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| **iSTATE OF NORTH DAKOTA** | **IN DISTRICT COURT** |
| **COUNTY OF CASS** | **EAST CENTRAL JUDICIAL DISTRICT** |

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| **MKB Management Corp, d/b/a Red River Women's Clinic, Kathryn L. Eggleston, M.D.,**<br><br>**Plaintiffs,**<br>**vs.**<br><br>**Birch Burdick, in his official capacity as State Attorney for Cass County, Terry Dwelle, M.D., in his official capacity as the chief administrator of the North Dakota Department of Health,**<br><br>**Defendants.** | ) | **File No. 09-2011-CV-02205** |

# MEMORANDUM OPINION

# AND

# ORDER FOR PERMANENT INJUNCTION

**JULY 15, 2013**

## Introduction

This litigation involves recent legislative enactments that place restrictions on physicians performing abortions in North Dakota. Initially, the laws in question were all enacted by the 2011 legislative session. Before the constitutionality of those laws could be finally determined, the 2013 session enacted additional legislation of a very similar nature. In the interest of judicial economy, plaintiffs were recently granted leave to file a supplemental complaint, which adds a challenge to the 2013 enactment (S.B. 2305). This opinion, however, does not resolve any issues involving the 2013 law. Instead, it focuses solely on the 2011 enactments.

Any disputed issues of fact were tried commencing April 16, 2013. Testimony was completed on April 18. Plaintiff (MKB) was represented at trial by attorneys Autumn Katz, David Brown and Janet Crepps, all from the Center for Reproductive Rights. Defendants were represented by Douglas Anderson and Jeanne Steiner, both from the state attorney general's office.

As they do not advance a compelling state interest, and seem to have been tailored to cause rather than to avoid unnecessary infringement, the 2011 enactments fail to withstand strict scrutiny. All portions must be declared to be unconstitutional and invalid.

## Procedural Background

This state court action focuses on state laws enacted by the Legislature of North Dakota, specifically the 2011 amendments to the North Dakota Abortion Control Act (amendments). The amendments place restrictions on the performance of medical (a/k/a medication) abortions in this state. H.B. 1297, § 1 & 6, 62nd Legis. Assemb.

(N.D. 2011), codified at N.D. Cent. Code § 14-02.1-03.5. They were scheduled to take effect on August 1, 2011, but enforcement has been continuously stayed as a result of this litigation.

MKB is a North Dakota corporation. R. at 167. Since 1998, it has owned and operated the only medical facility in this state where abortion services are provided. R. at 123, 126. Most of its patients are North Dakota residents. R. at 127.

Although all of MKB's arguments are constitutional in dimension, it does not rely on the federal constitution, or any of the cases that define the reproductive rights protected by that constitution. Instead, it relies solely on the corresponding rights protected by our state constitution.

Cross motions for summary judgment were submitted in late 2011. MKB's motion was supported by detailed affidavits and exhibits. In response, the state filed an equally detailed affidavit from its medical expert. Although that affidavit failed to controvert many material facts, other facts were disputed.

A decision on the cross-motions was issued on February 16, 2012 (preliminary opinion). Based on an assessment of the existing record, it was determined that MKB was likely to prevail on the merits. However, because decisions of this nature should only be based on a full record and fact-intensive analysis, MKB's motion for summary judgment was denied.

Although it did not conclusively resolve all issues, the preliminary opinion did decide many of them. The state's threshold argument, that this is an invalid and premature challenge, was rejected. Prelim. Op., pp. 3-9. The role of the United States Food and Drug Administration (FDA) in the marketing of the relevant drugs was

reviewed and clarified. Id. at 11-14. Facts that had not been controverted were specified, and determined to be established without the need for any further showing. Id. at 16-18. Finally, a comprehensive analysis of the over-arching constitutional questions was performed - leading to the conclusion a women's right to choose must be regarded as fundamental under our state constitution. Id. at 20-44.

None of these determinations will be revisited here, but a quick review of the constitutional analysis is appropriate. In order to provide a complete discussion in this final opinion, other parts of the preliminary opinion will also be summarized.

**Constitutional Analysis – An Overview**

Although initial decisions were based in part on an inferred right to privacy, it is now clear the federal constitutional protection of reproductive rights is founded on the due process clause of the fourteenth amendment, and the controlling word is "liberty." Planned Parenthood of SE Penn. v. Casey, 505 U.S. 833, 846 (1992). Liberty is also one of the freedoms protected by the Constitution of North Dakota. N.D. Const., art. 1, §§ 1 & 12. The language in our state charter, however, is more expansive. Liberty is not an afterthought that was added by amendment. Instead, the first section of our state constitution has always recognized liberty as one of the foremost of the "inalienable rights" that must be zealously protected. Id. § 1. The same is true of the pursuit of happiness, a right nowhere mentioned in the federal constitution. Id.

Because state constitutions are also "a font of individual liberties … state courts cannot rest when they have afforded their citizens the full protections of the federal constitution." William J. Brennan, Jr., State Constitutions and the Protection of Individual Rights, 90 Harv. L.Rev. 489, 491 (1977). If federal law is "allowed to inhibit

the independent protective force of state law ... the full realization of our liberties cannot be guaranteed." Id.

The North Dakota Supreme Court has repeatedly recognized that "our constitution can and has given our citizens greater protection than the federal constitution." State v. Jacobson, 545 N.W.2d 152, 157 (N.D. 1996) (Levine, J., dissenting). However, the converse can never be true. It is axiomatic that rights guaranteed by the state constitution cannot be interpreted to be narrower or less expansive than corresponding rights guaranteed by the federal constitution. See, e.g., State v. Herrick, 1997 ND 155, ¶ 19, 567 N.W.2d 336.

Sections 1 and 12 of the state constitution must be construed together. The first section defines the individual rights that are guaranteed. Section 12 "protects and insures the use and enjoyment" of those rights. State v. Cromwell, 9 N.W.2d 914, 918 (N.D. 1943).

Although the scope and extent of the inalienable rights protected by section 1 has been addressed infrequently in court decisions, the cases that do exist stress two points. First, the freedoms thus protected are to be expansively construed and strictly protected. Second, the right to pursue happiness can, if anything, be even more expansive than the right to liberty.

