IN THE SUPREME COURT OF IOWA

PLANNED PARENTHOOD OF THE HEARTLAND, INC. and DR. JILL MEADOWS, M.D.,	)	S. Ct. No. 14-1415
Petitioners/Appellants,	)	
v.	)	
IOWA BOARD OF MEDICINE,	)	
Respondent/Appellee.	)	

APPEAL FROM THE IOWA DISTRICT COURT
IN AND FOR POLK COUNTY
THE HONORABLE JEFFREY D. FARRELL

PETITIONERS/APPELLANTS' REPLY BRIEF

Sharon K. Malheiro, AT0004936
Davis, Brown, Koehn, Shors& Roberts, P.C.
215 10th Street, Suite 1300
Des Moines, Iowa 50309
Telephone: (515) 288-2500
Facsimile: (515) 243-0654
Email:
sharonmalheiro@davisbrownlaw.com

ATTORNEYS FOR
PETITIONERS/APPELLANTS

Of counsel:
Alice Clapman, *admitted pro hac vice in District Court and admission in this court is pending*
Planned Parenthood Federation of America
1110 Vermont Ave., N.W., Suite 300
Washington, DC 20005
Telephone: 202-973-4862
Facsimile: 202-296-3480
Email: alice.clapman@ppfa.org

Roger Evans
Planned Parenthood Federation of America
434 W. 33rd Street
New York, N.Y. 10001
Telephone: 212-261-4708
Facsimile: 212-247-6811
Email: roger.evans@ppfa.org

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INTRODUCTION

When the record is considered in its entirety—the unprecedented haste with which a rulemaking petition engineered by forces opposed to abortion was adopted verbatim, the opposition of major Iowa medical organizations, the approval of Petitioners' practices by the major relevant national medical organization, and Respondent's failure to explain why it departed both from its general support of telemedicine and from its prior investigation and implicit approval of Petitioners' telemedicine abortion protocols—the conclusion is inescapable: The Rule will cut off access to safe and legal abortion for hundreds of Iowa women for no medical reason, simply for the impermissible purpose of restricting access to abortion.

The Rule should be invalidated.

ARGUMENT

I. Petitioners' Evidence Is Properly Before the Court.

Respondent concedes, as it must, that in evaluating Petitioners' constitutional claims, this Court has the authority to consider "legislative facts" beyond what the agency or district court considered. Resp't Br. 22-23.[1] As *Varnum v. Brien* explains, it is important to "review all the material

[1] Contrary to Respondent's representation, Petitioners asked the District Court to reconsider the struck evidence as legislative facts. (June 16, 2014 Hearing Transcript 58:14-59:2 ("Tr.")). Respondent is also incorrect that this

tendered by the parties" and consider "the most compelling data in order to give needed intellectual legitimacy to the law or rule crafted by the court." 763 N.W.2d 862, 881 (Iowa 2009) (citation omitted).

The parties agree that Iowa Code § 17A.19(7) also allows evidence from outside the administrative record to support non-constitutional claims. Resp't Br. 17; App. 388-409 - Arthur Bonfield, *Amendments to Iowa Administrative Procedure Act, Report on Selected Provisions to Iowa State Bar Association and Iowa State Government* 65 (1998). Respondent and the lower court take the position that this rule requires a showing that the evidence was possessed by the individual members of the Board. To the contrary, the court may consider "evidence in the possession of the agency at the time it took the action in question and any other evidence relevant to the legality of the matter" including "relevant new evidence to support or impeach" the agency's contemporaneous statement of reasons. App 401 at 65.

The information in dispute is offered both to establish that the Board "overlooked" relevant evidence that negates the justification for the Rule, and to support the argument that the information was "overlooked" because,

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category does not include the e-mail between a petition signatory, the Governor's office, and various anti-abortion groups, reflecting the ideological origins of the rulemaking petition. *See* Pet'rs Br. 37 & n.18.

given the true motivation behind the Rule, the entire process was a foregone conclusion. Much of that information was in the possession of the Board in the "institutional sense," *i.e.*, in the possession of senior staff and in the Board's records. Respondent's narrow reading of § 17A.19(7) conflicts with the legislature's clear intent to allow for a broadened record that would include this kind of evidence so that this Court can ascertain what actually occurred at the agency level and whether the agency's contemporaneous justification is sound.[2]

Accordingly, the Court should consider the excluded material not just on Petitioners' constitutional claims but also on their other claims.

II. The Rule is Invalid.

A. Properly Understood, the Rule Cannot Be Justified.

1. There is no reason to compel the physician's physical presence.

Respondent repeatedly characterizes the Rule as only requiring a physical exam. *See, e.g.*, Resp't Br. 69 ("If a basic physical examination

[2] Moreover, if proof is required that the information was actually possessed by individual members, the lower court abused its discretion in not allowing Petitioners to conduct additional discovery to establish those facts. Respondent misrepresents what occurred below. Far from having "months to conduct discovery," Petitioners had less than two months from the court's scheduling order in which to conduct discovery *and* submit their opening brief. Amended Schedule, Dec. 9, 2013. And far from cooperating fully with Petitioners' requests, Respondent objected to many of them and provided limited responses without representation that these answers were complete.

cannot survive, this Court will be holding that the Board cannot regulate abortion."). PPH already provides a physical examination that meets the standard of care for a medication abortion. Pet'rs Br. 9-10, 11-12. The problem with the Rule is not the requirement of a physical examination, but rather the requirement that a physician be present in the room with the patient during the examination and the administration of the first medication.

