Nos. 11-4062

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al*.,

Plaintiffs-Appellants,

v.

MIKE DEWINE, Attorney General of Ohio, *et al*.,

Defendants-Appellees.

On Appeal from the Southern District of Ohio, No. 04-00493

BRIEF OF *AMICI CURIAE* SPEAKER OF THE U.S. HOUSE OF REPRESENTATIVES JOHN BOEHNER, U.S. SENATOR TOM COBURN, M.D., AND U.S. REPRESENTATIVES STEVE AUSTRIA, DAN BENISHEK, M.D., DIANE BLACK, R.N., CHARLES BOUSTANY, M.D., PAUL BROUN, M.D., BILL CASSIDY, M.D., STEVE CHABOT, JOHN FLEMING, M.D., BOB GIBBS, ANDY HARRIS, M.D., BILL JOHNSON, JIM JORDAN, ROBERT LATTA, JEAN SCHMIDT, STEVE STIVERS, AND PAT TIBERI, IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMATION OF THE SOUTHERN DISTRICT OF OHIO

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CORPORATE DISCLOSURE STATEMENT

Pursuant to 6th Cir. R. 26.1, *Amici Curiae* Speaker of the U.S. House of Representatives John Boehner (OH), U.S. Senator Tom Coburn, M.D. (OK), and U.S. Representatives Steve Austria (OH), Dan Benishek, M.D. (MI), Diane Black, R.N. (TN), Charles Boustany, M.D. (LA), Paul Broun, M.D. (GA), Bill Cassidy, M.D. (LA), Steve Chabot (OH), John Fleming, M.D. (LA), Bob Gibbs (OH), Andy Harris, M.D. (MD), Bill Johnson (OH), Jim Jordan (OH), Robert Latta (OH), Jean Schmidt (OH), Steve Stivers (OH), and Pat Tiberi (OH), make the following disclosures:

1) Are said parties subsidiaries or affiliates of a publicly owned corporation? No

2) Is there a publicly held corporation, not a party to the appeal, that has a financial interest in the outcome? No

Dated: January 10, 2012

s/ Mailee R. Smith
Mailee R. Smith
Counsel for Amici Curiae

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

The constitutionality of Ohio's regulation requiring use of the Food and Drug Administration's (FDA) protocol for the administration of RU-486 (also referred to as mifepristone or Mifeprex) has been called into question in this case. *Amici Curiae* Speaker of the U.S. House of Representatives John Boehner (OH), U.S. Senator Tom Coburn, M.D. (OK), and U.S. Representatives Steve Austria (OH), Dan Benishek, M.D. (MI), Diane Black, R.N. (TN), Charles Boustany, M.D. (LA), Paul Broun, M.D. (GA), Bill Cassidy, M.D. (LA), Steve Chabot (OH), John Fleming, M.D. (LA), Bob Gibbs (OH), Andy Harris, M.D. (MD), Bill Johnson (OH), Jim Jordan (OH), Robert Latta (OH), Jean Schmidt (OH), Steve Stivers (OH), and Pat Tiberi (OH) are United States Senators and Representatives who support adherence to the FDA protocol, at a minimum, for the administration of RU-486. Several are also from Ohio. *Amici* have a strong interest in the proper

[1] According to Fed. R. App. P. 29, Counsel for *Amici* has filed a Motion for Leave to file this brief. Counsel for *Amici* has contacted the parties for consent to file. Counsel for the State of Ohio has consented; Counsel for Defendant Joseph Deters, as representative of the class of all prosecuting attorneys, stated that he will not raise any objection to the request to file an *amicus* brief; Planned Parenthood has not consented, as is reflected in *Amici's* Motion. No counsel of a party has authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief. No person (other than *Amici*, its members, or its counsel) has contributed money that was intended to fund preparing or submitting the brief.

interpretation and administration of a federal guideline, especially when, as here, that guideline protects women from medical risks.

In addition, Senator Tom Coburn, M.D., and Representatives Dan Benishek, M.D., Diane Black, R.N., Charles Boustany, M.D., Paul Broun, M.D., Bill Cassidy, M.D., John Fleming, M.D., and Andy Harris, M.D., are healthcare providers who have a particular interest in ensuring that women receive the safest care possible. As healthcare providers, *Amici* affirm the State's decision to require that RU-486 be administered in the safest way possible and in a manner supported by concrete medical data.

Amici urge this Court to affirm the lower court's decision and uphold the constitutionality of OHIO REV. CODE § 2919.123.

