IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients, Plaintiffs/Appellees, vs. TERRY CLINE, in his official capacity as Oklahoma Commissioner of Health; and LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and CATHERINE V. TAYLOR, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners, Defendants/Appellants.	)	No. 110,765 Oklahoma County Case No. CV-2011-1722

Appeal from District Court of Oklahoma County
Case No. CV-2011-1722
The Honorable Donald L. Worthington

***AMICUS CURIAE* BRIEF OF 57 OKLAHOMA SENATORS AND REPRESENTATIVES, INCLUDING THE SPONSORS OF HB 1970, AND AMERICANS UNITED FOR LIFE ACTION IN SUPPORT OF THE DEFENDANTS/APPELLANTS AND REVERSAL OF THE DISTRICT COURT OF OKLAHOMA COUNTY, FILED ON CONSENT OF THE PARTIES**

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TABLE OF CONTENTS AND AUTHORITIES

Code of Federal Regulations

Other Authorities

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici Curiae Representative Randy Grau (sponsor), Senator Greg Treat (sponsor), Senator Brian Bingman (President Pro Tempore), Senators Cliff Aldridge, Mark Allen, Don Barrington, Josh Brecheen, Rick Brinkley, Bill Brown, Greg Childers, Brian Crain, Kim David, Eddie Fields, John Ford, AJ Griffin, Jim Halligan, Rob Johnson, Clark Jolley, Ron Justice, Bryce Marlatt, Mike Mazzei, Dan Newberry, Steve Russell, Mike Schulz (Majority Floor Leader), Ralph Shortey, Frank Simpson, and Gary Stanislawski, and Representatives Don Armes, Gary Banz, Dennis Casey, Josh Cockroft, Donnie Condit, Ann Coody, Marian Cooksey, David Dank, George Faught, Elise Hall, Tommy Hardin, Dennis Johnson, Sally Kern, Scott Martin, Steve Martin, Mark McCullough, Skye McNiel, Lewis Moore, Glen Mulready, Jason Murphey, Tom Newell, Charles Ortega, Leslie Osborn, Pat Ownbey, Marty Quinn, Dustin Roberts, Sean Roberts, Mike Sanders, Todd Thomsen, and Paul Wesselhoft are legislators in the state of Oklahoma who support House Bill 1970, codified at 63 Okla. Stat. § 1-729a (the "Act"). In fact, Senator Greg Treat and Representative Randy Grau were the official sponsors of the Act when it was considered in the Oklahoma State Legislature.

As Legislators who sponsored, voted for, and/or support the Act, *Amici* have a special interest in the outcome of this case. First, *Amici* have an interest in ensuring that a constitutional law enacted by the Legislature is upheld and enforced.

Second, *Amici* have an interest in protecting the health and welfare of women seeking abortion in the state. As affirmed time and time again by the U.S. Supreme Court, this is an important interest that vests in the State at the outset of pregnancy.

[1] Per Okla. Sup. Ct. R. 1.12, *Amici* file this brief with consent of the parties.

Third, *Amici* have an interest in ensuring that certain documents and evidence presented to the trial court are appropriately and adequately considered. When the Legislature passed the Act, it did so relying on evidence that was given no consideration by the trial court.

Amicus Americans United for Life Action (AULA) is the legislative action arm of Americans United for Life, a nonprofit, public-interest law and policy organization founded in 1971. AULA provides expert legislative consultation to state legislators on issues involving abortion and its maternal health implications. AULA assisted the Oklahoma Legislature in its drafting and enactment of the Act and has a particular interest in seeing the language upheld. AULA seeks to protect women from the harms inherent in abortion through the enactment and enforcement of commonsense abortion regulations.

Amici seek to demonstrate to this Court that the U.S. Supreme Court has given the Legislature wide discretion in enacting regulations protecting women from harms inherent in abortion, that the Legislature relied upon evidence that medical abortion poses specific harms to women, and that as such the Plaintiffs cannot substantiate their "undue burden" claim. As such, the decision of the court below should be reversed.

