration of Independence, and the words and terms used, whether in the Declaration of Independence, the Constitution of the United States, or the Constitutions of the several states, convey a commonly accepted meaning. . . . Within the meaning of the term 'liberty' is also included . . . in general, the opportunity to do those things which are ordinarily done by free men.

... 'Liberty', as used in the Constitution embraces the free use by all citizens of their powers and faculties subject only to the restraints necessary to secure the common welfare.

This latter expression (the pursuit of happiness) is one of a general nature, and the right thus secured 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'. The happiness of men may consist in many things or depend on many circumstances. But in so far as it is likely to be acted upon by the operations of government, it is clear that it must comprise personal freedom, exemption from oppression or invidious discrimination, the right to follow one's individual preference in the choice of an occupation and the application of his energies, liberty of conscience, and the right to enjoy the domestic relations and the privileges of the family and the home. The search for happiness is the

mainspring of human activity. And a guarantied constitutional right to pursue happiness can mean no less than the right to devote the mental and physical powers to the attainment of this end, without restriction or obstruction, in respect to any of the particulars thus mentioned, except in so far as may be necessary to secure the equal rights of others. Thus it appears that this guaranty, though one of the most indefinite, is also one of the most comprehensive to be found in the constitutions.

<u>Id.</u> (citations and internal quotation marks omitted). Although the specific holding in <u>Cromwell</u>—that a statute requiring professional photographers to be licensed was unconstitutional—has been limited by subsequent cases, <u>see Johnson v. Elkin</u>, 263 N.W.2d at 128-30, its concept of fundamental rights under our state constitution has not.

# 1. Right to Abortion

[¶92] The State argues that the district court erred in finding a right to abortion. In its order of February 16, 2012, the district court held there is a right to an abortion under the North Dakota Constitution and the right is fundamental. The district court noted:

Although initial decisions were based in part on an inferred right to privacy, it is now clear that federal constitutional protection of reproductive rights is founded on the due process clause of the Fourteenth Amendment, and the controlling word is "liberty." Casey, 505 U.S. at 846. Liberty is also one of the freedoms protected by the Constitution of North Dakota. N.D. Const. art. 1, §§ 1, 12. Therefore, by itself the axiom that our state constitution may grant greater but not lesser protections would resolve the first of the threshold issues. At a minimum, the state constitution must protect a woman's right to have an abortion to the same extent as that right is protected by the Fourteenth Amendment to the federal constitution.

[¶93] The district court noted the highest courts of at least eleven states recognized their state constitutions protect a woman's right to an abortion: State of Alaska, Dep't of Health & Human Servs. v. Planned Parenthood of Alaska, Inc., 28 P.3d 904 (Alaska 2001); Comm. to Defend Reprod. Rights v. Myers, 625 P.2d 779 (Cal. 1981); In re T.W., 551 So.2d 1186 (Fla. 1989); Moe v. Sec'y of Admin. & Fin., 417 N.E.2d

387 (Mass. 1981). Women of the State of Minnesota v. Gomez, 542 N.W.2d 17 (Minn. 1995); Pro-Choice Mississippi v. Fordice, 716 So.2d 645 (Miss. 1998); Armstrong v. State, 989 P.2d 364 (Mont. 1999); Right to Choose v. Byrne, 450 A.2d 925 (N.J. 1982); Hope v. Perales, 634 N.E.2d 183 (N.Y. 1994); New Mexico Right to Choose/NARAL v. Johnson, 975 P.2d 841 (N.M. 1998); and Planned Parenthood of Middle Tennessee v. Sundquist, 38 S.W.3d 1 (Tenn. 2000). One decision from a state appellate court held there is no protection under its state constitution. That case was decided by an intermediate court in Michigan. Mahaffey v. Attorney Gen., 564 N.W.2d 104 (Mich. Ct. App. 1997). The Michigan Supreme Court had not yet ruled on this issue.

[¶94] Most of the cases hold that strict scrutiny is the appropriate standard of review. However, the Mississippi Supreme Court adopted the <u>Casey</u> undue burden standard. <u>Pro-Choice Mississippi</u>, 716 So.2d at 655. It is the only state high court that has taken this approach. The intermediate court in Ohio adopted the <u>Casey</u> undue burden test in <u>Preterm Cleveland v. Voinovich</u>, 627 N.E.2d 570, 577 (Ohio Ct. App. 1993), <u>cert. denied</u>, 624 N.E.2d 194 (Ohio 1993). Other courts have explicitly rejected the <u>Casey</u> test, applying strict scrutiny—a "recognized principle of constitutional law" that "has been applied repeatedly over the years." <u>Planned</u> Parenthood of Middle Tennessee, 38 S.W.3d at 16. The Tennessee court stated:

Thus, the <u>Casey</u> test offers our judges no real guidance and engenders no expectation among the citizenry that governmental regulation of abortion will be objective, evenhanded, or well-reasoned. This Court finds no justification for exchanging the long established constitutional doctrine of strict scrutiny for a test, not yet ten years old and applicable to a single, narrow area of the law, that would relegate a fundamental right . . . to the personal caprice of an individual judge.

Id. at 17.

[¶95] The constitutional provisions of New Jersey and Tennessee are most similar to article 1, section 1 of the North Dakota state constitution. California, Florida, Alaska, and Montana have express rights of privacy in their constitutions. Many of

the remaining decisions were based on less expansive provisions, more similar to section 12 of our state constitution or the due process clause of the Fourteenth Amendment to the federal constitution. The New Jersey decision is based on constitutional language very close to article 1, section 1 of our constitution, declaring liberty and the pursuit of happiness among the inalienable rights guaranteed to all persons. See Byrne, 450 A.2d at 934; N.J. Const. art. 1, § 1. The New Jersey court noted:

Thus, the statute impinges upon the fundamental right of a woman to control her body and destiny. That right encompasses one of the most intimate decisions in human experience, the choice to terminate a pregnancy or bear a child. This intensely personal decision is one that should be made by a woman in consultation with trusted advisors, such as her doctor, but without undue government interference.

<u>Id.</u> "Where an important personal right is affected by governmental action, the Court often requires the public authority to demonstrate a greater 'public need' than is traditionally required in construing the federal constitution." <u>Id.</u> at 936. The state funding restrictions on Medicaid abortions at issue were held to violate the New Jersey Constitution, even though they were permissible under the federal constitution. <u>Id.</u> at 937-38. <u>See also Moe v. Sec'y of Admin. & Fin.</u>, 417 N.E.2d at 404 (same). "We think our Declaration of Rights affords a greater degree of protection to the right asserted here than does the Federal Constitution as interpreted by Harris v. McRae. . . ." Id. at 400.

[¶96] Many states describe the right to an abortion to be a right of privacy; we do not find this difference to be significant. New Jersey, for example, described its right of privacy as arising under the following language of its constitution: "All persons are by nature free and independent, and have certain natural and unalienable rights, among which are those of enjoying and defending life and liberty, of acquiring, possessing, and protecting property, and of pursuing and obtaining safety and happiness." Byrne, 450 A.2d at 933. Tennessee, similarly found a right of privacy, determining that:

The concept of ordered liberty embodied in our constitution requires our finding that a woman's right to legally terminate her pregnancy is fundamental. The provisions of the Tennessee Constitution imply protection of an individual's right to make inherently personal decisions, and to act on those decisions, without government interference. A woman's termination of her pregnancy is just such an inherently intimate and personal enterprise. This privacy interest is closely aligned with matters of marriage, child rearing, and other procreational interests that have previously been held to be fundamental. To distinguish it as somehow non-fundamental would require this Court to ignore the obvious corollary.

### Planned Parenthood of Middle Tennessee, 38 S.W.3d at 15.

[¶97] The district court's analysis was thorough. We agree a fundamental right to choose abortion before viability exists under a woman's liberty interest in article 1, section 1 of the North Dakota constitution and that interest is protected under article 1, section 12.

# 2. Right to Choose Medical Treatment

[¶98] This Court previously held that individuals have both a federal and state constitutional liberty interest in refusing unwanted medical treatment, and that "a person's interest in personal autonomy and self-determination . . . is a 'fundamentally commanding one . . . . " State ex rel. Schuetzle, 537 N.W.2d at 362 n.2. We conclude, as other states have held, that this liberty interest includes the right of a woman, with the advice of her doctor, to choose the course of medical treatment that she believes is best among comparable alternatives. See Matter of Guardianship of Ingram, 689 P.2d 1363, 1368 (Wash. 1984) ("Unless outweighed by some state interest, a person has the right to choose one medical treatment over another . . . "); Hondroulis v. Schuhmacher, 553 So. 2d 398, 417 (La. 1988) ("[A] patient's right to choose her own medical treatment plan necessarily implies that she has a right to make considered and careful selections among the alternative medical options available in her case . . . . "). This decision, like the decision to refuse medical treatment, is an exercise of a woman's personal autonomy and self-determination. Thus, the choice is a fundamental one and is protected under the right to liberty found

in the North Dakota Constitution. The challenged legislation impacts the doctor's right to advise his or her patient about the current standard of medical care and the woman's right to choose the current standard of medical care, limiting instead the woman's choice to a protocol that the evidence describes as "outmoded," and making it criminal for the physician to offer the current standard of care.

# B. Strict Scrutiny Application

[¶99] Prior to the passage of H.B. 1297, medication abortions could be completed following the protocol for administration found on mifepristone's FDA label, or they could be completed following the "off-label," evidence-based regimen that has become standard practice in the medical community. The testimony indicated the evidence-based regimen had been used at the Clinic since 2007. The FDA label provision of H.B. 1297 takes the decision out of the hands of the woman and her doctor by requiring medication abortions to be performed in accordance with mifepristone's FDA label.

[¶100] When a state statute is alleged to burden a liberty right under the state constitution, this Court applies strict scrutiny. Hoff, 1999 ND 115, ¶13, 595 N.W.2d 285. "Where fundamental rights or interests are involved, a state regulation limiting these fundamental rights can be justified only by a compelling state interest and legislative enactments must be narrowly drawn to express only the legitimate state interests at stake." Id.

Generally, a statute is narrowly tailored, for purpose of determination whether it survives strict scrutiny review, only if it targets and eliminates no more than the exact source of the "evil" it seeks to remedy. As with the compelling interest determination, whether or not a regulation is narrowly tailored for purposes of a strict scrutiny analysis is evidenced by factors of relatedness between the regulation and the stated governmental interest.

16A Am. Jur. 2d <u>Constitutional Law</u> § 403 (2009). "The state, generally, has the burden of establishing that a state restriction which affects a fundamental right is necessarily related to a compelling interest." <u>Id. See Matter of K.A.S.</u>, 499 N.W.2d at 565 ("[w]hen we use strict scrutiny, we do not defer to the legislative choice of

classification but, instead, subject the classification 'to close analysis in order to preserve substantive values of equality. . . . "). Because H.B. 1297 burdens a woman's liberty interest under the North Dakota state constitution, strict scrutiny applies to the determination of whether the challenged provisions of H.B. 1297 are constitutional.

## 1. Compelling State Interest

[¶101] The State's only expressed purpose for the off-label administration ban portion of H.B. 1297 is "to protect the health of women seeking abortions by regulating medication abortions." (State's Appellate Brief, 24). In passing H.B. 1297, the legislature treated the administration of medication abortions differently than any other medical procedure under North Dakota law. The justification was that abortion "is a very unique situation and sometimes in unique situations they call for unique remedies." Hearing on H.B. 1297 Before the Senate Human Services Comm., 62nd N.D. Legis. Sess. (March 15, 2011) (Senate Standing Committee Minutes) (testimony of Senator Spencer Berry).

[¶102] Because prior to 1975 the state statutorily prohibited abortion, we must determine whether the state's justifications in interfering with a woman's liberty interest have changed over the years. The United States Supreme Court, in all decisions through <u>Gonzales v. Carhart</u>, instructs us that protection of unborn human life is not a sufficient justification to interfere with the liberty interest before viability. 550 U.S. 124, 146 (2007) ("Before viability, a State 'may not prohibit any woman from making the ultimate decision to terminate her pregnancy."").

[¶103] However, as noted by the Supreme Court of California, early anti-abortion legislation could be justified by the fact that abortion was dangerous. "When California's first anti-abortion statute was enacted, any surgical procedure which entered a body cavity was extremely dangerous. Surgeons did not know how to control infection, and mortality was high." People v. Belous, 458 P.2d 194, 200 (Cal. 1969).