ARGUMENT

OHIO REV. CODE § 2919.123 is a medical regulation enacted to protect women from the dangerous off-label use of the RU-486 abortion drug regimen. Specifically, it requires that RU-486 be administered in the way approved by the U.S. Food and Drug administration (FDA). It does not ban the use of RU-486; it simply requires that RU-486 be administered in the way deemed safest by the FDA. While the FDA determined that RU-486 should not be used past 49 days gestation, other alternatives—indeed, alternatives deemed "very safe" by Planned

Parenthood[2]—exist for women with pregnancies beyond 49 days gestation. Section 2919.123 imposes no obstacle to obtaining an abortion.

Important here is the fact that § 2919.123 was enacted to protect the health and welfare of women—a state interest that has been declared "important" and "legitimate" by the U.S. Supreme Court. As declared by the Court, states have wide discretion to enact protective laws where parties disagree as to the medical safety of a particular procedure or method. Thus, in order to prove its "undue burden" claim, Planned Parenthood must demonstrate that the state has no evidence that off-label use of RU-486 can be harmful to women. As discussed below, this it cannot do, because ample evidence demonstrates that off-label use of RU-486 poses significant health risks for women.

While Planned Parenthood claims to have "research" supporting its off-label use of RU-486 and/or that issues of material fact remain, all Planned Parenthood is really demonstrating is that it disagrees with the state's use of evidence showing that RU-486 can be harmful to women. To that end, Planned Parenthood's claims of an "undue burden" fail.

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[2] *See*, *e.g.*, Planned Parenthood, *In-Clinic Abortion Procedures* (2011), available at http://www.plannedparenthood.org/health-topics/abortion/abortion-procedures-4359.htm (last visited Jan. 7, 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*.

I. THE U.S. SUPREME COURT HAS GIVEN STATE AND FEDERAL LEGISLATURES "WIDE DISCRETION TO PASS LEGISLATION IN AREAS WHERE 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 previabilty abortion procedure, but a *complete ban* of a particular previability procedure. *See Gonzales*, 550 U.S. at 147, 156 (noting that the partial-birth abortion ban applies both previability and postviability).[3] 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 partial-birth abortion ban created certain health risks to women, which in turn created an undue burden—but the Court unequivocally rejected this claim.

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[3] Planned Parenthood attempts to distinguish first trimester abortions as being distinct from and more protected than other previability abortions. *See*, *e.g*., Brief of Plaintiffs-Appellants, at 52-53. This is a complete distortion of Supreme Court case law, which has unequivocally rejected this type of trimester framework. *See*, *e.g*., *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

Noting that there were documented medical disagreements over whether the partial-birth abortion ban would impose significant health risks to women, the Court stated that the question became 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 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…." *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 Planned Parenthood has a very high burden to meet. Because states are given wide discretion to legislate in areas where there is medical and scientific uncertainty, in order to sustain its "undue burden" claim Planned Parenthood must demonstrate that the state has no medical evidence that off-label use of RU-486 can be harmful to women. However, medical data demonstrating that Planned Parenthood's preferred off-label use of RU-486 can be harmful to women strips Planned Parenthood of its ability to meet this high standard.[4]

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[4] Recently, Judge Raymond Gruender of the Eighth Circuit utilized the "wide discretion" standard in supporting South Dakota's provision requiring that women be informed of the risk of suicide following abortion. *Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 653 F.3d 662, 678 (2011) (Gruender, J., concurring in part and dissenting in part). In his opinion concurring and dissenting in part, he wrote that "the Supreme Court 'has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.'" *Id*. at 679. He went on to explain the applicable standard:

II. SECTION 2919.123 IS SUPPORTED BY MEDICAL DATA

A. RU-486 poses substantial health risks for women

Both the FDA and the drug manufacturer have acknowledged that RU-486 poses health risks for women, including the risk of death. The Mifeprex drug label acknowledges that "[*n*]*early all of the women* who receive Mifeprex and misoprostol [the RU-486 regimen] *will report adverse reactions*, and *many can be expected to report more than one* such reaction."[5] These adverse reactions include abdominal pain, uterine cramping; nausea; headache; vomiting; diarrhea; dizziness;

> Planned Parenthood would have to show that any "medical and scientific uncertainty" has been resolved into a certainty *against* any causal role for abortion. In other words, in order to render the suicide advisory unconstitutionally misleading, Planned Parenthood would have to show that abortion has been ruled out, to a degree of scientifically accepted certainty, as a statistically significant causal factor in post-abortion suicides. An examination of Planned Parenthood's evidence reveals that it cannot meet this burden.

