No. 17-15208

UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

WEST ALABAMA WOMEN'S CENTER, et al.,
on behalf of themselves and their patients

Plaintiffs-Appellees,

v.

DR. THOMAS M. MILLER, M.D., et al.,
in his official capacity as State Health Officer, et al.,

Defendants-Appellants.

On Appeal from the District Court of the United States
for the Middle District of Alabama, Northern Division
No. 2:15-cv-00497 (Hon. Myron H. Thompson)

BRIEF FOR THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rules 26.1-1 and 27-1(a)(9), *Amicus Curiae* American College of Obstetricians and Gynecologists ("ACOG") certifies that the following individuals and entities have an interest in this litigation. To the best of *amicus's* knowledge, none of the following individuals or entities are a corporation that issues shares to the public:

Alabama Women's Center – Appellee

American Association of Pro-Life Obstetricians and Gynecologists – *Amicus Curiae*

American Civil Liberties Union – Counsel for Appellees

American Civil Liberties Union Foundation – Counsel for Appellees

American Civil Liberties Union Foundation of Alabama – Counsel for Appellees

American College of Obstetricians and Gynecologists – *Amicus Curiae*

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STATEMENT OF THE ISSUES

1. Decades of Supreme Court precedent holds that a law prohibiting the most common method of abortion in the second trimester is unconstitutional. *See Gonzales v. Carhart*, 550 U.S. 124, 150–54, 164–65 (2007); *Stenberg v. Carhart*, 530 U.S. 914, 930 (2000); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 77–79 (1976). Alabama Senate Bill 363, Reg. Sess. 2016 prohibits the most common second-trimester abortion procedure. Did the District Court correctly hold that this prohibition on the most common second-trimester abortion method is likely unconstitutional?

2. The District Court found that Alabama Senate Bill 363, Reg. Sess. 2016 would all but eliminate access to abortions in Alabama after the fifteenth week of pregnancy because it bans the only abortion method available in abortion clinics from that point forward, and because the State's proposed methods for circumventing the Ban are unfeasible and would subject women to significant medical risks. Did the District Court correctly hold that the Ban would likely impose an unconstitutional undue burden?

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The American College of Obstetricians and Gynecologists ("ACOG" or the "College") submits this *amici curiae* brief in support of the Plaintiffs-Appellees.[1]

ACOG is a national non-profit educational and professional organization that works to promote the advancement of women's health through continuing medical education, practice, research, and advocacy. With more than 58,000 members, including 473 obstetrician-gynecologists in Alabama, ACOG is the leading organization of women's health care providers. ACOG is dedicated to continuously improving all aspects of health care for women, establishing and maintaining the highest possible standards for education and clinical practice, promoting high ethical standards, publishing evidence-based practice guidelines, encouraging contributions to medical and scientific literature, and increasing awareness among its members and the public about the changing issues facing women's health care.

ACOG opposes laws regulating medical care that unduly interfere with the patient-physician relationship or patient care absent a substantial public health

[1] Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for ACOG certify that: no party's counsel authored this *amici curiae* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amici curiae* brief; and no person or entity, other than ACOG, its members, or its counsel, contributed money intended to fund the preparation or submission of this *amici curiae* brief. All parties have consented to ACOG filing this *amici curiae* brief in this litigation.

justification.[2] While individual members' views on abortion may vary, ACOG recognizes that abortion is "an essential component of women's health care," that "[l]ike all medical matters, decisions regarding abortion should be made by patients in consultation with their health care providers and without undue interference by outside parties," and that "[l]ike all patients, women obtaining abortions are entitled to privacy, dignity, respect and support."[3] All ACOG members share an interest in opposing legislation that "weakens the patient-physician relationship" and prevents a patient from receiving counsel or treatment "according to the best available medical evidence and the physician's professional medical judgment."[4]

ACOG's work has been cited frequently by federal courts, including the Supreme Court of the United States, as authoritative medical data regarding childbirth and abortion.[5]

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[2] ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013) ("ACOG Leg. Policy Statement"), http://www.acog.org/~/media/Statements%20of%20Policy /Public/ 2013LegislativeInterference.pdf (last accessed April 11, 2017) ("Laws that veer from these functions and unduly interfere with patient-physician relationships are not appropriate. Absent a substantial public health justification, government should not interfere with individual patient-physician encounters.").

