IN THE SUPREME COURT OF IOWA

SUPREME COURT NO. 14-1415
POLK COUNTY NO. CVCV046429

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

vs.

IOWA BOARD OF MEDICINE
Respondent-Appellee

Final Amicus Curiae Brief of the American College of Obstetricians and Gynecologists

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APPEAL FROM THE IOWA DISTRICT COURT FOR POLK COUNTY
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INTRODUCTION

The American College of Obstetricians and Gynecologists ("ACOG") supports the availability of medication abortion services throughout Iowa, including medication abortions administered through telemedicine. Telemedicine is an important tool that increases access to numerous health care services in Iowa, including early abortions, particularly in rural parts of the state. An ACOG Practice Bulletin concluded that "[m]edical abortion can be provided safely and effectively via telemedicine with a high level of patient satisfaction; moreover, the model appears to improve access to early abortion in areas that lack a physician health care provider."[1]

In August 2013, the Iowa Board of Medicine ("Board") adopted ARC 1034C ("Rule"), which prohibits physicians from administering medication abortions via telemedicine. Specifically, the Rule requires, among other things, that (1) before the provision of an abortion-inducing drug, a physician must first perform a physical examination of the patient; (2) a physician "must be physically present with the woman at the time the abortion-inducing drug is provided"; and (3) the physician inducing the abortion must schedule a follow-up appointment with the woman to occur within 12-18 days at the same facility where the abortion-inducing drug was provided.

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[1] ACOG Practice Bulletin No. 143, *Medical Management of First-Trimester Abortion*, at 12 (2014), *available at* http://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb143.pdf?dmc=1&ts=20150120T1821554703.

The Board gave several "Principal Reasons Presented in Support of the Rule" in its Statement on Adopted and Filed Rule ARC 1034C ("Statement"). Summarized, these reasons are: (1) to protect the health and safety of patients; (2) to address supposed inconsistencies between the practices of physicians who provide telemedicine abortions and the protocols described on the drug label approved by the FDA in 2000; (3) to uphold Iowa law allowing only physicians to perform abortions; (4) to require physicians rather than other trained health care professionals to conduct a physical examination of the patient prior to the prescription and administration of abortion-inducing medications; and (5) to require patients to schedule follow-up appointments with the physician who provided the abortion, at the facility where the abortion was provided, rather than with another healthcare provider at a facility convenient to the patient.[2]

The Rule does not fulfill the reasons stated by the Board for its approval. Contrary to the Board's purported goal of protecting the health and safety of patients, the Rule is actually detrimental to patient health and safety. If implemented, the Rule will make safe and effective first trimester abortions inaccessible to hundreds of thousands of Iowa women—particularly the fifty-one percent of Iowa women who live in the ninety-one percent of Iowa counties that lack any known in-person abortion provider—putting these women at additional medical risk.

[2] Iowa Board of Medicine's Statement on Adopted and Filed Rule ARC 1034C.

Moreover, medical and scientific evidence makes clear that the requirements of the Rule, and the Board's purported reasons underlying them, bear no rational relationship to any legitimate public health objective. Indeed, although the Board has generally supported and promoted the use of telemedicine as an innovative means of providing healthcare services, the Rule arbitrarily singles out medication abortions as a procedure that cannot be delivered by telemedicine.

Finally, implementation of the Rule will unreasonably impinge on the physician-patient relationship, and interfere with physicians' best medical judgment, by imposing blanket regulations on a highly individualized medical decision. ACOG opposes the Rule because it impairs the ability of physicians to provide the best, safest or most appropriate care for their individual patients.[3]

ABOUT ACOG AND ACOG'S INTEREST IN THE CASE

The American College of Obstetricians and Gynecologists is a non-profit educational and professional organization founded in 1951. The College's objectives are to foster improvements in all aspects of healthcare of women; to establish and maintain the highest possible standards for education; to publish evidence-based practice guidelines; to promote high ethical standards; and to encourage contributions to medical and scientific literature. The College's companion organization, the

[3] See American College of Obstetricians and Gynecologists, *College Statement of Policy: Abortion Policy*, (Nov. 2014), *available at* http://www.acog.org/-/media/Statements-of-Policy/Public/ sop069.pdf?la=en ("ACOG is opposed to laws and regulations that operate to prevent advancements in medicine).

American Congress of Obstetricians and Gynecologists (the "Congress"), is a professional organization dedicated to the advancement of women's health and the professional interests of its members. Sharing more than 57,000 members, the College and the Congress are the leading professional associations of physicians who specialize in women's healthcare. The 377 members of the Iowa Section of the Congress provide medical care to the women of Iowa.