To support its position that the standard of care requires an in-person physician examination, Respondent cites to webpages (nowhere referenced in the administrative record). Resp't Br. 12-13. These sources do not support Respondent. *None* state that the physician herself must perform any particular examination, rather than delegating to trained staff. Moreover, some are geared toward providing information to patients about what may happen at their visit, and are not intended as clinical guidance for providers.[3] And all but two of these sources relate to abortion generally, rather than medication abortion specifically.

[3] The only two sources for providers are designed for use internationally, including in developing countries without ready access to ultrasonography. One of these documents, from the World Health Organization, *undermines* Respondent's assertions, stating that medication abortion is *indicated* when a pelvic examination "is not feasible." WHO, *Clinical Practice Handbook for Safe Abortion* (2014), *available at* http://apps.who.int/iris/bitstream/10665/97415/1/9789241548717_eng.pdf.

Finally, Respondent cites a "FAQ" on the American College of Obstetricians and Gynecologists ("ACOG") website. Resp't Br. 13. This is mystifying, given that ACOG *endorses* as safe telemedicine protocols in which the physician is not physically present during the screening process. ACOG, *Practice Bulletin Number 143: Medical Management of First-Trimester Abortion*, 123 Obstetrics & Gynecology at 11 (Mar. 2014) ("ACOG Bulletin").[4] ACOG states: "Medical 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 healthcare provider." *Id.* ACOG also warns that those states that have restricted telemedicine abortion services are acting "[d]espite the medical evidence." *Id.*[5]

Respondent's requirement makes even less sense given that ACOG has also endorsed as safe the provision of medication abortion by advanced-practice clinicians *who are not physicians*, a common practice in many other states. ACOG Bulletin at 10; Pet'rs Br. 11 n.4. And contrary to Respondent's representation, *see* Resp't. Br. 40, the FDA does not require

[4] *Available at* http://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb143.pdf?dmc=1&ts=20141212T1628262602.

[5] A previous composition of the Board agreed. *See* Pet'rs Br. 15-16.

that mifepristone be administered by a physician. (App. 113-114 ¶ 29 (quoting FDA approval letter)).[6]

Respondent tries to evade the fact that it is targeting abortion by asserting that it "requires in-person histories and physical examinations in other contexts." Resp't Br. 36. Again, the issue here is not whether a physical exam is necessary (PPH already provides one), but whether the physician must be physically present in the room at the time. In no other area of medicine does Respondent require this. Even in the field of pain management, where the potential for abuse and addiction creates a special imperative for in-person examination, Respondent does not require *the physician* to examine the patient. *See* Iowa Admin. Code ("I.A.C.") r. 653-13.2(5)a.[7]

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[6] Amici Physicians for Life et al. ("PFL") attempt to turn the FDA's statement that non-physicians can provide medication abortion "provided state law permits this" into an endorsement of the Rule. Amicus Brief of PFL 14-15 ("PFL Br."). The significant part of the FDA's statement is its recognition that non-physicians can perform these steps, not its appropriate acknowledgement that this must comport with state law. More generally, PFL's brief is riddled with distortions about the FDA's position on medication abortion, including citing to a preliminary "approvable" letter, *see id*. at 11, that was expressly superseded by the FDA's final approval letter. FDA Approval Letter (Sep. 28, 2000), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm.

[7] Respondent also asserts without support that "[y]ou must still go see your doctor for a physical examination prior to diagnosis of something as simple

More generally, across medical fields, physicians routinely rely on examinations by non-physician staff. (App. 118 ¶¶ 43-44; App. 41-42). And with respect to telemedicine, The Federation of State Medical Boards' Model Policy For The Appropriate Use Of Telemedicine Technologies In The Practice Of Medicine (April 2014), *available at* http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf, states that the decision whether to prescribe medication without an in-person examination should be left to "the professional discretion of the physician," provided she exercises that discretion "in accordance with current standards of practice." *Id.* at 8. The Model Policy also confirms that an appropriate physician-patient relationship can be established "whether or not there has been an encounter in person between the physician (or other appropriately supervised healthcare practitioner) and patient." *Id.* at 4.

2. There is no reason to require follow-up at the same clinic.

Respondent also characterizes the Rule as merely requiring "that a physician make reasonable efforts for follow-up examination." Resp't Br.

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as an ear infection and prior to the prescription of antibiotics." Resp't Br. 37. In fact, non-physician clinicians are authorized to prescribe antibiotics in Iowa, as well as riskier medications. I.A.C. r. 655-7.1(152) (advanced-practice nurses); *id*. r. 645-327.1(1)s (physician assistants).

26.[8] Not true. The Rule requires that the physician schedule a follow-up appointment "at the same facility" where the patient received the abortion medications, and "use all reasonable efforts to ensure that the woman . . . returns for the appointment" even if a closer facility could provide her with the same care. I.A.C. r. 653-13.10(4); Pet'rs Br. 53 n.23.

Respondent has never presented any reason for this requirement (taken verbatim from a petition submitted by those opposed to abortion). Tellingly, Respondent's attorney had no response when the District Court asked her what purpose this requirement served. (Tr. 28:21-29:12). Respondent's Resistance is similarly silent on this point.

As a practical matter, this unexplained requirement means, *e.g.*, that, even though PPH is equipped to provide a patient from Sioux City with follow-up care near her home, PPH will have to "use all reasonable efforts to ensure" that she makes an unnecessary trip hundreds of miles merely to receive that care at the same clinic that provided her with the abortion medications. As studies show, this will cause more women to *miss* their follow-up appointment, which is directly contrary to public health. Pet'rs Br. 14; Amicus Brief of ACOG 23-24 ("ACOG Br.").

[8] Respondent incorrectly asserts that Petitioners' brief "does not challenge the subparts relating to follow-up appointment." Resp't Br. 64 n.24.

