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; and, (5) CATHERINE C. TAYLOR, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners, Defendants.	Case No. CV-2011-1722 Judge Donald L. Worthington

REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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I. Defendants Have Not Introduced Sufficient Evidence to Create a Genuine Dispute Over Any Facts Material to Plaintiffs' Claims.

Defendants' response to Plaintiffs' Motion for Summary Judgment is rife with misstatements and inaccuracies, resting on materials that fall short of the standard of "acceptable probative substitutes" for admissible evidence that applies at the summary judgment stage.[1] *See Liddell v. Heavner*, 2008 OK 6, ¶ 6, 180 P.3d 1191, 1195. But even if the Court accepted all of Defendants' evidence, there would be no dispute "substantial" enough to defeat summary judgment for the Plaintiffs on any claims. First, most of the facts that are material to Plaintiffs' claims are undisputed, as discussed in more detail *infra*. *See Hadnot v. Shaw*, 1992 OK 21, 826 P.2d 978, 985 ("A fact is 'material' if proof of that fact would have the effect of establishing or refuting one of the essential elements of a cause of action."). Second, Defendants have not introduced any evidence that could enable reasonable minds to draw different inferences from the facts that are material to Plaintiffs' claims. *See Jones v. Mercy Health Ctr., Inc.*, 2006 OK 83, 155 P.3d 9, 12. Taking the record as a whole—even with the improper materials Defendants have offered—it is quite clear that there are no genuine questions of material fact and that, accordingly, summary judgment for the Plaintiffs is proper on each claim.

II. Defendants' Interpretation of the Act Is Mistaken.

Defendants claim that ectopic pregnancy management is not affected by the Act because the definition of an abortion elsewhere in Oklahoma law explicitly excludes termination of an ectopic pregnancy. But the definition of an abortion elsewhere in Oklahoma law clearly cannot take precedence over the plain text of the Act itself. The Act's

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[1] Plaintiffs object to the testimony offered by Donna Harrison, M.D., and are filing a motion to strike her testimony, attached to Defendants' brief as Appendix Y, with this Reply.

restrictions do not apply to "abortion," or even to termination of an intrauterine pregnancy, but rather to "termination of a clinically diagnosable pregnancy." House Bill 1970 ("HB 1970" or "the Act") § 1(A)(1). Moreover, the legislative history supports the conclusion that the Legislature intended the Act to regulate off-label use of methotrexate for ectopic pregnancy treatment; a sponsor considered, *and decided not to offer*, an amendment that would have explicitly excluded treatment for ectopic pregnancy. Oklahoma House of Reps., Floor Debate, HB 1970 (Mar. 17, 2011) at 8:23.35-8:24.43, *available at* http://okhouse.granicus.com/MediaPlayer.php?view_id=&clip_id=242&meta_id=16954. Notably, this interpretation of the Act only intensifies the fundamental irrationality of the Act's restrictions on off-label use of only some FDA-approved medications.

III. The Act Violates the Non-Delegation Doctrine.

No facts are material to Plaintiffs' claim that the Act violates the non-delegation doctrine, and summary judgment for the Plaintiffs is proper on this claim. Defendants claim that the policy of the Legislature is "to ensure proper administration of medication for the purposes of inducing an abortion," Defs.' Resp. to Pls.' Mot. for Summ. J. ("Defs.' Opp. Br.") 29. Even if this were an acceptable policy, the Act establishes no standards for determining what constitutes "*proper* administration" of medications and creates no safeguards to ensure accountability for that determination to the electorate. Contrary to Defendants' assertions, federal regulations governing the FDA do not preempt states from regulating the practice of medicine; indeed, the federal courts have expressly held that the FDA lacks the power to regulate medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001); *see also United States v. Evers*, 643 F.2d 1043, 1049 (5th Cir. 1981). The FDA has the power to approve drugs for sale and marketing in the U.S., but it

does not have the power—much less the exclusive authority—to restrict the uses of an approved drug. *Buckman*, 531 U.S. at 351 n.5; *Evers*, 643 F.2d at 1049. Therefore, the Act's restrictions on the use of FDA-approved medications do not "turn on a benchmark" established by the FDA. *See* Defs.' Opp. Br. 29. They do, however, give the force of law to a discretionary determination made by the FDA that is wholly independent of any guidance provided by the Oklahoma legislature and wholly unrelated to the purpose for which the FDA made the determination in the first place. As a result, the Act is in clear violation of the non-delegation doctrine. *Cf. Oklahoma City v. Department of Labor*, 1995 OK 107, 918 P.2d at 29-30.

