**IN THE DISTRICT COURT OF OKLAHOMA COUNTY**
**STATE OF OKLAHOMA**

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| (1) OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and<br>(2) NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients,<br><br>Plaintiffs,<br><br>v.<br><br>(3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and,<br>(4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and,<br>(5) CATHERINE C. TAYLOR, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners,<br><br>Defendants. | ) | Case No. _____<br><br>Judge CV -2011-1722 |

FILED IN THE DISTRICT COURT
OKLAHOMA COUNTY, OKLA.

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by _____ DEPUTY

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY INJUNCTION OR, ALTERNATIVELY, A TEMPORARY RESTRAINING ORDER PENDING THE OUTCOME OF THAT MOTION**


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## I. Introduction

This case challenges the validity of House Bill 1970 ("HB 1970" or "the Act"), which imposes unconstitutional restrictions on physicians' ability to provide and women's ability to receive sound medical treatment. The Act forbids off-label use of medications for the purpose of ending a woman's pregnancy, but specifically and explicitly permits off-label use of medications for any other purpose. In so doing, the Act burdens the rights secured by the Oklahoma Constitution to Plaintiffs and those whose interests they represent without a justifiable legislative objective. If allowed to go into effect, the Act will irreparably harm women seeking pregnancy terminations by foreclosing their physicians' ability to use the safest and most effective non-surgical methods available. Plaintiffs seek temporary injunctive relief against the Act during the pendency of this litigation in order to preserve the *status quo*, which would allow physicians to continue providing medical treatment for patients seeking pregnancy terminations according to the same standards that govern medical treatment for all other patients. To ensure that the motion is decided before the Act goes into effect on November 1, 2011, Plaintiffs also move for expedited briefing and hearing of the motion. In the alternative, Plaintiffs request that the Court issue a temporary restraining order enjoining enforcement of the Act pending the determination of Plaintiffs' motion for a temporary injunction.

## II. Statement of Facts

### A. The FDA Drug Approval Process

A drug may not be sold or marketed in the United States until it has been approved by the United States Food and Drug Administration ("FDA"). Affidavit of Lisa D. Rarick, M.D.

("Rarick Aff.") ¶ 4.[1] The FDA's formal process for new drug approval begins after a drug sponsor submits an application, typically following a long period of research and development. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 8 (2008) (hereinafter "GAO Report").[2] The FDA reviews each new drug application to determine whether it provides sufficient evidence to demonstrate that a drug is safe and effective for the proposed use, including whether the benefits of the drug outweigh its risks. *Id.* During a preliminary review, the FDA determines whether the application is sufficiently complete to be reviewed and, if so, designates it for either standard or priority review, depending on the therapeutic potential of the drug. *Id.* The agency then assigns a team of reviewers—including medical officers, chemists, statisticians, microbiologists, pharmacologists, and other experts—within the relevant FDA review division. *Id.* at 9. This review team, which is usually led by a medical officer, conducts a comprehensive evaluation of the clinical and non-clinical information in the application including the safety and efficacy data for the drug, the design and quality of the studies used to support the application, and the proposed labeling for the drug. *Id.* Thus, the FDA does not, itself, test protocols or conduct clinical trials as part of its approval process for drugs; rather, it reviews the evidence submitted to it by a drug's sponsor. Rarick Aff. ¶ 4.

Along with approving a drug, the FDA must also approve its labeling, often referred to as the Final Printed Labeling or Final Printed Label ("FPL"). The purpose of the FPL,

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[1] Dr. Rarick formerly worked at the FDA as, among other things, the Director of the Reproductive and Urologic Drug Products.

[2] This report is available through the Government Accountability Office's website at http://www.gao.gov/products/GAO-08-751. For the court's convenience, it is attached to the motion as Appendix 2.

which is drafted by a drug's sponsor and submitted to the FDA with the drug's application for approval, is to provide physicians with guidance about how to use the drug for particular purposes. Rarick Aff. ¶ 5. The FDA does not require drug sponsors to list all possible uses for a drug in the drug's FPL; a drug's sponsor controls what the FPL says about the uses for which it wants to market the drug. Rarick Aff. ¶ 6.