The College has previously been granted leave to appear as amicus curiae in various courts throughout the country, including the United States Supreme Court. In addition, the College's work has been cited frequently by the Supreme Court and other federal courts seeking authoritative medical information regarding childbirth and abortion, as well as the accepted practice guidelines for these and other women's healthcare issues.[4]

[4] *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 932-36 (2000) (quoting ACOG's amicus brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's amicus brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-78, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as "experts" and repeatedly citing ACOG's amicus brief and congressional submissions regarding abortion procedure); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients").

ACOG recognizes that abortion is an essential health care service.[5] ACOG opposes laws that restrict access to abortion and other healthcare services when such laws are unsupported by scientific evidence and are not necessary to achieve an important public health objective. ACOG submits the present brief amicus curiae in support of Petitioners Planned Parenthood of the Heartland, Inc. ("PPH") and Dr. Jill Meadows, M.D., in light of its significant interest in, and dedication to, the advancement of women's health care and the promotion of access for all women, including those in Iowa, to safe and high-quality healthcare services.

SUMMARY OF MEDICAL EVIDENCE REGARDING MEDICATION ABORTION

I. Modern Medication Abortion is a Safe and Effective Method of Abortion Based on the Best Available Scientific and Medical Evidence

Medication abortion involves the use of medications, rather than surgical techniques, to induce abortion. Over the past thirty years, various methods of medication abortion have been developed through scientific research. Medication abortion is now a standard and proven method of providing safe and effective abortions in the United States.[6]

In 2000, the Food and Drug Administration ("FDA") approved the drug mifepristone, which is used in combination with another drug, misoprostol, for medication abortions. When it approved mifepristone, the FDA approved a Final

[5] *College Statement of Policy, supra* note 3.
[6] ACOG Practice Bulletin No. 143, *supra* note 1, at 1.

Printing Label ("FPL") for the drug, which described the dosing regimen (or protocol) that was used in the research studies that were submitted in support of the application for the drug.[7] Under the FPL protocol, a patient took 600 mg of mifepristone orally at a clinic and then came back to the clinic 1-2 days later to take 400 μg of misoprostol orally. The FPL protocol is ninety-two percent effective up to forty-nine days gestation.

Since the FDA first approved mifepristone, medical research has identified a number of evidence-based regimens that make medical abortion safer, faster, less expensive, more effective, and that result in fewer complications as compared to the abortions induced using the fourteen-year old regimen. Such improvements upon protocols for FDA-approved drugs are very common. Indeed, using a drug differently than as originally described by the FDA, which is known as off-label use, is not only legal but at times *encouraged*.[8] FDA guidance unequivocally states that "[g]ood

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[7] An FPL is *not* a restriction on how physicians may use the drug. Rather, an FPL is a description of the clinical trials upon which the FDA based its approval of a drug. American Medical Association National Task Force on CME Provider/Industry Collaboration, *Fact Sheet: On-Label and Off-Label Usage of Prescription Medicines and Devices, and the Relationship to CME*, *available at* https://cme.wustl.edu/forms/On_Label_and_Off_Label_Usage_of_Prescription_Medicines_and_Devices_and_the_Relationship_to_CME.pdf.

[8] "Evidence-based" describes uses or regimens that are based on scientific evidence but are "off-label"—in other words, that depart from the regimen included on the Final Printed Label for a particular drug as approved by the FDA. *See* U.S. Food and Drug Administration, *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, *available at* http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm (updated June 25, 2014).

medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices *according to their best knowledge and judgment*."[9]

In March 2014, ACOG issued its Practice Bulletin No. 143 on the Medical Management of First-Trimester Abortion ("Practice Bulletin No. 143").[10] The conclusions in Practice Bulletin No. 143 are premised on recent studies that have shown the superiority of evidence-based regimens[11] as compared to the outdated FPL regimen. For example, it concluded, among other things, that "[b]ased on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the

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[9] *Id.* (emphasis added).

[10] ACOG Practice Bulletin No. 143, *supra* note 1. ACOG's guidelines are designed to aid practitioners in making decisions about appropriate patient care, but do not dictate an exclusive course of treatment or procedure. *See id.* at 1. *See generally*, ACOG, *Reading the Medical Literature*, http://www.acog.org/Resources_And_Publications/Department_Publications/Reading_the_Medical_Literature (2014) (describing in detail ACOG's methodical and comprehensive guideline development process).

