IN DISTRICT COURT, COUNTY OF CASS, STATE OF NORTH DAKOTA

MKB Management Corp, d/b/a Red River Women's Clinic, Kathryn L. Eggleston, M.D., **Plaintiffs,** **vs.** **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,** **Defendants.**	**File No. 09-2011-CV-02205**

MEMORANDUM OPINION AND ORDER

February 16, 2012

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Introduction

This action challenges the validity of most of the amendments to the North Dakota Abortion Control Act pertaining to medical or medication abortions (amendments). They were passed by the 2011 Legislative Assembly, as part of House Bill 1297.

The following portions of section 6 are at issue:

> (2) It is unlawful to knowingly give, sell, dispense, administer, otherwise provide, or prescribe any abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in that pregnant woman, or enabling another person to induce an abortion in a pregnant woman, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician, and the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug.
>
> (4) Any physician who gives, sells, dispenses, administers, prescribes, or otherwise provides an abortion-inducing drug shall enter a signed contract with another physician who agrees to handle emergencies associated with the use or ingestion of the abortion-inducing drug. The physician shall produce the signed contract on demand by the patient, the department of health, or a criminal justice agency. Every pregnant woman to whom a physician gives, sells, dispenses, administers, prescribes, or otherwise provides any abortion-inducing drug must be provided the name and telephone number of the physician who will be handling emergencies and the hospital at which any emergencies will be handled. The physician who contracts to handle emergencies must have active admitting privileges and gynecological and surgical privileges at the hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.
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> (5) When an abortion-inducing drug or chemical is used for the purpose of inducing an abortion, the drug or chemical must be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient.

H.B. 1297, § 6, 62nd Legis. Assemb. (N.D. 2011), codified at N.D. Cent. Code § 14-02.1-03.5.

Several relevant definitions are also included in this challenge. They are set forth in section 1, and provide as follows:

> "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of causing an abortion.
>
> "Drug label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the federal food and drug administration and agreed upon by the drug company applying for the federal food and drug administration authorization of that drug. Also known as "final printing labeling instructions", [sic] drug label is the federal food and drug administration document that delineates how a drug is to be used according to the federal food and drug administration approval.

Id. § 1, codified at N.D. Cent. Code § 14-02.1-02.

The amendments were scheduled to take effect on August 1, 2011. On July 21, 2011, an order was entered restraining defendants from enforcing any of the challenged provisions until plaintiffs' motion for a temporary injunction could be heard and decided. At the request of all parties, the schedule was subsequently extended on multiple occasions. In the interim, cross motions for summary judgment were also submitted and briefed. Most recently, plaintiffs filed a motion in limine.

A hearing on all pending motions was held on January 27, 2012. Suzanne Novak argued on behalf of plaintiffs, and Kirsten Franzen on behalf of defendant Terry Dwelle, M.D. ("DOH" or "state"). Both sides were resolute, unwilling to make any significant concessions. On one point, however, there was agreement. All of the challenges put forth by plaintiffs are constitutional in dimension. Accordingly, there is no room for the maxim that courts should avoid decisions on constitutional grounds when an alternative means of resolving the dispute is available. State v. Friedt, 2007 ND 108, ¶ 7, 735 N.W.2d 848.

By way of preview, this opinion concludes further proceedings are necessary, but plaintiffs are likely to ultimately prevail with their primary constitutional challenge, regardless of whether the result is based on state or federal law. Accordingly, enforcement of the amendments will continue to be enjoined during the pendency of these proceedings. Consideration of the alternative constitutional challenges will be deferred until the record is complete.

Threshold Arguments

As a constitutional ruling cannot be avoided, the next question is whether plaintiffs have met the threshold requirements to proceed. For several related reasons, DOH asserts that it would be improper to even address the merits in a substantive way. First, because the "overwhelming majority" of the abortions performed in North Dakota utilize the surgical approach, any obstacle or burden placed in the way of the medical option is argued to be insignificant, and not entitled to consideration. Second, DOH asserts the facial challenges mounted by plaintiffs are based only on hypothetical scenarios. Accordingly, it suggests any issues regarding constitutionality should either be "ignored," or at least deferred until some woman is personally burdened by the amendments and goes through all that is required to mount an "as-applied" challenge.

DOH appears to be relying on distinctions some federal cases make between "facial" and "as-applied" challenges.[1] This position was clarified during oral arguments. DOH asserts that in order to proceed plaintiffs must show there is no possible

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[1] Plaintiffs say this is a pre-enforcement as-applied challenge. Semantically this seems to be an odd combination of terms, and technically this does seem to clearly be a "facial" challenge.

application that could result in a "constitutional way of interpreting this law." Transcript of Proceedings, p. 28 (Jan. 27, 2012)(Trans.).

The first challenge is to sort out the relevant federal law. In U.S. v. Salerno, 481 U.S. 739 (1987), the Court set the bar very high for facial attacks. It was noted that this was "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." Id. at 745. For a short period of time, some decisions from the Supreme Court did apply the Salerno test to abortion cases. See, e.g., Ohio v. Akron Ctr. for Rpro. Health, 497 U.S. 502, 514 (1990). However, in Planned Parenthood of SE Penn. v. Casey, 505 U.S. 833 (1992), the plurality opinion held that a facial challenge to an abortion law may proceed if the law will operate as a substantial obstacle "in a large fraction of the cases in which [it] is relevant." Id. at 895. In his dissent, Chief Justice Rehnquist argued that the Salerno standard should apply. Id. at 973 (Rehnquist, C.J., dissenting). This is typical of the complexities that surround any attempt to follow and apply federal abortion law. It seems to depend, quite literally, on which justice is writing and what they are writing about.

Compounding the uncertainty, in Gonzales v. Carhart, 550 U.S. 124 (2007) (Carhart II), the Court noted that the burden imposed by a facial challenge "has been a subject of some question" in abortion cases, but then explicitly failed to answer that question. Id. at 167. Nonetheless, over time the Rehnquist view has failed to gain traction, and clearly most courts follow the test set forth in the Casey plurality opinion. Significantly, those courts now include the Eighth Circuit. Planned Parenthood v. Miller, 63 F.3d 1452, 1456-58 (8th Cir. 1995). As this threshold question involves federal law,

and the Supreme Court has created, but failed to resolve the confusion, the most recent decision[2] of the highest federal court in this circuit controls.

Simply put, Miller chose "to follow what the Supreme Court actually did" in Casey, and apply its undue burden test to facial challenges. Id. at 1458. This was felt to be a better reflection of the Court's intent "than what it failed to say" – that Salerno did not apply to abortion cases. Id.

Therefore, it is clear DOH does not correctly interpret the federal law it relies on. In order to proceed with their pre-enforcement challenge, plaintiffs would only need to show it is likely that enforcement of the amendments would create a "substantial obstacle" in a "large fraction" of the "relevant" cases. Planned Parenthood Minnesota, North Dakota, South Dakota v. Daugaard, 799 F.Supp.2d 1048, 1059 (D. S.D. 2011). Furthermore, "[t]he 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 894.

The available record establishes that approximately twenty percent of Red River's abortion patients chose the medical approach. Kromenaker aff. ¶ 7.[3] DOH argues this is such a small number it is not entitled to consideration. This ungenerous argument completely misses the point. "The analysis does not end with the [twenty]

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[2] In Fargo Women's Health Org. v. Schafer, 18 F.3d 526 (8th Cir. 1994), the court recognized the uncertainty regarding the appropriate standard, but felt no need to resolve it. The result in that case would have been the same under either Salerno or Casey. Id. at 526.

[3] The existing record only provides information for calendar year 2010. It would be helpful to have more current statistics. If available, the same would be true of patient income information similar to that referenced in Daugaard, 799 F. Supp. 2d at 1048.

percent of women upon whom the [amendments operate]; it begins there." Id.[4] The preliminary analysis outlined in this opinion suggests all of the relevant cases would be adversely impacted should these laws take effect. In addition, the amendments do not just create substantial obstacles to the performance of medical abortions in North Dakota. They create insurmountable barriers. Therefore, to the extent plaintiffs had the burden to make some threshold showing, they have more than met that burden.

Furthermore, the distinctions between facial and as-applied challenges have more to do with "the breadth of the remedy" ultimately employed by the court, rather than the sufficiency of the plaintiff's initial pleadings. Citizens United v. Fed. Election Com'n, 130 S.Ct. 876, 893 (2010). Regardless of how the parties characterize their dispute, a reviewing court is obligated to consider the facial validity of the statute. If it is not capable of constitutional application, a determination of facial invalidity becomes a matter of "judicial responsibility." Id. Otherwise, the "chilling effect" of the law will continue to infringe on the constitutional rights of any person who does not fall within the scope of a narrower ruling. Id. Stated differently, if the entire law is clearly invalid on its face, there is no reason to wait until irreparable harm results, and to then tear the law down piecemeal.

DOH is certainly correct in noting that a constitutional attack cannot be based on speculation, or on hypothetical scenarios that may never become reality. See, e.g., Glaspie v. Little, 1997 ND 108, ¶ 15, 564 N.W.2d 651. However, fact does not become

[4] In Casey, it was estimated the law that required spousal notification would act as a restriction for only one percent of the women seeking abortion. Casey, 505 U.S. at 894. Nonetheless, this was sufficient to support a finding of facial invalidity. Id. at 898.

supposition simply because one party refuses to address or acknowledge it.[5]

Although it expressed some initial skepticism regarding the percentage, DOH has done nothing to refute the fact that many of Red River's patients select medical abortion over surgical abortion. Assuming it is a reasonably safe and effective procedure, the legislative culling of medical abortions from the list of available options is by itself a concern of constitutional dimension. Even under Casey, the amendments would impose an undue burden on all women who would otherwise elect to have their abortion performed by medication rather than surgery. Moreover, for many patients it is not a matter of choice.

Some patients have anatomical conditions that make it unreasonable to perform a surgical abortion in a clinical setting. For women in this category, the surgical option involves an inpatient procedure which trades increased risk, cost and inconvenience for impaired results. In cases involving victims of rape, incest, or other forms of sex abuse, the physically invasive nature of a surgical abortion often results in a form of emotional re-traumatization. This is usually avoided with the medical procedure. Finally, medical abortions often represent the only viable solution for women living in abusive relationships.

DOH has done nothing to controvert any of this. How could it? There is nothing hypothetical about the fact some women have physical conditions that are contraindications to surgical abortion. Rape, incest, sexual abuse, and domestic

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[5] This is particularly true when that party has been subject to the affirmative obligations imposed by Rule 56(e)(2).

violence are real. These crimes occur with shocking regularity.[6] Pregnancies result. To simply ignore these harsh realities is not a tolerable or conscionable result.

Before moving on, the impracticality of an as-applied challenge should also be considered. In short, the ability of that approach to provide a meaningful remedy is illusory, not real. Medical abortions are only available for a short period of time, very early in the pregnancy. The record indicates that most providers, including MKB, do not offer this procedure after 63 days following the first day of the patient's last menstrual period (LMP). If measured from the onset of pregnancy, the acceptable time window becomes even shorter. Obviously, the opportunity for a medical abortion would be long gone before any as-applied challenge could ever be heard and decided.

Citizens United involved an analogous situation. That law had a chilling effect on some forms of speech in political campaigns. The Court recognized that political campaigns are conducted in short timeframes.[7] Citizens United, 130 S.Ct. at 895. To require that the impacted individual first bring a protracted lawsuit in order to vindicate the right to speak was no remedy. "By the time the lawsuit concludes, the election will be over and the litigants in most cases will have neither the incentive nor, perhaps, the resources to carry on, even if they could establish that the case is not moot ... ." Id.

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[6] For example, in 2010 a total of 188,380 rapes or sexual assaults were reported nationwide. U.S. Dep't. of Justice, Bureau of Justice Statistics, Criminal Victimization, 2010, available at http://www.nij.gov/nij/topics/crime/rape-sexual-violence/rape-notification.htm. The majority of these crimes go unreported. Id. The undisputed record in this case indicates that approximately 17 percent of all women will experience a sexual assault in their lifetimes. Needle aff. ¶ 5.

[7] "Short" in time is, of course, a relative thing. The time period covered by most modern political campaigns is vast in comparison to the few weeks during which a medical abortion is available.

For women who are already victimized by an abusive relationship, the suggestion that they should personally be compelled to bring suit is particularly cruel and insensitive. How would they keep that from their abuser, or find the time and resources required to pursue a case of this nature? Similarly, is a rape victim likely to bring suit, knowing how much publicity that would direct against her and her past? The most compelling justification for pre-enforcement challenges may well be the reality that the very women who would be most burdened would also be least likely to vindicate their rights through an as-applied challenge. A Woman's Choice-East Side Women's Clinic v. Newman, 904 F. Supp. 1434, 1448 (S.D. Ind. 1995).[8]

Therefore, this case will proceed. In turn, that will require an analysis of every scenario which could possibly lead to a constitutional interpretation or result. This does add greatly to the magnitude of the task, but there is no getting around it. Although the primary constitutional analysis outlined here is in some respects preliminary, it will still be comprehensive in scope. All these issues ultimately need to be addressed, and there is no reason not to make a good start here. The logical place to begin is with the motion in limine.

Motion In Limine

From the outset, plaintiffs have supported their arguments with detailed factual affidavits. DOH has taken a very different approach. Even when submitting its own motion for summary judgment, DOH did nothing to establish factual support for the amendments. The sole factual affidavit submitted by DOH arrived as part of its

[8] Casey acknowledged this reality when it struck down the provision requiring notification of husbands. Casey, 505 U.S. at 897.

opposition to plaintiffs' cross-motion for summary judgment. The affiant is a physician in Michigan named Donna Harrison. Based on her resume, Dr. Harrison practiced as an obstetrician and gynecologist until sometime in 2000. Since then, she has apparently been devoting all of her professional efforts to the American Association of Pro-Life Obstetricians and Gynecologists. She has been a committed and vocal opponent of the use of medication to induce abortions. Therefore, in many respects she should be ideally suited to provide expert opinions in support of this legislation, as it purports to regulate medical abortions.

At the same time, plaintiffs argue that discreet portions of Dr. Harrison's affidavit are not entitled to consideration. They have filed a motion in limine, arguing Dr. Harrison lacks the expert qualifications necessary to support some of her opinions, and has no basis for some of her factual conclusions. It is also argued Dr. Harrison makes legal conclusions that are not entitled to consideration.

Plaintiffs make good arguments, but this is not the best time to make exclusionary rulings. Whether sufficient foundation exists is typically an issue that should be reserved for trial, and motions in limine have limited utility in non-jury cases. Shark v. Thompson, 373 N.W.2d 859, 864 (N.D. 1985). Therefore, any final determinations will largely be deferred until a more complete record has been established. There are, however, some issues that will be addressed now. They involve substantive issues of law, and none of the facts material to the application of that law have been genuinely controverted. To this extent, the motion does provide a good vehicle for the elimination of unnecessary confusion and contention.

Dr. Harrison suggests the United States Food and Drug Administration (FDA) has prohibited, or at least strongly discourages, the off-label use of mifepristone. Harrison aff. ¶¶ 51-55. This is a recurrent theme that runs through much of the state's case. As a matter of law, it proceeds on an impossibly flawed premise.

