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FILED IN DISTRICT COURT
OKLAHOMA COUNTY

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and (2) NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients, Plaintiffs, v. (3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and, (4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, Defendants.	Case No. _____ Judge _____ CV-2014-1886

VERIFIED PETITION

Plaintiffs Oklahoma Coalition for Reproductive Justice and Nova Health Systems d/b/a Reproductive Services ("Reproductive Services"), by and through their undersigned attorneys, bring this Petition against the above-named Defendants, their employees, agents, and successors in office, and in support thereof allege the following:

I. PRELIMINARY STATEMENT

1. This is a civil rights action challenging Oklahoma House Bill 2684 ("H.B. 2684" or "the Act"), under the Constitution of the State of Oklahoma. 2014 Okla. Sess. Laws Serv. Ch. 121 (West). H.B. 2684 is scheduled to take effect November 1, 2014. The Act is attached hereto as Exhibit A.

2. The Act is an unconstitutional intrusion on women's reproductive rights that will harm women's health and well-being.

3. This lawsuit seeks to safeguard Oklahoma women's reproductive autonomy by preserving their ability to safely and effectively terminate an early pregnancy using medications alone, rather than undergoing surgery. This procedure is known as a "medication abortion." The medications most commonly used for medication abortion in the United States are mifepristone and misoprostol, which are taken in tandem according to a specific regimen.

4. The U.S. Food and Drug Administration ("FDA") approved mifepristone in 2000 (under its commercial name Mifeprex) as an effective method of terminating an early pregnancy.

5. However, medical research and physicians' clinical experiences do not stop after a medication is approved. Instead, as with other medications, the way that physicians prescribe abortion medications has continued to evolve based on new medical research and clinicians' own experiences, making medication abortion increasingly safer, more effective, able to be used later in pregnancy, more accessible, and with fewer side effects.

6. Using an FDA-approved drug in a different dosage or method of administration, or for a different purpose than that for which the manufacturer sought FDA approval, is known as "off-label" use.

7. When off-label use reflects clear, significant, generally-accepted developments in medical research, it is commonly referred to as "evidence-based" medicine. Evidence-based medicine is the gold standard of patient care.

8. The American Medical Association ("AMA") and the American College of

Obstetricians and Gynecologists ("ACOG") recognize that evidenced-based regimens for medication abortion are superior to the regimen that appears in the FDA-approved final printed labeling for mifepristone (hereinafter, the "Mifeprex regimen").

9. In 2012, the Oklahoma Supreme Court affirmed a district court decision striking down as unconstitutional a 2011 law very similar to the one challenged in this litigation. The State appealed the decision all the way to the United States Supreme Court, which initially accepted the case for review, but eventually declined review and let stand the Oklahoma Supreme Court's decision. *See Okla. Coal. for Reprod. Justice v. Cline*, No. CV-2011-1722 (Okla. Cnty. Dist. Ct. May 11, 2012), *aff'd*, 2012 OK 102, 292 P.3d 27 (affirming the district court's ruling in a memorandum opinion), *cert. granted*, 133 S. Ct. 2887 (2013), *certifying questions*, 2013 OK 93, 313 P.3d 253 (answering certified questions), *cert. dismissed as improvidently granted*, 134 S. Ct. 550 (2013), all attached hereto as Exhibits B–F.

10. H.B. 2684, like the statute restricting medication abortion that preceded it, requires physicians to ignore decades of medical research, the opinion of leading medical organizations, and their own clinical experience, and instead administer medication abortion according to the outdated and inferior Mifeprex regimen.

11. As a result, the Act will prevent some of Reproductive Services' patients from obtaining a medication abortion altogether. For others, the Act's arbitrary and burdensome restrictions will prevent them from receiving medical treatment according to current scientific evidence and advances in medicine.

12. For these reasons, the Act violates the constitutional rights of Oklahoma women to choose to terminate a pregnancy, to bodily integrity, and to equal protection under the Oklahoma Constitution.

13. In addition, the Act violates the Oklahoma Constitution's prohibition against special laws and its equal protection guarantee, and constitutes an improper delegation of legislative authority.

14. Preliminary and permanent injunctive relief is necessary to protect the constitutional rights of Plaintiffs, their patients, and their members, and the health and safety of Oklahoma women.

II. JURISDICTION AND VENUE

15. Jurisdiction is conferred on this Court by OKLA. CONST. art. VII, § 7(a).

16. Plaintiffs' claims for declaratory and injunctive relief are authorized by OKLA. STAT. tit. 12, §§ 1651 and 1381 and by the general equitable powers of this Court.

17. Venue is appropriate under OKLA. STAT. tit. 12, § 133 because Defendants have official residences in Oklahoma County.

III. PARTIES

18. Plaintiff Oklahoma Coalition for Reproductive Justice ("OCRJ") is a non-profit organization dedicated to promoting reproductive justice in Oklahoma through education and advocacy. OCRJ is dedicated to ensuring that reproductive health care is available to all women in Oklahoma, and OCRJ's membership includes women of reproductive age who may need to terminate a pregnancy in Oklahoma in the future.

19. OCRJ's members pay taxes to the State of Oklahoma.

20. OCRJ brings claims on behalf of itself and its members.

21. Plaintiff Reproductive Services, a part of NOVA Health Systems, a non-profit charitable corporation, is a medical clinic in Tulsa, Oklahoma that has been in operation since 1974. Reproductive Services provides a range of reproductive health care services to

women in Oklahoma, including surgical and medication abortions, contraception counseling and services, pregnancy testing, options counseling, adoption counseling, and referrals for other medical and social services, including referrals to an on-site licensed adoption agency. It is a member of the National Abortion Federation ("NAF") and is licensed as an abortion facility by the Oklahoma State Department of Health.

22. Reproductive Services brings claims on behalf of itself, its staff, and its patients.

23. Defendant Terry L. Cline is the Oklahoma Commissioner of Health. He oversees the Oklahoma State Board of Health, which issues licenses to facilities at which abortions are performed and oversees compliance with the regulation of such facilities. OKLA. STAT. tit. 63, §§ 1-706(A), (B)(1); OKLA. ADMIN. CODE § 310:600-7-3. He is sued in his official capacity.

24. Defendant Lyle Kelsey is the Executive Director of the Oklahoma State Board of Medical Licensure and Supervision (the "Medical Board"). The Medical Board, among other things, issues medical licenses and has the authority to take disciplinary action against licensees. OKLA. STAT. tit. 59, §503, *amended by* 2014 Okla. Sess. Law Serv. Ch. 176 (H.B. 2791) (effective Nov. 1, 2014); OKLA. STAT. tit. 59, § 509. He is sued in his official capacity.

IV. FACTUAL BACKGROUND AND LEGISLATIVE HISTORY

A. Safety of Medication Abortion

25. Women seek abortions for a variety of medical, familial, economic, and personal reasons. Approximately one in three women in the United States will have an abortion in their lifetimes.

26. Most women having abortions (over 60%) already have at least one child, and most (66%) also plan to have children in the future—many when they are older, financially able to

provide for them, and/or in a supportive relationship with a partner so their children will have two parents.

27. Since 2000, when Mifeprex first received FDA approval, over two million women have used medication abortion to safely and effectively terminate a pregnancy in the United States.

28. Currently, and for over a decade, Oklahoma women in the first nine weeks of pregnancy, as measured from the woman's last menstrual period ("LMP") have had the option of choosing between surgical abortion and medication abortion. Both are extremely safe and effective procedures.

29. Surgical abortions are typically performed in an outpatient setting. Surgical abortion procedures are done through insertion of instruments through the vagina and into the uterus. The procedure is short in duration, typically lasting about five to ten minutes for an uncomplicated first trimester abortion. Medication abortions typically involve the use of mifepristone, which is taken by the patient at her health care facility, in conjunction with misoprostol, which is usually taken by the patient at home.

30. Over half of Plaintiff Reproductive Services' patients choose to have a medication abortion. These women choose to have a medication abortion for a variety reasons.

31. Many prefer medication abortion because it feels more natural, like a miscarriage, and/or because they can complete a medication abortion in the privacy of their homes rather than in a medical clinic, with a support person present, and at a time of their choosing.

32. Other women choose medication abortion because they fear any procedure with surgical instruments, or because they do not wish to undergo mild or moderate sedation, which may be administered in conjunction with a surgical abortion. Victims of rape or

women who have experienced sexual abuse or molestation may choose medication abortion to feel more in control of the experience and to avoid the trauma of having instruments placed in their vagina.

33. For some, medication abortion offers important clinical advantages over surgical abortion. In particular, some women have medical conditions that make medication abortion a safer option, with a lower risk of both complications and failure than a surgical abortion. These conditions, including obesity, uterine anomalies (i.e. bicornuate or double uterus, or an extremely flexed uterus), large uterine fibroids, and cervical stenosis (tightly closed uterus), make it difficult to access the pregnancy inside the uterus as part of a surgical abortion.

34. The risk of complications associated with medication abortion are comparable to the risk associated with surgical abortion. Major complications from medication abortion are extremely rare, and far rarer than those associated with pregnancy and childbirth.

B. Safety of Evidence-Based Medication Abortion Regimens

35. Virtually all medication abortions performed in the United States, including those performed at Reproductive Services, use an off-label, evidence-based regimen involving a lower dose of mifepristone, a different route of administration for the misoprostol, and self-administration of misoprostol by the patient rather than a physician, as compared to the Mifeprex regimen. *See Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 260-61.

36. Indeed, once mifepristone was approved in 2000, the overwhelming majority of abortion providers in the United States began following evidence-based regimens in light of newer research showing that the lower dose of mifepristone (200 milligrams instead of 600) combined with a different dose and route of self-administered misoprostol was equally safe and effective, able to be used by women through at least 63 days LMP, and more convenient for patients.

37. Evidence-based medication abortion regimens have been endorsed by leading medical organizations, including ACOG and the World Health Organization, as "safer and more effective than the now-outdated [Mifeprex] regimen." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261. ACOG's 2014 Practice Bulletin, Medical Management of First-Trimester Abortion, recognizes evidence-based regimens as medically superior to the Mifeprex regimen.

38. Under the evidence-based regimen used by Plaintiff Reproductive Services, medication abortion patients take 200 milligrams (mg) of mifepristone at the provider's office, and approximately six to twenty-four hours later, take 800 micrograms (μg) of misoprostol at home (or another location of their choosing) by inserting the tablets vaginally or buccally (allowing the tablets to dissolve between the gum and cheek). The physicians at Reproductive Services have chosen this regimen based upon the medical literature, including recommendations from ACOG, and their own experience providing medication abortions.

39. Evidence-based regimen offers a number of other advantages as compared to the Mifeprex regimen.

40. *First*, they are effective for longer in pregnancy, allowing medication abortions to be performed up to 10 weeks (70 days) LMP, which in turn allows many more women to avail themselves of that method. Those additional weeks are significant because many women do not realize they are pregnant until close to 7 weeks (49 days) LMP, the cutoff under the Mifeprex regimen.