FDA approval of the drug and the content of the FPL allows the drug's sponsor to market the drug for the purposes described in the label; FDA approval does not limit the way that physicians may use an approved drug to treat patients. Rarick Aff. ¶¶ 4-5. To the contrary, physicians are expected to use FDA-approved drugs in accordance with medical evidence and their patients' needs. Rarick Aff. ¶ 4; Affidavit of Daniel A. Grossman, M.D.[3] ("Grossman Aff.") ¶ 6. The common practice of providing approved medications using dosage and administration regimens different from the regimen detailed in the FPL, and/or for purposes different from the purpose for which the manufacturer sought FDA approval, is known as "off-label use." Rarick Aff. ¶ 7; Grossman Aff. ¶ 5. The FDA has repeatedly acknowledged that off-label use is common, permissible, and sometimes required by good medical practice. Rarick Aff. ¶ 9.

### B. Off-Label Use of Methotrexate to Terminate Ectopic Pregnancies

An ectopic pregnancy occurs when a fertilized egg implants outside a woman's uterus. Grossman Aff. ¶ 10. Approximately two percent of all pregnancies are ectopic pregnancies. An ectopic pregnancy is always a risk to a woman's health and can threaten her life. *Id.* Roughly 97% of ectopic pregnancies are located in the woman's fallopian tubes;

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[3] Dr. Grossman is an assistant Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Services at the University of California, San Francisco. He is also a Senior Associate with Ibis Reproductive Health, a nonprofit organization that conducts clinical and social science research concerning sexual and reproductive health.

such pregnancies are commonly referred to as "tubal" ectopic pregnancies. *Id.* An ectopic pregnancy can be treated either surgically or with a medication called methotrexate. *Id.* ¶ 12.

Surgical management of a woman's ectopic pregnancy carries risks to her health and can carry risks to her future fertility. For example, surgery for a tubal ectopic pregnancy can involve incising a woman's fallopian tube to remove the pregnancy and then repairing it, or removing the fallopian tube in whole or in part. Grossman Aff. ¶ 11. Because of the risks associated with surgical management of ectopic pregnancy, an injection of methotrexate, a cancer-treating drug, to terminate the pregnancy is often the preferred method of treatment. *Id.* ¶ 12. As compared to surgical treatment of a tubal ectopic pregnancy, methotrexate poses fewer risks to a woman's health and may reduce the risk of future infertility. *Id.* ¶¶ 12-13. Use of methotrexate is recommended by the American College of Obstetricians and Gynecologists ("ACOG") as a treatment option for certain women with ectopic pregnancies. *Id.* ¶ 12. Methotrexate is used off-label for this purpose. *Id.* ¶ 13.

### C. Off-Label Use of Mifepristone and Misoprostol to Terminate Intrauterine Pregnancies

For decades, the only treatment option available to women seeking to terminate first-trimester intrauterine pregnancies was a surgical procedure. In 1996, a new drug application was submitted for Mifeprex, which is also known as mifepristone (its generic name) or RU-486 (its French counterpart), to be used for termination of first-trimester intrauterine pregnancies as an alternative to surgery. As the first drug that would be approved for this purpose, Mifeprex was a therapeutic advance because it was the first alternative to surgery and its attendant risks for women seeking abortions. GAO Report 15; Rarick Aff. ¶ 16. The FDA gave the application a "priority review" designation accordingly. GAO Report 15; Rarick Aff. ¶ 16. For women with certain medical conditions, an abortion using medication

is a less complicated and less risky option than a surgical procedure. Grossman Aff. ¶ 14. For all women, having a non-surgical treatment option provides the opportunity for more individually-tailored care. Rarick Aff. ¶ 8.

The new drug application for Mifeprex provided information about safety and efficacy of Mifeprex to terminate pregnancies for women up to 49 days pregnant, calculated from the first day of a woman's last menstrual period ("lmp"), as it was used in three clinical trials. GAO Report 15; Rarick Aff. ¶ 18. The treatment regimen followed in all three clinical trials consisted of two medications: mifepristone and misoprostol. GAO Report 15. Mifepristone works by blocking the hormone progesterone, which is needed to maintain a pregnancy. Grossman Aff. ¶ 17. Misoprostol causes a woman's cervix to open and her uterus to contract and expel its contents. Grossman. ¶ 18. Misoprostol is sold in the United States under the brand name Cytotec and is not labeled for use in medication abortions. Rarick Aff. ¶ 6; Grossman Aff. ¶ 19. The regimen used in the clinical trials is described in the Mifeprex FPL: on Day One, the patient read the Medication Guide, signed the Patient Agreement, and took three 200 milligram tablets of Mifeprex orally at the health care facility; on Day Three, the patient returned to the health care facility and, unless the abortion had already occurred, took two 200 microgram tablets of misoprostol orally; and on Day 14 (approximately) after taking mifepristone, the patient returned to the health care facility to confirm that the pregnancy had completely terminated. Rarick Aff. ¶ 18; Affidavit of Abigail Long, Exhibit A.

