MIFEPRISTONE PROTOCOL LEGISLATION— THE ANTI-CHOICE MOVEMENT'S DISINGENUOUS METHOD OF ATTACK ON THE REPRODUCTIVE RIGHTS OF WOMEN AND HOW COURTS SHOULD RESPOND

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INTRODUCTION

In the past decade, five states have passed laws prohibiting the off-label use of the abortion-inducing drug mifepristone.[1] While these laws are ostensibly passed to protect women from misuse of a dangerous drug, in actuality they represent one of the latest steps in the anti-choice movement's efforts to dismantle the abortion right iterated in *Roe v. Wade*[2] and controlled by *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[3] These laws prevent doctors from practicing evidence-based medicine in the manner that they believe best serves their patients, and cost women time and money while potentially

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1 Mifepristone is also known as RU-486, Mifeprex, and Early Option. As of April 29, 2014, these states are Arizona, North Dakota, Ohio, Oklahoma, and Texas.

2 Roe v. Wade, 410 U.S. 113, 153 (1973) ("This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.").

3 Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 837 (1992) ("To protect the central right recognized by *Roe* while at the same time accommodating the State's profound interest in potential life, the undue burden standard should be employed. An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place substantial obstacles in the path of a woman seeking an abortion before the fetus attains viability.").

exposing them to unnecessary side effects and risks. In addition, these laws force[4] women with pregnancies of forty-nine to sixty-three days of gestation to undergo surgical abortions when medical abortions would be equally appropriate. As with most anti-choice initiatives, the women who are the most affected are those who are most vulnerable.[5] Women without economic or family resources, those in abusive relationships, and teenagers, who often discover their pregnancies later than adult women, are required to undergo unnecessary surgical procedures and spend money and time that they cannot afford because of politically-motivated legislation without a legitimate medical rationale.

Courts examining mifepristone-regulating legislation have come to different conclusions. Two state courts have addressed these laws and determined that they are unconstitutional: Judge Wickham Corwin of North Dakota's East Central Judicial District enjoined North Dakota's law requiring adherence to the Federal Drug Administration (FDA) protocol pending further proceedings,[6] and the Supreme Court of Oklahoma held that Oklahoma's FDA protocol law was unconstitutional under *Casey*.[7] This issue has also come up in federal court. In a constitutional challenge to Ohio's ban on off-label use of mifepristone, a Sixth Circuit panel affirmed the state's motion for summary judgment on Planned Parenthood's claims that the law was unconstitutionally vague, violated patients' right to bodily integrity, and that it posed an undue burden to women seeking an abortion in the state of Ohio.[8]

On June 27, 2013, the Supreme Court granted certiorari to decide whether Oklahoma's

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4 Ohio argues that women are not forced to undergo surgical abortions because they can choose to carry the pregnancy to term. The Sixth Circuit discussed this rationale in *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 506–08 (6th Cir. 2012).

5 Sylvia A. Law & Rachael N. Pine, *Envisioning a Future for Reproductive Liberty: Strategies for Making the Rights Real*, 27 HARV. C.R.-C.L. L. REV. 407, 443 (1992).

6 MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205 (Cass Cnty. Ct. N.D. 2012), *available at* http://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20(2).pdf.

7 Okla. Coal. for Reprod. Justice v. Cline, 292 P.3d. 27, 28 (Okla. 2012), *cert. granted*, 133 S. Ct. 2887 (2013), *certified question answered*, 313 P.3d 253 (Okla. 2013), *cert. dismissed as improvidently granted*, 134 S. Ct. 550 (2013).

8 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 494. Since this Note was written, the Fifth Circuit has reversed a stay pending appeal of Texas's 2013 abortion law, H.B. 2, including a mifepristone protocol section. The mifepristone protocol legislation is currently in effect in Texas. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 734 F.3d 406, 409 (5th Cir. 2013), *aff'd*, No. 13A452, 2013 WL 6080269 (U.S. Nov. 19, 2013) (denying petitioner's request to vacate the stay).

mifepristone protocol legislation violates the constitution under *Casey*.[9] Due perhaps to re-election concerns in a state with strong anti-choice leanings,[10] the Supreme Court of Oklahoma was very succinct in the opinion being appealed. In affirming the trial court's determination that the law was unconstitutional, the Oklahoma Supreme Court did not fully explain its reasoning, but instead wrote briefly that the "matter is controlled by the United States Supreme Court decision in *Planned Parenthood v. Casey*" and "this Court is duty bound by the United States and the Oklahoma Constitutions to 'follow the mandate of the United States Supreme Court on matters of federal constitutional law.'"[11] The United States Supreme Court sought clarification from the Oklahoma Supreme Court on the breadth of H.B. No. 1970, Section 1, Chapter 216, O.S.L. 2011, the Oklahoma mifepristone protocol law, before proceeding with the case,[12] and dismissed the writ of certiorari as improvidently granted after the answer was received.[13] Because the Oklahoma opinion is so brief, this Note focuses on the Sixth Circuit and North Dakota opinions in more detail because they fully set forth the constitutional reasoning of courts upholding and striking down mifepristone protocol legislation.

This Note argues that courts should strike down legislation restricting mifepristone use to the FDA protocol because it fails rational basis review, the lowest standard for judging legislation.[14] There is no evidence that the protocol approved by the FDA is any safer for women than the protocol currently being used by abortion providers, and the risks from mifepristone are lower than those of many other medications commonly prescribed off-label. While it is within a state's police power to regulate the practice of medicine within its borders, it is not permissible for it to use this power to punish a politically unpopular group of people (in this case pregnant women seeking abortions) without a rational justification.[15]

Following this introduction, I will examine the positive and negative ways that courts

9 SUPREME COURT, ORDER LIST: 570 U.S. (June 27, 2013), *available at* http://www.supremecourt.gov/orders/courtorders/062713zr_c0nd.pdf [hereinafter ORDER LIST].

10 *Widening Regional Divide over Abortion Laws*, PEW RESEARCH CTR. FOR THE PEOPLE & THE PRESS (July 29, 2013), http://www.people-press.org/2013/07/29/widening-regional-divide-over-abortion-laws/.

11 *Cline*, 292 P.3d at 27–28.

12 ORDER LIST, *supra* note 9.

13 Cline v. Oklahoma Coal. for Reprod. Justice, 134 S. Ct. 550 (2013).

14 I have chosen to use rational basis review for analysis in this Note because if the statute does not pass rational basis review, it certainly will not pass possible intermediate or strict scrutiny.

15 Perry v. Brown, 671 F.3d 1052, 1082 (9th Cir. 2012).

have reacted to mifepristone protocol legislation and explain why these decisions are important for women's reproductive rights beyond medical abortions. Part I explains the history of mifepristone's approval and use in the United States. Legislation regulating the use of mifepristone is discussed in Part II. Part III outlines the judicial response to mifepristone protocol legislation, while Part IV explains why this type of legislation fails rational basis review. Finally, the significance of this type of legislation and judicial responses is described in the conclusion.