Although development was slow, techniques of antisepsis and asepsis became major general advances in surgery at and after the turn of the century. In due course safe procedures were developed for specific operations. Curettage, used for abortion in the first trimester, became a safe, accepted and routinely employed medical technique, especially after antibiotics were developed in the early 1940's. (Douglas, Toxic Effects of the Welch Bacillus in Postabortal Infections (1956) 56 N.Y.State J.Med. 3673.) It is now safer for a woman to have a hospital therapeutic abortion during the first trimester than to bear a child.

<u>Id.</u> at 200-01 (footnote omitted); <u>accord Roe v. Wade</u>, 410 U.S. at 149; <u>Doe v. Bolton</u>, 410 U.S. 179, 190-91 (1973).

[¶104] The California court's attention to the dangers of abortion is echoed in the North Dakota newspapers which reported death or near death by abortion in a roughly ten-year period near the time North Dakota enacted its first anti-abortion laws. See Revised Codes of the Territory of Dakota, Penal Code, §§ 337, 338 (1877); Compiled Laws of the Territory of Dakota, Penal Code, §§ 6538, 6539 (1887); Revised Codes of the State of North Dakota, Penal Code, §§ 7177, 7178 (1895). See An Abortion Murder, Bismarck Tribune, Nov. 18, 1878; A Strange Case, Bismarck Tribune, May 6, 1881; Condensed Telegraph, Bismarck Tribune, April 28, 1882; Telegraphic Ticks, Bismarck Tribune, October 20, 1882; Death Caused by an Abortion, Bismarck Daily Tribune, October 9, 1891; Bowman Arraigned, Bismarck Daily Tribune, Oct. 16, 1891. The state's interest in maternal health has, in fact, changed with the advances of medical practice.

[¶105] In 1969, the Supreme Court of California invalidated a criminal abortion statute requiring certainty of a woman's impending death before abortion could be performed by a doctor. In so holding, the court noted "a definition requiring certainty of death would work an invalid abridgment of the woman's constitutional rights." Belous, 458 P.2d at 199. The court reasoned:

The fundamental right of the woman to choose whether to bear children follows from the Supreme Court's and this court's repeated acknowledgment of a "right of privacy" or "liberty" in matters related to marriage, family, and sex. That such a right is not enumerated in either the United States or California Constitutions is no impediment to the existence of the right. It is not surprising that none of the parties who have filed briefs in this case have disputed the existence of this fundamental right.

The critical issue is not whether such rights exist, but whether the state has a compelling interest in the regulation of a subject which is within the police powers of the state, whether the regulation is "necessary . . . to the accomplishment of a permissible state policy" and whether legislation impinging on constitutionally protected areas is narrowly drawn and not of "unlimited and indiscriminate sweep."

Id. at 199-200 (citations omitted).

[¶106] <u>Belous</u> pre-dated <u>Roe v. Wade</u>, but <u>Roe</u> is consistent with the strict scrutiny applied to the abridgements of fundamental rights under state constitutions. Although <u>Roe</u> recognized states may "properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life," the state's interest under Roe was minimal early in pregnancy. 410 U.S. at 154.

[¶107] The evidence in this case shows that medication abortions are in no more need of regulation than the multitude of other pharmaceutical drugs and medical procedures left unregulated by the legislature. As noted by the district court, the safety of medication abortions was a substantial focus of the trial, and the district court made findings based upon the evidence introduced. (Footnotes to the district court's opinion appear in an Appendix to this opinion.). The district court summarized:

## 1. Safety and Efficacy of Medical Abortions

The threshold issue is whether some compelling justification for regulation exists. Absent such need, even the most benign forms of infringement would be constitutionally infirm.

Certainly no medical procedures performed in the United States have been subject to more criticism, opposition or scrutiny than those performed to electively terminate a pregnancy. Medical abortions are no exception. At the same time, elective abortion is a very common procedure.<sup>3</sup> For example, an estimated 1.75 million medical abortions have been performed in the United States since Mifeprex was first approved for marketing and distribution in 2000. R. at 209. A wealth of solid medical evidence regarding safety and

efficacy exi[s]ts, particularly regarding the procedures commonly performed in the first trimester. This was a substantial focus of the trial.

#### a. MKB's Record

During the first several months of gestation, abortion is most commonly performed surgically, using a variation of the vacuum aspiration technique. Most clinics also offer patients the option of a medical abortion. MKB has been providing medical abortions since 2007. R. at 14. This option is generally offered through 63 days of gestation, as measured from the first day of the last menstrual period (LMP). R. at 21-22. It is selected by approximately 20% of patients.<sup>4</sup> R. at 19. As of March 31, 2013, a total of 1,417 medical abortions had been performed in Fargo. R. at 127.

Medical abortion patients of MKB are provided with detailed aftercare instructions. Exs. 30 and 31; R. at 133-34. They are also provided with a number they can call should they experience complications, or otherwise have questions or concerns. This phone service is provided on a continuous (24/7) basis, and is staffed by well qualified individuals. R. at 84. Patients are also instructed to return to the clinic two to three weeks following the initiation of the procedure. Approximately 75% of MKB's patients comply with this instruction, and return for a follow-up evaluation. R. at 45-46. Therefore, MKB certainly has knowledge of the vast majority of any adverse events associated with the medical abortions it has performed.

To the best of its knowledge, no patient of MKB has died following a medical abortion. Furthermore, no patient has experienced an infection requiring treatment, or required any form of follow-up surgery on an emergent basis. R. at 106. One patient did require a blood transfusion for hemorrhage. This is the only instance of emergency care known to MKB that may be associated with a medical abortion performed at its clinic. R. at 50.

In terms of efficacy, approximately 2% of MKB's medical abortion patients require a vacuum evacuation to complete the procedure. R. at 34. This additional treatment is provided at the clinic on a routine and non-emergent basis. R. at 51. It is usually performed at the time of the follow-up examination. R. at 35, 173.

Furthermore, MKB's results are completely consistent with the overwhelming medical evidence that is now available at the national and international levels.

# b. Credibility of Expert Testimony

At trial, the primary experts regarding the safety and efficacy of medical abortions were Drs. Grossman and Harrison. From a

standpoint of their training and experience, both of these experts are highly qualified. They are board certified in obstetrics and gynecology. Both have closely followed developments in the use of medication to perform abortions, and they have both done so since before Mifeprex was first approved for distribution in the United States.

From an ideological standpoint, however, these two witnesses could not be more different. Dr. Grossman's personal and professional bias is to increase access to abortions. R. at 183-84. Dr. Harrison is opposed to abortion in all forms. In 2000, she left her medical practice in order to devote all of her time and energy to the American Association of Pro-life Obstetricians and Gynecologists. Dr. Harrison is the executive director of that organization. She also serves as its director of research and public policy. R. at 374-80.

It would be naive to assume that the opinions of either of these experts have not been influenced by their diametrically opposed convictions. At the same time, there are significant differences that should be noted.

Dr. Grossman's opinions were consistent and they were expressed with confidence. Those opinions are also supported by a very substantial body of medical evidence and literature. His answers were generally responsive, and appeared to be completely candid.

By contrast, Dr. Harrison's opinions have shifted dramatically over time, and appear to be shaped primarily by the position she is advocating at the moment. As a prime example, in 2002 she coauthored a "citizen petition" which urged the FDA to revoke its earlier approval of Mifeprex, and to conduct a comprehensive audit of the clinical studies commissioned by the drug's sponsor. R. at 377. This petition argued vehemently that the performance of medical abortions in accordance with the FDA approved documents represented a substantial and unacceptable risk to women's health.<sup>5</sup> In this litigation, Dr. Harrison supports the proposition that adherence to that same protocol should be legislatively mandated as a means of safeguarding women's health.

Furthermore, Dr. Harrison's opinions lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence. To the extent she referenced published studies during her testimony, Dr. Harrison tended to present the results in an exaggerated or distorted manner. Finally, her demeanor on the stand was guarded and defensive.

For all these reasons, it must be concluded that Dr. Grossman was a very credible witness, but the same cannot be said for Dr. Harrison. As Dr. Harrison was the state's sole witness, this further detracts from any weight that can be given to the state's evidence.

# c. Studies and Statistics

In his testimony, Dr. Grossman provided a detailed analysis of the relative safety and efficacy of medical abortions. For comparison purposes, he relied primarily on morbidity and mortality statistics applicable to childbirth and early surgical abortions. Before turning to any of this, however, a different and stark reality should be acknowledged.

The alternative to safe and legal abortion is, of course, illegal abortion. When it is not performed by a skilled physician, utilizing acceptable medical techniques and procedures, abortion is a notoriously unsafe practice. According to the World Health Organization (WHO), on a global basis illegal abortions continue to result in an estimated 47,000 deaths each year. Approximately one-fourth of all women who survive such procedures are left with some form of disability. These realities fall disproportionately on the poor, who cannot afford to travel to places where abortions are legal. WHO, Safe Abortion: Technical and Policy Guidance for Health Systems, p. 1 (2d ed. 2012) (WHO, 2012 Guidance Document). If medical abortions are no longer legal, safe and available in North Dakota, it must be assumed some women will feel compelled to resort to self-help. Although this is neither safe nor legal, virtually any medication is now readily available over the Internet. R. at 232, 354-55.

By comparison, when performed by physicians in accordance with the evidenced-based protocol followed by MKB, medical abortion is an extremely safe and effective procedure. The risk of a significant adverse event is so low it becomes hard to quantify.

A very recent study analyzed data from 233,805 medical abortions performed by Planned Parenthood affiliates in 2009 and 2010. Almost all of those procedures utilized the same protocol followed by MKB. The overall incidence of significant adverse events was very low. Emergency room treatment was required in only 0.10% of all cases. The hospitalization rate was even lower—0.06%. R. at 240. The study also confirmed that the evidence-based regimen is more effective through 63 days LMP than the FDA approved protocol was through 49 days LMP.

The revised and updated guidance document released by the WHO in 2012 is an excellent summary of current medical evidence and standards. R. at 197. It reports the evidence-based regimens have "been proven highly effective, safe and acceptable" for abortions up to 63 days LMP. WHO, 2012 Guidance Document, p. 44. It goes on to indicate that efficacy rates up to 98% are achieved, and that only a small percentage of patients require surgical intervention to complete the procedure or to control bleeding. Id.

#### d. The State's Arguments

The state failed to effectively refute any of this.

It was suggested not all adverse events resulting from medical abortions may be reported, but this is certainly true of any medical procedure. R. at 264-78. Moreover, due to the intense scrutiny medical abortions receive, under-reporting should be a relatively insignificant concern in this case. R. at 317-18.

The state also suggests that most of the data regarding medical abortions does not come from closely controlled medical trials, and therefore may not have comparable reliability. R. at 381-87. This criticism is equally unavailing. Because adverse events are so rare, any clinical study designed to analyze or quantify the risks would necessarily require a huge number of cases—a very unfeasible proposition. R. at 311.

Dr. Harrison's opposition to medical abortions has largely focused on her concern that this procedure may somehow be associated with an extremely rare and usually fatal form of bacterial infection. In her affidavit, she claimed that: "The death rate from <u>C. sordellii</u> infection alone in medical abortions is ten times the death rate from all causes in surgical abortion at a comparable gestational age." Harrison aff., ¶ 12. The evidence introduced at trial painted a very different picture.

The FDA has analyzed the adverse incident reports submitted in connection with the use of Mifeprex through the end of April 2011. This reflects data from an estimated total of 1.52 million cases. Ex. 6. Fourteen post-procedure mortalities have been reported. Some of those deaths were clearly unrelated. Seven cases tested positive for Clostridium sordellii, and one case tested positive for Clostridium perfringens. Id. fn. 1. The eight deaths that appear to be the result of bacterial infection have been the subject of intense scrutiny and debate.

Dr. Harrison theorizes that the combination of mifepristone and misoprostol, when administered in accordance with the evidence-based protocol, may impair or interfere with natural immune systems or clotting mechanisms. R. at 395-97, 418. She provided no credible, scientific support for this theory. Despite the continued and concerted efforts of abortion opponents, the FDA continues to indicate that no causal connection has been established between medical abortions and the reported <u>Clostridium</u> deaths. The same is true for the CDC. R. at 446-47. Furthermore, deaths from the same bacterial infection have been reported following other medical events, including childbirth and surgical abortions, which suggests the absence of a causal link to medical abortions. R. at 210.