IV. The Act Violates the Oklahoma Constitution's Guarantee of Equal Protection.

Contrary to Defendants' assertions, the Court should apply strict scrutiny to the Act's classifications because they infringe upon women's fundamental due process rights to abortion and to bodily integrity, *see* Pls.' Summ. J. Br. 14-16; Pls.' Br. in Opp. to Defs. Mot. for Summ. J. ("Pls.' Opp. Br.") 18-22. Defendants do not dispute that Oklahoma citizens have a fundamental right to bodily integrity, and make no attempt to defend the Act under strict scrutiny. Accordingly, summary judgment should be granted to Plaintiffs on this claim.

Even under rational basis review, the undisputed material facts demonstrate that the Act's classifications bear no rational relationship to any legitimate state interest.[2] *Cf. Callaway v. City of Edmond*, 1990 OK CR 25, 791 P.2d 104, 107. The fundamental flaw in Defendants' equal protection argument is that it fails to identify a rational basis for the Act's *classifications—i.e.*, the legislature's choice to treat one set of similarly situated persons

[2] The purported state interests identified by Defendants, *see* Defs.' Opp. Br. 31-32, make this even more evident, as Plaintiffs have explained, *see* Pls.' Opp. Br. 9 (each of these state interests is actually undermined by the Act).

differently from another. Defendants have proffered no rational basis for restricting off-label use of FDA-approved drugs when used to terminate a pregnancy but not when used for other purposes. The only conceivable basis for such a classification is animus toward those who seek or perform abortions, but that basis is not *rational* under the law. *See, e.g., U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973) (holding that congressional dislike of hippies was not a rational basis for barring their participation in the food stamp program) ("[I]f the constitutional conception of 'equal protection of the laws' means anything, it must at the very least mean that a bare . . . desire to harm a politically unpopular group cannot constitute a legitimate governmental interest."); *accord Romer v. Evans*, 517 U.S. 620, 635 (1996) (striking down law with classification based on animus towards gays and lesbians); *City of Cleburne v. Cleburne Living Ctr. Inc.*, 473 U.S. 432, 447-50 (1985) (striking down law with classification based on animus toward mentally disabled).

Instead of a credible legal argument, Defendants proffer only a litany of false and misleading factual allegations that are unsupported by admissible evidence. For example, Defendants erroneously suggest that there is a causal relationship between evidence-based medication abortion regimens and fatal infections with *Clostridium* bacteria.[3] Yet undisputed

[3] Defendants' statements concerning the risk of death from *Clostridium* bacteria following a medication abortion, Defs.' Opp. Br. 19, are demonstrably false. Defendants cite an article by Marc Fischer, et al., as showing that "the risk of death from *C. sordellii* alone after medical abortion is ten times the death rate from all causes in surgical abortion at a comparable gestational age." *Id.* By contrast, the Fischer article explains that "serious infection can occur after medically induced abortion, much as it can occur after childbirth, spontaneous abortion, and surgical abortion. However, available data suggest that the risk of such infection is low. ... *there are no published estimates for the rate of maternal death after surgical abortion performed during the first trimester,*" which is when medication abortions are performed. Marc Fischer, et al., *Fatal Toxic Shock Syndrome Associated with* Clostridium sordellii *after Medical Abortion*, 353 N.E. J. Med. 2352, 2358 (2005) (emphasis added). Thus, the evidence fails to create a basis for reasonable minds to draw different inferences on this point.

