No. 12-1094

In The
Supreme Court of the United States

TERRY CLINE, ET AL.,

Petitioners,

v.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The Oklahoma Supreme Court

AMICUS CURIAE BRIEF OF 79 OKLAHOMA LEGISLATORS IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici Curiae are 27 Senators and 52 Representatives in the state of Oklahoma who support House Bill (HB) 1970, codified at 63 Okla. Stat. § 1-729a. *Amici* represent the majority of the Oklahoma Legislature, including a majority of each Chamber.

Amici include Senators Cliff Aldridge, Mark Allen, Don Barrington, Brian Bingman,[2] Josh Brecheen, Rick Brinkley, Corey Brooks, Bill Brown, Brian Crain, Nathan Dahm, Kim David, Eddie Fields, John Ford, Ann Griffin, Jim Halligan, Rob Johnson, Clark Jolley, Kyle Loveless, Bryce Marlatt, Mike Mazzei, Dan Newberry, Mike Schulz,[3] Wayne Shaw, Frank Simpson, Rob Standridge, Gary Stanislawski, and Greg Treat,[4] and Representatives Gary Banz, John Bennett, Scott Biggs, Lisa Billy, Gus Blackwell, David Brumbaugh, Dennis Casey, Mike Christian, Bobby Cleveland, Josh Cockroft, Donnie Condit, Lee

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[1] Pursuant to this Court's Rule 37.2(a), the parties have received at least 10 days notice of the intent to file this brief, and the parties have represented that they will submit to the Clerk blanket consents to the filing of all *amicus* briefs. Written consent is also filed along with this brief. Pursuant to this Court's Rule 37.6, *Amici* state that no counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

[2] President Pro Tempore of the Senate.

[3] Majority Floor Leader of the Senate.

[4] Official sponsor of HB 1970 when it was considered in the Oklahoma Senate.

Denney, David Derby, Jon Echols, John Enns, Dan Fisher, Randy Grau,[5] Elise Hall, Tommy Hardin, Arthur Hulbert, Mike Jackson,[6] Dennis Johnson, Charlie Joyner, Sally Kern, James Lockhart, Scott Martin, Mark McBride, Mark McCullough, Randy McDaniel, Skye McNiel, Lewis Moore, Glen Mulready, Jason Murphey, Jason Nelson, Tom Newell, Jadine Nollan, Charles Ortega, Leslie Osborn, Pat Ownbey, Marty Quinn, Dustin Roberts, Mike Sanders, T.W. Shannon,[7] Jason Smalley, Todd Thomsen, Mike Turner, Steve Vaughan, Ken Walker, Weldon Watson, Paul Wesselhoft, Justin Wood, and Harold Wright.

As Legislators who sponsored, voted for, and/or support HB 1970, *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 by this Court, this is an important interest that vests in the State at the outset of pregnancy.

Third, *Amici* seek to demonstrate that the Legislature should be afforded the "wide discretion" this Court has given legislatures when there is medical

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[5] Official sponsor of HB 1970 when it was considered in the Oklahoma House of Representatives.

[6] Speaker Pro Tempore of the House of Representatives.

[7] Speaker of the House of Representatives.

uncertainty about the safety of a particular abortion method.

Amici urge this Court to grant the petition for certiorari and reverse the court below.

SUMMARY OF THE ARGUMENT

There are two general categories of abortion: surgical and chemical (or medical). Surgical abortion involves the use of instruments to empty the uterus. Examples include aspiration and dilation and evacuation (D&E). Abortion providers consider surgical abortion in the first trimester "extremely safe." *See*, *e.g.*, *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490, 494 (6th Cir. 2012); Planned Parenthood, *In-Clinic Abortion Procedures* (2013).[8] According to the Guttmacher Institute, the majority of first trimester abortions are surgical abortions. *See* Guttmacher Institute, *Facts on Induced Abortion in the United States* (Aug. 2011).[9]

Chemical abortion, on the other hand, involves the use of abortion-inducing drugs. The recommended method of chemical abortion in the United States is the combined use of mifepristone and misoprostol. American College of Obstetricians and Gynecologists

[8] http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp.

[9] http://www.guttmacher.org/pubs/fb_induced_abortion.html.

(ACOG), *ACOG Practice Bulletin 67 Medical Management of Abortion* (Oct. 2005). In the United States, mifepristone is marketed under the brand name "Mifeprex." *Mifeprex Final Printed Labeling* ("*Mifeprex FPL*").[10] Together, the administration of Mifeprex and the second drug, misoprostol – the only method of chemical abortion approved by the Food and Drug Administration (FDA) – is known as the Mifeprex regimen. The Guttmacher Institute reports that chemical abortion accounts for only one-fourth of abortions during the first nine weeks of pregnancy. Guttmacher Institute, *supra*.

