No. 14-284

In The
Supreme Court of the United States

WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity,

Petitioner,

v.

PLANNED PARENTHOOD OF ARIZONA, INC., et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF WOMEN INJURED BY RU-486, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS AND CONCERNED WOMEN OF AMERICA AS AMICI CURIAE IN SUPPORT OF PETITIONER

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The Amici respectfully submit this amicus curiae brief in support of Petitioner. Consent to file the amicus curiae brief was given by both parties. This brief supporting Petitioner was prepared by counsel for Amici.[1]

STATEMENT OF INTEREST OF THE AMICI CURIAE

This case is of great national importance and consequence because it goes to the heart of this Court's decision in *Planned Parenthood v. Casey*. The State may impose reasonable regulations that do not create an undue burden on a woman's right to decide. But there is a split of authority in the circuit courts of appeals on the undue burden standard as applied to RU-486.

The women Amici who have taken RU-486, their families, and former abortion facility workers have personal knowledge as to how RU-486 affects women

[1] The parties were notified ten days prior to the due date of this brief of the intention to file. The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. Trinity Legal Center is a nonprofit organization and is supported through private contributions of donors who have made the preparation and submission of this brief possible. No person other than Amici, their counsel, or donors to Trinity Legal Center made a monetary contribution to its preparation or submission.

and how they are not adequately warned of the dangers of the drug regimen. Based on their personal experiences, they believe that on-label use of RU-486 is necessary, reasonable, and not an undue burden. The Amici are Jennifer Baros (Colorado); Carol Everett (Texas); Abby Johnson (Texas); J.N. (Arizona), a minor when she took RU-486; Monty Patterson, father of Holly Patterson who died after a RU-486 abortion (California); and, Leslie Wolbert (New York). They urge this Court to grant certiorari and reverse the Court of Appeals' decision.

Amici American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) was founded in 1973 as a pro-life voice and recognized group within the American College of Obstetricians and Gynecologists (ACOG). AAPLOG has approximately 2,500 members, mostly ob-gyn physicians, from across the United States. These physicians understand the importance to women of accurate and truthful information to make an informed decision about the outcome of their pregnancy, as well as the importance to women of understanding the risks to their body and their health of various abortion methods such as RU-486. AAPLOG believes that it is the responsibility and duty of the physician to properly advise and counsel his/her patient. They have also had patients who were not fully informed and who experienced adverse physical and psychological effects of abortion. Members of AAPLOG have served as expert witnesses on the abortion issue in the courts and before

legislative bodies. They have members across the country as well as in Arizona.

Amici Concerned Women of America (CWA) is a 501(c)(3) public policy women's organization. It is the nation's largest public policy women's organization which was founded in the 1970's. CWA's membership consists of half a million women with nearly 500 chapters in almost every state. CWA of Arizona has more than 3,600 members. Two of CWA's six core issues are the family and the sanctity of human life which includes the abortion issue.

SUMMARY OF THE ARGUMENT

I.

The physical complications after RU-486 exceed those from surgical abortion, and therefore, the FDA approved RU-486 under the special restrictive code section that was intended to preclude off-label use of the drug. The Arizona Legislature enacted legislation to ensure that the FDA instructions for RU-486 would be followed. Because this was a reasonable regulation that does not impose an undue burden on a woman's right to decide, the United States Court of Appeals for the Ninth Circuit erred in its application of this Court's decision in *Planned Parenthood v. Casey*. The Court of Appeals erred in its application of the undue burden standard and only this Court can correct the error. This case is certworthy because there is a split in the circuit courts as to the application of the undue

burden standard in RU-486 cases. Therefore, Amici urge this Court to grant the writ of certiorari.

II.

Scientific studies demonstrate an increased risk for both physical and psychological harm to women who use the RU-486 regimen for medical abortions. In addition, the women Amici have taken RU-486 and have experienced the physical and psychological harm of this drug. Therefore, the Arizona Legislature was justified in providing for safety measures as articulated by the FDA to protect women. Providing those safety measures was well within the State's authority under the rulings of this Court. Accordingly, the Court of Appeals for the Ninth Circuit erred.

