ORIGINAL 2016 OK 17

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; and LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision,

Defendants/Appellants.

No. 114,307

FOR OFFICIAL PUBLICATION

ON APPEAL FROM THE DISTRICT COURT OF OKLAHOMA COUNTY,
THE HONORABLE PATRICIA G. PARRISH, PRESIDING

¶0 In the district court, Plaintiffs challenged H.B. 2684 as unconstitutional under several theories. The district court agreed and found H.B. 2684 to be unconstitutional. Defendants appeal, only presenting Plaintiffs' theories that H.B. 2684 violates two sections of the Oklahoma Constitution and the question of issue preclusion based on this Court's opinion in *Cline v. Okla. Coalition for Reprod. Justice*, 2013 OK 93, 313 P.3d 253. This Court retained the appeal for disposition.

REVERSED AND REMANDED.

Patrick R. Wyrick, Cara N. Rodriguez, Jared B. Haines, Office of the Attorney General, Oklahoma City, Oklahoma, for appellants.

J. Blake Patton, Walding & Patton PLLC, Oklahoma City, Oklahoma, for the appellees.

TAYLOR, J.

¶1 The dispositive question presented to this Court is whether H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 375-80 (codified at 63 O.S.Supp. 2014, § 1-729a), violates either of two sections of the Oklahoma Constitution: Article V, Section I (vesting legislative authority in the Oklahoma House and Senate); or Article V, Section 59 (prohibiting special laws). We answer in the negative. A challenge to H.B. 2684 as violative of any other Oklahoma constitutional provision or as violative of the United States Constitution is not before this Court, and we are thus limited in our decision.[1]

I. HISTORY

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[1] As a non-dispositive issue, the Plaintiffs claim that the district court and this Court are bound by many facts and issues that were determined in *Cline v. Okla. Coalition for Reprod. Justice*, 2013 OK 93, 313 P.3d 253 (*Cline II*). Specifically, the Plaintiffs contend that the courts in the present case are bound by

> [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.

Cline II, 2013 OK 93, ¶ 27, 313 P.3d at 262.

Under the doctrine of issue preclusion, "once a court has decided an issue of fact or of law necessary to its judgment, the same parties or their privies may not relitigate that issue in a suit brought upon a different claim." *Miller v. Miller*, 1998 OK 24, ¶ 25, 956 P.2d 887, 897. Only the question of whether this finding "was necessary and essential to the outcome of that prior case" is at issue here. *State ex rel. Tal v. City of Okla. City*, 2002 OK 97, ¶ 20, 61 P.3d 234, 245. "[T]he issue is necessarily determined if the judgment would not have been rendered but for the determination of that issue." *Nealis v. Baird*, 1999 OK 98, ¶ 51, 996 P.2d 438, 457-58.

In *Cline II*, this Court was not asked to rule on the restrictive use of RU-486 (Mifeprex), but on the restrictive use of misoprostol and of methotrexate. The quote on which the Plaintiffs rely could be excised from *Cline II* without changing this Court's answer to the certified questions. We therefore disregard the Plaintiffs' issue-preclusion argument.

¶2 In determining the questions now before this Court, it is necessary to review 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), and our two pronouncements addressing it. In 2011, the Oklahoma Legislature enacted H.B. 1970, prohibiting the off-label use of Mifeprex (generally known as mifepristone or RU-486) and misoprostol (brand name Cytotec) for use in abortions.[2] The effect of H.B. 1970 was to ban medication abortions in Oklahoma. *Cline II*, 2013 OK 93, ¶ 25, 313 P.3d at 262.