According to the FDA, there have been 2,207 reported adverse events related to use of the Mifeprex regimen, including 14 deaths. Eight deaths were the result of bacterial infection, and each death followed an unapproved use of the Mifeprex regimen. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011).[11] On the other hand, the FDA has not received a single report of a woman dying from bacterial infection following the use of the FDA-approved protocol.

Concerned that women were dying following misuse of the Mifeprex regimen, many state legislatures around the country sought to protect maternal health

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[10] http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf.

[11] http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

by limiting the administration of the regimen to that protocol approved by the FDA. In 2004, Ohio became the first state to enact such a law, and the Sixth Circuit Court of Appeals has determined that it does not pose an "undue burden." *See DeWine*, 696 F.3d 490 (one issue remains before the trial court).[12]

Then in 2011, the legislature in Oklahoma enacted House Bill (HB) 1970 – a law designed and enacted to protect women from the dangerous unapproved use of abortion-inducing drugs. Specifically, it requires that the Mifeprex regimen be administered in the way approved by the FDA. It does not ban the use of the Mifeprex regimen, nor does it ban any abortion before or after 49 days gestation. HB 1970 simply requires that the regimen be administered in the way deemed safest by the FDA. Other "safe" alternatives exist for women with pregnancies beyond 49 days gestation. The Act imposes no obstacle to obtaining an abortion.

Despite the fact that eight women have died from bacterial infection after unapproved use of the Mifeprex regimen – with the FDA reporting no deaths from bacterial infection following administration of the FDA-approved protocol – the Respondents filed this facial attack in state court, seeking to continue the unapproved use of the Mifeprex regimen. The

[12] Similar laws have been enacted in Arizona and North Dakota. The law in Arizona has not been challenged and is currently in effect; the law in North Dakota is in litigation.

Oklahoma Supreme Court issued an opinion stating, without discussion, that HB 1970 is facially unconstitutional under *Planned Parenthood of Southeastern Pennsylvania v. Casey,* 505 U.S. 833 (1972).

Important here is the fact that HB 1970 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. It is an interest the state maintains from the "outset of pregnancy." *See* Part I, *infra*. 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, and such laws do not pose an "undue burden." *See* Part II, *infra*.

However, the Oklahoma Supreme Court completely ignored this Court's decision in *Gonzales v. Carhart*, 550 U.S. 124 (2007) and misapplied *Casey,* concluding that the law violates federal precedents. The court did so without even mentioning the abundant data – presented by both Petitioners and Respondents – demonstrating that the Legislature should have been afforded "wide discretion" in regulating a procedure with known risks and "safe" alternatives. This data included evidence that the FDA intended to restrict use of the Mifeprex regimen for safety reasons; that chemical abortion poses significant risks; that eight women have died from bacterial infection following misuse of the Mifeprex regimen, while no women have died from bacterial infection following use of the FDA-approved protocol;

and that standard, safer alternatives to chemical abortion are available to women. *See* Part III, *infra*.

When this Court's precedents in *Casey* and *Gonzales* are properly examined, it becomes clear that a regulation aimed at protecting maternal health that does not prevent a woman from obtaining an abortion is not an "undue burden" and must survive a facial challenge. *See* Part IV, *infra*.

ARGUMENT

I. States have a legitimate interest in the woman's health from the outset of pregnancy and rational medical regulations do not pose an "undue burden."

In both *Gonzales v. Carhart* and *Planned Parenthood v. Casey*, this Court affirmed *Roe v. Wade*'s "essential" holding, which specifically included "the principle that the State has legitimate interests from the outset of pregnancy in protecting the health of the woman." *Gonzales*, 550 U.S. 124, 145 (2007); *Casey*, 505 U.S. at 846 (both citing *Roe v. Wade*, 410 U.S. 113 (1973)). *Roe* "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 876-77. This principle must "coexist" with other principles outlined in *Roe*. *Gonzales*, 550 U.S. at 158.