ARGUMENT

I. THIS CASE IS CERTWORTHY BECAUSE THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT MISAPPLIED THIS COURT'S DECISION IN *PLANNED PARENTHOOD V. CASEY* AND ONLY THIS COURT CAN CORRECT THE ERROR.

A. The Court of Appeals for the Ninth Circuit Erred Because the State Has the Right to Provide Reasonable Regulations for the Health and Safety of Women That Do Not Create an Undue Burden, and Therefore, the Arizona Law Limiting On-Label Use of RU-486 Is Constitutional.

Because this Court found a constitutional right to decide whether to have an abortion in *Roe v. Wade*[2] and *Doe v. Bolton,*[3] only this Court can correct the lower court's errors in interpretation and application. The United States Court of Appeals for the Ninth Circuit, relying on this Court's decision in *Planned Parenthood v. Casey*,[4] held ARIZ. REV. STAT. § 36-449.03(E)(6) and its implementing regulation, ARIZ. ADMIN. CODE § R9-10-1508(G), unconstitutional and

[2] 410 U.S. 113 (1973).

[3] 410 U.S. 179 (1973).

[4] 505 U.S. 833 (1992).

placed it squarely within the constitutional framework that this Court would have to decide.

The Court of Appeals for the Ninth Circuit erred in its interpretation and application of *Casey*. This Court recognized in *Casey* that because the State has a substantial interest in the life of the unborn child, the State may promulgate regulations that do not create an undue burden on the woman's right to decide.[5] In particular, regulations that are "designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden."[6] This Court articulated the undue burden standard:

> As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.[7]

But, "not every law which makes a right more difficult to exercise is, *ipso facto*, an infringement on that right."[8] One commentator surmised that "[t]he Court implied that an undue burden exists only if a court concludes that a regulation will prevent women

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[5] Planned Parenthood v. Casey, 505 U.S. 833, 876 (1992).

[6] *Id*. at 877.

[7] *Id*. at 878.

[8] *Id*. at 873.

from receiving an abortion."[9] Thus, an undue burden will exist only if the plaintiffs show that the regulation will keep women from getting an abortion.[10] That principle was demonstrated when this Court in *Casey* found that spousal notification was likely to prevent a significant number of women from obtaining an abortion,[11] but requirements such as 24-hour waiting periods[12] and other such regulations for her health and safety would not.

Furthermore, this Court has upheld abortion regulations that "are not efforts to sway or direct a woman's choice, but rather are efforts to enhance the deliberative quality of that decision or are neutral regulations on the health aspects of her decision."[13] Following the on-label FDA instructions for RU-486 are neutral regulations to protect her health and safety, and therefore, constitutional.

In a case interpreting an Ohio statute that was very similar to the Arizona provision, the Court of Appeals for the Sixth Circuit concluded that there was no evidence the Act would impose an undue

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[9] ERWIN CHEMERINKSY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 830 (3d ed. 2006).

[10] *Id*.

[11] Planned Parenthood v. Casey, 505 U.S. 833, 894 (1992).

[12] *Id*. at 887.

[13] *Id*. at 917 (1992) (Stevens, J., concurring in part and dissenting in part) (providing examples of valid regulations including written informed consent, recordkeeping and reporting, pathology reports, and licensing and qualification provisions).

burden on a woman's ability to decide whether to have an abortion, and therefore, the statute was constitutional.[14] The court emphasized that the right concerned the right to decide and not to choose the method of abortion.[15] In commenting on Planned Parenthood's evidence, the court said that the statements gave rise to an inference that some women might prefer an RU-486 medical abortion, but "they do not support the conclusion that the unavailability of a medical abortion would create a substantial obstacle for a large fraction of women in deciding whether to have an abortion."[16] Therefore, the court held that there was no evidence that the Act was a substantial obstacle to the ultimate abortion decision.[17]

The Court of Appeals for the Sixth Circuit also rejected the argument that an increased cost related to a medical abortion would create an undue burden. The court stated that Planned Parenthood had not produced any evidence that the increased cost would unduly burden the right to choose an abortion for a large fraction of women.[18] In fact, Planned Parenthood had submitted evidence that surgical abortion would remain available at a lower cost.[19] Therefore,

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[14] Planned Parenthood v. DeWine, 696 F.3d 490, 514 (6th Cir. 2012).