I. Mifepristone Use in the United States

Mifepristone is a drug used in combination with misoprostol to induce abortions.[16] It began to be used widely in Europe in the 1980s, and the FDA approved it for use in America in 2000. There was much debate in the United States about mifepristone prior to its approval, and the anti-choice movement fought vociferously to prevent its approval as an abortion agent.[17] Mifepristone is taken in pill form and blocks the hormone progesterone. This breaks down the lining of the uterus. Two to three days after taking mifepristone, misoprostol is taken to expel the fetus. Most women abort within hours of taking the misoprostol, and according to Planned Parenthood's literature, ninety-seven percent of patients abort within days. If there are complications or the fetus is not expelled, a surgical abortion is necessary.[18]

The FDA has not mandated that abortion providers prescribe mifepristone exactly according to agency specifications. When the FDA approved mifepristone for medical abortions, the agency considered mandating that it be prescribed strictly according to the FDA recommendation, but this requirement was never created.[19] The final labeling includes the language, "medicines are sometimes prescribed for purposes other than those listed in a [medication guide]."[20] The regimen that the FDA approved was 600 mg of mifepristone

16 *The Abortion Pill (Medication Abortion)*, PLANNED PARENTHOOD, http://www.plannedparenthood.org/health-topics/abortion/abortion-pill-medication-abortion-4354.asp (last visited Apr. 6, 2014) [hereinafter *The Abortion Pill*].

17 *RU-486, Nearing Approval*, N.Y. TIMES (July 23, 1996), *available at* http://www.nytimes.com/1996/07/23/opinion/ru-486-nearing-approval.html; Margaret Talbot, *The Little White Bombshell*, N.Y. TIMES (July 11, 1999), *available at* http://www.nytimes.com/1999/07/11/magazine/the-little-white-bombshell.html.

18 *The Abortion Pill*, *supra* note 16.

19 Gillian E. Metzger, *Abortion, Equality, and Administrative Regulation*, 56 EMORY L.J. 865, 879 (2007).

20 Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, Planned Parenthood Cincinnati Region v. Taft, 337 F. Supp. 2d 1040 (S.D. Ohio 2004) (No. 1:04CV493), 2004 WL 2255762; *MEDICATION*

followed by 400 mcg of misoprostol taken orally in a doctor's office. In studies, this regime was shown to be effective up to forty-nine days of gestation.[21]

Due to politically motivated delays and protests orchestrated by the anti-choice movement, by the time that the FDA approved use of mifepristone, the FDA regimen was no longer considered the state-of-the-art method of using the drug. Since it began prescribing the drug, Planned Parenthood and other providers across the country have used an alternative evidence-based protocol (200 mg of mifepristone followed by 800 mcg of misoprostol).[22] This regime is effective up to sixty-three days of gestation and actually has a better success rate at sixty-three days (more than 98%) than the FDA regimen does at forty-nine days (92%).[23] As Planned Parenthood's Reply Brief in the Ohio case summarizes, "every study that has considered the evidence-based regimen followed by the plaintiff clinics concluded that medical abortion is highly safe and effective up to [nine] weeks."[24] In addition to being effective two weeks longer than the FDA regime, the regime preferred by Planned Parenthood and other abortion providers also eliminates extraneous amounts of mifepristone, which can lead to fewer side effects, gives women greater control over the timing and location of their abortion, eliminates a doctor visit, and costs less for women choosing medical abortions and medical abortion providers.[25] The World Health Organization, the American College of Obstetricians and Gynecologists, and the Royal College of Obstetricians and Gynecologists all endorse this method of performing medical abortions.[26] Overall, 96% of medical abortions in the United States are performed using the

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GUIDE Mifeprex® (MIF-eh-prex) (mifepristone), FDA (2009), http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf.

21 *MIFEPREX™ (mifepristone) Tablets, 200 mg For Oral Administration Only*, FDA, http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf (last visited Apr. 16, 2014) (label after approval in 2000).

22 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 495 (6th Cir. 2012).

23 Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, *supra* note 20; Brief of Plaintiffs-Appellants at 14–15, Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490 (6th Cir. 2012) (No. 11-4062). Memorandum Contra of Defendants at 3, Planned Parenthood Cincinnati Region v. Taft, 337 F. Supp. 2d 1040 (S.D. Ohio 2004) (No. 1:04CV493), 2002 WL 32673929.

24 Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, *supra* note 20.

25 Brief of Plaintiffs-Appellants, *supra* note 23, at 13–14.

26 *Id.* at 12.

alternative protocol.[27]

It is not unusual, necessarily dangerous, or underhanded for abortion providers to use mifepristone off-label. In fact, "[t]he *Food and Drug Law Journal* estimated in 2003 that off-label uses account for between 25 and 60 percent of all prescriptions in the United States."[28] Once a drug is approved, it is approved for any use, not just those tested by the FDA.[29] Off-label use is important for a number of reasons. These reasons include that off-label methods often represent the "'best practice' standard of care," that it is not financially possible or useful for the FDA to approve drugs for use in all possible situations, and that physician autonomy is an important aspect of the practice of medicine.[30] In 1994 congressional testimony, physician and former editor of *The Journal of the American Medical Association* George Lundberg stated: "For a product to have the most effective potential benefits, law and regulation . . . must follow, not precede, science."[31] According to one American Medical Association officer: "[I]n some cases, if you didn't use the drug in the off-label way you'd be guilty of malpractice."[32] While using mifepristone according to the FDA label does not necessarily rise to the level of malpractice, it is certainly out of

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27 Brief in Opposition at 4, Cline v. Okla. Coal. for Reprod. Justice, No. 12-1094, 2013 WL 2352228 (U.S. May 28, 2013).

28 Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1160 (2005). The very wide range cited in this quote reflects the fact that off-label usage of drugs is not closely tracked by the FDA and varies widely across different fields of medicine. For example, most drugs are not tested on children, so the majority of pediatric prescriptions are off-label. *See also* David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-label Prescribing Among Office-Based Physicians*, 166 ARCH INTERN MED. 1021 (2006), *available at* http://archinte.jamanetwork.com/article.aspx?articleid=410250 ("In 2001, there were an estimated 150 million (95% confidence interval, 127–173 million) off-label mentions (21% of overall use) among the sampled medications. Off-label use was most common among cardiac medications (46%, excluding antihyperlipidemic and antihypertensive agents) and anticonvulsants (46%), whereas gabapentin (83%) and amitriptyline hydrochloride (81%) had the greatest proportion of off-label use among specific medications. Most off-label drug mentions (73%; 95% confidence interval, 61%–84%) had little or no scientific support. Although several functional classes were associated with increased off-label use ($P<.05$), few other drug characteristics predicted off-label prescription.").

29 Fox, *supra* note 28, at 1164.

30 *Id.* at 1165–66.

31 *Id.* at 1165.

32 Amy E. Todd, *No Need for More Regulation: Payors and Their Role in Balancing the Cost and Safety Considerations of Off-Label Prescriptions*, 37 AM. J.L. & MED. 422, 425 (2011).

step with the established standard of care across the nation.

