

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

FILED IN DISTRICT COURT
OKLAHOMA COUNTY

AUG 27 2015

TIM RHODES
COURT CLERK

89

- (1) OKLAHOMA COALITION FOR)
REPRODUCTIVE JUSTICE, on behalf of)
itself and its members; and)
)
- (2) NOVA HEALTH SYSTEMS, D/B/A)
REPRODUCTIVE SERVICES, on behalf)
of itself, its staff, and its patients,)
)
Plaintiffs,)
- v.)
- (3) TERRY L. CLINE, in his official capacity)
as Oklahoma Commissioner of Health; and,)
)
- (4) LYLE KELSEY, in his official capacity as)
Executive Director of the Oklahoma State)
Board of Medical Licensure and)
Supervision,)
)
Defendants.)

Case No. CV-2014-1886

Judge Patricia G. Parrish

**ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT,
GRANTING PLAINTIFFS' MOTION TO STRIKE THE AFFIDAVIT OF REJI T.
VARGHESE, AND GRANTING IN PART PLAINTIFFS' MOTION TO STRIKE
THE AFFIDAVIT OF DONNA HARRISON, M.D.**

The Court has before it Plaintiffs' Motion for Partial Summary Judgment; Defendants' Cross-Motion for Summary Judgment; Plaintiffs' Motion to Strike Defendants' Exhibit C, "Affidavit of Reji T. Varghese;" and Plaintiffs' Motion to Strike the Affidavit of Donna Harrison, M.D. The Court heard oral argument on the motions on August 10, 2015. Plaintiffs appeared by Autumn Katz, Martha Hardwick, and Blake Patton. Defendants appeared by Deputy Solicitor General Mithun Mansinghani and Assistant Solicitor General Sarah Greenwalt. Having considered the arguments and evidence presented, and for the reasons set forth below, the Court GRANTS Plaintiffs' Motion for Summary Judgment; DENIES AS

MOOT Defendants' Cross-Motion for Summary Judgment; GRANTS Plaintiffs' Motion to Strike Defendants' Exhibit C, "Affidavit of Reji T. Varghese;" and GRANTS IN PART and DENIES IN PART Plaintiffs' Motion to Strike the Affidavit of Donna Harrison, M.D.

Findings of Fact

1. This action is a constitutional challenge to House Bill 2684, 2014 Okla. Sess. Laws Ch. 121 (hereinafter "HB 2684" or the "Act"), which regulates the provision of medication abortion in Oklahoma.

2. Plaintiffs are Oklahoma Coalition for Reproductive Justice and Nova Health Systems, d/b/a Reproductive Services (collectively "Plaintiffs"). Defendants are 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 (collectively "Defendants" or the "State").

3. Medication abortion is a procedure aimed at ending an early pregnancy using medications, rather than undergoing surgery. Defs.' Answer ¶ 3.

4. The medications most commonly used for medication abortion in the United States are mifepristone and misoprostol, which are taken in tandem according to a specific regimen. *Id.*; *Cline v. Okla. Coal. for Reproductive Justice* ("*Cline I*"), 2013 OK 93, ¶¶ 12-13, 313 P.3d 253, 258.

5. In 2000, the United States Food and Drug Administration ("FDA") approved mifepristone (also known by its brand name Mifeprex) for marketing purposes as an effective method of inducing an abortion early in a woman's pregnancy. Defs.' Answer ¶ 4.

6. As part of that approval process, the FDA approved a Final Printed Label ("FPL") for Mifeprex. *Id.* ¶ 28. The FPL is "an informational document providing guidance

about a drug's indications, precautions, and dosage.” *Cline I*, 2013 OK 93, ¶ 9, 313 P.3d at 257.

7. The FDA approved mifepristone under the agency's Subpart H regulations, which enabled the FDA “to restrict distribution of [the] approved drug by its sponsor to ensure safe use,” but did not “require that administering physicians utilize mifepristone according only to the protocol described in the FDA-approved label.” *See id.* ¶ 21 n.17, 313 P.3d at 261 n.17 (citing 21 C.F.R. § 314.520).

8. “Ninety-six percent of medication abortions in the United States are now provided according to a regimen different from the one described in mifepristone's FDA-approved label.” *Id.* ¶ 21, 313 P.3d at 260-61. These regimens vary the dosage and/or administration of the two drugs, and permit use of the drugs to induce an abortion further into pregnancy (from 49 days to 63 or more days of pregnancy, as measured from the first day of a woman's last menstrual period). *See id.* ¶¶ 10-11, 313 P.3d at 258.

9. Plaintiff Reproductive Services follows an “off-label” or “evidence-based” protocol that differs from the one described in the Mifeprex FPL and has been endorsed by the American College of Obstetricians and Gynecologists and the World Health Organization. *See id.* ¶ 21, 313 P.3d at 261.