ARGUMENT

The Act is a medical regulation designed and enacted to protect women from the dangerous unapproved use of abortion-inducing drugs. Specifically, it requires that the Mifeprex regimen (also known as the RU-486 regimen) be administered in the way approved by the U.S. Food and Drug Administration (FDA). It does not ban the use of the Mifeprex regimen and does not ban abortion between seven and nine weeks gestation. The Act simply requires that the regimen be administered in the way deemed safest by the FDA. While the FDA determined that the Mifeprex regimen should not be used past 49 days gestation, other alternatives—indeed, alternatives deemed "very safe" by abortion providers[2]—exist for women with pregnancies beyond 49 days gestation. The Act imposes no obstacle to obtaining an abortion.

Important here is the fact that the Act aims to protect the health and welfare of women—a state interest that has been declared "important" and "legitimate" by the U.S. Supreme Court. In fact, the Court has determined that states have wide discretion to enact protective laws where parties disagree as to the medical safety of a particular abortion procedure or method. Thus, in order to prevail on its "undue burden" claim, Plaintiffs must demonstrate that the state has no evidence that the unapproved use of the Mifeprex regimen can be harmful to women. As discussed below, this they cannot do, because ample evidence

[2] *See, e.g.*, Planned Parenthood, *In-Clinic Abortion Procedures* (2011), in Exhibit Z to Defendants' Response to Plaintiffs' Motion for Summary Judgment, also available at http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp (last visited Sept. 28, 2012). "In-clinic abortion procedures are very safe." *Id.* Planned Parenthood uses "in-clinic abortion procedures" to describe aspiration and dilation and evacuation (D&E) procedures—*i.e.*, surgical abortion procedures. *Id.*

in the record demonstrates that the unapproved use of the Mifeprex regimen poses significant health risks for women.

While Plaintiffs claim to have "research" supporting off-label use of the Mifeprex regimen, all Plaintiffs are really demonstrating is that they disagree with the state's reliance on evidence showing that the regimen can be harmful to women. To that end, Plaintiffs' claims of an "undue burden" fail.

While the court below relied on U.S. Supreme Court precedent in *Planned Parenthood of Southeastern Pennsylvania v. Casey* in its conclusions of law, it did not interpret *Casey* properly. Further, the court inexplicably ignored *Gonzales v. Carhart*, which builds upon the *Casey* precedent. When these cases—and the medical evidence in the record—are properly examined, it is clear that federal precedent supports the Act.

PROPOSITION 1:

THE U.S. SUPREME COURT GIVES STATE LEGISLATURES "WIDE DISCRETION" TO REGULATE ABORTION WHEN THERE IS "MEDICAL AND SCIENTIFIC UNCERTAINTY."

In *Gonzales v. Carhart*, the U.S. Supreme Court explicitly held that state and federal legislatures are given "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." 550 U.S. 124, 163 (2007).

The context in which the Court enunciated this standard is significant here. The Court was considering the constitutionality of not just a *regulation* of a pre-viabilty abortion procedure, but a *complete ban* of a particular pre-viability procedure. *See Gonzales*, 550 U.S. at 147, 156 (noting that the partial-birth abortion ban applies both pre-viability and post-viability). The Court stated, "Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to *bar* certain procedures and substitute

others, all in furtherance of its legitimate interests in regulating the medical profession…." *Id*. at 158 (emphasis added).

The plaintiffs in *Gonzales* posited that the federal partial-birth abortion ban created certain health risks to women, which in turn created an undue burden; however, the Court unequivocally rejected this claim.

Noting that there were documented medical disagreements over whether the partial-birth abortion ban would impose significant health risks to women, the Court determined that the relevant question was whether the ban could stand when such medical uncertainty persists. *Id*. at 162-63. Citing numerous cases, the Court held that state legislatures are given wide discretion in areas where there is medical and scientific uncertainty. *Id*. at 163 (citing *Kansas v. Hendricks*, 521 U.S. 346, 360 n. 3 (1997); *Jones v. United States*, 463 U.S. 354, 364-65 n. 13, 370 (1983); *Marshall v. United States*, 414 U.S. 417, 427 (1974) ("When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad"); *Lambert v. Yellowley*, 272 U.S. 581, 597 (1926); *Collins v. Texas*, 223 U.S. 288, 297-98 (1912); *Jacobson v. Massachusetts*, 197 U.S. 11, 30-31 (1905)).