There is no known evidence that the FDA protocol will protect women's health, and it is potentially harmful to women to force them to use it against the best medical judgment of their doctors. First, it requires three times more mifepristone than most doctors believe is necessary. While no one is alleging that this dosage is unsafe, it possibly exposes women to an increased risk of side effects, forces them to ingest an extra amount of a drug that is serving no medical purpose, and costs them hundreds of extra dollars.[33] In the Sixth Circuit, Ohio argued that Planned Parenthood's objection to the increased dosage of mifepristone was misleading because the alternative protocol they prescribe uses a higher dosage of misoprostol than the FDA protocol.[34] This argument misses the point of Planned Parenthood's objection—the problem is not the extra dosage, it is the fact that it is not medically required or recommended. Taking more misoprostol, unlike more mifepristone, is scientifically believed to make the medical abortion safer and more effective.[35]

Second, taking the extra mifepristone costs women hundreds of extra dollars. The Sixth Circuit panel in *DeWine* dismissed this extra cost because surgical abortion is a less expensive alternative,[36] but this should not have been rejected as there is no rational reason why the procedure is being made more expensive. The states that have passed these laws are, in essence, compelling poorer women to choose an invasive procedure that they would prefer to avoid because the legislature has decided that women who choose medical abortions must ingest drugs that serve no medical purpose and potentially cause side effects and other harm. Poorer women will be disproportionately pushed by these laws into having surgical rather than medical abortions because of the increased cost of medical abortions under the FDA protocol.[37] Women prefer medical to surgical abortions for many reasons: it feels more "natural," they have more control over timing, it is less intimidating than

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33 Brief of Plaintiffs-Appellants, *supra* note 23, at 13–14; Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 497 (6th Cir. 2012).

34 Brief of Defendant-Appellee at 35, Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490 (6th Cir. 2012) (No. 11-4062).

35 Interview with Doctor Rebecca Taub, Or. Health & Sci. Univ. Hosp. (Mar. 19, 2013) ("Misoprostol is a prostaglandin analog which causes cervical ripening and uterine contractions, so [using 800 mcg versus 400 mcg] makes it more likely the abortion will be complete.").

36 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 516.

37 *Id.* (quoting affidavit submitted in support of Planned Parenthood: "If a medication abortion were offered at a price that was $100–$200 higher than a surgical abortion, it would be really difficult for me. I am not certain I would be able to still choose medication, though I would try to raise more money, because it would

a surgical procedure, it can be less traumatic,[38] and it can be disguised as an unintended miscarriage.[39] It is wrong that some women cannot afford this option because the state has arbitrarily increased the cost.

Third, the FDA protocol requires that a woman make an extra visit to the doctor's office to take the misoprostol under supervision. This means that women in the states that have passed mifepristone protocol legislation must make four visits to a doctor for their medical abortion, only two of which are medically indicated. Under the alternative protocol followed by nearly all abortion providers, women take misoprostol at home following their doctor's instructions. Two weeks after taking the misoprostol (assuming no complications), she then goes to the abortion provider or another, more convenient, doctor to make sure that the pregnancy was terminated.[40] This extra doctor's visit to take the misoprostol in her abortion provider's office is a big inconvenience for many women, especially those who live in rural areas or want to keep their abortion private.[41] Before these protocol laws were enacted in Arizona, North Dakota, Ohio, Oklahoma, and Texas, women already had to make at least three visits to an abortion provider to obtain a medical abortion. These states have a twenty-four hour waiting period, so women seeking abortions were required to make a preliminary visit to their abortion provider for options counseling and learning about the procedure.[42] After twenty-four hours, a woman could return to the clinic to receive the medications necessary for the medical abortion and be given instructions for their use. Two weeks after the misoprostol was taken, the woman would then return to her doctor. The FDA protocol requires an additional visit to take the misoprostol approximately forty-eight hours after the mifepristone.[43] This extra visit is not only inconvenient, potentially dangerous for women in abusive relationships and teenagers, and possibly enough of a time commitment that it will force some women to choose surgical abortions which require one less office visit. It also puts women at medical risk by creating a significant potential

be worth a lot to me.").

38 Brief of Plaintiffs-Appellants, *supra* note 23, at 18.

39 *What are the Advantages of the Abortion Pill?*, EARLY OPTIONS BLOG (Jun. 26, 2012, 10:15 AM), http://info.earlyabortionoptions.com/blog/bid/174780/What-are-the-advantages-of-the-Abortion-Pill.

40 *The Abortion Pill*, *supra* note 16.

41 Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 885–86 (1992) (the Court ultimately concluded that the burden posed by a waiting period was not "undue").

42 STATE POLICIES IN BRIEF: COUNSELING AND WAITING PERIODS FOR ABORTION, GUTTMACHER INSTITUTE (2014), http://www.guttmacher.org/statecenter/spibs/spib_MWPA.pdf.

43 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 495 (6th Cir. 2012).

that they will miscarry on their drive home from the abortion provider's office instead of at home or another safe place.[44]

Fourth, the FDA protocol recommends that mifepristone be used for abortions only up to forty-nine days of gestation, while providers using the alternative evidence-based protocol were providing medical abortions up to sixty-three days of gestation.[45] As stated earlier, the alternative protocol was shown to be as safe and effective at sixty-three days as the FDA protocol at forty-nine days.[46] Therefore, women who have pregnancies of seven to nine weeks are being denied the option of a medical abortion without justification. Medical and surgical abortions are both effective and safe, but women often prefer one or the other and should not be denied their preference without reason.

Lastly, there are women with conditions that make surgical abortions inappropriate or impossible. These 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

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44 MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205, at 82–83 (Cass Cnty. Ct. N.D. 2012), *available at* http://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20(2).pdf; Mary Tuma, *Texas Abortion Drug Bill Could Mean More Side Effects and Higher Costs*, AM. INDEP. (Dec. 19, 2012), http://rhrealitycheck.org/article/2012/12/19/texas-abortion-drug-bill-could-mean-more-side-effects-and-higher-costs/ ("Texas OB-GYN and abortion provider Dr. Bernard Rosenfeld says the FDA guideline requiring women to take the misoprostol in a clinic was meant to standardize a variable in the trial and that several subsequent studies have shown women can safely take it at home. Rosenfeld, who has practiced medicine for more than three decades, says the rule goes against 'good medical practice' and advises all his patients to take the pills at home. 'There is zero medical basis or benefit to take the pills in the clinic,' he said. 'To make a woman come back to the doctor's office and then find a way to get back home after taking the drug is really just mean and cruel and puts them at medical risk . . . It's really just meant to give women a hard time[.]'").

45 Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, *supra* note 20. Brief of Plaintiffs-Appellants, *supra* note 23, at 13.

46 Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, *supra* note 20.

