ORIGINAL

2019 OK 33

IN THE SUPREME COURT OF THE 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/Appellees,

v.

TERRY L. CLINE in his official capacity as OKLAHOMA COMMISSIONER OF HEALTH,

Defendant,

and

LYLE KELSEY, in his official capacity as EXECUTIVE DIRECTOR OF THE OKLAHOMA STATE BOARD OF MEDICAL LICENSURE AND SUPERVISION,

Defendant/Appellant,

and

PRESTON L. DOERFLINGER, in his official capacity as OKLAHOMA INTERIM COMMISSIONER OF HEALTH,

Appellant.

No. 116,603

For Official Publication

ON APPEAL FROM THE DISTRICT COURT OF OKLAHOMA COUNTY

The Honorable Patricia G. Parrish, Trial Judge

¶0 After we reviewed plaintiff's two Oklahoma constitutional challenges to House Bill 2684, we remanded the cause to the district court to consider the plaintiff's remaining challenges to the bill. The district court found H.B. 2684 to be unconstitutional, and the State appealed. We retained the appeal for disposition. On June 4, 2018, we stayed resolution of this cause pending the outcome of an Arkansas case which involved a similar statute. The Arkansas case concluded with a dismissal by the appealing parties, thus rendering it ineffective precedent to apply to this cause. We hereby vacate our stay and hold that: 1) decisions from the United States Supreme Court are binding on this Court and where the United States Supreme Court has spoken, this Court is bound by its pronouncements; and 2) the Legislature's requirement that physicians adhere to the Federal Drug Administration's (FDA) 2000 label protocol for medication terminated pregnancies, rather than the more effective current 2016 label protocol, places a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's rights pursuant to United States Supreme Court precedent as it currently exists.

STAY LIFTED;
TRIAL COURT AFFIRMED.

Mithun S. Mansinghani,
Solicitor General
Michael K. Velchik,
Assistant Solicitor General
State of Oklahoma,
Oklahoma City, Oklahoma, For Defendants/Appellants.

J. Blake Patton,
Oklahoma City, Oklahoma, For Plaintiffs/Appellees.

PER CURIAM:

¶1 We decided Oklahoma Coalition for Reproductive Justice v. Cline, 2016 OK 17, 368 P.3d 1278 (Cline III) on February 23, 2016, which addressed whether House Bill (H.B.) 2684 violated two provisions of the Oklahoma Constitution. The provisions in question were art. 5, §1, delegation of legislative authority[1] and art. 5, §59 prohibition of special laws.[2] We held that neither provision was violated, and we remanded the cause to the trial court for a determination of the bill's validity under other state and federal constitutional provisions. The trial court held a hearing on October 6, 2017, and on November 9, 2017, it granted summary judgment and declared H.B. 2684 "unconstitutional in all applications" and "therefore void and of no effect." The State appealed on December 8, 2017, and we retained the cause on January 2, 2018.

¶2 On June 4, 2018, we stayed resolution of this cause pending the outcome of an Arkansas case, Planned Parenthood Arkansas & Eastern Oklahoma v. Jegley,

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[1]The Okla. Const., art. 5, §1 provides:

The Legislative authority of the State shall be vested in a Legislature, consisting of a Senate and a House of Representatives; but the people reserve to themselves the power to propose laws and amendments to the Constitution and to enact or reject the same at the polls independent of the Legislature, and also reserve power at their own option to approve or reject at the polls any act of the Legislature.

[2]The Okla. Const., art. 5, §59 provides:

Laws of a general nature shall have a uniform operation throughout the State, and where a general law can be made applicable, no special law shall be enacted.

2016 WL 6211310 (E.D. Ark. 2016), which involved a similar statute. The Arkansas case concluded with a dismissal by the appealing parties, thus rendering it ineffective to persuasively apply to this cause.[3] We hereby vacate the stay and

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[3]Planned Parenthood Arkansas & Eastern Oklahoma v. Jegley, 2016 WL 6211310(E.D. Ark. 2016) was decided on March 14, 2016, before the 2016 protocol was adopted. The United States District Court for E.D. Arkansas, Western Division, in an unpublished order issued a preliminary injunction enjoining Arkansas from enforcing the Arkansas Abortion-Inducing Drugs Safety Act (Arkansas Act). The Arkansas Act required that medication abortions follow the FDA's 2000 protocol as outlined in the drug label rather than any off-label use. The plaintiffs were following an off-label protocol that resembled the current 2016 protocol in both requirements, usage through gestation (63 days instead of 70), administration of the medication and hospital or clinical visits. In issuing the injunction, the court made several findings regarding the FDA 2000 label protocol. It referred to the dosage and usage through gestation of 63 day or 9 weeks as "evidence-based regimen" because of the large body of evidence regarding safety and effectiveness. It also determined, based on record evidence very similar to the evidence in this cause that: 1. The evidence showed that the failure rate was far less than the 2000 label protocol; 2. The ACOG and the American Medical Association found the 2016 protocol to be superior and safer and to cause fewer complications as compared to the 2000 protocol; 3. The FDA has expressly recognized the evidence-based use of medications is an appropriate part of medical practice and has never taken steps to restrict it or preclude doctors from such off-label use; 4. There is no established causal link between the abortion inducing drugs and the eight contracted fatal infections and even if there was, there is a very low risk of such a fatal infection; 5. The 2000 regimen takes far longer to complete and clinical observation under it may not be feasible for patients; 6. The 2000 regimen has an additional increased cost, and the 600 mcg of required mifepristone is a very expensive medicine; 7. Under the 2000 regimen women between 50 and 63 days would not have access to medication abortions at all; 8. Every time women travel for access for abortion services, they will have to arrange necessary funds, transportation, child care, and time off work required to travel; 9. Increased travel distances and costs, both monetary and otherwise, may cause women who otherwise would have obtained an abortion not to obtain one at all; 10. Increased travel distance and costs will force women into later abortions that are both riskier and more expensive, if they can obtain them at all and may cause some women to take desperate measures, such as attempting to self-abort or seek care from unsafe providers, putting their health at risk. 11. Cost is a significant barrier for women because 42.4% of abortion patients have incomes below the poverty line; 12. Far fewer women chose medication abortions in states which restrict doctors to the 2000 regimen; and 13. Medical negligence or malpractice actions arise when providers render care that falls below the acceptable standard of care and today, the 2000 regimen falls below the acceptable standard of care as the evidence-based regimen is used by providers across the county. On appeal, the 8th Circuit, in an unpublished opinion on July 28, 2017, remanded the cause for additional fact finding and the United States Supreme Court denied certiorari on May 29, 2018. Subsequently, the parties filed a joint motion to vacate the preliminary injunction and dismiss appeal which was granted by the

hold that: 1) decisions from the United States Supreme Court are binding on this Court, and because the United States Supreme Court has spoken, this Court is bound by its pronouncements;[4] and 2) the Legislature's requirement that physicians adhere to the Federal Drug Administration's (FDA) 2000 label protocol for medication-induced abortions, rather than the more effective current 2016 label protocol places a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's rights pursuant to United States Supreme Court precedent as it currently exists.

