IN THE SUPREME COURT OF THE 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 / Appellees, 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 / Appellants.	)	No. 114,307

PLAINTIFFS-APPELLEES' BRIEF

Appeal from the District Court of Oklahoma County, State of Oklahoma

Case No. CV-2014-1886
The Honorable Patricia G. Parrish

District Court Final Order: Summary Judgment

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By order dated August 27, 2015, the District Court of Oklahoma County (Parrish, J.) granted summary judgment in favor of Plaintiffs-Appellees the Oklahoma Coalition for Reproductive Justice and Nova Health Systems d/b/a Reproductive Services ("Reproductive Services") (collectively, "Plaintiffs-Appellees"), declaring Oklahoma House Bill 2684, 2014 Okla. Sess. Laws Ch. 121 ("House Bill 2684" or the "Act"), an unconstitutional special law and permanently enjoining its enforcement. Order Granting Pls.' Mot. for Summ. J., Granting Pls.' Mot. to Strike the Aff. of Reji T. Varghese, and Granting in Part and Den. in Part Pls.' Mot. to Strike the Aff. of Donna Harrison, M.D. ("Order"), R. Vol. III, Tab 20. Plaintiffs-Appellees respectfully submit this brief asking the Court to affirm the district court's judgment.

PRELIMINARY STATEMENT

This appeal presents a single question: does House Bill 2684, a law that drastically restricts access to medication abortion, a safe and effective non-surgical alternative for ending an early pregnancy, violate the Oklahoma Constitution? Because the challenged Act, like its predecessor, House Bill 1970, restricts the "the manner" and "the regimen" by which physicians may prescribe medications to end a pregnancy, and because this Court has already determined that such a restriction fails to serve any legitimate state interest, the answer to this question is yes.

The Oklahoma Legislature enacted House Bill 2684 shortly after this Court struck down a similar law, House Bill 1970, 2011 Okla. Sess. Laws Ch. 216. House Bill 1970 singled out certain medications when used for the purpose of terminating a pregnancy, and restricted "the manner" and "the regimen" by which physicians were permitted to prescribe those medications. *See Cline v. Okla. Coal. for Reprod. Justice* ("*Cline I*"), 2013 OK 93, ¶

27, 313 P.3d 253, 262 (per curiam) (quoting *Okla. Coal. for Reprod. Justice v. Cline*, No. CV-2011-1722, slip op., ¶ 7 (Dist. Ct. Okla. Cty. May 11, 2012)). As construed by the Court, House Bill 1970's restriction on abortion-inducing drugs resulted in a complete ban on all medication abortions.

This Court affirmed the district court's order permanently enjoining enforcement of House Bill 1970 on December 4, 2012. *Okla. Coal. for Reprod. Justice v. Cline*, 2012 OK 102, 292 P.3d 27 (per curiam). On October 29, 2013, this Court issued an opinion further clarifying its decision and responding to two questions certified to it by the U.S. Supreme Court. *Cline I*, 2013 OK 93, 313 P.3d 253. This Court declared that House Bill 1970's restriction on the off-label use of certain medications, when used to terminate a pregnancy, was "**so completely at odds with the standard that governs the practice of medicine** that it [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 (emphasis in original) (quoting *Okla. Coal. for Reprod. Justice*, No. CV-2011-1722, slip op., ¶ 7).

House Bill 2684 was introduced approximately three months later. The challenged Act, like its predecessor, restricts the provision of medication abortion by mandating that physicians who provide mifepristone and misoprostol[1] for the purpose of terminating a pregnancy comply with the obsolete protocol outlined in the drug label for Mifeprex approved by the U.S. Food and Drug Administration ("FDA") in 2000 (the "Mifeprex Label

[1] Mifepristone, also sometimes referred to by the name RU-486, is the first of two drugs administered in a medication abortion. It is sold in the United States under the brand name Mifeprex. The second drug administered, misoprostol, is sold in the United States under the brand name Cytotec.

Protocol"). H.B. 2684 § 1(D). As a result, many medication abortions in Oklahoma will be prohibited.

The Act, if permitted to take effect, would force patients to ingest three times the amount of medication than is medically necessary, increase the likelihood of patients needing a follow-up surgical procedure to complete the abortion, and require women to make an additional, unnecessary trip to their provider's office at a time when it would be safer for them to remain at home. Aff. of Daniel A. Grossman, M.D., in Supp. of Pls.' Mot. for Partial Summ. J. ("Grossman Aff.") ¶¶ 31, 36–38, 41, R. Vol. I, Tab 7. And because the cost of each mifepristone tablet is approximately $80, the cost of a medication abortion will go up by at least $160. Aff. of Marilyn Eldridge in Supp. of Pls.' Mot. for Partial Summ. J. ("Eldridge Aff.") ¶ 27, R. Vol. I, Tab 7.

Like its predecessor, the challenged Act restricts the off-label use of certain medications in a manner that directly contravenes prevailing medical standards, the recommendations of leading medical organizations, and a physician's ethical duties to provide the best possible care for each patient. To the extent that House Bills 1970 and 2684 differ, these differences do not have any constitutional significance under Oklahoma Law. The challenged Act does not advance the State's asserted interest in protecting patient health and safety; instead, it serves only to expose women to unnecessary health risks and deny them access to scientific advances in medicine. For the reasons set forth below, the district court's decision should be affirmed.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff-Appellee Oklahoma Coalition for Reproductive Justice is a non-profit organization dedicated to promoting reproductive justice in Oklahoma, and whose

membership includes women of reproductive age who may need to obtain abortions in Oklahoma in the future. Pls.' Verified Pet. ¶ 18, R. Vol. I, Tab 2. Plaintiff-Appellee Reproductive Services is a non-profit corporation founded by a Christian minister whose mission is to provide high-quality and affordable reproductive health care services to women in underserved communities. Eldridge Aff. ¶ 1, R. Vol. I, Tab 7. Reproductive Services has operated a medical clinic in Tulsa since 1974 that provides a range of reproductive health care, including abortion, contraception counseling and services, pregnancy testing, options counseling, and adoption counseling and referrals. *Id.*