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.[47]

Ohio argued that medical abortions should not be used for these women after forty-nine days and that the ban on medical abortions past forty-nine days of gestation is not harmful because the medications only have a 77% to 83% success rate after forty-nine days (using the FDA protocol).[48] In effect, the state is arguing that doctors should go straight to hysterectomy before attempting a medical abortion after forty-nine days for women for whom surgical abortion is precluded because an outdated treatment method creates a significant risk of failure. This is an absurd argument because hysterectomy abortion is serious surgery that can be avoided most of the time through medical abortions.[49] The alternative protocol used by Planned Parenthood and the vast majority of other abortion providers has a success rate of over 98% at sixty-three days.[50] Ohio's position on this issue illustrates a complete lack of respect for the health and bodily integrity of its female citizens.

II. Mifepristone Protocol Legislation

In 2004, Ohio became the first state to pass mifepristone protocol legislation. Ohio's legislature passed Ohio Rev. Code § 2919.123, which regulates abortion providers.[51] The relevant section reads:

> (A) No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the RU-486 (mifepristone) is a physician, the physician satisfies all the criteria

47 *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 65.

48 Memorandum Contra of Defendants, *supra* note 23.

49 *Id.*

50 Brief of Plaintiffs-Appellants, *supra* note 23, at 14–15.

51 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 496 (6th Cir. 2012).

> established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions. A person who gives, sells, dispenses, administers, otherwise provides, or prescribes RU-486 (mifepristone) to another as described in division (A) of this section shall not be prosecuted based on a violation of the criteria contained in this division unless the person knows that the person is not a physician, that the person did not satisfy all the specified criteria established by federal law, or that the person did not provide the RU-486 (mifepristone) in accordance with the specified provisions of federal law, whichever is applicable.[52]

The statute criminalizes prescribing the abortion-causing drug mifepristone in any way that does not comply with federal law. While on its face this seems to be a reasonable regulation created to protect women from dangerous uses of a drug, in actuality, it forbids doctors from using the medically preferred method of prescribing mifepristone,[53] exposes women to three times the necessary dosage of the drug, potentially causes them to suffer more side effects, costs them hundreds of unnecessary dollars, requires an unneeded visit to a doctor's office,[54] and increases the likelihood that a woman will have an abortion in her car on the way home from the doctor's office instead of at home or another safe place of her choosing.[55]

This law was passed in the aftermath of deaths that were attributed by the media to medical abortions.[56] In all, fourteen of the 1.52 million women who chose medical abortions between FDA approval of mifepristone in 2000 and April 2011 died from infections.[57]

52 OHIO REV. CODE ANN. § 2919.123 (West 2013).

53 The majority of abortion providers believe that using the *Schaff* protocol (200 mg of Mifepristone followed by 800 mcg of Misoprostol) is better than the FDA protocol (600 mg of Mifepristone followed by 400 mcg of Misoprostol) for patients. *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 496.

54 Brief in Opposition, *supra* note 27, at 4.

55 MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205, at 82–83 (Cass Cnty. Ct. N.D. 2012), *available at* http://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20(2).pdf.

56 Steven R. Kochheiser, *B. Abortion Regulation,* Cordray v. Planned Parenthood Cincinnati Region, 36 OHIO N.U.L. REV. 1131, 1142 (2010).

57 *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011*, FDA (Apr. 30,

This rate is very low. A woman has a 0.00000921052% chance of dying from a medical abortion according to this statistic,[58] compared to an overall maternal mortality rate of 0.000161% in the United States.[59] This means that a woman is significantly safer having a medical abortion than carrying a pregnancy to term. If there is a connection between the drug and the deaths, it is not clear that the FDA method would have prevented them. The FDA investigated the deaths and found no "causal relationship" between the use of the drugs and the deaths.[60] Following the deaths, Planned Parenthood shifted its practice and began prescribing mifepristone to be taken orally or buccally, between the cheek and gums, instead of vaginally.[61]

Further evidence that the mifepristone protocol legislation is not motivated out of a concern for women's health comes from its origins. The Chicago-based anti-choice group Americans United for Life (AUL) drafted FDA protocol legislation that state legislatures have now passed as part of a comprehensive strategy to end all access to abortion in America. The organization describes itself as "the nation's premier pro-life legal team, work[ing] through the law and legislative process to one end: Achieving comprehensive legal protection for human life from conception to natural death."[62] This work is partially achieved by providing legislators with ready-to-use model bills that can be introduced to

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2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf/ [hereinafter *Mifepristone U.S. Postmarketing*].

58 *Id.* (Not all of these deaths were clearly related to the medical abortion. "All but one fatal sepsis case reported vaginal misoprostol use; buccal misoprostol use was reported in one case. The six remaining U.S. deaths involved unique events; there was one case each of substance abuse/drug overdose, methadone overdose, suspected homicide, and a delayed onset of toxic shock-like syndrome . . . and there were two cases of ruptured ectopic pregnancy. There were five additional deaths in women from foreign countries [non-US] who used mifepristone for termination of pregnancy. These included one death associated with septic shock . . . and four deaths identified from post-marketing data that were associated with a ruptured gastric ulcer, uterine hemorrhage, 'multivisceral failure' and thrombotic thrombocytopenic purpura leading to intracranial hemorrhage, respectively.").

59 *U.S. Health Law May Curb Rising Maternal Deaths*, FORBES (July 30, 2012), http://www.forbes.com/sites/womensenews/2012/07/30/u-s-health-law-may-curb-rising-maternal-deaths/. The risk of death from mifepristone is also lower than that from using penicillin. Brief in Opposition, *supra* note 27, at 7 n.3.

60 Brief in Opposition, *supra* note 27, at 20.

61 Gardiner Harris, *After Two More Deaths, Planned Parenthood Alters Method for Abortion Pill*, N.Y. TIMES (Mar. 18, 2006), *available at* http://www.nytimes.com/2006/03/18/national/18abort.html.

62 *About*, AMS. UNITED FOR LIFE, http://www.aul.org/about-aul/ (last visited Apr. 6, 2014).

advance the anti-choice agenda:

> We are continually working to help legislators enact new pro-life laws that will go into effect and not be unnecessarily tied up in court so they can save lives today while continuing to roll back *Roe v. Wade* in the courts. To do that, we educate legislators on the issues and provide them with model legislation and legal advice on legislative language. We work hand-in-hand with legislators to minimize avoidable problems so activist judges can't easily tie a good law up for years in court or strike it down completely.[63]

According to the introduction to AUL's "Abortion-Inducing Drugs Safety Act," variance from the FDA protocol is motivated by greed: "Abortion providers misuse the Mifeprex regimen because it is more convenient—and more profitable. By providing it to women through [sixty-three] days from the last menstrual period (LMP) and sending them home to ingest misoprostol (the second drug) alone, abortion providers can charge more women for abortions, increasing their profits exponentially."[64] The legislation passed in states across the country and challenged in the Supreme Court is nearly identical to AUL's "Abortion-Inducing Drugs Safety Act."