The combination of mifepristone and misoprostol is the most common method of inducing an abortion with medication in the United States, and it is the one used by Plaintiffs.

Grossman Aff. ¶ 14; Affidavit of Marilyn Eldridge[4] ¶ 13 ("Eldridge Aff."). In the years since the FDA approved Mifeprex, scientific research has demonstrated that other dosages and methods of administering mifepristone and misoprostol are safer and more effective than the regimen described in the Mifeprex FPL. Grossman Aff. ¶¶ 20-25. For example, ACOG has recommended a regimen that combines 200 mg of mifepristone and 800 mcg of misoprostol over the regimen described in the Mifeprex FPL. Grossman Aff. ¶ 22. As a result of the medical evidence, leading health organizations, including ACOG and the World Health Organization, have recognized that, as compared to the regimen described in the Mifeprex FPL, these evidence-based regimens are safer, more effective, less expensive, can have fewer side effects, and can be made available to women up to 63 days pregnant lmp. *Id.* ¶¶ 22-23.

**D. Plaintiffs' Interests in Protecting the Health of Oklahoma Women**

Plaintiff Oklahoma Coalition for Reproductive Justice ("OCRJ") is a non-profit charitable corporation dedicated to promoting reproductive justice in Oklahoma through education and advocacy. Declaration of Martha Skeeters, PhD.¶.[5] OCRJ is dedicated to ensuring that reproductive health care is available to all women in Oklahoma, and OCRJ's membership includes women of reproductive age who may want to obtain abortions or who may experience ectopic pregnancies in Oklahoma in the future. *Id.* ¶¶ 3, 5. OCRJ's members pay taxes to the State of Oklahoma. *Id.* ¶ 6.

Plaintiff Nova Health Systems d/b/a Reproductive Services ("Reproductive Services") is a nonprofit organization whose mission is to provide high-quality and

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[4] Marilyn Eldridge is the co-founder and President of Nova Health Systems d/b/a Reproductive Services.

[5] Dr. Skeeters is the President and co-Founder of OCRJ.

affordable reproductive health care services to women in underserved communities. Its Tulsa clinic provides a range of reproductive health care services to women in Oklahoma and neighboring states, including medication and surgical abortion, contraceptive counseling and services, pregnancy testing, options counseling and referrals for other medical and social services, including referrals to an on-site licensed adoption agency. Eldridge Aff. ¶ 2. When performing medication abortions, Reproductive Services' physicians follow an evidence-based regimen in furtherance of Reproductive Services' mission of providing high-quality and affordable services: evidence-based regimens are safer and more effective than the regimen that is described on the FPL for mifepristone; they are also less expensive because they require less than half the dosage of mifepristone. *Id.* ¶ 13.

## III. Statutory Framework

Until April 20, 2010, when OKLA. STAT. tit. 63, § 1-729a became effective, Oklahoma law did not distinguish between medication abortion and surgical abortion. That law, which is currently in effect, imposes several conditions on physicians' use of Mifeprex.

On November 1, 2011, Oklahoma House Bill 1970 will go into effect, dramatically altering the scope and effect of OKLA. STAT. tit. 63, § 1-729a. 2011 Okla. Sess. Laws 1276. The Act expands OKLA. STAT. tit. 63, § 1-729a to apply to not only mifepristone, but also any "abortion-inducing drug." The Act defines the term "abortion-inducing drug" as:

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

H.B. 1970 § 1(A)(1). In addition, the Act imposes several new restrictions on physicians' ability to provide abortion-inducing drugs (including mifepristone) to patients.

Currently, physicians have the option of providing Mifeprex to patients using a regimen based on scientific evidence (an "evidence-based regimen"). OKLA. STAT. tit. 63, § 1-729a(C). The Act prohibits the use of evidence-based regimens. Instead, it requires physicians to provide abortion-inducing drugs "according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug." H.B. 1970 § 1(C). The term "drug label" is defined as:

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

H.B. 1970 § 1(A)(2).