¶3 In the first pronouncement, this Court, following *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), affirmed the district court's decision that H.B. 1970 was unconstitutional. *Okla. Coal. for Reprod. Justice v. Cline*, 2012 OK 102, ¶ 3, 292 P.3d 27, 27-28 (*Cline I*). After this Court rendered the *Cline I* decision, the appellees filed a petition for certiorari in the United States Supreme Court. *See Cline v. Okla. Coal. for Reprod. Justice*, 133 S. Ct. 2887 (2013). 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." *Cline II*, 2013 OK 93, ¶ 8, 313 P.3d at 257. In *Cline II*, our second pronouncement, we answered both questions

[2] Misoprostol's label specified that it was for use in treating gastric ulcers. *Cline II*, 2013 OK 93, ¶ 12, 313 P.3d at 258.

affirmatively. *Id.* ¶ 1, 313 P.3d at 255. The U.S. Supreme Court then dismissed the petition for certiorari as improvidently granted. *Cline v. Okla. Coal. for Reprod. Justice*, 134 S.Ct. 550 (2013).

¶5 In 2014, in response to the *Cline II* 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. In H.B. 2684, the Legislature made 16 factual findings, including that the use of medication-inducing drugs presents significant risk to women, the complications of abortion-inducing drugs were higher than those for surgical abortions, fourteen women had died after off-label use of abortion-inducing drugs, and the Federal Drug Administration (FDA) had been unable to determine whether the off-label use caused the deaths.[3]

[3] Section A of H.B. 2684 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

The Legislature expressed its intent that the act not prohibit all medication abortions or the use of methotrexate in treating ectopic pregnancies. H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 377, § 1-729a(A)(16) ("[T]his act does not ban the use of

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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.

misoprostol in chemical abortion (and allows it as part of the FDA-approved Mifeprex regimen) . . . .").

¶6 H.B. 2684 restricts Mifeprex and misoprostol use for abortions to the FDA-approved final Mifeprex label, prohibits methotrexate use for abortions except to terminate ectopic pregnancies,[4] provides for liability of physicians who knowingly or recklessly perform an abortion in violation of H.B. 2684, and makes doctors subject to discipline and liability for violating H.B. 2684. *Id.* at 377-79, § 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.

¶7 The Oklahoma Coalition for Reproductive Justice and Nova Health Systems (Plaintiffs) filed this challenge to H.B. 2684's restriction of 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). The Plaintiffs alleged, as a factual matter and without submitting evidentiary support, that H.B. 2684 will prevent some of Reproductive Services' patients from obtaining a medication abortion and will prevent others from receiving the medical treatment according to the most current scientific evidence and

[4] Each time the ban on off-label use of methotrexate in H.B. 2684 is discussed, the exception for methotrexate use for ectopic pregnancies should be understood even though not continuously repeated.

advances in medicine. The Plaintiffs 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. As stated in the first paragraph, only the last two challenges are properly before this Court.

¶8 While this case was pending before the district court, this Court, in an interim proceeding, enjoined enforcement of H.B. 2684 until its constitutionality "is fully and finally litigated." *Okla. Coal. for Reprod. Justice v. Cline*, 2014 OK 91, ¶ 1, 339 P.3d 887. Both sides then moved for summary judgment in the district court. The district court rendered judgment in favor of the Plaintiffs, finding that H.B. 2684 is a special law in violation of Article V, Section 59 of the Oklahoma Constitution. The State appealed, raising only the questions of issue preclusion, unauthorized delegation of legislative authority, and special law under Article V, Section 59. We retained the appeal for disposition and asked for additional briefs specifically addressing the differences in H.B. 1970 and H.B. 2684.

II. STANDARD OF REVIEW

¶9 Summary judgment settles only questions of law. *Pickens v. Tulsa Metropolitan Ministry*, 1997 OK 152, ¶ 7, 951 P.2d 1079, 1082. The standard of review of questions of law is *de novo*. *Id.* Summary judgment will be affirmed only if the appellate court determines that there is no dispute as to any material fact and

that the moving party is entitled to judgment as a matter of law. *Id.* Summary judgment will be reversed if the appellate court determines that reasonable men might reach different conclusions from the undisputed material facts. *Runyon v. Reid*, 1973 OK 25, ¶ 15, 510 P.2d 943, 946.