Importantly, the Court concluded that "physicians are not entitled to ignore regulations that direct them to use reasonable alternative procedures. The law need not give abortion doctors unfettered choice in the course of their medical practice, nor should it elevate their status above other physicians in the medical community." *Gonzales*, 550 U.S. at 163. "Medical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts." *Id*. at 164. In *Gonzales*, the

medical uncertainty over whether the ban's prohibition created a significant health risk provided sufficient basis to conclude that the ban did not impose an undue burden. *Id*.

The Court's conclusion that the federal partial-birth abortion ban did not impose an undue burden was also based upon the fact that alternatives to the procedure are available. *Id*. A "commonly used and generally accepted method" of abortion remained available to women, so the ban did not "construct a substantial obstacle to the abortion right." *Id*. at 165. Specifically, the Court held:

> Considerations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends. When standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not follow that the State is altogether barred from imposing reasonable regulations.

Id. at 166.

Moreover, the Court has repeatedly affirmed the states' interest in protecting women from the harms of abortion. At the outset of the Court's decision in *Planned Parenthood v. Casey*, the Court reaffirmed an "essential holding" in *Roe v. Wade* that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman…." *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992); *see also Gonzales*, 550 U.S. at 145 (quoting this central holding of *Roe* and *Casey*). The Court then repeated this premise, stating that "*Roe v. Wade* was express in its recognition of the State's 'important and legitimate interests in preserving and protecting the health of the pregnant woman….'" *Casey*, 505 U.S. at 875-76.

In addition, regulations that are "designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden." *Id*. at 878. As part of the Court's summary of its "undue burden" standard, the Court stated, "As with any medical

procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion." *Id.*

Taken together, U.S. Supreme Court precedent demonstrates that Plaintiffs have a very high burden to meet. Because states are given wide discretion to legislate in areas where there is medical and scientific uncertainty, to prevail on their "undue burden" claim Plaintiffs must demonstrate that the state has no medical evidence that unapproved use of the Mifeprex regimen can be harmful to women. However, medical data demonstrating that Plaintiffs' preferred unapproved use of the Mifeprex regimen can be harmful to women strips Plaintiffs of their ability to meet this substantial burden.

PROPOSITION 2:

THE MEDICAL BASIS FOR THE ACT IS SUPPORTED IN THE RECORD.

When the Legislature passed the Act in 2011, it relied on evidence demonstrating that the Mifeprex regimen carries significant risks, especially when misused. This evidence is detailed in the record,[3] but was ignored by the district court. As explained below, the FDA intended to restrict use of the Mifeprex regimen because the drugs pose significant risks to women's health and safety. When the regimen is used in an unapproved manner, those risks are heightened. Every documented death from a bacterial infection following use of the Mifeprex regimen is tied to the misuse of the regimen. Misusing the Mifeprex regimen and taking such a risk with women's lives is inexcusable, especially in light of the availability of safer alternatives.

[3] References to the specific exhibits in the record are documented in the footnotes the first time a particular document or source is cited in each section.

A. The FDA intended to restrict use of the Mifeprex regimen for safety reasons.

The recommended method of medical abortion in the United States is the combined use of mifepristone and misoprostol. ACOG, *ACOG Practice Bulletin 67 Medical Management of Abortion.*[4] In the United States, mifepristone is marketed under the brand name "Mifeprex." *Mifeprex Final Printed Labeling* ("Mifeprex FPL").[5] Together, the administration of Mifeprex and misoprostol—the only method of medical abortion approved by the FDA—is known as the Mifeprex regimen.

As documented in the record, the FDA approved the Mifeprex regimen under the auspices of "Subpart H," a special provision in the Code of Federal Regulations for drugs that "can be safely used ***only if*** distribution or use is ***restricted***." 21 C.F.R. § 314.520 (emphasis added).[6] Under Subpart H, the FDA can "require such postmarketing restrictions as are needed to assure safe use" of the drug approved. *Id*. In other words, the authorization of the Mifeprex regimen was conditioned upon the FDA's ability to restrict the use of the drug.