41. *Second*, self-administration of misoprostol eliminates an unnecessary trip to the health facility, allowing the woman greater control over the timing of the procedure. In addition, it ensures that patients will experience the bleeding and cramping that follow in a

location of their choosing, rather than in a car, at rest stop, or some other equally inappropriate and potentially dangerous location.

42. *Third*, evidence-based regimens have been shown to have a higher rate of effectiveness and require fewer surgical interventions to complete the procedure, as compared to the Mifeprex regimen.

43. *Fourth*, the lower mifepristone dosage reduces the cost of the procedure significantly.

C. The FDA's Approval of Mifeprex for Marketing Purposes in 2000

44. The FDA is an agency within the U.S. Department of Health and Human Services. Drug manufacturers wishing to market a new prescription drug in the United States must obtain FDA approval to do so.

45. A drug manufacturer submits to the FDA a new drug application with information about the drug's test results, the manufacturer's ability to manufacture the drug properly, and the manufacturer's proposed label for the drug. If the FDA determines that the benefits of the drug outweigh its known risks, it is approved for marketing in the United States.

46. The drug manufacturer's proposed label for the drug is called the Final Printed Label ("FPL"). The FPL contains information about a drug's indications, warnings, precautions, side effects, dosage, and method of administration.

47. The FDA's regulatory authority with respect to drugs is limited to approving new drug applications for marketing purposes; the FDA does not regulate the practice of medicine. Neither a drug's FPL nor any FDA regulations "limit the manner in which a physician may use an approved drug;" thus, physicians are free to prescribe approved drugs "for uses or in treatment regimens or patient populations that are not included in approved labeling." *Cline*, 2013 OK 93, ¶ 20, 313 P.3d at 260 (citing FDA Drug Bulletin 12:4-5,

1982).

48. In 2000, the FDA approved Mifeprex (generically known as "mifepristone" or "RU-486") for marketing purposes as an effective alternative to surgical abortion in early pregnancy. As part of that approval process, the manufacturer of Mifeprex proposed, and the FDA approved, an FPL that reflected the regimen used in the clinical trials for Mifeprex, which were completed prior to 1996 and involved fewer than 3000 women.

49. Under the protocol used in the Mifeprex clinical trials, the patient first takes 600 milligrams (mg) of mifepristone orally at her physician's office. Mifepristone works by blocking the hormone progesterone, which is necessary to maintain a pregnancy. The patient then returns to the health center 48 hours later to take 400 micrograms (μg) of misoprostol orally. Misoprostol, sometimes known by its brand name Cytotec, causes the uterus to contract and expel its contents. Approximately 14 days later, the patient returns for a follow-up visit to ensure that a complete abortion has occurred.

50. The Mifeprex clinical trials found this regimen to be safe and effective through 49 days LMP. Thus, the Mifeprex FPL reflects this regimen and this gestational age limit.

51. In approving mifepristone, the FDA did not authorize or prohibit the use of any particular regimen for administering the drug. The FDA has never required that prescribers of mifepristone follow any particular regimen and has never imposed a gestational age limit on its use. *Cline*, 2013 OK 93, ¶ 21 n.17, 313 P.3d at 261 n.17.

52. "[M]edical research and advances do not stop upon a particular drug's approval by the FDA." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 260. Indeed, "[r]esearchers continue to perform clinical trials, doctors continue to gain experience, and widespread use of a particular treatment allows the medical community to collect data about side effects,

alternative doses, and potential new uses for treatments." *Id.* Moreover, an FDA-approved FPL does not, and is not required to, provide information about any safe and effective uses of a medication outside of the regimen for which it originally received FDA approval. Thus, a drug's FPL can often be out of date or not based on the most current scientific evidence.

53. It is standard medical practice for physicians to prescribe or dispense FDA-approved drugs in dosages and for indications that were not specifically approved or contemplated by the FDA, particularly when supported by adequate study. The FDA has repeatedly acknowledged that use of such evidence-based regimens, which vary from the drug's FPL, is common, and can be required by "[g]ood medical practice and the best interests of the patient." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261 (quoting U.S. Food and Drug Administration, *Regulatory Information: "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm).

D. Oklahoma Laws Governing Abortion and Recent Restrictions on the Provision of Medication Abortion

54. The provision of abortion in Oklahoma is subject to extensive regulation by the State. Indeed, the Oklahoma Legislature has enacted over 20 restrictions that dictate when and under what conditions a woman may have an abortion.

55. For example, any facility performing first trimester abortions must be licensed as an abortion facility. OKLA. STAT. tit. 63, §§ 1-701, 1-705, 1-737; OKLA. ADMIN. CODE 310:600-3-1. Licensed abortion facilities are subject to extensive regulations addressing patient care, physician qualifications, staffing and personnel, emergency protocols, equipment and supplies, medications, laboratory testing, recordkeeping, signage, and physical plant

requirements. *See* OKLA. STAT. tit. 63, §§ 1-729.1, 1-731, 1-733, 1-737, 1-737.4, 1-744.2, 1-745.6; OKLA. ADMIN. CODE §§ 310:600 *et seq.*

56. All abortion facilities are required to undergo on-site inspections by the Department of Health, and to comply with mandatory reporting requirements regarding every abortion procedure performed at the facility. OKLA. STAT. tit. 63, §§ 1-738i, 1-738j, 1-738k, 1-738n; OKLA. ADMIN. CODE 310:600-7-1.

57. At least twenty-four (24) hours before a woman can receive an abortion, she must undergo a mandatory state-directed counseling session and receive specific information and warnings related to the procedure and her pregnancy. *See* OKLA. STAT. tit. 63, § 1-738.2.

58. Over the past several years, the Oklahoma Legislature has passed a number of restrictions on physicians' use of medications to terminate an early pregnancy.

59. In 2011, the Legislature enacted House Bill 1970 (hereinafter "H.B. 1970"), which required physicians providing or prescribing any abortion-inducing drug to do so according to the drug's FDA-approved label. *Cline*, 2013 OK 93, ¶ 16, 313 P.3d at 259.

60. Under H.B. 1970's plain language, the use of misoprostol as part of a medication abortion regimen and the use of methotrexate as a treatment for ectopic pregnancies were prohibited, since neither drug was labeled for use as an abortifacient. *Cline*, 2013 OK 93, ¶ 25, 313 P.3d at 262.

61. In October 2011, Plaintiffs OCRJ and Reproductive Services filed a lawsuit against the named Defendants in this case,[1] seeking an injunction against H.B. 1970's ban on off-label use of abortion-inducing medications.

[1] In the prior case, Plaintiffs also sued the President of the Osteopathy Board, in her official capacity.

62. Following extensive briefing and evidentiary development, the district court granted summary judgment to OCRJ and Reproductive Services and permanently enjoined H.B. 1970. *Cline*, No. CV-2011-1722, slip op. at 3. The district court determined that H.B. 1970 violated women's fundamental rights to terminate a pregnancy and to bodily integrity guaranteed by Art. II, § 7 of the Oklahoma Constitution. *Id.* at 2-3.

63. In so ruling, the court made a number of factual findings that are relevant to the constitutionality of the Act challenged here.

64. First, the court expressly rejected the State's unsubstantiated claims regarding the relative safety and efficacy of evidence-based regimens as compared to FDA-labeled regimens, finding that "[g]ood medical practice and the best interests of the patient often includes drug use that is not displayed in the FPL of that drug and requires physicians use legally available drugs according to their best knowledge and judgment." *Id.* at 2.

65. The district court further recognized that, since 2000, when mifepristone was first approved for marketing by the FDA, "a regimen different from that set forth in the FPL has been used in a great majority of cases of medication abortions in the United States [which has been] demonstrated by scientific research to be safer and more effective than the regimen provided in the RU-486 FPL." *Id.*

66. The district court concluded that H.B. 1970's "restriction of the use of the drug RU-486 or any other abortion inducing drug, medicine or other substance in the manner and to the regimen set forth in the medication FPL when used for abortion is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those women who do." *Id.* at 2-3 (internal quotation and citation omitted).

67. The State appealed to the Oklahoma Supreme Court, which affirmed the judgment in a memorandum opinion, finding the challenged act unconstitutional under the standard set forth in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). *Cline*, 2012 OK 102, 292 P.3d 27.

68. The State petitioned the United States Supreme Court for a writ of certiorari. The United States Supreme Court granted certiorari and certified to the Oklahoma Supreme Court the following questions: "Whether H. B. No. 1970, Section 1, Chapter 216, O.S.L. 2011 prohibits: (1) 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; and (2) the use of methotrexate to treat ectopic pregnancies." *Cline*, 133 S. Ct. at 2887.

69. The Oklahoma Supreme Court answered both certified questions in the affirmative, finding that under the plain meaning of the statute, both misoprostol and methotrexate were "abortion-inducing drugs," and that their off label use was prohibited by H.B. 1970. *Cline*, 2013 OK 93, ¶¶ 10-19, 313 P.3d at 258-60.

70. In addition, the Oklahoma Supreme Court found that "FDA-approved labeling is 'not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.'" *Cline*, 2013 OK 93, ¶ 20, 313 P.3d at 260 (quoting *Weaver v. Reagan*, 886 F.2d 194, 198 (8th Cir. 1989)). The Court further found that "the FDA-approved label for mifepristone requires a dosage level no longer considered medically necessary." *Cline*, 2013 OK 93, ¶ 25, 313 P.3d at 262.

71. The Oklahoma Supreme Court also recognized that both "the American College of Obstetricians and Gynecologists and the World Health Organization have endorsed these

alternate regimens as safer and more effective than the now-outdated regimen provided for in mifepristone's FDA-approved label," and further, that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to the best knowledge and judgment." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261 (internal quotation marks and citations omitted).

72. Finally, the Oklahoma Supreme Court ratified the district court's conclusion that forcing doctors to adhere to the Mifeprex drug label regimen was "**completely at odds with the standard that governs the practice of medicine**" and therefore "serve[d] no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." *Cline*, 2013 OK 93, ¶ 27, 313 P.3d at 262 (emphasis in original).

73. Upon receiving the answers from the Oklahoma Supreme Court, the U.S. Supreme Court dismissed the writ of certiorari as improvidently granted, and let stand the Oklahoma Supreme Court's earlier decision striking down H.B. 1970 as unconstitutional. *Cline*, 134 S. Ct. 550 (2013).

E. The Legislature Enacts H.B. 2684 in Response to the Oklahoma Courts

74. Mere months after the Oklahoma Supreme Court issued its decision and the U.S. Supreme Court dismissed the State of Oklahoma's appeal, the Legislature passed H.B. 2684, once again seeking to impose medically unwarranted and burdensome requirements on the provision of medication abortion in Oklahoma.

75. The bill's sponsors, Representatives Grau and Treat, were also the co-sponsors of H.B. 1970.

76. Governor Mary Fallin signed the bill into law on April 22, 2014. The Act is scheduled to take effect on November 1, 2014.

77. Like its predecessor, H.B. 2684 restricts the use of medications for purposes of terminating a pregnancy. However, H.B. 2684 clarifies that the Act does not prohibit the off-label use of abortion-inducing drugs for the purpose of treating an ectopic pregnancy.