[3] ACOG, *Statement of Policy, Abortion Policy* (Nov. 2014) ("ACOG Abortion Policy"), http://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf?dmc=1&ts=20170403T2243447833 (last visited April 11, 2017).

[4] ACOG Leg. Policy Statement.

[5] *See, e.g., Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315 (2016) (citing ACOG's *amicus* brief in assessing disputed admitting privileges and surgical center requirements); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing

SUMMARY OF THE ARGUMENT

The patient-physician relationship is essential to the provision of safe and quality medical care and should be protected from undue interference by unnecessary and burdensome regulation. Absent a substantial public health justification—which Alabama Senate Bill 363, Reg. Sess. 2016 ("SB 363" or the "Ban") is entirely lacking—laws regulating medical care that unduly interfere with a physician's ability to act in the best interest of his or her patient should be struck down. This is especially critical where, as with SB 363, the legislative enactment does nothing to protect the health of the women it affects and threatens women's long-recognized right to safe and effective abortion care.[6]

The Ban undermines the patient-physician relationship and endangers patient safety by preventing health care providers from performing the safest and most common method of second-trimester abortions, dilation and evacuation ("D&E"), without first making their patients undergo a medically unnecessary and risky

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ACOG's *amicus* brief in assessing disputed parental notification requirement); *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 916-17 (9th Cir. 2014) (citing ACOG and the American Medical Association's ("AMA") *amicus* brief as further support for a particular medical regimen), *cert. denied*, 135 S. Ct. 870 (2014); *Stuart v. Camnitz*, 774 F.3d 238, 251-52, 254, 255 (4th Cir. 2014) (citing ACOG and the AMA's *amicus* brief in assessing how an ultrasound requirement exceeded the bounds of traditional informed consent and interfered with physicians' medical judgment), *cert. denied*, 135 S. Ct. 2838 (2015).

[6] *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 887-98 (1992); *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016).

procedure to cause fetal demise. Contrary to the State's assessment, the fetal demise procedures outlined by the legislature (umbilical cord transection, digoxin injection, and potassium chloride injection) could pose serious health risks to patients. In inflicting the legislature's political views and superseding the medical judgment of Alabama's physicians, the Ban interferes with the integrity of the medical profession and the quality of medical care available to women seeking abortions within the state.

Moreover, the Ban conflicts with medical professionals' ethical obligations of beneficence, non-maleficence, and patient autonomy. Although the State defends the Ban on the basis that it promotes the integrity and ethics of the medical profession, defining a patient's course of treatment according to political, rather than medical, considerations forces doctors into an ethical conundrum: physicians will be required to either (i) violate the law, or (ii) violate their ethical obligations to patients by advising against their medical judgment in requiring a risky and unnecessary procedure.

Finally, allowing the political branches to impose a one-size-fits-all medical requirement regardless of the patient's circumstances and to criminalize physicians for performing a common and accepted medical procedure that is in the best interest of their patients sets a dangerous precedent for infringing on the patient-physician relationship. The examination room is simply an inappropriate place for the political

views of the legislature, and permitting such interference could have broad sweeping consequences for public health. For these reasons, the permanent injunction on Alabama's SB 363 should be upheld.