Even if some causal connection is ultimately established, this concern has already been addressed by changes to the evidence-based protocol. Before these deaths were reported, most centers were instructing patients to self-administer the misoprostol vaginally. Seven of the reported fatal sepsis cases involved vaginal misoprostol use. Only one such death followed the buccal administration of this drug. Id., fn. 1. The vast majority of providers, including MKB, now recommend the buccal administration of misoprostol, and prescribe an antibiotic on a prophylactic basis. R. at 283. On a national basis, perhaps 750,000 medical abortions have now been performed utilizing the current, evidence-based protocol. R. at 315. Even if the one fatality due to a bacterial infection is related, the mortality rate is infinitesimal.

# e. Risk Comparisons

In comparative terms, childbirth is far more likely to result in death or significant complications. Dr. Grossman's testimony underscores this reality. He cited a recent study which indicates a live birth is 12.5 times more likely to result in maternal mortality than a medical abortion. R. at 208-09. A comparison of morbidity rates also results in large disparities. For example, a blood transfusion is 10 times more likely following childbirth, and the risk of serious infection is increased by a factor of 5.2. R. at 205-06.

Because all the rates are so low, it is more difficult to compare the potential risks associated with a medical abortion to those associated with an early surgical abortion. Dr. Grossman testified that, based on his thorough knowledge of the relevant studies, the overall risks are very comparable. R. at 200. In its 2012 guidance document, the WHO concludes "complications are impressively rare and the risk of death is negligible" with any modern abortion procedure. WHO, 2012 Guidance Document, p. 47. This quote accurately captures the overall record.

#### f. Conclusion

In short, the record establishes, in a very convincing manner, medical abortions are very safe and effective through 63 days LMP, when performed in accordance with current standards. Accordingly, the state has failed to demonstrate any need to regulate this procedure, much less a compelling need.

The district court's findings accurately reflect the testimony given. The evidence establishes that there is no safety reason based on maternal health to limit medication abortions to the FDA label.

[¶108] The findings of the district court on this issue are supported on appeal by the amicus brief filed by the North Dakota Medical Association in support of affirmance, which urges this Court:

The [challenged portions of H.B. 1297] intrude[] on the patient-physician relationship in three concrete ways. First, following the Act's treatment protocol, a physician is required to administer three times more medication than a patient needs. Second, the physician is required to instruct the patient to appear at the clinic during a time when it is safer for the patient to remain at home. Third, the physician is required to give the patient erroneous and dangerous instructions regarding what the patient should do if she experiences a medical emergency. All of these intrusions force a physician to violate prevailing standards of medical care and good medical judgment.

[¶109] In <u>Doe v. Bolton</u>, the United States Supreme Court, applying strict scrutiny, struck down Georgia statutes regulating the manner in which abortions could be performed in that state as a constitutionally impermissible interference with the woman's right to receive medical care and the doctor's right to practice medicine. 410 U.S. at 197, 199. Criminal sanctions were imposed on the doctor for violations of the statute. <u>Id.</u> at 188. "Viewing the Georgia statute as a whole, we see no constitutionally justifiable pertinence in the structure for the advance approval by the abortion committee. . . . We are not cited to any other surgical procedure made subject to committee approval as a matter of state criminal law. The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." <u>Id.</u> at 197. "Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice." <u>Id.</u> at 199.

[¶110] The State cannot establish that the legislation serves the purpose of protecting maternal health, let alone a compelling interest. Since the decision of the district court, other states have failed to provide evidence that similar legislation restricting the use of off-label, evidence-based protocols for medication abortions protects

maternal health. <u>Planned Parenthood Arizona v. Humble</u>, 753 F.3d 905, 916 (9th Cir. 2014), <u>petition for cert. filed</u>, 2014 WL 4467076 (U.S. Sept. 2, 2014) (No. 14-15624) ("Plaintiffs have introduced uncontroverted evidence that the Arizona law substantially burdens women's access to abortion services, and Arizona has introduced no evidence that the law advances in any way its interest in women's health.").

[¶111] Like the California Supreme Court in <u>Belous</u>, we conclude that considerations of maternal health do not provide a compelling state interest to support the constitutionality of the challenged legislation.

# 2. Narrowly Tailored

[¶112] Even where the State has a compelling interest in the regulation of medication abortions, the State has an additional burden to show that state legislation limiting the exercise of fundamental rights is narrowly tailored to address its compelling interest. See Hoff, 1999 ND 115, ¶13, 595 N.W.2d 285. Evidence in this case shows the challenged legislation is not narrowly tailored. As discussed below, the provisions of H.B. 1297 at issue do not satisfy the less-stringent, undue burden analysis's requirement that the challenged legislation further the State's purpose. These provisions do not promote women's health in any way, let alone in the most narrowly tailored way. Because we hold below that these provisions cannot stand under the less-stringent undue burden standard, we do not repeat the analysis here. The challenged provisions of H.B. 1297 are not narrowly drawn to address the State's proffered interest.

[¶113] We agree with Minnesota, Montana, California, Alaska, New Jersey, Tennessee, and other courts that the State must establish a compelling interest to interfere with a woman's fundamental right to an abortion prior to viability and must establish a narrow means of addressing its interest. The challenged legislation fails both tests. The decision of the district court permanently enjoining enforcement of H.B. 1297 should be affirmed.

## V. Undue Burden Analysis

[¶114] Although the district court determined the challenged portion of H.B. 1297 was unconstitutional under a strict scrutiny analysis, it also determined the challenged portion of H.B. 1297 was unconstitutional under the undue burden standard of analysis developed in federal caselaw. The district court's undue burden analysis is required under both the federal and our state constitution. We interpret our state constitution in light of the text and history of that document. "[W]e cannot interpret our state constitution to grant narrower rights than guaranteed by the federal constitution." Southeast Cass Water Res. Dist. v. Burlington N. R.R. Co., 527 N.W.2d 884, 890 (N.D. 1995). Plaintiffs brought this action under several sections of the state constitution, primarily article I, sections 1 and 12. Although, as discussed above, the language in section 1 is more expansive than language in the federal constitution, section 12 virtually mirrors the language of the Fifth and Fourteenth Amendments to the federal constitution. Decisions arising under the comparable provision of the federal constitution must inform our decisions under the same language of our state constitution. Federal decisions interpreting and applying the Fourteenth Amendment become a minimum to our interpretation of section 12 of the state constitution in this context. Our own constitution requires this. See N.D. Const. art. I, § 23. We must therefore, at a minimum, consider the constitutionality, under our state constitution, of legislation regulating abortion under the undue burden standard developed in federal caselaw.

[¶115] In 1973, in Roe v. Wade, 410 U.S. at 117-18, the United States Supreme Court considered a federal constitutional challenge to Texas statutes prohibiting abortions except for the purpose of saving the mother's life. The Court concluded an individual's right to privacy under the Fourteenth Amendment's concept of personal liberty was broad enough to cover the abortion decision. Id. at 152-55. The Court concluded, however, an individual's right to an abortion was not absolute and was subject to some limitations, and at some point, the state's interest in the protection of a woman's health, medical standards, and the potential for prenatal life became dominant. Id. The Court explained "[w]here certain 'fundamental rights' are

involved, . . . regulation[s] limiting these rights may be justified only by a 'compelling state interest,' and that legislative enactments [regulating those fundamental rights] must be narrowly drawn to express only the legitimate state interests at stake." <u>Id.</u> at 155 (citations omitted). The Court balanced the respective interests and announced a trimester framework for evaluating abortion regulations. Id.

[¶116] In 1992, in <u>Casey</u>, 505 U.S. at 844, the United States Supreme Court considered a federal constitutional challenge to several provisions of the Pennsylvania Abortion Control Act of 1982. In <u>Casey</u>, a plurality of the Supreme Court reaffirmed the "essential holding" in <u>Roe</u> that the right to terminate a pregnancy before viability is a liberty interest under the Fourteenth Amendment's due process clause:

First is a recognition of the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State. Before viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure. Second is a confirmation of the State's power to restrict abortions after fetal viability, if the law contains exceptions for pregnancies which endanger the woman's life or health. And third is the principle that the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child.

<u>Id.</u> at 846.

[¶117] In <u>Casey</u>, 505 U.S. at 852, 871-72, the plurality discussed the practical difficulty in applying strict scrutiny to abortion regulations because of a state's important and legitimate interests in a woman's health and in potential life. The plurality opinion abandoned the trimester framework from <u>Roe</u> and instead applied an "undue burden" standard under the federal constitution to evaluate the constitutionality of abortion regulations before viability. <u>Id.</u> at 869-79. The plurality decision described the undue burden standard:

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 of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends. . . . Understood another way, we answer the question, left open in previous opinions discussing the undue burden formulation, whether a law designed to further the State's interest in fetal life which imposes an undue burden on the woman's decision before fetal viability could be constitutional. The answer is no.

Some guiding principles should emerge. What is at stake is the woman's right to make the ultimate decision, not a right to be insulated from all others in doing so. Regulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose. See [505 U.S.] at 899-900 (addressing Pennsylvania's parental consent requirement). Unless it has that effect on her right of choice, a state measure designed to persuade her to choose childbirth over abortion will be upheld if reasonably related to that goal. Regulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden.

- .... We give this summary:
- (a) To protect the central right recognized by <u>Roe v. Wade</u> while at the same time accommodating the State's profound interest in potential life, we will employ the undue burden analysis as explained in this opinion. An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.
- (b) We reject the rigid trimester framework of <u>Roe v. Wade</u>. To promote the State's profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and measures designed to advance this interest will not be invalidated as long as their purpose is to persuade the woman to choose childbirth over abortion. These measures must not be an undue burden on the right.
- (c) As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or

effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.

- (d) Our adoption of the undue burden analysis does not disturb the central holding of <u>Roe v. Wade</u>, and we reaffirm that holding. Regardless of whether exceptions are made for particular circumstances, a State may not prohibit any woman from making the ultimate decision to terminate her pregnancy before viability.
- (e) We also reaffirm <u>Roe</u>'s holding that "subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."

Id. at 877-79 (citations omitted).

[¶118] In <u>Gonzales</u>, 550 U.S. at 129, 132-33, the United States Supreme Court considered the validity of the Partial-Birth Abortion Act of 2003, 18 U.S.C. § 1531, a federal statute regulating certain partial-birth abortion procedures in the second trimester, passed with the purpose of respecting the life of the fetus. The Court described "assume[d]" principles from Casey for purposes of its decision:

Before viability, a State "may not prohibit any woman from making the ultimate decision to terminate her pregnancy." 505 U.S., at 879 (plurality opinion). It also may not impose upon this right an undue burden, which exists if a regulation's "purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability." <u>Id.</u>, at 878. On the other hand, "[r]egulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose." <u>Id.</u>, at 877. <u>Casey</u>, in short, struck a balance.

<u>Id.</u> at 146.

[¶119] In <u>Gonzales</u>, the Court construed the Partial-Birth Abortion Act and concluded it prohibited intentionally performing an intact dilation and evacuation procedure, but did not prohibit a standard dilation and evacuation procedure in which the fetus was removed in parts. 550 U.S. at 150-67. The Court compared the two procedures and determined the regulation furthered the government's interest in promoting respect for life. <u>Id.</u> at 156-58. The Court also determined there was

disagreement whether the prohibited procedure was safer than the allowed procedure, therefore the challengers had not met their burden of proving that the regulation had the effect of imposing an undue burden by requiring women to undergo a less safe procedure. <u>Id.</u> at 161-63.

# A. Purpose—Women's Health

[¶120] Unlike Gonzales, in this case, the State's expressed purpose for H.B. 1297 is "to protect the health of women seeking abortions by regulating medication abortions." (State's Appellate Brief, 24). Protecting women's health can be a legitimate purpose for pre-viability abortion regulation. See Casey, 505 U.S. at 878 (plurality opinion). However, courts cannot simply take the legislature at its word that the law serves this interest. When conducting purpose prong analysis, courts must ensure that the state's interest in women's health is actually served by the legislation. See Gonzales, 550 U.S. at 158 (analyzing a law under the purpose prong of the undue burden test and concluding the law "further[ed] the Government's objectives"); Humble, 753 F.3d at 913 (noting that a court must "ask[] whether and to what extent the challenged regulation actually advances the state's interest"). In Casey, the Court reasoned that "the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it." 505 U.S. at 877. "The same is true for laws purporting to protect women's health: they 'must be calculated' to advance women's health, 'not hinder it." Humble, 753 F.3d at 913 (citation omitted).