The next mifepristone protocol laws were passed by Oklahoma and North Dakota in 2011. The relevant portion of Oklahoma's law states:

> C. No physician who provides RU-486 (mifepristone) or any abortion-inducing drug shall knowingly or recklessly fail to provide or prescribe the RU-486 (mifepristone) or any abortion-inducing drug according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any

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63 *Legislation*, AMS. UNITED FOR LIFE, http://www.aul.org/legislative-resources/ (last visited Dec. 3, 2013).

64 *Abortion-Inducing Drugs Safety Act (RU-486 & Response to "Telemed" Abortions)*, AMS. UNITED FOR LIFE, http://www.aul.org/wp-content/uploads/2012/11/Abortion-Inducing-Drugs-Safety-Act-2013-LG.pdf (last visited Apr. 6, 2014).

abortion-inducing drug.[65]

The corresponding section of the North Dakota law is very similar, though wordier:

> 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, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes 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.[66]

These laws are broader than that passed by Ohio in 2004, and potentially bar all medical abortions instead of just limiting mifepristone abortions. As discussed above, mifepristone is used in conjunction with misoprostol to cause abortions in both the FDA and alternative evidence-based protocols. However, misoprostol has not been approved by the FDA for this use, and thus is being used off-label. In addition, doctors use the drug methotrexate off-label to end dangerous ectopic pregnancies.[67]

This technical bar on all medical abortions appears to be a drafting error and the Supreme Court certified a question to the Oklahoma Supreme Court asking for a clarification of the meaning of the Oklahoma statute before hearing arguments in *Cline*.[68] On October 29, 2013, the Supreme Court of Oklahoma responded:

> The plain language of the statute and the manner in which H.B. 1970 restricts the long-respected medical discretion of physicians in the specific context of abortion compels an affirmative answer to both of the questions asked, a position entirely consistent with our decision to affirm the ruling of the district court: H.B. 1970 prohibits the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration

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65 Abortion–Inducing Drugs Safety Act, OKLA. ST. ANN. tit. 63, § 1-729a (West 2013).

66 N.D. CENT. CODE ANN. § 14-02.1–03.5 (West 2013).

67 Brief in Opposition, *supra* note 27, at 10.

68 ORDER LIST, *supra* note 9.

and prohibits the use of methotrexate to treat ectopic pregnancies.[69]

A broad ban of this nature is patently unconstitutional under existing precedent. The United States Supreme Court dismissed the writ for certiorari as improvidently granted after receiving this answer.[70]

Arizona followed North Dakota and Oklahoma, passing its own broad legislation in 2012. The pertinent section of Arizona's law, Section 36-449.03, Arizona Revised Statutes, requires "that any medication, drug or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the United States food and drug administration and that is outlined in the final printing labeling instructions for that medication, drug or substance."[71] Due to the legislative similarities, the legal analysis of any of these three laws can be used to better understand the others.

The Texas legislature broke from the North Dakota, Oklahoma, and Arizona model in drafting its 2013 legislation, H.B. 2.[72] It allows abortion providers to follow either the FDA protocol *or* the alternative evidence-based dosage advocated by the American College of Obstetricians and Gynecologists so long as the drugs are prescribed according to the methods of the FDA protocol.[73] In addition, it excepts the use of such drugs in the case of ectopic pregnancies from the regulation. This law appears to respond to the judicial evaluations of North Dakota and Oklahoma's laws by addressing many of the judges' concerns, discussed below.

III. Mifepristone Protocol Legislation in Federal and State Courts

After Ohio Rev. Code § 2919.123 was passed in 2004, Planned Parenthood, through its Ohio regional offices and two of its doctors, brought a suit in federal court to enjoin the statute from being enforced. Planned Parenthood challenged the statute on four constitutional grounds: vagueness, Fourteenth Amendment bodily integrity, undue burden,

69 Cline v. Oklahoma Coal. for Reprod. Justice, 313 P.3d 253 (2013).

70 Cline v. Oklahoma Coal. for Reprod. Justice, 134 S. Ct. 550 (2013).

71 ARIZ. REV. STAT. ANN. § 36-449.03 (2013).

72 TEX. HEALTH & SAFETY CODE ANN. § 171.063 (West 2013).

73 *Id.* This means that the choice does not actually exist, since the FDA protocol requires taking the pills orally, whereas as the pills are taken buccally in the alternative protocol. Consequently, doctors will be forced to provide medical abortions according to the FDA protocol, even though there is, on paper, a reasonable choice about dosage.

and the Fourteenth Amendment right to health and life.[74] The district court, in *Planned Parenthood Cincinnati Region v. Taft*,[75] enjoined the Act from being enforced because it lacked a health or life exception.[76] The court of appeals affirmed the injunction pending further proceedings.[77] After much litigation, the district court granted the defendants' motion for summary judgment on the first three of the plaintiffs' claims.[78] The plaintiffs appealed this ruling under Federal Rule of Civil Procedure 54(b).[79]

A three-judge panel of the Sixth Circuit affirmed the district court's grant of summary judgment with one dissent on the question of whether summary judgment was appropriate to decide whether the legislation posed an undue burden on women seeking an abortion in Ohio.[80] The question of whether the statute violates women's right to health and life under the Fourteenth Amendment is still awaiting trial in the district court.[81]

Judge McKeague, writing for the majority on the undue burden inquiry, held that the law did not create an undue burden because women could still get an abortion, just not an abortion of their choosing.

> I agree with the common-sense inference that because "the differences between the procedures from the perspective of the woman are substantial," some—maybe even most—women will prefer medical abortion over surgical abortion . . . However, our consideration cannot end there. The abortion right as it has been described by the Supreme Court protects the "freedom to decide whether to terminate" a pregnancy. *Casey*, 505 U.S. at 874. The Court has not extended constitutional protection to a woman's preferred method, or her "decision concerning the method" of terminating a pregnancy. *Benten*, 505 U.S. at 1085 (Stevens, J., dissenting). Therefore,

74 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 494 (6th Cir. 2012).

75 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 499 n.11 ("Bob Taft was the Governor of Ohio at the time, succeeded by Ted Strickland. The parties have since stipulated to the dismissal of the Governor Appellant . . . The lead defendant is now Ohio's Attorney General, Mike DeWine.").

76 Planned Parenthood Cincinnati Region v. Taft, 337 F. Supp. 2d 1040 (S.D. Ohio 2004).

77 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 498–99.

78 *Id.* at 499.

79 FED. R. CIV. P. 54(b).

80 *Planned Parenthood Sw. Ohio Region,* 696 F.3d at 507.

81 *Id.* at 500.

> without any evidence that the Act is a substantial obstacle to the ultimate abortion decision, our own common-sense conclusions about what women may prefer do not create a genuine dispute of material fact.[82]

Judge McKeague rejected the argument that the increased cost of the FDA protocol posed an undue burden because a surgical abortion was a less expensive abortion option available to pregnant women.[83]

According to the Sixth Circuit's logic, any burden, no matter how illogical, placed in the way of pregnant women would be acceptable so long as a safe alternative abortion technique existed and was accessible to women. However, it is not enough that women are able to choose to have an abortion. Legislating against abortion does not give elected representatives the right to put any obstacle in an abortion seeker's path—all legislation must be rationally related to a legitimate state interest.[84]

Mifepristone-regulating statutes have not fared as well in other courts. As discussed above, the Arizona,[85] North Dakota,[86] Texas,[87] and Oklahoma[88] legislatures all passed legislation modeled on AUL's "Abortion-Inducing Drug Safety Act." Mifepristone protocol legislation in North Dakota, Oklahoma, and Arizona has been struck down[89] or enjoined from being enforced.[90]

Judge Corwin of the North Dakota County of Cass District Court has issued the most full-throated opinion in the mifepristone protocol legislation context and enjoined

82 *Id.* at 516.