Id. (emphasis in original). Following Judge Gruender's strong and well-reasoned dissent, the Eighth Circuit Court of Appeals agreed to rehear (*en banc*) arguments related to the suicide advisory in South Dakota's informed consent law. Oral arguments were heard on January 9, 2012.

[5] *See* MIFEPREX™ Label, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm (last visited Jan. 7, 2012) (emphasis added); *see also* Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006).

fatigue; back pain; uterine hemorrhage; fever, viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis/salpingitis/pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting.[6]

In 2011, the FDA issued a report accounting for 2,207 adverse events (complications) in the U.S. related to the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.[7] Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").

This high number of serious adverse events is even more troubling in light of widespread and consequential inadequacies in reporting on drug-induced abortions. A 2006 review of Adverse Event Reports (AERs) related to the use of the RU-486 drug regimen found, "AERs relied upon by the FDA to monitor mifepristone's postmarketing safety are grossly deficient due to extremely poor quality."[8] The

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[6] *See* MIFEPREX™ Label, *supra*; *see also* Staff Report, *supra*, at page 30.

[7] Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011), available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited Jan. 7, 2012).

[8] M.M. Gary & D.J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40(2) ANNALS OF PHARMACOLOGY 191 (2006).

review concluded, "[A] majority of the AERs analyzed do not provide enough information to accurately code the severity of the adverse event in question. The deficiencies were so egregious in some instances as to preclude analysis." Thus, it is likely that the AERs reported by the FDA do not reflect all adverse events or the severity of the events.

Despite the potential underreporting of adverse events, we know that at least eight women in the U.S. have died due to serious infections following use of RU-486.[9] Significantly, mifepristone, the first drug used in the RU-486 regimen, interferes with the body's immune response, allowing bacteria, if present, to flourish and cause widespread, multi-organ infection in the woman.[10] The causal chain between mifepristone and death by toxic shock syndrome has been

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[9] FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011*, *supra*; *see also* Food and Drug Administration, *Mifeprex Questions and Answers* (updated Feb. 24, 2010), available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm (last visited Jan. 7, 2012).

[10] *See*, *e.g.*, 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 181:207-221 (2004); R.P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Colstridium Sordellii*, ANNALS OF PHARMOCOTHERAPY (Sept. 2005), at 39. *See also* Staff Report, *supra*, at 13-14, 32-33.

demonstrated in multiple animal models of septic shock, where the mortality rate increased from 13 percent to 100 percent in mifepristone-treated animals.[11]

Even previously healthy women face a risk of fatal infection following the use of RU-486. From September 2003 through June 2005, there were at least four U.S. deaths due to *C. sordellii* bacterial infection in women, ages 18-34, who had undergone mifepristone abortions. These four U.S. women were reported by the U.S. Centers for Disease Control and Prevention (CDC) and FDA as having been previously healthy, without any underlying immunoconditions. They had no risk factors predisposing them to infection or death—especially from a bacterium that rarely affects humans with a normal immune system.[12]

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[11] *Emerging Clostridial Disease Workshop*, at 91, 108, 115 (CDC-FDA-NIH Transcript May 11, 2006) (CDC Workshop); Sternberg, *Proceedings of the Nat'l Acad. Sci.* 86:2374-78 (1989); Statement by Donna Harrison, M.D., for *RU-486: Demonstrating a Low Standard for Women's Health?*, Hearing before the Committee on Government Reform, House of Representatives (May 17, 2006), Serial No. 109-202, at 135, 138.

[12] *See*, *e.g.*, Food and Drug Administration, *FDA Public Health Advisory: Sepsis and Medical Abortion* (updated Nov. 4, 2005), available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/UCM051734 (last visited Jan. 7, 2012); CDC Workshop, *supra*; M. Fischer et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medical Abortion*, N.E. J. MED. 353:2352-53, 2356 (2005); Statement by Donna Harrison, *supra*, at 135, 139.

Moreover, the U.S. trials relied upon by the FDA in granting approval to RU-486 tested safety and efficacy only in women aged 18 to 45 years old.[13] Safety and efficacy in pediatric patients has not been established, despite the fact that Planned Parenthood and other abortion providers routinely provide the RU-486 drug regimen to minors.