For over a decade, Oklahoma women in the first nine weeks of pregnancy (as measured from the woman's last menstrual period (LMP)) have had the option of choosing between two extremely safe and effective abortion methods: surgical abortion or medication abortion. *See id.* ¶¶ 7, 19. Medication abortion is the chosen method for approximately 50% of Reproductive Services' patients, *see id.* ¶ 8, and almost 40% of all Oklahoma women seeking abortions. *See* Okla. Dep't of Health, Abortion Surveillance in Oklahoma: 2002–2013 Summary Report, at Table 13, Ex. D to Defs.' Resp. to Pls.' Partial Mot. for Summ. J. and Defs.' Cross-Mot. for Summ. J. ("Defs.' Summ. J. Resp.") – Vol. 3, R. Vol. III, Tab 10. Patients choose medication abortion for a variety of reasons, such as the fact that it can be completed in private rather than in a medical clinic, offers patients more control over the time and place of the abortion, and feels more natural to some women. Eldridge Aff. ¶ 22, R. Vol. I, Tab 7. For some patients, including women with uterine anomalies and women who are obese, medication abortion may be medically indicated. Grossman Aff. ¶ 26, R. Vol. I, Tab 7. For others, it is strongly preferred for personal reasons, including women who have experienced sexual abuse or molestation, and women who fear surgery or having instruments

placed in the vagina. *Id.* ¶ 25. When the new drug application for mifepristone was filed, it received priority review by the FDA because it presented a new, non-surgical therapeutic advance for women seeking a first-trimester abortion. Aff. of Lisa D. Rarick, M.D., in Supp. of Pls.' Mot. for Partial Summ. J. ("Rarick Aff.") ¶ 8, R. Vol. I, Tab 7.

Currently, and as they have done for over a decade, Reproductive Services' physicians follow an evidence-based protocol involving the administration of two medications: 200 mg (milligrams) of mifepristone, followed by 800 μg (micrograms) of misoprostol, to be self-administered by the patient at home (or in another location of her choosing) either buccally or vaginally, within 6 to 24 hours of taking the mifepristone. Eldridge Aff. ¶¶ 7, 9, 15, R. Vol. I, Tab 7. Evidence-based medication abortion protocols—which vary the dosage, timing, and route of administration of mifepristone and misoprostol—were developed in an effort to reduce side effects and make medication abortion safer, more effective, and less expensive. Grossman Aff. ¶ 30, R. Vol. I, Tab 7. As explained in the current Practice Bulletin on Medical Management of Abortion issued by the American College of Obstetricians and Gynecologists ("ACOG") in 2014, evidence-based medication abortion protocols, including the protocol followed by Reproductive Services, "are superior to the FDA-approved regimen" in terms of efficacy and adverse effects. ACOG Practice Bulletin No. 143: Medical Management of First-Trimester Abortion (March 2014), at 11, Ex. B to Grossman Aff., R. Vol. I, Tab 7; *see also* Brief for ACOG and the American Medical Association as Amici Curiae Supporting Plaintiffs-Appellants ("ACOG and AMA Amicus Br."), Planned Parenthood of Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir.) (No. 14-15624), 2014 WL 1759869, at *11, *cert. denied*, 135 S. Ct. 870 (2014), Ex. C to Grossman Aff., R. Vol. I, Tab 7 ("[G]ood and consistent scientific research shows the evidence-based regimens

are low risk and supports the use of evidence-based protocols over the regimen described on the FDA-approved label."). Reproductive Services' physicians follow an evidence-based protocol because it has proven to be safer and more effective for patients, and they do not want to subject patients to increased medical risks or practice medicine in a manner inconsistent with prevailing medical standards. Eldridge Aff. ¶ 21, R. Vol. I, Tab 7.

In its certified questions opinion, this Court explained that House Bill 1970 prohibited physicians from prescribing mifepristone, misoprostol, and methotrexate unless those medications were administered "according only to their respective FDA-approved drug labels." *Cline I*, 2013 OK 93, ¶ 25, 313 P.3d at 262. The Court construed the act to prohibit the use of methotrexate to treat ectopic pregnancies and the use of misoprostol in a medication abortion, including as part of the Mifeprex Label Protocol. *Id.* ¶ 27, 313 P.3d at 262. Thus, the effect of House Bill 1970 was to prohibit *all* medication abortions, since any administration of misoprostol was prohibited, while House Bill 2684 prohibits *many*, but not necessarily all medication abortions, since it permits the administration of mifepristone and misoprostol according the obsolete Mifeprex Label Protocol.

House Bill 2684 was introduced in early February 2014, approximately three months after this Court issued its certified questions opinion in *Cline I*. The Act was authored by Representative Grau and Senator Treat, the same legislators who co-authored the Act's predecessor, House Bill 1970. The two bills are almost identical. Both were enacted by the Legislature purportedly to protect women's health and safety. *Cf.* H.B. 2684, § 1(A)(15) (noting purpose of the Act to "protect women"); H.B. 1970 (describing the act as "relating to public health and safety"). House Bill 2684, like its predecessor, amends title 63, section 1-729a of the Oklahoma Statutes by defining certain terms, and mandates that physicians

comply with a specific drug protocol when providing or prescribing medications for the purpose of inducing an abortion:

> No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug, including the Mifeprex regimen, shall knowingly or recklessly fail to provide or prescribe the ~~RU-486 (mifepristone) or any abortion-inducing~~ drug according to the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration and as ~~authorized~~ outlined in the ~~drug~~ FDA-approved label ~~for the RU-486 (mifepristone) or any abortion-inducing drug~~. In the specific case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (brand name Mifeprex) and misoprostol, and any provision accomplished according to that labeling is not prohibited.

