IN THE IOWA SUPREME COURT

Planned Parenthood of the Heartland, Inc. and **Dr. Jill Meadows, M.D**., Petitioners-Appellants, v. **Iowa Board of Medicine**, Respondent-Appellee.	Case No. 14-1415

On appeal from the Iowa Dist. Ct. for Polk County
(No. CVCV 046429, Hon. Jeffrey Farrell)

Amicus Curiae Brief of Physicians for Life, National Association of Pro Life Nurses, Christian Medical Association, National Association of Catholic Nurses, and The National Catholic Bioethics Center In Support of Respondent-Appellee

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

The U.S. Supreme Court noted in *Planned Parenthood v. Casey*, 505 U.S. 833, 850 (1992), that "[m]en and women of good conscience can disagree" about the implications of terminating a pregnancy. The same is true within the medical community, where there are differing opinions on a wide range of issues facing physicians and patients. Of course, it is such disagreement that spurs the medical community as a whole toward further research and improved treatments and techniques.

Likewise, a professional medical opinion differing from that of the Plaintiffs on the use of "telecommunications" in the abortion context better equips this Court to evaluate the important issues in this case. It also demonstrates the need for proper deference to the Iowa Board of Medicine in its primary role of evaluating medical data and making determinations it concludes are best for patients in Iowa.

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[1] Per Iowa R. App. P. 6.906(1), a motion for leave to file was simultaneously submitted to the Court with this brief. No counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

Amici curiae are national organizations whose members include physicians, nurses, bioethicists, and other healthcare professionals, ***including professionals practicing in Iowa***, who have a profound interest in protecting maternal health. As healthcare professionals, *Amici* provide this court with a wide range of data supporting the Iowa Board of Medicine's decision to adopt the Board rule at issue in this case (hereinafter "Board Rule" or "the Rule").

Prior to adopting the Rule, the Board was presented with comprehensive studies and various data on chemical abortion and the use of telemedicine in administering abortion-inducing drugs. After examining that data, the Board concluded that a proper physician-patient relationship is in the best interest of a woman's health and safety and that such a relationship will be furthered by requiring 1) physician presence and 2) that the physician physically examine a woman before administering abortion-inducing drugs. Such an examination is medically necessary in the abortion context to determine where chemical abortion may be contraindicated because of the stage or location of the pregnancy.

The trial court properly deferred to the Board's medical determination, and *Amici* urge this Court to affirm the decision below.

Amici include the following medical and ethics associations:

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

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

Christian Medical Association, founded in 1931, is a non-profit national organization of Christian physicians and allied

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

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

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

ARGUMENT

There are two general types of abortion: surgical and chemical (or "medical"). Surgical abortion involves the use of instruments to empty the uterus. Examples include aspiration and dilation and evacuation (D&E). Abortion providers consider surgical abortion in the first trimester "extremely safe." *See*, *e.g.*, *Planned Parenthood v. DeWine*, 696 F.3d 490, 494 (6th Cir. 2012); *see also* Planned Parenthood, *In-Clinic Abortion Procedures* (2014).[2] According to the Guttmacher Institute, the vast majority of first-trimester abortions are surgical abortions. *See* Guttmacher Institute, *Fact Sheet: Induced Abortion in the United States* (July 2014).[3]

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

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[2] http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp. All websites were last visited on November 12, 2014.

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

is marketed under the brand name "Mifeprex." *Mifeprex Final Printed Labeling* ("*Mifeprex FPL*").[4] Together, the administration of Mifeprex and the second drug, misoprostol, is the only method of chemical abortion approved by the Food and Drug Administration (FDA) and is known as the RU-486 (or "Mifeprex") regimen.[5] The Guttmacher Institute reports that chemical abortion accounts for only 36 percent of abortions before nine weeks gestation. Guttmacher Institute, *Fact Sheet.*

As this Court is well aware, "the State has a significant role to play in regulating the medical profession." *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007). In Iowa, the Board of Medicine was created to license and regulate physicians practicing in the state. *See generally* IOWA CODE chapters 147, 148, 272C. As explained

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

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

by the trial court, the Board has the authority to adopt all rules necessary and proper to administer and interpret its governing statutes. *See* Slip Op. at 5; *see also* IOWA CODE 147.76. The Board is statutorily tasked with disciplining physicians who are guilty of a number of offenses, including a willful departure from or the failure to conform to the minimal standard of acceptable and prevailing practice of medicine. IOWA CODE 148.6(2)(g).