III. THE UNDISPUTED FACTS WHICH ARE SUPPORTED BY COMPETENT EVIDENTIARY MATERIALS

¶10 Medication abortion is a procedure for terminating a pregnancy using medications alone. In the United States, medication abortion generally follows a protocol using both Mifeprex and misoprostol, which are taken one after the other respectively. Methotrexate is used to abort ectopic pregnancies. In 2000, based on previously conducted clinical trials, the FDA approved Mifeprex's final printed label (FPL) pursuant to Subpart H of Part 314, Subchapter D, Chapter I, Title 21 of the Code of Federal Regulations, entitled "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses." The Mifeprex FPL only applies to marketing and distribution by the manufacturer, and it requires:

(1) Mifeprex distribution only to doctors who have read and understand the prescribing information,[5]
(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

[5] These doctors must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding or make such plans through others, to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, and to sign and return a prescriber's agreement.

agreement before treatment,[6]
(5) administration of one dose of 600 milligrams(mg) of Mifeprex,
(6) oral administration of 400 micrograms (μg) 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,[7] and
(9) warning to patients that heavy or moderate bleeding is an indication of an incomplete abortion.

This protocol was approved for use up to the first 49 days after a woman's last menstrual period. 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 manufacture of any ongoing pregnancy or serious adverse events. 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.

¶11 Within a year of the FDA's approval of Mifeprex in 2000, ninety-six percent of medication abortions did not follow the FPL or the protocol used in the clinical trials on which the FPL's approval was based. Since the FPL's approval,

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[6] For the patient agreement in the Mifeprex FPL, see U.S. Food and Drug Administration, *Patient Agreement: Mifeprex (mifepristone) Tablets* (last visited Nov. 23, 2015), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111361.pdf.

[7] The warning also notes that eight percent of women experience this type of bleeding for more than thirty days.

eight fatal bacterial infections have been reported in the United States where the women were administered Mifeprex and misoprostol for a medication abortion 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.[8] These same fatal bacteria also occur following other obstetric and gynecologic processes. The ACOG materials state that the off-label protocol is more effective with fewer adverse effects. Mifeprex is on the list of medications that require a Risk Evaluation and Management Strategy (REMS).[9]

¶12 Plaintiff Reproductive Services follows an off-label protocol which is endorsed by the American College of Obstetricians and Gynecologists (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

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[8] The Mifeprex FPL now warns:

> Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical and medical abortions, including following Mifeprex use. No causal relationship between the use of Mifeprex and misoprostol and these events has been established."

[9] REMS are "plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks." U.S. Food and Drug Administration, *A Brief Overview of Risk Evaluation & Mitigations Strategies (REMS)* (last visited Nov. 23, 2015) http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf.

to the 600 milligrams of FDA on-label protocol, followed by 800 micrograms of misoprostol to be patient administered, compared to FDA's protocol of 400 milligrams to be doctor administered. The ACOG materials provide that medication abortions 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).

IV. IMPROPER DELEGATION OF LEGISLATIVE AUTHORITY

¶13 The Plaintiffs contend that H.B. 2684 improperly delegates legislative authority to the FDA. Articles IV and V of the Oklahoma Constitution are the foundation underlying Oklahoma's non-delegation doctrine. Article IV, Section 1 requires separation of the three branches of government. Okla. Const. art. IV, § 1. Article V, Section 1 vests legislative authority "in a Legislature consisting of a Senate and House of Representatives." Okla. Const. art. V, § 1. Based on these two provisions, it is well settled that the Legislature may not delegate its policy-making authority. *Tulsa Cnty. F.O.P., Lodge No. 188 v. Bd. of Cnty. Comm'rs of Tulsa Cnty.*, 2000 OK 2, ¶ 8, 995 P.2d 1124, 1129. Although the Legislature is restrained from delegating policy-making authority, it can nonetheless delegate rule-making authority to implement its policies. *Id.* ¶ 9, 995 P.2d at 1129.