3. The Rule harms, rather than benefits, rural women in Iowa.

Respondent argues that the Rule was motivated by a "finding that women in rural areas were entitled to the same level of health care as women in urban areas." Resp't Br. 32. To the contrary, telemedicine services such as Petitioners' mitigate the inequities of access to medical care between rural and urban communities. That is why governments give grants to *promote* telemedicine, and why the Board has previously supported expanding telemedicine practices generally. Pet'rs Br. 25-26 & n.15.

Respondent claims there is "no evidence showing that the rule would actually require PPH to stop offering medical abortions at any location," Resp't Br. 31. Not true again. To begin with, the very reason telemedicine exists is that it is not possible to staff and equip rural sites, with lower patient volume and fewer providers, comparably to urban sites. Moreover, Petitioners presented sworn written testimony, from PPH's Chief Operating Officer, providing specific reasons why the Rule would make it impossible for PPH to provide abortion services at most of its Iowa clinics, because PPH only has physicians on site in or near Iowa City and Des Moines. (App. 239 ¶ 4).

Specifically, Ms. Dickey explained that PPH "had been providing in-person physician services in Sioux City and Quad Cities *at a financial loss*,

out of a commitment to ensuring that women throughout the state have access to abortion services," but "could no longer financially sustain that loss." (*Id.* ¶ 3 (emphasis added)). She stated that financial difficulties have required PPH to cease *telemedicine* services at a number of sites as well. (*Id.* ¶ 2). Other evidence shows that abortion providers are scarce in rural areas throughout the country, and that the only known abortion provider in Iowa, other than PPH, is in Iowa City. Pet'rs Br. 19 n.12.[9]

Thus, instead of comparable care and a "real choice," as Respondent imagines, Resp't Br. 49, rural women will be subjected to greater burdens, and greater risk. Contrary to Respondent's representation, the record is replete with evidence, with reference to peer-reviewed studies, that the Rule would cause delay and require women to travel farther to access care, which will be particularly harmful to women suffering domestic violence or living in poverty. *See* Pet'rs Br. 14-15, 20-23 (including citations to record alerting Board that PPH's program improved public health and reduced second-

[9] As a constitutional matter, it would be improper to proceed on the assumption that abortion providers must devise solutions to unnecessary hurdles the state creates for women seeking an abortion. *See Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 916 (9th Cir. 2014), *cert. denied*, No. 14-284, 2014 WL 4447210 (Dec. 15, 2014); *Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 795-96 (7th Cir. 2013), *cert. denied*, 134 S. Ct. 2841 (2014); *Planned Parenthood Se., Inc. v. Strange*, ___ F. Supp. 2d ___, 2014 WL 3809403, at *10-24 (M.D. Aug. 4, 2014).

trimester abortions; and that Rule would delay women, thereby exposing them to medical risk and other harms). *See also* Amicus Brief of Iowa Coalition Against Domestic Violence et al. 10-28 ("ICADV Br.").

Not only do the risks associated with abortion increase as a pregnancy progresses, but the risks associated with pregnancy and childbirth are exponentially higher than those associated with abortion (App. 109 ¶ 17), and are higher still for women living in rural areas far from medical care. *See* Thomas S. Nesbitt et al., *Access to Obstetric Care in Rural Areas: Effect on Birth Outcomes*, 80(7) Am. J. Pub. Health 814 (1990) (rural women with less access to prenatal and other obstetric care have significantly higher rates of birth-associated complications and premature delivery); Jonathan M. Snowden et al., *The Impact of Hospital Obstetric Volume on Maternal Outcomes in Term, Non-Low-Birthweight Pregnancies*, Am. J. Obstetrics & Gynecology (Sep. 28, 2014) (women delivering in low-volume rural hospitals experience higher rates of postpartum hemorrhage).

Respondent seems to suggest that, even so, the Rule is beneficial because it ensures that medication (versus surgical) abortion does not become a "de facto" choice simply by virtue of being more accessible. Resp't Br. 32. This paternalistic justification overlooks that many women strongly prefer medication abortion *over* surgical abortion. (App. 116 ¶ 36;

App. 124 - Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine*, 23(2) Women's Health Issues e117, e119 (2013) (women reported it was important for them to make the gestational age cut-off for medication abortion)). Respondent's argument also trivializes how important it is to women to have an option they can access despite transportation barriers, scheduling constraints, inclement weather, and other obstacles; for many women this is far more important than being in the same room physically with a physician. (Pet'rs Br. 20-21; App. 123-124 at e118-19; ICADV Br. 10-28).

Respondent notes that surgical abortion may be the medically preferable option for some women, but PPH's protocols take that into account.[10] If a woman states an initial preference for medication abortion, that does not end the matter. The physician then makes sure she understands

[10] Respondent states concern over women's access to emergency care. Resp't Br. 32. This cannot conceivably support the Rule, for several reasons. First, the risk of complications requiring hospital admission is exceedingly small—0.31%, Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, Obstetrics & Gynecology 4 (Dec. 5, 2014)—and outweighed by the risks that the Rule will cause by delaying or preventing women from obtaining an abortion and follow-up care. Second, these rare complications are treated in the same way miscarriages are treated, and emergency rooms—rural and urban—routinely see and treat miscarriages. (App. 110 ¶ 19). Finally, the Rule does not prevent most rural women from having a medication abortion; it just forces them to drive further for care, which does nothing to ensure they have access to emergency care after they return home.

there is a very small risk of a complication and is prepared in that case to travel to the appropriate provider—which may be a physician-staffed clinic or, in exceedingly rare circumstances, an emergency room. *See* FDA Approval Letter (providers must "provide each patient with a Medication Guide and . . . fully explain the procedure"); Mifeprex Medication Guide (Apr. 22, 2009), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088643.pdf (explaining risks).