evidence demonstrates that all of the scientific bodies that have studied the infections, including the FDA and CDC, have concluded that there is no evidence of a causal link between these infections and medical abortions. This conclusion is reflected by the FDA-approved text on the Mifeprex FPL. Decl. of Abby Long (attached to Pls.' Mot. for Summ. J. as App'x 6), Ex. A ("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."). Indeed, the same type of infections has been reported following childbirth and pelvic surgery. Decl. of Daniel A. Grossman, M.D. (attached to Pls.' Mot. for Summ. J. as App'x 4) ("Grossman Decl.") ¶ 35. Accordingly, the occurrence of a small number of unexplained *Clostridium* infections does not provide a rational basis for the Act's classifications.

Similarly, Defendants suggest that a greater number of adverse events are associated with evidence-based regimens for medication abortion than with the regimen set forth on the FPL for Mifeprex. But undisputed facts show that, within a year after the FDA approved Mifeprex for marketing in the United States, 96% of medication abortions were provided according to an evidence-based regimen. *See* Grossman Decl. ¶ 31. It is unsurprising that the regimen used 96% of the time is associated with more adverse events than one used only 4% of the time; this fact fails to provide a rational basis for the Act's classifications.

In addition, Defendants attach unwarranted significance to statements by the FDA that evidence-based regimens for medication abortion are "unapproved." Such statements mean that the FDA has not given the drug's sponsor approval to market the medication using that regimen. *E.g.* Defs.' Ex. D at 1; Decl. of Lisa D. Rarick, M.D. (attached to Pls. Mot. for

Summ. J. as App'x 2) ("Rarick Decl.") ¶ 4. Calling a regimen "unapproved" has no bearing on whether a physician can use the particular medication in a way that is supported by medical research; use of medications is a part of the practice of medicine, which the FDA does not regulate. *See supra* p.2; Rarick Decl. ¶ 4. Thus, these statements do not provide a rational basis for the Act's classifications.[4]

Finally, Defendants erroneously suggest that the fact that the FDA approved Mifeprex for marketing under the provisions known colloquially as Subpart H makes Mifeprex unique. In fact, a multitude of drugs are approved under Subpart H.[5] The constitutional problem here is that the Act only restricts off-label use of one of them, and further restricts off-label use of two other drugs—methotrexate and misoprostol—that were not approved under Subpart H. Thus, the fact that Mifeprex was approved under Subpart H does not provide a rational basis for the Act's classifications.

V. The Act is an Unconstitutional Special Law.

Contrary to Defendants' assertions, the second and third prongs of the *Reynolds* test are clearly alternative. The wording of the test makes that quite plain: "1) Is the statute a

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[4] Defendants are mistaken about the significance of the FDA's statements that the available data did not support at-home administration of misoprostol at the time Mifeprex was approved for sale in the United States. These statements do not mean that there could *never* be evidence supporting the safety of at-home use of misoprostol, simply that the FDA did not have such evidence in 1996-2000 when it was considering the Mifeprex application. Thus, these statements cannot create a genuine dispute concerning the fact that today, over a decade later, studies support the safety of at-home use as part of an evidence-based regimen for medication abortion. *See* Grossman Decl. ¶ 31.

[5] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX (2008) (attached to Pls.' Mot. for Summ. J. as App'x 3) ("GAO Report") 10. Among other things, Defendants are mistaken about the effects of approval pursuant to Subpart H. FDA approval of medications under Subpart H, like all other FDA approval of medications, governs the way that a drug sponsor may market the drug in the United States and not the way physicians use the drug. The FDA, notably, "wanted to minimize the burdens" of the Subpart H restrictions to make Mifeprex widely available. *Id.* 25.

special or a 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?" *Reynolds v. Porter*, 1988 OK 88, 760 P.2d 816, 822 (emphasis added). Plainly, if a court determines that a general law is applicable, it need not reach the third prong of this test. Thus, if a statute fails either the second or third prong of the *Reynolds* test, it is an impermissible special law under Art. V, § 59, of the Oklahoma Constitution. *See Orthopedic Hosp. of Okla. v. Oklahoma State Dep't of Health*, 2005 OK CIV APP 43, ¶ 15, 118 P.3d 216 (concluding that the challenged statute failed the second prong, and striking it without considering the third prong). Here, as Plaintiffs have demonstrated using undisputed facts, the Act violates the first and second prongs of the *Reynolds* test, and, if the Court concludes it fails the second prong, violates the third prong also. *See* Pls.' Summ. J. Br. pp.17-20.