The FDA is a federal agency that 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 duly-approved medication travels through the arteries of interstate commerce and reaches a licensed physician, its subsequent use by that physician is in no manner constrained or 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)[9]; U.S. v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981).

The new drug application (NDA) for Mifeprex was submitted to the FDA in 1996. Rarick aff. ¶ 4. The safety and efficacy data contained in that application was based solely on the results of three clinical trials, two conducted in France and one conducted in the United States. Id. ¶ 6. Collectively, these trials involved approximately 2500 subjects, none of whom were more than 49 days LMP.[10] Each participant was treated based on the same trial protocol. Id. ¶ 7.

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[9] Buckman involved a medical device, but this distinction is immaterial. The fundamental restrictions on the role played by the FDA apply universally to both drugs and devices.

[10] Detailed information regarding the trials is contained in the Mifeprex FPL. In turn, that document is attached to the Long affidavit as Exhibit A.

Based on comments from the FDA, the NDA was amended and supplemented over the next four years. Id. ¶ 4. On September 28, 2000, the FDA issued its final approval for the marketing and distribution of Mifeprex. As is generally the case, the FDA did not independently test protocols or conduct clinical trials before taking this action. Moreover, the FDA does not establish or limit the protocols available to physicians utilizing approved medications. Rather, approval of an NDA simply allows the drug sponsor to advertise and promote the drug consistent with the protocols used in its clinical trials. Id. ¶ 8.

The FDA approval process extends to the documentation that accompanies any prescription medication. As part of its application, the drug sponsor is required to submit proposed labels and informational inserts. Collectively this documentation is referred to as the drug's final printed label (FPL). Id. ¶ 11. The current FPL for Mifeprex consists of four parts. Respectively, those parts are labeled "Prescribing Information," "Medical Guide," "Patient Agreement," and "Prescriber's Agreement." However, all of the information on dosage, administration, safety, and efficacy is still based solely on the protocol followed, and results obtained, in the initial clinical trials. Id. ¶ 11.

Accordingly, the Mifeprex FPL does not reflect evidence accumulated, or studies performed, subsequent to the initial trials. For the same reasons, it also provides no information regarding any advances in the relevant medical science made since physicians were first authorized to use this medication. Grossman aff. ¶ 6.

An FPL does not constitute a federal law and does not impose binding obligations on physicians. In the words of the FDA, the role played by this

documentation in medical practice is "informational only." FDA Drug Bulletin, vol. 12, no. 1, p. 3 (April 1982) (FDA, 1982 Bulletin).[11] In approving any FPL, the FDA only "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.

Once a drug is approved for marketing, medical knowledge gained through its wide-spread use often supplants or replaces the results of the initial clinical trials. As the usages and regimens set forth in the drug's FPL are often quickly out of date, and make no attempt to reflect current or best medical practices, physicians are free to prescribe any medication for usages and in dosages other than those expressly set forth in the drug's label. This common practice by physicians is known as "off-label" use. Rarick aff. ¶ 13; Grossman aff. ¶ 6.

Off-label use is neither prohibited nor discouraged by the FDA. Planned Parenthood Cincinnati Region v. Strickland, 531 F.3d 406, 408 (6th Cir. 2008); Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502, 505 (6th Cir. 2006).[12] 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. In the FDA's own words, "[v]alid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by

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

[12] It is likewise not prohibited by any other enactment of the North Dakota Legislature. In 1997, however, the legislature did pass a law prohibiting any language in a health insurance policy "which excludes coverage of a drug for a particular indication on the grounds the drug has not been approved by the federal food and drug administration for that indication if the drug is recognized for treatment of the indication in one of the standard reference compendia or medical literature." N.D. Cent. Code § 26.1-36-06.1(2).

well-planned and executed clinical investigations." FDA, 1982 Bulletin, p. 3.

The "subpart H" regulations (21 C.F.R. § 314.500 et seq.) adopted by the FDA do nothing to alter any of this. Consistent with its regulatory authority, the agency may impose restrictions on the distribution of an approved medication. 21 C.F.R. § 314.520. It did so in the case of mifepristone by restricting distribution to physicians who meet the specified qualifications. However, nothing in either the subpart H regulations or the final approval letter has any limiting effect on a physician's use of mifepristone.[13]

The amendments restrict the use of mifepristone, not its marketing or distribution. It is understandable that the legislature may have been confused regarding the proper role of the FDA, or the very limited significance of the FDA approval process. However, this should be construed as notice to all parties that any subsequent attempts to blur fundamental distinctions in this regard will be met with little patience.

Dr. Harrison's references to malpractice and patient abandonment also warrant comment. These comments are gratuitous, irrelevant, and inappropriate. This should be all that need be said.

Summary Judgment Motions

The standards applicable to the review of motions for summary judgment are well established. The same is true of the strong presumptions favoring the constitutionality of duly-enacted laws. Teigen v. State, 2008 ND 88, ¶ 7, 749 N.W.2d

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[13] The final approval letter was issued on September 28, 2000. Rarick aff. ¶ 8. In her affidavit, Dr. Harrison improperly quotes from an earlier letter. Harrison aff. ¶ 54. The concerns expressed in that earlier letter had obviously been addressed by the time the final approval was issued. Whether this constitutes a deliberate distortion, or should be considered when assessing credibility, will both be fair topics at trial.

505. Overcoming this presumption requires a clear and convincing showing that the statutory enactment "contravenes the state or federal constitution." In re P.F., 2008 ND 37, ¶ 7, 744 N.W.2d 724.[14] Finally, the issues raised by any pre-enforcement challenge deserve "a fact-intensive analysis." Fargo Women's Health Org. v. Schafer, 18 F.3d 526, 530 (8th Cir. 1994). One reason facial challenges are "disfavored" is that they often "rest on speculation." Wash. State Grange v. Wash. State Repub. Party, 552 U.S. 442, 450 (2008). "As a consequence, they raise the risk of a premature interpretation of statutes on the basis of factually barebones records." Id.

Taken together, these considerations compel a most cautious, careful and deliberate approach. Any doubt as to the sufficiency of the existing record must be resolved in favor of further proceedings. An evidentiary hearing will facilitate critical distinctions between speculation or unfounded claims, and credible medical evidence. Furthermore, the motion for a temporary injunction required a preliminary assessment of the merits. That review underscored other realities. Material facts are genuinely controverted. In other respects, the existing record is inadequate. It does not allow the full and informed decision the issues demand. Therefore, the cross-motions for summary judgment will both be denied.

Much of the discussion that follows elaborates on the issues that are deemed to be material, the fact issues that have been controverted, and the areas where elaboration is required. Only a brief overview is necessary here.

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[14] An analogy frequently used by the North Dakota Supreme Court is that parties mounting constitutional challenges "should bring up the heavy artillery or forgo the attack entirely." Rose v. United Equitable Ins. Co., 2002 ND 148, ¶ 23, 651 N.W.2d 683. To continue with the same analogy, plaintiffs likely have sufficient artillery to press home a successful attack, but it is best to hear some of it fired before the final outcome is declared.

The first subsection of the amendments prohibits the off-label usage of any abortion-inducing drug. H.B. 1297, § 6(2). As part of the analysis, it is appropriate to consider the safety and efficacy of medical abortions, and whether the restrictions are, in fact, necessary to promote women's health. All of these issues are controverted. Furthermore, the record does not adequately reflect current medical knowledge, including the results of the most recent studies or experience.

The second subpart requires that any physician performing medical abortions must enter into an exclusive emergency services contract with another physician. Id. § 6(4). Plaintiffs have addressed some of the practical implications of this requirement, but there is need for both elaboration and confirmation. Furthermore, DOH indicates there is compelling medical justification for this requirement, and Dr. Harrison's affidavit is sufficient to create genuine issues in this regard.

The last subsection requires that the prescribing physician be in the same room whenever an abortion-inducing drug is administered. Id. § 6(5). Neither DOH nor Dr. Harrison have provided any explanation of the therapeutic benefit that results from this requirement, but the record is also largely silent as to any resulting burdens.

Although neither side is entitled to summary judgment at this juncture, this does not mean that all will be fair game at trial. Rule 56(d)(1) requires a specification of the material facts that are not genuinely at issue. N.D.R.Civ.P. 56(d)(1). This is the logical corollary of the rule that a nonmoving party must make a specific showing in support of each fact dispute they intend to preserve for trial. N.D.R.Civ.P. 56(e)(2).

In many respects, it is easy to identify the uncontested facts. Dr. Harrison's affidavit clearly indicates who and what she takes issue with. Conversely, DOH has

done nothing to controvert anything contained in the affidavits of Abigail Long, Rachel Needle, or David Orentlicher. Because Dr. Harrison's critique of the Lisa Rarick affidavit fails as a matter of law, this must also be addressed. Accordingly, it is hereby determined:

- All of the events or descriptions contained in the Long affidavit have been established, and all attachments will be received into evidence without the need for any further foundation. Although presumably none of this could be disputed in any event, any attempt to do so is now barred.
- Although this does not extend to any legal conclusions, all facts outlined in Dr. Needle's affidavit have likewise been conclusively established, and will not be subject to challenge at trial. Stated differently, DOH has failed to controvert the special burdens the amendments would impose on victims of sexual assault and abuse.
- The factual portions of Dr. Orentlicher's affidavit are likewise conclusively established. This includes the quoted portions of the codes adopted by the American Medical Association (AMA) and the American College of Obstetricians and Gynecologists (ACOG). Therefore, DOH will not hereafter be permitted to challenge either the nature or existence of any of the ethical or professional obligations outlined in this affidavit.
- With one exception, all of the facts or events described in Dr. Rarick's affidavit are conclusively established and may not be

rebutted. All documents attached to that affidavit may be introduced without any further showing. However, the comments in paragraph 19 regarding the risks and relative risks associated with the use of mifepristone and misoprostol will be a continuing issue for trial. To this extent only, Dr. Rarick's affidavit has been disputed.

- No direct testimony from Dr. Harrison will be permitted regarding the regulatory role played by the FDA, the process that led to the approval of mifepristone or Mifeprex, or the legal effect of any of this. Plaintiffs will be permitted to cross-examine Dr. Harrison regarding paragraphs 51-55 of her affidavit, but only to the extent this is relevant to the issue of credibility.

Of course, Dr. Harrison's affidavit also fails to refute many of the facts collectively described in the Kathryn Eggelstone, Tammi Kromenaker, and Daniel Grossman affidavits. At this point, no attempt has been made to isolate the undisputed portions of those affidavits, but it does seem the issues in dispute have been well defined. As these witnesses will presumably all be testifying at trial, there is little to be gained by any attempt to limit that testimony in advance. Furthermore, even if it involves covering some undisputed ground twice, there is a natural preference for fact findings based on live testimony, rather than cold and lifeless affidavits.

Because both dispositive motions have been denied, there is one remaining issue that must be resolved. That is, of course, the appropriateness of continuing the temporary injunctive relief until a final decision is reached.

Temporary Injunctions

The factors governing requests for temporary injunctive relief are well established. It is necessary to consider: 1) the probability of success on the merits; 2) any threat of irreparable injury; 3) potential harm to the parties; and 4) the public interest. See, e.g., Vorachek v. Citizens State Bank of Lankin, 461 N.W.2d 580, 585 (N.D. 1990); F-M Asphalt, Inc. v. North Dakota State Highway Dep't, 384 N.W.2d 663, 664 (N.D. 1986).

For an expanded analysis of these factors, North Dakota decisions uniformly defer to Dataphase Systems, Inc. v. C L Systems, Inc., 640 F.2d 109 (8th Cir 1981). Dataphase instructs that no factor "is determinative" or can be viewed "in isolation." Id. at 113. Where the other factors tip strongly in the applicant's favor, a probability of success may require only "questions so serious and difficult as to call for more deliberate investigation." Id.

The Eighth Circuit recently revised the Dataphase test, when applied to challenges to duly enacted statutes. It concluded laws passed through the democratic process are entitled to a "higher degree of deference ... ." Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds, 530 F.3d 724, 732 (8th Cir. 2008). Therefore, in such cases it is never sufficient for the moving party to establish that there is a "fair chance" of success. Instead, the appropriate standard is "likely to prevail on the merits." Id. Furthermore, this becomes the threshold requirement. Only if the applicant has demonstrated that they are likely to prevail should the remaining factors be considered. Id.

Although the North Dakota Supreme Court has not had occasion to adopt the Rounds modifications to the Dataphase test, this is the approach that will be followed here. There is no question regarding the deference courts must show towards legislative enactments. At every turn, it is necessary to adopt, or at least to consider, the approach that is most favorable to the state. Therefore, the first question that must be answered is whether plaintiffs are likely to prevail on the merits, under one or more of the theories asserted in their complaint.

Those theories start with the claim the amendments infringe on fundamental rights protected by the Constitution of North Dakota. There is no shorthand approach to even the preliminary assessment of this contention. The arguments advanced by plaintiffs raise questions that are both unresolved and cut to the core of the controversy that surrounds abortion.

State Constitutional Rights

1. Introduction

Plaintiffs argue that under Article 1, Sections 1 and 12 of the Constitution of North Dakota, a woman has a fundamental right to choose whether to terminate a pregnancy. In turn, this implicates the strict scrutiny standard of review. Both in its briefs and during argument, DOH has failed to offer any good reason to ignore the state constitution. However, it does strenuously assert that the rights implicated in this case are not fundamental, and should be analyzed pursuant to the undue burden test developed by federal courts interpreting the United States Constitution.

This debate raises two issues of first impression. Do the “inalienable rights” protected by the state constitution include a woman’s right to choose to have an

abortion? If so, is this right so fundamental that any legislative infringement is subject to strict scrutiny? Resolution of the fact disputes will not impact these issues. Moreover, because this case cannot be decided other than on constitutional grounds, this is the time to address them. Difficult as this may be to do, the task is to resolve these issues "by constitutional measurement, free of emotion and predilection." Roe v. Wade, 410 U.S. 113, 116 (1973).

We now know, more or less, how to measure the reproductive rights protected by the United States Constitution. The unresolved questions involve how any state rights measure up. As in any case, it is best to start with the general rules that govern all cases.

Although the federal constitution tends to be the predominant force behind the protection of personal freedoms, this is not necessarily true. Most state constitutions also protect the same, or similar, rights. State constitutions are also "a font of individual liberties ... ." William J. Brennan, Jr., State Constitutions and the Protection of Individual Rights, 90 Harv. L Rev. 489, 491 (1977). Accordingly, "state courts cannot rest when they have afforded their citizens the full protections of the federal Constitution." Id. 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). See State v. Herrick, 1999 ND 1, 588 N.W.2d 847 (probable cause requirements); Grand Forks-Traill Water Users v. Hjelle, 413 N.W.2d 344 (N.D. 1987)

(protection from takings for public use); State v. Orr, 375 N.W.2d 171 (N.D. 1985) (right to counsel); City of Bismarck v. Altevogt, 353 N.W.2d 760 (N.D. 1984) (jury trial rights); State v. Nordquist, 309 N.W.2d 109 (N.D. 1981) (grand jury protections); State v. Lewis, 291 N.W.2d 735 (N.D. 1980) (right to appeal); State v. Stockert, 245 N.W.2d 266 (N.D. 1976) (protection from illegal searches); Johnson v. Hassett, 217 N.W.2d 771 (N.D. 1974) (right to uniform application of laws); State v. Matthews, 216 N.W.2d 90 (N.D. 1974) (standing to challenge illegal searches).