H.B. 2684 § 1(D) (alterations from House Bill 1970 noted with underlined and crossed-out text for additions and deletions, respectively). Both acts require that any "abortion-inducing drug [] be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient." *Id.* § 1(G). Like its predecessor, House Bill 2684 subjects physicians who fail to adhere to its requirements to civil liability and disciplinary action.[2] It was scheduled to take effect on November 1, 2014. *Id.* § 2.

The challenged Act defines a new term, "Mifeprex Regimen," and thereby permits the administration of misoprostol in accordance with the now-obsolete Mifeprex Label

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[2] H.B. 2684 § 1(I)–(J) (authorizing the abortion patient, her spouse, or her parents to bring an action for actual and punitive damages against any person who violates the Act's provisions); *Id.* § 1(H)(2) (subjecting any physician who fails to file a report required under the Act to sanctions by the relevant licensing board); 63 O.S. § 1-706(B) (providing that the Commissioner of Health can suspend or revoke a facility's license for any violation of title 63, article 7, including the challenged Act); O.A.C. § 310:600-7-3 (implementing 63 O.S. § 1-706(B)); 59 O.S. § 503 (providing that the 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); *id.* § 509 (defining "unprofessional conduct" for which a physician may be disciplined); O.A.C. § 435:10-7-4 (implementing 59 O.S. § 509); *see also* Defs.' Answer ¶¶ 46–47, R. Vol. I, Tab 3.

Protocol. H.B. 2684 §§ 1(B)(4), (D). In addition, it carves out an exception in its definition of "abortion-inducing drug" to allow for the administration of methotrexate to treat ectopic pregnancies. *Id.* § 1(B)(1).[3] The only other notable difference between the two acts is the inclusion of legislative findings in House Bill 2684.[4]

If the Act were to take effect, Reproductive Services' physicians would be faced with a difficult choice: either subject women to an inferior and obsolete medication protocol that falls short of the standard of care, or deny patients the medication abortion option altogether. Compliance with the Act would subject women to increased health risks that they would otherwise be able to avoid, and interfere with physicians' ability to exercise sound medical judgment in determining the best care for each individual patient. The Mifeprex Label Protocol requires patients to ingest three times the amount of medication than is medically necessary, thereby increasing the risk of side effects such as nausea. Grossman Aff. ¶¶ 36, 45, R. Vol. I, Tab 7. It also requires patients to return to their abortion provider's office to take the second medication, misoprostol, thereby increasing the likelihood that patients expel the products of conception away from home. *Id.* ¶ 38. Because the known side effects of medication abortion include pain, cramping, bleeding, nausea, vomiting, chills, and diarrhea, the additional trip mandated by the Act would make it more likely that patients would experience these side effects while in the car, or some other equally inappropriate location. *Id.* ¶¶ 38, 45, 62. Requiring patients to travel in order to receive the second medication will

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[3] House Bill 2684 also includes a definition for the term "abortion," which mirrors exactly the definition of "abortion" found at title 63, section 1-730 of the Oklahoma Statutes. H.B. 2684 § 1(B)(2).

[4] For the reasons discussed *infra* pp. 11-14, House Bill 2684's legislative findings are not supported by the medical evidence and have no relevance to the outcome in this case.

also make it difficult for them to access pain medications, and to monitor their bleeding, body temperature, pain level, and possible signs of infection. *Id.* ¶ 38. In addition, the Act would increase a patient's risk of needing additional surgical intervention to complete the abortion, because the Mifeprex Label Protocol calls for a lower dose of misoprostol and oral administration, making it less effective than evidence-based protocols. *Id.* ¶ 35. Finally, Defendants-Appellants (the "State") do not dispute that, for patients who are between 50 and 63 days of pregnancy, the Act would force them to undergo a surgical abortion, even if there are medical reasons favoring the less invasive medication option. Defs.' Answer ¶ 56, R. Vol. I, Tab 3.

Plaintiffs-Appellees filed this challenge to defend the rights of women seeking abortions in Oklahoma, and to safeguard the integrity of the physician-patient relationship from unwarranted government intrusion. Pls.' Verified Pet., R. Vol. I, Tab 2. House Bill 2684 was temporarily enjoined during almost the entire pendency of the district court proceedings. *Okla. Coal. for Reprod. Justice v. Cline*, 2014 OK 91, ¶ 1, 339 P.3d 887, 887–88 (per curiam), R. Vol. I, Tab 6. The district court entered summary judgment for Plaintiffs-Appellees by order dated August 27, 2015, R. Vol. III, Tab 20. This appeal followed.

ARGUMENTS AND AUTHORITIES

I. Standard of Review

The district court's decision granting summary judgment is subject to *de novo* review, "because the ultimate decision turns on purely legal determinations, i.e. whether a party is entitled to judgment as a matter of law because no material disputed factual questions exist." *Fehring v. State Ins. Fund*, 2001 OK 11, ¶ 3, 19 P.3d 276, 278 (citation omitted). "An

appellate court, like a trial court, examines the pleadings and evidentiary materials submitted by the parties to determine if there is a genuine issue of material fact." *Id.* While legislative acts are presumed constitutional, that presumption is overcome by a showing that an act is inconsistent with the Oklahoma Constitution. *See, e.g., Okla. State Chiropractic Indep. Physicians Ass'n v. Fallin*, 2011 OK 102, ¶ 14, 290 P.3d 1, 7 (holding statute targeting certain health care providers for special treatment to be an unconstitutional special law); *EOG Res. Mktg., Inc. v. Okla. State Bd. of Equalization*, 2008 OK 95, ¶¶ 21–24, 196 P.3d 511, 521–22 (holding statute that targeted certain gas companies for special treatment an unconstitutional special law); *Zeier v. Zimmer, Inc.*, 2006 OK 98, ¶¶ 17–18, 152 P.3d 861, 868 (holding statute that targeted certain tort victims for special treatment an unconstitutional special law). As discussed *infra* pp. 14-23, the district court's grant of summary judgment to Plaintiffs-Appellees on the special law claim was proper as a matter of law. Furthermore, Plaintiffs-Appellees' unlawful delegation claim provides an alternate basis to support the district court's judgment striking down House Bill 2684 as unconstitutional.