Similarly, under current law, physicians providing Mifeprex are required to explain to patients "whether the physician is using the drug in accordance with the U.S. Food and Drug Administration regimen or an evidence-based regimen, and, if using an evidence-based regimen, specifying that the regimen differs from the U.S. Food and Drug Administration regimen and providing detailed information on the evidence-based regimen being used." OKLA. STAT. tit. 63, § 1-729a(C). The Act modifies this explanation. It requires physicians who provide abortion-inducing drugs to tell their patients "that the drug is being used in accordance with the protocol tested and authorized by the U.S. Food and Drug Administration and as outlined in the drug label for RU-486 (mifepristone) or any abortion-inducing drug," and to provide each patient with "a copy of the drug manufacturer's

medication guide and drug label for RU-486 (mifepristone) or any abortion-inducing drug being used." H.B. 1970 §§ 1(D)(1),(2).

The Act creates a section that provides:

> Because the failure and complications from medical abortion increase with increasing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because RU-486 (mifepristone) or any abortion-inducing drug does not treat ectopic pregnancies but rather is contraindicated in ectopic pregnancies, the physician ... providing or prescribing RU-486 (mifepristone) or any abortion-inducing drug shall first examine the woman and document, in the woman's medical chart, gestational age and intrauterine location of the pregnancy prior to ... providing or prescribing RU-486 (mifepristone) or any abortion-inducing drug.

H.B. 1970 §1(E).

A physician who "knowing[ly] and reckless[ly]" fails to comply with the Act is subject to civil liability for actual and punitive damages. OKLA. STAT. tit. 63, § 729a(F). In addition, failure to comply exposes a physician to disciplinary sanctions by the relevant licensing board, and exposes the licensed health care facility at which the physician performs a medication abortion to license suspension or revocation. *See* OKLA. STAT. tit. 63, § 1-706(B)(1); OKLA. STAT. tit. 59, §§ 503, 509, 637; OKLA. ADMIN. CODE § 310:600-7-3.

## IV. Argument and Authorities

### A. Standard for Temporary Injunctive Relief

Temporary injunctive relief is appropriate when it appears that "the plaintiff is entitled to the relief demanded," all or part of which consists of restricting the commission of an act that "would produce injury to the plaintiff." OKLA. STAT. tit. 12, § 1382. One critical function of a temporary injunction is to preserve the *status quo* pending resolution of a case. *Hastings v. Kelly*, 2008 OK CIV APP 36, ¶ 13, 181 P.3d 750, 753. A court must consider four criteria in determining whether to issue a temporary injunction: (1) the applicant's

likelihood of success on the merits; (2) irreparable harm to the party seeking relief if injunctive relief is denied; (3) relative effect on the other interested parties; and (4) public policy concerns arising out of the issuance of injunctive relief. *Tulsa Order of Police Lodge No. 93 v. City of Tulsa*, 2001 OK CIV APP 153, ¶ 24, 39 P.3d 152, 158. As set forth below, each of these four criteria weighs in favor of granting Plaintiffs' motion for temporary injunctive relief.

### B. Plaintiffs are Likely to Succeed on the Merits of Their Claims[6]

#### 1. The Act Treats Similarly Situated People Differently, in Violation of the Oklahoma Constitution's Guarantee of Equal Treatment.

The Oklahoma Constitution's guarantee of equal treatment under Art 2 § 7 "contains a built-in anti-discrimination component which affords protection against unreasonable or unreasoned classifications serving no important governmental objectives." *Fair School Finance Council of Oklahoma, Inc. v. Oklahoma*, 746 P.2d 1135, 1148 n.48 (Okla. 1987) (internal quotation marks and citation omitted). As a general matter, this obliges the Legislature to treat similarly situated persons alike unless different treatment of a certain classification of persons is "rationally related to a legitimate governmental purpose." *Gladstone v. Bartlesville Independent School District*, 2003 OK 30, ¶ 9, 66 P.3d 442, 447; *Callaway v. City of Edmond*, 791 P.2d 104, 106 (Okla. Crim. App. 1990). However, when a statute touches on a fundamental right, courts apply a more searching review: the State must articulate an interest that is not only legitimate but also compelling, and it must prove that the statute is necessary to further that interest. *Callaway*, 791 P.2d at 106 (citing *Thayer v. Phillips Petroleum Co.*, 613 P.2d 1041, 1045 (Okla.1980)).