¶14 The Plaintiffs rely on *City of Okla. City v. State ex rel. Okla. Dept. of Labor*, 1995 OK 107, 918 P.2d 26 (*Oklahoma City*), *Democratic Party of Okla. v. Estep*, 1982 OK 106, 652 P.2d 271, and *In re Initiative Petition No. 366*, 2002 OK 21,

46 P.3d 123, for support that H.B. 2684 improperly delegates legislative authority to the FDA. In *Oklahoma City*, this Court determined that Oklahoma's Minimum Wages on Public Works Act, 40 O.S.1991, §§ 196.1 to 196.14, violated Article IV, Section 1 and Article V, Section 1 of the Oklahoma Constitution by delegating "the power to determine prevailing wages to [the United States Department of Labor] without setting standards for the exercise of that determination." *Oklahoma City,* 1995 OK 107, ¶ 1, 918 P.2d at 28. The provisions required the Oklahoma Labor Commissioner to adopt the United States Department of Labor's prevailing wage on an on-going basis. *Id.* ¶ 9, 918 P.2d at 29. The act allowed the United States Department of Labor to change Oklahoma's prevailing wage law without legislative action. *Id.* ¶ 8, 918 P.2d at 29.

¶15 In *In re Initiative Petition No. 366, State Question No. 689*, 2002 OK 21, 46 P.3d 123, this Court ruled an initiative petition unconstitutional before it was submitted to a vote of the people. The petition called for the State Board of Education and the State Board of Regents for Higher Education to promote principles, but failed to state any principles. *Id.* ¶ 16, 46 P.3d at 128. Because the legislation failed to provide guidelines for implementing rules, the legislation was deemed to have improperly delegated the Legislature's authority by allowing agencies unfettered discretion to make law. *Id.* ¶ 18, 46 P.3d at 129.

¶16 Similarly to *In re Initiative Petition No. 366,* in *Estep,* this Court ruled that the Oklahoma Campaign Finance Act, in effect at the time, violated the non-

delegation doctrine. 1982 OK 106, ¶ 1, 652 P.2d 271, 272. The act allowed the Campaign Commission unfettered discretion to promulgate rules without legislative standards for guidance. *Id.* ¶ 16, 652 P.2d at 277. These three cases teach that the Legislature, or the voters acting as a legislature through the initiative process, delegates its authority when it enacts legislation giving an agency (particularly a federal agency that is not bound by Oklahoma's legislative policies) the power to alter Oklahoma law. When the Legislature allows an agency, or other entity, to make rules without sufficient legislative guidelines by setting binding policy on the agency, the Legislature has unconstitutionally delegated its authority to determine Oklahoma policy.

¶17 With this lesson in mind, the question before us is whether H.B. 2684 allows the FDA to change Oklahoma abortion laws by changing a FPL of currently approved drugs or adopting a FPL for future drug approvals or whether it restricts only Mifeprex, misoprostol, and methotrexate to the current Mifeprex FPL when used for inducing abortions. We are guided by well-established principles in assessing the conformity of a challenged state statute to our fundamental law. *Liddell v. Heavner*, 2008 OK 6, ¶ 16, 180 P.3d 1191, 1199–1200. Our state constitution is a bulwark to which all statutes must yield. In reviewing a statute for conformity to Oklahoma's constitution, we begin with a presumption of constitutionality. *Id.* A statute will be upheld unless it is clearly, palpably, and plainly inconsistent with the Constitution. *Id.* The party challenging a statute's constitutionality has a heavy burden to establish

that it is in excess of legislative power. *Id.* Bound by these rules, we must, if possible, construe H.B. 2684 as not allowing the FDA's decisions to change Oklahoma law; the means of doing so is to apply H.B. 2684's restrictions only to Mifeprex, misoprostol, and methotrexate use in abortions, excluding ectopic pregnancies, according to the current Mifeprex FPL.