VI. The Act Is Unconstitutionally Vague.

In opposing Plaintiffs' Motion for Summary Judgment, Defendants advance yet another interpretation of the Act – their third such interpretation in the course of this litigation.[6] The Act's susceptibility to multiple interpretations by the State is the very

[6] *Compare* Defs.' Opp. to Pls.' Mot. for Temp. Inj. 6-7 (referring to the Act as restricting off-label use of the "three 'M' abortion inducing drugs... (1) Mifepristone ... (2) Misoprostol ...; and (3) Methotrexate") *with* Defs.' Summ. J. Br. 24 ("Abortion is either a use described on the drug's label or it is not. If it is, the protocol on the drug's label must be followed."); *and with id.* 3 (claiming that the Act "effectively prohibited the use of any medication other than Mifeprex for purposes of inducing an abortion, as such a use would be 'off-label'"); *and with* Defs.' Opp. Br. 35 (arguing that the Act requires "use of abortion-inducing drugs in a manner consistent with the FDA-approved drug label"); *and with id.* 14-15 (claiming the misoprostol FPL is irrelevant with respect to use of misoprostol for pregnancy terminations).

essence of unconstitutional vagueness.[7] *See In re Initiative Petition No. 366*, 2002 OK 21, ¶¶ 14-15, 46 P.3d 123, 128. As Defendants' shifting interpretations make plain, the Act does not provide a reasonable person with an opportunity to know whether a physician may provide misoprostol as part of a medication abortion regimen under the Act, nor how a physician may otherwise comply with its terms. *Cf. State Bd. of Exam'rs in Optometry v. Lawton*, 1974 OK 69, 523 P.2d 1064, 1066-67. Thus, summary judgment is proper for Plaintiffs as a matter of law.

VII. The Act Violates Women's Fundamental Right to Bodily Integrity.

Defendants do not dispute that the effect of the Act is to force women who are between 49 and 63 days pregnant to undergo surgery to terminate their pregnancies even if they do not want to use that treatment option, and even if there are significant medical reasons for a patient to elect to have a non-invasive medication abortion. Defendants, further, do not dispute that the effect of the Act is to force women who are less than 49 days pregnant to choose between an inferior regimen of medication abortion or surgery. To the contrary, they appear to claim that because medication abortion is contraindicated for *some* women, it should not be available to *any* women in this group. *See* Defs.' Opp. Br. 10. But because bodily integrity is a fundamental right under the Oklahoma Constitution, strict

[7] Defendants' latest interpretation of the Act's requirements injects even more uncertainty with respect to the "drug label"; conceding that the FPL for misoprostol does not describe its use in a medication abortion, Defendants claim that the *Mifeprex* FPL is the one to which the Act requires physicians to look for an understanding of how to use misoprostol. The Act gives no indication that a physician should use a protocol for one drug that is described in the FPL for another drug. Indeed, given that the FDA approves the text of a drug's FPL based on information specific to that drug, Defendants' interpretation is fundamentally at odds with the FDA's approval process.

scrutiny is appropriate and this claim does not survive.[8] Defendants do not claim any compelling interest is advanced by the Act, but even if they did, it almost goes without saying that a restriction imposed on *all* women is not narrowly tailored to advancing any compelling state interest that the State might claim with respect to only *some* women.