FACTS AND PROCEDURAL HISTORY

¶3 The undisputed facts in this appeal which are supported by competent evidentiary materials which are nearly identical to those in Cline III, supra, ¶¶9-11, and are summarized here. Cline III, supra, also discussed the procedural history of both the caselaw and legislation leading up to the enactment of H.B. 2684 in ¶¶2-7. (We summarize that history here as well as previously stated in Cline III, supra.)

¶4 Medication terminated pregnancy is a procedure for terminating a pregnancy using medications alone, generally following a protocol using both

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8th Circuit on November 9, 2018.

[4]Art. 1, §1, Okla. Const., see page 13, infra; Art. 6, the United States Const., see page 14, infra.

Mifeprex and misoprostol, which are taken one after the other respectively. Methotrexate is used to terminate or treat ectopic pregnancies. In 2011, the Oklahoma Legislature enacted H.B. 2684's predecessor, H.B. 1970, ch. 216, 2011 Okla. Sess. Laws 821-23 (codified at 63 O.S.Supp. 2011, § 1-729a), which prohibited the off-label use of Mifeprex (generally known as mifepristone or RU-486) and misoprostol (brand name Cytotec) for use in treatment. The effect of H.B. 1970 was to ban medication terminated pregnancies in Oklahoma.[5]

¶5 In the first challenge to H.B. 1970, this Court followed Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992), and affirmed the district court's decision that H.B. 1970 was unconstitutional.[6] The appellees filed a petition for certiorari in the United States Supreme Court.[7] The U.S. Supreme Court granted the petition and certified two questions to this Court: whether H.B. 1970 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."[8]

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[5]Okla. Coal. for Reprod. Justice v. Cline, 2013 OK 93, ¶ 25, 313 P.3d at 262 (Cline II).

[6]Okla. Coal. for Reprod. Justice v. Cline, 2012 OK 102, ¶3, 292 P.3d 27, 27-28 (Cline I).

[7]*See* Cline v. Okla. Coal. for Reprod. Justice, 570 U.S. 930, 133 S. Ct. 2887, 196 L.Ed.2d 932 (2013).

[8]Cline II, see note 5, supra at ¶8.

¶6 In our second pronouncement, we answered both questions affirmatively and the United States Supreme Court then dismissed the petition for certiorari as improvidently granted, leaving our decision intact.[9] In 2014, in response to our second decision, the Legislature passed H.B. 2684, amending Title 63, Section 1-729a of the Oklahoma Statutes. H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 375-80. H.B. 2684 was approved by the Governor and became effective on November 1, 2014.

¶7 In 2000, based on previously conducted clinical trials, the FDA approved Mifeprex's final printed label (FPL) protocol for marketing and distribution by the manufacturer. The approved use is for up to the first 49 days of gestation as measured from the first day after a woman's last menstrual period[10] and it requires:

(1) Mifeprex distribution only to doctors who have read and understand the prescribing information.
(2) Three office visits for patients.
(3) Administration of Mifeprex only in a clinic, medical office, or hospital, by or under the supervision of a physician able to assess the gestational age of an embryo and to diagnose ectopic pregnancies.
(4) Patients to read the medication guide and read and sign the patient agreement before treatment.

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[9]*See* Cline II, see note 5, supra at ¶1; Cline v. Okla. Coal. for Reprod. Justice, 571 U.S. 985, 134 S.Ct. 550 (Mem.), 187 L.Ed.2d 361 (2013).

[10]The FPL states that before administrating Mifeprex, physicians should provide patients with an explanation of the procedure along with a copy of the medication guide and patient agreement. The FPL also states that afterward, the physician should provide notice to the manufacturer of any ongoing pregnancy or serious adverse events.

(5) Administration of one dose of 600 milligrams(mg) of Mifeprex.
(6) Oral administration of 400 micrograms (g) of misoprostol given two days later unless an abortion has been confirmed.
(7) A follow-up visit about fourteen days after the administration of the Mifeprex to confirm complete termination of the pregnancy.
(8) Warning to patients that some women may experience vaginal bleeding or spotting up to sixteen days.
(9) Warning to patients that heavy or moderate bleeding is an indication of an incomplete termination.

It is uncontested that the FDA's requirements apply to the manufacturer and are marketing restrictions and other special distribution conditions, but the requirements do not restrict or control a doctor's practice of medicine or the use of medication once it is distributed.

¶8 Within a year of the FDA's approval of Mifeprex in 2000, ninety-six percent of medically terminated pregnancies did not follow the FPL protocol used in the clinical trials on which the FPL's approval was based.[11] The American College of Obstetricians and Gynecologists (ACOG) materials state that the off-label protocol actually used by most doctors is more effective with fewer adverse effects.