In addition, RU-486 is contraindicated if a patient does not have adequate access to medical facilities equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation during the period from the first visit until discharged by the administering physician.[14] Thus, it is contraindicated for those very women in "rural areas" that Planned Parenthood is targeting.

B. Off-label use of RU-486 is particularly dangerous

As Planned Parenthood has admitted, abortion providers routinely administer RU-486 in a number of ways that fall outside the safety guidelines established by the FDA. Such off-label use includes administering misoprostol, the second drug in the regimen, vaginally or buccally (instead of orally); failing to

[13] *See* MIFEPREX™ Label, *supra*.

[14] *Id*.

adequately examine women prior to or after administration;[15] and administering the drugs outside of the 49-day gestational window approved by the FDA.

Significantly, there are no peer-reviewed studies demonstrating that such off-label use of mifepristone is safer than the FDA protocol. In fact, all credible information points to the contrary: off-label use of mifepristone is dangerous, and even deadly.

For example, the FDA has stated that off-label use has not been sufficiently tested to establish safety and has issued a public health advisory warning in light of off-label usage associated with the deaths of several patients.[16] Specifically discussing four of the women who died from the bacterium *C. sordellii* following use of RU-486, the FDA noted that "[a]ll cases involve the off-label dosing regimen consisting of 200 mg of oral Mifeprex followed by 800 mcg of intra-vaginally placed misoprostol."[17] The FDA went on to reiterate the requirements of the "approved Mifeprex regimen," emphasizing that the "safety and effectiveness

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[15] Many abortion providers are now providing abortion-inducing drugs like RU-486 through teleconferencing systems and may not even be in the same physical building as the woman seeking an abortion, meaning that the physician has not personally examined the woman—increasing the risk of misdiagnosed ectopic pregnancy or other contraindication. This practice is frequently referred to as "telemed abortion."

[16] *See* FDA, *FDA Public Health Advisory: Sepsis and Medical Abortion, supra.*

[17] *Id*.

of other Mifeprex dosing regimens, including use of oral misoprostol tablets intravaginally has not been established by the FDA."[18]

Since that time, the FDA has reported that a total of eight women have died in the U.S. from bacterial infection following use of RU-486—and each death followed off-label use (either vaginal or buccal administration, as preferred by Planned Parenthood here).[19]

Further, because symptoms of ectopic pregnancy mimic the symptoms of completed mifepristone abortions, ectopic pregnancies go easily undiagnosed.[20] Improper screening (*e.g.*, the use of "telemed abortions," failure of a physician to examine the patient, etc.) and failure to follow the FDA protocol (specifically, for follow-up evaluation and care) place the lives of women with unknown ectopic pregnancies at even greater risk of death by ruptured ectopic pregnancy. The FDA has reported that 2 of the 14 U.S. women reported to have died after using RU-486

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[18] *Id*.

[19] FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011*, *supra*.

[20] *See*, *e.g.*, ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician Gynecologists: Medical Management of Abortion* 26(4):1-20 (2001); B.C. Calhoun & D.J. Harrison, *Challenges to the FDA Approval of Mifepristone*, ANNALS OF PHARMOCOTHERAPY (Jan. 2004), at 165.

died from ruptured ectopic pregnancies.[21] The absence of ultrasound use and follow-up care also increases the risk of retained tissue, thereby increasing the risk of infection.[22]

Thus, it is not an improper conclusion that potentially 10 out of the 14 reported U.S. deaths could possibly have been prevented by proper administration of mifepristone under the FDA protocol. At the very least, it demonstrates that medical uncertainty exists in regard to the causal relationship between off-label use of RU-486 and death.

Further, it is generally understood that the percentage of incomplete RU-486 abortions requiring emergency surgical intervention increases with gestational age. Thus, as the failure rate of RU-486 increases with gestational age, so does the medical risk. Abdominal pain, nausea, diarrhea, and vaginal bleeding also increase with advancing gestational age.[23]

C. RU-486 offers no therapeutic benefits over other abortion alternatives

Despite the fact that there are serious inadequacies in the reporting of adverse events involving RU-486, medical evidence shows that there are more

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[21] FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011, supra.*

[22] Calhoun & Harrison, *supra*, at 165.