Prior to approving the Mifeprex regimen, the FDA informed the drug sponsor (the applicant for FDA approval) that restrictions "on the distribution and use of mifepristone are needed to assure safe use" of the Mifeprex regimen. FDA, *Feb. 2000 Approvable Letter*.[7] At

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[4] Appendix 4, Exhibit B to Plaintiffs' Motion for Summary Judgment.

[5] Appendix 6, Exhibit A to Plaintiffs' Motion for Summary Judgment; Exhibit V to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited Sept. 28, 2012).

[6] Exhibit Q to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[7] Exhibit R to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

that time, the FDA also instructed the sponsor to use the FDA-recommended language for the product's final printed labeling (FPL). *Id*. The FDA concluded that available data did not support the safety of home use of misoprostol and ***rejected*** the sponsor's suggestion that the FPL include information on self-administering misoprostol at home. U.S. Government Accountability Office ("GAO"), *GAO Report*, at 23.[8] In its approval letter, the FDA reiterated that Subpart H applies when it concludes that a drug can be safely used only if its distribution or use is restricted. FDA, *Sept. 2000 Approval Letter*.[9]

The FPL for the Mifeprex regimen outlines the FDA-approved dosage and administration of both Mifeprex and misoprostol (the Mifeprex regimen). *Mifeprex FPL*, *supra*. The FPL states explicitly that the Mifeprex regimen is indicated only for the medical termination of intrauterine pregnancy through 49 days' pregnancy. It has no other approved indication for use during pregnancy. *Id*. at 5, 9. A woman should not take Mifeprex if "it has been more than 49 days (7 weeks) since" her last menstrual period began. *Id*. at 17.

In addition to restricting the time frame in which the Mifeprex regimen is to be used, the FDA provided explicit dosage and administration instructions, directly linking mifepristone (Mifeprex) and misoprostol into one regimen:

> Treatment with ***Mifeprex and misoprostol*** for the termination of pregnancy ***requires*** three office visits by the patient. Mifeprex should be prescribed only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

[8] Appendix 3 to Plaintiffs' Motion for Summary Judgment. Also available at http://www.gao.gov/new.items/d08751.pdf (last visited Sept. 28, 2012).

[9] Exhibit S to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

> **Day One: Mifeprex Administration**
> Patients must read the MEDICATION GUIDE and read and ***sign the PATIENT AGREEMENT*** before Mifeprex is administered.
> Three 200 mg tablets (600 mg) of Mifeprex are taken in a single dose.
>
> **Day Three: Misoprostol Administration**
> The patient ***returns to the health care provider*** two days after ingesting Mifeprex. Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient ***takes two 200 µg tables (400 µg) of misoprostol orally***….
>
> **Day Fourteen: Post-Treatment Examination**
> Patients ***will return for a follow-up visit approximately 14 days after*** the administration of Mifeprex. The visit is very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred.

Id. at 13-14 (emphasis added).

Not only did the FDA outline the "required" regimen in the FPL, but it also mandated that a patient sign the "Patient Agreement." This requirement is detailed not only in the FPL (as quoted above), but was also explained in the FDA's September 2000 Approval Letter. FDA, *Sept. 2000 Approval Letter*.[10]

The "Patient Agreement"—which must be signed by both the abortion provider and the patient—provides further evidence that the FDA intended to limit use of the Mifeprex regimen to only the FDA-approved protocol found in the FPL. Before administration of the Mifeprex regimen, the patient must attest to the following: 1) I believe I am no more than 49 days (7 weeks) pregnant; 2) I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3); and 3) I will do the following… return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will

[10] Exhibit S to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

give me misoprostol if I am still pregnant. *"Patient Agreement" in Mifeprex FPL*, *supra*, at 19.

That means that if abortion providers are administering the Mifeprex regimen in an unapproved manner (*i.e.*, after 49 days and/or with the second dose in the regimen administered away from the office, as the Plaintiffs admit), such providers are signing false documents and are having their patients sign false documents. It can hardly be claimed that the FDA mandated a signed "Patient Agreement" that it does not intend for the provider or patient to follow.