In Cromwell the pursuit of happiness was described as "the aggregate of many particular rights," including the rights encompassed by "the general guaranty of 'liberty'." Id. at 918. It includes the personal freedom to make choices regarding work and family life "without restriction or obstruction." Id. at 918-19. Accordingly, this guaranty is "one of the most comprehensive" found in the state constitution. Id. at 919.

Subsequent court decisions recognize that an individual's "interest in personal autonomy and self-determination is a fundamentally commanding one, with well-established legal and philosophical underpinnings." State ex. rel. Schuetzle v. Vogel, 537 N.W.2d 358, 360 (N.D. 1995). Similarly, parental rights have been described as among the most "essential" of the freedoms protected by our constitution, "far more precious ... than property rights." Hoff v. Berg, 1999 ND 115, ¶ 8, 595 N.W.2d 285. As such rights are "of the highest order," only a compelling state interest justifies their infringement. Id. ¶ 10. Furthermore, even when such necessity exists, the legislation must be "narrowly drawn to express only the legitimate state interests at stake." Id. ¶ 13.

To date, the highest courts of at least eleven states have recognized that their state constitutions protect a women's reproductive rights. With the exception of Mississippi, all these decisions have regarded the right as fundamental, which implicates the strict scrutiny standard of review.[1]

Because federal decisions do not set the upper limit of state guaranteed liberties, they must not be followed "indiscriminately." Schweigert v. Provident Life Ins. Co., 503 N.W.2d 225, 227 (N.D. 1993). At the same time, it is appropriate to look to federal cases for guidance "when it is helpful and sensible to do so." Id.

The United State Supreme Court has repeatedly felt compelled to confront the issue of abortion. Its decisions provide a thoughtful analysis of the policy considerations that have forced successive majorities of that Court to conclude, or to reaffirm, a woman has the right to choose an abortion, and to select from the medical options that are safe

[1] These decisions are discussed in greater detail on pages 37 through 40 of the preliminary opinion.

and effective. Federal opinions have also paid great attention to the significant interests a state may assert when regulating abortion. It is helpful and sensible to look to these cases for guidance.

The Supreme Court decisions recognize that at stake in cases challenging abortion restrictions is a woman's ability "to retain the ultimate control over her destiny and her body, claims implicit in the meaning of liberty." Casey, 505 U.S. at 869. "The ability of women to participate equally in the economic and social life of the Nation" is intimately and inextricably connected to an "ability to control their reproductive lives." Id. at 856. Since Roe, successive generations of women have come of age free to assume that liberty includes the right to make reproductive decisions. Id. at 860. Through the exercise of that right, these women have been able to engage in intimate relationships and make "choices that define their views of themselves and their places in society, in reliance upon the availability of abortion should contraception fail." Id. at 856.

"Thus, [federal] challenges to undue restrictions on abortion procedures do not seek to vindicate some generalized notion of privacy; rather, they center on a woman's autonomy to determine her life's course, and thus enjoy equal citizenship stature." Gonzales v. Carhart, 550 U.S. 124, 172 (2007) (Ginzburg, J., dissenting) (Carhart II). Our state constitution also guarantees the right to personal autonomy and self-determination. Furthermore, this right is "precious", and must be protected in a manner that is both "comprehensive" and "commanding." Hoff, 1999 ND 115, ¶ 8; Cromwell, 9 N.W.2d at 919; Schuetzle, 537 N.W.2d at 360.

There is no difference between the lives led by women in North Dakota, as compared to the nation generally. The relevant biology is the same. All women

conceive and bear children in the same manner. The profound implications of parenthood are universal. The costs associated with raising and educating children continue to rise at a dramatic rate. It is now common for women to defer children until they have completed their education and reached a position in life that allows them to meet these demands. Some women elect to forgo children altogether, choosing to devote their time and energy to careers, avocations and other interests. Such autonomy and self-determination becomes unachievable if women are deprived of the right to terminate an unwanted pregnancy. Therefore, in every respect, the compelling rational supporting the federal decisions applies with equal force here.

The federal holdings also recognize that people have fundamentally different views regarding many issues, particularly abortion. There will always be an unbridgeable divide between the absolute convictions of those opposed to abortion and a woman's right to choose to terminate a pregnancy. The judiciary's obligation, however, "is to define the liberty of all." Casey, 505 U.S. at 856. This cannot be done by adopting the moral code of those who find the practice abhorrent. Id. See also, Roe v. Wade, 410 U.S. 113, 117 (1973). Furthermore, nothing can be gained by inflaming the passions that fuel this "intensely divisive controversy." Casey, 505 U.S. at 866. Instead, it is better to rule in a manner that "calls the contending sides ... to end their ... division by accepting a common mandate rooted in the Constitution." Id. at 867.

Finally, although they have recognized and protected a woman's right to choose, the Supreme Court decisions also show great deference to the significant interests a state may assert when regulating abortion. They hold a state may "properly assert important interests in safeguarding health, in maintaining medical standards, and in

protecting potential life." Roe, 410 U.S. at 154. More specifically, a state has a "legitimate interest in seeing to it that the abortion … is performed under circumstances that ensure maximum safety for the patient." Id. at 150. This interest extends "at least to the performing physician and his staff, to the facilities involved, to the availability of aftercare, and to adequate provision for any complication or emergency that might arise." Id.

For the reasons summarized above, it has already been concluded the inalienable rights protected by the Constitution of North Dakota must include a woman's right to terminate a pregnancy, and to select from any safe and effective procedures that may be available. These rights are fundamental. Any legislative infringement is subject to strict scrutiny. At a minimum, that law must be narrowly tailored, and necessary to promote a compelling state interest.

**State's Asserted Interests and Selected Means**

As the personal liberties and rights guaranteed by the state constitution must be equal to or greater than their federal counterparts, federal cases effectively set the upper limit on permissible state restrictions. At the same time, there is no reason to conclude the state's interests are entitled to less consideration under our state constitution. Therefore, it continues to be assumed the state interests recognized under both the federal and state constitutions are co-extensive.

Roe held that during the first trimester of pregnancy a woman, in consultation with her physician, must be permitted to decide free from any interference by the state. Id. at 163. Only later in the pregnancy does the state have a sufficient interest to justify legislation designed to safeguard women's health or maintain medical standards. Id. at

164. Casey does abandon the trimester approach, but that decision was focused on a state's interest in ensuring decisions are properly informed. Casey, 505 U.S. at 878. Of course, this is not the interest the amendments purport to promote.