83 *Id.* at 518.

84 Gonzales v. Carhart, 550 U.S. 124 (2007).

85 ARIZ. REV. STAT. ANN. § 36-449.03 (2013).

86 N.D. CENT. CODE ANN. § 14-02.1–03.5 (West 2013).

87 TEX. HEALTH & SAFETY CODE ANN. § 171.063 (West 2013).

88 Abortion–Inducing Drugs Safety Act, OKLA. ST. ANN. tit. 63, § 1-729a (West 2013).

89 Okla. Coal. for Reprod. Justice v. Cline, 292 P.3d 27 (Okla. 2012), *cert. granted*, 133 S. Ct. 2887 (2013) *certified question answered*, 313 P.3d 253 (Okla. 2013), *cert. dismissed as improvidently granted*, 134 S. Ct. 550 (2013).

90 MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205 (Cass Cnty. Ct. N.D. 2012), *available at* http://reproductiverights.org/sites/crr.civicactions.net/files/documents/MKB%20v%20Burdick%20Order%2021612%20(2).pdf. Although the United States District Court for the Western District of Texas enjoined much of

the North Dakota Abortion Control Act until further proceedings.[91] He evaluated North Dakota's law under strict scrutiny because the legislation infringes on a fundamental right, but his findings would also be applicable under rational basis review because he argues that the legislation is not rationally related to the legitimate state goal of protecting citizens' health.[92] He wrote:

> 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?[93]

He went on to say: "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."[94] The Sixth Circuit failed this duty in *DeWine* when it upheld the district court's grant of summary judgment to the state and held that legislation limiting the use of mifepristone to the FDA protocol did not violate women's right to bodily integrity, did not pose an undue burden, and was not unconstitutionally

H.B. 2, Texas's recent abortion bill, and created a health exception for the medical abortion portion of the bill, the Fifth Circuit Court of Appeals stayed the injunction and narrowed the health exception. "Pending appeal, we stay the injunction in the Final Judgment pertaining to medical abortions with this exception: the district court's injunction continues to apply pending appeal with respect to a mother who is [fifty] to [sixty-three] days from her last menstrual period if the physician who is to perform an abortion procedure on the mother has exercised appropriate medical judgment and determined that, due to a physical abnormality or preexisting condition of the mother, a surgical abortion is not a safe and medically sound option for her." Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, No. 13-51008, 2013 WL 5857853, at *11 (5th Cir. Oct. 31, 2013), *motion to vacate stay denied*, 134 S. Ct. 506 (2013).

91 *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 3.

92 Romer v. Evans, 517 U.S. 620, 631 (1996) (defining rational basis review as "if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the legislative classification so long as it bears a rational relation to some legitimate end").

93 *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 60.

94 *Id.* at 60–61.

vague.[95]

In conclusion, Judge Corwin denied both sides' motions for summary judgment and wrote:

> In summary, from a medical or therapeutic standpoint, it appears a requirement for adherence to the Mifeprex FPL [the FDA protocol] 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 [forty-nine] days LMP. The 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. 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.[96]

He concluded, "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."[97]

Judge Corwin's opinion is quoted extensively here to show what a serious examination of mifepristone-limiting legislation would look like. Corwin's opinion can serve as a roadmap for those fighting such legislation since he methodically outlines the ways in which mifepristone protocol legislation fails to advance a legitimate state goal and how it harms women.

Mifepristone protocol legislation has also been struck down in Oklahoma. On December 4, 2012, the Supreme Court of Oklahoma held that, under *Casey* and the Supremacy Clause,

95 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 499 (6th Cir. 2012).

96 *MKB Mgmt. Corp.*, No. 09-2011-CV-02205, at 84–85.

97 *Id.* at 85.

the Abortion Inducing Drugs Safety Act[98] was unconstitutional.[99] The Act limited the use of mifepristone to the FDA protocol.[100] District Judge Donald Worthington, whose decision was affirmed by the Oklahoma Supreme Court, wrote that the legislative limitation on the use of mifepristone was unconstitutional because it was "so completely at odds with the standard that governs the practice of medicine that [the bill] can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those women who do."[101] As discussed *supra*, the Oklahoma Supreme Court's opinion affirming Judge Worthington is very brief, holding only that the case is controlled by *Casey* and the Supremacy Clause. Their response to the Supreme Court's certified question was more detailed, and focused exclusively on statutory interpretation.[102]

IV. Mifepristone Regulating Legislation Fails Rational Basis Review

Courts generally give legislatures broad discretion to legislate to protect the citizens of their state. In the abortion realm, the statute in question must not present an undue burden to a woman seeking an abortion.[103] Abortion legislation must also, at least, be rationally related to a legitimate state goal, usually protecting fetal life or protecting the woman's health.[104] Mifepristone protocol legislation accomplishes neither of these objectives and does not advance a different state interest, such as respect for human life.[105] It cannot rationally be believed that legislators were really trying to protect women with these laws. Even a member of the Sixth Circuit panel in *DeWine* had doubts about the purpose of the legislature. Footnote seventeen in Judge Moore's partial dissent states:

> Although *Casey* discusses the "purpose or effect" of the challenged legislation, Planned Parenthood does not attempt to argue that Ohio had an illicit purpose in passing the Act and focuses solely on the Act's effects.

98 Abortion–Inducing Drugs Safety Act, OKLA. ST. ANN. tit. 63, § 1-729a (West 2013).

99 Oklahoma Coal. for Reprod. Justice v. Cline, 292 P.3d 27 *cert. granted*, 133 S. Ct. 2887 (2013), *certified question answered*, 313 P.3d 253 (Okla. 2013), *cert. dismissed as improvidently granted*, 134 S. Ct. 550 (2013).

100 Abortion–Inducing Drugs Safety Act, OKLA. ST. ANN. tit. 63, § 1-729a (West 2013).

101 Oklahoma Coal. for Reprod. Justice v. Cline, No. CV–2011–1722, slip op., para. 7 (Dist. Ct. Okla. Cnty. May 11, 2012).

102 Cline v. Oklahoma Coal. for Reprod. Justice, 313 P.3d 253 (2013).

103 Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 837 (1992).

104 Gonzales v. Carhart, 550 U.S. 124, 158 (2007).

105 *Id.* at 163.

