IN THE SUPREME COURT OF IOWA

SUPREME COURT NO. 14-1415
Polk County Case No. CVCV046429

PLANNED PARENTHOOD OF THE HEARTLAND, INC. and
DR. JILL MEADOWS, M.D.,
Petitioners-Appellants

v.

IOWA BOARD OF MEDICINE,
Respondent-Appellee

Appeal from Iowa District Court, Polk County, Hon. Jeffrey Farrell

---

Amicus Curiae Brief of the American Association of Pro-Life Obstetricians & Gynecologists, Donna Harrison, M.D., Iowa Right to Life, and Susan Thayer In Support of Respondent-Appellee

---

Timm Reid
Counsel for Amicus Curiae
Iowa Bar No. AT0006547
300 Walnut Street, Suite 5
Des Moines, IA 50309
Telephone: (515) 282-3333
Facsimile: (515) 282-0318
treid@galliganlaw.com

Michael J. Norton*
Natalie L. Decker*
Counsel for Amicus Curiae
ALLIANCE DEFENDING FREEDOM
7951 E. Maplewood Ave., Suite 100
Greenwood Village, CO 80111
Telephone: (720) 689-2410
Facsimile: (303) 694-0703
mjnorton@alliancedefendingfreedom.org
ndecker@alliancedefendingfreedom.org
**pro hac vice admission pending*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

***Cases*:**

***Statutes and Rules*:**

Other Authorities

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are a national professional medical organization, a state pro-life organization, and individuals who have a profound interest in protecting maternal health and the sanctity of human life.

Amici are:

American Association of Pro-Life Obstetricians & Gynecologists ("AAPLOG") is a non-profit professional medical organization consisting of 2,500 obstetrician-gynecologists. AAPLOG was designated as a "special interest group" within the American College/Congress of Obstetricians and Gynecologists ("ACOG") from 1973 to 2013 until ACOG discontinued this designation. AAPLOG is concerned with assuring that quality healthcare is provided to pregnant women and the adverse consequences of abortion on women's health are minimized. AAPLOG explores and compiles data from around the world on abortion-associated complications to provide the public and others with current and reliable data and thus a realistic appreciation of abortion-related health risks.

Donna Harrison, M.D., is the Executive Director of AAPLOG. Dr. Harrison is board certified by the American Board of Obstetrics and Gynecology. She has authored several published research articles on the topic of medication abortions, including the adverse consequences associated with RU-486. Dr.

Harrison teaches physicians about the medical complications of abortions, including medication abortions. Dr. Harrison has testified on these issues before numerous governmental bodies, including several U.S. House and Senate Committees and the U.S. Food and Drug Administration.

Iowa Right to Life Committee is the largest pro-life organization in the State of Iowa. Its mission is to support laws and regulations that protect human life, born and unborn, at all stages of biological development consistent with the belief that every human life has intrinsic value and is entitled to be treated with dignity and respect.

Susan Thayer is a former employee and clinic manager of Planned Parenthood of the Heartland. Since leaving Planned Parenthood of the Heartland in 2009, Ms. Thayer has become one of the Nation's foremost pro-life spokespersons.

SUMMARY OF THE ARGUMENT

Iowa law prohibits anyone other than a licensed physician from performing an abortion. In 2008, Planned Parenthood of the Heartland ("PPH") implemented its webcam medication abortion regime. PPH provided medication abortions to patients who were never personally seen or examined by a doctor at any time in the process. Sixteen States have enacted laws similar to the Iowa Board of Medicine ("IBOM") rule at issue here, *i.e.*, Iowa Administrative Code 653-13.10 (the "Rule"). Just as the IBOM Rule does, these States require the personal involvement of a doctor in medication abortions.

As implemented, non-medical personnel in PPH's more remote Iowa facilities administer medication abortions to patients. A doctor is involved in the process by closed circuit television ("webcam"). Following a brief "webcam" encounter with the patient located in another PPH facility, the doctor causes two medication abortion pills, *i.e.*, mifepristone and misoprostol, to be dispensed to the patient. The patient is instructed to take one of the pills while at the PPH clinic and to take the second pill at home 24 to 48 hours thereafter.

A medication abortion is a dangerous, potentially life-threatening procedure. The IBOM therefore properly established the Rule so as to establish a minimum standard of care for medication abortions. The Rule requires a doctor to perform a physical examination on the patient, to be physically present when the abortion-

inducing drugs are dispensed to the patient, and to schedule and perform a personal follow-up examination on the patient at the same facility at which the medication abortion was administered so as to confirm that the medication abortion achieved its intended purposes and the patient was not experiencing adverse health effects.

Because PPH's webcam medication abortion regime fails to meet this minimum standard of care, PPH sought judicial review, claiming that the Rule threatened women's health by denying them access to medication abortions. PPH contends that its webcam medication abortion regime sufficiently protects a woman's health and safety, in spite of the fact that it is performed by unlicensed medical personnel, and a doctor is not personally involved with the patient at any time before, during, or after the medication abortion procedure.

Because that is fallacious, the District Court correctly upheld the IBOM Rule as a valid and proper exercise of the IBOM's statutory authority. This Court should do likewise.