Likewise, the Court concluded in *Casey* that some interpretations of *Roe* could not be "reconciled with the holding in *Roe* itself that the State has legitimate interests in the health of the woman," and such interpretations "contradicted the State's permissible exercise of its powers." *Casey*, 505 U.S. at 871, 872. The Court then "rejected . . . the interpretation of *Roe* that considered all previability regulations of abortion unwarranted." *Gonzales*, 505 U.S. at 146. Such interpretations "led to the striking down of some abortion regulations which in no real sense deprived women of the ultimate decision." *Casey*, 505 U.S. at 875. Those interpretations went too far. *Id*.

Thus, instead of supporting such "zero tolerance policies" as had been applied to some abortion regulations in the past, the Court utilized an "undue burden" standard, examining whether a state regulation had the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. *See Gonzales*, 550 U.S. at 166; *Casey*, 505 U.S. at 877, 878. What is at stake is the "woman's right to make the ultimate decision" – not a right to be insulated from all others in doing so. *Casey,* 505 U.S. at 877. Likewise, it is not a right to be insulated from restrictions enacted to protect her health and safety. There is no constitutional right to abortion on demand. *Id*. at 887. There is no right to an unsafe abortion.

Both *Casey* and *Gonzales* demonstrate that a reasonable medical regulation enacted to protect the woman's health is not an undue burden. In fact, "[a]s

with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion." *Id*. at 878. Only those restrictions that are *unnecessary* and have the purpose or effect of presenting a *substantial obstacle* impose an undue burden. *Id*. But as demonstrated in *Gonzales*, states are given "wide discretion" when there is uncertainty about a particular procedure, and as such a regulation of that procedure cannot be deemed "unnecessary." Further, the presence of safe alternatives means that a regulation of one particular abortion method cannot impose a "substantial obstacle." *See* Part II, *infra*.

Recently, the Sixth Circuit Court of Appeals concluded that Ohio's law requiring physicians to abide by the FDA-approved protocol when administering the Mifeprex regimen does not pose an "undue burden." *DeWine*, 696 F.3d 490. In fact, the Sixth Circuit concluded that there was *no evidence* that the Ohio law would impose an undue burden. *Id*. at 514. Instead, the evidence showed that women who were affected by the limitations in the law went on to obtain surgical abortions. *Id*. at 516. Relying on *Casey*, the Sixth Circuit 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." *Id*. at 514-15.

II. States have "wide discretion" to regulate abortion when there is "medical and scientific uncertainty," and such regulations do not pose an "undue burden."

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

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-viability abortion procedure, but a *complete ban* of a particular pre-viability procedure. *See Gonzales*, 550 U.S. at 147, 156.

After recognizing that the government "has an interest in protecting the integrity and ethics of the medical profession" and declaring that the state has a "significant role to play in regulating the medical profession," the Court stated, "[w]here 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 157, 158 (emphasis added).

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, 163. This Court then concluded that precedents *instruct* that such laws survive facial attacks. *Id*. at 163. 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 *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")) (other citations omitted).

Importantly, the Court concluded that "[p]hysicians 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. . . ." *Id*. at 163. In *Gonzales*, the medical uncertainty over whether the ban's prohibition created a significant health risk provided sufficient basis to conclude (in that facial attack) that the ban did not impose an undue burden. *Id*. at 164.

The Court also stated that its conclusion was supported by other considerations. First and foremost, alternatives to partial-birth abortion were available. *Id*. One alternative procedure had "extremely low rates of medical complications" and was "generally the safest method of abortion." *Id*. The Court contrasted the situation in *Gonzales* with the situation in *Planned Parenthood of Central Missouri v. Danforth*, in which the Court invalidated a

prohibition on saline amniocentesis – then the dominant method of second-trimester abortion. *Id*. at 164-65 (citing *Danforth*, 428 U.S. 52 (1976)). Unlike the prohibition in *Danforth*, the prohibition in *Gonzales* allowed "a commonly used and generally accepted method, so it [did] not construct a substantial obstacle to the abortion right." *Id.* at 165.

Further, the Court concluded that a "zero tolerance policy" – which would strike down legitimate abortion regulations if some part of the medical community is disinclined to follow the regulation – is too exacting a standard to impose on legislative power. *Id*. at 166. Instead, considerations of marginal safety, including the balance of risks, are within the legislative competence when a regulation is rational and in pursuit of legitimate ends. *Id*. The Court stated, "[w]hen 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*.

Simply put, when there is uncertainty over the safety of a regulated procedure and there is availability of other procedures that are considered to be safe alternatives, a law cannot be invalid on its face. *Id*. at 164-65. In fact, this Court held that such facial attacks should not be entertained in the first place. *Id*. at 167.