10. HB 2684 mandates that physicians who provide mifepristone and misoprostol for the purpose of inducing an abortion comply with the protocol described in the Mifeprex FPL authorized by the FDA. HB 2684 prohibits physicians from prescribing these medications according to off-label or evidence-based protocols. HB 2684 § 1(D). Physicians who fail to

adhere to the FDA protocol are subject to civil liability, HB 2684 §§ 1(H)(2), (I), and (J), as well as other statutory and regulatory consequences.¹

11. In 2011, the Oklahoma Legislature enacted House Bill 1970 (“HB 1970”), which required physicians providing or prescribing any abortion-inducing drug to do so according to the drug’s FDA-approved label, the effect of which was to prohibit all medication abortions. The district court held HB 1970 unconstitutional, and the Oklahoma Supreme Court affirmed, finding the law facially unconstitutional pursuant to *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). *Okla. Coal. for Reproductive Justice v. Cline*, 2012 OK 102, ¶ 3, 292 P.3d 27, 27-28. The United States Supreme Court granted *certiorari* and certified two questions to the Oklahoma Supreme Court: Whether HB 1970 prohibited “(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 v. Okla. Coal. for Reproductive Justice*, 133 S. Ct. 2887 (2013) (mem.). The Oklahoma Supreme Court answered both the certified questions in the affirmative, *Cline I*, 2013 OK 93, 313 P.3d 253, and the U.S. Supreme Court subsequently dismissed the writ of *certiorari* and let stand the Oklahoma Supreme Court’s decision striking down HB 1970. *Cline v. Okla. Coal. for Reproductive Justice*, 134 S. Ct. 550 (2013) (mem.).

¹ See 63 O.S. § 1-706(B) (providing that Commissioner can suspend or revoke a facility’s license for any violation of tit. 63, art. 7, under which the provisions of HB 2684 fall); OAC § 310:600-7-3 (implementing 63 O.S. § 1-706(B) as to abortion facility licenses); 59 O.S. § 503 (providing that State Board of Medical Licensure and Supervision may suspend, revoke or order any other appropriate sanctions against the license of any physician for unprofessional conduct); 59 O.S. § 509 (defining “unprofessional conduct” for which a physician may be disciplined); OAC § 435:10-7-4 (implementing 59 O.S. § 509).

12. In this litigation, Plaintiffs moved for partial summary judgment on two claims: i) that HB 2684 violates Article V, § 59 of the Oklahoma Constitution, which prohibits special laws where a general law could be made applicable, and ii) that it violates Articles IV and V of the Oklahoma Constitution, which prohibit the Legislature from abdicating its policy-making power. Defendants cross-moved for summary judgment on all of the claims asserted by Plaintiffs' petition, including special law, improper delegation, due process, and equal protection. Plaintiffs further moved to strike the affidavits of Reji T. Varghese and Donna Harrison filed with Defendants' cross-motion for summary judgment.

Conclusions of Law

I. Motions for Summary Judgment

A. Applicable Standard

13. Summary judgment is proper when the moving party shows there is no substantial controversy as to any material fact. *See* Okla. Dist. Ct. R. 13(a); *see also Fehring v. State Ins. Fund*, 2001 OK 11, ¶ 3, 19 P.3d 276, 278 (a party is "entitled to judgment as a matter of law" where "no material disputed factual questions exist"). An "opposing party has the obligation of showing some probative evidence, formulated as specific facts, to justify a trial of the issues. A party cannot merely rely upon conjecture or suppositions, and assert 'that facts exist or might exist, [because such] is not sufficient to create a substantial controversy.'" *First Nat. Bank & Trust Co. of Vinita v. Kissee*, 1993 OK 96, 859 P.2d 502, 505 (citation omitted). If it appears to the Court that there is no substantial controversy as to the material facts and that one of the parties is entitled to judgment as a matter of law, the Court shall render judgment for said party. Okla. Dist. Ct. R. 13(e).

B. The Supreme Court's Decision in *Cline I*

14. In *Cline I*, the Oklahoma Supreme Court answered two certified questions from the U.S Supreme Court and found that as a matter of plain meaning and statutory construction, HB 1970 prohibited off-label uses of mifepristone, misoprostol, and methotrexate when used to terminate a pregnancy, effectively banning all medication abortions. 2013 OK 93, ¶¶ 1-19, 25, 313 P.3d at 258-60.

15. The Court observed that the “FDA has stated that evidence-based regimens are common, permissible, and can be required by good medical practice.” *Id.* ¶ 10, 313 P.3d at 258. It further noted that “FDA-approved labeling is not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient,” and “[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment.” *Id.* ¶¶ 20, 21, 313 P.3d at 260-61 (internal citations and quotation marks omitted).

