IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

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

Plaintiffs,

v.

(3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and,
(4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision,

Defendants.

Case No. CV-2014-1886

Judge Patricia G. Parrish

ORDER GRANTING SUMMARY JUDGMENT

The Court heard arguments on Plaintiffs' Cross-Motion for Summary Judgment and Opposition to Defendants' Renewed Motion for Summary Judgment and Defendants' Renewed Motion for Summary Judgment on August 25, 2017, and on October 6, 2017. Plaintiffs appeared by Autumn Katz and Blake Patton. Defendants appeared by Solicitor General Mithun Mansinghani and Assistant Solicitor General Michael Velchik. For the reasons stated on the record at the October 6, 2017 hearing, and for the reasons set forth below, the Court hereby GRANTS Plaintiffs' Cross-Motion for Summary Judgment and Opposition to Defendants' Renewed Motion for Summary Judgment in this matter.

1. During the first trimester of pregnancy, women in the United States may generally obtain an abortion by two different methods. Women can receive a surgical abortion,

which in the first trimester involves a 5 to 10 minute procedure that uses suction or vacuum aspiration to empty the uterus. Women can also receive a medication abortion, which involves the use of medications taken in tandem according to a specific protocol. Currently, in Oklahoma, medication abortion is available up to 10 weeks of pregnancy.

2. House Bill 2684, 2014 Okla. Sess. Laws Serv. Ch. 121 ("the Act") requires physicians who provide medication abortion to do so according to the protocol originally approved by the United States Food and Drug Administration ("FDA") almost two decades ago, in 2000 (hereinafter the "Original FDA Regimen"). Under this protocol, administration of mifepristone for the purpose of terminating a pregnancy requires three office visits by the patient. During the first office visit, the patient is given 600 mg of mifepristone orally. Two days later, the patient returns to the office. Unless the initial dose of mifepristone has already terminated the pregnancy, the patient receives 400 μg of misoprostol orally. After two weeks, the patient returns to the office for a third visit to verify the procedure was successful. The Original FDA Regimen permits medication abortions up to 7 weeks (49 days) of pregnancy.

3. Under the Act, physicians who fail to adhere to the Original FDA Regimen are subject to civil liability. H.B. 2684 §§ 1(H)(2), (I), and (J). In addition, they could face a host of other statutory and regulatory consequences. 63 O.S. § 1-706(B); Okla. Admin. Code § 310:600-7-3; 59 O.S. § 503; 59 O.S. § 509; Okla. Admin. Code § 435:10-7-4.

4. Plaintiff Nova Health Systems, d/b/a Reproductive Services, operates a clinic in Tulsa, Oklahoma that provides medical and surgical abortion services. At the time the Act was passed, the medication abortion protocol that Reproductive Services followed deviated from the Original FDA Regimen in several respects. First, Reproductive Services' patients were given 200 mg of mifepristone rather than 600 mg. Second, rather than being administered

400 μg of misoprostol orally, patients received 800 μg to be administered buccally or vaginally. Third, patients were instructed to self-administer misoprostol between 6 and 24 hours after taking the mifepristone at home or another location of their choosing, rather than returning to the clinic in order to receive the misoprostol (the timing varied depending on the chosen route of administration). Fourth, patients could undergo a medication abortion up to 9 weeks (63 days) of pregnancy, as opposed to the limit of 7 weeks (49 days) indicated by the Original FDA Regimen.

5. In March 2016, a new Mifeprex drug label was approved by the FDA. The manufacturer of Mifeprex submitted several proposed changes to the Mifeprex label and the dosing regimen described therein, and provided the FDA with evidence and data in support of these proposed changes to the label, including medical studies and clinical trials published after the agency's approval of Mifeprex in 2000.

6. The new Mifeprex drug label approved in 2016 describes a dosing regimen that differs in several key respects from the Original FDA Regimen:

1) usage is approved through 70 days gestation (an increase from 49 days);

2) the dose of Mifeprex on Day 1 was decreased to 200 mg (from 600 mg);

3) the dose of misoprostol was changed to 800 μg buccally, 24 to 48 hours after Mifeprex (from 400 μg orally, 48 hours after Mifeprex);

4) the misoprostol may be self-administered by the patient at home;

5) a repeat 800 μg buccal dose of misoprostol may be used if needed; and

6) the requirement that the follow up occur in the clinic 14 days after taking the Mifeprex was deleted.

7. This updated dosing regimen (hereinafter "the Current FDA Regimen") was determined to be safe and effective by the FDA based on the agency's review of the safety and efficacy data submitted by the manufacturer.

8. Plaintiff Reproductive Services updated its practices shortly after the Mifeprex label update and began providing medication abortion according to the Current FDA Regimen.

9. In light of the instructions provided by the Oklahoma Supreme Court in *Oklahoma Coalition for Reproductive Justice v. Cline*, 2016 OK 17, 368 P.3d 1278, this Court has now considered the constitutionality of the Act under both state and federal constitutional provisions. Consistent with Oklahoma Supreme Court precedent, this Court will evaluate the constitutionality of the Act under the federal undue burden standard. *See, e.g., Burns v. Cline*, 2016 OK 121, ¶ 5, 387 P.3d 348, 351; *Burns v. Cline*, 2016 OK 99, ¶ 1, 382 P.3d 1048, 1054 (Combs, V.C.J., concurring); *Okla. Coal. For Reprod. Justice v. Cline*, 2012 OK 102, ¶ 2, 292 P.3d at 27.

10. This Court finds that the Act fails under the undue burden standard because it would place a substantial obstacle in the path of a woman seeking a pre-viability abortion. Specifically, this Court finds that the burdens imposed by the Act exceed its benefits, and further, that the burdens imposed by the Act are undue. *See Whole Woman's Health v. Hellerstedt*, 579 U.S. ___, 136 S. Ct. 2292, 2300 (2016).

11. It is HEREBY ORDERED:

i) Plaintiffs' Cross-Motion for Summary Judgment is GRANTED.

ii) Defendants' Renewed Motion for Summary Judgment is DENIED AS MOOT.

iii) House Bill 2684, 2014 Okla. Sess. Laws Serv. Ch. 121, is declared unconstitutional in all applications, and is therefore void and of no effect.

iv) The Defendants, their employees, agents, and successors in office are hereby permanently enjoined from enforcing the provisions of House Bill 2684.

v) Judgment is entered for the Plaintiffs.

IT IS SO ORDERED this 8th day of November 2017.

THE HONORABLE PATRICIA G. PARRISH
JUDGE OF THE DISTRICT COURT

Approved as to form:

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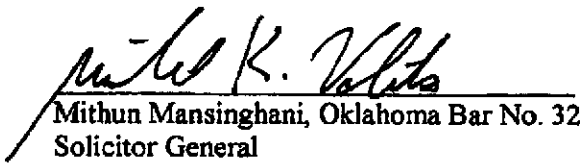

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CERTIFICATE OF SERVICE

I hereby certify that on the 17th day of November, 2017, a true and correct copy of the foregoing Order Granting Summary Judgment was sent via U.S. mail, postage pre-paid, and electronic mail to the following:

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