¶18 Subsection B(1) of H.B. 2684 defines "[a]bortion-inducing drug" as a "medicine, drug, or any other substance prescribed or dispensed with the intent of inducing an abortion." The next sentence limits the previous sentence by stating "[t]his 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 second sentence only refers to drugs which were in use at the time of H.B. 2684's enactment, not drugs subsequent to its enactment. Because we give meaning to all words in a statute, we must construe these sentences as limiting the definition to drugs known at the time of H.B. 2684's enactment to have abortion-inducing properties and prescribed with the specific intent of causing an abortion. *See Moore v. Hayes*, 1987 OK 82, ¶ 7, 744 P.2d 934, 937. ("Legislative enactments must be interpreted so as to render every word and sentence operative, rather than in a manner which would render a specific provision nugatory.") To construe the statute to include any future FDA-approved abortion-inducing drugs would make the second sentence superfluous. And the almost complete incorporation of the Mifeprex FPL in H.B. 2684 only strengthens this

construction.

¶19 Both the Plaintiffs' and the State's evidence show that the only three drugs which come within this definition are Mifeprex, misoprostol, and methotrexate. The parties do not even mention other drugs in the submissions or evidence. Thus, we read H.B. 2684 as defining abortion-inducing drugs to include only Mifeprex, misoprostol, and methotrexate, the only currently known drugs prescribed and used with the intent of causing an abortion. No other drugs fall within Subsection B(1)'s definition of abortion-inducing drugs.

¶20 We next turn to Section D of H.B. 2684 which prohibits the use of all abortion-inducing drugs with the exception of the Mifeprex FPL protocol. Having defined abortion-inducing drugs as Mifeprex, misoprostol, and methotrexate (except when used in ectopic pregnancies), Section D prohibits the off-label use for intentional abortions of Mifeprex, misoprostol, and methotrexate, allowing only the Mifeprex FPL protocol for these three drugs when they are used to induce abortions.

¶21 In addition to limiting the definition of abortion-inducing drugs to the three referenced in the bill, the Legislature has shown its intent to restrict only these three drugs in other parts of H.B. 2684. Subsection B(4) defines the Mifeprex regimen as the regimen found in "the FDA-approved Mifeprex" FPL and as the only FDA-approved abortion-inducing drug regimen. Subsections E through H parrot the Mifeprex FPL and clarify the Legislature's intent that H.B. 2684 only allows the use of the Mifeprex FPL to induce abortions using the three mentioned drugs.

¶22 H.B. 2684 restricts the use of only Mifeprex, misoprostol, and methotrexate to the Mifeprex FPL protocol when they are used to induce abortions. In so doing, it does not allow the FDA any authority. Rather, H.B. 2684 merely incorporates the Mifeprex FPL as the only allowed use of Mifeprex, misoprostol, and methotrexate in medication abortions, and unlike *Oklahoma City*, it does not allow a federal agency's actions to affect Oklahoma's law. Simply, H.B. 2684 is not unconstitutional as an improper delegation of legislative authority.

V. SPECIAL LAW

¶23 The Plaintiffs also challenge H.B. 2684 as a violation of the Oklahoma Constitution, Article V, Section 59. Section 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.

Okla. Const. art. V, § 59. To determine whether a statute violates Section 59, we must begin with the three-pronged inquiry identified in *Reynolds v. Porter*, 1988 OK 88, ¶ 13, 760 P.2d 816, 822. "1) Is the statute a special law or general law? 2) If the statute is a special law, is a general law applicable? and 3) If a general law is not applicable, is the statute a permissible special law." *Id.* We examine each prong in turn.

A. Is H.B. 2684 a Special or General Law?

¶24 We must identify the subject the law seeks to classify ("the class") to determine whether H.B. 2684 is a special or general law. *Elias v. City of Tulsa*, 1965

OK 164, ¶ 9, 408 P.2d 517, 519. "A statute relating to all persons or things of a class is a general law; one relating to particular persons or things of a class is a special law." *Reynolds*, 1988 OK 88, ¶ 14, 760 P.2d at 822. Where a class is underinclusive, the statute is a special law. *Id.* ¶ 21, 760 P.2d at 824.