PPH's physicians also make sure patients understand the importance of returning for a follow-up to confirm the termination. *Id.* Finally, a physician reviews each blood test, vital signs, ultrasound, and medical history to ensure that medication abortion is a safe and appropriate course of treatment. (Buchacker Comments, Audio Recording of Public Hearing at 57:55). If there is any doubt, and any further tests are needed (such as a pelvic examination), PPH treats the patient at a clinic staffed with the appropriate level of professional (an advanced-practice nurse or physician). (*Id.* at 1:02:50).

Women and their medical providers are capable of making these decisions and undertaking these responsibilities. They are no different from the decisions and trade-offs rural Iowans make every day when they

experience health issues and find their local healthcare options limited. Ultimately, telemedicine *expands* options for rural residents and *improves* the care they receive, bringing that care *closer* to parity with urban residents. Respondent's suggestion of the opposite is disconnected from the real world and must be rejected.

B. Respondent Mischaracterizes Petitioners' Claims.

Finally, Respondent attempts to avoid addressing several of Petitioners' arguments by mischaracterizing them. Petitioners are not "challenging the Board's ability to regulate abortion as a whole," Resp't Br. 26, or to regulate "individual specialties," *id*. at 36. The Board unquestionably has the authority to regulate abortion services, or any other specialty, based on "acceptable and *prevailing* practice." Iowa Code § 148.6(2)(g) (emphasis added). But it cannot do what it has done here: manufacture standards of practice, unsupported by any mainstream medical organization and applied exclusively to abortion services, in a transparent effort to restrict access to these services.

Nor are Petitioners "ask[ing] this Court to essentially create and add rule-making requirements to Iowa Code section 17A.4." Resp't Br. 28. Petitioners' point is that Respondent's defective process reveals that the Rule proceeded from an improper motive, and that it was a foregone

conclusion, in violation of § 17A.19(10)(j)'s requirement that it "consider" material matters. The text of § 17A.19(10)(j) puts "process" at the center of its inquiry, directing the Court to consider whether the Rule was "[t]he product of a decision-making process in which the agency did not consider" a material matter.

Still less are Petitioners "mislead[ing] this Court regarding the Board's past policy on abortion-inducing drugs." Resp't Br. 33. Petitioners' point is that the Board extensively investigated an Operation Rescue complaint against PPH's protocols in 2010, and determined that there was no need for PPH's physicians to modify the protocols or cease using them. Pet'rs Br. 15-16. The Board's about-face raises serious questions about the Rule's reasonableness and the current Board's motives.

It is not "simply false" that "the Board previously approved its program," *see* Resp't Br. 34. The Board's letter informing Operation Rescue that its complaint had been dismissed stated that the Board had "reached its decision after a full review of the investigative record" and that its "primary responsibility is to protect the public by ensuring that physicians provide appropriate medical care to patients [and] the Board takes seriously all complaints it receives." Letter from Executive Director Mark Bowden to Cheryl D. Sullenger (Jan. 11, 2011), *available at*

http://archive.desmoinesregister.com/section/documentcloud&dckeyword=26167-jan-11-letter-from-iowa-board-of-medicine-to-operation-rescue-activist-cheryl-sullenger/.[11]

C. The Rule Was Motivated By An Impermissible Purpose.

While Respondent quibbles about the significance of each piece of evidence in isolation, taken together these facts lead to an inescapable conclusion of impermissible motive:

1) The Rule was based verbatim on a petition that had been secretly orchestrated by groups categorically opposed to safe and legal abortion. There is clear record evidence that the Board knew this. Pet'rs Br. 17 & n.9.

2) The Rule was opposed by all relevant and credible medical groups. Respondent characterizes the Iowa Medical Society's opposition as solely process-based, Resp't Br. 29 & n.17, but the IMS called the Rule "not credible," and criticized it not only for its procedural irregularities but also

[11] Respondent is wrong in claiming Petitioners failed to preserve the issues of whether the Rule was supported by "substantial evidence," Iowa Code § 17A.19(10)(f), or their claims under §§ 17A.19(10)(i) & (n), Resp't Br. 25. Petitioners argued a "substantial evidence" claim at oral argument. (Tr. 7:2-5). And although the district court did not specifically reference each of these statutory sub-sections, its conclusion that Respondent acted "reasonabl[y]" and its explanation that it viewed the various subsections of § 17A.19(10) as "more structured version[s] of" a general arbitrary and capricious standard, Final Ruling at 26, "indicate[] that the court *considered* the issue[s] and necessarily ruled on [them]," preserving them for appeal. *Lamasters v. State*, 821 N.W.2d 856, 864 (Iowa 2012); *Lee v. State, Polk Cnty. Clerk of Court*, 815 N.W.2d 731, 738-39 (Iowa 2012).

for Respondent's "lack of . . . evidence-based support for this government mandate," including the lack of "existing medical practice standards that support each of the rule's requirements." (App. 3-4).

3) Respondent's process was unprecedented in its haste.

4) The Rule's most vocal advocate within the Board had previously advocated banning telemedicine abortions precisely to make abortion less *accessible*. Pet'rs Br. 55.

5) The medical evidence of record does not support the Rule.

6) The Rule contrasts with Respondent's decision to allow all other forms of telemedicine and departs from its earlier decision following a complete investigation of Petitioners' practices. *Id*. at 25-27.