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[6] For purposes of seeking temporary injunctive relief, Plaintiffs address only some of their claims against the 2011 Act; Plaintiffs' Petition asserts additional claims for relief. *See* Petition, Claims for Relief.

Here, the Act creates two unreasoned, arbitrary classifications. First, it singles out physicians who provide FDA-approved medications as treatment options for pregnancy terminations. These physicians are similarly situated to physicians who provide FDA-approved medications as treatment options for any and every other purpose, particularly with respect to a physician's duty to use sound medical judgment and medical knowledge in providing individually tailored care. Second, the Act singles out women who seek pregnancy terminations. But these women are similarly situated to women and men seeking other forms of medical care, particularly with respect to the need to be able to choose from the variety of treatment options available, including advances in medical care

These classifications should be subject to strict scrutiny because they burden two rights that are protected as fundamental by the Oklahoma Constitution: the right to terminate a pregnancy and the right to bodily integrity.[7] As set forth below, however, the Act's classifications cannot survive even rational basis scrutiny. *A fortiori*, the State cannot meet its burden of proving that the Act satisfies the more exacting standard of strict scrutiny.

Although rational basis review is typically a deferential standard, it is not a rubber stamp. For example, in *City of Cleburne v. Cleburne Living Center*, the United States

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[7] The Oklahoma Supreme Court has long held that the protections afforded by the due process clause of the U.S. Constitution serve as a floor for the protections afforded by the due process clause of the Oklahoma Constitution. *Messenger v. Messenger*, 827 P.2d 865, 872 (Okla. 1992); *see Alva State Bank & Trust Co. v. Dayton*, 755 P.2d 635, 638 (Okla. 1988) (Kauger, J., concurring). Thus, there can be no doubt that the Oklahoma Constitution protects the right to terminate a pregnancy as a fundamental right because the U.S. Constitution does so. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 845-46 (1992) (joint opinion of O'Connor, Kennedy, and Souter, JJ.); *Roe v. Wade*, 410 U.S. 113, 153 (1973). Similarly, there can be no doubt that the Oklahoma Constitution protects the right to bodily integrity as a fundamental right because the U.S. Constitution does so. *See Washington v. Glucksberg*, 521 U.S. 702, 720 (1997); *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 278 (1990); *Riggins v. Nevada*, 504 U.S. 127, 134 (1992); *Rochin v. California*, 342 U.S. 165 (1952).

Supreme Court struck down on equal protection grounds a zoning ordinance that required a special use permit for group homes for mentally retarded people but not other kinds of group homes, such as fraternity houses or nursing homes. 473 U.S. 432 (1985). The Court observed that, even though people with mental retardation have differences from people in other groups, those differences were "largely irrelevant unless the [proposed group] home and those who would occupy it would threaten legitimate interests of the city in a way that other permitted uses such as boarding houses and hospitals would not." *Id.* at 448. The Court considered several governmental interests, but found that they were not implicated by the use of a group home for people with mental retardation any more than they would have been by a group home used for any other purpose and, accordingly, held that there was no rational basis for the ordinance's classification. *Id.*

The same is true here. No legitimate state interest is advanced by prohibiting off-label use of "abortion-inducing drug[s]," but no other drugs. There is absolutely no evidence to suggest that off-label use of medications for purposes of pregnancy termination by properly-trained physicians is less safe than off-label use of medications for any other purpose. In fact, the evidence overwhelmingly demonstrates that off-label use of methotrexate to treat ectopic pregnancy is not only safe, but carries substantial benefits over the surgical alternatives. Grossman Aff. ¶ 12. Likewise, the evidence overwhelmingly demonstrates that off-label use of mifepristone and misoprostol in accordance with the evidence-based regimens for medication abortion is both safer and more effective than use of those drugs in accordance with the regimen set forth on the FPL for mifepristone. *Id.* ¶ 14.

Additionally, there is nothing about the women who seek pregnancy terminations that could justify preventing them from accessing medical care that accounts for advances in

medicine supported by research and scientific evidence. In this area of medicine, as in all others, having a variety of safe and effective treatment options allows patients to receive individually-tailored care. The Act deprives women seeking pregnancy terminations of treatment options for no apparent reason. If anything, because the Act would deny women access to safer and more effective options, it actually contravenes legitimate state interests.