[11] Practice Bulletin No. 143 replaced ACOG Practice Bulletin Number 67, Medical Management of Abortions, which was issued in October 2005 and concluded, among other things, that then-available good and consistent scientific evidence demonstrated that, as compared with the FDA-approved regimen, regimens using 200 mg of mifepristone orally and 800 μg of misoprostol vaginally were associated with better outcomes, fewer side effects, and lower cost for women with pregnancies up to 63 days of gestation. ACOG, Practice Bulletin No. 67, *Medical Management of Abortion*, at 2, 8 (Oct. 2005). Thus, the state of scientific research and evidence, as of at least 2005, supported the use of certain alternative regimens over the regimen described in the FPL, which had been approved several years earlier.

gestational age range for use as compared with the FPL regimen."[12] Practice Bulletin No. 143 also concluded that lower doses of mifepristone (200 mg) have similar efficacy and lower costs compared with to those regimens that use mifepristone at 600 mg.[13] Moreover, it determined that women can "safely and effectively self-administer misoprostol at home as part of a medical abortion regimen," eliminating the need for women to return to a health care facility for the administration of misoprostol as called for in the FDA-approved FPL protocol.[14] And, in contrast to the FPL protocol, the evidence-based protocols are safe and effective up to 63 days gestation.[15]

Many medication abortions today, including medication abortions at PPH clinics in Iowa, are accomplished using the proven, evidence-based protocols described above, rather than the FPL protocol from fourteen years ago. The current, evidence-based medication abortion protocols are safer and more effective than the FPL protocol.[16]

II. Telemedicine Medication Abortions Are Medically Identical to and Administered Just as Safely as In-Person Medication Abortions

Telemedicine is an innovative tool that facilitates the safe and effective delivery of high-quality healthcare to patients in rural areas, who otherwise would not have

[12] ACOG Practice Bulletin No. 143, *supra* note 1, at 11.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.* at 2.

access to the care they need. Telemedicine is the "use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status."[17] Through telemedicine, a physician in one location is able to use audio, visual, and information technology equipment to communicate and provide treatment to a patient in real time, even though the physician may be in another city, state, or time zone. In this way, a patient can receive care from physicians who are located outside the geographic area where the patient lives.

Telemedicine is common, highly regulated, and based on scientific standards designed to assist physicians while improving patient access to quality care.[18] In fact, when the American Medical Association ("AMA") updated its guidelines related to telemedicine in June 2014, it stated that telemedicine is "a key innovation in support of health care reform [and] is being used in initiatives to improve access to care . . . as well as [to] reduce the rate of growth in health care spending."[19] The AMA also related that Medicare pays approximately $6 million for telemedicine services,[20] and forty-six states plus the District of Columbia offer some form of Medicaid payment

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[17] American Telemedicine Association, *What is Telemedicine?* , http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VFFln_nF_To (2012).

[18] Various medical groups have created telemedicine standards of practice, including the American Telemedicine Association, which issued practice guidelines to ensure quality patient care and safety. American Telemedicine Association, *ATA Standards & Guidelines*, http://www.americantelemed.org/resources/standards/ata-standards-guidelines#.VFFnEvnF_To (2012).

[19] American Medical Association Report 7 of the Council on Medical Service (A-14), *Coverage of and Payment for Telemedicine*, at 1 (2014).

[20] *Id.* at 2.

for telemedicine services.[21] Physicians can safely prescribe medicine through telemedicine, including medications that induce abortions.

Medication abortions performed through telemedicine at PPH clinics in Iowa employ a system that is configured through a private, secure, two-way video conferencing stream that is only accessible from health center to health center. This system is far more advanced than a regular internet-based system and ensures privacy between patients and physicians.[22] Ninety-nine percent of patients utilizing the PPH telemedicine technology say it is easy to see and hear the doctor.[23]

Medication abortions administered through telemedicine are medically identical to those administered in person, and PPH's protocol for medication abortion is the same regardless of whether telemedicine is used. The patient is in a health center surrounded by trained professionals, where she first reviews her options with a specially-trained educator. Next, a trained medical professional—who must be a Certified Medical Assistant (CMA), Registered Nurse, or Licensed Practical Nurse—takes the patient's medical history and performs a blood test to check for any potential contraindications.[24] If appropriate, an ultrasound is taken by a professional ultrasound technician—who has undergone comprehensive education and training

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[21] *Id.* at 3.
[22] Todd Buchacker Letter to Mark Bowden, Aug. 28, 2013 (App. 359–60).
[23] Daniel Grossman Comments to Iowa Board of Medicine, at 2 (App. 362).
[24] For example, if the woman has an intrauterine device in place (IUD) or an allergy to mifepristone or misoprostol, she may be an inappropriate patient to receive a medication abortion. ACOG Practice Bulletin No. 143, *supra* note 1, at 6; Buchacker Letter, *supra* note 22.