To the contrary, all FDA communications on the non-FDA-approved uses of the Mifeprex regimen refer to such uses as "unapproved" or "off-label"—it never refers to such deviations as "evidence-based." *See, e.g.*, GAO, *GAO Report*, *supra*, at 41. The regimen outlined in the Mifeprex FPL is repeated throughout communications on Mifeprex as the only "approved" use of Mifeprex and misoprostol. FDA, *Mifeprex (mifepristone) Information* (July 19, 2011);[11] FDA, *Mifeprex Questions and Answers* (Feb. 24, 2012);[12] FDA, *Public Health Advisory: Sepsis and Medical Abortion* (Mar. 17, 2006).[13]

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[11] Exhibit N to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111323.htm (last visited Sept. 28, 2012).

[12] Exhibit O to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm (last visited Sept. 28, 2012).

[13] Exhibit W to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm051298.htm (last visited Sept. 28, 2012).

Rather than recommend the unapproved use of the Mifeprex regimen, the FDA has stated that "[t]he safety and effectiveness of other Mifeprex dosing regimens, including the use of oral misoprostol tablets intravaginally, has not been established by the FDA." FDA, *Mifeprex (mifepristone) Information*, *supra*; FDA, *Mifeprex Questions and Answers*, *supra*; FDA, *Public Health Advisory: Sepsis and Medical Abortion*, *supra*.

The FDA warns against buying Mifeprex over the internet, because a woman would "bypass important safeguards designed to protect" the woman's health—*i.e.*, the safeguards enunciated through the approved regimen in the FPL. FDA, *Mifeprex (mifepristone) Information*, *supra*. Likewise, the FDA includes Mifeprex in a list of drugs that have "serious known effects," meaning that if safety controls are bypassed, patients are placed "at higher risk." FDA, *FDA Consumer Safety Alert: Don't buy these drugs over the Internet or from foreign sources* (Mar. 9, 2010).[14]

In sum, the FDA's actions both before and after approval of the Mifeprex regimen demonstrate the agency's intent to restrict administration of this potentially dangerous drug regimen. In addition to approving the drug regimen under the only provision allowing the FDA to restrict its administration, the FDA rejected the drug manufacturer's attempts to include home administration as part of the FPL. Since approval, the FDA has continued to point out that off-label use of the drug regimen is "unapproved" and that misuse results in the bypass of safeguards. Simply put, the FDA intended to restrict the administration of the Mifeprex regimen.

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[14] Exhibit X to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/ucm202893.htm (last visited Sept. 28, 2012).

B. Medical abortion poses significant risks.

There are known risks associated with medical abortion. For example, the Mifeprex FPL states that "[n]early all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction." *Mifeprex Final Printed Labeling*, at 11 ("Mifeprex FPL").[15] These risks include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease. *Id*. at 5, 12.

In July 2011, the FDA reported 2,207 adverse events in the U.S. after women used mifepristone for the termination of pregnancy. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011).[16] Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections"). *Id*. While minor complications arising after use of the Mifeprex regimen are within the range expected, the GAO indicates that the number of women dying from fatal infection is ***not within the expected range***. U.S. Government Accountability Office ("GAO"), *GAO Report*, at 38.[17] This may be due, in large part, to the misuse of the Mifeprex regimen, as documented in subsection C, *infra*.

Yet the incidence of maternal death from bacterial infections following use of the Mifeprex regimen should not come as a surprise. Mifepristone, the first drug in the regimen,

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[15] Appendix 6, Exhibit A to Plaintiffs' Motion for Summary Judgment; Exhibit V to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[16] Exhibit P to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited Sept. 28, 2012).

[17] Appendix 4 to Plaintiffs' Motion for Summary Judgment.

interferes with the body's immune response, allowing bacteria, if present, to flourish and cause widespread, multi-organ infection in the woman. J.I. Webster & E.M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, J. ENDOCRINOLOGY 181:207-21 (2004);[18] R.P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, ANNALS OF PHARMOCOTHERAPY 39 (Sept. 2005).[19] The causal chain between mifepristone and death by toxic shock syndrome has been demonstrated in multiple animal models of septic shock, where the mortality rate increased from 13 percent to 100 percent in mifepristone-treated animals. Declaration of Donna Harrison, M.D.[20]

The safety of Mifeprex has not been tested on a large population of women, including minors or women who are heavy smokers. *Mifeprex FPL*, *supra*, at 3, 7. Yet abortion providers, including Plaintiffs, continue to administer or advocate for the ability to provide the Mifeprex regimen to minors.