¶9 Plaintiff Nova Health Services (plaintiff/Nova) followed an off-label

[11]Since the FPL's approval, eight fatal bacterial infections have been reported in the United States where the women were administered Mifeprex and misoprostol for a medication termination and did not follow the FPL, but followed an off-label protocol. The FDA has not established a casual connection between the off-label protocol and the deaths. However, the FDA now warns on the FPL about the risk of a bacterial infection following Mifeprex's use. These same fatal bacteria also occur following other obstetric and gynecologic processes.

protocol which is endorsed by the ACOG. The ACOG recommended off-label, or "evidence-based," protocol is based on "good and consistent scientific evidence" and includes vaginal, buccal, and sublingual administration of misoprostol by the patient away from a clinic. The ACOG off-label protocol provides for administration of one 200 milligram dose of Mifeprex, compared to the 600 milligrams of FDA on-label protocol, followed by 800 micrograms of misoprostol to be patient self-administered, compared to FDA's protocol of 400 milligrams to be doctor administered. The ACOG materials provide that medication terminationss can be provided safely through nonphysician clinicians and that the protocol can be used for up to 63 days of gestation (calculated from the last menstrual period). ¶10 H.B. 2684 restricts Mifeprex and misoprostol use for treatment to the FDA-approved final Mifeprex label, prohibits methotrexate use for treatment except to treat ectopic pregnancies, provides for liability of physicians who knowingly or recklessly perform a termination in violation of H.B. 2684, and makes doctors subject to discipline and actual and punitive damages for violating H.B. 2684. Title 63 O.S. § 1-729a(C)-(H). Because the Mifeprex label only allows its use for 49 days after the last menstrual period and Mifeprex off-label use allows for its use up to 63 days, the effect of H.B. 2684 is to ban the use of the Mifeprex and misoprostol drugs for pregnancies between 49 and 63 days from the last menstrual period.

¶11 On September 30, 2014, the Oklahoma Coalition for Reproductive Justice and Nova filed a challenge to H.B. 2684's prohibition of the off-label use of Mifeprex in the district court against the Oklahoma Commissioner of Health and the Executive Director of the Oklahoma State Board of Medical Licensure and Supervision (State). Nova challenged H.B. 2684 as violating rights guaranteed by the Oklahoma Constitution, including the right to due process by limiting women's rights to choose to terminate a pregnancy, to bodily integrity, and to equal protection; violating the Oklahoma constitutional prohibition against special laws; and improperly delegating legislative authority.

¶12 The district court rendered summary judgment in favor of the plaintiffs, finding that H.B. 2684 is a special law in violation of art. 5, §59 of the Oklahoma Constitution.[12] The State appealed, raising only the questions of issue preclusion, unauthorized delegation of legislative authority, and special law. We retained the appeal for disposition and decided Oklahoma Coalition for Reproductive Justice v. Cline, 2016 OK 17, 368 P.3d 1278 (Cline III) on February 23, 2016, in which we reversed the district court and remanded for disposition of plaintiff's remaining challenges.

¶13 After our opinion in Cline III, supra, was decided, the FDA approved a new FPL protocol for Mifeprex on March 29, 2016. However, in Cline III, supra,

[12]The Okla. Const., art 5, §59, see note 2, supra.

we upheld H.B. 2684's constitutionality under the improper delegation of legislative authority challenge because the bill did not allow the FDA to change Oklahoma termination laws by changing protocols. Thus, H.B. 2684 was upheld as constitutional in Cline III, supra, because physicians were required to adhere to the label protocol at the time H.B. 2684's enactment (the FDA 2000 protocol) and not any new or revised protocols which might be adopted by the FDA.[13] According to the plaintiffs, this adherence under H.B. 2684 makes Oklahoma the only state in the nation to mandate that physicians adhere to an obsolete drug regimen that has been universally rejected by practitioners, medical experts, professional organizations, and the FDA.[14] The relevant regimen under the current 2016 FPL protocol is similar to what Nova followed and what the ACOG recommended as an off-label, "evidence-based" protocol prior to the FDA's 2016 change. It provides:

1. Usage approved through 70 days of gestation (an increase from 49 days).
2. Dosage of Mifeprex 200 mg orally on day 1 in a single dose (decreased from 600 mg).

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[13]The State, in its Renewed Motion for Summary Judgment acknowledges on page 3, subsection 5 that:

> In 2014, the Legislature passed H.B. 2684, citing the facts in the paragraph above in its legislative findings and allowing physicians to induce abortions using mifepristone and misoprostol only in accordance with the original FDA regimen.

[14]In the transcript of the August 25, 2017, hearing p. 22, the trial court stated "now the argument from the State is not so much prohibiting off-label use, but it is prohibiting even the current final printed label use, correct? To which the State replied "Yes."

3. Dosage of Misoprostol 800 mcg bucally, 24 to 48 hours after Mifeprex (from 400 mcg orally, 48 hours after Mifeprex).
4. The dosage and administration section of the prescribing information no longer requires that Mifepristone be administered under the supervision of a licensed health care provider and allows prescribers to dispense Mifepristone to patient to self-administer outside of a supervised setting.
5. A repeat of 800 mcg buccal dose of Misoprostol may be used if needed.
6. The requirement that the follow up occur in the clinic 14 days after taking the Mifeprex was deleted.

¶14 The State filed a renewed motion for summary judgment in the trial court on September 8, 2016. In it, the State alleged that H.B. 2684 does not violate Nova's due process rights under the Oklahoma Constitution, nor does it impose an undue burden on the federal right to termination, or violate state constitutional equal protection provisions. Nova filed a cross motion for summary judgment and the trial court held a hearing on the motions on October 6, 2017, and filed an order on November 9, 2017, declaring H.B. 2684 as unconstitutional in all applications, and therefore void and of no effect. The State appealed the order on December 5, 2017, and we retained the cause on January 2, 2018.

I.
¶15 DECISIONS FROM THE UNITED STATES SUPREME COURT ARE BINDING ON THIS COURT WHERE THE UNITED STATES SUPREME COURT HAS SPOKEN, THIS COURT IS BOUND BY ITS PRONOUNCEMENTS.

¶16 The Supremacy Clause of the United States Const. Art. VI provides in pertinent part:

. .This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and 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 notwithstanding. . . .

Art. 1, §1 of the Oklahoma Constitution provides:

> 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.

Decisions from the United States Supreme Court are binding on this Court and require the Legislature to promulgate rules of law consistent with the federal Constitution.[15] Because the United States Supreme Court has spoken, this Court is not free to impose its own view of the law as it pertains to the competing interests involved.[16] Where the United States Supreme Court has spoken, this Court is bound by its pronouncements.[17]

¶17 The Kansas Supreme Court in Hodes & Nauser v. Schmidt, No. 114, 153, 2019 WL 1868843, determined on April 26, 2019, that there was a constitutional right to abortion under the Kansas Constitution. We have never made such a determination under the Oklahoma Constitution, and we need not do

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[15]See, Burns v. Cline, 2016 OK 121, ¶5, 387 P.3d 348; United States v. Home Fed. S. & L. Ass'n of Tulsa, 1966 OK 135, ¶18, 418 P.2d 319.