The state justifies the amendments by arguing they are necessary to protect women's health and maintain medical standards. No other state interests have been, or could be, invoked. As Casey does not clearly indicate when a state's interest in protecting maternal health is entitled to consideration, a good argument can be made that to this extent Roe has not been overruled. Nonetheless, it will also be assumed that even during the first months of the pregnancy a state may regulate procedures if the need is compelling and the means selected are otherwise legitimate.

The amendments address the state's purported concerns in various ways.

First, the off-label usage of any abortion-inducing drug is prohibited. Instead, physicians are required to follow "the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug." H.B. 1297, § 6(2).[2]

Any physician performing medical abortions is next required to enter into a signed contract with another physician who agrees to provide exclusive coverage for

[2] To this extent, the amendments proceed on a false and flawed legal premise. The FDA does not test drugs, including the abortion-inducing drug mifepristone (which is marketed under the trade name Mifeprex). Instead, it merely reviews the results of the trials conducted by the drug's sponsor. More importantly, the FDA only regulates the marketing and distribution of drugs and medical devices. It has no authority to regulate or interfere with the practice of medicine. Once a new drug is approved for marketing and distribution, its subsequent use by physicians is in no manner restricted by the FDA approval process. Instead, all decisions regarding the appropriate dosage, administration and use of the medication are left to the professional judgment and discretion of the physician who prescribes it. Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 349-50 (2001); U.S. v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981).

any resulting emergencies. The physician performing the abortion must also give every patient "the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled." Id. § 6(4).

Finally, the amendments require that the patient be "in the same room and in the physical presence" of the prescribing physician whenever an abortion-inducing drug is administered. Id. § 6(5).

**Analysis and Discussion**

In short, both the declared legislative purpose and the means selected to advance that purpose are contrived and pretextual. The evidence introduced at trial only confirmed or strengthened initial impressions. When performed in accordance with the protocol used by MKB, medical abortions are extremely safe and very effective. There is no justification for regulation or restriction. Furthermore, even if some regulation was justifiable, the means selected by the legislature are both counterintuitive and counterproductive.

The amendments do nothing to promote women's health. They serve only to create insurmountable barriers that effectively eliminate medical abortions as an available option. Even if these barriers could be overcome, adherence to the amendments would force physicians to depart from well-established standards of care, to abandon the most fundamental tenets of their profession, and to provide patients with illogical and potentially tragic instructions regarding the availability of any follow-up treatment that may be required on an emergent basis. Compliance would also subject patients to unwarranted expense, inconvenience and discomfort.

There are many parts to a comprehensive analysis of the reasons the amendments are unconstitutional. Ultimately, each part only provides further support for the conclusions outlined above.

**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.[3] 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 exits, 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-

[3] 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.

22. It is selected by approximately 20% of patients.[4] 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.

[4] Nationwide this approach is selected by approximately 17% of the women who obtain early abortions. R. at 195.

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 co-authored 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.[5] 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

[5] A copy of the citizen petition was filed as an attachment to Harrison's affidavit.

morbidity and mortality statistics applicable to childbirth and early surgical abortions.[6] 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).[7] 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

[6] In Roe, 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. Roe, 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.

[7] Available at http://www.who.int/reproductivehealth/publications/unsafe abortion /97892415484341.

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.[8]

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.

[8] Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, Obstetrics and Gynecology, Vol. 121, No.1, 166-171 (Jan. 2004).

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 *C. sordellii* 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 *Clostridium* 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.[9] 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.

**2. De Facto Ban**

Nothing changes the conclusion that the prohibition of off-label usages constitutes a de facto ban of medical abortions in North Dakota. Although this may not have been the legislature's intent, the language they adopted leaves room for no other interpretation.

[9] 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.

It is undisputed that medical abortions require the administration of two different medications - mifepristone and misoprostol. R. at 214. This is true under both the FDA approved protocol and the evidence-based protocol followed by MKB. There is only one possible scenario that avoids the need for misoprostol, and this rarely occurs. In a very small percentage of cases, administration of the mifepristone alone quickly results in a completed abortion.[10]

Misoprostol is a prostaglandin analog. It causes the cervix to open. It simultaneously makes the uterus contract and expels its contents. A successful medical abortion requires the complete expulsion of the products of conception, without the need for a surgical intervention. Because this requires the administration of misoprostol in the vast majority of cases, it would be grossly inappropriate for any physician to start a medical abortion knowing the medication almost certainly required to complete the procedure was unavailable. There is no dispute about this.

Mifeprex is the only medication that has received FDA approval to be marketed for use with connection with medical abortions. Misoprostol is not labeled for such use.[11] Although the state has suggested in the past that misoprostol is not an abortion-

[10] In the clinical trials completed in the United States, mifepristone alone resulted in a completed abortion in 6.3% of the cases. The corresponding figure from the French trials was 5.3%. Ex. 3, p. 7.

[11] In addition to its almost universal usage in connection with medical abortions, misoprostol is also used off-label in connection with surgical abortions. It acts to soften or "ripen" the cervix, facilitating the passage of the necessary surgical instruments. R. at 192. No manufacturer has ever sought FDA approval to market the drug for such usages. There is no reason to expect this to change. The Mifeprex application well illustrates the extraordinary contention, difficulty and expense any such application would certainly generate. Because off-label use is generally endorsed and supported, no manufacturer has any incentive to go through this process with misoprostol. R. at 358-59.

inducing drug, the amendments leave no room for this interpretation. An “abortion inducing-drug” is defined as any drug “prescribed or dispensed with the intent of causing an abortion.” H.B. 1297, § 1. A portion of the 2011 amendments not challenged by this litigation changed the definition of "abortion." The current definition includes the use of medication to expel non-viable tissue, unless tissue death is due to a spontaneous abortion (miscarriage). N.D. Cent. Code § 14-02.1-02(1).

Therefore, if the amendments were enforced medical abortions could no longer be legally performed in North Dakota. The medication required to complete the procedure is not labeled for this use.[12] There is no getting around this. There is also no getting around the constitutional implications of this de facto ban.