The clear irrationality of the Rule is itself evidence of an impermissible underlying motivation. *Gartner v. Iowa Dep't of Pub. Health*, 830 N.W.2d 335, 353 (Iowa 2013) (When a state law seems poorly designed to further the state's asserted interest, that itself can "demonstrate . . . that some other unarticulated reason" is afoot.); *see also* Pet'rs Br. 56-57 & n.25.[12]

[12] Respondent relies on *Mazurek v. Armstrong*, 520 U.S. 968 (1997), arguing that courts should not infer improper motivation even when a law was drafted by anti-abortion groups and is medically unsupported. Resp't Br. 46. *Mazurek*'s reasoning expressly turned on the fact that the Montana restriction would have *no* perceptible effect on abortion access. 520 U.S. at

D. The Rule Is Unconstitutional.

Petitioners urge this Court to apply strict scrutiny to the Rule under the Iowa Constitution.[13] Respondent seeks to circumvent this Court's longstanding tradition of affording more protection to its citizens' individual rights than has been afforded by federal courts applying the federal constitution. Respondent suggests that this tradition be limited to search and seizure, cruel-and-unusual punishment, and equal protection cases. Resp't Br. 56. Leaving aside that Petitioners *are* making an equal protection claim, Respondent's proposed limitation finds no support in this Court's decisions.

To the contrary, *Varnum* stressed this Court's role "at the forefront in recognizing individuals' civil rights" in general. 763 N.W.2d at 877 n.4. More recently, this court reaffirmed that "the liberty and equality of Iowans is better served by departing from the federal" precedents where appropriate.

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974 (declining to infer improper motive when evidence showed that "no woman seeking an abortion would be required by the new law to travel to a different facility than was previously available").

[13] Alternatively, this Court could apply heightened scrutiny because the Rule constitutes a gender classification. Pet'rs Br. 63-64. Respondent argues that this exact argument was not preserved; that is cutting the principle of error preservation too fine. *See Lee*, 815 N.W.2d at 738 (allowing Tenth Amendment immunity argument on appeal, where defendant had previously argued under the Eleventh Amendment, stating: "[w]e will not exalt form over substance when the objectives of our error preservation rules have been met"); *cf. Gill v. I.N.S.*, 420 F.3d 82, 86 (2d Cir. 2005) (appellants generally not "limited to the exact contours of [their] argument below").

State v. Lyle, 854 N.W.2d 378, n.2 (Iowa 2014). This case raises concerns about women's civil rights—their liberty and equality—and thus fits squarely within this precedent.[14] *See* ICADV Br. 10-28; Amicus Brief of ACLU of Iowa 5-14 ("ACLU-I Br.").

A number of other state supreme courts have afforded greater protection to abortion than the undue burden standard under *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). Pet'rs Br. 60-62; ACLU-I Br. 11-14. Respondent seeks to dismiss these cases because of variations in the wording of state constitutions. But they all derive from the same theme: the central importance of reproductive freedom in women's lives. *See, e.g., Armstrong v. State*, 989 P.2d 364, 372-390 (Mont. 1999) (emphasizing a woman's "moral right and moral responsibility to decide, up to the point of fetal viability, what her pregnancy demands of her in the context of her individual values, her beliefs as to the sanctity of life, and her personal situation");[15] *Women of Minn. by Doe v. Gomez*, 542

[14] Although Respondent cites federal "undue burden" precedent to argue that Petitioners bear the burden throughout of establishing the Rule's unconstitutionality, Resp't Br. 63, under a heightened scrutiny standard, that burden shifts to Respondent to demonstrate that the Rule fits to the necessary degree with Respondent's asserted interest in patient safety. *Gartner*, 830 N.W.2d at 352.

[15] Respondent recasts *Armstrong* as standing for deference to medical boards, Resp't Br. 60-61—only because the *Armstrong* court cited that state

N.W.2d 17, 27 (Minn. 1995) ("[F]ew decisions [are] more intimate, personal, and profound than a woman's decision between childbirth and abortion," and "this decision is of such great import that it governs whether the woman will undergo extreme physical and psychological changes and whether she will create lifelong attachments and responsibilities."); *Valley Hosp. Ass'n, Inc. v. Mat-Su Coal. for Choice*, 948 P.2d 963, 968 (Alaska 1997) ("A woman's control of her body, and the choice whether or when to bear children, involves the kind of decision-making that is necessary for . . . civilized life and ordered liberty" (punctuation and citation omitted)); *Planned Parenthood of Cent. N.J. v. Farmer*, 762 A.2d 620, 622 (N.J. 2000) (abortion right rooted in women's "personal dignity and autonomy").

Respondent argues that a strict scrutiny standard would be impossible to administer. Resp't Br. 58. But numerous states have afforded abortion greater protection than the federal standard; these states have fewer restrictions aimed at *preventing* women from obtaining an abortion, but they also have reasonable, evidence-based abortion regulations that serve everyone's interest in ensuring that patients receive high-quality medical

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medical board's *opposition* to an abortion restriction as *one of numerous* reasons for overturning the restriction, 989 P.2d at 372. *Armstrong* is not about the scope of agency authority, and holds that any state abortion restriction is presumptively unconstitutional unless the *state* can *demonstrate* that it is narrowly tailored to a compelling state interest. *Id.* at 373-74.

care. *See, e.g.*, N.J. Admin. Code §§ 8:43A-1.1 – 8:43A-33.4 (licensure standards); Alaska Stat. Ann. § 18.16.010(a)(2) (same); Minn. Stat. § 145.4132 (requiring reporting of abortion complications).

Finally, Respondent argues that strict scrutiny would under-value "the state's interest in protecting fetal life or potential life." Resp't Br. 58-59. This argument is surprising because Respondent has always claimed that it adopted the Rule purely out of patient safety concerns and has disclaimed any interest in preventing abortions. The argument also misreads *Casey*. *Casey* recognized—as a matter of federal law—that states have valid interests in fetal life and women's health, but also that these interests have to be considered separately, and that a law purporting to serve women's health must actually do so. 505 U.S. at 900-01. In other words, Respondent cannot promote fetal life by imposing unnecessary regulations intended to reduce abortion access. *Id.* at 877; *see Planned Parenthood Se., Inc. v. Strange*, 9 F. Supp. 3d 1272, 1298 (M.D. Ala. 2014).