However, the converse can never be true. Rights granted by the state constitution cannot be interpreted to be narrower or less expansive than corresponding rights guaranteed by the federal constitution. S.E. Cass Water Res. Dist. v. Burlington Northern Railroad Co., 527 N.W.2d 884, 890 (N.D. 1995). This rule has been restated so many times that it is now deemed to be axiomatic. State v. Herrick, 1997 N.D. 155, ¶ 19, 567 N.W.2d 336.[15]

Although initial decisions were based in part on an inferred right to privacy, it is now clear that federal constitutional protection of reproductive rights is founded on the due process clause of the Fourteenth Amendment, and the controlling word is "liberty." Casey, 505 U.S. at 846.[16] Liberty is also one of the freedoms protected by the

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[15] Similarly, the United States Supreme Court has repeatedly noted that state constitutions may provide more expansive protection of individual freedoms or liberties than the United States Constitution. See, e.g., Oregon v. Kennedy, 456 U.S. 667, 680 (1982) (Brennan, J., concurring); Oregon v. Haas, 420 U.S. 714, 719 (1975); Cooper v. California, 386 U.S. 58, 62 (1967).

[16] Both during argument (trans., pp. 39-40) and in its supplemental brief, DOH asserts the federal abortion cases are all based on a right to privacy, something that does not exist under state law. This position is squarely at odds with the Casey plurality opinion, the decision the state holds out as controlling. Casey, 505 U.S. at 846.

Constitution of North Dakota. N.D. Const. art. 1, §§ 1, 12. Therefore, by itself the axiom that our state constitution may grant greater but not lesser protections would resolve the first of the threshold issues. At a minimum, the state constitution must protect a woman's right to have an abortion to the same extent as that right is protected by the Fourteenth Amendment to the federal constitution. At the same time, the conclusions reached in this opinion are based on much more than the application of a simple axiom.

2. Federal Guidance

As federal precedents do not set the upper limit of state guarantied liberties, they must not be followed "indiscriminately." Schweigert v. Provident Life Ins. Co., 503 N.W.2d 225, 227 (N.D. 1993). This does not mean they should be disregarded. It is appropriate to look to federal law for guidance "when it is helpful and sensible to do so ... ." Id. In this case, there are many reasons to turn to the leading federal decisions for insight.

The United States Supreme Court has repeatedly felt compelled to confront the issue of abortion. The resulting opinions reflect the considered judgment of the men and women who sit, or have sat, on our nation's highest court. At a minimum, their decisions warrant study.

In particular, the Supreme Court decisions provide a thoughtful analysis of the policy considerations and practical realities that have forced successive majorities of that Court to conclude, or to reaffirm, a woman has the right to choose an abortion. It is important to understand this rationale, and to consider if it applies with equal force here.

Conversely, federal decisions have also paid great attention to the significant interests a state may assert when regulating abortion. As this case involves such

regulations, it is certainly helpful and sensible to consider all available guidance in this regard.

Finally, the appropriate standard of review is another issue the United States Supreme Court has repeatedly addressed. Its recent decisions regarding the applicable standard may be lacking in both clarity and guidance, but the federal undue burden standard is still worthy of consideration, even if it is not controlling.

The seminal federal cases, of course, start with Roe v. Wade, 410 U.S. 113 (1973). Roe began by acknowledging the realities that make abortion such a difficult and contentious issue:

> We forthwith acknowledge our awareness of the sensitive and emotional nature of the abortion controversy, of the vigorous opposing views, even among physicians, and of the deep and seemingly absolute convictions that the subject inspires. One's philosophy, one's experiences, one's exposure to the raw edges of human existence, one's religious training, one's attitudes toward life and family and their values, and the moral standards one establishes and seeks to observe, are all likely to influence and to color one's thinking and conclusions about abortion.
>
> In addition, population growth, pollution, poverty, and racial overtones tend to complicate and not to simplify the problem.

Id. at 116 (internal punctuation omitted).

Ultimately, the Court concluded that the "Fourteenth Amendment's concept of personal liberties and restrictions on state action ... is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." Id. at 153. It went on to describe the clear detriment that would result from the denial of this choice:

> Specific and direct harm medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of

> bringing a child into a family already unable, psychologically and otherwise, to care for it. In other cases, as in this one, the additional difficulties and continuing stigma of unwed motherhood may be involved.

Id.[17]

Although it recognized a woman's right to choose, Roe also unequivocally held "that this right is not unqualified and must be considered against important state interests in regulation." Id. at 154. In particular, states may "properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life." Id. Furthermore, the state's interests become increasingly compelling as the pregnancy progresses. Id. at 162-63.

Weighing these competing interests, Roe ultimately concluded a trimester approach was most appropriate. During the first trimester of a pregnancy, abortion typically involves minimal risks, lower than those associated with normal childbirth. Therefore, during this period the Court held that no state regulation could be permitted to interfere with the decision. Instead, "the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated. If that decision is reached, the judgment may be effectuated by an abortion free of interference by the State." Id. at 163. Because the risks increase during the second trimester, during this period the

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[17] In his concurring opinion, Justice Douglas likewise noted an unwanted pregnancy "may deprive a woman of her preferred lifestyle and force upon her a radically different and undesired future." Roe, 410 U.S. at 214 (Douglas, J., concurring). He noted that such women are forced "to endure the discomforts of pregnancy; to incur the pain, higher mortality rate, and aftereffects of childbirth; to abandon educational plans; to sustain loss of income; to forgo the satisfaction of careers; to tax further mental and physical health in providing child care; and, in some cases, to bear the lifelong stigma of unwed motherhood, a badge which may haunt, if not deter, later legitimate family relationships." Id. at 214-15.

state may "regulate the abortion procedure in ways that are reasonably related to maternal health." Id. at 164. Finally, at a point approximating the commencement of the third trimester, the fetus becomes viable. Thereafter, the state's interest in potential life becomes the paramount consideration. During the final trimester, a state is free to regulate or prohibit abortion, except when necessary to preserve the life or health of the mother. Id. at 164-65.

Finally, Roe clearly held that the personal rights it recognized were both "fundamental" and "implicit in the concept of ordered liberty." Id. at 152. Accordingly, prior to viability any law that restricts the exercise of these rights must be both narrowly drawn and justified by a "compelling state interest." Id. at 155.[18]

Despite repeated attempts, Roe has never been overruled. This is not to say that its holdings are undiminished. Subsequent opinions do reduce the level of protection afforded to reproductive rights by the federal constitution. At least according to the state, one of those decisions is particularly relevant to this case.

In Casey, the Court began by reaffirming "Roe's essential holding." Casey, 505 U.S. at 846. It went on to explain that there were three parts to this holding:

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

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[18] Citing a dissenting opinion written by Justice Scalia, DOH suggests the Supreme Court no longer regards the right to abortion as fundamental. Lawrence v. Texas, 539 U.S. 558, 595 (2003) (Scalia, J., dissenting). A long line of precedent is not altered by a single dissent. In any event, this is insignificant to a consideration of the primacy of the rights protected by the state constitution.

> legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child. These principles do not contradict one another; and we adhere to each.

Id.

Casey described the rationale for these protections in the following manner:

> Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education. Our cases recognize the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child. Our precedents have respected the private realm of family life which the state cannot enter. These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.

Id. at 851 (internal citations and punctuation omitted).

Casey then went on to change the rules governing the regulation of abortions in significant ways. It abandoned the trimester framework, both because it was unnecessarily rigid and because it overly restrained a state's permissible powers during the early stages of pregnancy. Id. at 872. In its place, the Court substituted a new construct that drew distinctions based only on the presumed viability of the fetus. Before this point is reached, a woman still has a constitutional right to choose to terminate her pregnancy. Id. at 870. Even in the earliest stages, however, a state may enact regulations designed to ensure the decision is fully informed, and considers the factors that favor continuing the pregnancy to term. Id. at 872.

It also changed the applicable standard of review. In simplistic terms, Casey held only a state regulation which imposes an "undue burden" on a woman's ability to

decide is unconstitutional. By way of elaboration:

> A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.
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> * * *
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> As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.

Id. at 877-78.

At least in general, nothing at the federal level has changed since Casey. In Stenberg v. Carhart, 530 U.S. 914 (2000) (Carhart I), the Court stated that it would "not revisit" the constitutional principles enunciated in Roe and Casey. Id. at 921. Similarly, in Carhart II the majority opinion simply noted that it would follow Casey, and apply its standard to the cases under review. Carhart II, 550 U.S. at 146.

In her dissent to Carhart II, Justice Ginsberg did review and update the rationale for the federal protection of reproductive rights:

> As Casey comprehended, at stake in cases challenging abortion restrictions is a woman's control over her own destiny. There was a time, not so long ago, when women were regarded as the center of home and family life, with attendant special responsibilities that precluded full and independent legal status under the Constitution. Those views, this Court made clear in Casey, are no longer consistent with our understanding of the family, the individual, or the Constitution. Women, it is now acknowledged, have the talent, capacity, and right to participate equally in the economic and social life of the Nation. Their ability to realize their full potential, the Court recognized, is intimately connected

> to their ability to control their reproductive lives. Thus, legal 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 to enjoy equal citizenship stature.

Id. at 171-72 (Ginsberg, J., dissenting) (internal citations and punctuation omitted).

One last aspect of federal law should be mentioned, as it too provides cogent and sound guidance. This nation and our society have both changed in profound ways since the Fourteenth Amendment was ratified. The liberties that amendment now protects have likewise been interpreted to have evolved with the times.

Interracial marriage was illegal in most states in the 19th Century, but state restrictions were still found to be unconstitutional in Loving v. Virginia, 388 U.S. 1 (1967). Contraception practices that did not exist when the Fourteenth Amendment took effect are now protected as a result of its adoption. Griswold v. Conn., 381 U.S. 479 (1965); Eisenstadt v. Baird, 405 U.S. 438 (1972); Carey v. Population Services Inter'l, 431 U.S. 678 (1977). In the early to mid 19th Century, almost all states then in existence enacted laws prohibiting abortion except when necessary to save the life of the mother.[19] Such laws continued to be prevalent until they were held to be unconstitutional in Roe. Roe, 410 U.S. at 138-39. Accordingly, "[n]either the Bill of Rights nor the specific practices of States at the time of the adoption of the Fourteenth Amendment marks the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects." Casey, 505 U.S. at 848.

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[19] The first legislation in what is now North Dakota dates back to the territorial period. Act of Feb. 17, 1877, § 337, codified at Dakota (Terr.) Penal Code § 337 (1877).

3. Relevance

There is no difference between the lives lead by women in North Dakota, as compared to the nation generally. The relevant biology is the same. All women, regardless of where they live, bear children in the same manner. Therefore, the considerations and rational that support the federal decisions apply with equal force here. Moreover, to the extent that anything has changed since the early federal decisions were reached, that change only reinforces the soundness of this conclusion.

To an ever-increasing extent, women are choosing to pursue educations, professions, and careers.[20] When they become mothers, they are finding that devotion to this task has become increasingly expensive.[21] The notion that a woman's place is in the home, raising children, is now a complete anachronism. This is often both an expression of self-determination and a function of economic necessity. For many young couples today, meeting the costs of raising a family requires two incomes.[22] For single mothers, economic considerations may be an even more pressing concern.

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[20] By way of example, Roe was decided in 1973. That spring, the graduating class at UND's law school contained no women. Last year 41 percent of the graduates were women.

[21] Since 1960, the U.S. Department of Agriculture has provided child-rearing expense estimates from birth through age 17. U.S. Dep't of Agric., Center for Nutrition Policy and Promotion, No. 1528-2010, Expenditures on Raising Children, 2010 (2011), available at www.cnpp.usda.gov. Adjusting for inflation, the current estimate is $226,920. By comparison, the 1960 estimate was $185,856. Id. The disparity would dramatically increase if secondary education costs were taken into account.

[22] According to the American Academy of Pediatrics, more than half of the mothers with young children now work, as compared to one-third in the 1970s. Working Mothers, American Academy of Pediatrics, http://www2.aap.org/publiced/BK0_WorkingMothers.htm . One reason cited for this increase is that families today need the additional income. "For the children in many of these families being raised by one or two parents, the alternative to a working mother is poverty." Id.

Any consideration of population growth, pollution, and poverty leads to the same conclusions. The global human population has almost doubled since Roe was decided.[23] All those people place ever-increasing demands on an increasingly diminished planet. Poverty has become epidemic. Despite the recent economic windfalls that have been enjoyed by many in this state, North Dakota is not exempt from this reality.[24] Because pregnancy can come at the worst possible time, women are frequently faced with the prospect of raising a child when they lack essential skills, resources, and facilities. State assistance is limited and inadequate. Family assistance is not always available. In theory, fathers can be compelled to contribute support, but the reality is that many do not. The long-term impact for both the mother and child can be devastating. On too many occasions, cycles of poverty, neglect and abuse all trace back to a child or children born at the wrong time, or under the wrong circumstances.[25]

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[23] The United Nations estimates the global population in 1970 totaled 4.068 billion. United Nations, Dep't of Econ. and Social Affairs, Population Division, World Population to 2300 (2004), available at http://www.un.org/esa/population/publications/longrange2/ WorldPop2300final.pdf. According to the U.S. Census Bureau, the current global population is approximately 6.993 billion. U.S. Census Bureau, Population Division, U.S. & World Population Clocks, http://www.census.gov/main/www/popclock.html (last visited Feb. 10, 2012).

[24] The national poverty rate in 2010 was 15.1 percent, the highest rate since 1993. Carmen DeNavas, et al., U.S. Dep't of Commerce, U.S. Census Bureau, Income, Poverty, & Health Insurance Coverage in the United States: 2010 (2011), available at http://www.census. gov/prod/ 2011pubs/p60-239.pdf. North Dakota's poverty rate is currently below the national rate, but was still 12.5 percent in 2010. U.S. Dep't of Agric., Economic Research Service, State Fact Sheets: North Dakota (2011), available at http://www.ers.usda.gov/StateFacts/ND.htm.

[25] Studies estimate that two-thirds of families begun by young unmarried mothers live in poverty. Kalleen Kaye & Laura Chadwick. The Lives of Teen Parents After Welfare Reform and the Role of TANF, 2006, unpublished manuscript, U.S. Department of Health and Human Services, Assistant Secretary of Planning and Evaluation. The Department of Health and Human Services estimates that approximately 25 percent of teen mothers go on welfare within three years of the child's birth. Isabel Sawhill, Analysis of the 1999 Current Population Survey.

As a consequence of all this, other notable trends are occurring. Women are tending to have fewer children. They are also waiting longer, until their position in life is better suited to fulfill the demands imposed by raising a child.[26] Contraception is now generally available and increasingly effective, but it still fails to prevent pregnancies in a significant number of cases. Furthermore, abstinence or contraception are not practiced by all, and pregnancies that are both unplanned and unwanted continue to occur. Regrettably, this is particularly true in the case of young, unmarried women who are typically least prepared to be mothers.[27]

Adoption is an admirable option, but it too requires one of the most difficult and personal decisions any woman can ever be required to make. To carry the fetus to term, and to then surrender all rights to the child once it is born, involves dilemmas of unimaginable proportion.