> The fact that the Act focuses solely on abortions (and not other off-label uses of mifepristone) certainly raises some eyebrows, but we will not presume a harmful purpose without evidence of an illicit motive.[106]

It appears from the briefs that Planned Parenthood did not allege an illicit purpose in its filings because the case was at the summary judgment stage.[107] Nonetheless, the Sixth Circuit panel erred in not considering whether the ban on off-label use of mifepristone was valid legislation before evaluating it under the undue burden standard. It is not enough that a burden is not "undue," it must also be related to a legitimate state goal in order to pass constitutional muster.

In *Gonzales v. Carhart*, the Supreme Court stated that abortion regulation must be in pursuance of a legitimate state interest. Justice Kennedy wrote: "Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn."[108] Thus, the first step in analyzing abortion legislation is to ask if the legislature had "a rational basis to act." Kennedy elaborated further in saying: "Considerations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends."[109] The opinion also states that "state and federal legislatures [have] wide discretion to pass legislation in areas where there is medical and scientific uncertainty."[110] While *Carhart* sets a low bar for a law to be considered rational in the abortion context, the legislation must still meet such a bar.

Mifepristone protocol laws fail rational basis review. These laws are undoubtedly passed to chip away at women's right to abortion by limiting the time period when a woman can obtain a medical abortion and making a medical abortion more expensive and time consuming. This is an example of the type of incremental strategy advocated by James Bopp, Jr. and Richard E. Coleson in their memorandum on Pro-Life Strategy Issues.[111]

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106 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 507 n.17 (6th Cir. 2012).

107 Brief of Plaintiffs-Appellants, *supra* note 23.

108 *Carhart*, 550 U.S. at 158.

109 *Id.* at 166.

110 *Id.* at 163.

111 Memorandum from James Bopp, Jr. & Richard E. Coleson (Aug. 7, 2007) (on file with author) [hereinafter Bopp Memorandum]; *see also* Caitlin E. Borgmann, *Abortion, the Undue Burden Standard, and*

The strategic minds behind the anti-choice movement realize that fighting to directly overturn *Roe* is a losing battle in today's legal climate. Instead, anti-choice efforts should be focused on chipping away at abortion rights in a manner that does not seem extreme to most Americans.[112] In the words of Ohio's lawyers, "H.B. 126 does nothing more than regulate how mifepristone can be used in the State of Ohio. It does not ban abortion. All it does is require that mifepristone be used in accordance with the indications and protocol that the FDA has studied and found to be safe."[113] Mifepristone protocol legislation is the perfect product of such a strategy. It harms women seeking an abortion without advancing a legitimate state interest, all under the guise of protecting women from harmful use of a powerful drug.[114]

States have justified the mifepristone legislation using the rubric of protecting women. Oklahoma described the impetus behind its protocol law as: "In 2011, the Oklahoma Legislature acted to address this serious health and safety problem."[115] In a Memorandum

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the Evisceration of Women's Privacy, 16 WM. & MARY J. WOMEN & L. 291, 317 (2010). Borgmann states:

> State intrusions on medical decision-making have typically been justified as promoting public health or safety. Few abortion measures, however, can truly be defended as necessary for public health. First, their proponents' clear motive is to hinder abortion access, not to promote women's health. While anti-abortion-rights advocates often cast proposed restrictions as beneficial to women's health and well-being, these claims are mere rhetoric designed to make the restrictions politically more palatable. Second, as discussed below, these restrictions invade women's privacy, do not in fact promote women's health, and may, in some cases, impose serious health risks on women.

Id.

112 Bopp Memorandum, *supra* note 111.

113 Memorandum Contra of Defendants, *supra* note 23.

114 A quintessential example of this strategy of limiting abortion access while seemingly protecting women is a telemedicine bill in Michigan. In June 2012, the Michigan state legislature passed HB 5048 and HB 5421, pro-telemedicine bills hailed by the Governor—"I applaud the Legislature's initiative to use technology to save lives." Mere months later in December, the legislature passed a bill to ban telemedicine only in the context of abortion. This type of legislation is typical of efforts to restrict abortion access under the guise of protecting women from unsafe medical practices. Press Release, Center for Reproductive Rights, Extreme Anti-Choice Legislation to Head to Michigan Governor's Desk (Dec. 12, 2012), http://reproductiverights.org/en/press-room/extreme-anti-choice-legislation-to-head-to-michigan-governors-desk.

115 Petition for a Writ of Certiorari, Cline v. Oklahoma Coal. for Reprod. Justice, No. 12-1094, 2013 WL 873252, at *4 (2013).

opposing the plaintiffs' motion for a preliminary injunction, Ohio wrote:

> What the Clinics are trying to do here is to have this Court approve their expanded use of mifepristone based on what they believe to be medically appropriate, without seeking the regulatory approval of the FDA and in derogation of the states' traditional police powers to regulate the practice of medicine. The Court should decline this invitation.[116]

Earlier in the same document, Ohio's lawyers wrote: "Doctors quite simply do not have the right to practice medicine free from any oversight by the state."[117] They continued: "When the state believes that a medication is particularly dangerous or subject to abuse, the state has every right to regulate its use by doctors. Indeed, the state has the responsibility to do so in order to assure that the medication is being safely used."[118] The states defending these laws have tried to frame the issues as whether abortion providers should be allowed to slip around FDA regulations and whether women have a constitutional right to an abortion by a method of their choosing. These arguments are completely disingenuous. The real questions are whether abortion drugs and procedures should be subject to regulations that the FDA chose not to require and whether women should have their healthcare choices arbitrarily limited and made more difficult by the state.

If there were any real question about whether the FDA protocol is safer and better for women, *Carhart* would control and these protocol laws would be within the legitimate purview of state legislatures. However, where a full 96% of abortion providers choose to use an alternative evidence-based protocol and there have been no studies suggesting that the FDA protocol is superior, the "medical and scientific uncertainty" that *Carhart* describes as the realm for legislative discretion does not exist.[119] The Oklahoma legislature did not even make any factual findings to support its assertion that the FDA protocol should be followed.[120] While legislatures can regulate the medical field to protect citizens, the regulations must be based on some rational justification.

Ohio not only claimed that the purpose of the law was to protect women, it also argued

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116 Memorandum Contra of Defendants, *supra* note 23.

117 *Id.*

118 *Id.*

119 Gonzales v. Carhart, 550 U.S. 124, 163 (2007).

120 Brief in Opposition, *supra* note 27, at 19.

that the only reason that this legislation was the subject of litigations was because the drug is used for abortions.

> If mifepristone were a diet drug, a narcotic pain medication, or an anabolic steroid, this authority would not (and indeed has not) been questioned. The fact that mifepristone is a drug used to induce an abortion makes no difference. The state retains the right to regulate the use of this drug in order to protect the health and safety of its residents.[121]

This is brilliant as a legal strategy since it makes it seem that the state is just trying to protect women, but upon further inspection, this claim, that mifepristone is being treated just like other dangerous medications, fails because mifepristone is not dangerous. Prescription painkillers and anabolic steroids are drugs that are frequently recreationally abused and that have led to thousands of deaths. Mifepristone is used to cause abortions. There is no fun, recreational use for it. It is not addictive, and fewer than one out of 100,000 women have died after taking it.[122] There is no reason for the state to regulate this drug other than trying to further regulate abortions. If there were a non-abortion-causing drug with the same safety profile, it is hard to believe that the state would regulate it in this way.[123]

Contrary to arguments made by Ohio, Oklahoma, and North Dakota, mifepristone protocol legislation does not protect women. There is no conclusive evidence that the FDA protocol that is being forced on abortion practitioners and their patients is any safer than the

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121 Memorandum Contra of Defendants, *supra* note 23.