The medical concept of informed consent is based on a patient’s right to autonomy and self-determination, the same fundamental interests that are at the center of a woman’s reproductive rights. The physician’s role is to provide the information necessary to allow the patient to make an informed decision, but the patient must always make the final decision. This includes the right to choose from the treatment options that are available and appropriate. Orentlicher aff., ¶ 6.

The amendments were not designed to express the state’s interest in potential life, to inform women regarding the consequences of abortion, or to persuade them to continue their pregnancy. Instead, their clear purpose is “to cull the list of available

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[12] The citizen petition co-authored by Dr. Harrison stresses that a medical abortion requires the administration of mifepristone, followed by a prostaglandin such as misoprostol. Citizen Petition, pp. 41-42 (Aug. 2002). The petition goes on to argue that it was arbitrary and capricious for the FDA to approve the marketing of Mifeprex, when the protocol described in its label required the use of a second medication that had not been approved by it for use as part of an abortion regimen. Id. at 41-43.

abortion techniques" by placing severe restrictions on a method that was previously safe, legal and readily available. Rhode Island Med. Soc'y v. Whitehouse, 66 F. Supp. 2d 288, 313 (D. R.I. 1999).

It is true that laws designed to inform a woman's decision tend to be affirmed in a relatively cursory manner. See, e.g., Fargo Women's Health Org. v. Sinner, 819 F. Supp. 865 (D. N.D. 1993). Procedural bans are a very different matter. Laws which have the intentional or unintentional effect of prohibiting any safe and effective method of abortion, used on a pre-viability basis, have uniformly been held to violate federal constitutional protections. See, e.g., Road Island Med. Soc'y v. Whitehouse, 66 F. Supp. 2d 288, 313-14 (D. R.I. 1999), aff'd 939 F.3d 104 (1st Cir. 2001); Causeway Med. Ste. v. Foster, 43 F. Supp. 2d 604, 612 (E.D. La. 1999), aff'd 221 F.3d 811 (5th Cir. 2000); Little Rock Fam. Planning Serv., P.A. v. Jegley, 192 F.3d 794 (8th Cir. 1999); Planned Parenthood of So. Ariz., Inc. v. Woods, 982 F. Supp. 1369, 1376-78 (D. Ariz. 1997). Each of these decisions involved a broad, facial challenge brought on a pre-enforcement basis. Furthermore, they all involved laws which banned second trimester procedures. In relative terms, those procedures are much more complicated, and involve much more risk to the patient, compared to a medical abortion performed through 63 days LMP. As the state constitutional guarantees must be equal to or greater than their federal counterparts, by itself the de facto ban is clearly dispositive.

Furthermore, It makes no difference that the ban is unintentional, or due to inarticulate legislation. Planned Parenthood of Central New Jersey v. Farmer, 220 F.3d 127, 144 (3rd Cir. 2000). A woman's right to terminate a pregnancy includes the right to choose, in consultation with her physician, from among "the principal methods of

performing abortions in the United States." Hope Clinic v. Ryan, 195 F.3d 857, 861 (7th Cir. 1999). Without question, this includes the use of medication to induce the abortion. Id.[13]

**3. Mifeprex FPL Regimen**

The state has always defended this case as if the amendments would permit medical abortions to continue, provided the protocol outlined in the Mifeprex "label" is strictly followed. For the reasons just explained, this is an untenable position. "When the wording of a statute is clear and free of all ambiguity, the letter of it is not to be disregarded under the pretext pursuing its spirit." N.D. Cent. Code § 1-02-05. Although "every reasonable construction must be resorted to … the canon of constitutional avoidance does not apply if the statute is not genuinely susceptible to two constructions." Carhart II,, 555 U.S. at 153-54 (citations and internal quotations omitted). The legislature may have intended only to require compliance with the Mifeprex "label", but the law they passed is not susceptible to this interpretation. Furthermore, even if it was, there would be no justification for compelling physicians to follow a flawed and obsolete protocol that was never intended to constrain the practice of medicine.

[13] To date, the only procedural ban that has sustained a constitutional challenge is the ban on the intact dilation and extraction (D&X) procedure upheld in Carhart II, 550 U.S. 124. Furthermore, in that case the Court was careful to distinguish the common first-trimester abortion methods, including the use of medication to terminate the pregnancy. Id. at 134. The contrast between a medical abortion and an "intact D&X" could not be more stark. The latter procedure is performed late in pregnancy, when the fetus is well developed and the bones and ligature have begun to harden. It is the infamous "partial birth abortion." The surgeon dilates the cervix and then uses instruments to grab the fetus and extract it intact. In order to allow the head to pass through the cervix, the physician typically crushes the skull with instruments before completing the extraction. This also serves to ensure the fetus is not delivered both intact and alive. Id. at 137-38.

**a. FDA Approval Process**

By way of introduction and review, any manufacturer or sponsor applying for FDA approval to market a new drug must submit the results of the test trials it has conducted or commissioned. The safety and efficacy data contained in the Mifeprex application was based solely on the results of three clinical trials completed in 1996. Two of those trials were conducted in France, the third in the United States. Rarick aff., ¶ 6. Collectively, those trials involved approximately 2500 subjects, none of whom were more than 49 days LMP. Each participant was treated in accordance with the same test protocol. Id. ¶ 7.

The FDA approval process extends to any documentation that accompanies the prescription medication. Collectively, this documentation is referred to as the drug's final printed label (FPL). All information regarding dosage, administration, safety or efficacy must mirror the protocol followed, and the results obtained, in the clinical trials. Id. ¶ 11.

The Mifeprex FPL does not reflect evidence accumulated from any source other than the clinical trials. In particular, it does not provide any information regarding advances in the relevant medical science since those trials were performed. Ordinarily, this would be of no consequence, as an FPL does not define medical standards of care or impose any restrictions on the practice of medicine. In the words of the FDA, the role played by the FPL is "informational only." FDA Drug Bulletin, vol. 12, no. 1, p. 3 (April 1982) (FDA, 1982 Bulletin).[14] In approving any FPL, the FDA only

[14] A copy of this bulletin is attached to the Rarick affidavit as Exhibit B.

"tries to assure the prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based." Id.