[16]Cooper v. Aaron, 358 U.S. 1, 18, 78 S.Ct. 1401, 1410, __ L.Ed. __ (1958) [Interpretation enunciated by this Court is the supreme law of the land, and Art. VI of the Constitution or makes it of binding effect on the States.].

[17]United States Const. Art.VI, Okla. Const. Art. 1, §1, Burns v. Cline, see note 15, supra.

so now. The Okla. Const. Art. 1, §1 mandates this Court comply with federal constitutional law on issues of federal law. It is mandatory that we uphold and comply with the highest law of this land.[18] The limited role of this Court as with all state courts, "is to apply federal constitutional law, not to make it nor to guess what it may become."[19] By virtue of our constitutional oath of office, we have solemnly sworn to uphold the Constitution of the United States.[20]

¶18 Likewise, Art. VI, clause 3 of the United States Constitution provides:

> The Senators and Representatives before mentioned and Members of the several State Legislatures, and all executive and judicial Officers, both of the United States and of the several States shall be bound by Oath or Affirmation, to support this Constitution; but no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States.

¶19 In Cooper v. Aaron, 358 U.S. 1, 18, 78 S.Ct. 1401, 1410, _ L.Ed. __ (1958), the United States Supreme Court unanimously, stated that:

> Article VI of the Constitution makes the Constitution the 'supreme Law of the Land.' In 1803, Chief Justice Marshall, speaking for a unanimous Court, referring to the Constitution as "the fundamental and paramount law of the nation," declared in the notable case of Marbury v. Madison, 1 Cranch 137, 5 U. S. 177, that 'It is emphatically the province and duty of the judicial department to say what the law is.' This decision declared the basic principle that the federal judiciary is supreme in the exposition of the law of the Constitution, and that principle has ever since been respected by this

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[18]In re Initiative Petition No. 349, State Question 642, 1992 OK 122, ¶13, 838 P.2d 1, 7.

[19]Burns v. Cline, see note 15, supra.

[20]Burns v. Cline, see note 15, supra.

> Court and the Country as a permanent and indispensable feature of our constitutional system. It follows that the interpretation of the Fourteenth Amendment enunciated by this Court in the Brown case is the supreme law of the land, and Art. VI of the Constitution makes it of binding effect on the States 'any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.' Every state legislator and executive and judicial officer is solemnly committed by oath taken pursuant to Art. VI, cl. 3 'to support this Constitution.' Chief Justice Taney, speaking for a unanimous Court in 1859, said that this requirement reflected the framers' 'anxiety to preserve it [the Constitution] in full force, in all its powers, and to guard against resistance to or evasion of its authority, on the part of a State. . . .' Ableman v. Booth, 21 How. 506, 16 L.Ed.169.
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> No state legislator or executive or judicial officer can war against the Constitution without violating his undertaking to support it. . . . [21]

¶20 The United States Supreme Court's most recent pronouncement, Whole Woman's Health v. Hellerstedt, 579 U.S. __, 136 S.Ct. 2292, 195 L.Ed.2d 665 (2016) explains the analysis necessary to decide this cause. It is under Whole Woman's Health v. Hellerstedt, supra, Burns, supra, and the United States Constitution's guidance we answer the question in this cause. The test for such a challenge of a legislative health regulation concerning medical termination, has already been recognized by Burns, supra, and Hellerstedt, supra. It is whether a statute has the effect of placing a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's right which is the issue

[21] Byrd v. Trombley, 580 F. Supp. 2d 542, 552 (U.S. E.D. Michigan 2008).

here.[22]

II.
¶21 THE LEGISLATURE'S REQUIREMENT THAT PHYSICIANS ADHERE TO THE FDA'S 2000 LABEL PROTOCOL FOR MEDICATION TERMINATION, RATHER THAN THE MORE EFFECTIVE CURRENT 2016 LABEL PROTOCOL, PLACES A SUBSTANTIAL OBSTACLE IN THE PATH OF A WOMAN'S CHOICE AND IMPOSES AN UNDUE BURDEN ON THE WOMAN'S RIGHTS PURSUANT TO UNITED STATES SUPREME COURT PRECEDENT AS IT CURRENTLY EXISTS.

¶22 The arguments in this cause (Cline IV), concern the alleged violation of women's due process right under the Oklahoma and Federal Constitutions. Nova argues that H.B. 2684 imposes an undue burden on Oklahoma women because it offers no medical or health benefits, serves no compelling state interest or any valid state interest, and actually threatens the health and rights of Oklahoma women. It contends that H.B. 2684 prohibits the most up-to-date and scientifically-sound medication treatment practices and impinges upon a woman's fundamental right to choose termination, to bodily integrity, and to equal protection under the law.

¶23 The State argues that there is no protected right to termination under the Oklahoma Constitution. It also argues that H.B. 2684 does not create an undue

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[22]WholeWoman's Health v. Hellerstedt, 579 U.S. __, 136 S.Ct. 2292, 195 L.Ed.2d 665 (2016). This test evolved from the Court's re-affirmation of Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), in Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992), and subsequent decisions in Gonzales v. Carhart, 550 U.S. 124, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007), and Hellerstedt, supra.

burden under the Federal Constitution, and that it actually promotes methods safer than the methods being prohibited. The undisputed question before us is whether H.B. 2684, which requires physicians to adhere to the FDA's approved protocol at the time H.B. 2684's enactment (ie. the 2000 protocol) violates a woman's due process rights when the mandated adherence is to an obsolete drug regimen that has been updated by practitioners, medical experts, professional organizations, and the FDA itself (the 2016 protocol).

¶24 The equal protection clause of the fourteenth amendment requires that no state "deny to any person within its jurisdiction the equal protection of the laws."[23] Due process protections encompassed within the Okla. Const. art. 2, §7 are generally coextensive with those of its federal counterpart.[24] Due process has a procedural component, which requires an inquiry into the constitutional adequacy of the State's procedural safeguards.[25] It also has a substantive component which bars certain governmental action despite the adequacy of procedural protections

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[23]The United States Const., amend. XIV; Nelson v. Nelson, 1998 OK 10, ¶11, 954 P.2d 1219.