[15] *Id*. at 515.

[16] *Id*. at 516.

[17] *Id*.

[18] *Id*. at 517.

[19] *Id*.

the evidence did not give rise to a reasonable inference that an increased cost due to increased dosage would create a substantial obstacle to the choice to undergo an abortion.[20]

In another recent case on RU-486, the Court of Appeals for the Fifth Circuit upheld the on-label use of RU-486.[21] In that case, the district court ruled that the Texas law, which prohibited off-label use of RU-486 and required doctors performing abortion to have hospital admitting privileges, was unconstitutional.[22] The Court of Appeals upheld the provision and correctly balanced a woman's right with the State's interest. The Court of Appeals opined that the district court had erred for several reasons. First, "[i]t is not the courts' duty to second guess legislative factfinding" or to allow "relitigation of the facts that led to the passage of a law."[23] To do so "usurps the legislative power."[24] Thus, the court gave deference to the legislature which this Court has repeatedly recognized to

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[20] *Id*.

[21] Planned Parenthood v. Abbott, 748 F.3d 583 (5th Cir. 2014).

[22] Planned Parenthood v. Abbott, 951 F. Supp. 2d 891 (W.D. Tex. 2013), *rev'd in part on other grounds and aff'd in part*, 748 F.3d 583 (5th Cir. 2014).

[23] Planned Parenthood v. Abbott, 748 F.3d 583, 594 (5th Cir. 2014).

[24] *Id*.

be the appropriate approach when courts review legislation.[25]

Second, the Court of Appeals stated that the district court misapplied the undue burden test.[26] The court said the plaintiffs had the burden to show that the regulation created a substantial obstacle to a woman seeking an abortion.[27] The court discussed two factors. First, travel of less than 150 miles was not an undue burden because *Casey* "counsels against striking down a statute solely because women may have to travel long distances to obtain abortions."[28] Second, the court rejected the argument that the state law might result in closures of abortion facilities because

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[25] *See e.g.*, Gonzales v. Carhart, 550 U.S. 124, 155 (2007) (giving deference because evidence supported a legislative determination); Turner Broadcasting System, Inc. v. FCC (Turner I), 512 U.S. 622, 665-66 (1994) (stating "courts must accord substantial deference to the predictive judgments of Congress"); Jones v. United States, 463 U.S. 354, 365 (1983) (stating courts should "pay particular deference to reasonable legislative judgments" in a case where congressional findings that individuals acquitted by reason of insanity were likely to be dangerous); Marshall v. United States, 414 U.S. 417, 427 (1974) (stating "courts should be cautious not to rewrite legislation" in case where Congress determined that drug addicts were less likely to be rehabilitated); Lambert v. Yellowsley, 272 U.S. 581, 294-95 (1926) (deferring to Congress that alcohol had no medicinal uses).

[26] Planned Parenthood v. Abbott, 748 F.3d 583, 597 (5th Cir. 2014).

[27] *Id.*

[28] *Id.*

that is too vague.[29] The court stated that: "[a]lthough some clinics may be required to shut their doors, there is no showing whatsoever that *any* women will lack reasonable access to a clinic within Texas."[30] Thus, the Court of Appeals held that the provisions were constitutional.