[¶121] The court in <u>Humble</u> was examining similar Arizona legislation that restricted medication abortions to FDA label protocols. As in this case, the state of Arizona was unable to demonstrate the legislation advanced maternal health. The <u>Humble</u> court, relying on <u>Gonzales</u>, 550 U.S. at 165-66, noted the critical judicial function is to examine both the rationale for the legislation and the burden it imposes, determining that uncritical deference is "inappropriate" where constitutional rights are at stake. <u>Humble</u>, 753 F.3d at 913. <u>See also Planned Parenthood of Wisconsin, Inc.</u> <u>v. Van Hollen</u>, 738 F.3d 786, 798 (7th Cir. 2013) ("The cases that deal with abortion-

related statutes sought to be justified on medical grounds require not only evidence . . . that the medical grounds are legitimate but also that the statute not impose an 'undue burden' on women seeking abortions. The feebler the medical grounds, the likelier the burden, even if slight, to be 'undue' in the sense of disproportionate or gratuitous." (Internal citations omitted)).

[¶122] The Ninth Circuit was critical of the decisions in <u>Planned Parenthood of Greater Texas Surgical Health Services v. Abbott</u>, 748 F.3d 583 (5th Cir. 2014), and <u>Planned Parenthood Southwest Ohio Region v. DeWine</u>, 696 F.3d 490 (6th Cir. 2012), <u>reh'g & reh'g en banc denied</u> (Nov. 30, 2012), because of the failure in those cases to do a complete undue burden analysis as articulated and applied in <u>Casey</u> and <u>Gonzales</u>: "The Fifth and Sixth Circuits' approach fails to recognize that the undue burden test is context-specific, and that both the severity of a burden and the strength of the state's justification can vary depending on the circumstances." <u>Humble</u>, 753 F.3d at 914.

[¶123] The district court in this case took evidence which applied to both the State's proffered rationale for the legislation and to the burden it imposed. The district court did a complete <u>Casey/Gonzales</u> analysis.

#### 1. FDA Label Provision

#### a. De Facto Ban

[¶124] As discussed above, the testimony and evidence at trial shows that a de facto ban on medication abortions does not protect women's health.

#### b. Restriction to FDA Label

[¶125] Analyzing the FDA label provision on its face, the voluminous record in this case supports the district court's conclusion: requiring adherence to mifepristone's FDA label does not protect women's health. In order to conclude the FDA label provision of H.B. 1297 protects women's health, there must be credible evidence that off-label abortions, which had become accepted practice in the medical community prior to this legislation, are more dangerous than abortions performed under the regimen described in the FDA label. Legislation for legislation's sake that does not

protect women's health cannot be sustained applying either strict scrutiny or the undue burden standard of constitutional scrutiny under <u>Casey</u>. <u>See Casey</u>, 505 U.S. at 877-78.

[¶126] There is no evidence in the record to support the theory that the medication abortion protocol approved by the FDA is safer for women than the evidence-based medication abortion protocol being used by MKB. Similarly, when passing H.B. 1297, the legislature itself recognized, "There was no testimony that indicated there was more risk with off label use." Hearing on H.B. 1297 Before the Senate Human Services Comm., 62nd N.D. Legis. Sess. (March 15, 2011) (Senate Standing Committee Minutes).

[¶127] In its amicus brief, the North Dakota Medical Association described its opposition to H.B. 1297's FDA label provision:

The marketing, sale, and use of prescription medications in the United States are the subjects of a complex web of federal and state statutes, regulations, and oversight. The U.S. Food & Drug Administration (FDA) plays a prominent, but by no means exclusive role, in this web. The Act ham-handedly invokes the FDA's role by incorporating the FDA's medication marketing approval process, which the Act claims produces a "document that delineates how a drug is to be used according to the federal food and drug administration [sic]." H.B. 1297 § 1, 62[n]d N.D. Legis. Sess. (to be codified at N.D.C.C. § 14-02.1-02). The Act misconstrues the document at issue, the FDA's role in its creation and distribution, and its meaning and effect in the practice of medicine.

. . . .

The Act's required adherence to an outmoded protocol for administration of the drugs at issue is especially egregious because it forces North Dakota's physicians to administer three times the clinically appropriate dose of Mifeprex. It forces physicians to set aside their medical knowledge, training, and experience and practice medicine in a manner not consistent with the prevailing standard of care. The Act thus compels a physician to violate his or her oath to "serve the highest interests of my patients through the practice of my science and my art."

(Footnotes omitted).

[¶128] Testimony indicates that evidence-based, off-label medication abortion protocol is as safe as the FDA label protocol and, in fact, may even be more beneficial to women's health. With respect to off-label use, the FDA itself notes:

Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such . . . "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.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

<u>Use of Approved Drugs for Unlabeled Indications</u>, FDA Drug Bulletin, Vol. 12 No. 1, April 1982 at 4-5 (emphasis added).

[¶129] Dr. Eggleston, medical director of the Clinic, testified that they use an evidence-based protocol for medication abortions, rather than the FDA label protocol, because "numerous studies . . . have shown that the evidence-based method of medical abortion is safe and more effective [than the FDA label protocol] specifically up to 63 days gestational age." "There's been many evidence-based studies that show that the 600 milligrams, which is what was given—described in the [FDA label], is equivalent to 200 milligrams of the Mifepristone. And so there's—they're equally effective so there's no reason to give more medication than needed. And it's also three times as expensive." Dr. Daniel Grossman noted that "one of the studies found an increased risk of nausea with women who received [the FDA label's prescribed dosage] of Mifepristone compared to [the dosage given under evidence-based

protocol]." Dr. Eggleston testified, "[T]here's been numerous studies that have compared [evidence-based and off-label administration of misoprostol] and the—the [evidence-based administration] has been shown to be very safe and more effective especially in those women 50 to 63 days gestational age." There are "no increase in serious complications" associated with the evidence-based administration of misoprostol. Dr. Eggleston also testified:

- A. ... I can tell you in general we do not promote the FDA method because we use the evidence-based method which is safe and effective and is the standard of care in our region.
- Q. And when you say the evidence base is safe and effective, would you say the same thing about the FDA . . . protocol in terms of safety?
- A. Yes. It is safe and effective, yes.
- Q. It's just less convenient, that's what we're talking about, right?
- A. No. The evidence base method is more effective especially in those women 50 to 63 days gestational age.
- Q. It's more effective because it can't be provided under the FDA, correct?
- A. And I think if you take—if you just compare the two regimens and take the FDA restriction out the evidence-based method that we give is more effective, especially between 50 and 63 days gestational age.
- Q. But under the FDA the 50 to 63 days isn't even an issue, correct?
- A. It is not. They don't comment on that in the FDA protocol.
- Q. Okay. For the protocol up to the 50 days, to the 49th day, are both methods of medication abortion equally safe?
- A. They're both safe, yes.

[¶130] Dr. Grossman testified that a study conducted at National Abortion Federation member clinics the year after mifepristone was approved by the FDA found that only 4% of facilities surveyed were administering medication abortions in accordance with the FDA label protocol; "the vast majority of providers were using evidence-based regimens." Dr. Grossman also testified that this immediate shift away from the FDA label protocol indicated that protocol was "obsolete about the same time it was authorized." Dr. Grossman noted that, under the 2005 American College of Obstetrician's and Gynecologists ("ACOG") guidelines on medication abortions:

[T]he FDA approved protocol [for medical abortions] is safe and effective for medical abortion through 49 days of gestation. . . . [C]ompared with the FDA approved [protocol], [evidence-based protocols] are associated with a decreased rate of continuing pregnancies, decreased time to expulsion, fewer side [e]ffects, improved complete abortion rates, and lower cost for women with pregnancies up to 63 days of gestation based on last menstrual period.

Dr. Grossman testified the ACOG reaffirmed its findings in 2011, and noted that, "compared to the FDA regimen, the evidence-based regimen . . . is essentially more effective and associated with a lower cost and can be used up to 63 days gestation." Dr. Grossman concluded:

There is no medical benefit [to the FDA label dosage of Mifepristone]. As I mentioned, you know, the studies that have done direct randomized controlled trials, or 4 studies that have looked comparing the 200 to 600-milligram doses of Mifepristone, show no differences in efficacy. There's certainly ample safety data also with the 200-milligram regimen.

[¶131] The testimony of the State's only witness supports the conclusion that the off-label protocol for medication abortions is no more dangerous than administration pursuant to the FDA label protocol. Dr. Donna J. Harrison, Executive Director of the American Association of Pro-life Obstetricians and Gynecologists, testified:

So when we look at this and you say is there a concern about 3,200 milligram tabs versus 1,200 milligram tabs, well, you're getting more of the Mifepristone. Is that a concern? It depends on what you mean by a concern. It's not been shown to be any different in any of the studies that have been done so in and of itself that's not a concern.

There's not been shown to be a difference with 200 versus 600 as has been amply testified.

Dr. Harrison also acknowledged that the ACOG concluded, "Multiple large studies in the United States have demonstrated that a patient can safely and effectively administer the Misoprostol, paren, orally or vaginally in her home." Dr. Harrison also acknowledged that the World Health Organization concluded, "Home use of Misoprostol is a safe option for women." Dr. Harrison did not provide an explanation

as to why regulation of medication abortions should be limited to the FDA label, rather than the evidence-based protocol, instead stating that her opinion is that the FDA should revoke all approval of mifepristone.

[¶132] The evidence at trial supports the district court's conclusions that there was no evidence the FDA label protocol was beneficial or advantageous in protecting women's health, when measured against the evidence-based, medically-preferred, off-label protocol.

[¶133] In other areas of our statutes, the North Dakota legislature has recognized the importance of allowing physicians to prescribe medications based on best practices and their own medical judgment, rather than adhering to a drug's FDA label. N.D.C.C. § 26.1-36-06.1 controls health insurance coverage for off-label uses of drugs. That statute requires health insurance providers to provide coverage for drugs administered off-label "if the drug is recognized for treatment of the indication in one of the standard reference compendia or medical literature." Id. In passing this statute, the North Dakota legislature recognized that "[f]or [the FDA] to go back and reassign the drugs is very costly and through usage of drugs more advantages are found." Hearing on H.B. 1428 Before the Senate Human Services Comm., 55th N.D. Legis. Sess. (March 5, 1997) (Senate Standing Committee Minutes). They also recognized that medical doctors were in a better position to make judgments regarding the use of off-label drugs. Hearing on H.B. 1428 Before the House Industry, Business and Labor Comm., 55th N.D. Legis. Sess. (Jan. 27, 1997) (written testimony of Rep. Ralph Kilzer). No other statutes have been passed by the legislature to ban off-label administration in other areas of medicine.

[¶134] Off-label treatment is common in other medical contexts, such as the treatment of cancer:

Off-label therapy with cancer drugs is common in practice. When there is no established therapy for a cancer, or stage of cancer, it is common for oncologists to try different regimens or combinations of established drugs. . . . In their daily practice, many oncologists treat cancer patients with regimens that include off-label use of

drugs. They evaluate the published data and past clinical experience to assess the risk of such treatments.

Guidance for Industry IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer, U.S. Department of Health and Human Services, 4 (Jan. 2004).

[¶135] The restrictions at issue beg the question: would the legislature ban off-label treatment for other medical conditions? For example, use of off-label drugs is prevalent in the treatment of prostate cancer. See Zosia Chustecka, Significant Off-Label Use of Chemo in Elderly Cancer Patients, Medscape (June 13, 2013), http://www.medscape.com/viewarticle/805748 (noting there are 33 "unapproved" drugs used in the treatment of prostate cancer).

[¶136] Evidence at trial was consistent with our statutory recognition of off-label use. When asked whether Dr. Grossman was "aware of any other areas of medical practice where physicians are restricted from prescribing drugs off-label where such off-label use has been documented as safe either in published medical journals or as consistent with the standard of care," Dr. Grossman testified that he was "not aware of any other example."

#### 2. Emergency Contract Provision

[¶137] The testimony and evidence at trial supports the conclusion that the emergency contract provision of H.B. 1297 does not protect women's health, is unnecessary, is burdensome, can result in confusing instructions to patients, and is impossible to fulfill. The State argues that H.B. 1297 does not require physicians to direct patients to go to a specific physician and hospital if they have complications. Even assuming such an interpretation is plausible, it does not support the constitutionality of the challenged provision. The legislation provides:

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.