78. The Act defines "mifepristone" as "the first drug used in the Mifeprex regimen," and "misoprostol" as "the second drug used in the Mifeprex regimen." H.B. 2684 §§ 1(B)(5), (6). It further defines the term "Mifeprex regimen" as follows:

> "Mifeprex regimen" means the abortion-inducing drug regimen that is described in the FDA-approved Mifeprex final printed labeling, and which involves administration of mifepristone (brand name "Mifeprex") and misoprostol. It is the only abortion-inducing drug regimen approved by the FDA, and it does not include any dosage or administration not explicitly approved in Mifeprex final printed labeling. It is also commonly referred to as the "RU–486 regimen" or simply "RU–486" . . . .

H.B. 2684 § 1(B)(4).

79. The Act expressly bans the use of any off-label or evidence-based regimens:

> No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug, including the Mifeprex regimen, 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~~ outlined in the ~~drug~~ FDA-approved label ~~for the RU-486 (mifepristone) or any abortion inducing drug~~. In the specific case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (brand name Mifeprex) and misoprostol, and any provision accomplished according to that labeling is not prohibited.

H.B. 2684 § 1(D) (alterations from H.B. 1970 noted with underlined and crossed-out text for additions and deletions, respectively).

80. As with H.B. 1970, "drug label" is defined as "the pamphlet accompanying an abortion-inducing drug that outlines the protocol authorized by the U.S. Food and Drug Administration (FDA) and agreed upon by the drug company applying for FDA authorization of that drug." H.B. 2684 § 1(B)(3).

81. As with H.B. 1970, physicians providing abortion-inducing drugs must tell their patients that the drugs are being used in accordance with the protocol authorized by the FDA and as outlined in the drug label, and provide a copy of the drug manufacturer's medication guide and drug label to patients. H.B. 2684 § 1(E).

82. In a manner virtually identical to H.B. 1970, the Act requires that any "abortion-inducing drug [] be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient." H.B. 2684 § 1(G).

83. Like H.B. 1970, the Act subjects any physician who "knowing[ly] and reckless[ly]" fails to comply with the statute to civil liability for "actual and punitive" damages. *Compare* H.B. 1970 §§ 1(G), (H) *with* H.B. 2684 §§ 1(H), (I).

84. Likewise, failure to comply exposes a physician to disciplinary sanctions by the relevant licensing board, and exposes the licensed health care facility at which the physician practices to license suspension or revocation. H.B. 2684 § 1(H)(2); OKLA. STAT. tit. 63 § 1-706(B)(1); OKLA. STAT. tit. 59 § 503, *amended by* 2014 Okla. Sess. Law Serv. Ch. 176 (H.B. 2791) (West) (effective Nov. 1, 2014); OKLA. STAT. tit. 59 §§ 509, 509.1, 637; OKLA. ADMIN. CODE § 310:600-7-3.

F. Aside from the Act's Prohibitions, Off-Label Use of Medications is Protected By Oklahoma Law.

85. Outside of the context of abortion, Oklahoma law "recognize[s] the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling." *Cline*, 2013 OK 93, ¶ 22, 313 P.3d at 261.

86. For example, physicians are required by law to administer drugs according to "good medical practice," not FDA labels, and unprofessional conduct for physicians is defined to

include:

> Prescribing, dispensing or administering of controlled substances or narcotic drugs *in excess of the amount considered good medical practice*, or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards . . . .

OKLA. STAT. tit. 59, § 509(16) (emphasis added).

87. Oklahoma law also prohibits health insurers from denying coverage for drugs for cancer treatment because such off-label use has not been approved by the FDA. OKLA. STAT. tit. 63, § 1-2604.

88. The State also instructs the Medicaid Drug Utilization Review Board to create "a retrospective and prospective drug utilization review program for medical outpatient drugs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes." *Id.* § 5030.4(1).

89. The Board is instructed to focus on prescriptions that are medically appropriate and safe, giving deference to physician decision-making, rather than FDA-approved drug labeling.

G. Enforcement of H.B. 2684 Will Harm Plaintiffs and their Patients.

90. Reproductive Services currently provides approximately 150-250 abortions per month, on average. Over 50% of patients who obtain abortions at Reproductive Services choose a medication abortion.

91. The Act bars abortion providers from using any evidence-based regimens, which offer patients the safest and most effective option supported by medical evidence. Instead, the Act will force physicians, against their best medical judgment and the recommendations of leading medical organizations, including ACOG and the AMA, to adhere to an outdated, inferior regimen.

92. Following the FDA protocol will impose a host of burdens on Reproductive Services and on women seeking to terminate a pregnancy. As an initial matter, if the Act is permitted to take effect, Reproductive Services could be forced to stop providing medication abortions altogether, because the Act requires the clinic's physicians to follow a medication protocol that serves no valid, medical purpose and to practice medicine in a way that does not comport with the current standard of care. Reproductive Services' physicians do not want to endanger the health and safety of their patients by following the inferior Mifeprex regimen.

93. Even if Reproductive Services' physicians were able to continue providing medication abortions, the Act's restrictions will subject all patients who choose a medication abortion to an inferior and outdated regimen and impose significant and unnecessary discomfort, inconvenience, and expense.

94. Compliance with H.B. 2684 will be particularly burdensome for women who have important personal reasons for choosing a medication abortion, and dangerous for women who have physical conditions that make medication abortion a significantly safer option than surgical abortion.

95. The Act's restrictions disregard the most up-to-date medical evidence, which clearly demonstrates that medication abortions using an evidence-based regimen can be safely and effectively offered to patients up to 70 days LMP.

96. Thus, for patients who are more than 49 days LMP, the Act will prevent them from obtaining a medical abortion altogether, regardless of whether a medication abortion might be the best medical option for a particular patient.

97. In addition, requiring women to take misoprostol at the clinic forces them to undergo the expected side effects of the medication, which always include bleeding and cramping and

may also include, nausea, vomiting, diarrhea, and fever, either at the clinic or, more likely, during their journey home.

98. The additional trip required by the Act for women to receive the misoprostol at the health care facility will interfere with patients' ability to monitor their pain level, bleeding, body temperature, and possible signs of infection, and may also interfere with their ability to take medications that minimize unpleasant side effects.

99. For this reason, the vast majority of medication abortion providers, including Plaintiff Reproductive Services, follow an evidence-based regimen permitting patients to self-administer misoprostol at home or another safe place of their choosing.

100. Women who seek treatment at Reproductive Services come from across the state of Oklahoma. Approximately 30% of patients seeking an abortion at Reproductive Services in the first half of 2014 traveled more than 50 miles, or around one hour of driving time each way, to reach the clinic.

101. Compliance with the Act will mean that women who have medication abortions at Reproductive Services must visit the clinic a minimum of three times and in some cases four times to complete treatment.

102. Oklahoma law already requires women seeking an abortion to undergo a mandatory twenty-four-hour waiting period prior to the procedure. OKLA. STAT. tit. 63, § 1-738.2(B).

103. Some women who seek a medication abortion at Reproductive Services receive this mandatory counseling by telephone, which is permitted under the applicable law, but approximately half of all patients seeking a medication abortion arrive in person at the clinic seeking care, and must therefore return to the clinic twenty-four hours after their initial

visit to begin the medication regimen. The extra trip required under the Act will entail additional travel and time away from home, children, and work.

104. This additional travel will be particularly difficult for low-income women, women who live far from a major metropolitan area, women who have limited access to transportation, and women who are victims of abuse. For some, the extra trip requirement will be cost prohibitive.

105. Finally, the Act will impose an additional financial obstacle for women. Reproductive Services currently charges patients $550 for a medication abortion.

106. Each Mifeprex pill containing 200 milligrams of mifepristone costs approximately $80.

107. In order to comply with the Act, which forces patients to ingest three times as much medication as is necessary, the cost of a medication abortion would increase by a minimum of $160.

108. In addition to the adverse impact on its patients, compliance with the Act will impose logistical and financial burdens on Plaintiff Reproductive Services. The Act requires the physician to be present with the patient when she takes the second drug, misoprostol.

109. This requirement will likely necessitate opening the clinic on Saturdays to permit timely administration of the misoprostol, as well as compensating staff to assist patients on those dates. Additional costs may arise in order to ensure the presence of the same physician at both appointments where the medications are administered.

110. The vast majority of Reproductive Services' patients self-pay because they lack insurance coverage that will cover the cost of the procedure. A significant number of women who seek treatment at Reproductive Services require financial assistance to pay for

abortions. Approximately 20% of patients qualify for financial assistance from private organizations that help pay for a portion of the procedure cost; in order to qualify to receive such assistance, patients must demonstrate that their household income is at or below 100% of the Federal Poverty Guidelines.

111. As a result of the Act's requirements, far fewer women will be able to have a medication abortion, since most women who choose this option do so primarily because it can be done at home and affords them more privacy, which will no longer be the case. The additional travel, increased expense, and other burdens imposed by the Act will prevent some women from obtaining a medication abortion altogether, and delay others who must first make the necessary arrangements for payment, transportation, childcare, and time off work. Even for patients who are willing and able to make the necessary arrangements, unforeseen and uncontrollable circumstances, such as bad weather or road conditions, could impose additional delays.

112. Furthermore, because there is only a small window of time when medication abortions are performed, any delay could foreclose the option altogether for some women, including those for whom a medication abortion is medically-indicated or highly preferred for important personal reasons. Moreover, while legal abortion is an extremely safe procedure, delaying the procedure until later in pregnancy increases the risks of the procedure and the rate of complications.

V. CLAIMS FOR RELIEF

First Claim for Relief
(Substantive Due Process)

113. The allegations of paragraphs 1 through 112 are incorporated as though fully set forth herein.

114. The Act violates women's fundamental rights to choose to terminate a pregnancy and to bodily integrity in violation of OKLA. CONST. art. II, § 7.

115. The Act violates women's fundamental rights to terminate a pregnancy and to bodily integrity in violation of OKLA. CONST. art. II, § 2.

Second Claim for Relief
(Special Law)

116. The allegations of paragraphs 1 through 115 are incorporated as though fully set forth herein.

117. The Act creates a special law where a general law could be made applicable in violation of OKLA. CONST. art. V, § 59 by, among other things, singling out for special treatment women seeking medication abortions, and physicians who treat those women.

118. The Act creates a special law regulating the practice or jurisdiction of the courts in violation of OKLA. CONST. art. V, § 46 by affording a private right of action to a special class of litigants.

Third Claim for Relief
(Equal Protection)

119. The allegations of paragraphs 1 through 118 are incorporated as though fully set forth herein.

120. The Act denies equal protection of the laws to women seeking medication abortions and physicians who treat those women, in violation of OKLA. CONST. art. II, § 7.

Fourth Claim for Relief
(Improper Delegation)

121. The allegations of paragraphs 1 through 120 are incorporated as though fully set forth herein.

122. By requiring physicians who provide medication abortions to adhere to "the

protocol authorized" by the FDA, the Act impermissibly delegates legislative authority to a federal agency in violation of OKLA. CONST. arts. IV and V.