II. House Bill 2684 Does Not Differ, Substantively or Effectively, from House Bill 1970

Despite the plain relevance of this Court's findings and conclusions in *Cline I* to the current litigation, Defendants-Appellants argued below that House Bill 2684 and House Bill 1970 are "completely different piece[s] of legislation," and that the Court's findings in *Cline I* have no bearing on the issues presented in this case. *See, e.g.*, Reply in Supp. of Defs.' Cross-Mot. for Summ. J., at 2–3, R. Vol. III, Tab 16. Defendants-Appellants are mistaken. In its opinion answering the two certified questions from the U.S. Supreme Court concerning the statutory construction of House Bill 1970, this Court explained its reasoning in striking down that act as an unconstitutional violation of Oklahoma women's due process rights, and

made a number of legal findings that bear directly on the issues presented in this case. The Court's reasoning in *Cline I* is unquestionably relevant here, because House Bill 2684 does not differ in any way that is significant under the Oklahoma Constitution from its predecessor, House Bill 1970.

First and foremost, this Court determined that a ban on the off-label use of certain drugs to end a pregnancy does not advance any valid state interest. The fact that House Bill 1970, as construed by the Court, banned the off-label use of misoprostol altogether, while House Bill 2684 permits its use under the Mifeprex Label Protocol, in no way diminishes the relevance of the Court's reasoning in *Cline I*.[5] Regardless of whether *most* medication abortions would be prohibited, as with House Bill 2684, or *all* medication abortions, as with House Bill 1970, the Court's reasoning applies with equal force. Thus, the district court appropriately relied on the findings and conclusions set forth in *Cline I* in striking down House Bill 2684.

Second, the legislative findings set forth in House Bill 2684 purporting to justify the Act's prohibitions do not create any meaningful difference, in substance or effect, between

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[5] As Plaintiffs-Appellees urged in the proceedings below, Defendants-Appellants should have been precluded from arguing that House Bill 2684's restrictions serve any valid state interest. The fact that this Court issued its decision in *Cline I* in response to certified questions from the U.S. Supreme Court does not, as Defendants-Appellants contended below, render its findings and conclusions irrelevant. *See, e.g.*, *Equitable Life Assur. Soc. of U.S. v. Davis*, 1943 OK 174, 137 P.2d 548, 553 ("[T]he mere fact that a case might have been decided on another theory does not render what was said dictum, if what was said bears directly upon the theory upon which the decision proceeded and upon an issue of law treated as decisive."). At the very least, this Court's conclusions constitute "judicial dictum" and carry persuasive weight. *See Stark v. Watson*, 1961 OK 17, 359 P.2d 191, 196 (stating that a court's statements and conclusions "on a question directly involved, argued by counsel, and deliberately passed on by the court, though not necessary to a decision," constitute "judicial dictum," which is "highly persuasive" (citation omitted)).

the challenged Act and its predecessor. As the Supreme Court recognized in *Gonzales v. Carhart*, courts "retain[] an independent constitutional duty to review factual findings where constitutional rights are at stake." 550 U.S. 124, 165 (2007). Here, the legislative findings included in the challenged Act are flatly contradicted by this Court's findings in *Cline I* and by the overwhelming weight of the medical evidence.

For example, the first eight paragraphs of the legislative findings suggest that the FDA's approval of Mifeprex under the agency's Subpart H restrictions *requires* physicians to adhere to the Mifeprex Label Protocol. *See* H.B. 2684 § 1(A)(1)–(8). However, as this Court already concluded in *Cline I*, FDA-approved labeling "is not intended to limit or interfere with the practice of medicine," 2013 OK 93, ¶ 20, 313 P.3d at 260 (quoting *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989)), and the FDA's approval of mifepristone "did not . . . require that administering physicians utilize mifepristone according only to the protocol described in the FDA-approved label." *Id.* ¶ 21 n.17, 313 P.3d at 261 n.17. Other courts have reached the same conclusion: that a drug's approval under Subpart H does not restrict a physician's ability to prescribe that drug for off-label uses. *See Planned Parenthood of Ariz., Inc. v. Humble*, 753 F.3d 905, 907 (9th Cir.) ("The Subpart H restrictions, Medication Guide, and Patient Agreement do not require doctors to administer mifepristone according to the on-label regimen."), *cert. denied*, 135 S. Ct. 870 (2014); *In re Actiq Sales & Mktg. Practices Litig.*, 307 F.R.D. 150, 170 (E.D. Pa. 2015) ("[T]he FDA does not regulate the practice of medicine, even when approving a drug . . . under Subpart H.").