and whose performance is monitored and assessed throughout the year—to determine the gestational age and intrauterine location of the pregnancy, and to check for further complications, such as ectopic pregnancy.[25] The ultrasound machine itself, and not a human, estimates the gestational age of the pregnancy.[26]

The physician reviews the results of these tests and the patient's medical history, and obtains informed consent from the patient if she chooses to go forward with the procedure. Then, if the physician believes it appropriate based on his or her medical judgment, mifepristone is dispensed to the patient, who takes the mifepristone in view of the physician. The physician then dispenses misoprostol, and directs the woman to take the misoprostol twenty-four to forty-eight hours later, while at home. Finally, the physician instructs the patient to schedule a follow-up visit within two weeks. Before the patient leaves the clinic, she is given emergency contact information whereby a physician can be contacted at any time of day or night.[27]

The only difference between a medication abortion provided via telemedicine and one provided in person is that during the telemedicine abortion, the physician provides the drug remotely rather than while physically present with the patient. In both cases, the physician, not any other health care provider, decides whether or not

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[25] ACOG Practice Bulletin No. 143, *supra* note 1, at 8.
[26] Affidavit of Daniel Grossman, M.D. ¶ 44 (Jan. 15, 2014) ("Grossman Aff.")(App. 118).
[27] *Id.* at ¶ 26 (App.112–13).

to provide the drug, and in both cases, the physician observes the patient taking the mifepristone.

Planned Parenthood began providing medication abortions via telemedicine in Iowa in 2008. Its patients have consistently experienced the same low complication rate for medication abortions delivered via telemedicine as those conducted in-person. A scientific study recently analyzed the adverse events occurring after medication abortions administered by PPH's program between July 2008 and October 2009. This study found *absolutely no difference* in the complication rate between a woman whose medication abortion was administered via telemedicine and a woman who had an in-person visit with a physician.[28]

In addition to the fact that medication abortions are just as safe when conducted via telemedicine, many women are more comfortable obtaining the procedure via telemedicine. Without a doctor physically in the room, these women may feel less risk of judgment, which may ease some of their anxiety.[29] This is particularly true for those who have experienced or are experiencing sexual abuse or trauma.

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[28] Dan Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstet. Gynecol. 296, 299-300 (2011).

[29] See Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study*, Women's Health Issues 23-3 at e119-20 (2013) (App. 123–24).

ARGUMENT

Contrary to the Board's purported rationale for the Rule, the Rule arbitrarily imposes barriers of access to a safe and effective medical procedure. First, the Rule fails to create any public health benefit and, instead, actually harms thousands of Iowa women by severely limiting their access to safe and effective first-trimester medical abortions, and exposing them to increased medical risks associated with, among other things, later abortions. Second, the Board's pretextual reasons for the Rule are not based on scientific or medical evidence and, therefore, the Rule arbitrarily singles out medication abortions to ban their delivery via telemedicine. Finally, the Rule unreasonably impinges upon the physician-patient relationship by imposing inflexible limitations on patient care decisions that should be based on physicians' medical judgment concerning the best and most appropriate care in light of the individual circumstances of their patients.

I. Contrary to The Board's Purported Rationale of Protecting The Health And Safety of Patients, The Rule Actually Harms Patient Safety by Increasing Healthcare Risks for Iowa Women.

The Board's overarching purported rationale for the Rule is to protect the health and safety of patients. Unfortunately for Iowa women, implementation of the Rule would have the contrary effect. Scientific studies have proven the overwhelming safety and efficacy of telemedicine medication abortions. By eliminating the option of safe first-trimester medication abortions administered via telemedicine, the Rule

harms many Iowa women, particularly those women who lack in-person access to physicians, by increasing the likelihood that they will be forced to choose riskier options, including second-trimester abortions. The Rule also increases the chances that patients who are able to obtain a medication abortion will not receive necessary follow-up care.

A. Scientific and Medical Studies Prove that Medication Abortions Via Telemedicine are Extremely Safe Procedures That Provide a Tremendous Medical Benefit To Iowa's Women.