¶25 In *Reynolds*, the Court first identified the overarching subject classified by the legislation—limitations of civil actions. *Id.* ¶ 18, 760 P.2d at 823. The *Reynolds* legislation carved out special treatment for "actionable medical malpractice claims which cannot be discovered with reasonable diligence until after three years." *Id.* As the statute carved out a subclass apart from all statutes on limitations of civil actions, it was underinclusive and a special law. *Id.*

¶26 The Plaintiffs argue H.B. 2684 is a special law in two ways: 1) the law classifies the drugs Mifeprex and misoprostol only for off-label use in ending a pregnancy from any other off-label use of the drugs; and 2) the law classifies only women who seek and doctors who provide abortions from all other women seeking or doctors providing medical care. The district court agreed with the Plaintiffs, ruling that the general class must be all FDA-approved drugs or all FDA drugs approved under Subpart H. The State argues that H.B. 2684 is a general law that seeks to classify all abortion-inducing drugs.

¶27 H.B. 2684 incorporates 16 provisions of legislative findings, each related to the use of abortion-inducing drugs. H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 375-77, § 1-729a(A)(1)-(16). We have already construed H.B. 2684 to regulate only

Mifeprex, misoprostol, and methotrexate and only when used to induce abortions. Just as the legislation in *Reynolds* was a special law because it classified a smaller class than all limitations on civil actions, so too is H.B. 2684 as it classifies Mifeprex, misoprostol, and methotrexate only when used as abortion-inducing drugs. We agree with the Plaintiffs that the subject of H.B. 2684 does not cover the use of these drugs in any other instance or any other drugs; therefore, H.B. 2684 is a special law. According to *Reynolds*, it is subject to further scrutiny.

B. Is a general law applicable?

¶28 The second prong of the *Reynolds* inquiry is to determine if a general law is applicable. 1988 OK 88, ¶ 13, 760 P.2d at 822. More specifically, the question is whether "the subject of the legislation is reasonably susceptible of general treatment or . . . there is a special situation possessing characteristics impossible of treatment by general law." *Id.* ¶ 15, 760 P.2d at 822. The subject of H.B. 2684 is Mifeprex, misoprostol, and methotrexate when used as abortion-inducing drugs. To determine if the subject is susceptible to general treatment, we examine the nature and objective of the legislation and the conditions and circumstances of its enactment. *See id.*

¶29 The Plaintiffs maintain a general law could better address the subject of the legislation, arguing that a law that encompasses all off-label uses of FDA-approved drugs is the more appropriate vehicle for general treatment. Therefore, H.B. 2684 would fail the second prong of the *Reynolds* inquiry. The State argues that

a general law would not be feasible as it would regulate far beyond the scope of H.B. 2684—for instance, a general law regulating all uses of misoprostol would ban uses such as the induction of labor. We agree with the State.

¶30 Section 16 of H.B. 2684 lays out the statute's nature and purpose—to ban the off-label use of Mifeprex, misoprostol, and methotrexate when used as abortion-inducing drugs. The factual findings, specifically the deaths and hospitalizations caused by off-label use of Mifeprex and misoprostol and the dangers of methotrexate, establish the basis for their legislative restrictions by special law. Based on our construction of H.B. 2684, we agree that the Legislature specifically tailored a special law to address the use of Mifeprex, misoprostol, and methotrexate when prescribed with the intent of inducing abortions. To broaden the scope with a general law would force the Legislature to restrict off-label use of these and other drugs without a showing of harm from the off-label use. The regulation of the use of Mifeprex, misoprostol, and methotrexate when used as abortion-inducing drugs does not currently present characteristics for general treatment; we therefore agree with the State that a general law is not applicable under prong two of the *Reynolds* inquiry.