Moreover, Mifeprex is contraindicated for women who do not have immediate access to emergency care, including medical facilities equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation. *Id*. at 5. Women are instructed that they should not take Mifeprex if they cannot easily get such emergency help in the two weeks following ingestion of Mifeprex, and the American College of Obstetricians and Gynecologists (ACOG) admits that women are not good candidates for medical abortion

[18] Exhibit 7 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[19] Exhibit 8 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[20] Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

if they cannot return for follow-up visits. *Id*. at 17; AGOG, *ACOG Practice Bulletin 67 Medical Management of Abortion*, at 6.[21] Yet the Plaintiffs advocate that their misuse—sending women home with the second dose in the Mifeprex regimen—is necessary for those women in "rural areas" or who would have trouble accessing the provider on multiple days. But it is these exact women—women who have trouble accessing physicians or medical care—for which the Mifeprex regimen is explicitly contraindicated.

C. Deaths following Mifeprex regimen are tied to unapproved use of the drugs.

As of April 2011, fourteen women had died following use of the Mifeprex regimen. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011).[22] Eight of these women died of bacterial infection. *Id*.

As noted by the GAO, ***these women "used a regimen of Mifeprex and misoprostol that has not been approved by the FDA,"*** and the number of deaths from bacterial infection is not within the expected range. U.S. Government Accountability Office ("GAO"), *GAO Report*, at 38-40 (emphasis added).[23] Seven of the women used misoprostol (the second drug in the regimen) vaginally—the preferred regimen of the Plaintiffs. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11, supra*. One woman died after using misoprostol buccally. *Id*.

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[21] Appendix 4, Exhibit B to Plaintiffs' Motion for Summary Judgment.

[22] Exhibit P to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited Sept. 28, 2012).

[23] Appendix 3 to Plaintiffs' Motion for Summary Judgment.

Significantly, ***no women have died from bacterial infection following administration of the FDA-approved protocol***, which, as explained above, requires oral administration of misoprostol. *Id*.

While the FDA has stated that it does not know whether using Mifeprex and misoprostol *caused* the deaths associated with bacterial infection, it repeatedly points out that the deaths resulted after unapproved off-label use. *See id*. Further, the FDA has never said that the unapproved use of the Mifeprex regimen did *not* cause the deaths; it simply states that it is not yet known.

Moreover, the FDA has continually warned against the unapproved use advocated by the Plaintiffs. After the first four women died from bacterial infection, the FDA issued a safety warning, noting that the deaths "involved the off-label dosing regimen" utilizing vaginal administration of misoprostol. FDA, *Public Health Advisory: Sepsis and Medical Abortion* (Mar. 17, 2006).[24]

By August 2008, six women had died from bacterial infection. As reported by the GAO, the FDA determined that "in all six of the deaths, the women used a Mifeprex treatment regimen that has not been approved by the FDA." GAO, *GAO Report*, *supra*, at 7.

In response to concerns about these fatal infections, Planned Parenthood—the nation's largest abortion provider—stopped administering misoprostol vaginally. *See* M. Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortion*,

[24] Exhibit W to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm051298.htm (last visited Sept. 28, 2012).

N.E.J.M. 361:145-51 (2009).[25] Yet that is the unapproved administration that is advocated by the Plaintiffs here.

Thus, in 2011, the Legislature was faced with the following facts: eight women have died from bacterial infection following unapproved use of the Mifeprex regimen. These deaths sparked warnings from the FDA and had caused a major abortion provider to switch to a different (albeit still unapproved) administration of the drugs. On the other hand, not a single woman has died from bacterial infection following the FDA-approved administration of the Mifeprex regimen. While direct causation has not yet been established, neither has it been established that the unapproved use did not cause the deaths. The Legislature passed the Act in an attempt to ensure that no other women die following unapproved use of a dangerous abortion-inducing drug. As discussed in Part III, *infra*, at the very least this decision is entirely in accord with the wide discretion given the Legislature to protect women's health and safety by regulating abortion in areas of "medical uncertainty."