ARGUMENT

ACOG is committed to the right of every woman to access the "best available scientifically based health care" and the right to "autonomous decision-making."[7] Consequently, ACOG opposes political interference with the patient-physician relationship and a physician's ability to act in the best interest of his or her patient, especially where the legislative enactment does nothing to protect the health of the patient it affects and threatens women's access to safe and effective abortion care.[8] In its Statement of Policy, adopted by its Executive Board, the College states:

> Laws should not interfere with the ability of physicians to determine appropriate treatment options and have open, honest, and confidential communications with their patients. Nor should laws interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's

[7] *See* ACOG, *Statement of Policy, Global Women's Health and Rights* (July 2012, reaffirmed 2015), http://www.acog.org/-/media/Statements-of-Policy/Public/2012GlobalWmHlthRights.pdf?dmc=1&ts=20170403T1939443711.

[8] *See* ACOG, *Committee on Health Care for Underserved Women Committee Opinion, Increasing Access to Abortion* (Nov. 2014, reaffirmed 2017), http://www.acog.org/Clinical-Guidance-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Increasing-Access-to-Abortion ("Access to abortion is threatened by state and federal government restrictions. . . . Legislative restrictions fundamentally interfere with the patient-provider relationship . . . .").

> professional medical judgment. . . . Laws that require physicians to give, or withhold, specific information when counseling patients, or that mandate which tests, procedures, treatment alternatives or medicines physicians can perform, prescribe, or administer are ill-advised.[9]

By mandating a one-size-fits-all course of treatment for the patient, SB 363 interferes with the patient-physician relationship by unduly restricting a physician's ability to counsel patients "according to the best currently available medical evidence" and within the "physician's professional medical judgment." The Ban's fetal demise requirement prohibits a physician from deciding, in consultation with her patient, to perform D&E without the additional procedure.

As the District Court recognized, in enacting SB 363 the Alabama legislature superseded the medical judgment of Alabama physicians and interfered with the quality of medical care by forcing upon patients procedures that create risks to the patient.[10] Physicians alone are able to take a holistic look at all of the factors involved in a potential procedure on a case-by-case basis, including time, cost, safety, and the available treatment facilities, before advising what is best for the

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[9] ACOG Leg. Policy Statement.

[10] *See* Appellants' Appendix Doc. 139 at 83-84 ("Physicians have an ethical obligation not to subject patients to potentially harmful, experimental procedures without any medical benefit and the patient's consent. The fetal-demise law forces women to either undergo a risky procedure with no any [*sic*] medical benefit or give up their right to pre-viability abortion; placing women in such a predicament negates any opportunity for meaningful consent.").

individual patient. What a physician deems to be an appropriate course of treatment for one patient may not be the safest or most appropriate course for another. However, the Ban artificially restricts a physician from recommending the best treatment by looking at the specific circumstances and needs of each patient. This interference makes patients less safe, weakens the patient-physician relationship, and sets damaging precedent.

I. The Ban Unduly Interferes with the Patient-Physician Relationship, an Essential Element of Safe, High Quality Medical Care.

SB 363 prohibits a physician from performing a routine and safe abortion procedure. This intrusion into the patient-physician relationship cannot be justified on medical or ethical grounds. Far from advancing women's health, the Ban restricts the safest and most frequently preferred method for performing second-trimester abortions and mandates that the patient first undergo a procedure that could impose significant health risks.

A. SB 363 Bans the Safest and Most Commonly Used Procedure for Second-Trimester Abortion.

While most abortions are performed in the first trimester, a number of reasons cause some women to obtain an abortion in the second trimester.[11] At that point, there are effectively two abortion options available: medical induction, by which a

[11] ACOG, *Practice Bulletin No. 135: Second Trimester Abortion*, 121 Obstetrics & Gynecology 1394 (June 2013) ("Practice Bulletin No. 135").

physician uses medication, such as misoprostol, to induce labor, and D&E.[12] For most women in Alabama, though, D&E is the only available method.

Although medical induction is generally safe, there are a number of potential health risks associated with this procedure, including complications such as incomplete abortion or prolonged labor and delivery.[13] Consequently, the procedure must be performed in a facility that can admit patients for extended stays.[14] Because hospital-based abortion services are nearly unavailable in Alabama,[15] medical induction is practically unattainable to women in the state. D&E is effectively the only second-trimester abortion method available to women in Alabama.