The Rule, which would eliminate access to safe and effective early medication abortions for thousands of Iowa women, does nothing to advance the health and safety of patients. Research shows that medication abortions are extremely safe. A recent study of medication abortions in Planned Parenthood affiliated clinics nation-wide measured the frequency of significant adverse events in women obtaining such abortions. This study found that significant adverse events occurred in only 0.16% of patients.[30] Another recent study of medication abortions at Planned Parenthood clinics found there were no deaths related to infection from medication abortions during the 81-month period between 2006 and 2012.[31]

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[30] Kelly Cleland et al., *Clinically Significant Adverse Events and Outcomes after Medical Abortion*, 121 Obstet. Gynecol. 166, 169 (Jan. 2013) (measuring rate of hospital admission, blood transfusion, emergency department treatment, intravenous antibiotic administration, infection, or death among women obtaining medication abortions at Planned Parenthood clinics in 2009 and 2010).

[31] James Trussell et al., *Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion*, 89 Contraception 193 (2013) (analyzing results of 711,556 medication abortions between April 1, 2006 and December 31, 2012).

Nor is there any rational justification for prohibiting, as the Rule does, all medication abortions performed through telemedicine. The practice of telemedicine, whether used for safe medication abortions or other procedures, is revolutionizing the practice of medicine and providing significant benefits to thousands of patients each year. Telemedicine improves access for patients in distant or remote locations, reduces costs for both doctors and patients, improves quality of healthcare services, and helps to meet a high patient demand.[32] Moreover, research has proven that telemedicine medication abortions are just as safe and effective as medication abortions provided in person, both having the identical low complication rate.[33] Ninety-four percent of patients report being "very satisfied" with their telemedicine medication abortion, and seventy-three percent actually prefer being in a different room than the doctor.[34]

The Board itself has recognized the benefits of telemedicine, and in fact, has promoted its use within the State of Iowa. As recently as 2009, the Director of the Board confirmed that the Board would participate in a grant project with the goal of "reduc[ing] statutory and regulatory barriers to telemedicine services."[35] Yet the Rule inexplicably singles out medication abortion by completely banning its delivery via

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[32] American Telemedicine Association, *supra* note 17.
[33] ACOG Practice Bulletin No. 143, at 11; *see* ACOG Committee Opinion No. 613, *Increasing Access to Abortion* (Nov. 2014).
[34] Grossman, *supra* note 28, at 301.
[35] Letter from Mark Bowden (Oct. 23, 2009) (App. 29).

telemedicine, while continuing to allow and even endorse the use of telemedicine for other procedures.

B. Contrary To and Undermining Its Stated Purpose, the Rule Increases Medical Risks Faced by Iowa Women

1. The Primary Effect of the Rule is to Force Women, Particularly Rural Women, to Choose Among Riskier Healthcare Alternatives

Perhaps the most substantial consequence of the Rule will be that many women, especially those women living in rural Iowa, who otherwise would have had access to and chosen an early safe telemedicine medication abortion will be compelled to choose among riskier alternatives. ACOG embraces the basic tenet that should guide evaluation of medical practices: "As with any medical care, treatments that are safer and more effective are medically preferable."[36] Although abortions in the second trimester are generally safe procedures, the comparative safety, cost-effectiveness, and efficacy of medication abortions in the first trimester are unmatched. A recent scientific study examined medication abortions performed at Planned Parenthood health centers between 2009-2010, and found only a single death out of 233,805 medication abortions performed, for a mortality rate of 0.4 deaths per

[36] *The Woman's Health Protection Act: Hearing on S. 1696 Before the S. Comm. on the Judiciary*, 113th Cong. (2014) (testimony of Hal C. Lawrence, Executive Vice President and CEO, American Congress of Obstetricians and Gynecologists), *available at* http://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/20140715S1696Testimony.pdf.

100,000, or 0.000004%.[37] As pregnancy continues, the risks of complications increase. For abortions performed at thirteen to fifteen weeks, early in the second trimester yet generally too advanced to be eligible for a medication abortion, the mortality rate climbs to 1.7 per 100,000 legal terminations.[38] At twenty-one weeks or more, the mortality rate increases to 8.9 per 100,000 legal terminations,[39] roughly the same rate as mortality during childbirth, which is 8.8 per 100,000 live births.[40]

While mortality is extraordinarily uncommon in medication abortions, so too are other complications. The study of medication abortions performed at Planned Parenthood health centers between 2009-2010 found that other clinically significant adverse events or outcomes due to medication abortions were rare, at 0.65%.[41] By far, the most common adverse event was ongoing intrauterine pregnancy—which simply means that the medication abortion failed—which was found in 0.5% of cases. Undiagnosed ectopic pregnancy was exceedingly rare, occurring in only 0.007% of cases.[42]

Since early medication abortion is safer than later abortion or childbirth, the Rule puts Iowa women's health at risk by diminishing their access to a procedure that