The Court of Appeals for the Ninth Circuit contended that there would be an undue burden if the clinic would close. Even if the clinic would have to close for some reason, this does not create an undue burden. The woman is not directly burdened by the legislation itself nor because a clinic decides not to comply with the regulation and closes instead. A regulation should not be ruled unconstitutional simply because it closes clinics, nor should this be the standard. In addition, the opposite conclusion is not true. For example, if Planned Parenthood decides to change its business model and comply with the Arizona regulation, does that make the regulation constitutional? Constitutional law cannot be framed around how a business reacts to the law. The Supreme Court properly framed the standard on whether it is an undue burden to the woman. A standard that meets the needs of a business is unworkable. A legislature cannot be forced to draft laws by second-guessing whether a clinic will close or whether a business would change its business model.

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[29] *Id*. at 598.

[30] *Id*. (emphasis in the original).

As long as there is a "commonly used and generally accepted method" of abortion, there is not a "substantial obstacle to the abortion right."[31] Specifically, this Court stated in *Gonzales v. Carhart*:[32]

> 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.[33]

As this Court articulated, mere inconvenience in obtaining an abortion does not create an undue burden.[34] Certainly for abortion providers, dispensing RU-486 is far more convenient than surgical abortions. Initially, it may seem more convenient for a woman considering abortion, but the drug poses

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[31] Gonzales v. Carhart, 550 U.S. 124, 165 (2007).

[32] 550 U.S. 124 (2007).

[33] *Id*. at 166.

[34] Gonzales v. Carhart, 550 U.S. 124, 166 (2007); *see also* Whole Woman's Health, et al. v. Lakey, 2014 WL 4930907 (5th Cir. 2014) (holding the ambulatory surgical center regulation had a legitimate purpose and effect that did not create a substantial obstacle or an undue burden on the woman).

greater risks for physical and psychological complications than surgical abortions.[35]

Under Arizona law, standard medical options are available including surgical abortions. The Court of Appeals for the Ninth Circuit incorrectly rejected surgical abortions in some cases. The Court of Appeals for the Fifth Circuit discussed the evidence concerning certain cases where Planned Parenthood's expert said RU-486 would be preferable when surgical abortions are contraindicated. However, the State's expert stated:

> . . . when surgery is already contraindicated for a woman, it would be medically irresponsible and contrary to her best interest for a physician to submit her to a medication abortion, for in the event an emergency surgical abortion is later needed, she will be placed at an even higher risk of adverse health risks.[36]

Furthermore, the Court of Appeals for the Ninth Circuit makes the unsupported assertion that the Food and Drug Administration (FDA) "expects" and "encourages" off-label use of drugs.[37] However, in approving RU-486, the FDA specifically required on-label

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[35] *See generally* ANGELA LANFRANCHI, IAN GENTLES, & ELIZABETH RING-CASSIDY, COMPLICATIONS: ABORTION'S IMPACT ON WOMEN ch. 13 (2013).

[36] Planned Parenthood v. Abbott, 748 F.3d 583, 602 (5th Cir. 2014).

[37] Planned Parenthood v. Humble, 753 F.3d 905, 915 (9th Cir. 2014).

use to assure the safety of the drug and that it was commensurate with "the specific safety concerns presented."[38] The FDA approved RU-486 under a special code section which is used for drugs that "can be safely used only if distribution or use is restricted."[39] Even assuming arguendo that the FDA would encourage off-label use of some drugs, that was not true with RU-486 based on the FDA's own restrictions.

Also recognizing the safety concerns for women, the American College of Obstetricians and Gynecologists (ACOG) stated: "Medical abortion should be considered a medically acceptable alternative to surgical abortion in selected, carefully counseled and informed women."[40] The reason for this advice was that " . . . social or psychological contraindications to

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[38] 21 C.F.R. § 314.520. That section provides:

> (a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:
>
> (1) Distribution restricted to certain facilities or physicians with special training or experience; or
>
> (2) Distribution conditioned on the performance of specified medical procedures.
>
> (b) The limitations imposed will be commensurate with the specific safety concerns presented.

[39] *Id*.