The Legislature's findings also purport to show that medication abortion poses significant risks to women's health, and that such risks justify the Act's prohibition on evidence-based protocols. H.B. 2684, § 1(A)(10)–(14). However, all evidence points to the

contrary. Leading medical groups, including the American College of Obstetricians and Gynecologists, the American Medical Association, and the World Health Organization have universally concluded, on the basis of the most current medical research, that medication abortion is safe and effective for women up to at least 63 days LMP, and that evidence-based protocols are superior to the now-obsolete Mifeprex Label Protocol. *See, e.g.*, *Cline I*, 2013 OK 93, ¶ 21, 313 P.3d at 260–61; Grossman Aff. ¶¶ 45–47, 56, R. Vol. I, Tab 7; ACOG and AMA Amicus Br., Planned Parenthood of Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir. 2014) (No. 14-15624), 2014 WL 1759869, at *6–7, Ex. C to Grossman Aff., R. Vol. I, Tab 7 ("[E]vidence-based regimens . . . make medical abortion safer, faster, and less expensive, and [] result in fewer complications as compared to the protocol set forth on the label approved by the FDA."). In *Cline I*, this Court rejected Defendants-Appellants' unsupported claims regarding the relative safety and efficacy of evidence-based protocols as compared to the Mifeprex Label Protocol, and found that evidence-based protocols are widely used across the United States, accounting for 96% of all medication abortions in the United States. *Cline I*, 2013 OK 93, ¶ 21, 313 P.3d at 260–61. This Court further found that "the FDA-approved label for mifepristone requires a dosage level for mifepristone [that is] no longer considered medically necessary." *Id.* ¶ 25, 313 P.3d at 262.

House Bill 2684's findings also claim that "off-label" or "evidence-based" medication abortion protocols "may be deadly." H.B. 2684 § 1(A)(13). However, the State's attempt to link evidence-based protocols with eight previously reported deaths "attributed to severe bacterial infection" is both misleading and inaccurate. As noted in the legislative findings, the FDA itself has "not . . . conclude[d] one way or another whether off-label use led to the eight [reported] deaths." *Id.* Moreover, medical research shows that

deaths due to the same severe bacterial infection have occurred following other obstetric and gynecological procedures, including childbirth, surgical abortion, and miscarriage. Grossman Aff. ¶ 53, R. Vol. I, Tab 7. Given the fact that 96% of all medication abortions in the United States have been administered according to off-label or evidence-based protocols, it is to be expected that most adverse events reported by the FDA would have occurred with evidence-based practices. Grossman Aff. ¶ 55, R. Vol. I, Tab 7.

House Bill 2684's legislative findings are wholly unsupported both as a legal and as a factual matter. If anything, the scientific and medical evidence attesting to the safety and efficacy of evidence-based medication abortion protocols has only grown in the intervening time period between passage of House Bill 1970 and the challenged Act. *See, e.g.*, ACOG Practice Bulletin No. 143: Medical Management of First-Trimester Abortion (March 2014), Ex. B to Grossman Aff., R. Vol. I, Tab 7 (replacing prior ACOG guidance on medication abortion in order to reflect the findings of recent studies demonstrating the superiority of evidence based regimens over the FDA-approved regimen). Accordingly, the Legislature's attempt to "overrule" this Court's decision in *Cline I* should not be countenanced. H.B. 2684 § 1(A)(16).

III. The District Court Correctly Held that the Act Violates the Constitutional Prohibition on Special Laws

Under the Oklahoma Constitution, "Laws of a general nature shall have 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. This Court has adopted a three-pronged test for determining whether a statute violates this provision of the Oklahoma Constitution: (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 applicable, is the statute a permissible special law?

Reynolds v. Porter, 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.* As the district court found, the Act "fails under each prong of the *Reynolds* test," Order ¶ 21, R. Vol. III, Tab 20, and its decision should be affirmed.

A. The Act is a Special Law Because it Singles out Women Who Seek Abortion and Physicians Who Provide Them for Special Treatment

Under the first prong of the *Reynolds* test, the inquiry is whether a law "single[s] out less than an entire class of similarly affected persons or things for different treatment." *Reynolds*, 1988 OK 88, 760 P.2d at 822. The district court correctly found that the Act does so in at least two ways. First, it "singles out certain FDA-approved medications and prohibits their off-label use *solely* when used for the purpose of inducing abortion." Order ¶ 22, R. Vol. III, Tab 20. Second, the Act "singles out women who seek, and doctors who provide, abortions from those involved in all other forms of medical care." *Id.*

As the district court noted, 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 the same drugs *for any other purpose* . . . ." Order ¶ 25, R. Vol. III, Tab 20 (emphasis added). Thus, the very same drugs that the State claims are dangerous to women's health can still be administered off-label for any purpose other than inducing an abortion. Obstetricians/gynecologists use misoprostol off-label for many purposes, including induction of labor and as a non-surgical intervention for early miscarriage. Aff. of Dana Stone, M.D., in Supp. of Pls.' Mot. for Partial Summ. J. ("Stone Aff.") ¶ 9, R. Vol. I, Tab 7; Grossman Aff. ¶ 10, R. Vol. I, Tab 7. The fact that the challenged Act permits off-label use of mifepristone and misoprostol for purposes other than to induce abortion and contains an exemption for the off-label use of abortion-inducing drugs to treat ectopic pregnancies

further demonstrates that the State is treating similarly affected medications differently, and singling out women based on their reproductive choices.

In addition, the Act singles out physicians who offer medication abortion to their patients from all other physicians who provide FDA-approved medications for any other condition or purpose. Physicians have a duty to exercise their best medical judgment when treating patients, including by prescribing medications off-label to ensure patients receive the best and most appropriate care. *See Cline I*, 2013 OK 93 ¶ 25, 313 P.3d at 262 (noting the State's "deference to physicians regarding treatment decisions in almost all other areas of medicine"); *Scott v. Bradford*, 1979 OK 165, 606 P.2d 554, 558 (acknowledging that the "primary duty of a physician is to do what is best for his patient"); Stone Aff. ¶ 11, R. Vol. I, Tab 7 (noting "patients should have the option of choosing the treatment that is best suited to their individual circumstances"). Yet the Act infringes upon a physician's medical judgment by requiring adherence to the Mifeprex Label Protocol regardless of an individual patient's health needs or individual circumstances.