D. Medical abortion poses more complications than surgical abortion alternatives.

As this court is aware, the Act requires that abortion-inducing drugs be administered according to the protocol outlined in the final printed labeling. In the case of the Mifeprex regimen, the Mifeprex FPL controls the administration of both Mifeprex and misoprostol. That FPL requires that the Mifeprex regimen be administered only through 49 days gestation. The Plaintiffs, on the other hand, want to administer the Mifeprex regimen through 63 days gestation.

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[25] Instead, Planned Parenthood began administering misoprostol buccally, which is still an unapproved use. *See* M. Fjerstad et al., *supra*. In fact, ACOG does not recognize buccal use as an appropriate administration. *See generally* ACOG, *ACOG Practice Bulletin 67 Medical Management of Abortion*, in Appendix 4, Exhibit B to Plaintiffs' Motion for Summary Judgment.

That is the difference of two weeks—from 7 weeks to 9 weeks. During those two weeks, which are still in the first trimester and early in pregnancy, other surgical abortion alternatives are available. As such, the Act is not in any way an abortion ban, but is a restriction predicated upon which procedures can be safely used. Furthermore, abortion providers consider surgical abortion in the first trimester to be "very safe." Planned Parenthood, *In-Clinic Abortion Procedures* (2012).[26]

Moreover, evidence in the record demonstrates that medical abortion actually poses more complications than surgical abortion. Peer-reviewed studies have found that the overall incidence of immediate adverse events is ***fourfold higher*** for medical abortions than for surgical abortions. M. Niinimaki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBSTET. GYNECOL. 114:795 (Oct. 2009).[27]

In particular, hemorrhage and incomplete abortion are more common after medical abortions. One study found the incidence of hemorrhage is 15.6 percent following medical abortions, compared to 5.6 percent for surgical abortions. *Id*. The study also found 6.7 percent of medical abortions result in incomplete abortion, compared to 1.6 percent of surgical abortions. *Id*. Further, 5.9 percent of women required surgery after medical abortion up to 63 days gestation. *Id*. Yet another study found that medical abortion failed in 18.3 percent of patients and that surgical abortion failed in only 4.7 percent of patients. J.T.

[26] Exhibit Z to Defendants' Response to Plaintiffs' Motion for Summary Judgment. Also available at http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp (last visited Sept. 28, 2012).

[27] Exhibit 4 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

Jenson et al., *Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study*, CONTRACEPTION 59:153-59 (1999).[28]

Patients who undergo medical abortions also report significantly longer bleeding and higher levels of pain, nausea, vomiting, and diarrhea than women who undergo surgical abortions. *Id*.

Medical abortion also poses a greater risk of bacterial infection than does surgical abortion. The Centers for Disease Control and Prevention (CDC) has found a risk of death from C. sordelli (bacterial infection) in medical abortion to be 1/100,000, while the risk of death from surgical abortion at the same gestational age is 0.1/100,000. This means that the death rate from a C. sordelli infection alone during or following a medical abortion is ten times the death rate from all causes following a surgical abortion at a comparable gestational age. Declaration of Donna Harrison, M.D.;[29] M. Fisher et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordelli after Medical Abortion*, N.E. J.M. 353:2352-60 (2005).[30]

Moreover, admissions by ACOG—entered into the record by the Plaintiffs—confirm that surgical abortion is not only an alternative to medical abortion, but perhaps a better, safer alternative. ACOG admits that medical abortion fails more often than surgical abortion. ACOG, *ACOG Practice Bulletin 67 Medical Management of Abortion*, at Table 2;[31] *see also*

[28] Exhibit 5 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[29] Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[30] Exhibit 6 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment.

[31] Appendix 4, Exhibit B to Plaintiffs' Motion for Summary Judgment.

J.T. Jenson et al., *supra*. The success rate of medical abortion is only 95 percent, while the success rate of surgical abortion is 99 percent. ACOG, *ACOG Practice Bulletin 67 Medical Management of Abortion*, *supra*, at Table 2. ACOG also outlines that medical abortion requires two or more visits, while surgical abortion usually requires only one. *Id.* Medical abortion can take days or weeks to complete, but surgical abortion is complete in a shorter, predictable period of time. *Id*. Medical abortion requires follow-up to ensure completion of the abortion, but surgical abortion does not require follow-up in all cases. *Id*. And finally, medical abortion requires patient participation throughout a multistep process, while surgical abortion requires patient participation in a single-step process. *Id*.[32]

Thus, adequate "safe" alternatives to medical abortion exist in the first trimester.