VIII. The Act Violates Women's Fundamental Right to Abortion.

Defendants have offered no evidence to support an inference that would defeat Plaintiffs' motion for summary judgment on this claim. While it is quite clear, and undisputed, that surgical abortion is extremely safe, *see* Pls.' Summ. J. Br. 25; Defs.' Opp. Br. 13, the safety of surgical abortion is not germane to the central question here: whether the Act unjustifiably infringes upon Oklahoma women's right to obtain an abortion. Defendants do not dispute that surgical abortion is not the medically-preferred treatment option for some women; rather, they attempt to create a dispute over who those women are. *See* Defs.' Opp. Br. 10. Similarly, Defendants do not dispute that the Act would prevent women who are 50-63 days pregnant from obtaining a medication abortion, but rather claim that medication abortion is contraindicated for *some* of those women. Again, however, under strict scrutiny review the impact on *some* women is not sufficient to justify the Act's restrictions on the treatment options available to *all* women. *See* Pls.' Summ. J. Br. 26-30 (arguing that strict scrutiny is appropriate because abortion is a fundamental right).

Defendants appear to be taking the position that, if the Court determines that strict

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[8] As Plaintiffs have explained elsewhere, *see* Pls.' Opp. Br. 18-22, there is no support for Defendants' cramped reading of Art. II, § 7, and, indeed, that reading ignores controlling precedent. The Oklahoma Supreme Court has consistently, repeatedly, and without exception, explained that the protections afforded by the due process clause of the U.S. Constitution are a floor below which the protections of the due process clause of the Oklahoma Constitution will not fall. *See, e.g., E. Okla. Bldg. & Constr. Trades Council v. Pitts*, 2003 OK 113, ¶¶ 7-8, 82 P.3d 1008, 1012; *Messenger v. Messenger*, 1992 OK 27, ¶ 17; 827 P.2d 865, 872; *In re Initiative Petition No. 349*, 1992 OK 122, 838 P.2d at 10.

scrutiny is not appropriate, it should apply an even lower standard than the federal undue burden standard. This is plainly inconsistent with the Oklahoma Supreme Court's repeated and explicit rejection of the argument that the protections afforded by the Oklahoma Constitution somehow fall below the floor of protections secured by the federal Constitution. It is quite clear that an abortion restriction violates the undue burden standard if it unjustifiably subjects women seeking abortions to health risks. *See* Pls.' Summ. J. Br. 30-31. As discussed above, Defendants have offered no basis for concluding that the Act would not subject women seeking abortions to unjustifiable health risks.[9]

IX. The Act Unconstitutionally Compels Physicians to Make False Statements.

The only fact material to this claim is undisputed: the FDA does not test protocols. *See* Pls.' Summ. J. Br. 3; Defs.' Mot. for Summ. J. Ex. D ("The FDA doesn't actually test drugs itself."). And, as a matter of law, the FDA cannot authorize protocols because it is not permitted to regulate the practice of medicine. *Buckman*, 531 U.S. at 350-51. Thus, the statement that the Act requires physicians to make to their patients—namely, that a medication abortion is provided "in accordance with the protocol tested and authorized by the [FDA]," H.B. 1970 § D(2)—is patently false. The State has no compelling interest in forcing physicians to make false statements to their patients. *See In re Initiative Petition No. 366*, 2002 OK 21 ¶ 7, 46 P.3d at 126. Summary judgment for Plaintiffs is thus proper.

X. Conclusion

For the foregoing reasons, as well as the reasons set forth in Plaintiffs' prior briefing, summary judgment for the Plaintiffs is proper in this case.

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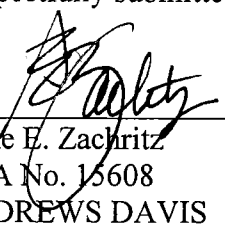
[9] Moreover, Defendants have not disputed Plaintiffs' claim that the Act is motivated by the improper purpose of preventing women from obtaining abortions and punishing women who seek to use medication for that purpose. *See* Pls.' Summ. J. Br. 31.

Dated: April 17, 2012

Respectfully submitted,



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I hereby certify that on the 17th day of April, 2012, true and correct copies of the foregoing brief were delivered by electronic mail to the following:

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