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[37] Cleland, *supra* note 30, at 168.
[38] Dan Grossman et al., *Complications after Second Trimester Surgical and Medical Abortion*, 16 Reproductive Health Matters 173 (2008).
[39] ACOG Practice Bulletin No. 135, *Second-Trimester Abortion*, at 4 (June 2013).
[40] Elizabeth Raymond & Daniel Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215, 216 (Feb. 2012).
[41] Cleland, *supra* note 30, at 169. This statistic includes events that can be treated outside a hospital, such as ongoing pregnancy.
[42] *Id.* at 168.

minimizes the risk of harm. Although some women, predominantly those who live near to one of the few Iowa clinics where physicians are physically on the premises, may still be able to obtain a medication abortion during the first trimester of pregnancy, eliminating access to telemedicine medication abortions would force numerous other Iowa women, especially those living in rural areas, to delay their abortions until after the first trimester has passed.

The dramatic difference in access to a first-trimester medication abortion that will occur if the Rule is implemented can be estimated by looking at the data from 2008, before the PPH telemedicine program was established, when ninety-one percent of Iowa counties lacked a known abortion provider.[43] Fifty-one percent of Iowa women live in these counties.[44] If the Rule is allowed to take effect, and telemedicine medication abortions are banned, nearly every clinic that offers medication abortions will be prevented from doing so. There are simply not enough physicians who are willing, capable, and sufficiently dispersed across Iowa to adequately provide medication abortions through in-person programs alone. Therefore, women living in rural areas lacking access to these physicians will be forced to travel substantially greater distances to reach a health center providing abortion services than women living in more urban or suburban centers.

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[43] Guttmacher Institute, *State Facts About Abortion – Iowa*, *in* Attachment to E-mail from Executive Director Mark Bowden to Greg Hoversten (Aug. 27, 2013) (App. 39).
[44] Matthew Reeves (Medical Director of National Abortion Federation) Letter to Mark Bowden, Aug. 28, 2013 (App. 354).

According to Google Maps, women living in Rock Rapids and traveling to and from Des Moines, where an in-person medication abortion could be obtained in compliance with the Rule, would have to drive nearly 9 hours and over 500 miles round trip. This need for extended travel will further delay—or even prevent—these women from obtaining an early, safe medication abortion until they are able to save up money and take time away from work.[45]

Because of these impediments, these women may be compelled to have a second-trimester abortion, which, while safe, carries a measurably increased risk of complication and mortality, and which is generally performed surgically.[46] Adding to this potential harm, research shows that where abortion is illegal or highly restricted, women resort to even more unsafe means to terminate a pregnancy, including self-inflicted bodily trauma or ingestion of dangerous chemicals.[47] Other women may be compelled to carry unwanted pregnancies to term, which also carries measurably higher risk than first trimester abortion.[48]

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[45] *See also* Theodore Joyce, *The Supply-Side Economics of Abortion*, 365; 16 N. Eng. J. Med. 1466 (Oct. 20, 2011) ("Making access to abortion unnecessarily costly will probably result in clandestine abortions and unintended childbearing among families with the least resources and the fewest options").
[46] ACOG Practice Bulletin No. 135, *supra* note 39, at 2-3 (June 2013); Cleland, *supra* note 30, at 168–69.
[47] ACOG Committee Opinion No. 613, *supra* note 33, at 2 (Nov. 2014).
[48] Raymond, *supra* note 40, at 216.

2. The Rule Disproportionately Harms Victims of Sexual Trauma and Domestic Violence

The Rule will also impose particular hardship on survivors of rape, sexual abuse, or other sexual trauma, who may prefer to undergo an abortion at home, on their terms, with their families or other loved ones, which is possible with a medication abortion but not with a surgical one. Forcing these women into more invasive and less private surgical procedures can re-traumatize them. Such women will therefore be disproportionately harmed by the Rule.

In addition, for women facing ongoing abuse at the hands of a partner or other abuser, the availability of telemedicine abortions can provide an opportunity to terminate an unwanted pregnancy quickly and discreetly, without alerting the abuser. By eliminating the telemedicine option, however, these women will be delayed in obtaining an abortion until they can find an opportunity to schedule an entire day (or longer) away to visit a physician in person, which exposes them to increased risk that their abusers will discover their plans.

3. Medication Abortion is Particularly Safer than Surgical Abortion for Women with Certain Medical Conditions

Other women who have medical conditions that make surgical abortion particularly risky will also face severely increased medical risks if the Rule is implemented. For instance, a woman may have a cervical abnormality, such as a stenotic, or narrow, cervix. Or abuse or female genital cutting may have caused anatomical irregularities. These conditions can make it difficult for a physician to

safely perform a surgical abortion. For women with such conditions, medication abortion is substantially safer than a surgical option.[49] Eliminating access to telemedicine medication abortions, which severely limits access to medication abortions, is particularly dangerous to such women, as the delays caused thereby can force them to choose an abortion method that is far riskier to them than telemedicine medication abortion is.