Physicians are professionally, ethically and legally obligated to follow current medical standards. Their recommendations must present only those options that can be provided in a manner consistent with good medical practice. Any threats to patient welfare must be minimized. Orentlicher aff. ¶¶ 5-9. A departure from these universal standards subjects a physician to civil liability. If abortion services are involved, criminal liability can also result if "medical standards" are not followed. N.D. Cent. Code § 14-02.1-04(1).

Off-label use is neither prohibited nor discouraged by the FDA. Planned Parenthood Cincinnati Region v. Strictland, 531 F.3d 406, 408 (6th Cir. 2008). Instead, the agency has consistently indicated that off-label use is common and accepted, and may be required by good medical practice. Rarick aff. ¶ 14. "Valid new uses for drugs already on the market are often first discovered through serendipitous observations and medical innovations, subsequently confirmed by well-planned and executed clinical investigations." FDA, 1982 Bulletin, p. 3.

Mifepristone was used in Europe long before it was first released for use in this country. This was particularly true of France, where the drug has been used to perform medical abortions since 1990. Evidence and experience from this use had demonstrated serious flaws in the FPL protocol by the time FDA approval was finally obtained in 2000. As a result, that protocol has never been followed on a wide-spread basis in the United States. Instead, from the outset most physicians followed evidence-

based protocols that have been proven to be more effective, less expensive and otherwise advantageous.[15] R. at 217-19, 230, 262-63, 308.

**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 µg 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."[16] 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.[17] 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.

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[15] As early as 2001, a large survey showed that only 4% of practitioners were following the FPL protocol. R. at 218. Today more than 99% of all medical abortions performed in the United States follow the evidence-based regimen used by MKB. R. at 218-19. The FPL protocol is only one of the regimens that comprise the small reminaing fraction (less than 1%). R. at 262-63.

[16] 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.

[17] 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.

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 µg 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 µg 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 mifepristone, followed by the buccal administration of 800 µg 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 Mifeprex FPL is now regarded in the medical community a relic of history.[18] 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

[18] 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.

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 Fargo Women's Health Org. v. Schafer, 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. Id. at 532. See also, Daugaard, 799 F. Supp. 2d at 1065.

[19] A copy of this bulletin is attached to the Grossman affidavit as Exhibit B.

### 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 a [sic] trained medical personal, 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.[20]

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. Id. 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.

[20] 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.

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. Haggard v. Meier, 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.[21] The results achieved at the Fargo clinic are comparable.[22] 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.

[21] 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.

[22] 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., Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Controlled Trial, Obstetrics and Gynecology, Vol. 112, No. 6, 1303-1310. (Dec. 2008).

**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.

**4. Emergency Services Contract**

The amendments require that every physician who performs medical abortions must enter into an exclusive contract with another physician to provide coverage on an emergency basis. In turn, the contracting physician must designate the hospital where he or she has "active admitting privileges and gynecological and surgical privileges,"

and where emergencies will be treated. H.B. 1297, § 6(4).[23] Furthermore, every patient must be "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." Id.

Over the course of this litigation, the state has struggled to address this extraordinary requirement. In particular, it has repeatedly suggested this portion of the amendments could be saved by an interpretation that it does not mean what it says. See, e.g., R. at 410-11. Again, laws must be construed based on what they say, not what they more reasonably might have said. N.D. Cent. Code § 1-02-05.

In her initial affidavit, Dr. Harrison opined that the complications typically resulting from medical abortions are so dire and so difficult that only a physician with unique training and experience is competent to handle them. This suggestion was a substantial focus of the trial. As a result, it has now been thoroughly dispelled.

The complications that most commonly result from a medical abortion are retained tissue (incomplete abortion) and hemorrhage. Infection may also be associated in very rare cases, but as already discussed causation is doubtful in a significant sub-set of these cases.

A miscarriage is an abortion that occurs spontaneously. The complications associated with miscarriage and medical abortions are identical. So is the treatment. R. at 243, 326-27, 331. The only real difference is that following a miscarriage such complications are both more frequent and more likely to be significant. The spontaneous abortion of a fetus can occur later in the pregnancy, when more tissue has

[23] S.B. 2305 imposes very similar requirements. The primary difference is that the 2013 legislation applies to physicians performing abortions, rather than to physicians providing subsequent care on an emergent basis.

developed. No drugs are administered to aid in the expulsion of that tissue. Moreover, the patient has not received any medication on a prophylactic basis.

Based on the evidence, it is likely that no physician in North Dakota has ever been required to treat the complications of a medical abortion on an emergency basis.[24] By comparison, treating complications associated with a miscarriage is a common medical event. Approximately one in seven pregnancies ends with spontaneous abortion. R. at 325. Furthermore, complications associated with childbirth can also be similar or identical, and they are even more prevalent.

In many cases, the complications that do result from a medical abortion require no treatment beyond monitoring. Retained tissue usually passes as a result of natural processes, and most bleeding stops on its own. R. 237-39. If a surgical intervention is required, it is almost always a vacuum aspiration or surgical curettage (D&C). If hemorrhaging is severe, a transfusion maybe required. These are all relatively common and simple medical procedures. They are routinely performed at most medical centers. R. at 244, 335-36.

According to the most recent information available from the Department of Health, North Dakota has forty-three medical facilities that provide emergency care. Ex. 15, p. 15. They are distributed throughout the state. Ex. 16. Similar emergency care providers are found throughout the adjoining states and provinces. The record confirms that most of these facilities could probably treat, on a very adequate basis, any complications that might result from a medical abortion.[25] R. at 340-43. Although such

[24] Only one case requiring emergent treatment (a blood transfusion) is known to MKB. That treatment was provided in Minnesota. R. at 103.

care is rarely required, in a true emergency time is of the essence. Delay can have serious or fatal consequences.

Of course, this explains why patients are invariably told that if they need emergency treatment they should immediately proceed to the closest hospital or emergency room. By law, no emergency care provider can refuse treatment. However, if the amendments take effect, physicians performing medical abortions in North Dakota will no longer be able to tell patients that when the need is urgent they should proceed to the closest emergency care provider. Instead, they would be required to instruct patients to go to one specific physician and one specific hospital, regardless of either the distance involved or the level of emergency. There is no logical, much less compelling, reason for compromising and obstructing care in this way.