122 *Mifepristone U.S. Postmarketing*, *supra* note 57.

123 Metzger, *supra* note 19, at 885:

> Approached from the health perspective, abortion becomes a type of procedure with regard to which men and women actually are similarly situated; although men will never have abortions, they frequently have minor surgeries posing a similar degree and kind of medical danger. Moreover, claims that surgeries and drugs of particular relevance to men and of comparable health risk (such as vasectomies or Viagra) are not subject to similar burdens serve to reinforce the facially gender discriminatory character of such abortion regulation. So does the paternalistic aura of extensively regulating abortion in the name of women's own interests, particularly given that the effect of such regulation is to substantially increase the cost of abortion and limit its availability. And while the Court's protection of access to abortion has weakened over the years, its enforcement of constitutional prohibitions on gender discrimination has remained strong; the Court consistently at least invokes intermediate scrutiny, demanding that sex-based classifications 'serve important governmental objectives' and be "substantially related to achievement of those objectives."

alternative evidence-based protocol in use at the time of the legislation's passing.[124] AUL and Oklahoma emphasize that no women have died from a bacterial infection following a medical abortion provided according to the FDA protocol, but that is likely because very few doctors prescribe abortion-causing drugs according to the FDA protocol due to their medical judgment that to do so would not be in their patients' best interest.[125] It is marginally possible that vaginal use of misoprostol contributed to deaths from infection following medical abortions, but providers have started giving women misoprostol buccally instead.[126] From the evidence currently available, there is no justification for requiring that the FDA protocol be used, nor any rational reason to think that the non-FDA protocol being used caused the medical abortion deaths. In fact, the FDA studied these deaths and did not conclude that mifepristone, let alone the alternative protocol, was the cause.[127]

Not only does the legislation fail to protect women, it also does not protect fetal life because it does not necessarily prevent any abortions. Abortions are still available to women past forty-nine days of gestation, and the available evidence indicates that, while the FDA protocol is inconvenient for women, they still go through with the abortion procedure.[128] Nobody is arguing that the FDA protocol prevents fetal "pain" or convinces women to carry pregnancies to term.[129] As such, mifepristone protocol legislation does not stop abortions; it just makes them less convenient, more expensive, and riskier for women.

While other abortion procedures have been upheld partially due to the effect of the procedure on the medical profession,[130] mifepristone protocol legislation does not protect the legitimacy of the medical profession because it removes physician autonomy with

124 Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 497–98 (6th Cir. 2012).

125 AMS. UNITED FOR LIFE, *supra* note 64; Petition for a Writ of Certiorari, *supra* note 115, at 4.

126 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 495, 498.

127 Brief in Opposition, *supra* note 27, at 20; *Mifeprex (mifepristone) Information*, U.S. FOOD & DRUG ADMIN. (July 19, 2011), http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatients andproviders/ucm111323; *Mifeprex Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 24, 2010), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.

128 *Planned Parenthood Sw. Ohio Region*, 696 F.3d at 515.

129 Brief of Defendant-Appellee, *supra* note 34 (Defendant-Appellees raise various points, but do not argue that the FDA protocol prevents fetal pain or convinces women to carry pregnancies to term); Tuma, *supra* note 44 ("Based on her experience, Perriera says the legislation has not deterred her patients from having abortions; it has simply affected how they have them. As a result of the seven-week gestational limit, more of them have switched to surgical abortions.").

130 Gonzales v. Carhart, 550 U.S. 124, 157–58 (2007).

no clear benefit. In the words of Caitlin E. Borgmann: "[A]bortion procedure bans force doctors to tailor their methods to vindicate not the woman's safety but some vaguely articulated moral indignation on the part of the state."[131] By choosing to use the alternative protocol, doctors across the country have definitively shown that they believe that the FDA protocol is not in the best interest of their patients.[132] Doctor Mitchell Creinin, chair of the University of California Davis Department of Obstetrics and Gynecology, says:

> The question here is: why would lawmakers, who say they are looking out for the health and welfare of their constituents, want to legislate that women must follow the label when sufficient medical literature shows the old guidelines are more dangerous and more expensive? . . . What they're really trying to say is that they know more than the doctor—but they really need to be getting out of this business.[133]

Doctors are not pawns of the state. It is within the police power of the state to regulate doctors when doing so protects the health of patients. States do not have the right to arbitrarily regulate the profession in a way that harms, or at least does not clearly benefit patients.

Lastly, these laws show a lack of respect for human life because they force women who choose abortions to take unnecessary medicine and undergo unnecessary surgery because of an arbitrary cutoff set by the state.[134] Mifepristone protocol legislation and the Sixth Circuit's response in *DeWine* are examples of anti-choice legislatures' willingness to jeopardize the health and autonomy of real women in order to express moral indignation by regulating abortion procedures.

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131 Borgmann, *supra* note 111, at 322.

132 Brief of the American College of Obstetricians and Gynecologists as Amicus Curiae in Support of Plaintiffs-Appellees, Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502 (6th Cir. 2006) (No. 04-4371).

133 Tuma, *supra* note 44.

134 The FDA protocol provides for medical abortions up to forty-nine days of gestation while the alternative protocol has been shown in studies to be safe and effective up to sixty-three days of gestation. Plaintiff's Reply Brief in Support of a Motion for a Preliminary Injunction, *supra* note 20; Brief of Plaintiffs-Appellants, *supra* note 23, at 13–14.

CONCLUSION

The fate of mifepristone protocol legislation is crucial for the future of reproductive rights. These laws violate one of the basic tenets of constitutional law, that legislation must be enacted to pursue a legitimate state goal and not simply to harm a politically unpopular group of people. Upholding these laws means that any burden put in front of a woman seeking an abortion, no matter how irrational and arbitrary, will be upheld as long as the woman can still access a safe and legal abortion. *Roe* stood for the dignity of women to make their own choices about their bodies, lives, and futures, while these laws stand for the proposition that women's healthcare and autonomy are playthings for the state to use in furtherance of a political goal. Upon close (or not so close) scrutiny, it is apparent that Oklahoma's Abortion Inducing Drugs Safety Act and its counterparts in Ohio, North Dakota, Arizona, and Texas serve no legitimate state purpose and are vehicles of the anti-choice movement to roll back abortion rights. Women's health and comfort are being overlooked or disregarded in the legislative process of crafting legislation to ostensibly protect women. These laws send the clear message that the political whims of the legislature are more important than the actual health and safety of women and should be struck down as unconstitutional.