I. The IBOM Rule is a valid and proper exercise of IBOM's statutory authority.

A. The IBOM Rule is consistent with *Roe v. Wade* and its progeny.

States have strong interests and rights to regulate abortion. *Roe v. Wade*, 410 U.S. 113, 162-64 (1973). The Supreme Court has recognized these two interests as

the "important interest" in protecting a pregnant woman's health and the "important and legitimate interest in protecting the potentiality of human life." *Id.*

Iowa may properly "proscribe abortion [after viability], except when it is necessary to preserve the life or health of the mother." *Id.* Iowa thus has a "legitimate interest in seeing to it that abortion, like any other procedure, is performed under circumstances that ensure maximum safety for the patient." *Id.* at 150.

The Supreme Court replaced *Roe*'s trimester framework with a bifurcated pre-viability/post-viability framework and applied a new "undue burden" standard (related to abortion *patients*, but not to abortion *physicians*) to gauge the constitutionality of abortion-related statutes and regulations. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). The Court reaffirmed *Roe*'s holding that "subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *Id.* at 878-79 (quoting *Roe*, 410 U.S. at 164-65). *Casey's* controlling plurality held that an abortion regulation would only be unconstitutional if, "in a large fraction of cases in which [the challenged regulation] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Id. at* 895.

In its most recent abortion decision, the Supreme Court affirmed that the government undoubtedly "'has an interest in protecting the integrity and ethics of the medical profession.'" *Gonzales v. Carhart*, 550 U.S. 124, 128 (2007) (citation omitted) (Court rejected a challenge by Planned Parenthood and abortionist Leroy Carhart to the federal Partial-Birth Abortion Ban Act). The Court added that States have "wide discretion in passing legislation in areas where there is medical and scientific uncertainty." *Id*. at 163.

Here, PPH cannot establish, as it must, that the Rule has the "purpose or effect [] to place a substantial obstacle in the path of a woman seeking an abortion." *Gonzales*, 550 U.S. at 146 (quoting *Casey*, 505 U.S. at 878). Moreover, PPH cannot show that the Rule operates as a "substantial obstacle" in a "large fraction of the cases in which it is relevant." *Casey*, 505 U.S. at 895.

B. The IBOM Rule is a proper exercise of IBOM's statutory authority.

The IBOM's purpose is to "safeguard[] the public health, safety and welfare by regulating" doctors.[1] *See* IAC 653—1.2(17A). The IBOM, which consists of ten members, seven of whom are practicing doctors, is directed by law to make all necessary and proper rules relating to the practice of medicine. Iowa Code

[1] IBOM, http://medicalboard.iowa.gov/index.html

§§147.76, 147.14(1)(b). This includes the authority to establish and enforce minimal standards of care for the practice of medicine. Iowa Code 148.6(2)(g).

In August 2013, after notice, comment and a public hearing,[2] the IBOM promulgated the Rule. The Rule established the minimum standard of care for medication abortions by requiring that, prior to administering a medication abortion, a doctor must personally examine the patient to determine and document the gestational age of the unborn child and the location of the pregnancy. In addition, a doctor is to be physically present when the abortion-inducing drugs are dispensed to the patient. Finally, a doctor must schedule and personally examine the patient at a follow-up appointment within 12 to 18 days of the medication abortion at the same facility at which the medication abortion was administered. The purpose of this follow-up examination is so the doctor may confirm that the pregnancy has been terminated and to determine if there are any post-abortion complications.

The IBOM, acting within the scope of its statutory authority, properly exercised its authority in establishing a minimum standard of care for medication abortions designed to protect the health and safety of women and to promote the integrity of the medical profession.

[2] The IBOM sought and received substantial public comment, including testimony from 28 individuals and written comments from 244 individuals, organizations and experts. Ruling on Judicial Review, p. 7.

C. Standard of judicial review.

Iowa Code, chapter 17A, governs judicial review of administrative agency rulemaking. *Iowa Med. Soc. v. Iowa Bd. of Nursing*, 831 N.W.2d 826, 838 (Iowa 2013). However, Iowa law requires a reviewing court to recognize that the administrative agency has special expertise and does not authorize a reviewing court to substitute its judgment for that of the administrative agency simply because the reviewing court might have come to a different conclusion or because there are conflicting views about the medical bases of a rule. This is particularly important in the context of abortion, a controversial subject that raises profound moral questions on which our society has yet to reach consensus, as the controversial nature of the abortion issue clouds valid decisions relating to the health and safety of women who may be considering an abortion.[3]

Thus, a district court may only grant relief if the agency has prejudiced the substantial rights of a plaintiff and the action meets the criteria set forth in §17A.19(10). *Auen v. Alcoholic Beverages Div.*, 752 N.W.2d 586, 598 (Iowa 2004). Moreover, an agency rule is presumed valid and the burden is on the

[3] *See, e.g., Roe v. Wade*, 410 U.S. 113, 116 (1973) (“[T]he sensitive and emotional nature of the abortion controversy” provokes “vigorous opposing views” and inspires “deep and seemingly absolute convictions.”); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 850 (1992) (The practice of abortion has “profound moral and spiritual implications,” and “men and women of good conscience can disagree” about those implications and can find abortion “offensive to [their] most basic principles of morality.”).

challenging party to prove that the IBOM, as a "rational agency," could not have concluded that the Rule was within the scope of its delegated authority. *Iowa Med. Soc.*, at 839 (citing *Overton v. State*, 493 N.W.2d 857, 859 (Iowa 1992) and Iowa Code 17A.19(8)(a)).