Furthermore, even if there was sound reason to require an exclusive emergency services contract, this requirement would be impossible to meet. The contracting physician would be continuously on call. Every physician who testified on behalf of MKB indicated this was an absurd requirement. R. at 55, 236-37, 346-48. Dr. Harrison agreed that "no human being" can be continuously available. R. at 469. Furthermore, assuming the emergency happened to arise while the contract physician was on duty, they would likely be otherwise occupied when their services were required. R. at 346-47. Emergency transport personnel proceed to the closest suitable medical facility,

[25] As a medical student, Dr. Fiebiger received part of her training at the hospital in Rolla, North Dakota. This is a level V trauma center, the lowest of the recognized levels. At least at the time, it was staffed exclusively by family practice physicians. Dr. Fiebiger testified that every one of those physicians was proficient in the performance of a D & C. R. at 336, 361.

which is almost certain not to be the hospital designated in the emergency services contract. R. at 338-39, 348.

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.[26] 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 personal 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. Even if a willing physician could be found, it is certain that no hospital they were associated with would be similarly inclined.

**5. Administration Requirement**

The last of the challenged provisions requires that the patient must be in "the same room and in the physical presence of" the prescribing physician when she takes any abortion-inducing drug. H.B. 1297, § 6(5). Assuming the amendments could be interpreted to allow the administration of misoprostol, this requirement also seems

[26] If any portion of the amendments does manifest an impermissible purpose, this is it. No justification for the disclosure requirement has been suggested.

calculated only to prevent further insurmountable barriers, without providing any offsetting benefits.

For most people, the self-administration of medication is a routine part of everyday life. Physicians and pharmacists provide any necessary instructions, but beyond that they play no essential or beneficial role. Because they want the medication to work, patients are highly motivated to follow such instructions. R. at 280, 332-33. Certainly having the physician in the same room when the medication is administered adds nothing to its efficacy.[27] On the other hand, adding a requirement for clinical administration makes perfect sense if your goal is to accomplish a de facto ban of medical abortions in North Dakota.

MKB has followed the same staffing schedule for years, and its practices are a matter of common knowledge. Procedures are typically only performed on Wednesdays, because that is the day a physician is present at the clinic. One week per month, a physician is also present on either Tuesday or Thursday. R. at 92-93. The Mifeprex FPL requires that misoprostol be administered two days after the mifepristone is ingested. Ex. 3, p. 21. Therefore, without changes to MKB's staffing schedule, a physician would never be present in the clinic when it was time to take the second medication. Assuming MKB could meet the increased staffing requirements, this would certainly result in a significant increase in costs that would need to be passed on to the patient. R. at 144.

[27] Dr. Harrison testified that misoprostol is bitter, and many patients dislike the taste created when it is administered buccally. She went on to suggest a monitoring physician could perhaps prevent the patient from swallowing the pills before they fully dissolved. R. at 408. This seems unlikely. In any event, if the amendments were enforced it would become illegal for any physician to permit buccal administration in the first place.

Finally, patient no-shows would be impossibly problematic if the clinical administration of misoprostol became the law. Unforeseen and uncontrollable circumstances, including weather and road conditions, would inevitably delay some of the patients who did return. R. at 317. A law that would impose criminal liability on a physician for eventualities they could not control makes no sense. It certainly does not withstand strict scrutiny.

**6. Lack of Exceptions**

The amendments contain no exception for cases where a medical abortion, in the considered judgment of her physician, is necessary to preserve a woman's health. The ban also applies indiscriminately to victims of rape, incest, other forms of sexual abuse, and domestic violence. The state has never attempted to justify these fundamental shortcomings, and it has already been determined the lack of appropriate exceptions is a fatal constitutional infirmity. Prelim. Op., pp. 64-71. In important respects, however, the record now contains confirmation and elaboration. In other respects, a review is appropriate.

Once again, federal law establishes the minimum requirements. Roe held that even when a state was otherwise free to regulate or prohibit abortion, any law must contain an exception when necessary to protect the life or health of the women. Roe, 410 U.S. at 163-64. "Since the law requires a health exception in order to validate even a post viability abortion regulation, it at a minimum requires the same in respect to pre-viability regulations." Stenberg v. Carhart, 530 U.S. 914, 930 (2000) (Carhart I). Therefore, "where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger a woman's health Casey requires the

statute to include a health exception when the procedure is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502, 511 (6th Cir. 2006). Furthermore, a health exception is necessary even if the circumstances that trigger it "rarely occur." Id.

**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,[28] 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. Taft, 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

[28] The evidence on this point was equivocal.

[29] 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.

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. Id.

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.

**7. Federal Law**

If it is ultimately determined that the liberty and freedoms guaranteed by the state constitution to not extend to a woman's reproductive rights, or if the state constitution is

subsequently amended to eliminate those rights,[30] then the protections afforded by the federal constitution will need to be considered. No state law can stand if it conflicts with federal constitutional protections, and therefore violates the supremacy clause. U.S. Const., art. VI, cl. 2.

Federal law invalidates any regulation or restriction that imposes an "undue burden" on a woman's right to choose. Casey, 505 U.S. at 877-78. In many respects, this unique standard has defied all subsequent attempts to provide uniformity or clarification. It has been criticized as an "ultimately standardless" and "subjective" test, that is a poor substitute for strict scrutiny - a "recognized principle of constitutional law" that "has been applied repeatedly over the years." Planned Parenthood of Middleton v. Sundquist, 38 S.W.3d 1, 16 (Tenn. 2000). On the other hand, there is a relative abundance of federal case law dealing with abortion. Those cases are not always easy to follow or reconcile, but they are uniform in multiple respects that would clearly be dispositive here. All this is discussed in some detail in the preliminary opinion. Only a quick review will be provided here.

As a threshold issue, the state has relied on distinctions federal cases make between "facial" and "as-applied" challenges. This is another murky area of the law, particularly in the case of abortion. Nonetheless, it does seem clear this case would proceed under federal law.