[40] American College of Obstetricians & Gynecologists, *Medical Management of Abortion,* ACOG PRACTICE BULLETIN No. 67 (Oct. 2005).

medical abortion are more common" than with surgical abortions.[41]

In addition, scientific studies document that medical abortions decline in efficacy and safety after forty-nine days gestation,[42] thus supporting the FDA's decision to limit the use of RU-486. The FDA correctly limited the use of RU-486 to protect women from the additional complications and risks to women taking the drug. There would be no need for the FDA if its warnings about drugs could arbitrarily be disregarded.

This case is certworthy because there is a split of authority among the circuit courts in applying the undue burden standard in RU-486 cases. The Court of Appeals for the Ninth Circuit erred in its application of the undue burden standard whereas the Courts of Appeals for the Fifth and Sixth Circuits correctly applied the standard. Furthermore, the Court of Appeals for the Ninth Circuit misapplied the undue burden standard as articulated in *Casey* and *Gonzales*. Providing for the safety of drugs and

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[41] *Id*.

[42] *See, e.g.*, G. Raymond, et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 CONTRACEPTION 26 (2013); M.J. Mentula, et al., *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 2011 HUMAN REPRO. 1; N.T.N. Ngoc, et al., *Comparing Two Early Medical Abortion Regimens: Mifepristone + Misoprostol vs. Misoprostol Alone*, 83 CONTRACEPTION 410 (2010).

medical procedures are within the legitimate function of the State, and therefore, the Court of Appeals erred by not upholding ARIZ. REV. STAT. § 36-449.03(E)(6) and its implementing regulation, ARIZ. ADMIN. CODE § R9-10-1508(G).

B. On-Label Use of RU-486 Should Be Required Because the Drug Poses a Substantial Risk to Women, and Therefore, the Court of Appeals for the Ninth Circuit Erred in Denying the State Its Legitimate Function to Protect Women Considering a Medical Abortion.

The RU-486 regimen poses a substantial risk to the physical health of women including the risk of death. Both the FDA[43] and Danco, the drug manufacturer,[44] have acknowledged that RU-486 poses health risks for women. The Mifeprex drug label

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[43] Food and Drug Administration, *Mifeprex* (*mifepristone*) *Information* (July 19, 2011), *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm (discussing mifepristone and that the FDA had received reports of serious adverse events, including several deaths); *see also* Congressional 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), *available at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf (*citing* FDA findings and reporting adverse reactions).

[44] *See* MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

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."[45] These adverse reactions include abdominal pain, uterine cramping, nausea, vomiting, diarrhea, pelvic pain, fainting, headache, dizziness, and asthenia.[46]

The Congressional Staff Report on RU-486 cited FDA findings concerning the physical risks to women taking RU-486 regimen.[47] These included: "abdominal pain; uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endometritis/salpingitis/pelvic inflammatory disease;

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[45] *See* MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm; Congressional 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), *available at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.

[46] MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[47] Congressional 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), *available at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.

decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting."[48]

The FDA's Medical Officer's review indicated that, "[m]ore than one adverse event was reported for most patients. . . . Approximately 23% of the adverse events in each gestational age group were judged to be severe."[49] The Congressional Staff Report calls these "startling adverse effects," which the FDA knew during the RU-486 NDA review process.[50]

Also of concern was "the incredibly high failure rate of the drug."[51] The FDA knew the failure rate was averaging 14.6% in the U.S. trial testing the drug through 63 days gestation. The findings were that 27% had ongoing pregnancies, 43% had incomplete abortions, 10% requested and had surgical terminations, and the remaining 20% of patients had surgical terminations performed because of medical indications directly related to the medical procedure.[52]

The Report stated the "best" outcome was in the patient group where the pregnancies were less than or equal to 49 days.[53] In this group, the Report stated

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[48] *Id*.

[49] *Id*.

[50] *Id*.

[51] *Id*.

[52] *Id*.

[53] *Id*. at 31.

that 7.9% of patients required surgical intervention after taking RU-486.[54] The Report also stated that as "the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group."[55] The Congressional Staff Report concluded that "[b]y any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the 'best' outcome is a dismal result."[56] Indeed, this is a dismal result.