It was under the Board's statutory role of regulating the practice of medicine that it adopted the Rule at issue in this case. Specifically, the Rule requires that 1) a physician perform an in-person physical exam of the patient to determine gestational age and intrauterine location in the pregnancy before inducing an abortion through an abortion-inducing drug (*i.e.*, a chemical abortion), 2) the physician be physically present at the time an abortion-inducing drug is provided, 3) the physician inducing the abortion schedule a follow-up visit with the patient at the same facility twelve to eighteen days after the use of the drug, and 4) parent(s) be notified if the patient is a minor.

In other words, the Board prohibited the use of "telemedicine"[6] in administering chemical abortion. As cited by the trial court below, the Board considered and weighed "principal reasons presented in support of the rule"—such as ending physical exams conducted by non-physicians without appropriate training for the purpose of confirming or discovering contraindications—as well as "principal reasons in opposition to the rule." Slip Op. at 7-9.

The Board noted that its motivation was to protect the health and safety of Iowans, concluding that a thorough medical history and physical exam is the cornerstone of good medical care. *Id*. at 8-9. The Board determined that the prescribing physician must be physically present to establish the proper physician-patient relationship necessary to conduct a safer chemical abortion, maintaining that an in-person physical exam and

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[6] The National Institutes of Health defines "telemedicine" as "the practice of medicine when the doctor and patient are widely separated using two-way voice and visual communication (as by satellite, computer, or closed-circuit television)." National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2014), http://www.merriam-webster.com/medlineplus/telemedicine.

consultation will strengthen the physician-patient relationship and result in improved and increased follow-up care. *Id*. at 9.[7]

Medical data supports the Board's rule and confirms that the trial court properly deferred to the Board's *medical* decision in this case. First, the FDA treats the RU-486 regimen differently than other drugs. Not only did the FDA approve the drug regimen with physician restrictions, but it has also placed Mifeprex on the list of drugs that require a Risk Evaluation and Management Strategy (REMS). *See infra*, Part I. It was, therefore, well within the Board's purview to ensure that Mifeprex, a drug which has been

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[7] Abortion advocates frequently decry legislation regulating abortion practices, filing challenges seeking to invalidate legislative actions they do not deem based on medical data. Here, however, a different situation arises: the Rule in litigation was promulgated by a state *medical* board comprised mostly of *physicians* (7 of the 10 members) and based on *medical* data reviewed and weighed by that *medical* board. Further, the Rule was adopted by an 8-2 vote of the Board, with neither of the dissenting members disagreeing publicly with the medical legitimacy of the Rule. Instead, the dissenting members were concerned with the speed of the process. Slip Op. at 7. In fact, one of the dissenting members also "shared health concerns with [the plaintiff's] telemedicine practice, citing issues with the training of clinic staff members and access to emergency care in the event of complications." *Id*.

specially categorized by the FDA, is also stringently evaluated and properly regulated by the Board.

Further, both the FDA and the drug manufacturer acknowledge that nearly all women who use the RU-486 regimen will experience adverse effects, and as of 2011 more than 2,200 complications related to the regimen had been reported to the FDA. *See infra*, Part II. Again, it is well within the role of the Board to regulate the practice of medicine to ensure the safest administration of potentially risky drugs.

Finally, there are known contraindications to the RU-486 regimen that support a physician's examination of a woman prior to administering abortion-inducing drugs. *See infra*, Part III.

While general use of telemedicine can be suitable and perhaps even advisable in some circumstances, the Board acted appropriately and within its medical discretion by examining data and then promulgating a rule that it believed best protected the health and welfare of Iowa women considering abortion. Plaintiffs' challenge and requested invalidation of the Rule would undermine the authority of the Board to weigh medical data and

make the medical decisions it believes are in the best interests of patients.