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[26] The demography of motherhood in the United States has changed dramatically. Mothers today are both older and better educated. Livingston & Cohn, The New Demography of American Motherhood (May 2010), available at http://pewresearchorg/pubs/1586/changing-demographic-characteristics-american-mothers. In 2008, 14 percent of births were to women 35 years of age or older. This was an increase of 64 percent compared to just two decades ago. Id.

[27] Research shows that teen mothers are less likely to further their education. K. Perper, et al., Diploma Attachment Among Teen Mothers (2010), available at http://www.childtrends.org /Files/Child_Trends-2010_01_22_FS_DiplomaAttainment.pdf. Only 38 percent of teen mothers obtain a high school diploma, and less than 2 percent of the women who have children before age 18 complete college before the age of 30. S.D. Hoffman, By the Numbers: The Public Costs of Adolescent Childbearing (2006), available at http://www.thenationalcampaign.org/ resources /pdf/pubs/btn_full.pdf. Not surprisingly, subsequent children make it even more difficult to finish school, obtain a job, and escape poverty. D.S. Kalmuss, et al., Subsequent Childbearing Among Teenage Mothers:The Determinants of Closely Spaced Second Birth, Family Planning Perspectives Vol. 26, No. 4 (Jul-Aug 1994), available at http://www.jstor.org/_pss/2136238.

Finally, not all pregnancies result from consensual acts. Some are the product of rape, incest, or other forms of abuse. We must be particularly sensitive to the rights and needs of these victims. They have already suffered a great personal wrong and violation. It would be unconscionable for the state to force further emotional trauma, when safe and effective options exist.

4. *Stare Decisis*

The very existence of the long-standing federal precedent is another consideration. To a substantial extent, the outcome of Casey appears to have hinged on the respect due to settled decisions. The plurality opinion owes much of its length to this topic. Casey, 505 U.S. at 853-69. It noted that since Roe an entire generation had come of age free to assume that liberty included the right to make reproductive decisions. Id. at 860. Through the exercise of that right, women were 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. Since Casey, yet another generation has come of age knowing the same freedom.

For all these reasons – even if a finding of lesser protection was a permissible result – the liberty protected by the state constitution must be at least coextensive with the federal rights recognized and refined by the long line of decisions that start with Roe. Furthermore, this conclusion is in complete harmony with the guiding principles outlined in Casey, the decision the state embraces.

Liberty, as well as the other personal freedoms enshrined in our constitutions, recognizes 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 women's right to choose to terminate a pregnancy. The judiciary's obligation, however, "is to define the liberty of all ... ." Id. at 850. This cannot be done by adopting the moral code of those who find the practice abhorrent. Id.[28] Similarly, personal liberty must be viewed as "a rational continuum," not a relic of history. Id. at 848. Nothing can be gained by inflaming the passions that fuel this "intensely divisive controversy." Id. at 866. Instead, it is better to hold in a manner that "calls the contending sides ... to end their ... division by accepting a common mandate rooted in the Constitution." Id. at 867.

This forces consideration of the second threshold issue: Does the Constitution of North Dakota demand more? The logical place to start when searching for an answer to this question is a comparison of the language in the respective constitutions.

5. Language and Interpretations

The federal abortion cases are all based on rights expressed or implied by the Fourteenth Amendment to the United States Constitution. In relevant part, this amendment declares that no state shall "deprive any person of life, liberty or property, without due process of law ... ." U.S. Const. Amend XIV, § 1. The corresponding portion of Article 1, Section 12 of the Constitution of North Dakota is almost identical. N.D. Const. art. 1, § 12. Section 1, however, does contain language that is more expansive. Excluding the irrelevant language added in 1984, it states:

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[28] Roe similarly noted that our constitutions were designed to protect freedom and liberty "for people of fundamentally differing views ... ." Roe, 410 U.S. at 117. Therefore, the fact conduct is shocking or repugnant to some does not conclude a constitutional analysis. Id.

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

N.D. Const. art. 1, § 1.[29] Therefore, our state constitution contains one clause that is very similar to its federal counterpart, and one clause that says more.

It is well established that sections 1 and 12 must be construed together. The first section defines the personal rights guarantied by our state constitution. Section 12 "protects and insures the use and enjoyment" of those rights. State v. Cromwell, 9 N.W.2d 914, 918 (N.D. 1943).

The scope or extent of the inalienable rights encompassed by section 1 has been addressed only infrequently in court decisions. Perhaps this reflects the simple reality that these rights are so unquestioned as to be beyond challenge. In any event, 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.[30]

Cromwell involved a very different issue, but the definitions it adopted extend far. This was particularly true of the pursuit of happiness, which was described as:

> ... the aggregate of many particular rights, some of which are enumerated in the constitutions, and others included in the general guaranty of 'liberty.' The happiness of men may consist of many things or depend on many circumstances. But in so far as it is likely to be acted upon by the

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[29] Very similar language appears in the Declaration of Independence, but was not repeated by the drafters of the federal constitution.

[30] In its supplemental brief, DOH suggests the pursuit of happiness should be downgraded from an inalienable right to an "aspirational" goal. Even if this view could be adopted, it would still leave liberty, a right guaranteed by both sections 1 and 12. Casey was undoubtedly correct when it identified "liberty" as the controlling word. Casey, 505 U.S. at 846.

> operations of government, it is clear that it must comprise personal freedom, exemption from oppression or invidious discrimination, the right to follow one's individual preference in the choice of an occupation and application of his energies, liberty of conscience, and the right to enjoy the domestic relations and the privileges of the family and the home. The search for happiness is the mainspring of human activity. And a guarantied constitutional right to pursue happiness can mean no less than the right to devote the mental and physical powers to the attainment of this end, without restriction or obstruction, in respect to any of the particulars thus mentioned, except in so far as may be necessary to secure the equal rights of others. Thus it appears that this guaranty, though one of the most indefinite, is also one of the most comprehensive to be found in the constitutions.

Cromwell, 9 N.W.2d at 918-19.

It would be fanciful to suggest the court gave any thought to reproductive rights when it adopted this language. Cromwell was written three decades before the United States Supreme Court seared abortion, and all it entails, into the national consciousness. Nonetheless, the considerations that have driven the federal abortion decisions fit completely within the Cromwell concept of pursuit of happiness, with room to spare.

Both Cromwell and the first section of our constitution have received little subsequent attention from the North Dakota Supreme Court. One notable exception, however, involved a closely-connected issue.

In Hoff v. Berg, 1999 ND 115, 595 N.W.2d 285, the court was required to assess "the constitutionally permissible bounds of state interference with parents' rights to raise their children." Id. ¶ 5. It concluded this was among the most "essential" of the freedoms protected by our constitution, "far more precious ... than property rights ... ." Id. ¶ 8. Under article 1, section 1 of the state constitution, it "is beyond question in this jurisdiction that parents have a fundamental constitutional right to parent their children

which is of the highest order ... ." Id. ¶ 10. Accordingly, only "a compelling state interest justifies burdening" this fundamental right. Id.[31] Furthermore, even when such necessity exists, the legislation must be "narrowly drawn to express only the legitimate state interests at stake." Id. ¶ 13.

The connections between child-bearing and child-raising are both obvious and inextricable. Decisions regarding the former necessarily precede the latter. To an ever increasing extent, a woman's personal freedom and autotomy require both the right to make parenting decisions, and the right to control whether and when to have children.

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). Vogel, like Cromwell, involved a very different issue. However, it was decided more than two decades after Roe, and three years after Casey. It is less fanciful to assume the Vogel court was unmindful of the implications of the broad language it used. Accordingly, it is no leap from existing North Dakota case law to conclude that a woman's fundamental rights include the freedom to have an abortion during the early stages of pregnancy.

6. Decisions From Other States

The final source of available guidance comes from other states. Particularly when the language in the respective constitutions is similar, decisions from other states

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[31] Similarly, In re Adoption of K.A.S., 499 N.W.2d 558 (N.D. 1993) the court stated: "[i]t is beyond question in this jurisdiction that parents have a fundamental constitutional right to parent their children which is of the highest order." Id. at 564.

can be highly persuasive. State v. Herrick, 1999 ND 1, ¶ 24, 588 N.W.2d 847.

To date, the highest courts of at least eleven states have recognized that their state constitutions also protect a woman's right to an abortion: Alaska;[32] California;[33] Florida;[34] Massachusetts;[35] Minnesota;[36] Mississippi;[37] Montana;[38] New Jersey;[39] New York;[40] New Mexico;[41] and Tennessee.[42] [43] Conversely, there is only one decision from a state appellate court that squarely holds there is no protection under its state constitution. That case was decided by an intermediate court in Michigan. Mahaffey v.

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[32] State of Alaska, Dep't of Health & Human Services v. Planned Parenthood of Alaska, Inc., 28 P.3d 904 (Alaska 2001).

[33] Comm. to Defend Reprod. Rights v. Myers, 625 P.2d 779 (Cal. 1981).

[34] In Re T.W., 551 So.2d 1186 (Fla. 1989).

[35] Moe v. Sec'y of Admin. & Fin., 417 N.E.2d 387 (Mass. 1981).

[36] Women of the State of Minnesota v. Gomez, 542 N.W.2d 17 (Minn. 1995).

[37] Pro-Choice Mississippi v. Fordice, 716 So.2d 645 (Miss. 1998).

[38] Armstrong v. State, 989 P.2d 364 (Mont. 1999).

[39] Right to Choose v. Byrne, 450 A.2d 925 (N.J. 1982).

[40] Hope v. Perales, 634 N.E.2d 183 (N.Y. 1994).

[41] New Mexico Right to Choose - NARAL v. Johnson, 975 P.2d 841 (N.M. 1998).

[42] Planned Parenthood of Middle Tennessee v. Sundquist, 38 S.W.3d 1 (Tenn. 2000).

[43] In 1975, the Supreme Court of Washington held that an abortion regulation violated both the state and federal constitutions. State v. Koome, 530 P.2d 260 (Wash. 1975). Washington was not added to the list because a recent decision suggests Koome was decided solely on federal law. Andersen v. King County, 138 P.3d 963, 987 (Wash. 2006). Similarly, Vermont was left off because the decision of the Vermont Supreme Court recognizing the right to an abortion does not clearly indicate if this conclusion was based on the state constitution, the federal constitution, or both. Beecham v. Leahy, 287 A.2d 836 (Vt. 1972). Finally, although the Ohio Court of Appeals has concluded the state constitution protects a woman's right to choose, the Ohio Supreme Court has yet to decide the issue. Preterm Cleveland v. Voinovich, 627 N.E.2d 570 (Ohio Ct. App. 1993), cert. denied, 624 N.E.2d 194 (Ohio 1993).

Attorney Gen., 564 N.W.2d 104 (Mich. Ct. App. 1997). The Michigan Supreme Court has not yet ruled on this issue.

With the possible exception of the case from Mississippi, every decision recognizing a right based on a state constitution has regarded that right as fundamental. Most of the cases also hold that strict scrutiny is the appropriate standard of review. The Mississippi Supreme Court did what the state urges here, and adopted the Casey undue burden standard. Pro-Choice Mississippi v. Fordice, 716 So.2d 645, 655 (Miss. 1998). It is the only state high court that has taken this approach.[44] Other courts have explicitly rejected the "ultimately standardless" and "subjective" Casey test, opting instead for strict scrutiny - a "recognized principle of constitutional law" that "has been applied repeatedly over the years." Planned Parenthood of Middle Tennessee v. Sundquist, 38 S.W.2d 1, 16 (Tenn. 2000). In the language of Sundquist:

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

Id. at 17.

There are differences in the precise wording, but the Alaska, California, New Jersey and Tennessee decisions were all based on constitutional provisions very similar to Article 1, Section 1 of the Constitution of North Dakota. Most of the remaining decisions were based on less expansive provisions, more similar to section 12 of our

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[44] The intermediate court in Ohio also adopted the Casey undue burden standard. Voinovich, 627 N.E.2d at 577.

state constitution or the due process clause of the Fourteenth Amendment.

The most similar language appears to be found in the New Jersey Constitution. The first section of that document is almost identical to the corresponding portion of North Dakota's constitution. Compare N.J. Const. art. 1, ¶ 1 to N.D. Const. art. 1, § 1. Both explicitly declare that liberty and the pursuit of happiness are among the inalienable rights guarantied to all persons.[45] Using words very similar to those found in the federal decisions, Byrne first concluded the New Jersey Constitution also protected the:

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

Byrne, 450 A.2d at 934. However, because the first section of the state constitution did contain language that was more expansive than that found in the federal constitution, these rights were entitled to greater protection under state law. Id. at 933. Accordingly, the state funding restrictions at issue were held to violate the New Jersey Constitution, even though they were permissible under the federal constitution. Id. at 937.

With one possible exception, there is no basis for distinguishing Bryne. The possible exception is the court's reference to a right to privacy. Id. at 933. That right has long been recognized in New Jersey, but has yet to be explicitly adopted by the

[45] Actually, North Dakota's constitution continues to refer only to "men" as the recipients of these protections. The New Jersey version has been modified by replacing "men" with "persons." This is the only difference between the documents, and it cannot be significant. The personal freedoms protected by the Constitution of North Dakota certainly extend in equal measure to both men and women.

North Dakota Supreme Court.[46] In light of Casey, however, this distinction is immaterial. As the controlling word is "liberty," the existence or nonexistence of a related right to privacy has become insignificant.[47] Furthermore, the rights that are explicitly mentioned in the Constitution of North Dakota have been defined in very broad terms. As noted above, the right to privacy discussed in Roe fits well within the Cromwell concept of the right to pursue happiness.

All this forces two inescapable conclusions. First, the Constitution of North Dakota must be construed to protect a woman's right to choose to have an abortion. Second, this right is fundamental.

7. Standard of Review

Ordinarily, this would fix the appropriate standard of review. North Dakota applies three different levels of scrutiny to constitutional challenges, depending on the importance of the right at issue. Legislation is subject to the highest level of scrutiny when it effects a fundamental right. Under this "strict scrutiny" standard, a statute that interferes with a fundamental right can be upheld only if the legislative infringement is

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[46] At least implicitly, it has been embraced. In City of Grand Forks v. Grand Forks Herald, Inc., 307 N.W.2d 572 (N.D. 1981), the court declined an invitation to recognize a right of "informational privacy," but went on to discuss with apparent approval the federal decisions "which have established a right of privacy ... in cases involving governmental intrusions into matters relating to marriage, procreation, contraception, family relationships, child rearing, and education." Id. at 578-79. See also, Hovet v. Hebron Public School Dist., 419 N.W.2d 189, 192 (N.D. 1988). Similarly, in Hoff the court adopted a quote which states "state limitations on a fundamental right such as the right of privacy are permissible only if they survive strict constitutional scrutiny." Hoff, 1999 ND 115, ¶ 13, 595 N.W.2d 285..