2011 N.D. Sess. Laws ch. 109, § 6.

[¶138] The district court described the required contract as an exclusive contract. The language of the legislation supports this description. From the perspective of the physician agreeing to take on the responsibilities, it would certainly be perceived as an exclusive contract requiring continuous availability to meet the needs of patients coming from North Dakota, South Dakota, and Minnesota. The legislation requires that this physician have privileges at "the hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug." 2011 N.D. Sess. Laws ch. 109, § 6. The district court found, with support in the record, that these conditions were impossible to fulfill. As the testimony indicated, in the event of a medical emergency, patients have been regularly told to refer to the nearest medical center. Even if the State's interpretation of the contract is correct, by requiring the physician to give the patient a copy of the contract indicating the "name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled," id., the State's interpretation, at best, allows for confusing information to be provided to the patient. This is not in the interest of maternal health and is not supported by the language of the legislation. [¶139] The district court found that the emergency contract provision did not advance maternal health because it was unnecessary. The district court noted the complications associated with miscarriage and medication abortion are identical and so is the treatment. The difference is that complications associated with a miscarriage often arise later in the pregnancy when the fetus is more developed. Treating complications associated with miscarriage is a common medical event as the evidence established that one in seven pregnancies ended in spontaneous abortion. Complications associated with childbirth are also common medical events treated regularly throughout the medical community. Forty-three medical facilities distributed throughout North Dakota are capable of providing emergency care if complications arise from an abortion. The evidence before the district court established that MKB was only aware of one emergent situation for the Clinic patients which required a blood transfusion which was given in Minnesota.

[¶140] The district court's findings accurately reflect the evidence and testimony. Even under the State's more forgiving interpretation, the emergency contract provision of H.B. 1297 does not protect women's health.

#### B. Effect

#### 1. FDA Label Provision

#### a. De Facto Ban

[¶141] With respect to the effect of the de facto ban on medication abortions, the district court found:

## a. Physical Anomalies

The state has never disputed that some patients have physical anomalies which make a surgical abortion more difficult and hazardous. R. at 30-32, 211. Although they are relatively rare, physicians at the Fargo clinic have experience with all or most of these conditions. R. at 99. On occasion, the physical contraindications to a surgical approach are known in advance. More frequently, they are not discovered until a routine surgical abortion is attempted. In that event, it may be impossible to proceed to a successful conclusion. R. at 33.

This scenario leaves the physician and her patient with two options. The first is a medical abortion. The second option is a more invasive and extensive surgical procedure, performed in a hospital setting. For obvious reasons, physicians at MKB almost invariably recommend the medical approach to patients who must make this decision. R. at 33. In relative terms, it is much safer and more convenient. It is also much less expensive.

MKB does not perform inpatient surgery at its Fargo clinic. Patients who require such surgery must be referred to another provider. The closest facility providing these services is in Minneapolis. In addition to requiring hospitalization, the surgery is performed under anesthesia. This involves additional risk. R. at 37-38, 101-02. The direct cost of an inpatient surgical abortion is a minimum of \$2,000 to \$4,000. R. at 480. To this must be added the extra travel costs, and a large increase in the loss of productive time. R. at 37. Recovery is also likely to be more difficult and prolonged.

Dr. Harrison and the state argue that a medical abortion is not a good option in these cases as the contraindications to a routine surgical abortion also impair the prospects for a successful medical abortion. Although there may be a slight drop in the efficacy rate, <sup>28</sup> even with physical complications the medical approach utilizing the evidence-based protocol will be successful in at least 95% of all cases.29 There is no justification for subjecting all patients to the significantly increased costs and risks associated with an inpatient surgical procedure, just because a small percentage of them will ultimately be forced to bear this burden in any event. <u>Taft</u>, 444 F.3d at 512; R. at 36, 241-42.

## b. Victims of Abuse

In addition to the cases where physical complications make medical abortion the safest option, there are two broad categories where the detrimental effect of the ban imposed by the amendments is uncontroverted, real, and extreme—victims of sexual abuse and women living in abusive relationships.

The surgical procedure performed at the Fargo clinic is a variation of vacuum aspiration. To allow adequate visualization, a metal speculum must first be inserted and expanded. The cervix is next dilated using a series of rigid probes that gradually increase in size. Once the cervix is sufficiently dilated, a cannula attached to a vacuum apparatus is inserted into the patient's uterus and used to aspirate the embryonic tissue. R. at 94-97. Although local anesthetic is used during part of the procedure, the patient is awake and conscious throughout. R. at 95.

All this reinforces the conclusion an early surgical abortion requires multiple physical invasions of the patient's genital area, performed while she is awake. It also places the provider in temporary control of that area. Needle aff., p. 6. Understandably, victims of rape and other sex crimes often have a profound aversion for such intimate invasions. If forced to proceed with a surgical abortion, the emotional re-traumatization can be extreme. For these

patients a medical abortion is not a matter of choice, it is essential to their mental health and well-being. <u>Id.</u>

Surgical abortions can also create unthinkable predicaments for women living with domestic violence. Victims of this form of abuse must often adjust their own life to the demands of their abuser. In particular, abusers often seek to control their partner's sexuality. An abuser may seek to prevent his female partner from having an abortion, or become violent if she proceeds without his knowledge or consent. Id. ¶ 10.

Having a child in an abusive relationship often carries with it a fear that the child will also be abused. There is also the inevitable concern the abuser will thereby become a permanent part of the mother and child's lives. Many women in this situation justifiably fear their partner will learn they are pregnant, or are terminating the pregnancy. Id. ¶ 8.

For victims of domestic violence, submitting themselves to the control of their abusive partners often requires that they account for their time, whereabouts, expenditures, and travel. Travel to an abortion clinic, particularly at some distant location, will necessarily be difficult to hide or explain. The consequences of discovery could well be dire. Even if there is no discovery, the stress and anxiety experienced by a woman in this situation is certain to be severe. Id. ¶ 8 and 11. Therefore, any legislation that requires additional trips to the clinic has very serious implications for women in this predicament.

To all outward appearances, the bleeding and other side effects associated with a medical abortion are identical to a spontaneous abortion. For women living in abusive relationships, this can allow for a convincing cover story. When necessary, the abortion can be disguised as a miscarriage. Id. ¶ 11.

There is nothing hypothetical about the scenario outlined above. Patients of MKB have described this dilemma in the past, and they have chosen the medical approach for these reasons. R. at 34, 98, 129-30, 145.

Therefore, for victims of rape or sexual abuse, and for women living in an abusive relationship, a medical abortion may well be the only viable option. It is essential to their physical and emotional health. It is unacceptable to simply ignore these victims. For them, the ban on medical abortions continues to be unconscionable.

[¶142] The district court's findings accurately reflect the evidence and testimony. A de facto ban on medication abortions places a substantial obstacle in the path of a

woman seeking a pre-viability abortion.

#### b. Restriction to FDA Label

[¶143] H.B. 1297's ban of off-label administration of abortion-inducing drugs would apply independently to misoprostol, if it ever becomes separately approved by the FDA for abortions. However, mifepristone's FDA label also regulates the use of misoprostol in conjunction with mifepristone. With respect to the effects of the plain language of the FDA label provision of H.B. 1297, the district court found:

### b. Mifeprex Dosage

The FPL requires three 200 mg tablets of Mifeprex. It is now universally recognized that a single tablet is equally effective when followed by 800  $\mu$ g of mifepristone administered buccally or vaginally. R. at 26-27, 222-23.

At trial, the state offered no evidence suggesting the higher Mifeprex dosage confers any medical benefit. The most Dr. Harrison could say was that the higher dosage has not been shown to be "a concern." R. at 399.

Mifeprex is a relatively expensive drug. The cost of a single pill is \$85. Therefore, following the Mifeprex FPL would increase the cost of each procedure by a minimum of \$170. It also increases the odds of unpleasant side effects. R. at 219-20.

Approximately 40% of MKB's patients fall below the federal poverty level. R. at 128. Medical Assistance does not cover abortions. N.D. Cent. Code § 14-02.3-01. North Dakota law prohibits or discourages insurance coverage for abortions. N.D. Cent. Code § 14-02.3-03. The vast majority of MKB's patients self pay. R. at 128-29. This means that those who can least afford to be a mother are also likely to have extreme difficulty paying for an abortion. For a woman who is poor and pregnant, even a small increase in the cost of a medical abortion could easily render that procedure unavailable. See, e.g., Planned Parenthood Minnesota, North Dakota, South Dakota v. Daugaard, 799 F. Supp. 2d 1048, 1065 (D. S.D. 2011). No legislative requirement that only adds cost and requires unnecessary medication can withstand strict scrutiny.

# c. Misoprostol Dosage and Route of Administration

The Mifeprex FPL calls for the oral administration of 400  $\mu g$  of misoprostol. By the time this documentation was approved by the FDA, however, it was widely reported and recognized that the vaginal administration of 800  $\mu g$  of misoprostol provided many advantages. It reduced the time to expulsion, caused fewer side

effects, and improved complete abortion rates. It also allowed excellent results to be achieved up to 63 days LMP. R. at 219-21, 227-28.

By the time MKB began to perform medical abortions in 2007, the buccal administration of misoprostol had become the standard of care. This change was a response to the C. sordellii concerns discussed above. R. at 283. The protocol used by MKB (the oral administration of 200 mg of misoprostol) is the current standard of care. R. at 44. This is the only protocol that has ever been used by MKB. R. at 66. It is also the regimen followed by the vast majority of all providers. By contrast, the Miseprex FPL is now regarded in the medical community a relic of history. R. at 217-19, 262-63.

## d. Clinical Administration

The FPL requires that the patient return to the healthcare provider for the administration of misoprostol. This requirement does make sense in the context of a clinical trial. In order to validate the results, such trials require special monitoring and controls. R. at 309-10. Because clinical administration provides no therapeutic benefit, however, it is not surprising that this approach was quickly and almost universally abandoned once Mifeprex was released for use in the United States.

#### I. Patient Privacy and Comfort

The reasons most patients chose a medical abortion are that it avoids the need for surgical intervention, and is more natural. It allows them to pass the products of conception in the privacy and comfort of their home. R. at 211-12. Expulsion typically commences very soon after the misoprostol has been administered. When the evidence-based protocol is followed, up to 90% of all patients complete expulsion within four to six hours. R. at 301.

Most patients who receive abortion services in Fargo must travel long distances to reach the clinic. For approximately two-thirds of those patients, a one-way trip requires more than two hours of travel. For approximately half the patients, that trip is at least four hours in duration. R. at 127. Therefore, if patients are required to return to the clinic for the administration of misoprostol, most of them will experience the process of expulsion in a car, rest stop, or some equally inappropriate and discomfiting location. R. at 42-43, 144.

Expulsion is often painful, and it always results in bleeding. It can also be accompanied by side effects such as nausea, vomiting and diarrhea. R. at 189-90. MKB provides all its patients with detailed home instructions, including a description of these likely

side effects. R. at 43, 133-34. The clinic will not perform a medical abortion if the patient is not able to comprehend these instructions, or may otherwise be unable to follow them. R. at 133-37.

In addition to pain management instructions, medical abortion patients are provided with an analgesic medication (Tylenol with codeine). R. at 43. They are also provided with anti-nausea medication. R. at 118. Finally, they are given easy to follow guidelines that allow them to self-monitor bleeding, and be vigilant for indications of excessive hemorrhage. R. at 48.

All this is completely consistent with the current standard of care. The home administration of misoprostol is now universally recognized as a safe and most appropriate approach. For example, the revised guidance document released by the WHO in 2012 indicates home administration of misoprostol "is a safe option for women", which avoids the need for a second visit to the healthcare facility. WHO, 2012 Guidance Document, p. 44. Similarly, home administration of misoprostol was one of the primary recommendations made by the American College of Obstetricians and Gynecologists (ACOG) in its 2005 practice bulletin. This recommendation was stated to the highest degree of confidence (level A), meaning it was supported by "good and consistent scientific evidence." ACOG Practice Bulletin No. 67 (Oct. 2005), p. 8. 19

#### ii. Economic Considerations

Although they pale in comparison to the consequences discussed above, the economic costs associated with clinical administration are also a significant consideration. It is a matter of simple geography. The clinic operated by MKB is located in Fargo. This is the only abortion provider in North Dakota. It serves an extensive geographical area. In the tri-state region, the closest alternative providers of abortion services are located in Sioux Falls, South Dakota and Minneapolis, Minnesota. R. at 168-70. The direct and indirect costs associated with long hours of travel represent a significant financial burden for many patients, particularly those with limited income. In extreme cases, the requirement for an extra trip would become cost prohibitive. R. at 44. By itself, this burden has constitutional implications.

In <u>Fargo Women's Health Org. v. Schafer</u>, 18 F.3d 526 (8th Cir. 1994), the court addressed the constitutionality of the 1991 amendments to the North Dakota Abortion Control Act. Plaintiff argued that one of those amendments would have the practical effect of requiring a second visit to the abortion clinic. The Eighth Circuit disagreed, interpreting the statutory language to allow a

telephone conversation in lieu of a clinic visit. Significantly, it went on to indicate "the facial validity analysis [would] be entirely different" if the statute had been interpreted to require a second visit. <u>Id.</u> at 532. <u>See also, Daugaard, 799 F. Supp. 2d at 1065.</u>

# iii. Victims of Abuse

For some patients living in abusive relationships, the requirement for an extra and extended clinic visit would dramatically increase the potential for discovery. This is discussed in greater detail below. The potential consequences for this subset of patients are both extreme and intolerable.