As Petitioners have argued, the Rule would be invalid even under a less protective "undue burden" standard for two independent reasons: 1) the Rule demonstrably does not serve Respondent's purported interest in patient safety; and 2) the Rule would impose a substantial obstacle on women seeking an abortion. Pet'rs Br. 64-66. Interestingly, after urging this Court to

reject the strict scrutiny standard in the name of "balance," and advocating the "undue burden" standard as a "balancing test," Resp't Br. 58-62, Respondent then proceeds to propose a version of the undue burden test that rejects balancing and, instead, substitutes what is essentially rational basis review: the Fifth Circuit's approach in *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 748 F.3d 583 (5th Cir. 2014), Resp't Br. at 62-68. Under that approach, the state may restrict abortion under the guise of promoting women's health, and courts cannot even look at evidence contradicting this rationale, so long as the restriction is supported by some "rational speculation" and cannot be shown, in advance, to absolutely prevent a large fraction of women from obtaining an abortion, *Abbott*, 748 F.3d at 594, 598.

Abbott is an extreme outlier and wrong.[16] Its rational basis-like approach is impossible to square with *Casey*'s rejection of rational basis as an appropriate standard. *See Casey*, 505 U.S. at 981 (Rehnquist, J., dissenting) (unsuccessfully advocating a rational basis standard). *Compare Van Hollen*, 738 F.3d at 798. (Posner, J.) ("The feebler the medical grounds, the likelier the burden, even if slight, to be 'undue' in the sense of

[16] Moreover, its future is in doubt. *See Whole Woman's Health v. Lakey*, 135 S. Ct. 399 (2014) (reinstating injunction against abortion restriction, which the Fifth Circuit had stayed).

disproportionate or gratuitous."); *Humble*, 753 F.3d at 914; *Strange*, 2014 WL 3809403, at *5-8; Priscilla J. Smith, *If The Purpose Fits: The Two Prongs of* Casey*'s Purpose Inquiry*, 71 Wash. & Lee L. Review 1135, 1156 (2014) (*Abbott* standard "is lower even than a traditional rational basis test and certainly fails to uphold the balance that *Casey* struck.").[17]

It is clear that under the correct standard discussed in *Van Hollen*, *Humble*, and *Strange*, the Rule would fail this standard, because: 1) Respondent's conclusory medical assertions (such as that in-person physician examinations are "the cornerstone of good medical care," Resp't Br. 67) are feeble at best, wholly belied by the widespread acceptance of telemedicine; and 2) the Rule would make abortion inaccessible in over half of the places where it is currently provided.

III. Respondent-Amici's Factual Assertions are False, Misleading and Irrelevant.

Respondent does not claim that the Rule is justified by any particular danger posed by medication abortion itself. *See* Resp't Br. 40 (noting that "[t]he issue in this case is not whether medical abortion is safe").

[17] Tellingly, Respondent presented this approach below as "rational basis" review (coupled with a narrow inquiry into the law's effect on access). Resp't Br. in Resistance at 43-46, May 5, 2014. Here, by contrast, Respondent assures this court that it is not proposing rational basis review, Resp't Br. 57 (without explaining how that is so).

Yet Amici supporting Respondent—American Association of Pro-Life Obstetricians & Gynecologists et al. ("AAPLOG") and other organizations dedicated to opposing safe and legal abortion[18]—seek to argue that medication abortion is unsafe.[19] Putting aside the relevance of this claim when it has not been raised by Respondent and thus relies entirely on "evidence" nowhere in the record, Amici's curious blend of medicine and anti-abortion ideology is on full display in the factual distortions that permeate their briefs.[20]

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[18] *See, e.g.*, AAPLOG, Our Mission Statement, http://www.aaplog.org/about-2/our-mission-statement/ ("[E]lective disruption/abortion of human life at any time from fertilization onward ... will have no place in our practice of the healing arts."); Catholic Medical Association, Mission, http://cathmed.org/about/mission_purpose/ (declaring "steadfast fidelity to the teachings of the Catholic Church, [and] to uphold[ing] the principles of the Catholic faith in the science and practice of medicine"), *and* U.S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services ¶ 45 (5th Ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf ("Abortion . . . is never permitted") (all sites last visited Dec. 12, 2014).

[19] Other Amici, PFL and Catholic Medical Association, et al., rely on AAPLOG's medical assertions. Thus, this Reply focuses mainly on the AAPLOG brief.

[20] Tellingly, AAPLOG is joined in its brief by its president, Dr. Donna Harrison, and PFL relies on her wholly unsupported "conclusion" that abortion complications are underreported, PFL Br. 19-20. Dr. Harrison recently testified on the risks associated with medication abortion, and was found not credible by the trial court. *MKB Mgmt. Corp. v. Burdick*, No. 09-2011-CV-02205, slip op. at 14 (N.D.E. Cent. Jud. Dist. Ct. July 15, 2013),

At the outset, AAPLOG inflates the risks of medication abortion by conflating them with known side effects about which women are counseled prior to the procedure, including bleeding and cramping. *Compare* Amicus Brief of AAPLOG 11 ("AAPLOG Br.") *with* ACOG Bulletin at 3 ("Bleeding and cramping will be experienced by most women undergoing medical abortion and are necessary for the process to occur."). Similarly, AAPLOG cites an outdated and consequently overinflated statistic[21] about failure rates. But just because medication abortion may rarely require surgical completion, does not mean that women should be deprived of the