[47] Although they tend to focus on one or the other, the decisions from other states all seem to regard "liberty" and "privacy" in ways that draw no significant distinctions. The first decision from California indicated that the rights to privacy and liberty both compel the recognition of a right to choose. People v. Belous, 458 P.2d 194, 199 (Cal. 1969).

narrowly tailored, and necessary to promote a compelling state interest. See, e.g., Hoff, 1999 N.D. 115, ¶ 14.

DOH acknowledges that the enjoyment of life and liberty are fundamental rights, but still suggests application of the Casey undue burden standard is the only permissible result. Indeed, it characterizes plaintiffs' constitutional interpretation as so flawed that it should be summarily rejected. This fails to comprehend the basic nature of plaintiffs' challenge. Plaintiffs do not rely on the federal constitution, or any of the cases that define federal abortion rights. Trans., p. 54. Instead, they rely solely on the corresponding rights protected by our state constitution. Although federal law establishes the least restrictive of the possible results,[48] it does not control to the extent the state constitution requires greater protection.

This state court action challenges a state law enacted by the North Dakota Legislature. MKB is a North Dakota corporation. Kromenaker aff. ¶ 1. The only facility it operates is located in this state. Id. ¶ 3. Many or most of its patients are also North Dakota citizens. Id. ¶ 4. Our state constitution guarantees the personal rights of citizens in expansive terms. Defaulting to federal decisions does not do justice to these rights, as they appear to require higher levels of protection.

A state law approach also has much to commend in terms of simplicity and judicial economy. The federal case law is extensive, but it is often confusing or even contradictory. This was underscored by the oral arguments. Counsel for DOH

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[48] This is true for two reasons. As has already been discussed, state protections can be equal to or greater than those guarantied by the federal constitution, but they can never be less. Furthermore, even if it is ultimately concluded that the state constitution affords no protection in this case, our statutes must still pass federal constitutional muster.

repeatedly noted that the federal case law she held out as controlling was often very hard to understand or apply. Trans., pp. 40-41, 53, 65. The Casey undue burden standard is vague, it is subjective, and the Supreme Court has provided almost no practical guidance regarding its application. As was noted at the time, it has no legal or historic basis. Casey, 505 U.S. at 987 (Scalia, J., dissenting and concurring). It is also "inherently manipulable and ... unworkable in practice." Id. at 986.

Moving a case of this dimension through the federal system is also exhaustive in terms of both time and money. The last federal challenge to a North Dakota abortion law was fast by federal standards, largely because it was resolved on summary judgment, and that judgment was affirmed on appeal. Schafer, 18 F.3d 526. That case involved a law that was initially scheduled to take effect on April 1, 1991. Id. at 527. The decision affirming summary judgment was dated February 10, 1994.

More typical may be the Ohio litigation involving a state statute that also seeks to impose restrictions on medical abortions. The Ohio statute was enacted in 2004. Although there have already been multiple appeals, and issues have been certified to the Ohio Supreme Court, proceedings at the trial court level have yet to be concluded.[49] When a decision on the merits is finally reached, further appeals are virtually assured. Ultimately, it will have taken a decade, or more, before the validity of the Ohio statute is conclusively resolved.

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[49] In fact, they are currently stayed pending yet another appeal to the Sixth Circuit. Planned Parenthood Cinncinatti Region v. DeWine, No. 1:04-CV-493, 2011 W.L. 4063999 (S.D. Ohio Sept. 13, 2011). This appeal is from a partial summary judgment. Even if that judgment is affirmed, significant issues will need to be tried once the stay is lifted.

At the same time, abortion is unique, and the state's interests are deemed by many to be greater than those of the individual. Although Roe held a woman's rights were fundamental, it also recognized a state has important interests it may properly assert. Roe, 410 U.S. at 154. Furthermore, in Casey the court concluded that Roe had gone too far, as it did not recognize the full extent of a state's interests. Casey, 505 U.S. at 872. These conclusions were the result of agonizing deliberations, conducted over time, by our nation's leading jurists. They are entitled to further consideration.

Fortunately, this dilemma does have a solution. Although it adds greatly to the complexity of the analysis, it is appropriate to consider if the amendments are likely to withstand challenge under the Casey undue burden standard, as well as the strict scrutiny standard. When in doubt, this is the safe thing to do. See, e.g., Schafer, 18 F.3d at 529. Furthermore, in light of the strong presumption favoring constitutionality, it would be imprudent to completely disregard the approach which favors that result. Conversely, if even the most conservative approach indicates the amendments are likely unconstitutional, this will be strong grounds for continuing the temporary injunction.

Likely Infringement

Turning to the probable merits of the constitutional challenge, there is much to address. It seems the best places to begin are the interests invoked by the state, and the means chosen by the legislature to promote that interest.

1. The State's Interests

Collectively, Roe and Casey recognize states do have legitimate interests that justify restrictions on a woman's right to choose. There is no reason to conclude these

interests are entitled to less consideration under our state constitution. Therefore, it will be assumed the federal and state constitutions both recognize the same state interests, and impose the same restrictions on a state's ability to promote those interests.

When it held that Roe had gone too far, Casey was focused on a state's interest in ensuring that decisions are properly informed. Casey, 505 U.S. at 878. However, this is not the interest the amendments purport to promote. Roe did squarely address the relevant interests, namely "safeguarding health [and] maintaining medical standards." Roe, 410 U.S. at 154.

Based on then-existing medical knowledge, Roe concluded that during the first few months of pregnancy the risks associated with abortion were less than those associated with childbirth. Therefore, during this period the woman, in consultation with her physician, should 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 protect a woman's health. Id. at 164. Roe also held a state has a "legitimate interest in seeing to it that the abortion ... is performed under circumstances that insure 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 after-care, and to adequate provision for any complication or emergency that might arise." Id.

Casey discussed health regulations and standards only in passing. Its abandonment of the trimester approach does create some room for state regulation during even the early months of pregnancy. At all times, however, "[u]necessary health regulations that have the purpose or effect of presenting a substantial obstacle"

are still invalid. Casey, 505 U.S. at 878.

The plaintiffs' affidavits indicate that complications from medication abortions are uncommon. When they do occur, such complications are usually similar to those associated with spontaneous miscarriage. Hemorrhage, retained tissue and infection are the primary concerns. Most hospitals and emergency rooms are very capable of providing appropriate treatment. Grossman aff. ¶ 30. As with any medical emergency, however, time may be of the essence. MKB tells its patients that in case of an apparent emergency they should proceed immediately to the closest facility that provides emergent care. Any confusion or delay in this regard may have critical consequences. Eggleston aff. ¶ 30.

Dr. Harrison's affidavit paints a rather different picture. She states "[m]ost recent studies have clearly demonstrated that Mifeprex abortions create a greater risk of hemorrhage, infection, continued pregnancies, retained tissue and need for emergency reoperation than surgical abortions." Harrison aff. ¶ 11. She also opines that it requires unique training and experience to deal with the complications typically associated with medical abortions. Id. ¶¶ 24, 34.

These competing contentions will necessarily be addressed at trial, and the ultimate fact findings must be deferred until all the evidence is in. At the same time, the record already contains a great deal of evidence that was considered as part of this preliminary assessment. In particular, nothing prevented an immediate review of the authoritative studies and reports both sides rely on. That review has formed two impressions. First, the references are all dated, and probably do not completely reflect the current state of medical knowledge. Second, they uniformly do support the

conclusion that properly performed medical abortions are safe and effective through 63 days LMP.

The WHO report was published in 2003, and appears to have been the end result of a conference held in September of 2000. It states that "[m]ifepristone with misoprostol or gemeprost has been proved to be highly effective, safe and acceptable for early first trimester abortions" up to 63 days LMP. WHO, Safe Abortion: Technical and Policy Guidance for Health Systems, p. 36 (2003) (WHO, 2003 Safe Abortion Report).[50]

In 2004, The Cochrane Collaborative (Cochrane)[51] reviewed thirty-nine separate trials involving medical abortion procedures, completed between 1986 and 2002. The conclusion was that "[t]he available data ... shows that the combination of mifepristone/misoprostol is a safe and effective method to terminate pregnancy in the first trimester up to 63 days." Kulier, et. al., "Medical Methods for First Trimester Abortion," Cochrane Database of Systematic Reviews 2004, Issue 1, art. no. CD002855, p. 7 (Cochrane, 2004 Medical Abortion Review).[52]

ACOG is generally regarded as the nation's leading association of physicians specializing in obstetrics and gynecology. Grossman aff. ¶ 1. In October 2005, it issued a practice bulletin designed to aid its members in the performance of state of the

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[50] Available at http://whqlibdoc.who.int/publications/2003/9241590343.pdf.

[51] According to its website (www.cochrane.org), this is a nonprofit entity headquartered in the United Kingdom. It publishes systematic reviews of reports from randomized and controlled medical trials. Its goal is the promotion of evidence-based medicine, which it defines as healthcare decision-making based on the results of high-quality and current research.

[52] Available at http://apps.who.int/rhl/reviews/langs/CD002855.pdf.

art medical abortions. ACOG Practice Bulletin No. 67 (October 2005) (ACOG, 2005 Practice Bulletin).[53] ACOG recommended various changes from the protocol described in the Mifeprex FPL, as this both reduced side effects and made "medical abortion less expensive, safer, and more rapid." Id. at 2. Subject to these modifications, however, it concluded that "[m]edical abortion should be considered a medically acceptable alternative to surgical abortion in selected, carefully counseled, and informed women." Id. at 8. This is true "up to 63 days of gestation based on LMP." Id. ACOG also reported that less than one percent of the women who receive this procedure will subsequently require an emergent surgical curettage for excessive hemorrhage. Id. at 5. Finally, it concluded that a positive connection had not been established to the few reported deaths due to infection, but "[e]ven if related, the death rate would be less than 1 per 100,000 mifepristone procedures, a rate comparable to that for early surgical abortion and miscarriage." Id. at 6.

By comparison, despite continued advances and improvements in maternal care, the mortality rate due to childbirth continues to be much higher than the death rate attributable to any form of early abortion. WHO recently updated its global assessment of maternal mortality. According to this estimate, 24 women die from maternity-related causes in the United States for every 100,00 live childbirths.[54] WHO, Trends in

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[53] This bulletin is attached to the Grossman affidavit as Exhibit B.

[54] This is up to five times higher than the maternal mortality ratio achieved in many developed countries, but much lower than the ratios in most developing nations. Developing countries continue to account for 99 percent of worldwide maternal deaths. In Afghanistan, it is estimated that one of eleven women will ultimately die from a maternal cause. WHO, Trends in Maternal Mortality: 1990-2008, p. 17 (2010). The explanation for these stark disparities boils down to access to high-quality reproductive health and family-planning services. Id. at 21-22.

Maternal Mortality: 1990-2008, p. 26 (2010).[55]

In summary, the available record clearly suggests that in most cases medical abortion is a safe and effective procedure for early abortions up to 63 days LMP. In relative terms, it appears to involve significantly less risk than childbirth, and no greater risk than the option of early surgical abortion. Complications or contraindications exist, but this is true of any medicine or medical procedure.[56] Whether any of the complications associated with medical abortions are of a nature or degree that warrants special standards involves disputed issues of fact. A careful review and balancing of the existing record, however, suggests that the state's overall interest in the regulation of medical abortions is low and not compelling.

2. The Chosen Means

It is hard to reconcile these conclusions with the blunt means chosen by the legislature to regulate this procedure. Furthermore, to the extent legitimate cause for concern may exist, in multiple respects the means chosen to address that concern are counterintuitive and counterproductive. Interests the state has every reason to protect - the ability of physicians to base treatment decisions on the best available medical

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[55] Available at http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf.

[56] The ACOG bulletin contains a summary of the contraindications to medical abortions. It lists a variety of medical contraindications, but indicates that even collectively they are only "infrequent" concerns. However:

> ... social or psychologic contraindications to medical abortion are more common. Women are not good candidates for medical abortion if they do not wish to take responsibility for their care, are anxious to have the abortion over quickly, cannot return for follow-up visits, or cannot understand the instructions because of language or comprehension barriers. Other non-medical criteria to be considered are access to a phone in case of an emergency and access to 24-hour emergency medical treatment (eg, surgical curettage for hemorrhage).

ACOG: 2005 Practice Bulletin, p. 6.

evidence; the development and implementation of safer, more effective, or less expensive medical protocols; and the discovery of new uses for drugs initially marketed for some other purpose - are all stymied by the amendments. In addition, the amendments interfere with healthcare decisions, invade the patient/physician relationship, and radically limit the availability of any emergency care that may be required.

Fundamental tenets of medical ethics reflect two basic requirements. First, mentally competent patients must give informed consent to medical treatment. Second, patients shall not be exposed to unnecessary risks to their health. Orentlicher aff. ¶ 5.

The requirement for informed consent recognizes that a patient's bodily integrity may not be violated without their permission. It also accepts that when treatment decisions need to be made, the patient is ultimately the most appropriate person to make those decisions. The physician's role is to provide all the information necessary to allow the patient to make a voluntary and informed choice. This includes information regarding: the different treatment options; the nature of the different options; the medical risks and benefits associated with each; and the potential each provides for a successful outcome. Although a physician will often indicate their recommendation regarding treatment options, the final decision belongs to the patient. Id. ¶ 6.

These principles have been incorporated into the standards of virtually all medical associations. For example, the AMA's code of ethics states:

> The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the

> patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.

Id. ¶ 7.

Similarly, a recent statement promulgated by ACOG's committee on ethics provides:

> Seeking informed consent expresses respect for the patient as a person; it particularly respects a patient's moral right to bodily integrity ... . It involves the ability to choose among options and to select a course other than what may be recommended ... . Informed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity. It is freedom from being acted on by others when they have not taken account of and respected the individual's own preference and choice.

Id. ¶ 8.

The principle the patients must not be exposed to unnecessary risks dates back to the Hippocratic Oath, and its admonition that doctors must first do no harm. Any threats to patient welfare must be minimized. Patients must be able to choose the treatment with the lower level of risk. Id. ¶ 9.

DOH has done nothing to controvert any of these fundamentals, but the amendments it defends would turn them on their heads.

a. Off-Label Ban

The amendments begin by prohibiting, in absolute and unequivocal terms, any off-label use of an abortion-inducing drug. H.B. 1297, § 6(2). Medical abortions are most commonly induced using a combination of the medications mifepristone and

misoprostol. Grossman aff. ¶ 11. The protocol followed at Red River is typical of the current state of the art. During the initial clinic visit, 200 milligrams (mg) of mifepristone is administered orally. Patients are given 800 micrograms (µg) of misoprostol to be taken buccally at home two days later. A follow-up visit is scheduled for two to three weeks following the first visit. Id. ¶ 19.

Mifepristone is an anti-progestogen. Because progestogen is essential to the continuation of pregnancy, termination results. WHO, 2003 Safe Abortion Report, p. 35. In the United States, mifepristone is manufactured and sold by Danco Laboratories, LLC, under the brand name Mifeprex. Mifeprex comes in 200 mg tablets. It must be taken orally. Grossman aff. ¶13.

To date, Mifeprex is the only medication that has received FDA approval to be marketed for use in connection with medical abortions. Rarick aff. ¶ 5. Misoprostol has only been approved by the FDA to be marketed as a treatment for gastric ulcers. Eggelston aff. ¶ 15.