This Court's reasoning and conclusions in *Cline I* further support the district court's determination that House Bill 2684 is a special law. "Abortion is the only area of medicine where it appears the Oklahoma Legislature has seen fit to restrict a physician's use of certain practices." *Cline I*, 2013 OK 93, ¶ 25 n.21, 313 P.3d at 262 n.21. As this Court previously found, "[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.* ¶ 21, 313 P.3d at 261 (quoting U.S. Food & Drug Administration, *Regulatory Information: "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices—Information Sheet*, available at

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm). Yet House Bills 1970 and 2684 both restrict a physician's ability to practice medicine and to prescribe medications based on the most up-to-date medical literature and evolving standards of care. In *Cline I*, the Court highlighted the contrast between the restrictions imposed by House Bill 1970 and "the deference physicians receive regarding treatment decisions in almost all other areas of medicine." *Id.* ¶ 25, 313 P.3d at 262. For example, apart from House Bills 1970 and 2684, Oklahoma law requires physicians to dispense drugs "in amounts considered good medical practice," not in the specific amounts or dosages described in FDA-approved labels. *Id.* ¶ 22, 313 P.3d. at 261 (citing 59 O.S. § 509(16)). Indeed, the Medicaid Drug Utilization Review Board is charged with developing guidelines for medical outpatient drugs that "are **appropriate, medically necessary, and not likely to result in adverse medical outcomes**." *Id.* ¶ 24, 313 P.3d. at 261–62 (emphasis in original) (quoting 63 O.S. § 5030.4(1)). The cited statute "uses the term 'medically necessary' in deference to the knowledge and expertise of physicians exercised in the practice of medicine." *Id.* That the Oklahoma Legislature has otherwise chosen to protect patient access to evidence-based medicine and physicians' discretion "to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling" further underscores the fact that the challenged Act singles out physicians who provide abortions for differential treatment. *Id.* ¶ 22, 313 P.3d at 261.

Defendants-Appellants' arguments to the contrary in the district court were, and are, unavailing. First, Defendants-Appellants argued below that the relevant class here consists of abortion-inducing drugs, rather than all FDA-approved drugs that have off-label applications. Defs.' Summ. J. Resp., at 18, R. Vol. I, Tab 8. Under this logic, the State could

single out certain classes for different treatment and then avoid constitutional scrutiny simply by defining the relevant class as the very group singled out for such treatment. This Court has rejected such an approach in other contexts, and the district court properly rejected it here. *Cf. Elias v. City of Tulsa*, 1965 OK 164, 408 P.2d 517, 521 (finding statute giving certain zoning powers to City of Tulsa, but no other cities, to be an unconstitutional special law, and noting the law's purported justification—"local conditions described as peculiar only to the City of Tulsa"—undercut any "legislative intent to enact a general law having a uniform operation throughout the State").

Defendants-Appellants' second argument, that the Act does not single out women for their reproductive choices because women seeking medication abortions can still obtain surgical abortions, Defs.' Summ. J. Resp. at 18, R. Vol. I, Tab 8, is fundamentally flawed. Medication abortion and surgical abortion are not interchangeable. Women who seek medication abortions typically do so because they have specific concerns in mind, such as fear of anesthesia or insertion of medical instruments, or a medical condition that makes medication abortion a safer alternative than surgical abortion. Grossman Aff. ¶ 25, R. Vol. I, Tab 7. Moreover, Oklahoma women are just as entitled to make autonomous decisions about their treatment options in the context of abortion as any other patient seeking medical treatment. *See Scott*, 1979 OK 165, 606 P.2d at 557 ("It is the prerogative of every patient to chart his own course and determine which direction he will take."). Physicians, too, have the same ethical obligations to their patients seeking abortions as all other physicians have to their patients. *See id.* at 558.

Because the Act treats similarly-situated medications, patients, and physicians differently, and deprives only women seeking medication abortion of the benefits of

evidence-based medicine, the district court correctly held that it is a special law. Order ¶¶ 21–22, R. Vol. III, Tab 20; *see Reynolds*, 1988 OK 88, 760 P.2d at 822. Accordingly, it must be held unconstitutional if it fails either the second or third prong of the test set forth by this Court. *See Reynolds*, 1988 OK 88, 760 P.2d at 822.

B. The Legislature Could Have, But Did Not, Enact a Generally Applicable Law

Under the second prong of the special laws test, a court must determine "if the subject of the legislation is reasonably susceptible of general treatment or if, on the other hand, there is a special situation possessing characteristics impossible of treatment by general law." *Id.* Courts should consider "both the nature and objective of the legislation as well as the conditions and circumstances under which the statute was enacted." *Id.* Here, as the district court properly found, the subject of the Act—off-label use of FDA-approved medications—is reasonably susceptible of general treatment. Order ¶ 23, R. Vol. III, Tab 20. As the district court recognized, "[t]he 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." *Id.* Indeed, as the district court noted, in *Cline I*, this Court recognized that "the Legislature has specifically protected the off-label use of other drugs in other contexts, and for other purposes apart from inducing an abortion." *Id.* (citing *Cline I*, 2013 OK 93, ¶¶ 22–25, 313 P.3d at 260). Alternatively, the Legislature "could have, but chose not to, regulate the off-label use of all medications approved under Subpart-H." *Id.*