[24]The Okla. Const. art. 2, §7 provides:

No person shall be deprived of life, liberty, or property, without due process of law.

Nelson v. Nelson, see note 23, supra.

[25]Nelson v. Nelson, see note 23, supra at ¶15; Matter of Adoption of J.R.M., 1995 OK 79, ¶12, 899 P.2d 1155; Zinermon v. Burch, 494 U.S. 113, 110 S.Ct. 957, 108 L.Ed.2d 100 (1990);.

provided.[26]

¶25 Regarding legislative medical treatment regulations, we recently noted in Burns v. Cline, 2016 OK 121, ¶¶8-9, 387 P.3d 348:

> Every woman in this country has a constitutionally protected right to choose whether to terminate her pregnancy before viability. This right is protected from undue interference from the State. Although the State has a legitimate interest in protecting the health of a woman, legislation may be found unconstitutional where the purpose or effect creates an undue burden or obstacle to a woman seeking a lawful abortion. The United States Supreme Court has been clear that "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on that right." . . . A "State has a legitimate interest in seeing to it that abortion ... is performed under circumstances that insure maximum safety for the patient." Roe v. Wade, 410 U.S. at 150, 93 S.Ct. at 725. However, "a statute which while furthering [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." Casey, 505 U.S. at 877, 112 S.Ct. at 2820, 120 L.2d. at 674. (Footnotes omitted).

¶26 Hellerstedt, supra, requires us to look at the burdens a law imposes on termination access together with the benefits the law confers. The benefit/burden question is not based solely upon the legislative findings explicitly set forth in the statute.[27] Rather, the Court must consider the evidence in the record — including expert evidence, presented in stipulations, depositions and testimony. The

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[26]Nelson v. Nelson, see note 23, supra at ¶15; Matter of Adoption of J.R.M., see note 25, supra at ¶13; Daniels v. Williams, 474 U.S. 327, 332, 106 S.Ct. 662, 665, 88 L.Ed. 2d 662 (1986).

[27] Hellerstedt, see note 22, supra at 2310.

asserted benefits are weighed against the burdens as presented by the evidence before the trial court.

¶27 Though Legislative findings are not dispositive, they must be considered.[28] H.B. 2684 contains numerous Legislative findings.[29]

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[28] Hellerstedt, see note 22, supra at 2310.

[29] Title 63 O.S. Supp. 2014 § 1-729a(A) provides:

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

These Legislative findings overwhelmingly reference, and give great deference to, an FDA FPL that is now outdated. The findings indicate that safe use of medical terminating drugs is heavily dependent upon adherence to the protocol approved by the FDA, while H.B. 2684 simultaneously requires physicians to adhere to a regime that **is no longer the current protocol approved by the FDA**. As several members of this Court noted in Burns:

> 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.

> [T]he detailed findings of 63 O.S. Supp. 2014 1–729a (based on the outdated FDA final printed labeling) which are used to justify adherence to the FDA final printed labeling, are now not only at odds with the prevailing standard of care but also at odds with the current FDA-approved regime itself.

2016 OK 99 at ¶11 (Combs, V.C.J., concurring specially).

¶28 We turn to the evidence before the trial court in this cause and the important differences between the protocols. There are three main differences in the original 2000 protocol and the current 2016 protocol: 1) the usage of the termination-inducing drugs through gestation requirements; 2) the required doctor's office visits, self-administration, and follow up visits; and 3) the change in the amount and timing of the dosage of the drugs. The current FDA approved regimen allows usage through 70 days of gestation. H.B. 2684 restricts usage to 49 days of gestation. The only legislative stated benefits of this restriction in the statute, besides to generally protect women from dangerous and potentially deadly off-label use of termination-inducing drugs and to ensure physicians abide by the FDA approved protocol, is to reduce the risk of complications which are alleged to increase with gestational age.[30]

¶29 The State contends that increased gestational age increases the risks of infection, failed termination necessitating surgical intervention, and clinically significant hemorrhaging and the need for blood transfusion increases. In support

[30]*See* 63 O.S. Supp. 2014 § 1-729a(A)(11), supra, note 29.

of this contention, the State relies on the affidavit of its medical expert, Dr. Donna Harrison, a Michigan doctor who serves as the executive director of the American Association of Pro-Life Obstetricians and Gynecologists.[31] Dr. Harrison's affidavit addresses the issue of gestational age and argues:

> [w]hile it is true that the buccal regimen outlines in the current FDA label is more effective AFTER 49 days than the doses of drugs and route of administration specified in the original FDA regimen, that effectiveness comes at the cost of significant safety issues surrounding the buccal use of Misoprostol....[32]

Dr. Harrison's statement indicates that even though failure rate increases with increased gestational age, the new regime is still overall more effective than the prior one. The safety issue with which Dr. Harrison appears to be most concerned is increased risk of bleeding, based on an ACOG practice bulletin determining that the risk of bleeding may be lower in women who undergo medical treatment of gestations up to 49 days as opposed to a longer period.[33]

¶30 Nova counters that the 2000 FDA protocol relied on clinical trials

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[31]Dr. Harrison relies on the cited study of Mentula, Maarit, Niinimaki M, Suhonen S., Hemminki E., Gissler M., and Heinkinheimo O., "Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study." Human Reproduction (0)(0) p 1-6 2011, the American College of Obstetricians and Gynecologist Practice Bulletin, and the original FDA protocol.

[32] Affidavit of Donna Harrison, M.D., Defendant's Renewed Motion for Summary Judgment, Record On Accelerated Appeal, V. 1, Ex. 4, Ex. B, p.4

[33]ACOG, Practice Bulletin No. 143: *Medical Management of the First-Trimester Abortion*, 2 (March 2014, reaffirmed 2016).

conducted in the early 1990's and after nearly two decades of clinical experiments and medical studies, it has been confirmed that mifepristone is as safe and effective when prescribed in lower dosages and later in pregnancy and that because of such studies, the 2016 protocol is superior to the 2000 protocol.[34] Nova relies on several sources to support its evidence including: 1) the affidavit of Dr. Lisa Rarick who worked at the FDA from 1988 to 2003 in a number of positions and who currently serves as a consultant for Reproductive Health and Regulatory Affairs; the Center for Drug Evaluation and Research Medical Review completed March 29, 2016; 2) the affidavit of medical expert Dr. Daniel Grossman, a professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco, who served as an active participant of many medical organizations including the ACOG; and 3) the March 2014 and 2016 ACOG bulletins.[35]

¶31 The burden imposed by the 49-day gestational period as opposed to the 70-day period is one of timing. The 49-day period gives much less time to discover the pregnancy, and to decide whether to terminate it. Beyond that, Dr. Grossman's affidavit details several reasons why a longer period for medication

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[34] Plaintiff's Cross Motion for Summary Judgment, Record on Accelerated Appeal, Ex. 5, pp. 6-7.