Misoprostol is a prostaglandin analog. It causes the cervix to open, and the uterus to contract and expel its contents. Misoprostol comes in 100 µg and 200 µg tablets. It may be taken orally, buccally, sublingually, or vaginally. Oral administration requires that the patient put the tablets in her mouth and swallow them. Buccal administration involves placing the tablets between the cheek and gums, and then allowing them to dissolve. Sublingual administration is similar, only the tablets are placed under the tongue. Vaginal administration is accomplished by inserting the tablets into the patient's vagina. Grossman aff. ¶ 14.

DOH suggested at the January 27 hearing that the amendments would still permit medical abortions to be performed using only mifepristone. Trans., p. 30-31. There are fundamental flaws in this scenario.

First, a successful medical abortion requires the complete expulsion of the products of conception, without the need for surgical intervention. Mifepristone alone achieves this result in only a small percentage of cases. Otherwise, misoprostol must be subsequently administered to stimulate the expulsion. For example, in the U.S. clinical trials for Mifeprex, only 6.3 percent of the participants did not require misoprostol.[57] 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.

Second, even if mifepristone could be used alone, such usage would not be consistent with that drug's label. The Mifeprex FPL requires that misoprostol be administered two days after the mifepristone is ingested, but misoprostol is not labeled for use in abortions. As the amendments are written, there is no getting around this repugnancy. Some language in the amendments clearly makes any use of misoprostol illegal. By reference, other language requires its use. Even worse, following the evidence-based protocol used by MKB would violate both the provisions that require strict compliance with the Mifeprex "label," and the provisions that ban the use of any drug not labeled for use in abortions.

[57] A description of the clinical trials is contained in the "Prescribing Information" section of the Mifeprex FPL, attached to the Long affidavit as Exhibit A.

The net effect is simple. If the amendments take effect, there will no longer be a legal and viable means of performing medical abortions in North Dakota. DOH suggests that some day the maker of misoprostol may seek FDA authorization to label and market this drug for use in abortions.[58] This is highly improbable. In any event, this decision must be based on the facts that exist today, not the remote chance that something may change in the future.[59]

Furthermore, the notion that health interests are promoted by legislative bans on off-label usage is an oxymoron. It also distorts the purpose and significance of the FDA approval process. None of this has been genuinely controverted.

When viewed against this background, the legislature's decision to ban the off-label use of abortion-inducing drugs is both illogical and inconsistent with the declared purpose of promoting women's health. Even if medical abortions did represent a significant threat, this would be a strange means of addressing that concern.

b. Emergency Services Contract

The second means selected by the Legislature is the requirement for a contract to provide exclusive coverage on an emergency basis. H.B. 1297, § 6(4). This is an unprecedented requirement. Moreover, it too appears to be contrary to the expressed goal of protecting women's health. On the other hand, it is probably a very effective

[58] Misoprostol is marketed under the brand name Cytotec. The current manufacturer is Pfizer Inc.

[59] Assuming misoprostol, or a comparable drug, is later approved to be marketed for use in connection with abortions, a different form of repugnancy would be certain to result. No drug sponsor conducting trials at this point would follow the outmoded protocol used in the Mifeprex trials. Therefore, even if a second drug is subsequently approved, the "label" accompanying that medication would be incompatible with the protocol in the Mifeprex FPL.

means of implementing a *de facto* ban on medical abortions in North Dakota.

All of Red River's medical abortion patients are given both oral and written aftercare instructions. Included in those instructions is a telephone number for patients to use – 24 hours a day, seven days a week – if they have questions or concerns. Kromenaker aff. ¶ 13. Patients are also given a copy of the Mifeprex medication guide. Id. ¶ 17. Patients are instructed to call Red River if they experience excessive bleeding, increased body temperature, pain, any indication of infection, or they are otherwise concerned about what they are experiencing. Id. ¶ 14.

Red River advises its patients that if they believe they need emergency treatment, or are advised by a healthcare professional to seek such treatment, they should immediately proceed to the closest hospital or appropriate care facility. Id. ¶ 16. Patients are also told that if they seek treatment in an emergency room, or from another healthcare provider, they should take the Mifeprex medication guide with them. Id. ¶ 17.

Particularly in rural states, access to health care is increasingly a concern. Nonetheless, North Dakota is still served by an extensive network of emergency care providers. Facilities offering urgent care are distributed throughout the state, providing reasonable access from all but the most remote areas. Furthermore, no provider can ever refuse emergency care.

The amendments require that every physician who performs medical abortions must enter into a contract with another physician. 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). Furthermore, every patient "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.

Therefore, if the amendments take effect physicians performing abortions will no longer be able to tell patients that when the need is urgent they should proceed directly to the nearest hospital or emergency room. Instead, they will 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.

During the January 27 arguments, DOH suggested the amendments could be saved by an interpretation that would allow a physician to tell patients they had the option of going to either the closest emergency room, or to the physician and hospital named in the contract. Trans., p. 75. The mandatory statutory language, however, does not support this interpretation. Even if it did, plaintiffs respond by pointing out the mixed message would be "confusing and contradictory which could also be detrimental to [patient] health if they don't know which [direction] to follow." Id.

In a further attempt to justify this extraordinary provision, DOH also suggests 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 does implicate fact issues and final judgment must be reserved, but the available information provides little support for DOH's position. Instead, the current record rather convincingly indicates that emergency medical treatment is rarely required following a

medical abortion. Moreover, when such treatment is required the appropriate procedure is typically surgical curettage (more commonly known as a "D&C"), perhaps combined with a blood transfusion. Although this needs to be fleshed out at trial, these are relatively simple procedures, that are probably performed on a routine basis at every hospital in the state. Finally, it does not appear the complications that may require emergency care are by any means unique to medical abortions. They are also commonly associated with childbirth and miscarriage. The only real difference is that following childbirth these complications are far more likely both to result, and to be serious.

Furthermore, even if there was sound reason to require an exclusive emergency services contract, this requirement is probably impossible to meet. The contract physician would be agreeing to be continuously on call, not a very appealing commitment under any circumstances. The amendments add further disincentive by providing the 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.[60]

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. Eggleston aff. ¶ 35. Threats of actual or feigned violence have been directed against Red River and its employees. In other states, medical personnel involved with abortions have been the

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

victims of violent assaults, including murder. Kromenaker aff. ¶ 26.

It is hardly surprising that numerous physicians have already rejected the prospect of contracting to provide emergency services, primarily because the contract would be tantamount to a public record. Eggleston aff. ¶ 36. Even if a willing physician could be found, it is hard to believe any clinic or hospital they were associated with would be similarly inclined.

c. Administration Requirement

Assuming the amendments could be interpreted to allow the administration of misoprostol, the requirement that the physician be physically present would likely also be very problematic for Red River. H.B. 1297, § 6(5). Although further detail will be needed at trial, none of the physicians who currently staff the clinic live in North Dakota. Kromenaker aff. ¶ 25. They are obviously not at the clinic every day. Abortions are only performed four to six days per month. Id. ¶ 5. Presumably this corresponds with the days a staff physician is typically present at the clinic.

Under the terms of the Mifeprex FPL, misoprostol is administered two days after the mifepristone is ingested. Because the amendments require that the physician be personally present for both these events, this is likely the third reason Red River would find it impossible to perform medical abortions should the amendments take effect.

Assuming Red River could cover increased staffing demands, this would presumably result in additional costs that would be passed on to the patient. The existing record also fails to describe the therapeutic benefit that results from having a physician in the same room when the misoprostol is swallowed. These are additional

issues that should be addressed at trial.

d. Lack of Exceptions

The means selected by the legislature to regulate medical abortions are significant in one further respect. They apply to every case. There is no stated exception for cases where the procedure, in the considered judgment of her physician, is necessary to preserve a woman's life or health. The ban also applies equally to victims of rape, incest, other forms of sexual abuse, and domestic violence. To this extent, it is the lack of exceptions that makes the amendments unacceptable.

For all these reasons, the amendments are not likely to withstand review under either the state or federal constitution, regardless of the standard of review. This is, of course, most obvious if the strict scrutiny standard is applied.

3. Strict Scrutiny

To withstand strict scrutiny, any law must be narrowly tailored and necessary to promote a compelling state interest. It is very hard to envision how a compelling state interest can possibly be established. At most, the state's interest in protecting the health of women who choose a medical abortion can be no greater than the relative risks that can fairly be attributed to this procedure, and they appear to be very low.

It is a fact of modern medicine that patients must be sent home at some point, protected only by their physician's instructions, warnings, any medication that may have been prescribed, and the network of emergency care centers. Complicated surgical procedures are now performed on an outpatient basis. When inpatient aftercare is required, every effort is made to reduce the amount of time the patient stays in the

facility. Both insurance policies and governmental programs typically impose strict limits in this regard. Conversely, patients are increasingly required to attend to their own follow-up care and medication.

In relative terms, the risks faced by a medical abortion patient when she leaves the clinic after taking the mifepristone appear to pale in comparison to those faced by the vast majority of patients who are discharged after major surgery, or some other significant medical event. Likewise, any risks associated with the self-administration of misoprostol also appear to be minimal in comparison to the risks associated with other medications people take at home on a routine basis. The legislature has not seen fit to involve itself when such risks are high. How can its justification for regulating medical abortions be regarded as compelling, when the risks appear to be so low?

Furthermore, the amendments have certainly not been narrowly tailored so they address only the state's legitimate concerns, while avoiding unnecessary infringement in all other areas. As indicated above, the amendments have the opposite effect. They apply broadly and without exception to every physician performing any medical abortion, regardless of whether there is good reason for concern regarding the patient's health or well being. Conversely, they provide no exception for victims of sex crimes or abuse, or for cases where, in the judgment of the physician, it is necessary to protect the health of the patient.

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 fundamental rights, 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.

5. Undue Burden – Casey

Turning to the most forgiving approach, it seems that application of the Casey undue burden standard likely leads to the same result.[61] It simply requires more explanation.

a. Procedural Bans

As a starting proposition, it is important to remember the laws under review in Casey all implicated a state's interest in ensuring the decision is properly informed. Without question, since that decision federal courts have typically upheld similar laws in a relatively cursory manner. See, e.g., Fargo Women's Health Org. v. Sinner, 819 F.Supp. 865 (D. N.D. 1993). The amendments, however, were not designed to express the state's interest in potential life, to inform women, or to persuade them to chose childbirth. Instead, their clear purpose is "to cull the list of available abortion techniques" by placing severe restrictions on a method that was previously legal and readily available. Rhode Island Med. Soc'y v. Whitehouse, 66 F. Supp. 2d 288, 313 (D. R.I. 1999), aff'd 939 F.3d 104 (1st Cir. 2001). The constitutional implications of procedural bans or restrictions are very different from those applicable to informational requirements of the type upheld in Sinner and Schafer.

[61] During the hearing, counsel for DOH confirmed that it regards the Casey plurality opinion as the controlling law. Trans., pp. 26-27. Counsel also conceded that federal law sets the "floor" for any analysis, and state constitutional rights must be at least co-extensive. Id. at 44-45.

The only procedural ban that has sustained a constitutional challenge to date is the ban on the intact dilation and extraction (D&X) procedure upheld in Carhart II, 550 U.S. 124 (2007). During oral argument, counsel agreed with this conclusion. Trans., p. 41. Furthermore, in Carhart II the Court was careful to distinguish the common first-trimester abortion methods, including the use of medication to terminate the pregnancy. Id. at 134.[62]

Conversely, 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 impose an undue burden under Casey. See, e.g., Whitehouse, 66 F. Supp. 2d at 313-14 (invalidating law that would eliminate common and safe second trimester procedure from list of legal procedures); Causeway Med. Suite v. Foster, 43 F. Supp. 2d 604, 612 (E.D. La. 1999), aff'd 221 F.3d 811 (5th Cir. 2000) (a law that has the effect of banning any common, readily-available, and safe method is invalid on its face); Little Rock Fam. Planning Serv., P.A. v. Jegley, 192 F.3d 794 (8th Cir. 1999) (striking law that inadvertently extended ban to D&E and suction curretage procedures commonly used during second trimester); Planned Parenthood of So. Ariz, Inc. v. Woods, 982 F. Supp. 1369, 1376-78 (D. Ariz. 1997) (ban on safe and commonly-used second-trimester procedures is facially unconstitutional). Furthermore, each of these decisions involved a broad, facial challenge brought on a pre-enforcement basis.

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[62] The contrast between a medical abortion and an "intact D&X" could not be more stark. The latter procedure is performed late in a pregnancy, when the fetus is well developed and its 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. Carhart II, 550 U.S. at 137-38.

Planned Parenthood of Central New Jersey v. Farmer, 220 F.3d 127 (3d Cir. 2000) is typical of these holdings. In 1997, the New Jersey Legislature passed a law that was only intended to ban the intact D&X procedure. Due to inarticulate language, however, the legislation was impossible to construe in such a limited manner. Instead, it had the effect of also banning some of "the safest, most common and readily available conventional pre- and post-viability abortion procedures." Id. at 144. For this reason, the law was found to be clearly unconstitutional, as it placed an undue burden on a woman's right to chose her preferred method of abortion. Id.

Similarly, in Hope Clinic v. Ryan, 195 F.3d 857 (7th Cir. 1999), the court discussed what were then "the principal methods of performing abortions in the United States." Id. at 861. The methods described included the use of medication to induce expulsion[63] and vacuum aspiration. Without feeling any need for elaboration, the court simply noted that prohibition of any one of these procedures "would conflict with the right of abortion" recognized by Casey. Id.

It is beyond dispute that a medical abortion is now a common and available method of terminating a pregnancy, particularly during its early stages. In general, the risks associated with any abortion tend to increase in proportion to the duration of the pregnancy. Likewise, efficacy tends to diminish over time. Due to the need for an abundance of judicial caution, it will be assumed the state has created issues of fact regarding the relative safety and efficacy of medical abortions. Nonetheless, it seems

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[63] This decision was written before the FDA approved the widespread distribution of mifepristone. Before this drug was generally available, methotrexate was frequently used in its place. Ryan, 195 F.3d at 861. Methotrexate was initially developed for use in chemotherapy (cancer treatment), and is not labeled for use in abortions.

highly improbable that such concerns could be comparable to those associated with the second trimester procedures courts universally regard as a matter of right. Therefore, it is very likely the *de facto* ban effectuated by the amendments would, by itself, result in a finding of facial unconstitutionality under Casey.

b. Lack of Health Exception

The lack of appropriate exceptions also appears to clearly be a fatal infirmity. 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 woman. Roe, 410 U.S. at 163-64. Casey reaffirmed that post viability a statute may restrict or prohibit abortion, except when the woman's life or health was endangered. Casey, 505 U.S. at 846. In Carhart I, this was clarified with the comment that "[s]ince 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 previability regulations." Carhart I, 530 U.S. at 930.

This may stop short of a *per se* constitutional requirement, "[b]ut where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women'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." Taft, 444 F.3d at 511. Furthermore, a health exception is necessary even if the circumstances that trigger it "rarely occur." Id.

In general, the procedures utilized at Red River to perform surgical abortions are regarded by the medical community as both highly effective and low in risk. However, complicating factors can significantly increase both the degree of difficulty and associated hazards, at the same time that they reduce the chances of a successful result. Eggelston aff. ¶ 20.