III. Data presented by both parties supports HB 1970 and the "wide discretion" of the Oklahoma legislature.

The Oklahoma Legislature relied on data demonstrating that the Mifeprex regimen carries significant risks, especially when misused. This evidence is detailed in the record – in testimony and documents provided by both the Petitioners and the Respondents – but was ignored completely by the courts below.[13] Specifically, the evidence demonstrated the following, which supported the legislature's "wide discretion" in enacting HB 1970: 1) the FDA intended to restrict use of the Mifeprex regimen for safety reasons; 2) chemical abortion poses significant risks; 3) eight women have died from bacterial infection following misuse of the Mifeprex regimen, while no women have died from bacterial infection following use of the FDA-approved protocol; and 4) standard, safer alternatives to chemical abortion are available.

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

The FDA's intent to restrict the use of the Mifeprex regimen was reflected throughout the approval process, with the authorization of the regimen explicitly

[13] The trial court decided the case on summary judgment. The evidence before that court consisted of affidavits and exhibits submitted by the parties. All sources referenced in Part III were submitted by one or both parties and were contained in the record.

conditioned upon the FDA's ability to restrict the use of the drugs. This intent continues to be specified in the Mifeprex final printed labeling (FPL), in the Patient Agreement required by the FDA, and in continued communications and safety warnings issued by the FDA.

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). Under Subpart H, the FDA can "require such postmarketing restrictions as are needed to assure safe use" of the drug approved. *Id*.

Prior to approving the Mifeprex regimen, the FDA informed the drug sponsor that restrictions "on the distribution and use of mifepristone are needed to assure safe use" of the Mifeprex regimen. FDA, *Feb. 2000 Approvable Letter*, page 5. At that time, the FDA also instructed the sponsor to use the FDA-recommended language for the product's FPL. *Id*. at 4-5. The FDA concluded that available data did not support the safety of home use of misoprostol, and – as documented in evidence presented by the Respondents – the FDA ***rejected*** information in the FPL on self-administering misoprostol at home. U.S. Government Accountability Office, *Food and Drug Administration: Approval and Oversight of the Drug*

Mifeprex (Aug. 2008), at 23 ("*GAO Report*").[14] In its approval letter, the FDA reiterated that the regimen was approved under Subpart H and outlined restrictions on use – including a required "Patient Agreement." FDA, *Sept. 2000 Approval Letter*.

The FPL for the Mifeprex regimen outlines the FDA-approved dosage and administration of both Mifeprex and misoprostol. *Mifeprex FPL*, *supra*. The FPL states explicitly that a woman should not take Mifeprex if "it has been more than 49 days (7 weeks) since" her last menstrual period began. *Id*. at 5, 9, 17.

In addition to restricting the time frame in which the Mifeprex regimen is to be used, the FDA-approved FPL provides explicit dosage and administration instructions for both mifepristone (Mifeprex) and misoprostol:

> Treatment with ***Mifeprex and misoprostol*** for the termination of pregnancy ***requires*** three office visits by the patient. Mifeprex should be prescribed only by physicians who have read and understood the prescribing information. Mifeprex may be administered 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. . . .

[14] http://www.gao.gov/new.items/d08751.pdf.

> **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).

The "Patient Agreement" – referenced in the FPL and the September 2000 Approval letter – provides further evidence that the FDA intended to limit use of the Mifeprex regimen to the FDA-approved protocol found in the FPL. Before administration of the Mifeprex regimen, the patient, along with the physician, must attest to a number of statements, including 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 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 Respondents 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 deviations as "evidence-based." The regimen outlined in the Mifeprex FPL is repeated throughout FDA communications as the only "approved" use. *See*, *e.g.*, FDA, *Mifeprex (mifepristone) Information* (July 19, 2011);[15] FDA, *Mifeprex Questions*

[15] http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111323.htm.

and Answers (Feb. 24, 2010);[16] FDA, *Public Health Advisory: Sepsis and Medical Abortion* (Mar. 17, 2006).[17]

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, *Public Health Advisory: Sepsis and Medical Abortion*, *supra*. And after four women died from bacterial infection following use of the Mifeprex regimen, 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*, *supra*.

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 regimen.

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[16] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm.

[17] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm051298.htm.

B. Chemical abortion poses significant risks.

There are known risks associated with chemical 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 FPL, supra*, at 11. These risks include, but are not limited to, uterine hemorrhage, viral infections, and pelvic inflammatory disease. *Id*. at 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*, *supra*. Among those were 14 deaths, 612 hospitalizations (excluding deaths), 339 blood transfusions, and 256 infections (including 48 "severe infections"). *Id*.