C. Is the legislation a permissible special law?

¶31The third prong of the *Reynolds* inquiry requires this Court to "determine if the special legislation is reasonably and substantially related to a valid legislative objective." *Reynolds*, 1988 OK 88, ¶ 16, 760 P.2d at 822. In *Reynolds*, the Court

scrutinized each of the legislation's aims with the classification to determine if there was "a degree of correlation between" them. *Id.* ¶ 23, 760 P.2d at 825. The legislation at issue was a three-year limitation on the amount of recoverable damages in a medical malpractice action even though a claim's existence was not discoverable during the three years. *Id.* ¶ 1, 760 P.2d at 818. One aim the Legislature put forth was to control the cost of medical malpractice insurance. *Id.* ¶ 22, 760 P.2d at 825. The Court rejected any correlation between the legislative aim and the class as no documented legislative findings existed to show that the class, actionable medical malpractice cases not discovered until after three years, created "an excessively high incidence of losses that it calls for special statutory treatment." *Id.*

¶32 Here, the Legislative objectives advanced by the State are two fold: 1) to protect women from dangerous off-label use of abortion inducing drugs; and 2) to require physicians to follow the Mifeprex FPL regime. H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 376, § 1-729a(A)(15). These objectives must be reasonably and substantially related to H.B. 2684's underinclusive class, Mifeprex, misoprostol, and methotrexate when used as abortion-inducing drugs. For the first objective, the Legislature has taken great pains to incorporate 16 legislative findings documenting the danger off-label use of these medications have for women when used as abortion-inducing drugs. The documented cases of death and injury are not disputed by the Plaintiffs, but we must acknowledge the Plaintiffs' evidence which identifies

the dangers of pregnancy and wide-variety of much more dangerous practices not regulated by the statute. However, it is not the place of this Court to question legislative wisdom. *EOG Res. Mktg., Inc. v. Okla. State Bd. of Equalization*, 2008 OK 95, ¶ 20, 196 P.3d 511, 521 ("It is not the role of this Court to question the desirability, wisdom, or logic of a valid statutory classification.").

¶33 Here, the State's evidence shows that the class restricted by H.B. 2684 is reasonably and substantially connected to protecting women, and so too to for the State's second objective, to require physicians to follow the Mifeprex FPL. Because the evidence is mixed, we must defer to the Legislature, when examining the evidence under Oklahoma's special law provision, and the Legislature's function as a policy-making body when it has support for its acts. While H.B. 2684 is a special law, it is a permissible special law as the legislative aims are reasonably and substantially related to the class H.B. 2684 seeks to protect.

VI. CONCLUSION

¶34 We find that H.B. 2684 does not violate the non-delegation doctrine of Article V, Section 1 because H.B. 2684 incorporates the current Mifeprex FPL, restricting only the off-label use of Mifeprex, misoprostol, and methotrexate when used to induce abortions. H.B.2684 is unaltered by any future FDA actions. We find also that H.B. 2684 does not violate Article V, Section 59 of the Oklahoma Constitution. This opinion does not address other Oklahoma constitutional provisions nor any United States constitutional provisions which H.B. 2684 may violate as those

questions are not before this Court and are, thus, improper considerations until presented to this Court. We also must recognize that, by the States' own evidentiary materials, more restrictions on abortions result in higher complication rates and in decreased women's safety. Because H.B. 2684 is the only effective Oklahoma legislation restricting abortion at this time, we need not address the impact of future abortion-related restrictions on H.B. 2684's constitutionality.

¶35 The district court's judgment is reversed. The matter is remanded to the district court for a determination of H.B. 2684's validity under other constitutional provisions, both state and federal. The stay entered in *Okla. Coalition for Reprod. Justice v. Cline*, 2014 OK 91, 339 P.2d 887, for HB 2684, remains in place until the constitutionality of the Act is fully and finally litigated.

REVERSED AND REMANDED.

Concur: Reif, C.J., and Kauger, Winchester, Taylor, and Gurich, J.J.

Concur Specially: Combs, V.C.J. (by separate writing).

Dissents: Edmondson, J.

Not Voting: Watt and Colbert, JJ.