16. Indeed, “the Oklahoma Legislature has recognized the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling” in other areas of the law. *Id.* ¶ 22, 313 P.3d at 261.

17. With regard to evidence-based protocols, “[b]oth the American College of Obstetricians and Gynecologists and the World Health Organization have endorsed these alternate regimens as safer and more effective than the now-outdated regimen provided for in mifepristone’s FDA-approved label,” *id.* ¶ 21, 313 P.3d at 261, which “requires a dosage level no longer considered medically necessary,” *id.* ¶ 25, 313 P.3d at 262.

18. The Oklahoma Supreme Court also determined that the district court was correct in concluding that

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

Id. ¶ 27, 313 P.3d at 262 (quoting *Okla. Coal. for Reproductive Justice v. Cline*, No. CV-2011-1722, slip. op., ¶ 7 (Dist. Ct. Okla. Cty. May 11, 2012)).

C. The Act Violates Oklahoma's Prohibition Against Special Laws

19. The Court finds that Plaintiffs' motion for summary judgment on the basis of the special laws provision of the Constitution, Article V, § 59, involves no disputed questions of fact and can be decided as a matter of law. The issues in this case have already been decided by the Supreme Court in *Cline*, 2013 OK 93, 313 P.3d 253, and this Court is bound by that decision.

20. Under the Oklahoma Constitution, "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. The three-pronged inquiry set forth in *Reynolds v. Porter* governs the analysis of a special laws claim: "1) Is the statute a special 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?" 1988 OK 88, 760 P.2d 816, 822. If a law is special under the first prong of the *Reynolds* test, and it fails either the second or third prong, it is unconstitutional. *Id.* The first inquiry asks whether a law "single[s] out less than an entire class of similarly affected persons or things for different treatment." *Id.* Under the second prong, courts assess whether the subject of the challenged statute is

“reasonably susceptible of general treatment or if there is a special situation possessing characteristics impossible of treatment by general law.” *Orthopedic Hosp. of Okla. v. Okla. State Dep’t of Health*, 2005 OK CIV APP 43, ¶ 13, 118 P.3d 216, 222 (citation omitted). The third prong examines whether the special law is “reasonably and substantially related to a valid legislative objective.” *Id.* ¶ 13, 118 P.3d at 223.

21. HB 2684 violates the constitutional prohibition on special laws because it fails under each prong of the *Reynolds* test.

22. Though the Oklahoma Legislature has acknowledged the importance of allowing physicians to practice medicine according to their best judgment, including the use of evidence-based protocols, *see Cline I*, 2013 OK 93, ¶¶ 22-25, 313 P.3d at 260-62, the Act singles out certain FDA-approved medications and prohibits their off-label use *solely* when used for the purpose of inducing an abortion. HB 2684 therefore singles out women who seek, and doctors who provide, abortions from those involved in all other forms of medical care.

23. The Oklahoma Legislature could have passed a generally applicable law regulating the off-label use of FDA-approved medications, instead of singling out one particular drug, for one particular use. In fact, as the Oklahoma Supreme Court has previously recognized, the Legislature has specifically protected the off-label use of drugs in other contexts, and for other purposes apart from inducing an abortion. *Cline I*, 2013 OK 93, ¶¶ 22-25, 313 P.3d at 260. Likewise, the Legislature could have, but chose not to, regulate the off-label use of all medications approved under Subpart-H.

24. With regard to the third prong of the special law inquiry, the State concedes that the Act takes away a physician’s discretion to use these drugs off-label, and in most other areas of medicine, physicians may prescribe drugs off-label when it is consistent with good medical

practice. The State claims that this legislation was necessary to address particular safety concerns with mifepristone, based on infection-related deaths that might be connected to off-label protocols, the increased rate of infection with certain off-label uses, the increased rate of clinically significant bleeding with use after 49 days of pregnancy, the availability of a safer surgical alternative, and the potential to eliminate the need for use of misoprostol at all if the on-label regimen is followed.

25. However, the Oklahoma Supreme Court has already held that the predecessor act's restrictions were "**so completely at odds with the standard that governs the practice of medicine** that [they could] serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." *Id.* ¶ 27, 313 P.3d at 262 (citation omitted). With regard to the State's asserted interests, the Legislature's own findings state, "[t]he FDA has not been able to conclude one way or another whether off-label use led to the eight deaths." HB 2684, § 1.² Moreover, the fact that the Act only imposes restrictions on off-label use of mifepristone and misoprostol when used to end a pregnancy, but permits off-label use of these same drugs for any other purpose, undercuts the State's argument that the Act is reasonably and substantially related to any legitimate safety concerns. This Court is bound as a matter of law by the Oklahoma Supreme Court's ruling in *Cline I* to hold that no valid state interest is served by prohibiting doctors from following evidence-based medication abortion protocols.