The IBOM Rule establishes a minimum standard of care for doctors who perform medication abortions. PPH's webcam medication abortion regime does not meet this standard. It also deviates significantly from FDA protocol for medication abortions, results in a breach of patient safety, and diminishes the integrity of the medical profession.

D. Other States have enacted similar medication abortion regulations.

Iowa is not alone in its effort to protect the health and safety of women and to promote the integrity of the medical profession by regulating medication abortions. Sixteen other States require prescribing physicians to personally attend to patients to whom a medication abortion is administered, *i.e.*, Alabama, Arizona, Indiana, Kansas, Louisiana, Michigan, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, and Wisconsin.[4]

[4] *See* National Right to Life Committee, Inc., *Webcam Abortion Bans*, updated August 22, 2014, for a summary of state laws and citations. Available at www.nrlc.org.

Thus, regulations such as the IBOM Rule are matters of significant concern for many States, including Iowa, and for good reason.

II. There is sound and reliable medical support for the IBOM's Rule.

A. Medication abortions pose even greater risks than do surgical abortions.

Abortion is a medical procedure that poses significant and well-documented health risks, both physical and psychological, to women.[5] These medication abortion risks are greater than risks of surgical abortions.

The risks associated with medication abortions are acknowledged by both the U.S. Food and Drug Administration ("FDA") and the manufacturers of both Mifeprex (the brand name of generic mifepristone) and misoprostol. The American College of Obstetricians & Gynecologists ("ACOG") has repeatedly acknowledged these risks in ACOG Practice Bulletins ("ACOG PB").[6]

The largest and most accurate study of medication abortions was published in 2009. It consists of a review of medical records of 22,368 women who underwent medication abortions predominantly using an off-label (non-FDA

[5] *See* J.M. Thorp, Jr., M.D., et al., *Long-Term Physical & Psychological Health Consequences of Induced Abortion: Review of the Evidence*, 58 OB/GYN SURVEY 67 (2003); M. Niinimäki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBSTET. GYNECOL. 114:795 (Oct. 2009).
[6] *ACOG Practice Bulletin 67: Medical Management of Abortion* 4-6 (Oct. 2005, reaffirmed 2011); *ACOG Practice Bulletin 143: Medical Management of First-Trimester Abortion* 3-5 (Mar. 2014)

approved) mifepristone and misoprostol similar to PPH dosing, compared with 20,251 women who underwent surgical abortions. This study concluded that the "overall incidence of adverse events was fourfold higher" in medication abortions than in surgical abortions.[7] These higher frequency "adverse events," or risks, included hemorrhaging, incomplete abortions, surgical re-evacuation, and injuries requiring post-abortion operative treatment.[8]

The FDA-approved Mifeprex final printed labeling ("FPL") warns 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."[9] The Mifeprix FPL states that "about 90% of patients report adverse reactions following administration of misoprostol on day three of the treatment procedure."[10] These risks include abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, anemia, and pelvic inflammatory disease.[11]

Other serious complications from misoprostol have been documented, including fatal septic shock, and acute hemolytic anemia.[12] The greatest risk,

---

[7] *See* M. Niinimäki, *supra* note 5.
[8] *Id.*
[9] Mifeprix FPL, available at http://www.accessdata.fda.gov.
[10] *Id.* at 11.
[11] *Id*. at 12 (Table 3).
[12] A. Filippini et al., *Acute hemolytic anemia with acanthocytosis associated with high-dose misoprostol for medical abortion*, ANN. EMERG. MED., 50(3):289-91; F.

however, is hemorrhage. Hemorrhage must be immediately attended to so as to avoid life-threatening blood loss. ACOG has recognized the sudden and severe nature of such hemorrhage.[13]

Research also documents that medication abortions present greater risks of death from Clostridium sordellii sepsis ("C. sordellii") than do surgical abortions. The risk of death from C. sordellii infection during a mifepristone abortion is at least ten times the risk of death from all types of infection after surgical abortion.[14] Significantly, Mark Fischer of the Centers for Disease Control reported no published rates of deaths from C. sordelli or other infections following surgical abortions performed at gestational ages similar to mifepristone abortion gestational ages in his review of C. sordellii infections from 1988 to 1997.

As of August 2008, six women had died from bacterial infection following medication abortions.[15] Subsequently, the number of complications—including

---

Cittadini et al., *A Case of Toxic Shock due to Clandestine Abortion by Misoprostol self-administration*, J. FORENSIC SCI. 10.1111/1556-4029.12536 (July 2014).

[13] "[J]ust as for women undergoing surgical abortion, surgical curettage must be available on a 24 hour basis for cases of hemorrhage. Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should work in conjunction with a clinician who is trained in surgical abortions." ACOG PB 67, *supra* note 6, at 6; reaffirmed in PB 143.

