No. 13-51008

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL HEALTH SERVICES, et al.,

Plaintiffs-Appellees,

v.

ATTORNEY GENERAL GREGORY ABBOTT, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Western District of Texas
(No. 13-862, Hon. Lee Yeakel)

Amicus Curiae Brief of **American Association of Pro-Life Obstetricians & Gynecologists**, **Christian Medical Association**, **Catholic Medical Association**, **Physicians for Life**, **National Association of Pro Life Nurses, National Association of Catholic Nurses, and The National Catholic Bioethics Center** in Support of Defendants-Appellants and Reversal of the District Court

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that the following listed persons or entities have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Plaintiffs-Appellees:

Planned Parenthood of Greater Texas Surgical Health Services

Planned Parenthood Center for Choice

Planned Parenthood Sexual Healthcare Services

Whole Women's Health

Austin Women's Health Center

Killeen Women's Health Center

Southwestern Women's Surgery Center

West Side Clinic, Inc.

Routh Street Women's Clinic

Houston Women's Clinic

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Other Interested Persons or Entities:

Amici are unaware of any other interested persons or entities.

***Amici**:*

American Association of Pro-Life Obstetricians & Gynecologists

Christian Medical Association

Catholic Medical Association

Physicians for Life

National Association of Pro Life Nurses

The National Catholic Bioethics Center

Amici have no parent corporations or stock of which a publicly held corporation can hold.

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae are national organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting maternal health in their roles as healthcare providers, medical experts, and consumers. As healthcare professionals, *Amici* provide this court with a wide range of data supporting the protection of women's health through the regulation of chemical abortions. When this data is evaluated in the context of *Planned Parenthood v. Casey* and *Gonzales v. Carhart*, it is clear that Texas House Bill (HB) 2 is a regulation aimed at protecting maternal health that does not prevent a woman from obtaining an abortion, is not an "undue burden," and does not require a broad "health" exception in order to be constitutionally viable.

Amici include the following medical and ethics associations:

American Association of Pro-Life Obstetricians & Gynecologists ("AAPLOG") is a non-profit professional medical organization consisting of 2,500 obstetrician-gynecologist members and associates. AAPLOG held the title of "special interest group" within the American College of Obstetricians & Gynecologists (ACOG) for 40 years, from 1973 until 2013, until ACOG

[1] In accordance with Fed. R. App. P. 29, the parties have consented to the filing of this *amicus* brief. No party's counsel has authored the brief in whole or in part. No party or party's counsel has contributed money intended to fund preparing or submitting this brief. No person other than *Amici*, their members, or their counsel has contributed money that was intended to fund preparing or submitting this brief.

discontinued the designation of "special interest group." AAPLOG is extremely concerned about the potential long-term adverse consequences of abortion on a woman's future health and continues to explore data from around the world regarding abortion-associated complications (such as depression, substance abuse, suicide, other pregnancy-associated mortality, subsequent preterm birth, and placenta previa) in order to provide a realistic appreciation of abortion-related health risks.

Christian Medical Association, founded in 1931, is a non-profit national organization of Christian physicians and allied healthcare professionals with almost 16,000 members. In addition to its physician members, it also has associate members from a number of allied health professions, including nurses and physician assistants. Christian Medical Association provides up-to-date information on the legislative, ethical, and medical aspects of abortion and its impact on maternal health.

Catholic Medical Association is a national non-profit organization comprised of almost 2,000 members covering over 75 medical specialties. Catholic Medical Association helps to educate the medical profession and society at large about issues in medical ethics, including abortion and maternal health, through its annual conferences and quarterly journal, *The Linacre Quarterly*.

Physicians for Life is a national non-profit medical organization that exists to draw attention to the issues of abortion, teen pregnancy, and sexually transmitted diseases. Physicians for Life encourages physicians to educate their patients not only regarding the innate value of human life at all stages of development, but also on the physical and psychological risks inherent in abortion.

National Association of Pro Life Nurses ("NAPN") is a national non-profit nurses' organization with members in every state. NAPN unites nurses who seek excellence in nurturing for all, including mothers and the unborn. As a professional organization, NAPN seeks to establish and protect ethical values of the nursing profession.

National Association of Catholic Nurses is a national non-profit organization that gives nurses of different backgrounds the opportunity to promote moral principles within the Catholic context in nursing and stimulate desire for professional development. The organization focuses on educational programs, spiritual nourishment, patient advocacy, and integration of faith and health.

The National Catholic Bioethics Center, established in 1972, conducts research, consultation, publishing, and education to promote human dignity in health care and the life sciences.