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available at http://rhrealitycheck.wpengine.netdna-cdn.com/wp-content/uploads/2013/07/2013-07-15_MKBvBurdick_Perm_Injunction.pdf ("Dr. Harrison's opinions lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence. To the extent she referenced published studies during her testimony, Dr. Harrison tended to present the results in an exaggerated or distorted manner. Finally, her demeanor on the stand was guarded and defensive."), *rev'd on other grounds by lack of supermajority affirmance required by North Dakota law*, 855 N.W.2d 31 (N.D. 2014). A different court drew the same conclusion after hearing testimony of Dr. John Thorp, another ideologue cited by Amici, AAPLOG Br. 10 n.5. *Planned Parenthood Se., Inc. v. Strange*, ___ F. Supp. 3d ___, 2014 WL 5339294, at *11 (M.D. Ala. Oct. 20, 2014) (rejecting Dr. Thorp's testimony after finding that he showed "a disturbing apathy toward the accuracy of his testimony," "a bias against abortion and a desire to inflate complication rates").

[21] AAPLOG cites an outdated study that used an outdated regimen in China, Cuba and India for its claimed failure rate. AAPLOG Br. 14 & n.21. More recent data, however, make clear that the actual rate is far lower. Mary Fjerstad et al., *Effectiveness of Medical Abortion with Mifepristone and Buccal Misoprostol through 59 Gestational Days*, 80 Contraception 282, 284 (2009) (current regimen has a 98.3% success rate).

chance (greater than 98 percent) of avoiding surgery. Fjerstad, *supra* n.21, at 284.

AAPPLOG misrepresents the medical literature in other ways as well. For example, AAPLOG claims that a study involving 22,368 medication abortions in Finland is the "largest" study of medication abortions, AAPLOG Br. at 10-11,[22] dismissing a more recent, peer-reviewed study of over 230,000 U.S. abortions (which showed extremely low rates of serious complications), *id.* at 16 & n.2; Kelly Cleland et al., *Significant Adverse*

[22] AAPLOG's reliance on the Finnish study shows desperation. That study does not specify the drug regimen followed (and given that the study uses data from 2000-2006, it is likely that the regimen differed significantly from the current standard of care). Moreover, it includes in its hemorrhage statistics women who self-reported heavy bleeding from a procedure for which bleeding is expected and necessary. M. Niinimaki et al., *Immediate Complications after Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 796 (Oct. 2009), *available at* http://realchoices.org.au/wp-content/uploads/2012/08/Immediate_Complications_After_Medical_Compared.14.pdf; *see id.* at 800 (acknowledging that lower rate of "uterine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy"). AAPLOG similarly misconstrues the other studies it cites for the claim that medication abortion is risky, AAPLOG Br. 13-14. Among other problems with those studies, they are either old, *see id*. at 14 nn.21-22, focus on procedures performed by providers without experience with medication abortion, *see id.* at 14 n.19, and/or involve outdated medication abortion regimens, *see id.* at 14 nn.19-22, small sample sizes, *see id.*, and/or populations outside the U.S., *see id.* at 14 nn.19-21. More fundamentally, however, AAPLOG ignores that each and every one of these studies concludes that medication abortion is a safe procedure.

Events and Outcomes After Medical Abortion, A121 Obstetrics & Gynecology 166, 166 (2013), and completely ignoring another involving over 900,000 U.S. abortions, (App. 109 ¶ 16 (citing Trussell study); App. 410-415).[23]

AAPLOG also falsely implies that the mortality rate for medication abortion is higher than that for surgical abortion, AAPLOG Br. 10-13 (using infection-related data from an outdated, inferior regimen and ignoring newer data showing no infection-related mortality in over 700,000 patients), when the rates are comparable, and both are lower than the mortality rate associated with penicillin. (App. 108-109 ¶¶ 13-17). Citing a 2011 FDA report that identified 14 deaths after women took the medications, AAPLOG omits that: 1) the FDA stated that no causal connection had been established and some of the deaths (including a homicide) clearly were medically unrelated to abortion, Mifepristone U.S. Postmarketing Events Summary, *available at*

[23] These large-scale studies, together covering over a million patients, do not exclude any category of patient, contrary to PFL's representation, PFL Br. 27-28. And while Amici complain that some patients in these studies may have been lost to follow-up, a new large-scale study has just been published tracking California Medicaid patients for all subsequent care (thereby avoiding any follow-up problems); this study similarly concludes that medication abortion has a low rate of serious complications, "much lower than that found during childbirth," Upadhyay, *supra* n.10, at 7.

http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf; and 2) the FDA report covers a period of more than 10 years, during which approximately *1.52 million women* had medication abortion (following different regimens). *Id.* The report, therefore, demonstrates the *safety* of medication abortion. (*See also* App. 108-109 ¶¶ 13-17 (citing FDA summary)).[24]

AAPLOG dismisses ACOG's recent practice bulletin about medication abortion safety, even though ACOG is the leading national organization of women's health professionals and is routinely cited by courts as an objective medical authority. ACOG Br. 4. Specifically, AAPLOG faults ACOG's citation to the Cleland study (App. 110 ¶ 18).[25] But

[24] For the proposition that "other serious complications" have been documented, AAPLOG Br. 11, AAPLOG cites articles that have nothing to do with the safe and legal medication abortion regimen used by PPH and U.S. providers generally. *See id.* at 11 n.12 (citing one article about "high-dose misoprostol" for medical abortion and another about a patient who suffered toxic shock after a self-induced "clandestine" abortion). Similarly, AAPLOG fails to note that the Fischer article, *id.* at 12 n.14—which it contends shows that medication abortion has a higher risk of death—not only is based on outdated data but actually concludes that "serious infection can occur after medically induced abortion, much as it can occur after childbirth, spontaneous abortion, and surgical abortion." Marc Fischer et al., *Fatal Toxic Shock Syndrome Associated with Clostridium Sordellii after Medical Abortion*, 353 N. Eng. J. Med. 2352, 2355 (2005).