# iv. State's Arguments

Dr. Harrison has always argued the benefits of clinical administration are incidental to the four to six hour period of observation that is required following this administration. She has not been consistent, however, in describing these benefits.

In her affidavit, Dr. Harrison suggested that expulsion for many patients will occur during the observation period, and for the patient's safety this should occur in a clinic setting "where bleeding can be monitored, their vital signs can be observed by [] trained medical [personnel], and they can receive sufficient pain medication." Harrison aff., § 39.

At trial, Dr. Harrison offered an alternative justification for the clinical administration of misoprostol, followed by an extended period of observation. She now argues that if all patients are required to make a second visit to the clinic for the administration of misoprostol, and to then remain at that facility for many additional hours, some could be told their abortion was complete and there was no need for a follow-up visit. R. at 404, 409-10. In other words, if all patients were forced to make a very extended and uncomfortable second trip to the clinic, some could avoid the need for a third trip.<sup>20</sup>

The absurdity of all this is self-evident. From the patient's standpoint, following the protocol suggested by Dr. Harrison would only subject them to significant expense, discomfort and inconvenience. It would also prevent them from completing the abortion in the comfort of their home—the prime advantage of the medical approach for most patients. R. at 27-28, 116, 144, 211-12, 229-30. From the clinic's standpoint, a requirement to proceed in the manner suggested by Dr. Harrison would probably be impossible. MKB has neither the facilities nor the staff that would be needed. At a minimum, any attempt to meet these unnecessary requirements would add significantly to the cost of the procedure. R. at 44, 57, 145-47.

An even bigger shortcoming is the simple fact that the amendments do not require any period of observation following the administration of misoprostol. Adherence to the Mifeprex FPL would require that the patient return "to the health care provider two days after ingesting Mifeprex" to then take two tablets of misoprostol orally. Ex. 3, pp. 12. However, there is no required or recommended observation period following this step. Instead, the FPL only directs that the patient be given appropriate instructions and contact information before being sent on her way. <u>Id.</u> The only requirement added by the amendments is the provision obligating the prescribing physician to be physically present when the patient swallows the misoprostol. H.B. 1297, § 6(5). Furthermore, the Mifeprex FPL requires a follow-up exam in all cases, even if the patient has been previously advised that expulsion is complete. Ex. 3, p. 21.

The state suggests the requirement for a period of clinical observation is implicit in the Mifeprex FPL. R. at 80-81, 402, 405. Interpretations, of course, must be based on the language that appears. Conversely, words cannot be read into a law in an attempt to support an interpretation the legislature did not express. <u>Haggard v. Meier</u>, 368 N.W.2d 539, 541 (N.D. 1985).

#### e. Gestational Limit

The last significant difference between the protocols involves the time window during which the procedure is performed. The Mifeprex test trials were conducted only on women through 49 days LMP. Because the FPL reflects the test protocol, this limitation is carried over. However, the record clearly establishes that 63 days LMP is now universally regarded as the appropriate cut-off date, at least when physicians are allowed to follow current and best medical procedures. R. at 413-15, 442.

From the outset, the state has argued the 49 day time limitation is justified because medical abortions are known to be progressively less effective as the pregnancy develops. This is generally true, but again a full assessment of the issue only underscores the disadvantages of following the FPL.

It has now been well established that the oral administration of misoprostol is the least effective route. Following the FPL protocol, the U.S. trials achieved a success rate of only 92.1% through 49 days LMP. Centers following the current standard of care achieve typical success rates of approximately 98% through 63 days LMP. WHO, 2012 Guidance Document, p. 44.<sup>21</sup> The results achieved at the Fargo clinic are comparable.<sup>22</sup> R. at 36.

The difference between 49 and 63 days is very significant.

Both time periods start from the first day of the woman's last menstrual period. Conception typically follows this event by several weeks. Therefore, if measured from the onset of pregnancy, the FPL protocol gives a woman approximately five weeks to discover she is pregnant, decide on a medical abortion, and make arrangements to have that procedure completed. For many women, the FPL time window would close before they were even aware of their pregnancy.

For any woman who wants a medical abortion between 50 and 63 days, a requirement to comply with the Mifeprex FPL would represent an insurmountable obstacle, imposed for no reason. One-third to one-half of all patients fall into this category. R. at 230-31. Moreover, for some of those patients a surgical abortion would not be a viable or acceptable option.

## f. Summary

In summary, the evidence introduced at trial confirmed the preliminary assessment—a requirement for adherence to the Mifeprex FPL has nothing to commend it. The amendments were enacted on the premise that strict compliance with the Mifeprex FPL was necessary to safeguard women's health. At trial, however, the state could not establish that a single aspect of that protocol was even beneficial or advantageous.

Conversely, the evidence did conclusively prove that following the amendments would increase cost and inconvenience, reduce effectiveness, and increase the incidence of unpleasant side-effects. It would make the procedure unavailable to any patient beyond 49 days LMP. The required trip to the clinic for the administration for misoprostol would involve unnecessary inconvenience and expense for all women. It would put some in dangerous and untenable predicaments, and force most to experience the process of expulsion in a car or some equally inappropriate location. The legislative mandate that physicians follow this flawed and outmoded protocol would force them to expose their patients to unnecessary risks, to abandon current standards of care, and to compromise fundamental canons of ethics. It would also foreclose further advances in evidence-based medicine. R. at 352-53.

[¶144] Dr. Eggleston testified about the effect of the criminal liability imposed by the FDA label provision of H.B. 1297:

- Q. Do all of your patients return for their follow-up visit?
- A. No. I believe approximately 75 percent do.
- Q. Can you ensure that all of them return?

- A. No. We stress it. We make their appointment before they leave. There's no charge, we do everything we can to get them there. But I cannot physically force them to come for follow up.
- Q. Would you have any reservations about complying with House Bill 1297 knowing that you could be subject to criminal penalties for failure to comply with all the requirements?
- A. Right. Because the follow up is required according to the Bill and there's no way that I can make all my patients return.

# Kromenaker testified similarly:

- Q. So can the Clinic assure that every patient returns?
- A. No. We can't physically go and get them. We talk with them at the appointment to make sure that they understand that's part of the process. We schedule it when they're there. We emphasize it and the doctor emphasizes it. But not everybody's a hundred percent compliant.
- Q. So if House Bill 1297, as I've asked you to assume, would require the Clinic to follow the Mifeprex Medication Guide would the Clinic still be able to provide medication abortion?
- A. I don't believe so because it would either make me as the administrator or the doctor a criminal if the patient didn't return for the follow up.

Thus, the effect of the criminal liability imposed by H.B. 1297 would be for providers to stop providing medication abortions.

[¶145] The district court's findings accurately reflect the evidence and testimony. The FDA label provision of H.B. 1297, on its face, places a substantial obstacle in the path of a woman seeking a pre-viability abortion.

# 2. Emergency Contract Provision

[¶146] With respect to the effects of the emergency contract provision of H.B. 1297, the district court found that it was impossible to fulfill because no doctor would be willing to enter into such an onerous contract. The district court found that the contract was unnecessary because emergency situations relating to abortion were extremely rare. MKB was aware of only one patient who needed a blood transfusion, which was provided in Minnesota. To the extent emergency situations might arise following a medication abortion, they were similar to complications arising from

spontaneous abortions or complications from childbirth. These were common medical events which medical centers around the state routinely and effectively treated. Patients were routinely told if they need emergency treatment to go the closest hospital or emergency room. If the legislation became effective, the requirement that the patient be provided with the contract of "the physician who will be handling emergencies and the hospital at which any emergencies will be handled" will be unnecessarily confusing to the patient, contrary to safe practices and safe emergency procedures. This would be particularly true for any patient living at some distance from "the physician who will be handling emergencies and the hospital at which any emergencies will be handled."

[¶147] With respect to the effects of the disclosure requirements of the emergency contract provision of H.B. 1297, the district court found:

The amendments add further roadblocks by providing the emergency services contract would be available to many upon demand, thereby assuring the identity of the contracting physician would soon become known to the most committed opponents of abortion. R. at 54. It is an irrefutable fact that physicians who provide abortion services, or otherwise associate themselves with this practice, subject themselves and their staff to protestors, harassment, potential violence, and professional isolation. Threats or acts of violence have been repeatedly directed against the clinic operated by MKB, as well as its employees. R. at 148. The original abortion clinic operated in Fargo was firebombed on several occasions. R. at 168. In other states, medical [personnel] involved with abortions have been the victims of violent assaults, including murder.

Therefore, it is hardly surprising that even the most sympathetic physicians have refused to consider entering into the emergency care contract required by the amendments. R. at 54.

(Footnote omitted).

[¶148] The State argues the district court's finding that the "contract would be available to many upon demand" is an incorrect interpretation of the statutory language. However, read in context, it is clear that the district court was merely considering the effect, that disclosure of the contract to the numerous people

identified in the statute, would have. Given the number of people to whom disclosure is mandatory, it is not unreasonable to conclude the identity of the parties to the contract will become public knowledge.

[¶149] The district court's findings accurately reflect the evidence and testimony. The emergency contract provision of H.B. 1297 places a substantial obstacle in the path of a woman seeking a pre-viability abortion.

[¶150] Because the challenged provisions of H.B. 1297 cannot withstand strict scrutiny and because they place an undue burden on a woman's right to an abortion under her liberty interest of our state constitution, we would affirm the district court's permanent injunction of H.B. 1297.

## VI. Effect on the Injunction

[¶151] One further comment needs to be made. Although it is my opinion that the district court correctly decided this case under substantive state and federal law, it is the opinion of three justices that the district court correctly applied federal constitutional law to these facts. See Crothers Opinion, at ¶ 165. It, therefore, becomes a question of whether an injunction correctly entered under federal constitutional law can be dissolved.

[¶152] We are faced with this question because of article VI, section 4 of our state constitution, which provides:

A majority of the supreme court shall be necessary to constitute a quorum or to pronounce a decision, provided that the supreme court shall not declare a legislative enactment unconstitutional unless at least four of the members of the court so decide.

[¶153] This Court has never faced a situation where the court has divided over interpretations under the state and federal constitutions so as to call into question the interpretation of article VI, section 4 itself. I am of the opinion that this section has to be read in harmony with article I, section 23:

The state of North Dakota is an inseparable part of the American union and the Constitution of the United States is the supreme law of the land.

[¶154] The supreme law of the land is even clearer. Article VI of the United States Constitution provides:

This Constitution, and the laws of the United States which shall be made in pursuance thereof... shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any state to the contrary notwithstanding.

[¶155] Where federal constitutional law speaks, it controls. A state may grant greater rights, but not lesser. Reading article VI, section 4 in harmony with article I, section 23, it is impermissible under article VI, section 4 to dissolve an injunction prohibiting the enforcement of a law that constitutes "an undue burden on a woman's right to an abortion before viability under the federal constitution," VandeWalle Opinion, at ¶11, when a majority of this Court agrees it was correctly entered under federal law.

[¶156] Carol Ronning Kapsner Mary Muehlen Maring, S.J.

## Appendix

- <sup>3</sup> By the time they are 45 years old, approximately one-third of all women in the United States have chosen an elective abortion. R. at 194.
- <sup>4</sup> Nationwide this approach is selected by approximately 17% of the women who obtain early abortions. R. at 195.
- <sup>5</sup> A copy of the citizen petition was filed as an attachment to Harrison's affidavit.
- <sup>6</sup> In <u>Roe</u>, the Court noted that the risks incident to childbirth were much higher than any associated with first trimester abortions. This was the basis for its holding that during this period no regulation purporting to safeguard women's health was permissible. <u>Roe</u>, 401 U.S. at 163. In this case, a relative risk assessment comparing early surgical abortions to medical abortions may be more appropriate. This is clearly the position taken by the state and its expert.
- <sup>7</sup> Available at <a href="http://www.who.int/reproductivehealth/publications/unsafe abortion/97892415484341">http://www.who.int/reproductivehealth/publications/unsafe abortion/97892415484341</a>.