Evidence provided to the trial court *by the Respondents* declared that the number of women dying from fatal infection is ***not within the expected range***. *GAO Report*, *supra*, at 38. This may be due, in large part, to the misuse of the Mifeprex regimen, as discussed in Part III.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, 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); R.P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, ANNALS OF PHARMOCOTHERAPY 39 (Sept. 2005).

Further, the safety of the Mifeprex regimen 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 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 should not take Mifeprex if they cannot easily get such emergency help in the two weeks following ingestion, and the American College of Obstetricians and Gynecologists (ACOG) instructs that women are not good candidates for chemical abortion if they cannot return for follow-up visits. *Id*. at 17; ACOG, *supra*, at 6. Yet abortion advocates, like the Respondents, continue to advocate for the unsupervised, unapproved use of the Mifeprex regimen for women in "rural areas" who do not have adequate access to healthcare.

C. Eight women have died from bacterial infection following misuse of the Mifeprex regimen, while no women have died from bacterial infection following use of the FDA-approved protocol.

As of April 2011, eight women had died of bacterial infection following use of the Mifeprex regimen. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11*, *supra*. As noted in Respondents' evidence, ***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***. *GAO Report*, *supra*, at 38-40 (emphasis added). Specifically, seven of the women used misoprostol (the second drug in the regimen) vaginally instead of orally – the preferred regimen of the Respondents. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11*, *supra*. One woman used misoprostol buccally. *Id*.

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 in an unapproved manner *caused* the deaths associated with bacterial infection, it repeatedly points out that the deaths resulted after unapproved use. *See* Part III.A., *supra*. 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.

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*, N.E.J.M. 361:145-51 (2009).[18] Yet this is the unapproved administration advocated by the Respondents here.

Thus, eight women have died from bacterial infection following unapproved use of the Mifeprex regimen. These deaths sparked warnings from the FDA and 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 HB 1970 in an attempt to ensure that no other women die following unapproved use of a dangerous abortion-inducing drug. At the very least, HB 1970 is

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[18] Instead, Planned Parenthood began administering misoprostol buccally, which is still an unapproved use. *See* M. Fjerstad et al., *supra*. ACOG does not recognize buccal use as an appropriate administration. *See generally* ACOG, *supra*.

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. Standard, safer alternatives to chemical abortion are available.

The Mifeprex FPL requires that the Mifeprex regimen be administered only through 49 days gestation. The Respondents, on the other hand, want to administer the Mifeprex regimen through 63 days gestation.

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, common surgical abortion alternatives are available. As such, HB 1970 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." *See*, *e.g.*, Planned Parenthood, *supra*.

Moreover, evidence before the trial court demonstrated that chemical abortion actually poses more complications than surgical abortion. One peer-reviewed study found that the overall incidence of immediate adverse events is ***fourfold higher*** for chemical 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).

In particular, hemorrhage and incomplete abortion are more common after chemical abortions. Researchers found the incidence of hemorrhage is 15.6 percent following chemical abortions, compared to 5.6 percent for surgical abortions. *Id*. Further, 6.7 percent of chemical abortions result in incomplete abortion, compared to 1.6 percent of surgical abortions. *Id*.

Yet another study found that chemical abortion failed in 18.3 percent of patients and that surgical abortion failed in only 4.7 percent of patients. J.T. Jensen et al., *Outcomes of suction curettage and mifepristone abortion in the United States: A prospective comparison study*, CONTRACEPTION 59:153-59 (1999). Patients who undergo chemical abortions also report significantly longer bleeding and higher levels of pain, nausea, vomiting, and diarrhea than women who undergo surgical abortions. *Id*.

Moreover, admissions by ACOG – entered into the record by the Respondents – confirm that surgical abortion is not only an alternative to chemical abortion, but perhaps a better, safer alternative. ACOG admits that chemical abortion fails more often than surgical abortion. ACOG, *supra*, at 4 (Table 2). Chemical abortion can take days or weeks to complete, but surgical abortion is complete in a shorter, predictable period of time. *Id*.[19]

[19] Similarly, at least one study has found that women prefer the FDA-approved oral administration of misoprostol to the

(Continued on following page)

Thus, commonly used "safe" alternatives to chemical abortion exist in the first trimester.

IV. The Oklahoma Supreme Court failed to properly apply *Casey* and *Gonzales* and should be reversed, providing appropriate guidance to the legislatures in all 50 states.