[23] *Id*.; I.M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, N.E. J. MED. 338:1241-47 (1998).

complications from drug-induced abortions than from surgical abortions. For example, a major review of nearly 7,000 abortions performed in Australia in 2009 and 2010 found that 3.3 percent of patients who used mifepristone in the first trimester required emergency hospital treatment, in contrast to 2.2 percent of patients who underwent surgical abortions.[24] Women receiving drug-induced abortions were admitted to hospitals at a rate of 5.7 percent following the abortion, as compared with 0.4 percent for patients undergoing surgical abortion.[25] Thus, women are more likely to be admitted and require surgical intervention after a first trimester drug-induced abortion than following a surgical abortion.

Another study has indicated that the overall incidence of immediate adverse events is fourfold higher for drug-induced abortions than for surgical abortions.[26] In particular, hemorrhage and incomplete abortion are more common after drug-induced abortions. Medical researchers identified immediate complications (within 42 days after abortion) using "high-quality registry data" obtained from all women in Finland who underwent abortions from 2000-2006 with a gestational duration of 63 days or less (942,619 women). The study found the incidence of

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[24] E. Mulligan & H. Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, AUSTRALIAN FAMILY PHYSICIAN 40(5):342-45 (May 2011).

[25] *See id*. at 344.

[26] M. Niinimaki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBST. & GYN. 114:795 (Oct. 2009).

hemorrhage is 15.6 percent following drug-induced abortions, compared to 5.6 percent for surgical abortions.[27] The study also found that 6.7 percent of drug-induced abortions result in incomplete abortion, compared to 1.6 percent of surgical abortions.[28]

Yet another study indicates that RU-486 fails more often than surgical abortion, involves more subsequent bleeding for a longer duration of time, requires more emergency surgical intervention, and is more painful than surgical abortions.[29]

Finally, there have been no reported deaths from C. *sordellii* following surgical abortion. In all, RU-486 does not offer women any therapeutic benefits; rather, it exposes women to greater medical risk.

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[27] *Id*.

[28] *Id*. *See also* M.F. Greene, *Fatal Infections Associated with Mifepristone-Induced Abortion*, N.E. J. MED. 353:22 (Dec. 1, 2005).

[29] *See* J.T. Jensen et. al, *Outcomes of Suction Curettage and Mifepristone Abortions in the United States: A Prospective Comparison Study*, CONTRACEPTION 59(3):153-59 (1999); Letter from Donna Harrison, M.D., to Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy and Human Resources, at Q.5.

III. PLANNED PARENTHOOD CANNOT MEET THE COURT-IMPOSED BURDEN OF PROVING THAT OFF-LABEL USE OF RU-486 IS NOT HARMFUL TO WOMEN'S HEALTH

Planned Parenthood completely fails to sustain its "undue burden" claim. First, Ohio has an important and legitimate interest in protecting women from the harms of abortion, and that includes the harms associated with the off-label use of RU-486. This state interest has been affirmed time and time again by the Supreme Court. Section 2919.123 is a regulation designed to "foster the health of a woman seeking an abortion." *Casey*, 505 U.S. at 878. 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 enacted § 2919.123. *See Gonzales*, 550 U.S. at 163. It is clear that, at most, Planned Parenthood can merely demonstrate that there is a range of opinion on the safety of off-label use of RU-486—and, therefore, its claims fail under *Gonzales*. Planned Parenthood attempts to shift the burden to the State to prove a causal connection between RU-486 and death. But *Gonzales* makes clear that it is Planned Parenthood's burden to prove that those deaths were *not* caused by RU-486. This is impossible for Planned Parenthood to do, given the FDA's warnings against off-label use, the fact that all eight women who died from bacterial infection used an off-label administration, as well as the aforementioned medical data demonstrating the harms of RU-486.

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 medical evidence indicates that these surgical procedures are *safer* than drug-induced abortions. Planned Parenthood is not "entitled to ignore regulations that direct [it] to use reasonable alternative procedures." *Gonzales*, 550 U.S. at 163. Planned Parenthood does not have "unfettered choice in the course of [its] medical practice." *Id*.

Moreover, § 2919.123 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.

Altogether, it is clear that § 2919.123 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

The decision of the Southern District of Ohio should be affirmed.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Counsel for *Amici Curiae* hereby certifies that the foregoing Brief of *Amici Curiae* complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 4,282 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirement of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using in 14 point font, Times New Roman font style.

s/ Mailee R. Smith
Mailee R. Smith
Counsel for Amici Curiae

PROOF OF SERVICE

I hereby certify that on January 10, 2012, I electronically filed the foregoing Brief of *Amici Curiae* with the clerk of the court by using the CM/ECF System, which will send a notice of electronic filing to:

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