[35] ACOG, Practice Bulletin No. 143: *Medical Management of the First-Trimester Abortion*, 2 (March 2014, reaffirmed 2016).

termination is beneficial to patients: because many choose it for privacy reasons; because it feels natural; because of past trauma; or because it is specifically medically indicated.[36] The alleged benefit to the 49-day period is that it lowers a risks of infection, surgical intervention and hemorrhaging. However, we have found nothing in the record which shows these risks are significantly increased at all by waiting 70 days, especially when combined with lower dosages.[37] Given the

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[36] As Dr. Grossman explains in his affidavit:

> 12. For some women, medication abortion offers important advantages over surgical abortion. It can be performed earlier in pregnancy than surgical abortion and is less invasive. Many women prefer medication abortion because they consider the process to be more private, by allowing them to complete the abortion in the privacy of their homes with the support of a loved one at the time of their choosing. Others consider it to be more natural than surgical abortion, because it feels like a miscarriage.
>
> 13. Some women choose medication abortion because they fear any procedure with surgical instruments, or wish to avoid anesthesia or sedation. Victims of rape or women who have experienced sexual abuse or molestation, in particular, may choose medication abortion to feel more in control of the experience and to avoid the trauma of having instruments placed in their vagina.
>
> 14. For some women with certain medical or anatomical conditions, medication abortion rather than a surgical abortion is medially indicated. These conditions include cervical stenosis (tightly closed uterus), uterine anomalies (*e.g.*, bicornuate or double uterus, or an extremely flexed uterus), large uterine fibroids, and obesity, all of which an make it difficult to access the pregnancy inside the uterus as part of a surgical abortion.

Affidavit of Daniel A. Grossman, M.D., Plaintiff's Cross Motion for Summary Judgment, Record on Accelerated Appeal, Ex. 5, Ex. D, p. 5.

[37] Again, from Dr. Grossman's affidavit:

FDA's rigorous review, it would be unimaginable that the FDA would revise and update a protocol to one less safe or less effective than the original it approved sixteen years earlier. Rather, the evidence shows the 2016 protocol to be safer with little to no significant health-related problems occurring.

¶32 Next, we consider the required three office visits for patients and administration of the drugs in a clinic, medical office or hospital, with a fourteen day follow up after administration to confirm termination under the 2000 protocol. Comparatively, the 2016 protocol allows self-administration outside of a supervised setting and no fourteen day follow up. The legislative statement in H.B. 2684 and the State note that at least 14 women have died after receiving a medication abortion.[38] Of those women, eight deaths were attributed to severe bacterial infections following the medication abortion. Nevertheless, the State

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> Numerous sources that Dr. Harrison cites—including those reviewed by the FDA and the ACOG Practice Bulletin—sanction the use of evidence-based medication abortion regimens for women up to a later point in pregnancy. **There is no valid safety or medical reason to limit availability to women up to 49 days' LMP, where the Updated Label Regimen followed by Reproductive Services allows medication abortions to be performed safely and effectively up to 10 weeks (*i.e*, 70 days) LMP.** This is particularly advantageous because many women do not detect their pregnancies until close to 49 days' LMP; thus, evidence-based regimens, like the Updated Label Regimen, allow more women to chose medication abortion.

Affidavit of Daniel A. Grossman, M.D., see note 36, supra at p. 16 (emphasis added) (footnotes omitted).

[38]The dates of the deaths are not noted, but H.B. 2684 relies on a July 2011 FDA report in support of its statement.

concedes that there have been no reports of women dying in the U.S. from bacterial infection after use of the medication as utilized by the original 2000 FDA regimen. Nor does the State attribute any of the deaths to the 2016 protocol.

¶33 According to the State, the benefit of the extra doctor's office visit and follow up appointment, as described by their expert witness, Dr. Harrison, is that one in twenty women will not need misoprostol at all because their termination is completed within 48 hours and a visit to the doctor's office would verify this and reduce exposure to some women of the risks of misoprostol which could have been avoided.[39] Self-administration will lead to an increased failure rate whereas in-clinic administration guarantees the correct timing of the drug administration, better monitoring for bleeding, vital signs, and pain by trained physicians and lower risk of hospital admission, unsuccessful termination and death.[40]

¶34 Nova counters with expert testimony describing several studies that show that only 1.6 out of every 1000 patients experienced any significant adverse events such as hospital admission, blood transfusion, intravenous antibiotics, infection, etc. and fewer than 6 out of 10,000 experienced complications resulting

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[39] Affidavit of Donna Harrison, M.D., see note 32, supra at pp. 8-9.

[40] *See* Affidavit of Donna Harrison, M.D., see note 32, supra at pp. 10-14

from hospital admissions.[41] Another study showed only 3.1 out of every 1000 patients experienced any similar major complications.[42] Regarding the total of eight fatal bacterial infections reported in the U.S. since the original protocol, the FDA has determined that no causal relationship can be established between the medical termination and the infections.[43] According to Dr. Grossman and the

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[41] From Dr. Grossman's affidavit:

> ... [T]he FDA concluded that serious adverse outcomes were exceedingly rare "and do not suggest a safety profile different from the original approved Mifeprex dosing regimen."
>
> 35. Consistent with these findings, a recent large-scale study that reviewed the outcomes of 233,805 medication abortions performed in the United States found that only 1.6 out of every 1,000 patients experienced a significant adverse event (defined as hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection requiring treatment with intravenous antibiotics or admission to the hospital, or death), and fewer than six out of eery 10,000 experienced complications resulting in hospital admission. Dr. Harrison fails to acknowledge thus study in her affidavit.

Affidavit of Daniel A. Grossman, M.D., see note 36, supra at p. 13-14 (footnotes omitted) (citing Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 Obstet. & Gynecol. 166, 169 (2013)).