II. The Board's Rationales for Enacting the Rule Have No Basis in Medicine or Science

In addition to the Rule's abject failure to protect the health and safety of patients, the Rule's specific requirements and the proffered reasons ostensibly supporting those requirements are unsupported by and indeed, are at odds with scientific evidence and accepted medical practices, and have no rational relationship to any legitimate medical or healthcare objective.

A. Requiring a Physician to Conduct a Physical Examination of the Patient Before Administering Abortion-Inducing Medication is Inconsistent With Accepted Medical Practices

The Rule states that a physician "shall not induce an abortion by providing an abortion-inducing drug unless the physician has first performed a physical examination of the woman to determine, and document in the woman's medical record, the gestational age and intrauterine location of the pregnancy." The gestational age and intrauterine location of a pregnancy is typically learned and

[49] Grossman Aff. ¶ 37 (App. 116–17).

verified via medical histories, laboratory tests, and (if necessary) ultrasounds, all of which are nearly always performed by non-physician staff members, regardless of whether the patient is seeking a medication abortion, a surgical abortion, or is planning to carry the pregnancy to term.

Requiring physicians to perform these routine tasks before providing a medication abortion serves no medical purpose whatsoever. Moreover, it is patently irrational because it imposes this unjustified burden on physicians providing a medication abortion, but not on physicians needing to determine the gestational age and intrauterine location of a pregnancy before performing a surgical abortion, or providing pre-natal care to a patient carrying her pregnancy to term. There is no reason, medical or otherwise, that the Board's apparent concern that there is a "lack of opportunity for a physician to perform a basic physical examination of the patient" should apply in the context of medication abortions, particularly given the absence of that concern with respect to any other procedure.[50]

B. Requiring the In-Person Dispensing of a Medication that is Self-Administered is Illogical and Medically Unnecessary

The Board has not identified any benefit to requiring the physician be physically present when the abortion-inducing medication is provided. And, indeed, no such benefit exists. The second medication is taken by the patient at home

[50] For this reason, the Board's concern over "uncertainty of whether clinic staff members providing the ultrasounds are actually qualified to produce useful images to sufficiently rely upon for diagnostic purposes" also makes no sense. Statement.

regardless of whether the medication abortion is performed in-person or via telemedicine. There is no conceivable means for a physician to be present, since any reactions to or consequences of the medicine occur one-to-two days later, outside of any clinical setting. As such, the Rule is completely illogical.

C. Requiring Follow-Up at the Same Clinic In Which the Abortion-Inducing Drug is Provided Increases the Chances the Patient Will Miss Her Needed Follow-Up, Further Endangering Her Health and Safety

The Rule's requirement that a physician schedule a follow-up appointment at the same facility where the abortion-inducing medication was provided imposes additional unjustified burden and risks on Iowa women who are able to obtain a medication abortion. Follow-up after undergoing a medication abortion is an important part of patient safety, as it is needed to confirm that the pregnancy was successfully terminated. It often involves tests such as a transvaginal ultrasound or serum hCG testing,[51] both of which can be performed at many clinics, including at those that do not themselves provide abortion services.[52] There is no medical reason whatsoever to conclude that better care could be provided at the same clinic where the medication abortion was provided.

Moreover, the Rule's requirement that the follow-up appointment take place at the same facility where the in-person medication abortion was provided will actually make it less likely that many patients receive the follow-up care they need. As might

[51] ACOG Practice Bulletin No. 143, *supra* note 1, at 9.
[52] *Id.*

be expected, a 2012 scientific study found patients who live more than ten miles from the health center where a follow-up appointment to a medication abortion would occur were less likely to obtain the needed follow-up examination.[53] Here, the Rule will require patients who had to travel hundreds of miles to obtain the abortion to make the burdensome trip a second time for their needed follow-up appointments, instead of allowing patients to schedule the appointment at a clinic much closer to home. The result would be that many of these women will simply skip their follow-up appointments, putting them at additional and unnecessary risk. Thus, instead of improving the health and safety of Iowa women, the Rule undermines it by actually creating unnecessary risks in connection with a medication abortion, which is an extremely low-risk procedure.