Fifth Claim for Relief
(Declaratory Judgment – Unconstitutional and Void)

123. The allegations of paragraphs 1 through 122 are incorporated as though fully set forth herein.

124. Because the Act violates the Oklahoma Constitution, and declaratory judgment would terminate the controversy giving rise to this proceeding, Plaintiffs request a declaration from this Court stating that the Act is unconstitutional and void. *See* OKLA. STAT. tit. 12, § 1651.

Sixth Claim for Relief
(Temporary Injunction or Temporary Restraining Order)

125. The allegations of paragraphs 1 through 124 are incorporated as though fully set forth herein.

126. Temporary injunctive relief is warranted because Plaintiffs, and those whose interests they represent, "will suffer [] irreparable injury" if the Act is allowed to take effect. *See id* § 1382.

Seventh Claim for Relief
(Permanent Injunction)

127. The allegations of paragraphs 1 through 126 are incorporated as though fully set forth herein.

128. Because the Act violates the Oklahoma Constitution, warranting a declaratory judgment stating that the Act is unconstitutional and void, Defendants should be permanently enjoined from enforcing the Act.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

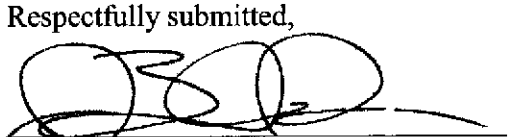
129. Issue a declaratory judgment that H.B. 2684 violates the Oklahoma Constitution and is void and of no effect; and

130. Issue permanent injunctive relief, without bond, restraining Defendants, their employees, agents, and successors in office from enforcing H.B. 2684; and

131. Grant such other and further relief as the Court may deem just and proper, including reasonable attorney's fees and costs.

Dated: Sept. 30, 2014

Respectfully submitted,



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**Out-of-State Attorney Applications Filed.*

ATTORNEYS FOR PLAINTIFFS

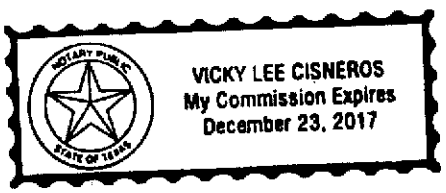
VERIFICATION

The undersigned represents Plaintiff Nova Health Systems d/b/a Reproductive Services. The undersigned has read the contents of the Verified Petition. The undersigned hereby verifies, under the penalty of perjury, that the contents of the Verified Petition are true and correct to the best of her present knowledge.

Marilyn Eldridge
President, Nova Health Systems d/b/a Reproductive Services

Sworn to before me this 29
day of September, 2014.

NOTARY PUBLIC



VERIFICATION

The undersigned represents Plaintiff Oklahoma Coalition for Reproductive Justice. The undersigned has read the contents of the Verified Petition. The undersigned hereby verifies, under the penalty of perjury, that the contents of the Verified Petition are true and correct to the best of her present knowledge.

Martha Skeeters
President, Oklahoma Coalition for Reproductive Justice

Sworn to before me this 26
day of September, 2014.

NOTARY PUBLIC

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and (2) NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients, Plaintiffs, v. (3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and, (4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, Defendants.	)	Case No. _____ Judge _____

CERTIFICATE OF SERVICE ON OKLAHOMA ATTORNEY GENERAL

Pursuant to Local Rule 37(D), the undersigned hereby certifies that true and correct copies of the petition, motion, and brief challenging Oklahoma House Bill 2684 were served on the Office of the Oklahoma Attorney General.

Respectfully submitted,

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**Out-of-State Attorney Applications Filed.*

ATTORNEYS FOR PLAINTIFFS

Exhibit A

An Act

ENROLLED HOUSE
BILL NO. 2684

By: Grau, Ritze and Derby of the House

and

Treat and Newberry of the Senate

An Act relating to public health and safety; amending 63 O.S. 2011, Section 1-729a, which relates to the sale or distribution of RU-486; making legislative findings; modifying, adding and deleting certain definitions; updating statutory references; providing specifications for certain regimen; and providing an effective date.

SUBJECT: Abortion-inducing drugs

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 2011, Section 1-729a, is amended to read as follows:

Section 1-729a. A. The Legislature finds that:

1. The U.S. Food and Drug Administration (FDA) approved the drug mifepristone (brand name "Mifeprex"), a first-generation [selective] progesterone receptor modulator ([S]PRM), as an abortion-inducing drug with a specific gestation, dosage, and administration protocol;

2. The FDA approved mifepristone (brand name Mifeprex) under the rubric of 21 C.F.R., Section 314.520, also referred to as "Subpart H", which is the only FDA approval process that allows for postmarketing restrictions. Specifically, the Code of Federal Regulations (CFR) provides for accelerated approval of certain drugs

that are shown to be effective but "can be safely used only if distribution or use is restricted";

3. The FDA does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process;

4. As approved by the FDA, and as outlined in the Mifeprex final printed labeling (FPL), an abortion by mifepristone consists of three two-hundred-milligram tablets of mifepristone taken orally, followed by two two-hundred-microgram tablets of misoprostol taken orally, through forty-nine (49) days LMP (a gestational measurement using the first day of the woman's "last menstrual period" as a marker). The patient is to return for a follow-up visit in order to confirm that the abortion has been completed. This FDA-approved protocol is referred to as the "Mifeprex regimen" or the "RU-486 regimen";

5. The aforementioned procedure requires three office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital and under supervision of a physician;

6. The Mifeprex final printed labeling (FPL) outlines the FDA-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

7. When the FDA approved the Mifeprex regimen under Subpart H, it did so with certain restrictions. For example, the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention (or has made plans to provide surgical intervention through other qualified physicians);

8. One of the restrictions imposed by the FDA as part of its Subpart H approval is a written agreement that must be signed by both the physician and patient. In that agreement, the woman attests to the following, among other statements:

a. "I believe I am no more than 49 days (7 weeks) pregnant",

b. "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)", and

c. "I will do the following: return to my provider's office in two days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant";

9. The FDA concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex final printed labeling (FPL) on self-administering misoprostol at home;

10. The use of abortion-inducing drugs presents significant medical risks to women, including but not limited to abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease;

11. Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process;

12. In July 2011, the FDA reported 2,207 adverse events in the United States after women used abortion-inducing drugs. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections");

13. "Off-label" or so-called "evidence-based" use of abortion-inducing drugs may be deadly. To date, fourteen women have reportedly died after administering abortion-inducing drugs, with eight deaths attributed to severe bacterial infection. All eight of those women administered the drugs in an "off-label" or "evidence-based" manner advocated by many abortion providers. The FDA has received no reports of women dying from bacterial infection following administration according to the FDA-approved protocol for the Mifeprex regimen. The FDA has not been able to conclude one way or another whether off-label use led to the eight deaths;

14. Medical evidence demonstrates that women who utilize abortion-inducing drugs incur more complications than those who have surgical abortions;

15. Based on the foregoing findings, it is the purpose of this act to:

a. protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, and

b. ensure that physicians abide by the protocol approved by the FDA for the administration of abortion-inducing drugs, as outlined in the drugs' final printed labeling (FPL); and

16. In response to the Oklahoma Supreme Court's decision in *Cline v. Oklahoma Coalition for Reproductive Justice* (No. 111,939), in which the Oklahoma Supreme Court determined, in contravention of this Legislature's intent, that this act prohibits all uses of misoprostol for chemical abortion and prohibits the use of methotrexate in treating ectopic pregnancies, it is also the purpose of this act to legislatively overrule the decision of the Oklahoma Supreme Court and ensure that should such questions be presented before that Court in the future it will reach the proper result that this act does not ban use of misoprostol in chemical abortion (and allows it as part of the FDA-approved Mifeprex regimen) nor prevent the off-label use of drugs for the treatment of ectopic pregnancy.

B. As used in this section:

1. "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of ~~terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child~~ inducing an abortion. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs, or for treatment of an ectopic pregnancy;

2. "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device intentionally to terminate the pregnancy of a female known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to remove an ectopic pregnancy, or to remove a dead unborn child who died as the result of a spontaneous miscarriage, accidental trauma, or a criminal assault on the pregnant female or her unborn child;

3. "Drug label" or "drug's label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration (FDA) and agreed upon by the drug company applying for FDA authorization of that drug. Also known as "final ~~printing~~ printed labeling ~~instructions~~ (FPL)" or referred to as the "FDA-approved label", it is the FDA-approved document which delineates how a drug is to be used according to the FDA approval;

~~3. "Federal law" means any law, rule, or regulation of the United States or any drug approval letter of the U.S. Food and Drug Administration that governs or regulates the use of RU-486 (mifepristone) or any abortion-inducing drug for the purpose of inducing abortions;~~

4. "Mifeprex regimen" means the abortion-inducing drug regimen that is described in the FDA-approved Mifeprex final printed labeling, and which involves administration of mifepristone (brand name "Mifeprex") and misoprostol. It is the only abortion-inducing drug regimen approved by the FDA, and it does not include any dosage or administration not explicitly approved in Mifeprex final printed labeling. It is also commonly referred to as the "RU-486 regimen" or simply "RU-486";

5. "Mifepristone" means the first drug used in the Mifeprex regimen;

6. "Misoprostol" means the second drug used in the Mifeprex regimen;

7. "Personal identifying information" means any information designed to identify a person and any information commonly used or capable of being used alone or in conjunction with any other information to identify a person; and

~~5.~~ 8. "Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine in the state.

~~B.~~ C. No person shall knowingly or recklessly give, sell, dispense, administer, prescribe, or otherwise provide ~~RU-486, also known as mifepristone, or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion in a pregnant female~~, including the Mifeprex regimen, unless the person who gives, sells, dispenses, administers, prescribes, or otherwise provides the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug is a physician who:

1. Has the ability to assess the duration of the pregnancy accurately;

2. Has the ability to diagnose ectopic pregnancies;

3. Has the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or has made and documented in the patient's medical record plans to provide such care through other qualified physicians; and

4. Is able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary~~; and~~

~~5. Has read and understood the prescribing information for the use of RU-486 (mifepristone) or any abortion-inducing drug as provided by the drug manufacturer in accordance with the requirements of the U.S. Food and Drug Administration~~.

~~C.~~ D. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug, including the Mifeprex regimen, 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~~ outlined in the ~~drug~~ FDA-approved label ~~for the RU-486 (mifepristone) or any abortion-inducing drug~~. In the specific case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (brand name Mifeprex) and misoprostol, and any provision accomplished according to that labeling is not prohibited.