I. The FDA's restrictions on distribution and use of the RU-486 Regimen support the Board's Rule

Even before the approval of mifepristone for termination of pregnancy, the FDA treated the drug regimen differently than the vast majority of drug approvals. In its "Approvable Letter" of February 2000, the FDA informed the drug sponsor that restrictions on the distribution and use of mifepristone were needed to assure safe use. FDA, Feb. 2000 Approvable Letter, at 5.[8]

The FDA subsequently approved the RU-486 regimen under the rubric of "Subpart H," a special provision in the Code of Federal Regulations for drugs that "can be safely used ***only if*** distribution or use is ***restricted***." 21 C.F.R. § 314.520 (emphasis added). Under Subpart H, the FDA can "require such

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[8] http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687approvable00.pdf

postmarketing restrictions as are needed to assure safe use" of the drug approved. *Id*.

To put this into perspective, out of almost 1,800 New Drug Applications (NDAs) approved between 1992 and 2011, only 69 were approved under Subpart H.[9] Thus, mifepristone is not comparable to the vast majority of drugs approved by the FDA between 1992 and 2011.

Per the Subpart H approval, the FDA's September 2000 "Approval Letter" restricted the distribution of Mifeprex by requiring that it be provided by or under the supervision of a physician who has the ability to assess the duration of pregnancy accurately, diagnose ectopic pregnancies, provide surgical intervention in cases of incomplete abortion or severe bleeding (or have made plans to provide such surgical intervention through

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[9] *See CDER Drug and Biologic Accelerated Approvals as of September 30, 2011*, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM278506.pdf; FDA, *Summary of NDA Approvals & Receipts, 1938 to the present* (updated 2013), http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAApprovalsReceipts1938tothepresent/default.htm

other qualified physicians), and assure patient access to medical facilities equipped to provide blood transfusions and resuscitation. FDA, Sept. 2000 Approval Letter, at 2.[10]

Under the Subpart H restrictions, providers who wish to prescribe the RU-486 regimen must first sign a "Prescriber's Agreement" which reiterates the restrictions and attests that the provider meets the prescribed qualifications. Mifeprex (Mifepristone) Tablets, 200 mg Prescriber's Agreement.[11]

The fact that the FDA has restricted the distribution and use of the RU-486 regimen is confirmed by a Department of Health and Human Services (HHS) memorandum on the approval of Mifeprex. Memorandum of Department of Health and Human Services to "NDA 20-687 MIFEPREX (mifepristone) Population

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10 http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf

11 http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111364.pdf

Council" (Sept. 28, 2000).[12] HHS determined that "goals of safe and appropriate use" of the RU-486 regimen can be achieved through the requirements that physicians be able to accurately date pregnancies and diagnose ectopic pregnancies:

> By coupling professional labeling with other educational interventions such as the Medication Guide, Patient Agreement, and Prescriber's Agreement, along with having physician qualification requirements of abilities to date pregnancies accurately and diagnose ectopic pregnancies (and other requirements), goals of safe and effective use may be achieved.

Id. at 2. That memo demonstrates the FDA's concern for an ongoing relationship between the patient and the physician administering the drugs, noting that returning to the health clinic for misoprostol "has the *additional advantage of contact between the patient and health care provider* to provide ongoing care." *Id*. at 3 (emphasis added).

Additionally, the FDA explicitly left room for states to require that physicians *directly* dispense the RU-486 regimen to patients. In its memo, HHS commented that the physician

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12 http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf

qualifications do "not preclude another type of health care provider, acting under the supervision of a qualified physician, from dispensing the drug to patients, *provided state laws permit this*." *Id*. at 4-5 (emphasis added).