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).[2] 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* (Oct. 2013).[3]

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 (ACOG), *ACOG Practice Bulletin 67 Medical Management of Abortion* (Oct. 2005). In the United States, mifepristone is marketed under the brand name "Mifeprex," but mifepristone is more commonly referred to as "RU-

[2] http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp. All citations listed herein were last visited on Nov. 19, 2013.

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

486." *Mifeprex Final Printed Labeling* ("*Mifeprex FPL*").[4] Together, the administration of mifepristone and the second drug, misoprostol—the only method of chemical abortion approved by the Food and Drug Administration (FDA)—is known as the RU-486 regimen.[5] 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 RU-486 regimen, including 14 deaths. Eight deaths were the result of bacterial infection, and each death followed an unapproved use of the RU-486 regimen. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011).[6] 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.

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

[5] In other words, chemical abortion is a two-drug process known by several names. The first drug can be referred to as either mifepristone (the generic name), Mifeprex (the brand name), or RU-486 (the more commonly known name). For clarity, *Amici* refer to the drug regimen as the "RU-486 regimen," and will refer generally to the first drug in the regimen as "mifepristone." When reference to the brand name is necessary, such as when referring to the drug label, *Amici* will use "Mifeprex."

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

Concerned that women were dying following misuse of the RU-486 regimen, state legislatures around the country sought to protect maternal health 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).

Then in 2013, the Texas Legislature enacted HB 2—a law designed and enacted to advance maternal health, including a provision protecting women from the dangerous, unapproved use of abortion-inducing drugs. That provision requires that the RU-486 regimen be administered in the way approved by the FDA. It does not ban the use of the RU-486 regimen, nor does it ban any abortion before or after 49 days gestation. HB 2 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 RU-486 regimen—with the FDA reporting no deaths from bacterial infection following administration of the FDA-approved protocol—the Plaintiffs filed this challenge, seeking to continue administering chemical abortion in an unapproved manner. In evaluating the Plaintiffs' claims, the district court

properly noted that the additional visit and potential additional cost that could accrue by following the FDA-approved protocol do not rise to an "undue burden." *See Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 2013 U.S. Dist. LEXIS 154069, *42 (W.D. Tex. Oct. 28, 2013) (Slip Op. at 23). It also noted that reasonable alternative procedures exist, and that when such procedures exist the state has broad discretion to regulate, "even if it means subjugating physician- or patient-preference." *Id*. at *41 (Slip Op. at 23). Because, the court concluded, "ample evidence establishes that a reasonable, safe, relatively inexpensive, and effective alternative exists for most women"—*i.e*., surgical abortion—Texas' regulation of chemical abortion does not rise to the level of an "undue burden" and is not unconstitutional. *Id*. at **41-42 (Slip Op. at 23).

However, the court then mistakenly accepted Plaintiffs' argument that there are some women for whom surgical abortions are not an option and who might "need" chemical abortions after 49 days. For those women, the court concluded, the regulation poses an undue burden. *Id*. at *44 (Slip Op. at 25). But instead of tailoring its decision to enjoin enforcement of the regulation when there "is a significant health risk during the period falling 50 to 63 days" gestation, the court went even farther and stated that the regulation "may not be enforced against any physician who determines… to perform a [chemical abortion] using the off-label

protocol for the preservation of the life or health of the mother." *Id*. at **44, 46 (Slip Op. at 25, 26).

Such a heath exception is overbroad and unnecessary, especially where, as here, the statute already contains an exception when necessary to avert death or substantial and irreversible impairment of a major bodily function. When U.S. Supreme Court precedent is 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," does not require a "health" exception, and survives this challenge.

Important here is the fact that HB 2 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 that vests in the state 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*.

Abundant data demonstrates that the legislature should be been afforded "wide discretion" in regulating a procedure with known risks and "safe" alternatives. This data includes evidence that that FDA intended to restrict use of the RU-486 regimen for safety reasons; that chemical abortion poses significant

risks; that eight women have died from bacterial infection following misuse of the RU-486 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*. For these reasons, HB 2 does not pose an "undue burden" on women seeking abortion in Texas. *See* Part IV, *infra*.

I. States have a legitimate interest in women'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*, the U.S. Supreme 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. 833, 846 (1992) (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 "zero tolerance policies" that had previously been applied to some abortion regulations, 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, there is no 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, when considering that uncertainty, 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 RU-486 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 law's limitations obtained 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*, the 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." *Gonzales*, 550 U.S. at 163.

The context in which the Court enunciated this standard is significant here. The Court was considering the constitutionality not of a *regulation* of a pre-viability abortion procedure, but a *complete ban* of a particular pre-viability procedure (*i.e*., partial-birth abortion). *See id*. at 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. 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 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 at issue 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 regulations—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 other procedures considered to be safe alternatives are available, a law cannot be invalid. *Id*. at 164-65.