~~D.~~ E. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion~~, including the Mifeprex regimen, shall knowingly or recklessly fail to:

1. Provide each patient with a copy of the drug manufacturer's medication guide and drug label for ~~RU-486 (mifepristone) or any abortion-inducing drug~~ the drug(s) being used; when the Mifeprex regimen is being utilized, this requirement is satisfied so long as the patient is provided the FDA-approved Mifeprex medication guide and final printed labeling;

2. Fully explain the procedure to the patient, including, but not limited to, explaining that the drug is being used in accordance with the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration and as outlined in the drug label for ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug;

3. Provide the female with a copy of the drug manufacturer's patient agreement and obtain the patient's signature on the patient agreement;

4. Sign the patient agreement; and

5. Record the drug manufacturer's package serial number in the patient's medical record.

~~E.~~ F. Because the failure and complications rates from ~~medical abortion~~ abortion-inducing drugs increase with increasing gestational age, and because the physical symptoms of ~~medical abortion~~ an abortion induced by drugs can be identical to the symptoms of ectopic pregnancy, ~~and because RU-486 (mifepristone) or any abortion-inducing drug does not treat ectopic pregnancies but rather is contraindicated in ectopic pregnancies,~~ thereby increasing the risk of ruptured ectopic pregnancy, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug shall first examine the woman and document, in the woman's medical chart, gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug.

~~F. When RU-486 (mifepristone) or any~~ G. An abortion-inducing drug ~~is used for the purpose of inducing an abortion, the drug~~ must be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient. The physician inducing the abortion, or a person acting on behalf of the physician inducing the abortion, shall schedule the patient for a follow-up appointment and make all reasonable efforts to ensure that the patient returns twelve (12) to eighteen (18) days after the administration or use of ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug for a follow-up visit so that the physician can confirm that the pregnancy has been terminated and assess the patient's medical condition. A brief description of the efforts made to comply with this subsection, including the date, time, and identification by name of the person

making such efforts, shall be included in the patient's medical record.

~~G.~~ H. 1. If a physician provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion and if the physician~~ and knows that the female who uses the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug ~~for the purpose of inducing an abortion~~ experiences within one (1) year after the use of ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug an incomplete abortion, severe bleeding, or an adverse reaction to the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug or is hospitalized, receives a transfusion, or experiences any other serious event, the physician shall, as soon as is practicable, but in no case more than sixty (60) days after the physician learns of the adverse reaction or serious event, provide a written report of the incomplete abortion, severe bleeding, adverse reaction, hospitalization, transfusion, or serious event to the drug manufacturer. If the physician is a doctor of medicine, the physician shall simultaneously provide a copy of the report to the State Board of Medical Licensure and Supervision. If the physician is a doctor of osteopathy, the physician shall simultaneously provide a copy of the report to the State Board of Osteopathic Examiners. The relevant Board shall compile and retain all reports it receives pursuant to this subsection. All reports the relevant Board receives under this subsection are public records open to inspection pursuant to the Oklahoma Open Records Act; however, absent an order by a court of competent jurisdiction, neither the drug manufacturer nor the relevant Board shall release the name or any other personal identifying information regarding a person who uses or provides ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug for the purpose of inducing an abortion and who is the subject of a report the drug manufacturer or the relevant Board receives under this subsection.

2. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug to a pregnant female ~~for the purpose of inducing an abortion~~ shall knowingly or recklessly fail to file a report required under paragraph 1 of this subsection. Knowing or reckless failure to comply with this subsection shall subject the physician to sanctioning by the licensing board having administrative authority over such physician.

~~H.~~ I. Any female upon whom an abortion has been performed, the father of the unborn child who was the subject of the abortion if the father was married to the woman who received the abortion at the

time the abortion was performed, or a maternal grandparent of the unborn child may maintain an action against the person who performed the abortion in knowing or reckless violation of this section for actual and punitive damages. Any female upon whom an abortion has been attempted in knowing or reckless violation of this section may maintain an action against the person who attempted to perform the abortion for actual and punitive damages.

~~I.~~ J. If a judgment is rendered in favor of the plaintiff in any action described in this section, the court shall also render judgment for a reasonable attorney fee in favor of the plaintiff against the defendant. If a judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court shall also render judgment for a reasonable attorney fee in favor of the defendant against the plaintiff.

~~J.~~ K. No pregnant female who obtains or possesses ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion~~ to terminate her own pregnancy shall be subject to any action brought under subsection ~~H~~ I of this section.

~~K.~~ L. If some or all of the language in this section is ever temporarily or permanently restrained or enjoined by judicial order, then this section shall be enforced as though such restrained or enjoined provisions had not been adopted; provided, however, that whenever such temporary or permanent restraining order or injunction is stayed or dissolved, or otherwise ceases to have effect, such provisions shall have full force and effect.

SECTION 2. This act shall become effective November 1, 2014.

Passed the House of Representatives the 10th day of March, 2014.

_____
Presiding Officer of the House
of Representatives

Passed the Senate the 15th day of April, 2014.

_____
Presiding Officer of the Senate

OFFICE OF THE GOVERNOR

Received by the Office of the Governor this _____

day of _____, 20_____, at _____ o'clock _____ M.

By: _____

Approved by the Governor of the State of Oklahoma this _____

day of _____, 20_____, at _____ o'clock _____ M.

_____
Governor of the State of Oklahoma

OFFICE OF THE SECRETARY OF STATE

Received by the Office of the Secretary of State this _____

day of _____, 20 _____, at _____ o'clock _____ M.

By: _____

Exhibit B

1018338885

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients

Plaintiffs,

v.

TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and CATHERINE C. TAYLOR, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners,

Defendants.

Case No. CV-2011-1722

Judge Donald L. Worthington

FILED IN THE DISTRICT COURT
OKLAHOMA COUNTY, OKLA.

MAY 11 2012

PATRICIA PRESLEY, COURT CLERK
by _____ DEPUTY

FINDINGS OF FACT

1. In the year 2000 the United States Food and Drug Administration (FDA) approved the abortion inducing drug RU-486 (also known as Mifeprex and Mifepristone) for marketing in the United States subject to a regimen of use described in the FDA final printed labeling (FPL) that accompanied the approval of the drug.

2. On May 11, 2011, Governor Mary Fallin signed into law Oklahoma House Bill 1970 (The Act) amending Section 1, Chapter 48, O.S.L. 2010 (codified as 63 O.S. Supp. 2010, § 1-729a) to become effective November 1, 2011 relating to the drug RU-486 or "any other abortion-inducing drug, medicine or other substance" prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman.

3. Plaintiffs on October 5, 2011 filed this case in this court seeking declaratory judgment that The Act violates the Oklahoma Constitution and seeking an injunction prohibiting enforcement of The Act.

4. On December 2, 2011, the Honorable Daniel L. Owens, a judge of this court entered an Order Granting Injunction temporarily enjoining the enforcement of The Act.

5. The Act provides a ban on medication abortion in the State of Oklahoma except as provided and in the manner and regimen set forth in the RU-486 FPL and it explicitly prohibits the "off label" use of RU-486 or any abortion drug or medication.

6. Good medical practice and the best interests of the patient often includes drug use that is not displayed in the FPL of that drug and requires physicians use legally available drugs according to their best knowledge and judgment.

7. Since the RU-486 FPL was issued by the FDA in 2000, a regimen different from that set forth in the FPL has been used in a great majority of cases of medication abortions in the United States demonstrated by scientific research to be safer and more effective than the regimen provided in the RU-486 FPL.

CONCLUSIONS OF LAW

1. The due process clause of the United States Constitution protects the right to bodily integrity as a fundamental right. *Washington v. Glucksberg, 521 U.S. 702 (1997); Planned Parenthood v. Casey 505 U.S. 833 (1992).*

2. Rights that are protected as fundamental by the United States Constitution are protected as fundamental rights by the Oklahoma Constitution to at least the same extent, *Eastern Oklahoma Building and Construction Trades Council v. Pitts, 2003 OK 113, 82 P.3d 1008; Messenger v. Messenger, 1992 OK 27, 827 P.2d 865 (Okla 1992).*

3. The due process clause of the United States Constitution protects the right to terminate a pregnancy as a fundamental right, *Roe V. Wade, 410 U.S. 113 (1973).*

4. The due process clause of the Oklahoma Constitution protects the right to terminate a pregnancy as a fundamental right. *Article II § 7, Oklahoma Constitution; Roe v. Wade, ante; Eastern Oklahoma Building and Construction Trades Council v. Pitts, ante; Messenger v Messenger, ante.*

5. A state regulation that has the effect of placing a substantial obstacle in the path of a woman seeking an abortion creates an "undue burden" on her ability to make that decision. *Planned Parenthood v. Casey, ante; Jane L. V. Bangerter, 102 F.3d 1112 (10th Cir. 1995); Davis v. Fieker, 1997, OK 156, 952 P.2d 505.*

6. A law violates the undue burden standard if its purpose is to impose a substantial obstacle in the path of women seeking a previable abortion. *Planned Parenthood v. Casey, ante; Jane L. V Bangerter, ante*

7. The Act's restriction of the use of the drug RU-486 or "any other abortion inducing drug, medicine or other substance" in the manner and to the regimen set forth in the medication FPL when used for abortion is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from

obtaining abortions and to punish and discriminate against those women who do. *Planned Parenthood v. Casey, ante.*

8. No material fact is in dispute in this case and Plaintiffs are entitled to judgment as a matter of law.

ORDER

The Motions for Summary Judgment of Plaintiffs and of Defendants come on this date for decision. The court heard argument of the attorneys on April 27, 2012, has reviewed and considered that argument, and the authority and material submitted by the parties, has found the facts as set forth herein and has reached the conclusions of law above noted.

It is therefore ordered that the Motion for Summary Judgment of Plaintiffs is sustained and the Motion for Summary Judgment of Defendants is overruled.

It is further ordered that Plaintiffs are granted judgment that Oklahoma House Bill 1970, 2011 Session Laws 1276 is an unconstitutional law in violation of the fundamental rights of women to privacy and bodily integrity guaranteed by Article II, § 7 of the Constitution of the State of Oklahoma.

It is further ordered that the Temporary Injunction issued by this court on December 2, 2011 is converted into a Permanent Injunction without bond and Defendants, their employees, agents and successors in office are restrained and prohibited from enforcing the said Oklahoma House Bill 1970, 2011 Sessions Law 1276.

The clerk is directed to send a copy of this order to the attorneys for the parties.

Dated this 11th day of May, 2012.

Donald L. Worthington
Judge of the District Court

Exhibit C

292 P.3d 27
Supreme Court of Oklahoma.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members and Nova Health Systems, d/b/a Reproductive Services, on behalf of itself, its staff, and its patients, Plaintiffs/Appellees,
v.
Terry CLINE, in his official capacity as Oklahoma Commissioner of Health, Lyle Kelsey, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, Catherine V. Taylor, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners, Defendants/Appellants.

No. 110,765. | Dec. 4, 2012.

Synopsis
Background: Coalition of reproductive rights organizations brought action challenging constitutionality of state statute prohibiting prescription of abortifacient medication. The District Court, Oklahoma County, Daniel L. Owens, J., held statute unconstitutional and enjoined enforcement thereof. State appealed.

[Holding:] The Supreme Court held that state statute prohibiting knowing or reckless prescription of abortifacient medication is facially unconstitutional.

Affirmed.