The significance of the FDA's restrictions is also evidenced by the enrollment of Mifeprex on the list of medications which require a Risk Evaluation and Management Strategy (REMS)—the category of drugs identified by the FDA as at high risk of post marketing complications. *See* FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)* (last updated Nov. 10, 2014).[13]

Specifically, one goal of the REMS for Mifeprex is "minimiz[ing] the risk of serious complications by requiring prescribers to certify that they are qualified to prescribe Mifeprex and are able to assure patient access to appropriate medical facilities to manage any complications." *See Risk Evaluation and Mitigation Strategy (REMS) for NDA 20-687 MIFEPREX*

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13 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm

(mifepristone) Tablets, 200 mg.[14] In a section entitled "Elements to Assure Safe Use," the REMS highlights that healthcare providers who prescribe Mifeprex will be specially certified, agree that they meet the qualifications, and follow the guidelines in the Prescriber's Agreement. *Id*. at 1. Significantly, Mifeprex is one of only 68 individual drugs for which the FDA is currently requiring a REMS. *See* FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, at Table 1 ("Currently Approved Individual REMS).

Thus, as a Subpart H drug, the RU-486 regimen is distinguishable from the vast majority of drugs. The FDA's emphasis on physician qualifications supports the Board's decision to ensure physician involvement by requiring that the physician examine a woman and be physically present when administering the drugs.

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14 http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM258412.pdf

II. The risks involved in chemical abortion support the Board's Rule

The known risks associated with chemical abortion provide a rational basis for the Board's determination that a physician be present and examine a woman before administering abortion-inducing drugs. For example, the Mifeprex FPL states that "[n]early all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction." *Mifeprex FPL*, at 11. These risks include, but are not limited to, uterine hemorrhage, viral infections, and pelvic inflammatory disease. *Id*. at 12 (Table 3).

In July 2011, the FDA reported 2,207 adverse events in the U.S. after women used mifepristone for the termination of pregnancy. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011).[15] Among those were 14 deaths, 612 hospitalizations (excluding deaths), 339 blood transfusions, and 256 infections (including 48 "severe infections").

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15 http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf

Id. Of the 14 deaths, eight women died following severe bacterial infections, and two died following ruptured ectopic pregnancies. *Id.*[16]

The risk of maternal death from bacterial infections following use of the RU-486 regimen is to be expected. Mifepristone, the first drug in the regimen, interferes with the body's immune response, allowing bacteria, if present, to flourish and cause widespread, multi-organ infection. J.I. Webster & E.M. Sternberg, *Role of the hypothalamic-pituitary-adrenal axis, glucocorticoids and glucocorticoid receptors in toxic sequelae of exposure to bacterial and viral products*, J. ENDOCRINOLOGY 181:207-21 (2004); R.P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, ANNALS OF PHARMOCOTHERAPY 39 (Sept. 2005).

Significantly, peer-reviewed data demonstrates that surgical abortion is safer than chemical abortion. The largest and most accurate study of medical abortions comes from a large 2009

[16] The FDA has not released an adverse event summary since 2011, and the current tally of deaths and complications from mifepristone is not publicly accessible.

review of the medical records of 22,368 women who underwent chemical abortions compared with 20,251 women who underwent surgical abortions. That study concluded that the overall incidence of adverse events was fourfold higher with chemical abortions than surgical abortions. M. Niinimäki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBSTET. GYNECOL. 114:795 (Oct. 2009). *See also* J.T. Jenson et al., *Outcomes of suction curettage and mifepristone abortion in the United States: A prospective comparison study*, CONTRACEPTION 59:153-59 (1999) (finding that chemical abortion failed in 18.3 percent of patients and that surgical abortion failed in only 4.7 percent of patients).

Finally, many potential complications from use of the RU-486 regimen may be unknown, as there are widespread inadequacies in reporting. A 2006 review of Adverse Event Reports (AERs) related to the use of the RU-486 drug regimen found that "AERs relied upon by the FDA to monitor mifepristone's postmarketing safety are grossly deficient due to extremely poor quality." 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). The 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." *Id*. Notably, the source of the majority of AERs submitted to the FDA is the pharmaceutical company that has a financial interest in the promotion of Mifeprex. The inadequacies in reporting mean that the prevalence and character of many complications may be unknown.