The last definitive word on this issue from the Supreme Court continues to be Casey. There the plurality opinion held a facial challenge to an abortion regulation may

[30] As part of the 2014 primary election, voters will be required to decide if the state constitution should be amended to recognize a "right to life of every human being at any stage of development." S.C.R. 4009, 63rd Legis. Assemb. (N.D. 2013).

proceed if the law will operate as a substantial obstacle "in a large fraction of the cases in which [it] is relevant." Casey, 505 U.S. at 895. Although there has been subsequent confusion and uncertainty, clearly this is the rule most federal courts now follow. See, e.g., Planned Parenthood v. Miller, 63 F.3d 1452, 1456-58 (8th Cir.1995); Daugaard, 799 F. Supp. 2d at 1059.

The state initially argued that the amendments do not affect a large fraction of cases, as 80% of MKB's patients opted for the surgical approach. This completely misses the point. "The proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant." Casey, 505 U.S. at 895. "The analysis does not end with the [20]% of the women upon who the [amendments operate]; it begins there." Id.

Furthermore, in Citizens United v. Fed. Election Com'n, 558 U.S. 310 (2010), the Court recognized that an as-applied challenge is often no remedy at all. By the time the litigation is over, for the litigant the issue is usually moot. Id. at 334. Therefore, if a statute is not capable of a constitutional application, a determination of facial invalidity on a pre-enforcement basis becomes a matter of "judicial responsibility." Id. at 329.

Because the amendments act as a de facto ban of medical abortions, their fate under federal law is certain. As outlined in a previous section, laws which have the intentional or unintentional effect of prohibiting any safe and effective method of abortion performed on a pre-viability basis have uniformly been held to impose an undue burden under Casey.

Under federal law, the lack of an exception when a medical abortion is necessary to preserve a women's health or well-being is another obvious infirmity. It is undisputed

that for women with physical anomalies a medical abortion is often the only alternative to an inpatient surgical procedure involving much greater risk. Banning medical abortions would subject many victims of sex crimes to extreme emotional harm. For some women living in abusive relationships, such a ban would not only subject them to emotional distress, it would create a very real risk of serious physical harm. The requirement for a health exception is something the Supreme Court has repeatedly emphasized. Roe, 410 U.S. at 163-64; Casey, 505 U.S. at 846; Carhart I, 530 U.S. at 930. It does not matter how rarely these concerns may arise. Taft, 444 F.3d at 511.

Finally, even if the amendments could be interpreted to allow medical abortions performed in accordance with the FPL protocol, this would still impose multiple undue burdens, without providing any offsetting benefit.

As indicated above, the FPL requirement for three tablets of Mifeprex provides no medical benefit. It serves only to increase the cost by $170, based on current prices. For a woman who is poor and pregnant, even a small increase in the cost could easily render the procedure unavailable. R. at 44. This is an undue burden. See, e.g., Daugaard, 799 F. Supp. 2d at 1065.

Any regulation that has the effect of requiring an extra trip to the clinic also creates an undue burden under federal law. See, e.g., Shafer, 18 F.3d at 532; Daugaard, 799 F. Supp. 2d at 1065. The clinical administration of misoprostol would require such a trip.

The gestational limit of 49 days LMP would obviously be an undue and unnecessary burden for any women between 50 and 63 days LMP. See, e.g., Daugaard, 799 F. Supp. 2d at 1061. Furthermore, even for women who present in time

to comply with the FPL protocol, following that regimen would only increase the potential for side effects, extend the typical time to completion, and significantly lower the odds of an ultimately successful result. It would also force patients to experience the process of expulsion in a very uncomfortable and inappropriate location. These are all undue burdens, particularly when they are also so unneccessary.

The Supreme Court of Oklahoma recently held a nearly identical law was facially unconstitutional, applying the federal undue burden standard. Okla. Goal for Reprod. Justice v. Cline, 292 P.3d 27 (Okla. 2012) (per curiam). They did so by summarily affirming the trial court's opinion. In turn, that opinion had concluded the requirement to follow the Mifeprex FPL was "so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against women who do." Okla. Goal. for Reprod. Justice v. Cline, CV-2011-1722 at 2-3 (Okla. Cty. Dist. Ct., May 11, 2012).

Therefore, it is clear the amendments also violate the fourteenth amendment of the United States Constitution. Should they go into effect, the amendments would do nothing "to further the health or safety of a woman seeking an abortion." Casey, 505 U.S. at 878. Instead, these unnecessary regulations would only have the effect of imposing undue burdens on the exercise of that right. Id.

## 8. Alternative Arguments

The alternative arguments put forth by MKB have thus far received little attention.[31] It is time to address them in a more definitive way, but doing that does nothing to change or strengthen the outcome.

### a. Vagueness

The amendments are not a model of clarity. They do misperceive the role of the FDA in the practice of medicine. They are not, however, so impossibly vague that they should be declared void for this reason alone. Indeed, many of the conclusions already outlined are based on a lack of ambiguity.

If the amendments were allowed to stand, any physician performing abortions would have adequate and fair warning that it would be illegal to use misoprostol in any manner. Similarly, they should understand that medical abortion patients must be given the name of the physician and hospital who would provide any emergent care that maybe required. Finally, they would be on notice that their physical presence was required during the administration of any abortion-inducing drug. These requirements are all unconstitutional, but it is not because they are vague.

### b. Bodily Integrity

A woman's interest in personal autonomy and self-determination is fundamental and commanding, but this has already been addressed. The separate bodily integrity argument made by MKB fails only because it is more of a restatement than an independent basis for deciding.

[31] In the preliminary opinion it was only noted that consideration of these arguments would be deferred until after the trial. Prelim. Op. at 86.

**c. Delegation of Authority**

The amendments do refer to the "label" authorized by the FDA. This is not an impermissible delegation of legislative authority. At most, it was an attempt to incorporate by reference.

**d. Special Law**

The North Dakota Constitution does generally prohibit "local or special laws." N.D. Const., art. IV, § 13. MKB argues the amendments also violate this portion of the state constitution.

The amendments certainly are special to the extent that they impose unique and onerous restrictions on a specific medical procedure. When it comes to medical care, patients typically have the unfettered right to choose from the available treatment options, and to select their preferred doctor or hospital. Decisions regarding the appropriate treatment protocol are typically left to the professional judgment of the physician. Managed health care is so often viewed as an anathema because it is perceived as something that may limit the ability to make these choices or decisions.