[14] *See* M. Fischer et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordelliii after Medical Abortion*, N.E.J.M. 353:2352, 2358 (2005); M.F. Greene, *Fatal Infections Associated with Mifepristone Induced Abortion*, N.E.J.M. 353:2317-2318 (Dec 1, 2005).

[15] U.S. Government Accountability Office, *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex* 38 (Aug. 2008).

deaths—has increased. In July 2011, FDA reported 2,207 cases of adverse events after using mifepristone for the termination of pregnancy.[16] Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[17] This is a minimum number because many potential complications from the use of the Mifeprex regime are unknown due to inadequacies in reporting.[18]

Despite reporting inadequacies, there are several methodologically-sound studies comparing the outcomes of surgical versus medical abortions which this Court may rely upon that are based on complete medical records of women who have had medication and surgical abortions at comparable gestational ages. These large registry-based studies document that there are more complications from medication abortions than from surgical abortions. A major review of nearly 7,000 abortions performed in Australia using off-label regimes 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

[16] *See* FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011).
[17] *Id*.
[18] *See* D.A, Kessler, *A New Approach to Reporting Medication and Device Adverse Effects and Product Problems*, JAMA 269: 2765 (1993).

surgical abortions.[19] Women receiving medication 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.[20] Additional research found similar results; failure rates for medical abortion (5.2–16.0%) exceeded those of surgical abortion (0–4.0%).[21] "Women receiving mifepristone/misoprostol are more likely to require an unplanned surgical intervention than women who undergo suction curettage. They experience more discomfort with their procedure and in the follow-up interval, bleed for a longer period, and remain at risk for surgical completion curettage for several weeks."[22]

Thus, evidence demonstrates that women are more likely to require medical intervention after a first trimester medication abortion than after a surgical abortion. In addition, other studies note the higher incidence of pain and side effects in Mifeprex abortion patients versus surgical abortion patients. Mifeprex

---

[19] *See* E. Mulligan & H. Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, AUSTRALIAN FAMILY PHYSICIAN 40(5):342-45 (May 2011).
[20] *Id*. at 344.
[21] B. Winikoff et al. *Safety, Efficacy, and Acceptability of Medical Abortion in China, Cuba, and India: A Comparative Trial of Mifepristone and Misoprostol Versus Surgical Abortion*. 176 AM. J. OBSTET. GYNECOL. 431 (1997).
[22] J.T. Jensen et al., *Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study*, CONTRACEPTION 59:153-59, 153 (1999).

patients report "significantly longer bleeding" and "significantly higher levels" of pain, nausea, vomiting, and diarrhea than do women who have surgical abortions.[23]

B. Studies PPH cites are biased and flawed.

In the District Court and again in this Court, PPH relies heavily on Dr. Daniel Grossman's study that concluded that PPH's webcam medication abortion regime is safe.[24] The Grossman study, co-authored by a PPH management official,[25] exhibits methodological bias, including a lack of randomization of the study patients, which allows for selection bias, small sample size, large loss to follow up (21 to 24%), and the "face to face" encounters had no physical examination. Consequently, it can provide neither an accurate complication rate for telemedicine, nor an accurate comparison with the true standard of physical examination prior to abortion.

In addition, after PPH commenced this litigation, Dr. Grossman co-authored ACOG Practice Bulletin 143 ("PB 143") upon which PPH also relies to assert the safety of its webcam medication abortion regime. PB 143 affirms that there are significant risks associated with medication abortion. However, it ignores five

[23] *Id. at* 156.

[24] D. Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, OBSTET. GYNECOL. 118: 296-303 (Aug. 2011).

[25] *Id.* at 1("From Ibis Reproductive Health, Oakland, California; [and] Planned Parenthood of the Heartland, Des Moines, Iowa"). Todd Buchacker, a then employee of PPH, is a co-author of this study. LinkedIn, https://www.linkedin.com/pub/todd-buchacker/6/318/b4b.

other studies in the medical literature documenting higher complication rates[26] and instead relies on an "anonymously" funded study ("PPFA study") whose authors include Deborah Nucatola, an employee of Planned Parenthood Federation of America, and Dr. Mitchell Creinin, who reportedly receives compensation from the mifepristone distributor, a drug dispensed by PPH pursuant to its webcam medication abortion regime,[27] for the proposition that adverse events from medication abortions are "rare." This PPFA study is also methodologically deficient.

Determining a rate of complications requires an accurate numerator (number of complications) and an accurate denominator (number of abortions). The numerator used in the PPFA study is not the number of complications, but rather the number of complications *reported to Planned Parenthood*, making it falsely low by excluding complications treated outside of PP facilities, an error the authors acknowledge: "[S]ome patients may have experienced a significant adverse event

---

[26] E.G. Raymond, et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 Contraception 26 (2012); Philip Goldstone et al., *Early Medication Abortion Using Low-Dose Mifepristone Followed By Buccal Misopristol: A Large Australian Observational Study*, Med. J. Aust. 197:282-286 (Sept. 3, 2012); Mulligan, *supra* note 19; N.T.N. Ngoc, et al., *Comparing Two Early Medical Abortion Regimens: Mifepristone+Misoprostol vs. Misoprostol Alone*, 83 CONTRACEPTION 410, 415 (2010); B. Winikoff et al, *Two Distinct Oral Routes of Misopristol in Mifepristone Medical Abortion*, OBSTET. GYNECOL. 112:1303-1310 (Dec. 2008).