While the Plaintiffs and their *amici* may cite conflicting data here (and in the proceedings before the Board), it was within the role and expertise of the Board to evaluate that data, weigh what information it felt was most accurate, and make a medical decision it concluded best protected women in the state. On the other hand, it is not within the discretion of a court to substitute its judgment for the professional judgment of the state medical board. *See*, *e.g.*, *Berger v. Iowa Dep't of Transp.*, 679 N.W.2d 636,

640 (Iowa 2004) ("We can only overturn the decision of the review committee if its application of the law to the facts is irrational, illogical, or wholly unjustifiable. Under this standard of review, the reviewing court must be deferential to the agency's action because the legislature decided that the agency's expertise justifies vesting primary jurisdiction over this matter in the discretion of the agency rather than in the court.") (citing A.E. Bonfield, *Amendments to Iowa Administrative Procedure Act, Report on Selected Provisions to Iowa State Bar Association and Iowa State Government* 70 (1998)).

In sum, the medical data on the risks inherent in chemical abortion confirms the legitimacy of the Board's concern for women's health and its decision to ensure physician involvement.

III. Known contraindications for the RU-486 regimen support the Board's Rule

Use of the RU-486 regimen for chemical abortion is contraindicated in a number of situations, all of which bolster the Board's decision to ensure physician involvement and presence before administering abortion-inducing drugs.

First, the Mifeprex FPL states explicitly that the regimen is "contradicted 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." *Mifeprex FPL*, at 5. Women are instructed that they should not take Mifeprex if they cannot easily get such emergency help in the two weeks following ingestion. *Id.* at 17. Notably, all of the patients in the U.S. clinical trial reviewed by the FDA prior to approval of RU-486 regimen were within one hour of emergency facilities or the facilities of the "principle investigator." Memorandum of Department of Health and Human Services, at 5.

HHS has stated that the Mifprex labeling "makes it clear that if there isn't adequate access to emergency services, the medication is contraindicated." *Id.*; *see also id.* at 3 ("The labeling has a contraindication if there is no access to medical facilities for emergency services."). Evidence in studies presented to the trial court also cautioned against chemical abortion for women with

"social or psychological contraindications" such as "women who do not want to take responsibility for their care, are anxious to have the abortion over quickly, [or] cannot return for follow-up visits…." Slip Op. at 3.

Thus, the very women Plaintiffs claim need telemedicine for abortion, due to travel and other potential obstacles, are actually the very women for whom the drugs are contraindicated. This known contraindication supports the Board's determination (as well as the trial court's decision) that physician presence is necessary and that women in rural areas are equally entitled as women in more urban areas to good standards of care.

Significantly, even statements made in the most recent practice bulletins of the American College of Obstetricians & Gynecologists (ACOG), a medical organization which filed a brief for Plaintiffs, support the Board's Rule. In a section entitled "Clinical Considerations and Recommendations," ACOG reports that "[w]omen are not good candidates for medical abortion if they… desire quick completion of the abortion process, [or] are not available for follow-up contact or evaluation…." ACOG, *Practice*

Bulletin 143: Medical Management of First-Trimester Abortion (Mar. 2014), at 6.[17] ACOG also notes that women who undergo chemical abortions may need to access emergency surgical intervention. *Id.* at 12.[18]

ACOG's previous Practice Bulletin was even more explicit. In addition to stating that women are not good candidates for chemical abortions if they cannot return for follow-up visits, ACOG included "access to 24-hour emergency medical treatment" as a criterion to be considered in whether a chemical abortion is appropriate for a particular woman. ACOG, *Practice Bulletin 67: Medical Management of Abortion* (2005), at 6. Thus, if ACOG does not consider a woman a good candidate for a chemical abortion if she does not have adequate access to emergency and follow-up

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[17] http://www.acog.org/~/media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20--%20Gynecology/Public/pb143.pdf?dmc=1&ts=20140703T1932230602

[18] ACOG also notes, without criticism, that referral to another healthcare provider is medically appropriate, but that "state or local laws may have additional requirements." ACOG, *Practice Bulletin 143*, at 12.

care, an abortion via telecommunications should be equally contraindicated for that woman.