D. The Rule Does Not Force Compliance with FDA Protocols, and Any Effort to Do So Would Undermine Improvements to Patient Safety

An alternate reason presented by the Board for enactment of the Rule—that "[t]he practices used by physicians who prescribe and administer abortion-inducing drugs using telemedicine are inconsistent with the protocols approved by the U.S. Food and Drug Administration (FDA) and the manufacturer of the drugs"[54]— is utterly irrelevant. First, it ignores the fact that widely accepted evidence-based protocols for medication abortions are safer, more effective, and otherwise superior

[53] *Id.*
[54] Statement at 1.

to the protocol on the FDA-approved label.[55] Where, as here, evidence shows that a protocol not included in the approved labeling yields better outcomes, physicians should follow—indeed, must follow, in keeping with appropriate standards of care—that evidence-based protocol. The Board completely misconstrues the purpose of an FDA–approved label: the purpose is *not* to restrict physicians in their practice of medicine, but rather to *inform* physicians about information gathered during the approval process, so as to enable physicians to practice medicine using all available scientific and medical evidence.[56]

The telemedicine practices at issue in this case are supported by the best available medical evidence, and are *safer than* the protocols described on the FPL approved over fourteen years ago. Apparently, even the Board recognizes that evidence-based protocols are safer and more effective, since the Rule makes no mention of the FPL protocol and does not align with its requirements.[57] Accordingly, the Board's professed concern about FDA compliance is purely pretextual.

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[55] See Part I, *supra* at 5.

[56] The AMA has estimated up to 20% of all drugs are prescribed and used off-label. AMA *Fact Sheet*, *supra* note 7. Off-label use has been described in such reputable organizations such as Consumer Reports and the Mayo Clinic. Consumer Reports Best Buy Drugs, *Shopper's Guide to Prescription Drugs – Number 6 "Off-Label" Drug Use*, *available at* http://consumerhealthchoices.org/wp-content/uploads/2012/01/Off-Label-FINAL.pdf (2007).

[57] For instance, the FPL protocol provides that the second drug in the regimen, misoprostol, be taken at a medical facility. The Rule includes no provision requiring that this drug be taken at a medical facility, as set forth in the FDA protocol. The FPL use requires dosages of 600 mg of mifepristone and 400 μg of misoprostol. Similarly, the Rule includes no provision requiring these dosages.

III. The Rule Unreasonably Impinges Upon the Physician-Patient Relationship By Imposing Blanket Regulations on Highly Individualized Medical Decisions

The Board's decision to require an in-person meeting and physical examination between a doctor and a patient in order to dispense the abortion-inducing medication is unreasonable because it imposes a needlessly broad regulation on what should be evidence-based individual decisions between a physician and a patient. As Judge Romano of the Iowa District Court for Polk County said when staying enforcement of the law, the Rule "unduly interfere[s] with relationships between physicians who provide telemedicine abortions and their patients" and could "force [women] to consider having a surgical abortion, or even forgo having an abortion altogether."[58] Because the Rule negatively impacts the rights of physicians and their patients to define an individualized course of treatment, it must be struck down unless there is evidence of benefits to them or to public health that justify the substantial harms to patients to choose their care and physicians to treat their patients. § 17A.19(10)(k); *see Zieckler v. Ampride*, 743 N.W.2d 530, 533 (Iowa 2007).[59] No such evidence exists. If an Iowa physician feels it is in the best interest of the patient and the practice of medicine to provide the drugs at issue here via telemedicine, the Board should not interfere.

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[58] Stay Ruling at 11 (App. 16).

[59] Doctors also act under an obligation of confidentiality. As described above, the PPH telemedicine program ensures total confidentiality, thus fulfilling the need of the physician to counsel a patient, answer questions, and obtain consent.

CONCLUSION

"Unfortunately, laws and regulations are blunt instruments. By reducing health care decisions to a series of mandates, lawmakers devalue the patient-physician relationship."[60] While the Board's Rule purports to increase patient safety and improve the physician-patient relationship, it unfortunately does just the opposite by putting patients at additional risk and improperly intruding on that relationship.

For all of these reasons, ARC 1034C should not be enforced under Iowa Code § 17A.19(10).

[60] Steven E. Weinberger et al., *Legislative Interference with the Patient-Physician Relationship*, 367; 16 N. Eng. J. Med. 1557 (Oct. 18, 2012).

CERTIFICATE OF SERVICE

I, Paige Fiedler, hereby certify that on the 20th day of January, 2015, I electronically filed the foregoing Motion with the Clerk of the Iowa Supreme Court by using the EDMS system. Service on all parties will be accomplished through EDMS.

By: */s/ Paige Fiedler*

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Iowa R. App. P. 6.903(1)(g)(1) because:

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January 20, 2015