[27] *See* K. Cleland, et al., *Significant Adverse Events and Outcomes After Medical Abortions*, OBSTET. GYNECOL. 121:166-71 (2013) ("PPFA study").

or outcome but did not follow up [with Planned Parenthood] after their medical abortion."[28] Thus the failure rate reported is not accurate, as the authors admit.[29]

The PPFA study does not include data on what abortion regimes were used, or even such basic information as what gestational ages were involved. "Therefore [as the PPFA study itself concludes] we are unable to analyze rates of significant adverse events and outcomes based on patient age, gestational age or other demographic variables, or to identify the exact regimens used in the 232,275 medical abortions with no reported complications."[30]

Thus, the PPFA study is unreliable. It does not provide an accurate success, failure or complication rate of medication abortions. What it does demonstrate is the inadequacy of record-keeping by Planned Parenthood's facilities nationwide.

C. Webcam medication abortions deviate from FDA protocol.

1. How PPH's Webcam medication abortion regime works.

In 2008, PPH, based in Des Moines, Iowa, implemented its webcam medication abortion regime. As is known to *Amicus* Susan Thayer, who was employed by PPH at its Storm Lake, Iowa facility, PPH sought to reduce costs and increase profits through its webcam medication abortion regime. A medication abortion candidate

---

[28] *Id.*
[29] *Id.* at 4 ("Although we present data for ongoing pregnancy rates, we are unable to assess an overall 'failure rate' for the 2-year reporting period.").
[30] *Id.*

would present at a rural Iowa PPH clinic that was not staffed, for cost reasons, by a doctor. Following a brief closed circuit television interview by a doctor in a different location, usually Des Moines, the doctor asked the patient if she wanted to proceed with a medication abortion. If her answer was "yes," the doctor pressed a button in the doctor's location which caused a drawer in front of the woman at her location to open in which she would find the two abortion-inducing dosages, *i.e.,* mifepristone and misoprostol. The patient was then requested to take the first dosage at the facility and to take the second dosage at home 24-48 hours later. That is the extent to which a patient was ever "seen" by a doctor.[31]

2. PPH's medication abortion regime is contrary to FDA protocol.

While the IBOM Rule does not require strict compliance with the entirety of FDA protocol for mifepristone and misoprostol, it does require compliance with several aspects of the FDA protocol. Notably, FDA approved mifepristone under the restricted distribution provision of Subpart H, a special code section used for drugs that "can be safely used only if distribution or use is restricted."[32] FDA

[31] *See* AAPLOG's August 21, 2013 letter to IBOM in support of the proposed rule.
[32] 21 C.F.R. § 314.520; U.S. GAO, *supra* note 15.

recognized mifepristone's inherent dangers and approved it with use restrictions.[33] FDA has never modified these restrictions.

The RU-486 label reflects FDA's approved protocol and describes the responsibilities of the physician and the patient:

> 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. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[34]

The Mifeprex FPL calls for three visits with a doctor.[35] On Day One, the label calls for administration of Mifeprex in a single oral dose of three 200 mg tablets (600 mg) of Mifeprex.[36] On Day Three, two days after ingesting Mifeprex, the patient is instructed to return to her healthcare provider. "Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan,

---

[33] Mifepristone FPL, available at www.accessdata.fda.gov; AAPLOG, Citizen Petition and Request for Administrative Stay [to FDA regarding Mifeprex], August 2002, at 4-5.
[34] Mifeprex FPL, *supra* note 9.
[35] *Id.*
[36] *Id.*

the patient then takes two 200 μg tablets (400 μg) of misoprostol orally."[37] Additionally, the patient is instructed to "return for a follow-up examination by the doctor approximately 14 days after the administration of Mifeprex to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred"[38] and there are no complications.

D. PPH's webcam abortion regime targets women for whom medication abortions are not advisable.

ACOG PB 67 and 143 both state that medication abortion should be limited to carefully screened women who are capable of returning for follow-up visits. If a woman is not capable of returning for follow-up examination, then she is not a candidate for a medication abortion, and should instead have a surgical abortion.[39]

One study documented that complications from medication abortions are severe enough that between 13–15% of women obtaining them consulted their general practitioner afterwards.[40] Thus, administration of a medication abortion requires that *both* the doctor and the patient be available for follow-up examination to assure there are no complications that require further medical care. The administration of webcam medication abortions to patients in remote regions

---

[37] *Id.*
[38] *Id.*
[39] ACOG PB 67 and 143, *supra* note 6.
[40] H. Hamoda, et al., *A Randomized Controlled Trial of Mifepristone in Combination with Misoprostol Administered Sublingually or Vaginally for Medical Abortion Up to 13 Weeks of Gestation*, 112 BJOG 1106 (2005).

increases risks to women who have post-abortion complications but who are unable to access quality medical care.

While *Amici* prefer fewer rather than more abortions, if a patient does seek a medication abortion in a remote region, it is more advisable for that woman to be provided with a surgical abortion which, according to authoritative studies, is less likely to result in serious or life-threatening post-abortion complications.

Thus, the women PPH targets for webcam medication abortions are the very women who should not be administered medication abortions.