[42] Affidavit of Daniel A. Grossman, M.D., see note 36, supra at p. 14 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstet. & Gynecol. 175, 175 (2015)).

[43] Dr. Rarick notes:

> The FDA has concluded that no causal relationship has been established between the use of mifepristone and misoprostol and the occurance of clostridial infections. Indeed, the FPL for Mifeprex states unequivocally that "[n]o causal relationship ... has been established."

Affidavit of Lisa A. Rarick, M.D., Plaintiff's Cross Motion for Summary Judgment, Record on Accelerated Appeal, Ex. 5, Ex. B, p. 11 (quoting FDA Medical Review, p. 26).

The same conclusion is expressed by Dr. Grossman. Affidavit of Daniel A. Grossman, M.D., see

ACOG, similar infections have also occurred following spontaneous terminations, term delivery, surgical termination and cervical cone or laser treatment for cervical dysplasia. Another study detailing the effects of a similar law in Ohio showed that following the old protocol women were 3 times more likely to need additional intervention and experienced more side effects.[44]

¶34 Nova also points to additional burdens: women who fall between the 50 and 70 day time limit would be forbidden from accessing a medical terminations, even when that is the best option for them due to fear of surgical instruments, anesthesia or sedation, being victims of sexual assault or having certain medical or

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note 28, supra at p. 15 (citing American College of Obstetricians and Gynecologists, Practice Bulletin No. 143 at p. 8; U.S. Food & Drug Admin., Mifeprex label, 2016 (revised Mar. 2016)).

[44] Dr. Grossman's affidavit addresses this issue succinctly:

> 42. In fact, a recent study found that after an Ohio law mandating compliance with the Outdated Label Regimen went into effect, women were more likely to need additional intervention, experienced more side effects, and faced higher costs relative to the evidence-based regimen previously in effect. Rather than improved abortion outcomes, the evidence demonstrated the opposite—costs and complications rose. Patients subjected to the Outdated Label Regimen were three times more likely to need an extra round of medication or a more invasive procedure (such as an aspiration abortion), three times more likely to have an incomplete abortion or possible incomplete abortion, and "significantly more likely" to suffer side effects such as nausea and vomiting. In addition, there was a significant decline in the percentage of medication abortions, from 22 percent before the law took effect, to 7 percent afterwards. This comparative study further demonstrates that laws adhering to outdated regimens, like HB 2684, fail to protect women or make abortion safer or more effective.

Affidavit of Daniel A. Grossman, M.D., see note 36, supra at pp. 17-18 (quoting Upadhyay et al., *Comparison of Outcomes Before and After Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study*, PloS Med. 13(8) (Aug. 30, 2016), available at https://doi.org/10.1371/journal.pmed.1002110.

anatomical conditions despite the well-documented saftety of the current protocol. Access under the original protocol is more burdensome, costly and unpleasant. Traveling from rural areas might require a long journey or a two night stay away from home to access care, which increases costs for low-income patients, childcare, and time off from work and increases the chance that something might occur while traveling, making the procedure uncomfortable and more difficult to manage.[45]

¶36 It again appears that the evidence shows that there are no significant health-related problems which occur by utilizing the current protocol. In fact, the sixteen-year-old 2000 protocol would impose more health risks and cost related burdens than the current protocol. The evidence strongly indicates adherence to the outdated protocol would make medication abortion more costly, less effective, and more prone to negative side effects.

¶37 Finally, we look at the difference in dosage requirements. The dosage of Mifeprex is decreased from 600 mg to 200 mg on day one in a single dose and then 800 mcg of misoprostol 24 to 48 hours after Mifeprex rather than 400 mcg. The State argues that the 2016 regimen may require double the dose of misoprostol, even if not necessarily needed and even though misoprostol is the

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[45] Plaintiff's Cross Motion for Summary Judgment, supra note 43, pp. 16-17; Affidavit of Daniel A. Grossman, M.D., see note 36, supra at pp. 16, 21, & 25.

drug most associated with infections that follow medication terminations.[46] It also contends that allowing women to self-administer at home will not guarantee the correct timing of the drug administration, or better monitoring of bleeding and vital signs.[47]

¶38 Nova's position, however, is that the widespread consensus within the medical community is that the current label protocol is the safest and most effective regimen for medication termination supported by nearly two decades of clinical experience and peer-reviewed medical literature confirming its safety and efficacy. Nothing in the record shows that the change in dosage requirement

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[46] Dr. Harrison asserts:

> 22. ... [T]he lower 200mg oral dose of Mifepristone used in the various off-label regimens, including plaintiffs' regimen, is known to be less effective in killing the fetus. This lower dosage of Mifepristone necessitates larger doses of Misoprostol to complete the abortion. (800 micrograms in the plaintiffs' regimen, compared to 400 micrograms in the original FDA regimen.)
>
> 23. The original FDA regimen offers a significant safety advantage over the plaintiffs' regimens by decreasing a woman's exposure to Misoprostol. This lower dose of Misoprostol is safer than the high dose used in the plaintiffs' regimens because it is the Misoprostol component of the drug-induced abortion regimen that has been most recently implicated in the massive fatal infections seen after some medical abortions, as explained above.

Affidavit of Donna Harrison, M.D., supra note 32, at p. 9 (footnotes omitted) (citing Creinin M., *Medical Abortion Regimens: Historical Context and Overview*, Am. J. Obstet. Gynecol. 183 (2) suppl. pp. S3-S9 (Aug. 2000); Spitz I.M., *Mifeprestone: Where do We Come from and Where are we Going? Clinical Developent Over a Quarter of a Century*, Contraception 82, pp. 442-452 (2010)).

[47] Affidavit of Donna Harrison, M.D., see note 32, supra at pp. 10-15.

presents an increase of significant health risks. The affidavits of Nova's experts —relying on far more recent data, studies, and the rigorous determinations of the FDA itself—strongly indicate: 1) there is no established link between medical termination and fatal infection, as discussed above, supra; and 2) the new dosing regimen is both more effective than the prior regimen and also safer.[48]

¶39 We recognize that the burden imposed by each of the changes to usage, doctor's office visits, self-administration, and follow up visits, and the amount and timing of the dosage of the drugs may not individually amount to an undue burden, but as the United States Supreme Court said in Hellerstedt, supra, at page 2313:

> But here, those increases are but one additional burden, which when taken together with others that the closing [of half of the Texas' clinics] brought about, and when viewed in light of the virtual absence of any health benefit, lead us to conclude that the record adequately supports the District Court's "undue burden" conclusion.