This Court's precedents in *Casey* and *Gonzales* make clear that the Oklahoma Supreme Court erred in holding HB 1970 facially unconstitutional. A proper application of *Casey* and *Gonzales* would acknowledge the state's interest in protecting women's health as well as the "wide discretion" afforded to legislatures when there is medical uncertainty concerning a particular abortion method.

First, HB 1970 is a regulation designed to "foster the health of a woman seeking an abortion." *Id*. at 878. Oklahoma has an "important" and "legitimate" interest in protecting maternal health from the outset of pregnancy. Over 2,200 adverse events related to the Mifeprex regimen have been reported to the FDA, and every woman that has died of bacterial infection following administration of the Mifeprex regimen used the drugs in an unapproved manner. The State

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unapproved buccal administration. B. Winikoff et al., *Two distinct oral routes of misoprostol in mifepristone medical abortion: A randomized controlled trial*, OBSTET. GYNECOL. 112:1303-10 (Dec. 2008).

is free to enact regulations ensuring safe use of drugs in order to further the health and safety of women in the state. *Id*.

Second, HB 1970 is a proper extension of the State's "wide discretion" to enact laws when there is medical uncertainty about a procedure. As in *Gonzales*, the medical disagreement over the safety of unapproved administration of the Mifeprex regimen is a sufficient basis to conclude that HB 1970 does not impose an undue burden. *Gonzales*, 550 U.S. at 164. Under *Gonzales*, HB 1970 cannot be invalid on its face because there is medical disagreement over the safety of off-label use of the Mifeprex regimen and because standard, safer medical options are available.

HB 1970 allows surgical abortion – a commonly used and generally accepted method of abortion – and, therefore, it does not construct a substantial obstacle to the "abortion right." *Id*. at 164-65. As noted in *DeWine*, a similar law in Ohio has not prevented women from obtaining surgical abortions. *DeWine*, 696 F.3d at 516. Thus, a medically appropriate regulation of one abortion method – when another "commonly used and generally accepted" abortion method is available – does not in any sense deprive women of the "ultimate decision." *See Gonzales*, 550 U.S. at 164-65; *Casey*, 505 U.S. at 875.

Respondents' preferences cannot displace these other options. *Gonzales*, 550 U.S. at 166. In fact, unlike the situation in *Danforth*, chemical abortion is not the dominant method of abortion used in the first

trimester. *See id.* at 164-65 (discussing *Danforth*); Guttmacher Institute, *supra*.

Third, Oklahoma has a "significant role to play in regulating the medical profession." *Gonzales*, 550 U.S. at 157. This includes prohibiting physicians from using a protocol that is not approved by the FDA and has been linked to the deaths of eight women. And as determined in *Gonzales*, the Respondents do not have "unfettered choice" and they are not entitled to "ignore regulations that direct them to use reasonable alternative procedures," whether that be following the FDA-approved protocol or performing a surgical abortion. Likewise, the Sixth Circuit noted that this Court has not suggested that the abortion "right" encompasses the right to choose a particular method of abortion. *DeWine*, 696 F.3d at 514-15.

Finally, Oklahoma has an "interest in protecting the integrity and ethics of the medical profession." *Gonzales*, 550 U.S. at 157. Here, it is clearly not ethical for physicians to sign a "Patient Agreement" claiming that the woman is not more than 49 days gestation when he or she knows that the woman's pregnancy dates longer than 49 days. Nor is it ethical for physicians to direct women to sign documents claiming to be only 49 days pregnant when they are not. In addition to protecting women from the potentially deadly effects of unapproved use of the Mifeprex regimen, Oklahoma is acting to curtail such falsifying of documents – clearly an unethical, dangerous practice in the medical field.

But instead of giving proper weight to the State's interests and wide discretion, the Oklahoma Supreme Court utilized a "zero tolerance policy" that was rejected in *Casey* and *Gonzales*. The Oklahoma Supreme Court's holding cannot be reconciled with the "holding in *Roe* itself that the State has legitimate interests in the health of the woman." *Casey*, 505 U.S. at 871-72. Nor can it be reconciled with the Sixth Circuit's recent decision upholding a virtually identical law. *See DeWine*, 696 F.3d 490.

Instead, the Oklahoma Supreme Court struck down a law "which in no real sense deprive[s] women of the ultimate decision." *Casey*, 505 U.S. at 875. HB 1970 is not an abortion ban. 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 the decision of the Oklahoma Supreme Court should be reversed.

CONCLUSION

The petition for writ of certiorari should be granted, and the decision of the Oklahoma Supreme Court should be reversed.

Respectfully submitted,

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