E. Requiring the physical presence of a doctor protects the health and safety of women and enhances the integrity of the medical profession.

The physical presence of and participation by a doctor for a potentially life-threatening procedure is an elementary standard of care in the medical profession. A doctor who remotely views an image of a woman for a few brief moments via closed circuit television cannot have a valid doctor-patient relationship and is severely handicapped in the diagnosis and treatment of the patient. PPH's webcam medication abortion regime does not protect the health and safety of women and degrades, not enhances, the integrity of the medical profession.

1. Doctors should conduct an in-person physical examination.

An in-person physical examination by a doctor accomplishes many different and important objectives, all of which are in the best interests of the patient.

Doctors are trained to gather information about their patients through talking with and personally observing patients.[41] Obtaining patient history and conducting a physical examination "are among the few commonalities in medicine, practiced by every physician trained in every country throughout the world."[42]

A doctor's knowledge of the patient and the patient's trust in the doctor is associated with patient adherence to the health advice provided by the doctor.[43] Since medication abortions require compliance with a lengthy process, this trust becomes a key component in compliance with the entire regimen. The length of a physician-patient relationship and the level of communication between the doctor and patient are predictors of trust, which is itself a predictor of receipt of clinical preventive services.[44]

---

[41] *See* A.Verghese et al., *The Bedside Evaluation: Ritual and Reason*, ANNALS OF INTERNAL MEDICINE, 155:550-553 (Oct. 2011).

[42] D. Olson & K. Roth, *Journal Discussion: Diagnostic tools and the hands-on physical examination*, VIRTUAL MENTOR, AMERICAN MEDICAL ASSOCIATION JOURNAL OF ETHICS, Vol.9, No. 2:113. Additionally, the standards for pre-operative examination of patients are well established. *See* 42 C.F.R. §416.52(a) (requiring that patients have a "comprehensive medical history and physical assessment completed by a physician ... or other qualified practitioner" to determine the patient's condition, readiness, risks, and appropriateness of the location of the procedure).

[43] *See* M. Parchman & S. Burge, *The Patient-Physician Relationship, Primary Care Attributes, and Preventive Services*, FAMILY MEDICINE 22 (Jan. 2004); *D. Sanfran, et al., Linking Primary Care Performance to Outcomes of Care*, J. FAM. PRACT. 47:213-20 (1998).

[44] Parchman, at 24; A. Mainmus et al., *Continuity of Care and Trust in One's Physician: Evidence from Primary Care in the United States and United Kingdom*, FAM. MED. 33(1):22-7 (2001).

A physical examination is even more important in a medication abortion to enable the doctor to accurately determine the gestational age and the location of the pregnancy, to rule out any contraindications, to establish a baseline for the patient, and to develop a doctor-patient relationship so as to determine whether the patient is a good candidate for a medication abortion. It is professionally negligent for doctors to fail to participate in any meaningful way in the examination of their patients and in the administration of a medication abortion. It is likewise unprofessional for a doctor to rely on an unlicensed "medical assistant"[45] hundreds of miles from the doctor's location for these purposes.

In addition, the Rule, for sound medical reason, requires doctors to physically examine the patient. IAC 653-13.10(3). This means that doctors, as they should be, will personally be with their patients when dispensing abortion-inducing drugs.

[45] A high school diploma is not required in order to be a "Certified Medical Assistant" for PPH. *Planned Parenthood of the Heartland, Employment, Certified Medical Assistant*, (Nov. 20, 2014), http://plannedparenthoodext.hire.com/viewjob.html?optlink-view=view-113681&ERFormID=newjoblist&ERFormCode=any. Neither physical examinations nor "telephone triage" appear in the scope of practice of CMAs. See Iowa Society of Medical Assistants, http://www.iowasma.org/cma.php; American Association of Medical Assistants,http://www.aama-ntl.org/medical-assisting/what-is-a-medical-assistant#.VGvgjYvF8uc.

2. Gestational age must accurately be determined.

It is also critical that gestational age be accurately determined for patients receiving a medication abortion, and that the rate of complications specific to the gestational age be disclosed during the informed consent process, because as the gestational age increases, the risks to the patient increase and the likelihood of the success of the procedure diminishes. A failed termination, particularly if undetected for some time, can have devastating health consequences for the woman, including death.

The risk of hemorrhage, retained tissue, and ongoing pregnancy increase after 49 days gestation regardless of the regime used.[46] It was because of the increase in complications after 49 days for all regimes of medical abortion that FDA limited use of the Mifeprex regime to 49 days or less.

The success rates of the off-label regime of mifepristone and buccal misoprostol at gestational ages greater than 49 days as compared with 49 days have been documented in a published study which found that the complete abortion rate at 49 days was 97.5% as compared to the complete abortion rate at 50-56 days, which was 89.3%. Similarly, the ongoing pregnancy rate at 49 days or less was 0.6% versus an ongoing pregnancy rate of 7.1% at 50-56 days gestation. And

[46] *See* E.G. Raymond, *supra* note 26.

finally, the rate of need for surgery for failures was 1.9% at 49 days or less compared with 3.6% at 50-56 days gestation.[47]

Misoprostol administration in pregnancy also carries significant risks, especially at gestational ages beyond the FDA limit of 49 days (seven weeks). The misoprostol label itself warns that uterine rupture may occur when administered to pregnant women beyond the eighth week of pregnancy.[48]

An in-person physical exam by a doctor and an ultrasound by a qualified practitioner are prudent before mifepristone is prescribed. This is the "medical gold standard" for dating early pregnancy.[49] Additionally, during the early stages of pregnancy, an ultrasound must be done transvaginally to visualize the fetal pole with enough clarity to establish an accurate gestational age and location, and confirm a heartbeat.