Off-label use of FDA-approved medications is a common practice in all areas of medicine. Scientific evidence has convincingly demonstrated the superiority of off-label regimens in the context of pregnancy terminations. It simply makes no sense to allow a physician to provide an FDA-approved medication to a pregnant patient for one purpose, while forbidding the physician to provide the same medication in the same dosage and method of administration to a pregnant patient for a different purpose. Like the zoning ordinance at issue in *City of Cleburne*, the Act draws an unsupportable distinction; here, between off-label uses of FDA-approved medications. *Cf. City of Cleburne*, 473 U.S. at 448; *accord Callaway*, 791 P.2d at 107 (holding that Edmond city ordinance that bars minors from entering pool halls but not other amusement establishments is not rationally related to government's interest in preventing minors from gambling). Accordingly, Plaintiffs are likely to prevail on the merits of their claim that the Act violates the equal protection guarantee contained in Article II, § 7 of the Oklahoma Constitution.

**2. The Act is an Unconstitutional Special Law.**

Like the equal protection doctrine, the Oklahoma Constitution's prohibition on special laws requires those who are similarly situated to be treated alike. OKLA. CONST. art. V, § 59. To evaluate whether a particular law is a special law, Oklahoma courts use a "three-pronged inquiry": "1) Is the statute a special or a general law? 2) If it is a special law, is a general law applicable? and 3) If not, is the statute a permissible special law?" *Orthopedic*

*Hospital of Oklahoma v. Okla. State Dep't of Health*, 2005 OK CIV APP 43, ¶ 13, 118 P.3d 216, 222 (citation omitted); *Ross v. Peters*, 846 P.2d 1107, 1119 (Okla. 1993).

Applying the three prongs, courts first assess whether the challenged statute singles out and treats differently less than an entire class of similarly situated persons or things. *Reynolds v. Porter*, 760 P.2d 816, 822 (Okla. 1988). Here, the Act singles out physicians who provide, and women who receive, medication for pregnancy terminations from among the larger group of physicians who provide, and patients who receive, other medical care. To evaluate the second prong, a court must 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 Oklahoma v. Oklahoma State Dept. of Health*, 2005 OK CIV APP 43, ¶ 13, 118 P.3d 216, 222. There is nothing distinctive about the physicians who provide medication for pregnancy terminations, nor about the women who receive it, that could justify the Act's restrictions. *See* Section IV(B)(1), *supra.* Under the third prong, a court must determine whether the special law is "reasonably and substantially related to a valid legislative objective." *Orthopedic Hosp. of Oklahoma*, 2005 OK CIV APP ¶ 13, 118 P.3d at 223. As discussed *supra*, Section IV(B)(2), no valid legislative objective is advanced by the Act and, to the contrary, the Act would actually jeopardize women's health. For all of these reasons, Plaintiffs are likely to succeed on the merits of their claim that the Act is an unconstitutional special law.

### 3. The Act Unconstitutionally Delegates Legislative Authority to A Federal Agency That Cannot Exercise It.

The Legislature's primary responsibility is to formulate policy; it receives the authority to do so from the electorate, and it is accountable to the electorate for exercising its authority. *Democratic Party of Oklahoma v. Estep*, 652 P.2d 271, 278 n.25 (1982). The

Oklahoma Constitution, accordingly, contains a "non-delegation doctrine" that prevents the Legislature from "abdicat[ing] its responsibility to resolve fundamental policy making by delegating that function to others or by failing to provide adequate directions for the implementation of its declared policy." *Id.* at 277 n.23.

A statute that neither sets forth a policy nor creates clear standards for execution of a legislative policy is constitutionally void, in part because it passes off the primary responsibility of the elected officials in the Legislature to unelected agency officials whose accountability to the electorate is much diminished. *Estep.* 652 P.2d, at 277-78. Applying the non-delegation doctrine, the Oklahoma Supreme Court struck down a statutory campaign finance scheme that created a mechanism for public funds to be given to political parties and candidates, and created a commission to establish rules for implementing it, but articulated no legislative policy to govern the commission's activities and created no standards to guide the commission's rulemaking. *Id.* at 276.