West Headnotes (2)

[1] Courts
Construction of federal Constitution, statutes, and treaties

State supreme court is duty bound by United States and state constitutions to follow the mandate of the United States Supreme Court on matters of federal constitutional law. U.S.C.A. Const. Art. 6, cl. 2; Const. Art. 1, § 1.

Cases that cite this headnote

[2] Abortion and Birth Control
Emergency contraception; abortifacients

State statute prohibiting knowing or reckless prescription of abortifacient medication is facially unconstitutional. 63 Okl.St.Ann. § 1–729a.

1 Cases that cite this headnote

West Codenotes

Recognized as Unconstitutional
63 Okl.St.Ann. § 1–729a

***27 MEMORANDUM OPINION**

PER CURIAM.

¶ 1 This is an appeal of the trial court's summary judgment which held House Bill 1970, 2011 Okla. Sess. Laws 1276, unconstitutional. Upon review of the record and the briefs of the parties, this Court determines this matter is controlled by the United States Supreme Court decision in *Planned Parenthood v. Casey,* 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992), which was applied in this Court's recent decision of *In re Initiative No. 395, State Question No. 761,* 2012 OK 42, 286 P.3d 637, *cert. den. sub nom. Personhood Okla. v. Barber et al.,* —— U.S. ——, 133 S.Ct. 528, 184 L.Ed.2d 340 (2012).

[1] ¶ 2 Because the United States Supreme Court has previously determined the dispositive issue presented in this matter, this Court is not free to impose its own view of the law. The Supremacy Clause of the United States Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the

> Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI, cl. 2. The Oklahoma Constitution reaffirms the effect of the Supremacy Clause on Oklahoma law by providing: "The State of Oklahoma is an inseparable part of the Federal Union, and the Constitution of the United States is the supreme law of the land." Okla. Const. art. 1, § 1. Thus, 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" *In re Initiative Petition No. 349, State Question No. 642,* 1992 OK 122, ¶ 1, 838 P.2d 1, 2; *In re Petition No. 395,* 2012 OK 42, ¶ 2, 286 P.3d 637.

[2] ¶ 3 The challenged measure is facially unconstitutional pursuant to ***28** *Casey,* 505 U.S. 833, 112 S.Ct. 2791. The mandate of *Casey* remains binding on this Court until and unless the United States Supreme Court holds to the contrary. The judgment of the trial court holding the enactment unconstitutional is affirmed and the measure is stricken in its entirety.

ALL JUSTICES CONCUR.

Parallel Citations

2012 OK 102

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Exhibit D

133 S.Ct. 2887

Related Westlaw Journal Article

Supreme Court of the United States

Terry CLINE, et al., petitioners,

v.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, et al.

No. 12–1094. | June 27, 2013.

Case below, 292 P.3d 27.

Opinion

Petition for writ of certiorari to the Supreme Court of Oklahoma granted. This Court, pursuant to the Revised Uniform Certification of Questions of Law Act, Okla. Stat., Tit. 20, § 1601 *et seq.* (West 2002), respectfully certifies to the Supreme Court of Oklahoma the following question: Whether H.B. No. 1970, Section 1, Chapter 216, O.S.L. 2011 prohibits: (1) 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; and (2) the use of methotrexate to treat eptopic pregnancies. Further proceedings in this case are reserved pending receipt of a response from the Supreme Court of Oklahoma.

Related Westlaw Journal Article(Back to Top)

21 NO. 3 Westlaw Journal Health Law 4

Parallel Citations

186 L.Ed.2d 932, 81 USLW 3518, 81 USLW 3712, 81 USLW 3714

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Exhibit E

313 P.3d 253

Related Westlaw Journal Article

Supreme Court of Oklahoma.

Terry CLINE, in his official capacity as Oklahoma Commissioner of Health, Lyle Kelsey, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, Catherine V. Taylor, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners, Petitioners,

v.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its Members and Nova Health Systems, d/b/a Reproductive Services, on behalf of itself, its staff, and its patients, Respondents.

No. 111,939. | Oct. 29, 2013.

Synopsis

Background: Coalition of reproductive rights organizations brought action challenging constitutionality of state statute prohibiting prescription of abortifacient medication. The District Court, Oklahoma County, Daniel L. Owens, J., held statute unconstitutional and enjoined enforcement thereof. State appealed, and the Oklahoma Supreme Court, 292 P.3d 27, affirmed. The United States Supreme Court granted certiorari and certified questions.

[Holding:] The Oklahoma Supreme Court held that statute prohibiting knowing or reckless prescription of abortifacient medication prohibited the use of misoprostol to induce abortions, including the use of misoprostol with mifepristone, and prohibited the use of methotrexate to treat ectopic pregnancies.

Questions answered.

West Headnotes (2)

[1] **Federal Courts**

Proceedings following certification

In answering a certified question, the Supreme Court does not presume facts outside those offered by the certification order; although it will neither add nor delete facts, it may consider uncontested facts supported by the record.

Cases that cite this headnote

[2] **Abortion and Birth Control**

Emergency contraception; abortifacients

Health

Effect of approval or non-approval; off-label use

Statute prohibiting knowing or reckless prescription of abortifacient medication prohibited 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 (FDA), and prohibited the use of methotrexate to treat ectopic pregnancies; statute required a physician to provide or prescribe mifepristone, misoprostol, and methotrexate according only to their respective FDA-approved drug labels, and it was undisputed that the FDA-approved label for mifepristone required a dosage level no longer considered medically necessary, that misoprostol had not been FDA-approved for abortion-related uses, and that methotrexate had not been approved for either abortion-related uses or for treating ectopic pregnancies. 63 Okl.St.Ann. § 1–729a.

2 Cases that cite this headnote

***254 CERTIFIED QUESTIONS OF LAW FROM THE SUPREME COURT OF THE UNITED STATES.**

¶ 0 On December 4, 2012, this Court issued a memorandum opinion, finding House Bill 1970, 2011 Okla. Sess. Laws 1276, facially unconstitutional pursuant to the U.S. Supreme Court's decision in *Planned Parenthood v. Casey,* 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992). *See Okla. Coal. for Reprod. Justice v. Cline,* 2012 OK 102, 292 P.3d 27. The Attorney General filed a Petition for Certiorari with the U.S. Supreme Court on March 4, 2013. On June 27, 2013, the U.S.

Supreme Court granted certiorari in the case and certified two questions of law to the Supreme Court of Oklahoma.
CERTIFIED QUESTIONS ANSWERED.

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Opinion

PER CURIAM.

¶ 1 The Supreme Court of the United States certified two questions of Oklahoma law under the Revised Uniform Certification of Questions of Law Act, 20 O.S.2011 §§ 1601–1611:

> Whether H.B. No.1970, Section 1, Chapter 216, O.S.L.2011 prohibits: (1) 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; and (2) the use of methotrexate to treat ectopic pregnancies.

We answer both certified questions in the affirmative.

Procedural Background

¶ 2 In May of 2011, the Governor signed House Bill 1970, 2011 Okla. Sess. Laws 1276, into law.[1] The Respondents challenged the bill in Oklahoma County District Court. The District Court found H.B. 1970 was unconstitutional and issued a permanent injunction, prohibiting enforcement of H.B. 1970. The Attorney General appealed the order and filed a Motion to Retain in this Court. We retained the case and issued a memorandum opinion on December 4, 2012, in Case No. 110,765, affirming the district court's decision. We found H.B. 1970 was facially unconstitutional pursuant to the U.S. Supreme Court's decision in *Planned Parenthood v. Casey,* 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992). *See Okla. Coal. for Reprod. Justice v. Cline,* 2012 OK 102, 292 P.3d 27. On January 15, 2013, the Chief Justice issued the mandate in Case No. 110,765.[2]

1 Section 1, Subsection C, of H.B. 1970 provides:

> 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 abortion-inducing drug.

Section 1, Subsection A, defines "abortion-inducing drug" as:

> [A] medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death

> of the unborn child. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs;
>
> H.B. 1970 was codified at 63 O.S.2011 § 1–729a.

2 *See* Mandate, *Okla. Coal. for Reprod. Justice v. Cline,* No. 110,765 (Jan. 15, 2013). This Court "can take judicial notice *of its own records* in litigation interconnected with a case before it." *Robinson v. Texhoma Limestone, Inc.,* 2004 OK 50, ¶ 13, 100 P.3d 673, 677.

¶ 3 The Attorney General filed a Petition for Certiorari with the U.S. Supreme Court on March 4, 2013. The U.S. Supreme Court Clerk filed a letter in Case No. 110,765 on March 14, 2013, advising this Court that a petition for certiorari review of the order in Case No. 110,765 had been filed on March 4, 2013. The Attorney General has not asked this Court to suspend the effectiveness of mandate in Case No. 110,765.

¶ 4 On June 27, 2013, the U.S. Supreme Court granted certiorari in the case and certified two questions of law to this Court. *See Terry Cline et al. v. Okla. Coal. for Reprod. Justice et al.,* —— U.S. ——, 133 S.Ct. 2887, 186L.Ed.2d 932 (2013). Further proceedings in the U.S. Supreme Court were reserved "pending receipt of a response from the Supreme Court of Oklahoma." *Id.* The certified questions were filed in this Court on July 1, 2013, in Case No. 111,939. The briefs filed in the U.S. Supreme Court were included with the certification order. After the certified questions were filed, the Attorney General filed a request for briefing schedule. This Court entered a briefing schedule on ***256** July 16, 2013. Applications for amicus briefs were filed by several organizations, and this Court granted those applications on August 16, 2013. Briefing was completed on October 2, 2013.

This Court Has Jurisdiction to Answer the Certified Questions

¶ 5 Petitioners sought certiorari to the U.S. Supreme Court from Oklahoma Supreme Court Case No. 110,765, which has been mandated and is not before this Court at this time. Oklahoma Supreme Court Rule 1.16 permits a party to file a motion to suspend the effectiveness of mandate if the party contemplates the filing of a petition for certiorari in the U.S. Supreme Court and authorizes suspension of the effectiveness of the mandate until 1) expiration of time to file the petition; or 2) notice of final disposition by the U.S. Supreme Court.[3] Until a party makes a request to suspend the mandate pursuant to Rule 1.16 in Case No. 110,765, or upon final disposition by the U.S. Supreme Court, this Court will not suspend or recall the mandate in Case No. 110,765.[4]

3 Okla. Sup. Ct. R. 1.16.

4 Although the Attorney General's failure to move to suspend the effectiveness of mandate is not fatal to our exercise of jurisdiction in this case, litigants practicing before this Court must conform to the rules and procedures of this Court. The file also indicates that no one from the Attorney General's office has filed an entry of appearance in Case No. 111,939 as required by Oklahoma Supreme Court Rule 1.5, which provides that "[a]ll parties to any proceeding in the appellate courts shall immediately, but no later than filing the first document in the appellate court, file an Entry of Appearance on the forms set forth in Rule 1.301, by counsel or an unrepresented party representing himself or herself." Okla. Sup. Ct. R. 1.5. "When no counsel enters a formal appearance on behalf of an appellate party this Court possesses the discretion to list as counsel the lawyer who has signed and submitted a brief or motion for that party." *State ex rel. Okla. Bd. of Medical Licensure and Supervision v. Pinaroc,* 2002 OK 20, n. 1, 46 P.3d 114, 116 n. 1.