III. Safety and medical data support HB 2 and the "wide discretion" of the Texas Legislature.

Overwhelming safety and medical data supports the legislature's wide discretion in enacting HB 2, including the following: 1) the FDA intended to restrict use of the RU-486 regimen for safety reasons; 2) chemical abortion poses significant risks; 3) eight women have died from bacterial infection following misuse of the RU-486 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 RU-486 regimen for safety reasons.

The FDA's intent to restrict the use of the RU-486 regimen was reflected throughout the approval process, with the authorization of the regimen explicitly 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.

The FDA approved the RU-486 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 RU-486 regimen, the FDA informed the drug sponsor that restrictions "on the distribution and use of mifepristone are needed to assure safe use" of the 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 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*").[7] 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 RU-486 regimen outlines the FDA-approved dosage and administration of both mifepristone and misoprostol. *Mifeprex FPL*, *supra*. The FPL states explicitly that a woman should not use the regimen 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 RU-486 regimen is to be used, the FDA-approved FPL provides explicit dosage and administration instructions for both mifepristone 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….
>
> **Day One: Mifeprex Administration**

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

> 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 RU-486 regimen to the FDA-approved protocol found in the FPL. Before administration of the RU-486 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 RU-486 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 did not intend for the provider or patient to follow.

To the contrary, all FDA communications on the non-FDA-approved uses of the RU-486 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);[8] FDA, *Mifeprex Questions and Answers* (Feb. 24, 2010);[9] FDA, *Public Health Advisory: Sepsis and Medical Abortion* (Mar. 17, 2006).[10]

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8 http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111323.htm.

9 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm.

10 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm051298.htm.

Rather than recommend the unapproved use of the RU-486 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 RU-486 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 RU-486 regimen demonstrate the agency's intent to restrict administration of this potentially dangerous regimen.[11]

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

[11] The district court acknowledged that the FDA has imposed restrictions on the use, dosage, and administration of the RU-486 regimen. *See Abbott*, 2013 U.S. Dist. LEXIS 154069 at **26-27 (Slip Op. 15-16) ("The FDA imposes restrictions on the use, dosage, and administration of mifepristone and misoprostol on mifepristone's final printed label.").

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*.

Commentary from the U.S. Government Accountability Office on the rate of complications is telling. It has reported that while some complications arising after use of the RU-486 regimen are within the range expected, ***the number of women dying from fatal infection is not within the FDA's expected range***. *GAO Report*, *supra*, at 38.[12] This may be due, in large part, to the misuse of the RU-486 regimen, as discussed in Part III.C., *infra*.

Yet the incidence of maternal death from bacterial infections following use of the RU-486 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. J.I. Webster &

[12] "FDA officials have concluded that, ***with the exception of the cases of fatal infection***, the reported serious adverse events associated with Mifeprex have been within or below the ranges expected…." *GAO Report*, *supra*, at 38 (emphasis added).

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 RU-486 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 RU-486 regimen to minors.

Moreover, the RU-486 regimen 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 use the regimen if they cannot easily get such emergency help in the two weeks following ingestion, and ACOG instructs that women are not good candidates for chemical abortion if they cannot return for follow-up visits. *Id*. at 17; AGOG, *supra*, at 6. Yet abortion advocates, like the Plaintiffs, continue to advocate for the unsupervised, unapproved use of the RU-486 regimen for women in "rural areas" who do not have adequate access to healthcare.

C. Eight women have died from bacterial infections following misuse of the RU-486 regimen, while there are no reports of women dying from bacterial infections following use of the FDA-approved protocol.

As of April 2011, eight women had died of bacterial infection following use of the RU-486 regimen. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11*, *supra*. These women used a regimen of mifepristone 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. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11*, *supra*. One woman used misoprostol buccally. *Id*.

Significantly, ***there are no reports of women dying from bacterial infections 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 mifepristone 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 RU-486 regimen did *not* cause the deaths, simply acknowledging that causes of death are unknown.

Thus, in 2013, the Legislature was faced with the following facts. Eight women had died from bacterial infection following unapproved use of the RU-486 regimen. These deaths were outside the range expected and sparked warnings from the FDA. On the other hand, there have been no reports of women dying from bacterial infections following the FDA-approved administration of the RU-486 regimen. While direct causation had not yet been established, neither had it been established that the unapproved use did not cause the deaths. The Legislature passed HB 2 in an attempt to ensure that no other women die following unapproved use of a dangerous abortion-inducing drug regimen. At the very least, HB 2 is in accord with the wide discretion given the Legislature to protect women's health and safety by regulating abortion in areas of "medical uncertainty."[13]

[13] In response to concerns about these fatal infections, Planned Parenthood—of which some Plaintiffs are affiliates—stopped administering misoprostol vaginally, and started administering it buccally. *See* M. Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortion*, N.E.J.M. 361:145-51 (2009). Importantly, buccal administration was not advocated by the pro-abortion ACOG in its practice bulletin on chemical abortion. *See generally*, ACOG, *supra*. Further, without statutory regulation, there is nothing to keep other providers from using misoprostol vaginally, nor is there anything to keep Planned Parenthood from returning to its use of the vaginal administration.