Even where a policy is articulated, the Legislature must not delegate the task of implementing its policy without clear standards and safeguards. In *Oklahoma City v. Department of Labor*, the Oklahoma Supreme Court applied the non-delegation doctrine to a statute that established a State policy of paying workers the prevailing hourly wage for comparable work in the locality, but deferred to the United States Department of Labor the task of determining the amount of the prevailing hourly wage. 918 P.2d 26, 29-30 (1995). The statute provided no standards to guide the federal Department of Labor in exercising this authority and provided no mechanism for the state Labor Commissioner or the people of Oklahoma to object to the Department of Labor's determinations. *Id.* at 30. As a consequence, the Court held, the Legislature had impermissibly delegated its legislative

power. *Id.*; *accord In re Initiative Petition No. 366*, 2002 OK ¶¶ 16-18, 46 P.3d 128-29.

Here, the Act violates both components of the non-delegation doctrine: it contains neither an articulation of legislative policy nor any standards. The consequence is an unconstitutional delegation of legislative authority—namely, to regulate the administration of medications—to an unelected federal agency. Like the campaign finance scheme struck down in *Estep*, the Act articulates no policy to govern the FDA's exercise of the authority that the Act purports to confer on that agency. Even if the FDA could test or authorize protocols for use of approved medications—which it cannot—the Act's omission of policy means that every time the FDA tested or authorized a protocol, it would be acting according to its own objectives and not furthering the Legislature's aims. Thus, the Act leaves the function of policy-making to the FDA.

Further, the Act provides no standards and contains no safeguards. Like the statute in *Oklahoma City*, the Act delegates to a federal agency the task of making a determination that is crucial to the purpose of the Act. Here, the FDA is to determine which protocols a physician must adhere to when administering medication for pregnancy terminations. The Court in *Oklahoma City* observed that a prior version of the challenged statute had given specific instructions about factors to be considered in establishing the prevailing wage, as well as creating a mechanism for objections and authority to issue subpoenas and administer oaths. 918 P.2d at 29. No such standards were present in the version of the statute at issue in that case, and none are present here. The Act does not specify, for example, criteria that the FDA should use to create tests of protocols or to determine that a particular protocol should be "authorized," nor does it prescribe a method for gathering input or dealing with objections. Thus, it "leaves an important determination to the unrestricted and standardless

discretion of unelected bureaucrats." *Id.* at 30.

Worse yet, the FDA is incapable of exercising the authority that the Act purports to confer upon it. The decision about which protocol should be employed in administering medication falls within the practice of medicine. The FDA is simply not capable of regulating the administration of medications, even if the Legislature could constitutionally confer authority upon it to do so. *See* Statement of Facts, Section II(A), *supra.* Accordingly, Plaintiffs are likely to prevail on the merits of their claim that the Act delegates legislative authority in an unconstitutional manner.

#### 4. The Act Unconstitutionally Fails to Give Fair Warning of the Conduct It Prohibits.

The due process clause of the Oklahoma Constitution requires statutory prohibitions to be clearly defined. *In re Initiative Petition No. 366*, 2002 OK 21 ¶¶ 13-14, 46 P.3d 123, 128; *see* OKLA. CONST. art. II, § 7. Under both federal and Oklahoma law, a statutory prohibition is clearly defined if and only if it affords a person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that the person may act accordingly. 46 P.3d at 128. A law that fails to satisfy this standard is void-for-vagueness. *Id.* It is well settled that "the most important factor affecting the clarity that the Constitution demands of a law is whether it threatens to inhibit the exercise of constitutionally protected rights." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.* 455 U.S. 489, 499 (1982); *accord In re Initiative Petition No. 366*, 2002 OK ¶ 15, 46 P.3d at 128; *Colautti v. Franklin*, 439 U.S. 379, 391 (1979). If it does, "a more stringent vagueness test should apply." *Vill. of Hoffman Estates*, 455 U.S. at 499. Because the Act threatens numerous rights protected by the Oklahoma Constitution, including the rights to abortion and bodily integrity, it is subject to the highest level of vagueness scrutiny. *See Vill. of Hoffman Estates*, 455 U.S. at 498-99.