While this cause does not involve any alleged closings, we agree with the Hellerstedt Court's analysis and also conclude that the trial court's decision in this cause was adequately supported by the record.

¶40 We are not alone in our assessment of the 2000 protocol vs the 2016 protocol. For example, in Planned Parenthood Arizona, Inc., v. Humble, 753 F.3d

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[48] *See* Affidavit of Lisa A. Rarick, M.D., see note 43, supra at pp. 11-12; Affidavit of Daniel A. Grossman, M.D., see note 36, supra at pp. 11-12.

905 (9th Cir. 2014), the Ninth Circuit Court of Appeals issued a preliminary injunction prohibiting enforcement of an Arizona statute which required compliance with the FDA 2000 protocol (called on-label), rather than the off-label, evidence-based regimen which is similar to the 2016 protocol. The Court noted that the evidence showed:

1) Virtually all abortion providers use the evidence-based regimen.
2) The ACOG strongly favors the evidence -based regimen over the on-label regimen.
3) The evidence-based regimen is considered the best practice and provides a clear advantage because most women do not discover their pregnancies until approximately 49 days.
4) Risk factors have been reduced or eliminated by the current regimen and fewer surgical interventions are necessary.
5) Medical abortion is less invasive than surgical abortion, and medical abortion is significantly safer.
6) The cost for the on-label is $160.00 more than the evidence-based regimen.
7) The evidence-based allows women to take misoprostol in their homes, eliminating the risk that they will pass the pregnancies, a process involving heavy bleeding and cramping, during their trip home.

The Court also noted that Arizona had presented no evidence whatsoever that the law furthered any interest in women's health. Taking into consideration the cost of the extra dosage of medicine, the cost of the clinic time and additional visits, including transportation, gas, lodging, the delay in terminations and increased in health risks, the law substantially burdened women's access to medical services. According, it granted the request for an injunction to preclude the law from going into effect because the plaintiffs were likely to succeed on the merits of their

undue burden claim.[49]

¶41 Although Humble, supra, involved a preliminary injunction rather than decisions on the merits of the plaintiff's claims, and it is not controlling here, the evidence presented is strikingly similar to this cause.[50] We agree with Nova that H.B. 2684 has the effect of placing a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's right. Under United States Supreme Court precedent, H.B. 2684 is unconstitutional and therefore void and of no effect.

CONCLUSION

¶42 Medical negligence or malpractice actions arise when a provider

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[49]The U.S. Court of Appeals for the Ninth Circuit, reversed the trial court's denial of the preliminary injunction and ordered that the law be blocked while the case proceeds. The law is currently not in effect. On December 15, 2014, the U.S. Supreme Court denied the State's petition to review the case. A second lawsuit in state court in Arizona was filed April 6, 2014, and alleged that the law violates the Arizona Constitution, which forbids the legislature from relinquishing its authority to make state law, and also that the Arizona Department of Health violated its own rulemaking procedures when it drafted the regulation. On October 15, the trial court permanently blocked the law, ruling that the statute is an impermissable abdication of the Arizona legislature's obligation to make state law. On May 17, 2016, the Governor signed a new law that effectively repealed the challenged statute.

[50]The State cites to two cases in support of their position. The more recent case, which we find unpersuasive, is Planned Parenthood of Greater Texas v. Abbott, 748 F.3d 583 (9th Cir. 2014) wherein the Ninth Circuit Court of Appeals partially upheld the constitutionality of a Texas law similar to H.B. 2684, The Court held, in part, that the Texas bill on its face did not impose an undue burden on the life and health of a woman. The second case, Planned Parenthood Southwest Ohio Region v. DeWine, 696 F.3d 490 (6th Cir. 2012) wherein the 6th Circuit Court of Appeals partially upheld an Ohio statute substantially similar to Oklahoma's, but did not expressly address whether the Ohio Act unduly burdens a women's right to health and life under the Fourteenth Amendment. The Court expressly noted the question was not at issue in the appeal.

renders care that falls below the acceptable standard of care. Today, nineteen years after the FDA approved the 2000 label protocol, the FDA has approved a 2016 regimen that providers across the country use as the superior protocol. Use of the 2000 protocol agreeably would necessarily now fall below the acceptable standard of care. Not only would doctors potentially be medically negligent for following such standards, but also pursuant to H.B. 2684 they would be charged with a felony, incarcerated, and lose their license to practice through disciplinary proceedings for not following such sub-standard practices.

¶43 Notwithstanding the effects H.B. 2684 has on doctors' liability, this Court's decision in Burns, supra, and the United States Supreme Court precedents require us to question whether a statute has the effect of placing a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's right.[51] Under the facts and evidence presented in this cause, we agree with the trial court that H.B. 2684 does place a substantial obstacle in the path of a woman's choice and imposes an undue burden on the woman's right. The Constitution and the laws of the United States made in pursuance thereof shall be the supreme law of the land and senators, representatives, executive and judicial

[51]United States Constitution, Art. VI, see pages 12-13, supra. WholeWoman's Health v. Hellerstedt, see note 22, supra. This test evolved from the Court's re-affirmation of Roe v. Wade, see note 22, supra, in Planned Parenthood of Southeastern Pa. v. Casey, see note 22, supra, and subsequent decisions in Gonzales v. Carhart, see note 22, supra, and Hellerstedt, supra.

officers of this state are bound by oath to support this Constitution. Consequently, we affirm the trial court's declaration that H.B. 2684 is unconstitutional, void and of no effect. We reiterate what we said in In re Initiative Petition No. 349, State Question 642, 1992 OK 122, ¶13, 838 P.2d 1, 7. "We will uphold the law of the land whatever it may be. Today the law of the land is that a woman has a constitutionally protected right to make an independent choice to continue or terminate a pregnancy before viability."

STAY LIFTED;
TRIAL COURT AFFIRMED.

GURICH, C.J., KAUGER, EDMONDSON, COLBERT, REIF, JJ., concur.

COMBS, J., concurs specially [by separate writing].

WINCHESTER, J., concurs in result.

DARBY, V.C.J., dissents [by separate writing].