Many physical conditions make it more difficult for physicians to locate or remove the embryonic tissue when attempting a surgical abortion. Such conditions include:

- Uterine anomalies including a bicornuate uterus (a uterus with two cavities) or a uterine didelphys (two complete uterine structures).
- Obesity or other conditions that increase the patient's body size.
- Female genital cutting, a cultural practice in some African, Asian, and Middle Eastern countries.
- Both severe antiflexion (when the uterus is tipped towards the abdomen) and severe retroversion (when the uterus is tipped towards the back of the abdomen).
- Obstructive uterine fibroids.
- Cervical stenosis (tightly closed uterus).
- Any other physical condition that makes the opening to the cervix unusually small, narrow, or scarred.

Id. ¶ 21; Grossman aff. ¶ 10 .

Patients with some medical conditions are not appropriate candidates for a surgical abortion. Common examples include individuals with a severe seizure disorder

or an allergy to lidocaine. Eggelston aff. ¶ 21.

In cases where a surgical abortion is contraindicated, the medical approach is usually the procedure of choice from a standpoint of minimizing risk to the patient's health. Grossman aff. ¶ 10. DOH has failed to controvert this. In her affidavit, Dr. Harrison essentially argues that the same contraindications to a surgical abortion also impair the prospects for a successful medical abortion. In turn, this increases the odds that a surgical procedure will still be required on a follow-up basis. Harrison aff. ¶ 19.

The same argument was advanced in Taft and found to be "unavailing." Taft, 444 F.3d at 512. Although complications may reduce the odds to some extent, medical abortions will still be successful in the vast majority of cases. The risky surgical follow-up would only be required in those rare cases where the medical approach failed. There is no justification for forcing all patients to undergo the surgical procedure that carries significantly increased risks, just because a few of them will ultimately be forced to assume those risks anyway. Id.

By the time Taft found its way back to the trial court, Carhart II had been decided. Accordingly, defendants then argued the lack of a health exception was no longer a proper basis for a facial challenge. Based on what appears to be an almost identical factual record,[64] the district court disagreed. Planned Parenthood S.W. Ohio Region v. DeWine, no. 1:04-CV-493, order at 22-27 (May 23, 2011). Carhart II was distinguished because in that case there was medical uncertainty as to whether an

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[64] This refers only to the record regarding physical contraindications for a surgical abortion. The health implications for rape and abuse victims do not appear to have been addressed in the Ohio litigation.

exception was ever necessary to preserve a woman's health. By contrast, in the Ohio case, as in this case, defendants have conceded "that surgical abortions pose greater risks for women with medical complications." Id. at 25.

c. 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.

Although the existing record provides little detail, it is assumed the surgical procedure performed at Red River is a variation of vacuum aspiration. This requires the insertion of a plastic or metal cannula into the woman's uterus, so the embryonic tissue can be evacuated utilizing a vacuum process. Dilation of the cervix, using mechanical or osmotic dilators, is usually required before insertion of the cannula. Eggelston aff. ¶ 20. Therefore, an early surgical abortion requires multiple physical invasions of the patient's genital area, performed while the patient is awake. It also places the provider in temporary control of that area. Needle aff. ¶ 6.

Most women who are victims of sexual assault suffer both short- and long-term emotional trauma. Common examples include fear and anxiety, flashbacks, depression, loss of sexual libido, and loss of a sense of autonomy or self-worth. Simply stated, if the pregnancy is the result of a criminal violation, terminating that pregnancy with a surgical abortion requires that the victim endure a second form of physical violation. Id. ¶ 5. For some victims – even when they fully intend and desire to end the

pregnancy – this can be unacceptable in psychological or emotional terms. If forced to proceed with the surgical procedure, the emotional re-traumatization can be extreme. Id. ¶ 6.

A medical abortion does not involve using dilators to stretch the cervix, or inserting a vacuum device into the uterus. Accordingly, the aversion that rape and abuse victims typically feel for the surgical approach does not usually extend to a medical abortion. 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. The risk of violence tends to increase when the woman does not comply. 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 inflict violence on her if she proceeds without his knowledge or consent. Id. ¶ 10.

Having a child when 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 and inextricable 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 usually 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. Potential outcomes include renewed physical violence, or worse. Even if there is no discovery, or there are no resulting consequences, the stress and anxiety experienced by any woman in this situation is certain to be severe. Id. ¶¶ 8, 11. Therefore, any circumstance that requires additional trips to the clinic has very serious implications for women faced with this conundrum. Kromenaker aff. ¶ 21.

Similar realities were recognized by the district judge in South Dakota when she enjoined the 2011 amendments to the South Dakota abortion laws. In the words of that decision:

> Moreover, it is generally accepted that women are often the victims of abuse. And abusers often forcibly impregnate their partners to maintain control or increase their control over their women. The abusers in such relationships closely monitor the women. For example, the abuser will often keep track of the mileage on the car or remove the distributor cap on the car to prevent the woman from leaving the house. Abusers will call the woman numerous times at work or home to ensure that she is there. An abuser will also regularly appear at the woman's place of work unexpectedly 'to check up on her.' For those women who are in such relationships the [challenged law] creates an incredible obstacle because it requires them to make separate trips, which for many is effectively impossible to do because two trips double the chances of being 'caught' and punished by the abusive partner.

Daugaard, 799 F. Supp. 2d at 1066.

Obtaining a medical abortion may also require fewer matters to be explained to an abusive partner. In particular, a medical abortion can be disguised, if necessary, as a spontaneous abortion. The bleeding and other attributes of medical abortion resemble those of a miscarriage. By comparison, a surgical abortion may be difficult or impossible to either disguise or explain. Needle aff. ¶ 11.

Dr. Harrison does opine in her affidavit that women who have abusive partners are "most in need of a competent caregiver to assess her for pain control and hemorrhage" following the administration of misoprostol. Harrison aff. ¶ 22. It seems to be common sense, however, that any woman can self-assess her level of pain and hemorrhage, without the need for assistance from a spouse or partner. Moreover, Dr. Harrison misses the essential concern. Because it requires the woman to make a second trip to the same destination within days, the requirement for clinical administration of misoprostol greatly increases the odds of discovery by her abuser. In any case where a woman has good reason to fear that discovery, the burden imposed by the amendments is unjustifiable and undue. Casey, 505 U.S. at 895.

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. DOH does not even mention pregnancies resulting from sex crimes in any of its responses. Through its expert's affidavit, it concedes that women living with abuse "deserve help and sympathy," but it fails to address their true plight. Harrison aff. ¶ 22. It is unacceptable to simply ignore these victims. For them, the ban on medical abortions is not simply an undue burden. It is unconscionable.

Because the need for appropriate exceptions has not been addressed or controverted by the state, to this extent the outcome is preordained. It would be appropriate to grant partial summary judgment on these issues, but that would not end the dispute. In Ayotte v. Planned Parenthood of Northern New England, 546 U.S. 320 (2006), the Court held laws that are constitutionally infirm due only to the lack of a

health exception are otherwise still enforceable. See also, Taft, 444 F.3d at 515-17. Because the broader challenges will still need to be tried, there is no advantage to a partial judgment at this juncture. Conversely, there is no need to limit the scope of the temporary injunction, as it appears likely the broad facial challenges will also succeed.

d. Others

Although the record provides no detail, it is hopefully safe to assume that most of the pregnancies terminated by medical abortion are the result of consensual sex acts. Likewise, the majority of the women who receive medical abortions at Red River undoubtedly do so with the support of their spouses or significant others. Finally, the contraindications to a surgical abortion are rare. Therefore, for most patients a medical abortion is simply a matter of choice.

For some, this results from a simple fear of surgery, or a desire for the emotional support family members or partners can provide if much of the process occurs in their home, or a comparable setting. Eggelston aff. ¶ 21. Other explanations for a preference for the medical approach include: it is more natural; it can be performed earlier in the pregnancy; and it is less invasive. Cochrane, 2004 Medical Abortion Review, p. 3.

DOH argues a woman has no right to choose her preferred method of abortion, and states are free to ban specific methods providing at least one remains. Trans., pp. 38-39. There is no basis, either in law or medicine, for such conclusions.

Part of the core holding in Casey was the affirmation that before viability a state may neither prohibit abortion nor impose a substantial obstacle on “the woman’s

effective right to elect the procedure." Casey, 505 U.S. at 846. States cannot be permitted to place "a heavy, and unnecessary, burden on women's access to a relatively inexpensive, otherwise accessible, and safe abortion procedure." City of Akron v. Akron Center for Reprod. Health, 462 U.S. 416, 438 (1983) (overruled on other grounds by Casey). As noted in a previous section, courts have uniformly held the legislative prohibition of previously viable and available methods or procedures is always a violation of the federal constitution, as interpreted in Casey.

It is also a violation of the fundamental medical tenets surrounding the requirement for informed consent. Patients, in consultation with their physician, have the absolute right to chose the method, whenever reasonable options exist. There is no place for legislative interference with such personal rights and decisions.

In Daugaard, the court described in detail the undue burdens that would result if all patients were required to make an additional trip to the clinic where the abortion procedure was performed. After discussing the practical and financial burdens, the court went on to note that associated delays may also eliminate the option of a medical abortion as the time window for performing this procedure could close in the interim. In the court's estimation, the burdens imposed by the additional trip to the clinic were "arguably insignificant" when compared to the denial of "the ability to undergo a medication abortion, which may be their chosen method of abortion ... ." Daugaard, 799 F. Supp. 2d at 1065.

In summary, although the amendments have the practical effect of banning medical abortions in all cases, the resulting burdens will not be the same in every case.

For patients with physical contraindications to the typical surgical approach, the ban could force them to undergo a more complicated and risk-prone surgical procedure in an inpatient setting. For patients who have already been victimized by sex crimes or abuse, the consequences are calculated to be extreme and unthinkable. For others the burdens may not be so great, but they still appear to be unnecessary and undue. Therefore, it is unlikely the amendments could sustain a facial challenge under the "effects prong" of the Casey undue burden standard.

e. Purpose Prong

Under Casey, a statute is also unconstitutional if its "purpose" was to place a substantial obstacle in the path of a woman's right to choose. Casey, 505 U.S. at 877. After thus indicating the legislature's purpose must be considered, Casey again provided almost no guidance as to how this task should be accomplished. All it said is that a statute "must be calculated to inform the woman's free choice, not hinder it." Id. at 877. Clearly the amendments were not designed to inform. Whether they were calculated to hinder is not so clear.

Following Casey, numerous lower federal courts have struggled to determine when and how an impermissible purpose inquiry should be performed. The Supreme Court has done little to clarify or resolve such issues. A single case well illustrates all this.

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 a 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).

Following Muzarek, the Casey purpose prong appears to have been largely ignored. An exception is Okpalobi v. Foster, 190 F.3d 377 (5th Cir. 1999), where the Fifth Circuit stated proper considerations include "the language of the challenged act, its legislative history, the social and historical context of the legislation, [and] other legislation concerning the same subject matter as the challenged measure." Id. at 354. Although all these things have been considered here, nothing jumps out.

The language of the amendments does not exude an improper motive.[65] Based on a review of the legislative history, there is no obvious indication that the proponents of H.B. 1297 did not believe what they said. There is no current means of assessing the social or historical context of the legislation. As they are unprecedented, there is also nothing to compare the amendments against.

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[65] As indicated above, the means selected by the legislature to regulate medical abortions all have the practical effect of banning the procedure. Without any offsetting benefit, this could certainly support an inference the amendments were designed only to impair access and choice. "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). Moreover, the amendments do seem to specifically target Red River, and its well known practices. Under both federal and state law, however, a finding of unconstitutionality requires more than an inference. Muzarek, 520 U.S. at 972; Palluck v. Bd. of Cnty. Com'rs, Stark Cnty., 307 N.W.2d 852, 857-58 (N.D. 1981).

In summary, a preliminary assessment of the Casey purpose prong is troubling, but inconclusive. It is also not known if this is an issue the parties will pursue at trial. Further consideration will be given if appropriate, but at this juncture it is not necessary. The Casey undue burden test "is disjunctive." Okpalbobi, 190 F.3d at 354. A finding the law fails either the purpose prong or the effect prong is dispositive. Id.

5. Severability and Judicial Surgery

Any constitutional analysis must also consider whether it is possible to construe the law in a manner that avoids infirmities. City of Fargo v. Salsman, 2009 ND 15, ¶ 21, 760 N.W.2d 123. Likewise, valid portions must be permitted to stand if it is possible to strike only the provisions that are clearly unconstitutional. N.D. Cent. Code § 1-02-20.

The requirement for an emergency services contract is exclusively set forth in a separate subsection of the amendments. H.B. 1297, § 6(4). The same is true of the language requiring the physical presence of the prescribing physician when an abortion-inducing drug is administered. Id. § 6(5). From a mechanical standpoint, it would be easy to invalidate and sever these provisions. However, that would solve only part of the problem. It would still leave the impossible conundrum created by the portions of the amendments that prohibit off-label usage.

Can subsection 6(2) be construed to permit medical abortions performed in strict compliance with the protocol set forth in the Mifeprex FPL? This seems to have clearly been the legislature's intent. In its supplemental brief, DOH argues in support of such an interpretation. The problem is that this result seems to be impossible to achieve due to the explicit language of the amendments.

"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 of 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).

In an attempt to save the amendments, DOH now suggests that misoprostol is not an "abortion-inducing drug." This is a real stretch. Misoprostol is an integral and essential part of the procedure. It causes the expulsion of the products of conception, and no medical abortion is deemed to be successful and complete until this occurs. Furthermore, the definition of "abortion" contained in the North Dakota Abortion Control Act has been amended to eliminate any possibility of this interpretation. N.D. Cent. Code § 14-02.1-02(1).

During the hearing, DOH also suggested that because misoprostol is required by the Mifeprex FPL, the requirement to follow this "label" is an implicit endorsement of the use of misoprostol. Trans., pp. 29-30. This might be a plausible interpretation, were it not for the other language in the subsection that unambiguously prohibits any medication not specifically labeled for use in medical abortions.

As DOH's response to these proceedings consists largely of an attempt to defend the protocol described in the Mifeprex FPL, the materiality of that response is called into question. Nonetheless, in keeping with the desire to explore any possible means of avoiding a finding of unconstitutionality, this has also been considered. It

does not appear to change the result.

6. Alternative Interpretation

Interpreting the amendments to only require compliance with the Mifeprex FPL would likely do nothing to alter the outcome of a strict scrutiny analysis. Likewise, it would also still be likely to impose undue burdens "in a large fraction of the cases in which [the amendments are] relevant." Casey, 505 U.S. at 895. Furthermore, this conclusion is based predominantly on considerations DOH does not dispute.

a. Mifeprex Dosage

The FPL requires that three 200 mg tablets of Mifeprex be initially administered. The evidence-based regime followed by Red River calls for only a single tablet. WHO, Cochrane and ACOG all support this modification, as the lower dosage provides comparable results at a third of the cost. DOH does not dispute this.