The amendments eliminate the medical option preferred by approximately 20% of all abortion patients in North Dakota, even though the surgical approach is not a viable alternative for many of those patients. They also mandate that only one specific physician and hospital can provide emergency care on a post-procedure basis. The amendments are unprecedented in these respects. R. 110, 315-16.

As a further example, misoprostol is a versatile medication. It is commonly used to induce labor, to ripen the cervix prior to delivery, and to control post-partum hemorrhage. All of these are off-label usages. R. at 192, 351. They are associated

with a medical event (childbirth) that necessarily involves much more risk to the patient than an early abortion. The amendments, however, only ban the off-label use of misoprostol in connection with abortions.

Many other medications are likewise commonly used in ways that bear no resemblance to the use the FDA initially considered. R. at 350-51. No other form of off-label usage is illegal in North Dakota. R. at 194. Indeed, we have a statute prohibiting health insurers from excluding coverage on the grounds the medication has not been approved by the FDA for the prescribed usage. N.D. Cent. Code § 26.1-36-06.1(2).

From a medical standpoint a requirement that physicians follow the protocol discussed in the Mifeprex FPL makes "absolutely no sense." R. at 352. Following this "inferior" regimen would equate to "sub-optimal" care. R. at 24, 230.

All this does bring into question the true purpose of the amendments. The de facto ban may not have been intended, but the restrictions do seem designed only to create obstacles to the performance of medical abortions in North Dakota. No other conclusion is plausible.

Casey invalidates any law that has the "purpose or effect" of placing an undue burden on "a woman seeking an abortion." Casey, 505 U.S. at 877. "Where a requirement serves no purpose other than to make abortions more difficult, it strikes at the heart of a protected right, and is an unconstitutional burden on that right." Planned Parenthood of Greater Iowa, Inc. v. Atchison, 126 F.3d 1042, 1049 (8th Cir. 1997). Similarly, "if a statute burdens constitutional rights and all that can be said on its behalf

is that it is the vehicle the legislators have chosen for expressing their hostility to those rights, the burden is undue." Hope Clinic, 195 F.3rd at 881 (Posner, J., dissenting).[32]

Returning to state law, Cromwell admonishes that courts must not allow themselves to "be misled by mere pretenses" on the part of the legislature. Cromwell, 9 N.W.2d at 920. If a statute infringes on a fundamental right, but "has no real or substantial relation" to the public health interest it purports to advance, it becomes the duty of the courts to declare that law unconstitutional. Id. at 921. This language is similar to the above-quoted enunciations of the Casey purpose prong. At the same time, there is no indication the drafters of the state constitution had any of this in mind when they proscribed special laws.

In Teigen v. State, 2008 ND 88, 749 N.W.2d 505, it was noted the constitutional prohibition against special laws was designed to ward against a practice prevalent in the late nineteenth century - legislation designed to benefit particular persons or localities. Id. ¶ 11. "The common inquiry in our special law cases is whether statutory classifications are written in general terms, rather than applying to particular persons or

[32] Most federal decisions, however, have ignored the purpose prong, and its continued viability is in some doubt. In Armstrong v. Muzarek, 906 F. Supp. 561 (D. Mont. 1995), the district court concluded plaintiffs would have to prove "none of the individual legislators approving the passage of [the restriction] was motivated by desire to foster the health of a woman seeking an abortion." Id. at 567. The Ninth Circuit reversed, reasoning the appropriate standard was proof the "predominant factor motivating the legislature's decision" was the desire to make abortions more difficult. Armstrong v. Muzarek, 94 F.3d 566, 567 (9th Cir. 1996). The Supreme Court granted certiorari and immediately reversed the Court of Appeals, without saying anything helpful regarding the appropriate standard. Muzarek v. Armstrong, 520 U.S. 968 (1997). Since Muzarek, lower court opinions have tended to omit discussion of the purpose prong, or to conflate it with the effects prong. Wharton et al, Preserving the Core of Roe: Reflections on Planned Parenthood v. Casey, 18 Yale J.L. & Feminism 317, 377-78 (2006).

things, and if written in general terms, whether the classification closes the door against accessions to the class." Id. ¶ 18 (inner quotations omitted).

Although portions of the amendments do seem to have been drafted with MKB in mind, the language would apply generally to any clinic or physician performing medical abortions. Similarly, although MKB is currently the only facility in the state where such procedures are performed, the amendments would apply equally to any clinic or physician who may otherwise provide such services in the future. The door to accessions has not been closed.

Therefore, the amendments do not appear to be a "special law." Whether something akin to a state law variant of the Casey purpose prong exists is a worthy question, but not one that need be decided here. All portions of the amendments are otherwise unconstitutional, and it is not possible to construe them in a manner that avoids the "infirmities." City of Fargo v. Salsman, 2009 ND 15, ¶ 21, 760 N.W.2d 123. Declaring the amendments to be a "special law", or determining the legislative purpose to be improper, would do nothing to change the outcome. See, e.g., Okpalobi v. Foster, 190 F.3d 337, 354 (5th Cir. 1999). The making of unnecessary constitutional pronouncements is not something district courts are encouraged to do.

**Conclusion**

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.

Accordingly, enforcement of sections 6(2), 6(4) and 6(5) of H.B. 1297, as enacted by the 62nd Legislative Assembly, must be permanently enjoined. These enactments have been codified as N.D. Cent. Code § 14-02.1-03.5, subs. 2, 4 & 5. The same is true for the definitions of "abortion-inducing drug" and "drug label" adopted as part of section 1 of H.B. 1297. These definitions are codified as N.D. Cent. Code § 14-02.1-02, subs. 2 & 4.

All issues regarding the constitutionality of the 2011 legislation challenged by this litigation have now been finally resolved. It is hereby expressly determined there is no just reason for delaying the entry of a final judgment as to these claims. The issues of state constitutional law raised by this case can only be settled by the North Dakota Supreme Court. In all respects, those issues are a matter of great public interest. They should be resolved as soon as possible. Accordingly, the clerk is directed to enter a final judgment pursuant to N.D.R. Civ. P. 54(b). This leaves for determination only any new issues created by the 2013 legislation - S.B. 2305.[33]

Dated this 15 day of July, 2013.

/s/ Wickham Corwin
Wickham Corwin
District Judge

[33] Although MKB has prevailed to this point, it also seems appropriate to defer any issues regarding the taxation of costs until all claims have been resolved.