Second, gestational age can be a contraindication for use of abortion-inducing drugs. The drugs become less effective as gestational age increases, and medical evidence demonstrates that complications increase as gestational age advances. *See*, *e.g.*, M.J. Mentula et al., *Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide study*, Human Reprod. 26:927-32 (2011).

While there are different dosage and administration protocols utilized by abortion providers, it is undisputed that at some point during pregnancy, the drugs should not be used to terminate pregnancy. The Mifeprex FPL states that a woman should not take the drugs if "it has been more than 49 days (7 weeks) since" her last menstrual period began. *Mifeprex FPL*, at 17. Conversely, Planned Parenthood claims to generally provide

chemical abortions up to 9 weeks (63 days). Planned Parenthood, *The Abortion Pill: What is the Abortion Pill* (2014).[19]

Regardless of the protocol utilized, however, it is clear that gestational age affects the efficacy of the drugs, making a proper determination of gestational age imperative. ACOG acknowledges that gestational age should be confirmed by clinical evaluation or ultrasound examination. ACOG, *Practice Bulletin 143*, at 12.[20] It is clearly well within the Board's role to conclude that it is in the best interest of maternal health for a physician to be present and physically involved in such a determination, especially where, as here, there is evidence that physical exams and ultrasounds are being conducted by non-physician staff members such as certified medical assistants (CMAs). Slip Op. at 4.

Third, the drugs are also contraindicated for women with ectopic pregnancies. AGOG, *Practice Bulletin 143*, at 6. Clearly,

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[19] http://www.plannedparenthood.org/health-info/abortion/the-abortion-pill

[20] While there are a variety of dosage and administration protocols (none of which are regulated by the Board's Rule), ACOG has noted that one study of a particular protocol noted a "steadily decreasing" efficacy rate in women with gestations at 12-13 weeks. ACOG, *Practice Bulletin 143*, at 6.

the FDA was concerned with the potential adverse effects of an undiagnosed ectopic pregnancy "treated" with the RU-486 regimen when it restricted administration to only those physicians able to determine whether there is an ectopic pregnancy. *See supra*, Part I.

Importantly, because symptoms of ectopic pregnancy mimic the symptoms of completed mifepristone abortions, ectopic pregnancies can go easily undiagnosed. Improper screening (*i.e.*, failure of a physician to examine the patient) places the life of a woman with an unknown ectopic pregnancy at even greater risk of death by ruptured ectopic pregnancy. The FDA has reported 58 adverse events related to ectopic pregnancies in women using the RU-486 regimen, and 2 of the 14 U.S. women reported to have died after using the regimen died from ruptured ectopic pregnancies. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11*.

Finally, the safety of the RU-486 regimen has not been tested on a large population of women, including minors or women

who are heavy smokers. *Mifeprex FPL*, at 3, 7. Yet abortion providers continue to administer the RU-486 regimen to minors.

In sum, the Board Rule requiring a physician to be physically present and examine a woman before providing abortion-inducing drugs helps to ensure that the abortion is performed within gestational limits and that there is no ectopic pregnancy.

CONCLUSION

There is ample medical data supporting the Board's medical determination that chemical abortions should not be administered or performed using telecommunication techniques. The Board determined that a patient's health outcome and follow-up care can be enhanced through a strengthened physician-patient relationship and a physical exam by the physician, which is the "cornerstone" of good medical care. Under the applicable standard of review, the trial court afforded proper deference to the Board's medical decision, and its decision should be upheld.

Respectfully submitted,

/s/ Arthur F. Gilloon

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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 **4,587** 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 Microsoft Word 2010 in Century Schoolbook font, size 14.

/s/ Arthur F. Gilloon
Counsel of Record for Amici

CERTIFICATE OF SERVICE

I, Arthur F. Gilloon, hereby certify that on the 21st day of November, 2014, I electronically filed the foregoing Proposed *Amicus Curiae* Brief with the Clerk of the Iowa Supreme Court by using the EDMS system. Service on all parties will be accomplished through EDMS.

/s/ Arthur F. Gilloon
Counsel of Record for Amici