[25] AAPLOG also claims that the ACOG Bulletin "ignores five other studies . . . documenting higher complication rates," AAPLOG Br. 15-16 & n.25, but this is incorrect. The ACOG Bulletin in fact cites two of the five studies,

AAPLOG ignores that the Cleland study, which is far larger than any study cited by AAPLOG, is just one of 113 studies relied upon by ACOG. AAPLOG cites the authors' acknowledgment that some patients might not have reported complications as a reason to reject that study's conclusions, but that is a common limitation in all medical research.

Finally, and perhaps most importantly, AAPLOG's focus on the alleged "dangers" of medication abortion completely avoids the question whether medication abortion performed via telemedicine is safe as compared with in-person medication abortion. Unable to cite to any studies that even remotely suggest that telemedicine medication abortion is less safe than in-person medication abortion, AAPLOG instead tries to discredit (on appeal, without evidence) as "biased and flawed" Dr. Grossman's study of the PPH's telemedicine program, which was published in the official publication of ACOG. AAPLOG Br. 15. This attempt again reveals AAPLOG's overriding anti-abortion bias and disregard for actual science.

AAPLOG complains that the study does not provide an accurate comparison because the in-person abortions studied did not include a physical exam; in fact, as explained in Pet'rs Br. 9, PPH always provides a

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ACOG Bulletin at 13 n.32, 14 n.52, and the other three use outdated regimens and/or report comparably low rates of complications.

physical examination. AAPLOG complains that over 20 percent of patients failed to return for follow-up appointments at PPH, but fails to note that the rate was consistent for both in-person and telemedicine abortions. (App. 119 ¶ 46). And finally, AAPLOG points out that the study was not "randomized" (because patients chose whether to receive care through telemedicine or at a physician-staffed clinic) but does not explain how researchers could have ethically randomized patients or how the lack of randomization could have biased the safety conclusions reached by the study.

In short, none of AAPLOG's complaints about the Grossman study undermines its conclusions that medication abortions provided via telemedicine are safe, and their blatant distortion of the medical data merely underscores the ideology behind efforts to restrict telemedicine abortion.

CONCLUSION

For the reasons set forth above, as well as in their initial brief, the Rule is invalid.

Sharon K. Malheiro, AT0004936
Davis, Brown, Koehn, Shors & Roberts, P.C.
215 10th Street, Suite 1300
Des Moines, Iowa 50309
Telephone: (515) 288-2500
Facsimile: (515) 243-0654
E-mail: sharonmalheiro@davisbrownlaw.com

Of counsel:

Alice Clapman, *Pro Hac Vice Application pending*
Planned Parenthood Federation of America
1110 Vermont Ave., N.W., Suite 300
Washington, DC 20005
Telephone: 202-973-4862
Facsimile: 202-296-3480
E-mail: alice.clapman@ppfa.org

Roger Evans
Planned Parenthood Federation of America
434 W. 33rd Street
New York, N.Y. 10001
Telephone: 212-261-4708
Facsimile: 212-247-6811
E-mail: roger.evans@ppfa.org

ATTORNEYS FOR
PETITIONERS/APPELLANTS

REQUEST FOR ORAL ARGUMENT

Petitioners/Appellants respectfully request that this matter be heard orally before this Court.

Sharon K. Malheiro, AT0004936
Davis, Brown, Koehn, Shors& Roberts, P.C.
215 10th Street, Suite 1300
Des Moines, Iowa 50309
Telephone: (515) 288-2500
Facsimile: (515) 243-0654
E-mail: sharonmalheiro@davisbrownlaw.com

Of counsel:

Alice Clapman, *Pro Hac Vice Application pending*
Planned Parenthood Federation of America
1110 Vermont Ave., N.W., Suite 300
Washington, DC 20005
Telephone: 202-973-4862
Facsimile: 202-296-3480
E-mail: alice.clapman@ppfa.org

Roger Evans
Planned Parenthood Federation of America
434 W. 33rd Street
New York, N.Y. 10001
Telephone: 212-261-4708
Facsimile: 212-247-6811
E-mail: roger.evans@ppfa.org

ATTORNEYS FOR
PETITIONERS/APPELLANTS

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Date: December 22, 2014

Sharon K. Malheiro, AT0004936
Davis, Brown, Koehn, Shors& Roberts, P.C.
215 10th Street, Suite 1300
Des Moines, Iowa 50309
Telephone: (515) 288-2500
Facsimile: (515) 243-0654
Email: sharonmalheiro@davisbrownlaw.com

ATTORNEYS FOR
PETITIONERS/APPELLANTS

CERTIFICATE OF FILING AND SERVICE

I, Sharon Malheiro, hereby certify that on the 22nd day of December, 2014, I electronically filed the foregoing Petitioners/Appellants' Reply Brief with the Clerk of the Iowa Supreme Court by using the EDMS system and all persons who have filed appearances are registered EDMS users and that service will be accomplished by the EDMS system on the following:

Thomas J. Miller
Iowa Attorney General
Julie J. Bussanmas
Assistant Attorney General
Iowa Department of Justice
Hoover State Office Building, 2nd Floor
1305 East Walnut Street
Des Moines, IA 50319

ATTORNEYS FOR RESPONDENTS/APPELLEES

Sharon K. Malheiro, AT0004936
Davis, Brown, Koehn, Shors& Roberts, P.C.
215 10th Street, Suite 1300
Des Moines, Iowa 50309
Telephone: (515) 288-2500
Facsimile: (515) 243-0654
Email: sharonmalheiro@davisbrownlaw.com

ATTORNEYS FOR
PETITIONERS/APPELLANTS