In 2011, the FDA issued a report on the post-marketing events of RU-486.[57] The FDA reported that there were 2,207 adverse events (complications) in the United States related to the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.[58] Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[59] The deaths were all in women who used the drug off-label.

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[54] *Id*.

[55] *Id*.

[56] *Id*.

[57] Food and Drug Administration, *Mifepristone U.S. Post-marketing Adverse Events Summary Through 04/30/2011* (July 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

[58] *Id*.

[59] *Id*.

Other researchers and physicians have studied RU-486 and its complications. There is continuing evidence both in the United States and foreign countries of the complications that women experience from RU-486.[60] When the FDA approved RU-486, it knew that there were inherent dangers with this drug, and therefore, the FDA approved it under a special code section that is used for drugs that "can be safely used only if distribution or use is restricted."[61]

Providing for the safety of drugs and medical procedures are within the legitimate function of the State, and therefore, the Court of Appeals for the Ninth Circuit erred in finding ARIZ. REV. STAT. § 36-449.03(E)(6) and its implementing regulation, ARIZ. ADMIN. CODE § R9-10-1508(G) unconstitutional.

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[60] *See generally* ANGELA LANFRANCHI, IAN GENTLES, & ELIZABETH RING-CASSIDY, COMPLICATIONS: ABORTION'S IMPACT ON WOMEN ch. 13 (2013).

[61] 21 C.F.R. § 314.520.

II. MEDICAL ABORTIONS EXPOSE WOMEN TO INCREASED RISKS OF PHYSICAL AND PSYCHOLOGICAL HARM, AND THEREFORE, THE ARIZONA LEGISLATURE WAS PROPER IN PROVIDING SAFETY MEASURES TO PROTECT WOMEN.

A. This Court Requires That Women Must Be Given Accurate and Truthful Information, and Therefore, the Court of Appeals for the Ninth Circuit Misapplied *Casey*.

In *Casey*, this Court emphasized the need for a woman to have full, accurate, and truthful information so that she could make an informed decision.[62] ARIZ. REV. STAT. § 36-449.03(E)(6) provides reasonable protections for women considering taking the RU-486 regimen based on FDA guidelines for the drug regimen. Off-label use of RU-486 regimen misleads women into thinking that it is safe and approved by the FDA. Furthermore, because women must sign the Mifeprex Medication Agreement[63] which states that their pregnancy is no further than 49 days gestation, the abortionist puts women in a position of providing a false statement by signing the Agreement if there is off-label usage of the drug.

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[62] Planned Parenthood v. Casey, 505 U.S. 833, 882 (1992).

[63] Mifeprex Medication Agreement, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111361.pdf.

This Court correctly stated that it is important for a woman to have full and accurate information to make an informed decision because of the psychological consequences of later realizing that she did not have accurate information or know the truth.[64] This Court stated in *Casey*:

> In attempting to ensure that a woman apprehend the full consequences of her decision, the State furthers the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed. If the information the State requires to be made available to the woman is truthful and not misleading, the requirement may be permissible.[65]

Approximately 1.2 million abortions are performed each year in the United States.[66] Of that number, 17% of all abortions are medical abortions.[67] For

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[64] Planned Parenthood v. Casey, 505 U.S. 833, 882 (1992).

[65] *Id*.

[66] Guttmacher Institute, *Fact Sheet: Facts on Induced Abortions in the United States* (Aug. 2011), *available at* http://www.guttmacher.org/pubs/fb_induced_abortion.html (stating "In 2008, 1.21 million abortions were performed, down from 1.31 million in 2000. However, between 2005 and 2008, the long-term decline in abortions stalled. From 1973 through 2008, nearly 50 million legal abortions occurred.").

[67] *Id*. (stating "In 2008, 59% of abortion providers, or 1,066 facilities, provided one or more early medication abortions. At least 9% of providers offered only early medication abortion

(Continued on following page)

pregnancies within the first nine weeks, that percentage rises to 25% medical abortions.[68] Therefore, approximately 200,000 women are at risk each year for physical and psychological harm from medical abortions such as the RU-486 regimen. These women are entitled to have the regimen examined and approved by the FDA instead of experimental off-label use of the drugs which the FDA restricted to a specific regimen out of concern for women's safety. Furthermore, women need to know accurate and truthful information about the drugs that they are taking and what side effects and risks may occur. To do any less would not be informed consent.