¶ 6 The jurisdictional basis for a majority of this Court's decisions is derived from the jurisdiction conferred upon the Court by Oklahoma Constitution Article VII, § 4.[5] This section vests five types of jurisdiction in the Supreme Court: (1) appellate jurisdiction over all civil matters; (2) jurisdiction to determine whether the Court of Criminal Appeals or the Supreme Court has jurisdiction over a controversy; (3) superintending control jurisdiction; (4) jurisdiction to issue writs of habeas corpus, mandamus, quo warranto, certiorari, prohibition, and such other remedial writs as may be provided by law; and (5) further jurisdiction conferred by statute.[6]

5 The Oklahoma Constitution, Article VII, § 4 provides:

> The appellate jurisdiction of the Supreme Court shall be co-extensive with the State and shall extend to all cases at law and in equity; except that the Court of Criminal Appeals shall have exclusive appellate jurisdiction in criminal cases until otherwise provided by statute and in the event

> there is any conflict as to jurisdiction, the Supreme Court shall determine which court has jurisdiction and such determination shall be final. The original jurisdiction of the Supreme Court shall extend to a general superintendent control over all inferior courts and all Agencies, Commissions and Boards created by law. The Supreme Court, Court of Criminal Appeals, in criminal matters and all other appellate courts shall have power to issue, hear and determine writs of habeas corpus, mandamus, quo warranto, certiorari, prohibition and such other remedial writs as may be provided by law and may exercise such other and further jurisdiction as may be conferred by statute. Each of the Justices or Judges shall have power to issue writs of habeas corpus to any part of the State upon petition by or on behalf of any person held in actual custody and make such writs returnable before himself, or before the Supreme Court, other Appellate Courts, or before any District Court, or judge thereof in the State. The appellate and the original jurisdiction of the Supreme Court and all other appellate courts shall be invoked in the manner provided by law.
>
> Okla. Const. art. VII, § 4.

6 *See* 20 O.S.2011 § 1602.

¶ 7 This Court may also exercise jurisdiction that arises independent of Article VII, § 4, and one example of this occurs when the Court answers a certified question from a federal court. In *Bonner v. Oklahoma Rock Corp.*, we said:

> This court needs no explicit grant of jurisdiction to answer certified questions from a federal court; such power comes from the United States Constitution's grant of state sovereignty. By answering a state-law ***257** question certified by a federal court, we may affect the outcome of federal litigation, *but it is the federal court who hears and decides the cause.* "Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the state." Certification assures that federal courts are apprised of the *substantive norms of the Oklahoma legal system.*

1993 OK 131, n. 3, 863 P.2d 1176, 1178, n. 3 (citations omitted).

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 and prohibits the use of methotrexate to treat ectopic pregnancies

¶ 8 The U.S. Supreme Court certified two questions of law under the Revised Uniform Certification of Questions of Law Act, 20 O.S.2011 §§ 1601–1611:

> Whether H.B. No. 1970, Section 1, Chapter 216, O.S.L.2011 prohibits: (1) 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; and (2) the use of methotrexate to treat ectopic pregnancies.

The certified questions are questions of statutory interpretation.[7] The meaning of statutory language presents a pure question of law. *W.R. Allison Enters., Inc. v. CompSource Okla.*, 2013 OK 24, ¶ 10, 301 P.3d 407, 410. Unresolved questions of state law may be answered by this Court if certified questions are presented in accordance with the Revised Uniform Certification of Questions of Law Act, 20 O.S.2011 §§ 1601–1611. Section 1602 outlines the discretionary power afforded this Court under the Act:

> The Supreme Court ... may answer a question of law certified to it by a court of the United States ... if the answer may be determinative of an issue in pending litigation in the certifying court and there is no controlling decision of the Supreme Court or Court of Criminal Appeals, constitutional provision, or statute of this state.

7 Curiously, although the Attorney General has not issued an opinion interpreting H.B. 1970, the Attorney General states:

> [I]t should not be overlooked that this interpretation comes from the Attorney General, whose opinion "is binding upon the state officials whom it affects." Thus, this interpretation of the law is not Petitioners' "best guess" as to how the law will be interpreted and enforced; it is in fact how it *will* be enforced.

Petitioners' Brief in Chief at 23, n. 41 (citations omitted).

The Supreme Court of Oklahoma "alone has the power to authoritatively determine the validity or invalidity of a statute." *State ex rel. York v. Turpen*, 1984 OK 26, ¶ 10, 681 P.2d 763, 767 (emphasis added).

20 O.S.2011 § 1602.

[1] ¶ 9 In 1996, a U.S. manufacturer filed a new drug application for mifepristone.[8] The FDA approved the application for mifepristone in 2000. According to mifepristone's FDA-approved final printed label, an informational document providing guidance about a drug's indications, precautions, and dosage, the protocol for administration of mifepristone for the termination of pregnancy requires three office visits by the patient.[9] During the first office visit, the patient is given 600 mg of mifepristone orally. Two days later, the patient returns to the office and is given 400 μg (0.4 mg) of misoprostol orally. Two weeks later, the patient returns to the office for a third visit to verify the ***258** procedure was successful. Mifepristone's FDA-approved label states mifepristone can be administered through forty-nine days of pregnancy.

8 "In answering a certified question, the Court does not presume facts outside those offered by the certification order. Although we will neither add nor delete facts, we may consider uncontested facts supported by the record." *McClure v. ConocoPhillips Co.*, 2006 OK 42, n. 3, 142 P.3d 390, 392, n. 3. Although the record on appeal to the U.S. Supreme Court is not before this Court, the facts recited are not disputed by the parties. Additionally, neither party disputes that these facts are included in the record, and neither party has provided a citation to the record indicating evidence to the contrary exists.

9 The FDA does not design or test the proposed protocol and does not conduct its own clinical trials; rather, FDA experts scrutinize submissions by the drug's sponsor, and other interested parties, concerning the safety and efficacy of the drug. *See* Petitioners' Brief in Chief at app. 2–3; *See also Planned Parenthood v. DeWine*, 696 F.3d 490, 495 (6th Cir.2012).

¶ 10 After FDA approval of mifepristone, additional clinical trials led to the development of new protocols for administering mifepristone. The practice of providing approved medications using regimens different from that described in the medication's final printed label is known as an "off-label use," or an "evidence-based regimen." The FDA has stated that evidence-based regimens are common, permissible, and can be required by good medical practice.[10]

10 *DeWine*, 696 F.3d at 496 (" '[I]t is standard medical practice in the United States for physicians to prescribe FDA-approved drugs in dosages and for medical indications that were not specifically approved—or even contemplated—by the FDA, particularly where the alternative use is supported by adequate study.' ").

¶ 11 Evidence-based regimens for administering mifepristone vary from the protocol in mifepristone's FDA-approved label in three ways. First, the evidence-based regimens allow women to take one-third the dosage of mifepristone at the first office visit. Second, the evidence-based regimens allow a woman to self-administer the second drug, misoprostol, in the privacy of her own home rather than at a medical facility. Third, evidence-based regimens extend the effective use of mifepristone from forty-nine days to sixty-three days into the pregnancy.

¶ 12 Both the protocol in mifepristone's FDA-approved label and the evidence-based regimens require mifepristone be used *in conjunction with* misoprostol to induce an abortion. Misoprostol has not been approved by the FDA for use in abortions but has been approved by the FDA to treat ulcers. The FDA-approved label for misoprostol is silent on abortion-related uses.

¶ 13 Although the most common evidence-based regimens involve some combination of mifepristone and misoprostol, other evidence-based regimens involve the use of methotrexate. Methotrexate is also a drug frequently used by physicians to terminate early ectopic pregnancies without surgery. Ectopic pregnancies pose grave health risks, and surgical intervention can result in serious complications, including future infertility, organ damage, and death. Methotrexate was approved by the FDA to treat neoplastic diseases, psoriasis, and rheumatoid arthritis. The FDA-approved label for methotrexate is silent on abortion-related uses.

¶ 14 In 2011, the Legislature passed H.B. 1970. Section 1, Subsection C, of H.B. 1970 provides:

> 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 abortion-inducing drug.[11]

11 Title 63 O.S. Supp.2010 § 1–729a regulated the specific drug RU–486 (mifepristone) prior to the passage of H.B. 1970. Section 1–729a was originally enacted by Senate Bill 1902, 2010 Okla. Sess. Laws 1086, and provided specific restrictions regarding the distribution and use of RU–486 (mifepristone). It required the prescribing physician to have certain qualifications and prescribe the medication under specific conditions, but it made no mention of drug labels and did not apply to other substances.

H.B. 1970 made several significant changes to § 1–729a. For example: 1) it extended the existing restrictions on RU–486 (mifepristone) to "any abortion-inducing drug" and defined that term to include "a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child"; 2) it added a definition for "drug label" to essentially reference FDA-approved guidelines for use of medications; and 3) in addition to earlier restrictions, it altered § 1–729a to require that RU–486 (mifepristone) and any "abortion-inducing drug" be provided or prescribed only "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 abortion-inducing drug."

To determine the meaning of H.B. 1970, we first look to the plain language of the statute. *W.R. Allison,* 2013 OK 24, ¶ 14, 301 P.3d at 411. "The Legislature is presumed to have expressed its intent in the text of the statute." *Id.* The rules of statutory construction ***259** are employed "[o]nly where the legislative intent cannot be ascertained from the statutory language, *i.e.,* in cases of ambiguity or conflict." *McClure,* 2006 OK 42, ¶ 12, 142 P.3d at 395.

¶ 15 Three times in Subsection C the phrase "RU–486 (mifepristone) or any abortion-inducing drug" is used. The Legislature's use of the word "or" to separate the term "RU–486 (mifepristone)" from "any abortion-inducing drug" shows its intent to treat the terms as separate and distinct. *In re J.L.M.,* 2005 OK 15, ¶ 7, 109 P.3d 336, 339 ("The Legislature's use of the disjunctive word 'or' indicates its intent that either the custodial parent alone (with whom the child was living), or both parents, may be ordered to pay restitution."); *Corp. Comm'n v. Union Oil Co.,* 1979 OK 30, ¶ 8, 591 P.2d 711, 715 ("The use of the word 'or' to connect these phrases in [the statute] indicates that the grounds for relief connected thereby are disjunctive, and each is sufficient in itself to authorize the relief requested."). [12]

12 *See also Hedrick v. Virginia,* 257 Va. 328, 513 S.E.2d 634, 640 (1999) ("[T]he use of the disjunctive word 'or' ... signifies the availability of alternative choices."); *Resolution Trust Corp. v. United Trust Fund, Inc.,* 57 F.3d 1025, 1033 (11th Cir.1995) ("[T]he disjunctive 'or' gives independent meaning to the words it separates."); *Knutzen v. Eben Ezer Lutheran Housing Ctr.,* 815 F.2d 1343, 1349 (10th Cir.1987) ("[T]he use of a disjunctive in a statute and regulations indicates that alternatives were intended."); *Azure v. Morton,* 514 F.2d 897, 900 (9th Cir.1975) ("As a general rule, the use of a disjunctive in a statute indicates alternatives and requires that they be treated separately.").