3. The location of the pregnancy must be accurately determined.

A *physical exam* and an *ultrasound* are essential to determine the location of the pregnancy and to enable the physician to rule out ectopic pregnancy or other

[47] N.T.N. Ngoc, *supra* note 26.
[48] Cytotec (misoprostol) Final Printed Label, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf.
[49] *See* AAPLOG, *supra* note 33; Kurt T. Barnhart, *Ectopic Pregnancy,* N. ENGL. J. MED. 361:379-387 (July 23, 2009).

contraindications.[50] It is not possible to diagnose an ectopic pregnancy at an early gestational age without an ultrasound.[51] Notably, mifepristone trials prior to marketing required ultrasound to determine fetal age and location.[52]

While an ultrasound by a certified sonographer[53] might pick up a retained IUD or an ectopic pregnancy, relying on an ultrasound by untrained facility personnel as, according to *Amici* Susan Thayer, is PPH's practice, is inadequate to rule out contraindications. The signs and symptoms of a rupturing ectopic pregnancy are identical to those a woman experiences from a mifepristone

[50]AAPLOG, Statement on Current Practice, *Mifeprex: The Degradation of a Standard of Care*, (Nov. 20, 2014), http://www.aaplog.org/position-and-papers/mifeprex/aaplog-statement-on-current-practice-mifeprex-the-degradation-of-a-standard-of-care/.

[51]AAPLOG, *supra* note 33.

[52]AAPLOG, *supra* note 50.

[53] There is no indication that PPH uses "certified sonographers." To the contrary, as the District Court noted, non-medical employees such as Sue Thayer were expected to perform transvaginal ultrasounds despite the lack of training. Ruling on Judicial Review, p. 25, fn 7. In fact, Todd Buchacker, the co-author PPH's "study" discussed above, told Thayer in response to her concerns regarding the lack of training or qualifications, that anyone who was "breathing" could do a "'vag' ultrasound," and that it really helps if the person has played videogames as it's "a lot like running a joystick." *See Former Planned Parenthood Manager Speaks out*, STORM LAKE PILOT TRIBUNE, Sept. 12, 2011, http://www.stormlakepilottribune.com/story/1761832.html.

abortion. A missed diagnosis of ectopic pregnancy is a life threatening mistake that has resulted in deaths of American women.[54]

4. Contraindications must be ruled out.

There are several contraindications for medication abortions, including confirmed or ectopic pregnancy, undiagnosed adnexal mass, an intrauterine device (IUD) in place, chronic adrenal failure, concurrent long-term corticosteroid therapy, history of allergy to mifepristone, misoprostol or other prostaglandin, hemorrhagic disorders, concurrent anticoagulant therapy, and inherited porphyrias.[55] Most clinical trials have also excluded women with anemia, severe liver, renal or respiratory disease or uncontrolled hypertension or cardiovascular disease (angina, valvular disease, arrhythmia or cardiac failure.)."[56] Additionally, the manufacturer of Mifeprex specifically states that the drug should not be used by anyone who "may be unable to understand the effects of the treatment procedure or to comply with its regimen." A doctor, not an unlicensed "medical

[54] *See* M.M. Gary & D.J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, ANNALS OF PHARMACOLOGY 40(2):191 (2006).
[55] Mifeprex FPL, *supra* note 9, at 5.
[56] ACOG PB 143, *supra* note 6, at 6 ("[T]he safety of medical abortions in women with anemia is unknown.").

assistant," should conduct a physical examination of the patient to rule out these contraindications.[57]

Additionally, a pelvic examination prior to administration of mifepristone is essential to minimizing the risks of medication abortion by identifying conditions which make emergency surgery especially difficult. Conditions such as cervical stenosis or enlarged fibroid uterus or severe anteflexion or retroflexion of the uterus increase the risks of emergency surgery for hemorrhage. Terminating the pregnancy of a woman with these high risk conditions should best be done surgically, under controlled conditions, where hemorrhage and perforation of the uterus is promptly managed. Furthermore, the identification of these conditions, and the degrees to which they increase the risk of emergency surgery should be discussed with each patient as part of the informed consent process, since a presentation of the risks of medication abortion versus surgical abortion is a required part of informed consent and informs a woman's choice of method.

Failure to diagnose these conditions due to a lack of due diligence in performing a physical examination and ultrasound constitutes malpractice. Without

[57]A trained physician will be able to identify many of these contraindications. For example, a physician can examine for liver disease. Stanford School of Medicine, *Stanford Medicine 25: An Initiative to Revive the Culture of Bedside Medicine*, http://stanfordmedicine25.stanford.edu/the25/liverDisease.html; http://stanfordmedicine25.stanford.edu/the25/liver.html.

a proper examination by a doctor, the risks of missing these conditions will be greatly increased.