D. Standard, safer alternatives to chemical abortion are available.

The Mifeprex FPL requires that the RU-486 regimen be administered only through 49 days gestation. The Plaintiffs, on the other hand, want to administer the regimen through 63 days gestation.

This represents a 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 2 is not an abortion ban, but rather a restriction predicated upon medical evidence as to 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, medical data demonstrates 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. Jenson 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 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). Moreover, chemical abortion can take days or weeks to complete, but surgical abortion is complete in a shorter, predictable period of time. *Id*.[14]

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

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[14] Similarly, at least one study has found that women prefer the FDA-approved oral administration of misoprostol to the unapproved buccal administration used by Planned Parenthood. 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).

IV. HB 2 is not an "undue burden."

The U.S. Supreme Court's precedents in *Casey* and *Gonzales* make clear that HB 2 is not unconstitutional. A proper application of *Casey* and *Gonzales* confirms 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 2 is a regulation designed to "foster the health of a woman seeking an abortion." *Casey*, 505 U.S. at 878. Texas has an "important" and "legitimate" interest in protecting maternal health from the outset of pregnancy. Over 2,200 adverse events related to the RU-486 regimen have been reported to the FDA, and every woman that has died of bacterial infection following administration of the RU-486 regimen used the drugs in an unapproved manner. Texas is free to enact regulations ensuring the safe use of drugs in order to further the health and safety of women. *Id*.

Second, HB 2 is a proper extension of the Texas' "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 RU-486 regimen is a sufficient basis to conclude that HB 2 does not impose an undue burden. *Gonzales*, 550 U.S. at 164. Under *Gonzales*, HB 2 cannot be invalid on

its face because there is medical disagreement over the safety of off-label use of the RU-486 regimen and because standard, safer medical options are available.

HB 2 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.

Plaintiffs' 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, Texas 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 Plaintiffs 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, as the Sixth Circuit noted, the abortion "right" does not encompass the right to choose a particular method of abortion. *See DeWine*, 696 F.3d at 514-15.

Fourth, a health exception is not required in order for HB 2 to pass constitutional muster. As in *Gonzales*, the Plaintiffs and Defendants disagree over whether the regulation will impose significant health risks to women, particularly to women the Plaintiffs claim need chemical abortion (as opposed to surgical abortion) for medical reasons. Each side has its own experts[15] and *amici*; specifically, *Amici* herein and their members maintain that women for whom surgical abortion is allegedly contraindicated are exactly those women who should *not* be use abortion-inducing drugs—and especially when administered in an unapproved manner, at home, and outside of medical supervision. However, as the Supreme Court noted, the relevant question is whether the regulation can stand when such medical disagreement, or "uncertainty," persists. *Gonzales*, 550 U.S. at 162, 163. Importantly, this is where states are given wide discretion to regulate procedures when there is medical and scientific uncertainty. *Id*. at 163. The most Plaintiffs can demonstrate is that they disagree with Texas (and its experts and

[15] The district court noted that each side had opposing declarations and that reasonable medical opinions may differ. *Abbott*, 2013 U.S. Dist. LEXIS 154069 at *38 (Slip Op. at 21).

amici) regarding the safety of the chemical abortion regulation in HB 2; and as such, Plaintiffs claims fail under *Gonzales*.[16]

Finally, Texas 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 RU-486 regimen, Texas is acting to curtail such falsifying of documents—clearly an unethical, dangerous practice in the medical field.

[16] Further, as the district court noted, the provision contains an exception when "necessary to avert the death or substantial and irreversible physical impairment of a major bodily function of the pregnant woman…." *Abbott*, 2013 U.S. Dist. LEXIS 154069 at *44 (Slip Op. at 25). As in *Gonzales*, no other "health" exception is necessary.

CONCLUSION

HB 2 is a medical regulation promulgated within Texas' wide discretion, aimed at protecting the health and welfare of women. For the foregoing reasons, the regulation of chemical abortion in HB 2 is not an "undue burden," and the decision of the district court should be reversed.

Respectfully submitted,

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Dated: November 25, 2013

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I hereby certify that on November 25, 2013, I electronically filed the foregoing *Amicus Curiae* Brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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