¶ 16 Therefore, under H.B. 1970 if a physician wishes to provide or prescribe RU–486 (mifepristone), the physician must provide or prescribe RU–486 (mifepristone) according to the FDA-approved label for *RU–486 (mifepristone).* If a physician wishes to provide or prescribe any abortion-inducing drug, the physician must provide or prescribe the abortion-inducing drug according to the FDA-approved label for *that abortion-inducing drug.*

¶ 17 Abortion-inducing drug is defined in Section 1, Subsection A, of H.B. 1970 as:

> a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs;

Misoprostol, when used in either the protocol described in the FDA-approved label for mifepristone or an evidence-based regimen, is an abortion-inducing drug as defined

by subsection A because it is prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. Similarly, methotrexate, when used either in an evidence-based regimen or to treat ectopic pregnancies, is an abortion-inducing drug as defined by subsection A because it too is prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child.

[2] ¶ 18 The Attorney General argues that 63 O.S.2011 § 1–730(A)(1) of the Public Health Code defines the term "abortion" to exclude the termination of ectopic pregnancies, so methotrexate can still be used off-label to treat ectopic pregnancies.[13] *But the operative term in H.B. 1970 is not the term* ***260** *"abortion," but rather the new, separately defined term "abortion-inducing drug."* The Legislature could have defined abortion-inducing drug to mean a medicine prescribed with the intent of causing an abortion. It did not. Instead, it defined it as a drug prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. The fact that the Legislature excludes ectopic pregnancies from the definition of abortion in § 1–730(A)(1), yet defines "abortion-inducing drug" without incorporating § 1–730(A)(1) or including similarly exclusionary language indicates the Legislature intended to ban the off-label use of methotrexate, including its use in the treatment of ectopic pregnancies.

13 Section 1–730(A)(1) provides:

> "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device intentionally to terminate the pregnancy of a female known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to remove an ectopic pregnancy, or to remove a dead unborn child who died as the result of a spontaneous miscarriage, accidental trauma, or a criminal assault on the pregnant female or her unborn child.

63 O.S.2011 § 1–730(A)(1).

¶ 19 The Attorney General states that "[w]hile the most common off-label protocols involve some combination of [mifepristone] and misoprostol, *other off-label protocols involve the use of methotrexate followed by misoprostol, and others yet involve the use of just misoprostol or just methotrexate.*" Petitioners' Brief in Chief at 9, n. 18 (emphasis added). The Legislature specifically referenced both misoprostol and methotrexate in the definition of an abortion-inducing drug: "This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate." We find that both misoprostol and methotrexate are abortion-inducing drugs as the term is used in Subsection A; therefore, under the plain language of Subsection C of the statute, the off-label use of both misoprostol and methotrexate is prohibited.[14]

14 We find no merit to the Attorney General's argument that an ectopic pregnancy is not a "true 'pregnancy,' " so methotrexate can still be used off-label to treat ectopic pregnancies. Petitioners' Brief in Chief at 22. Title 63 O.S.2011 § 1–730(A)(4) defines an "unborn child" as the "unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth including the human conceptus, zygote, morula, blastocyst, embryo and fetus." And 63 O.S.2011 § 1–730(A)(7) defines "conception" as "fertilization of the ovum of a female individual by the sperm of a male individual." Further discrediting this argument is the fact that the Legislature believed an ectopic pregnancy was a pregnancy having excluded the termination of ectopic pregnancies from the definition of "abortion" in 63 O.S.2011 § 1–730(A)(1).

¶ 20 FDA-approved labeling is "not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient."[15] In an often-cited bulletin specifically addressing the use of approved drugs for unlabeled indications, the FDA stated:

15 *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir.1989).

> The FD & C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

> The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigation.
>
> FDA Drug Bulletin 12:4–5, 1982. [16]

16 *See also* 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994).

¶ 21 As Respondents correctly point out, and as the FDA recognizes, human progress is not static: medical research and advances do not stop upon a particular drug's approval by the FDA. Researchers continue to perform clinical trials, doctors continue to gain experience, and widespread use of a particular treatment allows the medical community to collect data about side effects, alternative doses, and potential new uses for treatments. Ninety-six percent of medication abortions in the United States are now provided according to a regimen different from the one ***261** described in mifepristone's FDA-approved label. [17] At the clinic operated by Respondent Reproductive Services, an evidence-based regimen for administering mifepristone is the most prevalent method for terminating early pregnancies, accounting for two-thirds of all abortions performed by the clinic, and the physicians at Reproductive Services have concluded that the protocol in the mifepristone FDA-approved label likely no longer meets the standard of care. [18] Both the American College of Obstetricians and Gynecologists and the World Health Organization have endorsed these alternate regimens as safer and more effective than the now-outdated regimen provided for in mifepristone's FDA-approved label. [19] "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment." [20]

17 Respondents' Answer Brief at 7 (citing R. on Appeal, Tab 14, App. 4, ¶¶ 21–24). Neither side in this cause disputes that when the FDA originally approved mifepristone, it did so under a regulatory provision known as Subpart H, which allows the FDA to restrict distribution of an approved drug by its sponsor to ensure safe use. *See* 21 C.F.R. § 314.520. Although the FDA required mifepristone's sponsor to distribute the drug only under conditions where it would be provided by or under the supervision of a physician who was able to meet certain criteria, the FDA did not go so far as to require that administering physicians utilize mifepristone according only to the protocol described in the FDA-approved label.

18 Respondents' Answer Brief at 8 (citing R. on Appeal, Tab 14, App. 7, ¶¶ 9, 14–15, 21).

19 Respondents' Answer Brief at 7 (citing R. on Appeal, Tab 14, App. 4, Ex. B at 2).

20 United States Food and Drug Administration, *Regulatory Information: "Off–Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices – Information Sheet,* available at http://www. fda. gov/ RegulatoryInformation/Guidances/ucm126486.htm.

¶ 22 In other areas of the law, the Oklahoma Legislature has recognized the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling. Title 59 O.S.2011 § 509(16) provides that unprofessional conduct for physicians includes, among other criteria:

> Prescribing, dispensing or administering of controlled substances or narcotic drugs in excess of the amount considered **good medical practice,** or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards.

59 O.S.2011 § 509(16) (emphasis added).

While § 509(16) requires physicians only dispense certain drugs in amounts considered good medical practice, nowhere does it globally require physicians to dispense those drugs in accordance with their FDA-approved labels.

¶ 23 Title 63 O.S.2011 § 1–2604 prevents health insurers from denying coverage for prescription drugs for cancer treatment merely because their use in the treatment of cancer or study of oncology is off-label. It provides:

> **No individual policy of accident and health insurance issued which provides coverage for prescription drugs,** nor any group blanket policy of accident and health insurance issued which provides coverage for prescription drugs **shall exclude coverage of prescription drugs for cancer treatment or the study of oncology because the off-label use of such prescription drug has not been approved by the Federal Food and Drug Administration for that indication** in one of the standard

reference compendia, as defined in paragraph (d) of Section 1–1401 of Title 63 of the Oklahoma Statutes.

Any coverage of a prescription drug required by this section shall also include provisions for coverage of **medically necessary** services associated with the administration of the prescription drug....

63 O.S.2011 § 1–2604 (emphasis added).

¶ 24 Title 63 O.S.2011 §§ 5030.1–5030.5 provide authorization and guidelines for the Medicaid Drug Utilization Review Board. The board is charged to:

> develop and recommend to the Oklahoma Health Care Authority Board a retrospective ***262** and prospective drug utilization review program for medical outpatient drugs to **ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.**

63 O.S.2011 § 5030.4(1) (emphasis added).

Nowhere in §§ 5030.1–5030.5, however, is the board constrained by uses authorized in the FDA-approved labels for prescription drugs in making its determinations. Instead, the statute uses the term "medically necessary" in deference to the knowledge and experience of physicians exercised in the practice of medicine.

¶ 25 In contrast to the deference physicians receive regarding treatment decisions in almost all other areas of medicine, H.B. 1970 requires a physician to provide or prescribe mifepristone, misoprostol, and methotrexate according only to their respective FDA-approved drug labels.[21] It is undisputed that the FDA-approved label for mifepristone requires a dosage level no longer considered medically necessary. It is also undisputed that misoprostol has not been FDA-approved for abortion-related uses, and methotrexate has not been approved for either abortion-related uses or for treating ectopic pregnancies. The use of misoprostol in the protocol described in the mifepristone FDA-approved label is an off-label use prohibited by the terms of H.B. 1970, and the use of methotrexate in treating ectopic pregnancies is an off-label use also prohibited by H.B. 1970. **H.B. 1970 effectively bans all medication abortions.**

21 Abortion is the only area of medicine where it appears the Oklahoma Legislature has seen fit to restrict a physician's use of certain practices. *See also* 63 O.S.2011 § 1–745.3; 63 O.S.2011 § 1–745.5; 63 O.S.2011 § 1–745.5(A).

Conclusion

¶ 26 The role of the physician is to heal the sick and the injured, and physicians are required to undergo rigorous training to develop the required knowledge and experience to perform that role well. Physicians must inform their patient of the risks involved in any treatment, and together with the patient, must determine the best course of treatment. Part of the Hippocratic Oath requires Physicians to "follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[22]

22 Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered,* 44 Ariz. L. Rev. 313 (2002) (quoting 20 Encyclopedia Americana 217 (int'l ed., deluxe libr. ed.1993)).

¶ 27 When the district court originally found H.B. 1970 unconstitutional, it correctly concluded that:

> [t]he Act's restriction of the use of the drug RU–486 or "any other abortion inducing drug, medicine or other substance" in the manner and to the regimen set forth in the medication FPL when used for abortion is **so completely at odds with the standard that governs the practice of medicine** that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do.

Okla. Coal. for Repro. Justice v. Cline, No. CV–2011–1722, slip op., ¶ 7 (Dist.Ct.Okla.Cnty. May 11, 2012) (emphasis added). 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 and prohibits the use of methotrexate to treat ectopic pregnancies.**

CERTIFIED QUESTIONS ANSWERED.

¶ 28 REIF, V.C.J., KAUGER, WINCHESTER, EDMONDSON, TAYLOR, COMBS and GURICH, JJ., concur.

¶ 29 COLBERT, C.J. and WATT, J., not voting.

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Exhibit F

134 S.Ct. 550
Supreme Court of the United States

Terry CLINE, et al., petitioners,
v.
OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, et al.

No. 12–1094. | Nov. 4, 2013.

Case below, 292 P.3d 27.

Opinion
On writ of certiorari to the Supreme Court of Oklahoma. Writ of certiorari dismissed as improvidently granted.

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