The Act fails to satisfy the standard for clarity required by the Oklahoma Constitution in at least two ways. First, the Act requires physicians to provide medication for pregnancy terminations according to conditions that are impossible to discern. It allows physicians to provide an "abortion-inducing drug" only "according to the protocol tested and authorized by the [FDA] ... and as authorized in the drug label for the RU-486 (mifepristone) or any other abortion-inducing drug." H.B. 1970 § 1(C). But the FDA does not test or authorize protocols; it reviews information about clinical trials presented by a drug sponsor. *See* Statement of Facts, Section II(A), *supra*. Further, the FDA lacks authority to "authorize" any uses of or protocols for a particular drug, because such action falls within regulation of the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) (holding that Food, Drug, and Cosmetic Act does not regulate the practice of medicine and off-label use is generally permitted); Statement of Facts, Section II(A), *supra*. FDA approval of a drug allows its sponsor to market the drug in the U.S., but does not constitute authorization of any protocol. The FDA has repeatedly recognized that good medical practice sometimes *requires* use of a medication in a way not described in its FPL. Rarick Aff. ¶¶ 9-12. The requirement to provide an abortion-inducing drug "as authorized in the drug label" is similarly without meaning. There is no document that satisfies the Act's definition of a "drug label." *See* Rarick Aff. ¶ 23. Even if the term were interpreted to refer to the FPL, the FPL cannot "authorize" a particular use of a drug; it describes safe and effective use according to the purpose for which the drug sponsor sought FDA approval.

Second, in addition to the problems described above, the Act fails to provide sufficient clarity about whether a physician may provide misoprostol as part of a medication abortion regimen. The FPL for misoprostol does not describe, let alone "authorize," the use

of misoprostol in medication abortions; misoprostol is used off-label in the medication abortion regimen described in the Mifeprex FPL. *See* Statement of Facts, Section II(C), *supra*. Thus, it appears that there is no way that physicians could discern how to provide misoprostol for purposes of a medication abortion in compliance with the Act. But without being able to provide misoprostol, physicians would also be unable to provide mifepristone in compliance with the Act, because the Mifeprex FPL describes misoprostol as the second stage in that regimen. The Act, therefore, leaves physicians in a quandary.

Accordingly, Plaintiffs are likely to succeed on the merits of their claim that the Act is unconstitutionally vague.

### C. Absent Injunctive Relief, Plaintiffs Will Suffer Irreparable Harm.

Oklahoma law defines harm as "irreparable" where it "is incapable of being fully compensated by money damages, or where the measure of damages is so speculative that arriving at an amount of damages would be difficult or impossible." *Tulsa Order of Police Lodge No. 93*, 2001 OK CIV APP at ¶ 28, 39 P.3d at 159. If allowed to take effect, the Act would deprive Plaintiffs, and those they represent, of rights secured by the Oklahoma Constitution. Such deprivation of constitutional rights is *per se* irreparable harm. *See generally* 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, FEDERAL PRACTICE AND PROCEDURE § 2948.1 (2d ed. 1995) ("When an alleged constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary."); *accord Entertainment Merchants Ass'n v. Henry*, No. CIV-06-675-C, 2006 WL 2927884 at *2 (W.D. Okla. Oct. 11, 2006) (enforcement of a State law would cause Plaintiffs irreparable harm by violating their constitutional rights). In addition, the Act will be harmful to women's health, forcing doctors to provide, and women to accept, medical treatment for pregnancy termination that is less safe and less effective than alternatives that would be

available but for the Act.

### D. The Balance of Equities and the Public Interest Weigh in Favor of a Temporary Injunction.

While Plaintiffs and their patients would suffer several forms of irreparable harm if the Act were to take effect, Defendants would suffer no harm if a temporary injunction were granted. The only possible disadvantage to Defendants is delayed enforcement of the Act, which would pose no health or safety risk to women seeking abortions in Oklahoma. To the contrary, it would allow physicians to continue to provide—and women to receive—medication for pregnancy terminations in accordance with the best available medical evidence. This would preserve the *status quo* while the Court has an opportunity to carefully consider whether the Act would violate the constitutional rights of Plaintiffs and their patients. This is the very purpose of temporary injunctive relief. *Hastings*, 2008 OK CIV APP 36, ¶ 13, 181 P.3d at 753. Moreover, the public interest would be served by the issuance of a temporary injunction. It is well-settled that the enforcement of an unconstitutional law is contrary to the public interest. *See, e.g., Entertainment Merchants Ass'n,* 2006 WL 2927884 at *3; *Am. Civil Liberties Union v. Johnson*, 194 F.3d 1149, 1163 (10th Cir. 1999). Accordingly, both the balance of equities and the public interest weigh heavily in Plaintiffs' favor and support the issuance of temporary injunctive relief.

## V. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that this Court issue a temporary injunction to preserve the *status quo* and prevent enforcement of the Act during the pendency of this litigation.

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Respectfully submitted,

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