PROPOSITION 3:

PLAINTIFFS CANNOT MEET THEIR SUPREME COURT-IMPOSED BURDEN OF PROVING THAT UNAPPROVED USE OF THE MIFEPREX REGIMEN IS NOT HARMFUL TO WOMEN'S HEALTH.

Plaintiffs completely fail to sustain their burden of proof on their "undue burden" claim. First, Oklahoma has an important and legitimate interest in protecting women from the harms of abortion, and that includes the harms associated with the unapproved use of the Mifeprex regimen. This state interest has been affirmed time and time again by the Supreme Court. The Act is a regulation designed to "foster the health of a woman seeking an

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[32] Along similar lines, at least one study has found that women prefer the FDA-approved oral administration of misoprostol to the unapproved buccal administration. B. Winikoff et al., *Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial*, OBSTET. GYNECOL. 112(6):1303-10 (Dec. 2008), in Exhibit 9 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment. In that study, 93.6 percent of women who took misoprostol orally responded that they would prefer to take the drug orally again in a subsequent medical abortion, while only 34.0 percent of women who took misoprostol buccally responded that they would prefer buccal administration in a subsequent medical abortion. *Id*.

abortion." *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 878 (1992). The State is free to enact regulations to further the health or safety of women seeking abortion. *Id.*

Second, the State properly exercised its wide discretion and interest in protecting women when it passed the Act. *See Gonzales v. Carhart*, 550 U.S. 124, 163 (2007). It is clear that, at most, Plaintiffs can merely demonstrate that there is a range of opinion on the safety of unapproved use of the Mifeprex regimen—and, therefore, its claims fail under *Gonzales*. Plaintiffs attempt to shift the burden to the State to prove a causal connection between the Mifeprex regimen and death. But *Gonzales* makes clear that it is Plaintiffs' burden to prove that those deaths were *not* caused by off-label use of the Mifeprex regimen. This is impossible for Plaintiffs to do, given the FDA's warnings against unapproved use, the fact that all eight women who died from bacterial infection used an unapproved administration and no woman has died from a bacterial infection following the FDA-approved administration, as well as the aforementioned medical data demonstrating the harms of the Mifeprex regimen.

Third, adequate alternatives exist for women who are past the 49-day gestational limit imposed by the FDA. Not only are these alternative surgical procedures available to women, but peer-reviewed studies indicate that these surgical procedures involve fewer complications than medical abortions. Plaintiffs are not "entitled to ignore regulations that direct [them] to use reasonable alternative procedures." *Gonzales*, 550 U.S. at 163. Plaintiffs do not have "unfettered choice in the course of [their] medical practice." *Id.*

Moreover, the Act does not prohibit all "commonly used and generally accepted" methods of abortion and thus, as clearly indicated under *Gonzales*, it does not "construct a

substantial obstacle to the abortion right." *Id*. at 164. Where standard medical options are available—as they are here—"mere convenience does not suffice to displace them." *Id*. at 166.

Just last week, the Sixth Circuit Court of Appeals rejected a claim by Planned Parenthood that an Ohio regulation of the Mifeprex regimen creates an undue burden. *See Planned Parenthood Southwest Ohio Region v. DeWine*, Slip. Op., No. 11-4062 (6th Cir. Oct. 2, 2012). Relying on *Casey*, the court noted that "the Supreme Court has not articulated any rule that would suggest that the right to choose abortion encompasses the right to choose a particular abortion method." Slip. Op. at 34 (McKeague, J., writing the opinion for the majority as to Part VI). Like the Plaintiffs here, the court concluded that Planned Parenthood "[h]ad not carried its burden in this case." *Id*. at 33 n.1.

Altogether, it is clear that the Act is not an abortion ban. It is not aimed at inhibiting the "abortion right." To the contrary, it is a medical regulation promulgated within the State's wide discretion, aimed at protecting the health and welfare of women. As such, there is no "undue burden," and it must be upheld.

CONCLUSION

Amici respectfully request that the decision of the district court be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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