The Court of Appeals for the Ninth Circuit has set a bad precedent based on a misinterpretation and misapplication of this Court's decision in *Casey*. Therefore, the Amici urge this Court to grant certiorari.

B. Scientific Studies Demonstrate That Medical Abortions Present Increased Risks of Physical and Psychological Problems.

Physical Risks of RU-486

A woman should be given factual information about the physical and psychological risks of the

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services. Medication abortion accounted for 17% of all nonhospital abortions, and about one-quarter of abortions before nine weeks' gestation, in 2008.").

[68] *Id*. (stating one-quarter were medication abortions).

RU-486 regimen.[69] The purpose of "[i]nformed consent provisions serve not only to communicate information that would not necessarily be known to the patient, but also help the woman to make a fully informed decision."[70] Therefore, women should be given information that they are exposed to increased risk of physical and psychological problems by taking the RU-486 regimen.[71]

The Arizona Department of Health Services produced the *Woman's Right to Know* Booklet[72] to provide women accurate and truthful information. The booklet discusses the RU-486 procedure and side effects.[73] Included in the list of side effects are: infection, blood clots, hemorrhage, allergic reaction, and death. The possible medical risks that may occur with a medical abortion include: hemorrhage, infection, additional procedure resulting from an incomplete

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[69] *See* Planned Parenthood of Indiana, Inc. v. Commissioner, 794 F. Supp. 2d 892, 918 (S.D. Ind. 2011), *rev'd in part on other grounds and aff'd in part*, 699 F.3d 962 (7th Cir. 2012).

[70] *Id*.

[71] Planned Parenthood v. Rounds, 686 F.3d 889, 898 (8th Cir. 2012) (holding disclosure that an increased risk of suicide ideation and suicide is non-misleading and relevant to the patient's decision to have an abortion and other psychological distress was not challenged).

[72] Arizona Dep't of Health Services, *Woman's Right to Know* Booklet, *available at* http://www.azdhs.gov/phs/owch/informed-consent/right-to-know/documents/a-womans-right-to-know.pdf.

[73] *Id*. at 11, 13.

abortion, sterility, and continuation of the pregnancy.[74]

In reviewing and assessing the scientific literature, researchers have also concluded that there are increased risks of physical problems with the RU-486 regimen.[75] These include: more pain, more nausea or vomiting, higher failure rate, greater risks of acute bleeding requiring surgery, post-procedure bleeding continues for a longer period of time, more women require surgery for persistent bleeding, more total blood loss, and greater risk of massive, life-threatening hemorrhage.[76] They also report that "Mifepristone abortion has 10 times more risk of death from infection than surgical abortion and 50 times more risk of death from infection compared to childbirth."[77] And, if a woman takes misoprostol, the second drug in the RU-486 regimen, and changes her mind, studies document increased risk of fetal malformations.[78]

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[74] *Id*. at 13.

[75] Shuping, Harrison, Gacek, *Medical Abortion with Mifepristone* (*RU-486*) *Compared to Surgical Abortion*, *available at* http://rachelnetwork.org/images/Medical_Abortion_with_Mifepristone.pdf.

[76] *Id*.

[77] *Id*. (citations omitted).