By finding that a general law could be made applicable, the district court rejected Defendants-Appellants' flawed argument that the regulation of abortion constitutes a category unto itself. Defs.' Summ. J. Resp., at 19, R. Vol. I, Tab 8 (arguing that "no other area of off-label use so directly involves the unique and difficult context of abortion"). This

argument is inconsistent with Oklahoma special laws jurisprudence and this Court's decision in *Cline I*. *See* 2013 OK 93, ¶ 25, 313 P.3d at 262 (comparing deference afforded physicians when making medical decisions in other contexts with restrictions imposed by House Bill 1970); *cf. Nova Health Sys. v. Pruitt*, No. 2:12-CV-00395, 2012 WL 1034022 (Dist. Ct. Okla. Cty. Mar. 28, 2012) (finding mandatory ultrasound requirement, addressed only to abortion care, to be special law where general law have been made applicable), *aff'd on other grounds*, 2012 OK 103, 292 P.3d 28. Singling out abortion for different and more onerous regulation than is imposed on other procedures is inappropriate unless the State can demonstrate that the "unique" nature of abortion is directly related to the goal of the legislation itself. *See Grant v. Goodyear Tire & Rubber Co.*, 2000 OK 41, ¶ 9, 5 P.3d 594, 598. Defendants-Appellants have not made that connection here.[6]

The district court similarly did not accept Defendants-Appellants' arguments that medication abortion poses increased risks for women, or that there is disagreement within the medical community about the safety of medication abortion off-label protocols—because they are meritless. As this Court has explained, and the district court correctly acknowledged, there is nothing unique about the practice of evidence-based medicine in the context of medication abortion to warrant the differential treatment that the Act imposes. *See Cline I*, 2013 OK 93, ¶¶ 21–22, 313 P.3d at 260–61 (explaining that no health justification exists for singling out medication abortion for different treatment under Oklahoma law where

[6] To the extent that Defendants-Appellants assert that the State's interest in potential life is advanced by the Act, such argument must fail. The challenged Act lacks any legitimate connection to the State's interest in fetal life because it continues to allow surgical abortions and some medication abortions. Further, the Oklahoma Legislature's findings and Defendants-Appellants' summary judgment brief clearly indicate that House Bill 2684's underlying purpose was to protect women's health. *See* H.B. 2684 § 1(A)(15); Defs.' Summ. J. Resp., at 19, R. Vol. I, Tab 8.

evidence-based protocols have been demonstrated by scientific research to be superior); Order ¶ 23, R. Vol. III, Tab 20.

Because the Act is a special law that fails the second prong of the test set forth by this Court, the district court correctly held that it violates article V, section 59 of the Oklahoma Constitution. Order ¶ 26, R. Vol. III, Tab 20.

C. The Act is a Special Law Unrelated to Any Valid Legislative Objective

Under the third prong, a court must determine "if the special legislation is reasonably and substantially related to a valid legislative objective." *Reynolds*, 1988 OK 88, 760 P.2d at 822; *accord Orthopedic Hosp. of Okla. v. Okla. State Dep't of Health*, 2005 OK CIV APP 43, ¶ 13, 118 P.3d 216, 222–23. The district court further held that the Act fails the third prong of the *Reynolds* test because it is unrelated to any valid legislative goal. Order ¶ 26, R. Vol. III, Tab 20. As the district court recognized, this Court concluded that House Bill 1970, the predecessor to the challenged Act, failed to serve any valid legislative interest. Order ¶ 25, R. Vol. III, Tab 20 (citing *Cline I*, ¶ 27, 313 P.3d at 262). Specifically, this Court concluded that a ban on off-label use of misoprostol and methotrexate, when used to end a pregnancy, "serve[d] no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." *Cline I*, 2013 OK 93, ¶ 27, 313 P.3d at 262. Under Oklahoma law, discriminating against women is not a valid state interest. *See, e.g.*, *Account Specialists & Credit Collections, Inc. v. Jackman*, 1998 OK CIV APP 175, ¶¶ 6–8, 970 P.2d 202, 204 (striking down as unconstitutional an Oklahoma statute that discriminated against women by "perpetuat[ing] 'invidious, archaic, and overbroad stereotypes' about the relative status of men and women" under both the state and federal constitutions).

The district court held that, like its predecessor, the challenged Act's prohibition on evidence-based medication abortion protocols serves no valid state interest. In reaching its conclusion, the district court properly rejected Defendants-Appellants' argument that the Act promotes women's health and safety. The court acknowledged, "the fact that the Act imposes restrictions on off-label use of mifepristone and misoprostol when used to end a pregnancy, but permits off-label use of the same drugs for any other purpose, undercuts the State's argument that the Act is reasonably and substantially related to any legitimate safety concerns." Order ¶ 25, R. Vol. III, Tab 20. Rather than enhancing women's health and safety, requiring physicians to adhere to the Mifeprex Label Protocol would relegate women to an inferior and obsolete treatment protocol, Grossman Aff. ¶¶ 60–67, R. Vol. I, Tab 7, and force physicians to practice medicine in violation of their own medical judgment and their ethical obligations to provide the best possible care for their patients. ACOG and AMA Amicus Br., Planned Parenthood of Ariz., Inc. v. Humble, 753 F.3d 905 (9th Cir. 2014) (No. 14-15624), 2014 WL 1759869, at *13, *16–17, Ex. C to Grossman Aff., R. Vol. I, Tab 7.

The district court also noted the lack of evidence supporting Defendants-Appellants' argument that reported deaths after medication abortion are attributable to off-label use. Order ¶ 25, R. Vol. III, Tab 20 (citing H.B. 2684 § 1).[7] Because Defendants-Appellants cannot demonstrate that the Act actually serves any valid legislative goal, including the

[7] The district court noted that, according to the Legislature's own findings, "[t]he FDA has not been able to conclude one way or another whether off-label use led to the eight deaths." Order ¶ 25 (quoting H.B. 2684 § 1(A)(13)), R. Vol. III, Tab 20. The district court also noted that "neither the FDA nor the Centers for Disease Control and Prevention has found any specific connection between bacterial infections and medication abortion." Order ¶ 25 n.2 (citing ACOG Practice Bulletin No. 143: Medical Management of First Trimester Abortion (March 2014), at 8 & nn.67–68, Ex. B to Grossman Aff., R. Vol. I, Tab 7).

protection of women's health, the district court correctly held that it is an unconstitutional special law, and that "no valid state interest is served by prohibiting doctors from following evidence-based medication abortion protocols." Order ¶ 25, R. Vol. III, Tab 20. This Court should again affirm that holding.