- <sup>8</sup> Kelly Cleland et al., <u>Significant Adverse Events and Outcomes After Medical Abortion</u>, Obstetrics and Gynecology, Vol. 121, No.1, 166-171 (Jan. 2004).
- When specific forms of complication are viewed in isolation, some statistical differences do emerge. For example, the medical approach is more likely to cause excessive bleeding or to leave retained tissue. Conversely, the surgical approach is obviously more likely to result in operative complications such as a perforation. R. at 197-200. Dr. Harrison has tended to emphasize the specific risks that are higher in medical abortions, relying primarily on the results of a registry-based study performed in Finland. R. at 390. Even that study, however, concludes that both medical and surgical abortions are "safe." R. at 391. It also reports no discernible differences in the rates of infection, psychiatric morbidity or death. R. at 392.
- <sup>16</sup> Even this testimony is at odds with other portions of her testimony. If there is any validity to Dr. Harrison's theories that Mifeprex suppresses immune reactions, or interferes with natural clotting mechanisms, the administration of three times the necessary dosage obviously becomes even less defensible.
- <sup>17</sup> MKB only collects financial information from patients living in North and South Dakota, but there is no reason to conclude this evidence is not fairly representative.
- One aspect of that history does live on. As part of the Mifeprex approval process, the FDA did require that all patients sign an agreement which incorporates portions of the FPL protocol. Ex. 3, pps. 30-31. This unprecedented requirement serves no meaningful purpose, but it does create a conundrum for physicians. The typical solution is to have the patient also sign a second agreement requesting treatment consistent with the standard of care. This is the approach followed by MKB. Ex. 36; R. at 113-14. According to Dr. Grossman, it is also the approach followed by other providers. R. at 259, 316.
- <sup>19</sup> A copy of this bulletin is attached to the Grossman affidavit as Exhibit B.
- <sup>20</sup> The FPL protocol both decreases overall efficiency and increases the typical time to expulsion. In the U.S. trials, only 44.1% of patients completed expulsion within four hours. For many test participants, this process took more than 24 hours. Ex. 3, pp. 4-5.
- Among other things, the WHO is responsible for establishing norms and standards for evidence-based medical procedures. R. at 474. The combination of mifepristone and misoprostol is now included on the WHO model list of essential medicines. R. at 477.

## Crothers, Justice.

[¶157] On the merits, I concur in the result reached by Justice Kapsner. I respectfully disagree with the result reached by Chief Justice VandeWalle. I respectfully disagree with both of my colleagues that this case should be decided under the North Dakota Constitution because the federal constitutional interpretations which we must follow make analysis under our constitution unnecessary and doctrinally improper.

[¶158] I also respectfully disagree with Justice Sandstrom's suggestion that the challenge before this Court can be decided only under the North Dakota Constitution. Sandstrom opinion at ¶ 168. I find no support for that position and, apparently, neither do my colleagues. See VandeWalle opinion at ¶ 39 ("The district court's analysis was primarily under the state constitution, but the court also described case law analyzing the right to abortion under the federal constitution and said the challenged provisions also were unconstitutional under federal precedent prohibiting regulations placing an undue burden on a woman's right to an abortion before viability."); Kapsner opinion at ¶ 71 ("The court further ruled the state and federal constitutional provisions were violated . . . .").

One of the studies both parties frequently referred to at trial analyzed the relative efficacies of the oral and buccal administration of misoprostol. It demonstrated that buccal administration is more effective at every gestational stage, and achieves success rates in days 57 through 63 that are comparable to those achieved by oral administration in days 47 through 49. Beverly Winikoff et al., <u>Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Controlled Trial</u>, Obstetrics and Gynecology, Vol. 112, No. 6, 1303-1310. (Dec. 2008).

<sup>&</sup>lt;sup>28</sup> The evidence on this point was equivocal.

One notable exception is an ectopic pregnancy. Medical abortion is not a safe or viable approach in such cases. This is a well-known reality, something all providers are expected to guard against. To rule out an ectopic pregnancy, MKB performs an ultrasound on all patients before a medical abortion is initiated. This simultaneously confirms the pregnancy has not progressed beyond 63 days LMP. R. at 24-25.

[¶159] Justice Sandstrom describes the district court as making only brief reference to H.B. 1297 violating the United States Constitution. ("The district court . . . also said the statute violates the United States Constitution . . ."). Sandstrom opinion at ¶ 169. That is a description with which I must again respectfully disagree. The district court expressly decided the case under both the United States and the North Dakota Constitutions. In the district court's concluding words:

"The amendments violate the fundamental rights protected by the first and twelfth sections of article one of the Constitution of North Dakota. No compelling state interest justifies this infringement, and the amendments certainly have not been narrowly drafted to avoid unnecessary infringement. As the amendments place multiple undue burdens on a woman's rights to choose, they also fail under the fourteenth amendment to the United States Constitution."

(Emphasis added).

[¶160] The district court's holding was preceded by extensive citation to federal judicial rulings, including four pages of analysis under the heading "Federal Law." The district court's "Federal Law" discussion opened with the sentence, "If it is ultimately determined that the liberty and freedoms guaranteed by the state constitution to [sic] not extend to a woman's reproductive rights, or if the state constitution is subsequently amended to eliminate those rights, then the protections afforded by the federal constitution will need to be considered." (Footnote omitted). The district court's words were not merely a forecast of what might be required in the future. Instead, the district court proceeded in this case to decide the federal constitutional issue. This is evident by the holding cited above and by the conclusion of the district court's "Federal Law" discussion stating, "Therefore, it is clear the amendments also violate the fourteenth amendment of the United States Constitution."

[¶161] Because the district court decided the constitutionality of H.B. 1297, the North Dakota Supreme Court is obliged to adhere to our established principles of constitutional interpretation and application. The first of those principles is that the

North Dakota Constitution can grant greater rights, but we are not at liberty to construe the North Dakota Constitution to grant fewer rights than those ensured by similar provisions in the United States Constitution. This result obtains from our precedent. State v. Nordquist, 309 N.W.2d 109, 113 (N.D. 1981) ("It is a topic of little debate that the States are 'independently responsible for safeguarding the rights of their citizens.' In this regard a State may provide its citizens greater protection than the safeguards guaranteed in the Federal Constitution.") (citations omitted); State v. Matthews, 216 N.W.2d 90, 99 (N.D.1974) ("It is within the power of this court to apply higher constitutional standards than are required of the States by the Federal Constitution."); Lego v. Twomey, 404 U.S. 477, 489, (1972); State v. Taylor, 60 Wis.2d 506, 210 N.W.2d 873, 882 (1973); Southeast Cass Water Res. Dist. v. Burlington N. R.R. Co., 527 N.W.2d 884, 890 (N.D. 1995) ("[W]e cannot interpret our state constitution to grant narrower rights than guaranteed by the federal constitution."). This result obtains from the supremacy clause of the United States Constitution. U.S. Const. art. 6, cl. 2. And this result obtains from the North Dakota Constitution acknowledging federal constitutional interpretations as "the supreme law of the land." N.D. Const. art I, § 23.

[¶162] A second established principle of constitutional interpretation and application is that courts do not render advisory opinions. "A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them." Lyng v. Nw. Indian Cemetery Protective Ass'n, 485 U.S. 439, 445 (1988). "Courts should think carefully before expending scarce judicial resources to resolve difficult and novel questions of constitutional or statutory interpretation that will have no effect on the outcome of the case." Ashcroft v. al-Kidd, 131 S.Ct. 2074, 2080 (2011) (citations and quotation marks omitted).

[¶163] This Court long ago and consistently has recognized we are without authority to give advisory opinions. See, e.g., State v. State Bd. of Canvassers, 172 N.W. 80, 85 (N.D. 1919) ("The opinion of the court upon this question during the pendency of

legislative action would amount to no more than an advisory opinion for the guidance of the other departments. Under the Constitution we are not authorized to perform such a function."); Interest of C.W., 453 N.W.2d 806, 810 (N.D.1990) (We "should not give advisory opinions on academic questions where no actual controversy needs to be determined."). This is never more true than when the issue involves interpretation of a constitutional provision. See State v. King, 355 N.W.2d 807, 809 (N.D. 1984) ("Although both litigants have urged us to decide the constitutional question they have posited, to do so based on the present state of the 'record' would amount to nothing more than an advisory opinion on an abstract, hypothetical legal question."); State v. Meiers, 403 N.W.2d 392, 393 n.1 (N.D. 1987) ("Until a party aggrieved by the application of a statute raises the issue of its constitutionality in an actual litigated controversy, a determination of the constitutional question would constitute the rendering of an advisory opinion. It is well settled that courts cannot give advisory opinions.") (citations omitted); Rocky Mountain Oil & Gas Ass'n v. Conrad, 405 N.W.2d 279, 284 (N.D. 1987) ("Deciding the constitutional question without evidence of interstate commerce would amount to nothing more than giving an advisory opinion on an abstract, hypothetical legal question.").<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> My concern about advisory opinions and my aversion to obiter dicta are not new-found in this case, but has been articulated in many cases I have authored for this Court or in which I have written separately. See, e.g., Trosen v. Trosen, 2014 ND 7, ¶ 32, 841 N.W.2d 687 (Crothers, J., concurring in part and dissenting in part); Barrett v. Gilbertson, 2013 ND 35, ¶30, 827 N.W.2d 831 (Crothers, J., concurring specially); City of Grafton v. Wosick, 2013 ND 74, ¶ 15, 830 N.W.2d 550; City of Mandan v. Strata Corp., 2012 ND 173, ¶ 7-8, 819 N.W.2d 557; Dorothy J. Pierce Family Mineral Trust v. Jorgenson, 2012 ND 100, ¶ 8, 816 N.W.2d 779; Bakke v. D & A <u>Landscaping Co., LLC</u>, 2012 ND 170, ¶ 19, 820 N.W.2d 357; State v. Morin, 2012 ND 75, ¶ 16, 815 N.W.2d 229 (Crothers, J., concurring specially); Interest of G.K.S., 2012 ND 17, ¶ 4, 809 N.W.2d 335; Brandvold v. Lewis & Clark Pub. Sch. Dist. No. 161, 2011 ND 185, ¶ 8, 803 N.W.2d 827; Carlson v. Carlson, 2011 ND 168, ¶ 24, 802 N.W.2d 436; In the Matter of the Estate of Vestre, 2011 ND 144, ¶ 26, 799 N.W.2d 379; State v. Johnson, 2011 ND 48, ¶ 16, 795 N.W.2d 367; Seiler v. North Dakota Dep't of Human Servs., 2010 ND 55, ¶¶ 6-8, 780 N.W.2d 653; Saville v. Ude, 2009 ND 211, ¶24, 776 N.W.2d 31; White v. Altru Health System, 2008 ND 48, ¶19, 746

[¶164] On the substantive questions regarding constitutionality of the challenged provisions, the district court and the VandeWalle and Kapsner opinions of this Court all acknowledge that our holding here can recognize no less freedom from governmental intrusion than controlling federal constitutional interpretations. VandeWalle opinion at ¶ 41; Kapsner opinion at ¶ 114. They do this because the United States Constitution provides a floor below which a similar state constitution provision cannot be construed to provide those challenging the law with fewer or narrower rights. See Southeast Cass Water Res. Dist., 527 N.W.2d at 890. The analytical point of departure for my colleagues and me is that they first address the question under our state constitution. I would first answer the question under federal precedent. Only if the law survives federal constitutional review does it become necessary to determine whether more expansive individual rights are protected under the North Dakota Constitution. I recognize that states do not uniformly apply this approach; however, our precedent prohibiting advisory opinions and advocating judicial restraint direct that it is the proper approach here. See 16 C.J.S. Constitutional Law § 157 ("Some state courts address state constitutional claims before reaching the federal ones, while another reaches the federal constitutional claim first, unless it appears that the state provision is distinctive.") (footnotes omitted).

[¶165] Despite being asked to confine its ruling to the North Dakota Constitution, the district court found H.B. 1297 violated the United States Constitution. Supra, at ¶¶ 158-61; VandeWalle opinion at ¶ 39; Kapsner opinion at ¶ 71. For the reasons explained in, and on the federal authority cited throughout Justice Kapsner's opinion, particularly in Part V, the district court's analysis should be affirmed under substantive federal law and its findings are supported by evidence in the record. Upon determining that H.B. 1297 imposes an impermissible burden on the federal right to

N.W.2d 173; <u>Van Sickle v. Hallmark & Assocs., Inc.</u>, 2008 ND 12, ¶28, 744 N.W.2d 532; <u>Sandberg v. American Family Ins. Co.</u>, 2006 ND 198, ¶¶ 19-21, 722 N.W.2d 359 (Crothers, J., concurring specially).

an abortion, I submit we have nothing left to decide under the North Dakota Constitution. Even if we were so inclined, we are not constitutionally permitted to enforce an interpretation under the North Dakota Constitution protecting fewer rights than are protected under the coordinate provisions in the United States Constitution. As a result, the challenges to H.B. 1297 have been answered by analysis under federal constitutional law and we provide inappropriate advice by passing judgment one way or the other under North Dakota's Constitution. Therefore on the merits, I concur in the result of the opinion authored by Justice Kapsner.