Mifeprex is very expensive. Red River indicates that reducing the dosage to one pill results in a cost-savings to the patient of approximately $200. Kromenaker aff. ¶ 23.[66] No legislative requirement that only adds cost and requires unnecessary medication could pass strict scrutiny. Casey does say an incidental increase in cost cannot invalidate an otherwise necessary law. Casey, 505 U.S. at 874. This suggests the price differential may not be enough standing alone under federal law, but it is certainly part of the equation.

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[66] In her expanded notes, Dr. Harrison suggests price savings could be achieved if Red River was less concerned about its "profit margins." The justification for this comment is not immediately obvious. In any event, it is safe to assume the legislature was not motivated by a desire to inflate the profit margins of the manufacturer of Mifeprex.

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 costs could easily render the procedure unavailable. See, e.g., Daugaard, 799 F. Supp. 2d at 1065. Medical assistance does not cover abortions. N.D. Cent. Code § 14-02.3-01. In fact, North Dakota law even prohibits insurance coverage for abortions, unless an additional premium has been paid for an optional rider providing such coverage. N.D. Cent. Code § 14-02.3-03. As health insurance of any kind is now beyond the reach of many,[67] it is safe to assume that few poor women are protected by such riders.

b. Misoprostol Dosage and Administration

The Mifeprex FPL calls for the oral administration of 400 µg of misoprostol. Red River doubles the dosage, and directs patients to take this medication buccally. Misoprostol is not very expensive, so this dosage modification probably does not have a significant impact on cost. The difference between oral and buccal administration, however, may be more significant. It is widely reported that 800 µg of misoprostol administered vaginally provides many benefits when compared to the FPL protocol. It reduces the time to expulsion, causes fewer side effects, and improves complete abortion rates. It also allows excellent results to be achieved up to 63 days LMP. ACOG, 2005 Practice Bulletin, p. 2.

According to the U.S. trials, following the protocol outlined in the Mifeprex FPL obtained a successful result in only 92.1 percent of the cases. Mifeprex FPL, p. 4.

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[67] In 2010, approximately 16.3 percent of the people in this country did not enjoy the benefit of health insurance. The statistics for the Midwest region were only slightly better – 13 percent. U.S. Dep't. of Commerce, U.S. Census Bureau, Income, Poverty, and Health Insurance Coverage in the United States: 2010 (Sept. 2011) available at http://www.census.gov/prod/2011pubs/p60-239.pdf.

Moreover, all of those cases were performed within 49 days LMP, when the best results should be expected. By comparison, the ACOG bulletin indicates that increasing the misoprostol dosage and changing the route of administration achieves a success rate of 96 percent to 99 percent, between 49 and 63 days LMP. ACOG, 2005 Practice Bulletin, p. 6. Similarly, the Cochrane review concluded oral administration of misoprostol resulted in failure in a "statistically significant higher number" of cases. It also resulted in increased nausea and diarrhea. Cochrane, 2004 Medical Abortion Review, p. 5. The WHO report indicates that the oral ingestion of misoprostol impairs efficacy and is not "tolerated" as well by patients. WHO, 2003 Safe Abortion Report, p. 37.

In her expanded report, Dr. Harrison indicates the vaginal administration of misoprostol has recently been linked to increased infection rates, and buccal administration tends to cause the same side effects as swallowing the tablets. When ACOG published its recommendations, it only noted that further study of buccal administration may be warranted because it appeared to provide benefits similar to vaginal administration. ACOG, 2005 Practice Bulletin, p. 2. The current evidence-based recommendations regarding the administration of misoprostol will need to be developed at trial. It is very unlikely, however, that the final result will hinge on this.

c. Clinical Administration

The FPL requires that the patient return to the healthcare provider for the administration of misoprostol.[68] By comparison, Red River allows patients to self-

[68] The clinical administration of misoprostol does make sense in the context of a clinical trial. In order to validate the results, such tests require special monitoring and controls. 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. One study showed that by 2001 – only a year after Mifeprex was released for marketing – 96 percent of the medical facilities performing medical abortions were

administer this drug from the comfort and convenience of their home.

Dr. Harrison is correct when she notes that some of the early reports did recommend the clinical administration of misoprostol, followed by a period of observation. For example, this is the recommendation contained in the WHO report published in 2003. WHO, 2003 Safe Abortion Report, p. 37. This same report, however, goes on to indicate that some investigators were already questioning the need for this second visit. Id. When ACOG issued its recommendations several years later, this debate had apparently been resolved. According to those recommendations, "[m]ultiple large studies in the United States have demonstrated that a patient can safely and effectively self-administer the misoprostol (orally or vaginally) in her home." ACOG, 2005 Practice Bulletin, p. 2.

Although the requirement for a second trip to the clinic is a particular concern for women living with abuse, it would impose a burden on all patients. Furthermore, simple geographical considerations make this a very significant consideration. The only clinic operated by Red River is located in Fargo. Kromenaker aff. ¶ 3. Red River is the only abortion provider in North Dakota. It serves an extensive geographical area. Patients come predominantly from the states of North Dakota, South Dakota, and Minnesota. Id. ¶ 4. Most patients who receive abortion services at Red River must travel long distances to reach the clinic. For approximately 70 percent of those patients, a one-way trip requires more than two hours of travel. For almost half of the patients, the trip is at least four hours in duration. Id. ¶ 4. The direct and indirect costs associated with such travel represent a significant financial burden for many patients, particularly those with limited income. Id. ¶ 21.

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recommending that patients self-administer misoprostol at home. Grossman aff. ¶ 26.

In Schafer, 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 the second visit. Schafer, 18 F.3d at 532.

In the recent South Dakota case, the legislation in question clearly required an extra trip to the abortion clinic.[69] For approximately thirty percent of the patients, this required round-trip travel of at least 300 miles. After considering the practical implications for working women, stay-at-home mothers, or women with limited income, the court concluded that, by itself, the financial implications of the extra trip constitute an undue burden. Daugaard, 799 F. Supp. 2d at 1065. For a large fraction of the cases in North Dakota, the burden would be no less.

DOH has not directly controverted the burdens attributed to the requirement for the clinical administration of misoprostol, but it does suggest there is countervailing benefit. According to Dr. Harrison, the reason this second trip is so important is the four to six hour period of observation that is required following the administration of misoprostol. She suggests that expulsion for most patients will occur during this period,[70] and for the patient's safety this should occur in a clinic setting "where their

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[69] Like North Dakota, South Dakota has only a single abortion provider. That clinic is located in Sioux Falls.

[70] Even this part of Dr. Harrison's argument is inconsistent with the record, and implicates yet another reason not to follow the protocol in the Mifeprex FPL. Taking 400 µg of misoprostol orally slows down the typical time to expulsion. During the U.S. trials, only 44.1 percent of patients expelled the products of conception within four hours. For many test participants, it took more than 24 hours. Mifeprex FPL, pp. 4-5.

bleeding can be monitored, their vital signs can be observed by a [sic] trained medical personnel, and they can receive sufficient pain medication." Harrison aff. ¶ 39. For multiple reasons, this does not appear to be a compelling argument.

As noted above, multiple large studies have demonstrated that misoprostol can safely and effectively be self-administered at home. Indeed, ACOG gave this recommendation its highest available rating (level A). To receive this rating, a recommendation must be based on "good and consistent scientific evidence." ACOG, 2005 Practice Bulletin, p. 8.

Although Dr. Harrison suggests the observation period would also allow clinic staff to provide counseling and compassion, most patients would only find such an extended clinic visit to be very inconvenient, expensive, and unpleasant. From Red River's standpoint, it would also probably tax the available facilities and staff well beyond their capacity.

An even bigger shortcoming is the simple fact that the amendments do not require any period of observation following the administration of misoprostol. The Mifeprex FPL does indicate that the patient "returns to the health care provider two days after ingesting Mifeprex" and then takes two tablets of misoprostol orally. Mifeprex FPL, p. 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. 1297, § 6(5).

In reality, requiring that a woman return to her physician before she takes the misoprostol only creates the very significant potential that expulsion will occur, or at

least commence, before she can return home.[71] The likely alternative is a car, rest stop, motel room, or some equally inappropriate and discomfiting location. Grossman aff. ¶ 25. Furthermore, it is hard for a patient to monitor her bleeding or temperature when riding in a car. Id. As the possible side effects of misoprostol include nausea, vomiting, and diarrhea, this is still more reason to prefer the comfort of home.[72]

Therefore, the requirement for clinical administration of misoprostol imposes only undue burdens without any countervailing benefits. The outcome under Casey appears to be clear. The outcome under strict scrutiny is even more certain.

d. 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 49-day limitation is carried over.[73] However, the existing record clearly indicates that 63 days LMP is now universally regarded as the appropriate cutoff date, at least when physicians are allowed to follow current and best medical procedures.[74]

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[71] In all probability, it would also re-expose her to the gauntlet of protesters that typically forms outside Red River whenever procedures are being performed.

[72] The incidence of such side effects goes up significantly when the misoprostol is taken orally, as the amendments would require.

[73] Dr. Harrison refers to a "49 day limit as set by the FDA." Harrison aff. ¶ 37. Once again, she is clearly wrong. Nothing done by the FDA imposes a time limit on physicians. Moreover, although the sponsor chose to limit test subjects to women who were no more than 49 days LMP, the results provide no insight as to what could be expected with slightly more advanced pregnancies. This simply was not tested as part of the FDA approval process.

[74] The ultimate time window for medical abortions remains an open question. Some providers perform this procedure well into the second trimester. Cochrane recently published a review of trials examining medical regimes for terminating pregnancies between twelve and

The difference between 49 and 63 days is significant. Both time periods start from the first day of the woman's last menstrual period. This is another area where clarification will be helpful, but it is roughly understood 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. This is not much time. Even when the two weeks allowed by the evidence-based regime are added, logic forces the conclusion that the time window has closed before many women are even aware of their pregnancy.

For any woman who wants a medical abortion between 49 and 63 days, a requirement to comply with the Mifeprex FPL would represent an insurmountable obstacle imposed for no reason. Red River estimates that almost half of its medical abortion patients fall into this category. Kromenaker aff. ¶ 7. Moreover, for some of those women a surgical abortion would not be a viable or acceptable option.

e. Summary

In summary, from a medical or therapeutic standpoint, it appears a requirement for adherence to the Mifeprex FPL would have only negative impacts. It would add costs, reduce effectiveness, and increase the incidence of unpleasant side effects. It would make the procedure unavailable to any patient beyond 49 days LMP. The

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twenty-eight weeks. This review seems to conclude that mifepristone and misoprostol continue to be the drugs of choice, and that acceptable results can be achieved well beyond 63 days. At the same time, the odds of an incomplete result, or other complications, do go up over time. Wildschut et al., "Medical Methods for Mid-Trimester Termination of Pregnancy," Cochrane Database of Systematic Reviews 2011, Issue 1, art. no. CD005216, available at http://www.update-software.com/BCP/WileyPDF/EN/CD005216.pdf.

required trip to the clinic for the administration of misoprostol would involve unnecessary inconvenience and expense for all women, put some in dangerous and untenable predicaments, and force many more to experience the process of expulsion in a car or some equally inappropriate location. The legislative mandate that physicians follow this badly 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.[75] It would also foreclose further advances in evidence-based medicine. If the legislature is going to involve itself with the practice of medicine, it should do a better job than this.

As compliance with the mifeprex FPL appears to serve no legitimate interest, and to impose only adverse impacts on women's health, any such requirement is highly unlikely to withstand review under either the strict scrutiny or undue burden standard.

Conclusion

Therefore, there is a substantial likelihood the amendments are unconstitutional under both the state and federal charters. This is true regardless of the standard of review applied. Although the burden would not be the same in all cases, it would be unnecessary and undue in every case. Moreover, no amount of judicial surgery is likely to achieve a constitutional interpretation. These conclusions weigh heavily in favor of a temporary injunction.

[75] Ironically, a different provision in the North Dakota Abortion Control Act makes it criminal for any physician performing abortions not to follow "medical standards." N.D. Cent. Code § 14-02.1-04(1).

In light of the determination that MKB is likely to prevail on the merits of its primary constitutional challenge, the remaining arguments have no immediate significance. A temporary injunction is appropriate if the moving party is likely to prevail on any of its claims. Accordingly, resolution of the alternative constitutional challenges mounted by plaintiffs will be deferred until after the trial.

Remaining Factors

The remaining Dataphase factors can be quickly addressed. In large part, the proper weighing of these factors is necessarily determined by the conclusions already outlined.

1. Irreparable Harm

The loss of constitutional freedoms "unquestionably constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976). No further showing is necessary. 11A Wright, et al, Federal Practice and Procedure, § 2948.1, p. 161 (2d ed. 1995). Therefore, the threatened violation of a woman's constitutional right to have an abortion mandates a finding of irreparable injury because "once an infringement has occurred it cannot be undone ... ." Deerfield Med. Ctr. v. City of Deerfield Beach, 661 F.2d 328, 338 (5th Cir. 1981). Because enforcement of the amendments will likely deprive women of fundamental constitutional rights, or at least impose undue burdens on their ability to exercise those rights, it necessarily follows that the threat of irreparable injury weighs heavily in favor of continuing the injunction. Daugaard, 799 F. Supp. 2d at 1076-77.

2. Balance of Harms

The competing harms are easy to identify. If the stay should be improperly lifted, many women will be deprived of rights guaranteed to them by the state and federal constitutions. Conversely, if an unwarranted injunction is maintained defendants will be prevented from carrying out their official duties. Id. at 1077. In order to balance these harms, it is necessary to also consider "the nature of the parties' interests that are at stake ... ." Id.

The individual interests at stake are both fundamental and constitutional. Although the state has an interest in protecting women's health when necessary, the relative safety and efficacy of the procedure appears to give the state little valid interest in the regulation of medical abortions. The means chosen by the state to advance its interests have nothing apparent to commend them. Therefore, a balancing of the potential harms weighs in favor of continuing the injunction.

3. Public Interest

There is clearly much irony attached to this factor when the subject matter is abortion. Many members of the public are interested only in banning all or most abortions. Whatever my personal views may be, however, I must view the public interest in the light of the constitutional protections I have taken an oath to preserve.

When put in these terms, the correct answer is clear. The public's interest in the protection of constitutional rights is of the highest order. Phelps-Roper v. Nixon, 509 F.3d 480, 485 (8th Cir. 2007). The public's interest in enforcement of duly enacted laws is not of the same magnitude. Daugaard, 799 F. Supp. 2d at 1077. This factor also weighs heavily in favor of a temporary injunction.

Order

Accordingly, it is hereby ordered:

1. Any further consideration of plaintiffs' motion in limine will be deferred.
2. Plaintiffs' motion for summary judgment is denied.
3. DOH's motion for summary judgment is denied.
4. At trial, the facts specified on pages 17 and 18 of this opinion will be treated as established, without the need for any further evidence or support.
5. During the pendency of these proceedings, defendants shall continue to be enjoined from enforcing the amendments.
6. A Rule 16 scheduling conference will be held on March 16, 2012, commencing at 1:30 p.m (CST). This will be primarily intended to address trial preparation and readiness. Counsel may participate telephonically by making appropriate advance arrangements through the calendar control clerk, Gladys Schmidt (701)451-6942.

Dated this 16th day of February, 2012.

/s/ Wickham Corwin
Wickham Corwin
District Judge