IV. In the Alternative, the Act Should be Struck Down as an Unconstitutional Delegation of Legislative Authority to the FDA

Although the district court did not reach Plaintiffs-Appellees' claim that the Act violates the Oklahoma Constitution by delegating the Legislature's policy-making powers to an unelected, federal agency, summary judgment is also appropriate on that claim.

The Oklahoma Constitution vests the authority and responsibility for policy-making in the Legislature. *Democratic Party v. Estep*, 1982 OK 106, 652 P.2d 271, 277–78. A legislative enactment can run afoul of the non-delegation doctrine in two ways: by delegating the Legislature's policy-making function, or by delegating the task of implementing legislative policy without establishing adequate standards and guidelines to ensure accountability by the agency tasked with implementation. *Id.* at 277–78, 277 n.23; *Harris v. State*, 1952 OK 459, 593, 251 P.2d 799, 802–03.

Oklahoma courts have not hesitated to strike down laws that violate the non-delegation doctrine. For example, in *Oklahoma City v. State ex rel. Department of Labor*, 1995 OK 107, 918 P.2d 26, this Court struck down a statute that delegated the task of determining the prevailing hourly wage for Oklahoma workers to the United States Department of Labor. The Court held such a delegation to be improper because it gave a federal agency of unelected bureaucrats the authority to set the prevailing wage in Oklahoma, and failed to provide any method to challenge or protest the U.S. Department of Labor's determinations. *Id.* at 29–30. Along similar lines, in *Potter v. State*, 1973 OK CR 228, 509

P.2d 933, the Court of Criminal Appeals struck down a statute that criminalized the purchase or sale of any motion picture depicting sexual intercourse unless it had been approved by the Motion Picture Association of America. The court held that such a delegation of policy-making authority to a "privately controlled out of state association," without "narrowly drawn, reasonable and definite standards" for officials to follow, was an unconstitutional delegation of legislative authority. *Id.* at 935, 936.

Here, the challenged Act violates both components of the non-delegation doctrine. First, the Legislature has improperly delegated its authority to make Oklahoma law to the FDA. It is undisputed that the FDA is a federal agency unaccountable to the Oklahoma Legislature, and that the FDA itself lacks the authority to regulate how physicians practice medicine. Second, even if this delegation were somehow permissible, the Act would still be constitutionally infirm because the Legislature cannot "leave[] an important determination to the unrestricted and standardless discretion of unelected bureaucrats." *Okla. City*, 1995 OK 107, 918 P.2d at 30. The challenged Act fails to set forth any standards or guidelines for the FDA to follow, such as what criteria the FDA should use in determining whether a particular medication protocol should be "authorized." Of course, the establishment of such criteria would be impossible, since the FDA is a federal agency that exercises its discretion completely independent of the goals and objectives of the Oklahoma Legislature. The Act similarly lacks any safeguards to limit the FDA's discretion in implementing the authority it has been delegated by the Oklahoma Legislature. In sum, the Legislature has completely abdicated its lawmaking responsibility and bestowed "unbridled agency discretion" upon the FDA by adopting the Mifeprex Label Protocol as state law. *Cf. Democratic Party*, 1982 OK 106, 652 P.2d at 277; *accord Okla. City*, 1995 OK 107, 918 P.2d at 30.

The Act is also constitutionally impermissible because it authorizes the FDA to regulate the manner in which Oklahoma doctors may prescribe certain medications, including any changes the FDA might approve to the Mifeprex drug label in the future. The Act would automatically incorporate any such changes into Oklahoma law, without any oversight or exercise of legislative discretion, in violation of the Oklahoma Constitution. *Accord Planned Parenthood of Ariz., Inc. v. Christ*, No. CV-2014-006633 (Super. Ct. Maricopa Cty. Oct. 13, 2015), http://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/PPAZ-v-Nelson-ruling-2015-10-15.pdf (holding Arizona law restricting provision of medication abortion to the FDA-approved protocol to be an unconstitutional delegation of legislative authority under the Arizona state constitution).

In the district court proceedings, Defendants-Appellants declined to address the substance of Plaintiffs-Appellees' non-delegation claim. Instead, they argued that the Act does not delegate any legislative authority to the FDA. Defs.' Summ. J. Resp., at 14, R. Vol. I, Tab 8. This argument is unavailing. The challenged Act empowers the FDA to decide how medications can or cannot be used to terminate a pregnancy in Oklahoma, and thereby makes a federal agency with no accountability to the Oklahoma Legislature or Oklahoma voters responsible for determining Oklahoma policy. This abdication of legislative power is not permitted under the Oklahoma Constitution.

CONCLUSION

For the reasons set forth above, Plaintiffs-Appellees respectfully request that this Court affirm the judgment of the district court.

Respectfully submitted, this 4th day of November, 2015.

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 4TH of November, 2015 a true and correct copy of the above Plaintiffs-Appellees' Brief was sent via U.S. mail to the following:

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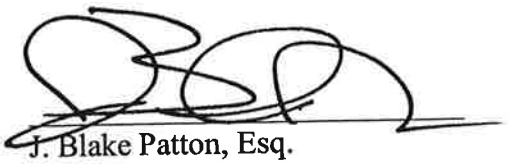

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