[¶166] Regarding the effect of this Court's ruling on the injunction, I agree with Chief Justice VandeWalle, and respectfully disagree with Justice Kapsner, that the division of positions in this case requires reversal of the judgment declaring H.B. 1297 unconstitutional and permanently enjoining the State from enforcing H.B. 1297. VandeWalle opinion at ¶60; Kapsner opinion at ¶151-55. Article VI, section 4, of the North Dakota Constitution, requires that at least four of five justices agree to declare a legislative enactment unconstitutional. That provision constricts this Court's ability to declare a statute unconstitutional. Article VI, section 4, does not specify that the restriction only operates when a legislative enactment is struck down under the North Dakota Constitution. Rather, the focus of Article VI, section 4 is on the striking down of a legislative enactment, and not whether unconstitutionality arises under the United States Constitution or the North Dakota Constitution. Because only three of five justices conclude H.B. 1297 is unconstitutional, the district court's judgment should be reversed.

[¶167] Daniel J. Crothers

### Sandstrom, Justice.

[¶168] The sole constitutional issue properly before this Court is whether the contested statute—House Bill 1297—violates the North Dakota Constitution. Whether that statute violates the United States Constitution is not an issue that was

pled or tried in the district court, it is not an issue specified on appeal by either party, and it is not properly before this Court.

[¶169] The plaintiffs made a conscious decision to seek to establish a separate state constitutional right to an abortion under the North Dakota Constitution. Presumably, they did so as a backup in case a right to an abortion ever ceases to exist under the United States Constitution. Plaintiffs never argued that the bill was unconstitutional under the United States Constitution. They never pled a United States Constitutional violation. A United States Constitutional violation was never tried by consent. The district court, in its 55-page order, also said the statute violates the United States Constitution, but the issue was not pled or tried by consent and thus was not before the district court, and the district court did not say how the issue was before it.

[¶170] The Chief Justice persuasively argues there is no separate state constitutional right to an abortion. I would not reach the U.S. Constitutional issue, which was never pled and was never tried by consent. Justice Crothers concludes that answering the question of whether the statute violates the North Dakota Constitution is inappropriate because it would be an "advisory opinion." That, too, would justify reversing, but it does not allow reaching a question not properly before the district court or this Court.

[¶171] I would reverse the district court.

[¶172] A court is limited to deciding issues properly before it. When an issue has not been raised in the pleadings, it cannot be tried except by the parties' express or implied consent. N.D.R.Civ.P. 15(b). This Court has explained the process for amending the pleadings in this manner:

Under N.D.R.Civ.P. 15(b), a pleading may be impliedly amended by the introduction of evidence which varies the theory of the case and which is not objected to on the grounds it is not within the issues in the pleadings. Aho v. Maragos, 2000 ND 14, ¶ 7, 605 N.W.2d 161; Schumacher [v. Schumacher], 1999 ND 149, ¶ 26, 598 N.W.2d 131. However, amendment of pleadings by implication may only arise when the evidence introduced is not relevant to any issue pleaded in the case.

Mann v. Zabolotny, 2000 ND 160, ¶ 12, 615 N.W.2d 526. Here all the evidence introduced was relevant to the state constitutional issue.

[¶173] Recently, in SolarBee, Inc. v. Walker, 2013 ND 110, ¶¶ 2-5, 833 N.W.2d 422, this Court, composed of all the same members who sit on this case, was asked to reverse the district court because it decided the case at least in part on an issue not pled. This Court affirmed because the issue not pled was specified in the pretrial brief and specifically argued at trial without objection. Id. at ¶¶ 14-16. "We conclude that the 'novelty' of the . . . issue was reasonably apparent and the intent to try the issue was 'clearly indicated by failure to object or otherwise." Id. at ¶ 16 (citing Mann, 2000 ND 160, ¶ 13, 615 N.W.2d 526).

[¶174] In this case the plaintiffs' complaint has seven claims for relief, each alleging H.B. 1297 violates the North Dakota Constitution. Those claims are as follows:

# First Claim for Relief

(Right to Terminate a Pregnancy)

- 94. The allegations of paragraphs 1 through 93 are incorporated as though fully set forth herein.
- 95. House Bill 1297 impermissibly burdens the Clinic's patients seeking medication abortions in violation of Article I, §§ 1 and 12 of the Constitution of the State of North Dakota by:
  - a. banning all medication abortions;
  - b. banning medication abortion for women between 50 and 63 days of pregnancy;
  - c. banning safer and more effective regimens for the provision of medication abortions;
  - d. banning medication abortions even when a surgical abortion would threaten a woman's health; and
  - e. requiring women to receive misleading information regarding treatment in the case of an emergency.

# Second Claim for Relief

(Vagueness)

- 96. The allegations of paragraphs 1 through 95 are incorporated as though fully set forth herein.
- 97. House Bill 1297 fails to give the Clinic, Dr. Eggleston and the Clinic's staff adequate notice of the conduct that will subject abortion providers to criminal liability and subjects them to arbitrary enforcement by:
  - a. using terms that are nonsensical;

- b. setting forth conditions that cannot be satisfied;
- c. incorporating standards that are imprecise.
- 98. The Act's vagueness deprives the Clinic, Dr. Eggleston and the Clinic's staff of the due process rights guaranteed by Article I, § 12 of the Constitution of the State of North Dakota.

# Third Claim for Relief (Improper Delegation)

- 99. The allegations of paragraphs 1 through 98 are incorporated as though fully set forth herein.
- 100. House Bill 1297 constitutes an improper delegation of legislative power in violation of Article III, § 1 of the Constitution of the State of North Dakota.

# Fourth Claim for Relief (Bodily Integrity)

- 101. The allegations of paragraphs 1 through 100 are incorporated as though fully set forth herein.
- 102. House Bill 1297 violates the right to bodily integrity of women seeking medication abortions within the State of North Dakota in violation of Article I, §§ 1 and 12 of the Constitution of the State of North Dakota.

# Fifth Claim for Relief (Special Law)

- 103. The allegations of paragraphs 1 through 102 are incorporated as though fully set forth herein.
- 104. House Bill 1297 creates a special [sic] in violation of Article IV, § 13 of the North Dakota Constitution by:
  - a. imposing restrictions on the off-label use of prescription medications only on women seeking medication;
  - b. imposing restrictions on the off-label use of prescription medications only on physicians providing medication abortions;
  - c. placing requirements regarding a contract with a backup physician for emergency care only upon physicians providing medication abortions; and
  - d. imposing requirements for the reporting of adverse events experienced during or after provision of a drug upon only those physicians prescribing abortion-inducing drugs.

# Sixth Claim for Relief

(Privileges and Immunities)

105. The allegations of paragraphs 1 through 104 are incorporated as though fully set forth herein.

106. House Bill 1297 denies women seeking medication abortions in North Dakota equal protection of the law in violation of the privileges and immunities clause, Article 1, § 21 of the North Dakota Constitution.

107. House Bill 1297 denies physicians providing medication abortions in North Dakota equal protection of the law in violation of the privileges and immunities clause, Article I, § 21 of the North Dakota Constitution.

# Seventh Claim for Relief

(Free Speech)

108. The allegations of paragraphs 1 through 107 are incorporated as though fully set forth herein.

109. House Bill 1297 violates Article I, § 4 of the North Dakota Constitution by forcing physicians to make, and women to hear, false and misleading statements.

[¶175] Plaintiffs did not ask for relief under the United States Constitution. Although the parties discussed and argued federal precedent at certain times during the proceedings in this case, they did so only in the context of establishing whether there is a right to abortion under North Dakota's constitution and whether H.B. 1297 violates that alleged state right. See Mann, 2000 ND 160, ¶ 12, 615 N.W.2d 526 ("[A]mendment of pleadings by implication may only arise when the evidence introduced is not relevant to any issue pleaded in the case."). The plaintiffs in this case made a strategic decision to limit the issue to one of state law—a situation very different from the one we were presented with in SolarBee, in which the unled issue was specifically argued and relied upon as a potential avenue for damages. See SolarBee, 2013 ND 110, ¶ 14, 833 N.W.2d 422. Here the plaintiffs do not argue that the U.S. Constitutional issue was tried by consent, the district court did not assert that it was, and the other justices cannot claim that it was.

[¶176] Because United States constitutional law was not tried or made an issue by the consent of the parties under N.D.R.Civ.P. 15, we should not separately address whether H.B. 1297 constitutes an undue burden on a woman's right to abortion under United States constitutional law.

[¶177] The issues on appeal are those identified by the parties in their statement of issues. N.D.R.App.P. 28. In the issues specified by the parties, below, neither identified unconstitutionality under the United States Constitution as an issue.

# [¶178] On appeal, the State identified the following issues:

- I. In interpreting a constitutional provision, a court's duty is to ascertain the intent of the people who adopted the provision. To do so, the court considers the contemporary legal practices and laws in effect when the provision was adopted. Before, when, and for decades after the North Dakota Constitution was adopted, North Dakota law prohibited abortion. Did the district court err by holding the North Dakota Constitution creates a fundamental right for a woman to have an abortion?
- II. Plaintiffs did not bring a claim under the Federal Constitution, and courts refrain from deciding constitutional issues not necessary to resolve the case before them. The district court held the challenged bill violates the Fourteenth Amendment to the Federal Constitution. Did the district court err in addressing the challenged bill's constitutionality under the Federal Constitution?

III. If a statute is capable of two constructions and one will render the statute constitutional, a court must select the constitutional interpretation. The district court rejected reasonable, constitutional interpretations of the challenged bill. Did the district court err by not selecting the constitutional interpretations?

# [¶179] The State further emphasized:

Despite the fact MKB did not bring a claim under the Federal Constitution, the district court <u>sua sponte</u> addressed the constitutionality of HB 1297 under the Fourteenth Amendment to the Federal Constitution.

### The State explained:

The State disputes that HB 1297 violates the Fourteenth Amendment. Because that issue was not raised below, it should not be decided by this Court. See City of Bismarck v. Nassif, 449 N.W.2d 789, 792 (N.D. 1989) ("Before this Court will address an issue on appeal, even a constitutional issue, that issue must have been sufficiently raised in the court below."). For that reason, the State's brief does not address HB 1297's constitutionality under the Fourteenth Amendment.

The State concluded this argument, saying, "The district court exceeded its jurisdiction by deciding an issue not raised in the Complaint or tried by consent of the parties. See N.D.R.Civ.P. 15(b)(2)."

[¶180] In its brief on appeal—responding to the brief that had been filed by the State—MKB identifies the following issues:

Did the Trial Court correctly construe HB 1297 to ban a safe and effective first-trimester abortion method?

Did the Trial Court correctly determine that the North Dakota Constitution protects individual rights to the same extent, or a greater extent, than the United States Constitution?

Did the Trial Court err in ruling HB 1297 unconstitutional under the North Dakota Constitution?

MKB's issues do not challenge the State's position that a U.S. Constitutional issue is not before this Court. MKB concludes its brief, "For the foregoing reasons, this Court should affirm the Trial Court's ruling that HB 1297 is unconstitutional under the North Dakota Constitution." The conclusion says nothing about violation of the U.S. Constitution.

[¶181] At oral argument, counsel for MKB responded to the Chief Justice, "I agree we haven't pled a federal constitutional violation." Later, when asked which of MKB's claims for relief raised a federal constitutional question, its counsel responded, "Plaintiffs aren't arguing that we raise any claims under the federal constitution."

[¶182] Justice Crothers mischaracterizes my position as saying "the challenge before this Court <u>can</u> be decided only under the North Dakota Constitution." My position is that we properly <u>must</u> decide only the North Dakota Constitutional issue because that was the only issue properly before the district court and is the only issue properly before this Court. The plaintiffs could have brought their case under both the federal and state constitutions, but they did not.

[¶183] I acknowledge that those who are not following our clear jurisprudence apparently do not agree with me that we have a duty to do so. That this is a

controversial and emotional issue does not justify improperly reaching an issue not properly before us.

[¶184] I would reverse the district court. I agree with the Chief Justice and Justice Crothers that the statute has not been declared unconstitutional under either constitution by a sufficient majority, as required by the North Dakota Constitution.

[¶185] Dale V. Sandstrom