[78] On the FDA approved Misoprostol Label, there are warnings on pages 1, 7, 8, and 13 about birth defects which are based on scientific studies. For example, on page 7 it states in bold letters: **"SPECIAL NOTE FOR WOMEN: Cytotec [Misoprostol] may cause birth defects, abortion (sometimes incomplete), or premature labor if given to pregnant women."**

(Continued on following page)

Psychological Risks of RU-486

The RU-486 regimen also has increased risks for psychological problems. The RU-486 regimen is a very difficult process and simply adds to emotional consequences. Unlike surgical abortion, the woman acts as the abortionist.[79] The drug is self-administered by her own hand and there is no one else to blame or project anger on such as the abortionist or others.[80] Because the woman plays an active role in the procedure and is conscious of each step, it is more likely that there will be psychological consequences.[81] Here is one of the profound differences between surgical and medical abortion. In a surgical abortion, the woman is usually given drugs to be relaxed or to wake up after the procedure is complete. With RU-486, however, "she will have a memory of each step and its effects on her body and the body of her child. She cannot close her eyes to the process and tell herself that someone else is doing this to her . . . Simply looking in the mirror can become a triggering event."[82]

FDA approved Misoprostol Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019268s047lbl.pdf.

[79] Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

[80] *Id*.

[81] *Id*.

[82] *Id*.

The trauma continues because the woman's home becomes a daily trigger. Instead of being a sanctuary or refuge, the home is a trigger for the abortion experience[83] because she is in her home and specifically the bathroom or bedroom. Women who take the RU-486 regimen do "not have the luxury of using the normal coping mechanisms, like avoidance of their abortion clinic and doctors. . . ."[84] These coping mechanisms allow her to distance herself from "the painful reality of what she has done."[85] Therefore, this "traumatic scene will be accessible each time a woman uses her bathroom, lays on her bed, or any other associations they make while waiting for the pill to do its job. Her very home becomes a daily trigger to traumatic feelings and sensations."[86]

The courts also have recognized the negative psychological impact that abortion has on women. For example, the Court of Appeals for the Fifth Circuit cited testimony that abortion as practiced is "almost always a negative experience for the patient. . . ."[87] This Court has recognized that abortion:

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[83] Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

[84] *Id*.

[85] *Id*.

[86] *Id*.

[87] Women's Medical Center v. Bell, 248 F.3d 411, 418 (5th Cir. 2001).

> Is an act fraught with consequences for others; for the woman who must live with the implications of her decision; for the persons who perform and assist in the procedure; for the spouse, family, and society which must confront the knowledge that these procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and depending on one's beliefs, for the life or potential life that is aborted.[88]

More recently, this Court recognized, "whether to have an abortion requires a difficult and painful moral decision" and is "fraught with emotional consequences."[89] In addition, women can suffer from depression, regret, guilt, and a loss of self-esteem following an abortion.[90] As Justice Ginsburg wrote, "The Court is surely correct that, for most women, abortion is a painfully difficult decision."[91] Indeed, the Court has recognized the impact that abortion can have on women.

The RU-486 medical abortion regimen creates greater risks of both physical and psychological harm to women than surgical abortion. The Arizona Legislature was correct in providing for the protection of women considering the RU-486 regimen and requiring

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[88] Planned Parenthood v. Casey, 505 U.S. 833, 852 (1991).

[89] Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

[90] *Id*.

[91] *Id*. at 184 n.7 (Ginsburg, J., dissenting).

the FDA guidelines be followed instead of the off-label use that abortionists are prescribing. This Court has allowed reasonable medical regulations, and therefore, the Court of Appeals for the Ninth Circuit misinterpreted and misapplied this Court's decisions.

CONCLUSION

This Court has held that the State can make reasonable regulations to protect women, and therefore, the Court of Appeals for the Ninth Circuit misinterpreted and misapplied this Court's decisions in *Casey* and *Gonzales*. Furthermore, this case is certworthy because there is a split of authority in the circuit courts as to the application of the undue burden standard in RU-486 cases. The Court of Appeals for the Ninth Circuit has erred in its application of the standard and only this Court can correct the error.

RU-486 creates greater risks of both physical and psychological harm to women than surgical abortion. Thus, the Arizona Legislature was correct in providing for the protection of women who are considering the RU-486 regimen and requiring the FDA on-label usage be followed when RU-486 is used. Women deserve to have accurate and truthful information so that they can make an informed decision about the

abortion procedure. Therefore, Amici urge this Court to grant certiorari.

Respectfully submitted,

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