5. The patient's baseline must be established.

A physical examination by a doctor will enable the doctor to obtain the patient's baseline. A patient's baseline includes information about the patient's condition at the outset of treatment and enables a doctor to use that information as a reference point in future examinations. This is particularly important since medication abortions require follow up to confirm the completion of the procedure and the absence of adverse consequences.

A physical examination, including a pelvic examination, by a doctor before any intervention is important in detecting early signs of complications which arise after the intervention. ACOG PG 143, upon which PPH relies, concedes that approximately 5% of women will need surgical completion.[58] When a doctor is aware of what is normal for that patient, the doctor can more easily detect early changes in a woman's pelvic exam which may signal serious complications, such as infection or hematoma. But, if there is no baseline examination by the doctor, then subtle early changes in the woman's pelvic examination will be missed and diagnosis delayed.

[58] ACOG PB 143, *supra* note 6, at 5.

6. Doctors should schedule and conduct a follow up examination.

It is also critical that the patient return for follow up examination by a doctor. A patient is more likely to follow the advice and instructions of her doctor when trust has been established in the physician-patient relationship at the outset.

The Rule requires the doctor who induced the medication abortion to schedule a follow-up appointment with the patient 12 to 18 days later to confirm that the pregnancy has been terminated and to assess the woman's medical condition. IAC 653-13.10(4). This is in the best interest of the patient and is necessitated by virtue of the drugs used in the process; failure to do so is dangerous to the patient's health and safety. Moreover, conducing the follow-up appointment at the facility where the medication abortion was performed, which has all of the records relating to the procedure and patient, minimizes errors due to missing information. Without such a follow-up examination by a doctor, termination cannot be confirmed, a requirement for medication abortions.

These visits, including the three directed by FDA protocol, focus on patient safety and assure that the doctor provides important information to the patient and that the patient responds to the doctor. Because IAC 653-13.10 does not require doctors to follow FDA protocol and have a second visit *before* administering misoprostol, it is imperative that the follow-up physical examination be done so the

doctor can confirm the pregnancy has been terminated and that there is no need for additional treatment.

7. Failure to follow up constitutes patient abandonment.

Failure of a doctor to perform a follow-up examination to confirm successful completion of the abortion and the absence of adverse health effects may well constitute patient abandonment. Abandonment of a patient is a recognized basis of professional liability for doctors in Iowa. *Surgical Consultants, P.C. v. Ball*, 447 N.W.2d 676, 682 (Iowa App. 1989). When a doctor assumes responsibility for a patient, the doctor is responsible for the patient until the employment is ended by mutual consent, the doctor is dismissed, or until the doctor's services are no longer required. *Manno v. McIntosh*, 519 N.W.2d 815, 820 (Iowa App.1994). Here, the doctor's duty to a patient is throughout the medication abortion procedure, including the follow-up examination. Abandonment and lack of diligence are two different forms of medical malpractice in Iowa. *Id.* A doctor's "failure to see a patient at intervals necessary to assure proper treatment" may be considered abandonment. *Id.*

Thus, for this reason alone, the Rule enhances the integrity of the medical profession in Iowa.

III. CONCLUSION

The IBOM, in the proper exercise of its statutory authority, established the minimum standard of care acceptable for the administration of medication abortions. PPH's webcam medication abortion regime falls well below this minimum standard of care. For its convenience, financial or otherwise, PPH should not be permitted to jeopardize the health and safety of women and denigrate the integrity of the medical profession.

The District Court's order should be affirmed.

Respectfully submitted this 25th day of November, 2014.

By: s/ Michael J. Norton
Michael J. Norton*
Natalie L. Decker*
Counsel for Amicus Curiae
ALLIANCE DEFENDING FREEDOM
7951 E. Maplewood Ave., Suite 100
Greenwood Village, CO 80111
Telephone: (720) 689-2410
Facsimile: (303) 694-0703
mjnorton@alliancedefendingfreedom.org
ndecker@alliancedefendingfreedom.org
*pro hac vice admission pending

Timm Reid
Counsel for Amicus Curiae
Iowa Bar No. AT0006547
300 Walnut Street, Suite 5
Des Moines, IA 50309
Telephone: (515) 282-3333
Facsimile: (515) 282-0318
treid@galliganlaw.com

CERTIFICATE OF SERVICE

I, Timm Reid, hereby certify that on November 25, 2014, I electronically filed the foregoing Proof Amicus Curiae Brief with the Clerk of the Iowa Supreme Court by using the EDMS system. Service on all parties was accomplished through EDMS.

By: /s/ Timm Reid

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Iowa R. App. P. 6.903(1)(*g*)(1) because this brief contains 6, 849 words, excluding the parts of the brief exempted by Iowa R. App. P. 6.903(1)(*g*)(1).

2. This brief complies with the typeface requirements of Iowa R. App. P. 6.903(1)(*e*) and the type-style requirements of Iowa R. App. P. 6.903(1)(f) because this brief has been prepared in a proportionally spaced typeface using Times New Roman in 14 point.

/s/ Michael J. Norton
Counsel for Amicus Curiae