² Neither the FDA nor the Centers for Disease Control and Prevention has found any specific connection between bacterial infections and medication abortion. *See American College of Obstetricians and Gynecologists Practice Bulletin No. 143: Medical Management of First-Trimester Abortion*, at 8 & nn.67-68.

26. Based on the Supreme Court's ruling in *Cline I*, 2013 OK 93, 313 P.3d 253, this Court finds that the Act creates a special law where a general law could be made applicable, and further, that it is not reasonably and substantially related to any legitimate legislative objective articulated by the State.

27. The Court declines to reach Plaintiffs' alternative claim that summary judgment should be granted on the unlawful delegation claim. Given the conclusion that HB 2684 is an unconstitutional special law, the Court need not address Defendants' motion for summary judgment on all of Plaintiffs' claims, which is rendered moot.

II. Motions to Strike

28. Defendants did not cite to or rely upon in any way the affidavit of Reji T. Varghese, and therefore the Court strikes that affidavit as irrelevant. *See* 12 O.S. § 2402 (irrelevant evidence is inadmissible); Okla. Dist. Ct. R. 13(c) (allowing a party to challenge admissibility of evidentiary material at summary judgment); 12 O.S. § 2056(E) (an affidavit supporting or opposing summary judgment must "set out facts that would be admissible in evidence").

29. The Court finds that Donna Harrison lacks sufficient qualifications to opine on the intent of the FDA in approving Mifeprex, given Defendants' admission that she was not actually part of the FDA's internal approval process for Mifeprex. Portions of her affidavit related to FDA intent must therefore be struck as follows:

- Paragraph 6: Strike everything except first sentence
- Paragraph 55: Strike everything except first sentence
- Paragraph 67: Strike the second sentence
- Paragraph 70: Strike the first sentence
- Paragraph 81: Strike the entire sentence
- Paragraph 91: Strike the entire paragraph

- Paragraph 95: Strike the entire paragraph
- Paragraph 131: Strike the last clause
- Paragraph 133: Strike everything except the second sentence
- Paragraph 134: Strike the entire paragraph
- Paragraph 136: Strike everything except first sentence
- Paragraph 148: Strike the entire paragraph
- Paragraph 155: Strike the entire paragraph
- Paragraph 158: Strike the entire paragraph
- Paragraph 159: Strike the first clause and the last sentence
- Paragraph 163: Strike the entire paragraph

The remainder of Dr. Harrison's affidavit stands as to all other issues.

Orders

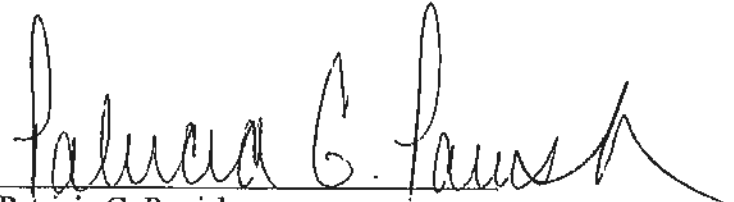
In light of the foregoing findings of fact and conclusions of law, IT IS HEREBY

ORDERED:

- i) Plaintiffs' Partial Motion for Summary Judgment is GRANTED.
- ii) Defendants' Motion for Summary Judgment is DENIED AS MOOT.
- iii) Plaintiffs' Motion to Strike Defendants' Exhibit C, "Affidavit of Reji T. Varghese," is GRANTED.
- iv) Plaintiffs' Motion to Strike the Affidavit of Donna Harrison, M.D., is GRANTED IN PART and DENIED IN PART.
- v) House Bill 2684, 2014 Okla. Sess. Laws Serv. Ch. 121, is declared unconstitutional and is void and of no effect.
- vi) The Defendants, their employees, agents, and successors in office are hereby permanently enjoined from enforcing the provisions of House Bill 2684.
- vii) Judgment is entered for the Plaintiffs.

IT IS SO ORDERED.

Dated: August 27, 2015



Patricia G. Parrish
District Court Judge

Respectfully submitted,



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**Admitted to Practice by Order dated
September 30, 2014.*

ATTORNEYS FOR PLAINTIFFS

Approved as to form*:



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ATTORNEYS FOR DEFENDANTS


*Defendants preserve all objections to the findings of fact and conclusions of law contained in this Order and, by signing this order, do not waive any issue on appeal.

*** Admitted to Practice by Order dated
May 4, 2015.*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 27th of August, 2015, of a copy of the foregoing was served via U.S. mail, postage prepaid, on the following:

Mithun Mansinghani, Deputy Solicitor General
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