Even outside Alabama, the majority of second-trimester abortions are performed by D&E.[16] A ban on D&E would affect the overwhelming percentage of

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[12] *Id.*

[13] *Id.* ("termination by induction with misoprostol is less cost-effective, is associated with a greater risk of complications, such as incomplete abortion, and may be prolonged"); *see also* A.M. Autry et al., *A Comparison of Medical Induction and Dilation and Evacuation for Second-Trimester Abortion*, 187 Am. J. Obstetrics & Gynecology 393 (Aug. 2002).

[14] Appellants' Appendix Doc. 139 at 72 n.22 ("State regulations do not allow outpatient clinics to initiate an abortion procedure that may entail more than 12 hours of clinical involvement, which means that [medical induction] must be performed in a hospital").

[15] *Id.*; *see also* Appellants' Appendix Doc. 54-4 ¶ 24; Doc. 54-6 ¶ ¶ 14-15.

[16] Practice Bulletin 135 (nationally, D&E accounts for 95% of all second-trimester abortions); *see also Gonzales v. Carhart*, 550 U.S. 124, 147 (2007) (recognizing that "D & E is the most common second-trimester abortion method," and that the Attorney General "[did] not dispute that [the ban at issue] would impose an undue

women in Alabama who, in consultation with the medical judgment of their health care providers, prefer this method.[17] Indeed, contrary to the State's anecdotal assertions,[18] research shows that D&E is the safest and most preferred method for second-trimester abortion.[19]

This preference is unsurprising, given that D&E is a safe and effective method and has fewer complications than many other standard medical procedures.[20] As

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burden if it covered standard D & E."); *id*. at 150-153 (distinguishing *Stenberg v. Carhart*, 530 U.S. 914 (2000) and finding no undue burden existed where law did not prohibit standard D&E procedures).

[17] The State takes the position that because second-trimester abortions are rare, only a small number of women in Alabama will be affected by the Ban. Brief of Appellant Thomas M. Miller, M.D., et al., *West Alabama Women's Ctr. v. Miller*, No. 167296 (11th Cir. Mar 10, 2017) ("State Br.") at 7. This argument misses the mark by ignoring the fact that all women seeking a legal second-trimester abortion in Alabama at or after 15 weeks of pregnancy in the Tuscaloosa and the Huntsville clinics rely on D&E. *See* Appellants' Appendix Doc. 139 at 72-73.

[18] State Br. at 6 (citing no data, claiming that "many physicians . . . have raised grave moral concerns" with performing D&E) and 24 (noting that "many medical professionals" reported "emotional reactions" and "moral anguish" about D&E).

[19] Grimes et. al., *Mifepristone and Misoprostol Versus Dilation and Evacuation for Midtrimester Abortion: A Pilot Randomized Controlled Rrial,* 111 Obstetrics & Gynecology 148, 153 (2004) (finding that the "failed feasibility trial" suggests most women prefer D&E and were therefore unwilling to participate in a randomized trial which may result in a different abortion procedure); Practice Bulletin 135 (nationally D&E accounts for 95% of all second-trimester abortions).

[20] Relying on *Gonzales*, the State claims that so long as there is "*any* documented medical support" in favor of their position that the Ban does not impose significant health risks on women, the Ban should be upheld. State Br. at 30 (emphasis in original). However, not only does this argument ignore the well-documented medical evidence on safety regarding D&E vis-à-vis alternative procedures, but it also ignores the Supreme Court's pronouncement in *Whole Woman's Health* that

accurately described in the District Court's opinion, D&E is "an extremely safe abortion method, with a less than 1% chance of major complications."[21] Forty years of cumulative data have shown that the D&E technique is the safest method, causing fewer complication, less pain, and fewer side effects than other means of second-trimester abortion.[22] The procedure is safer than many other common medical procedures. Indeed, before 21 weeks (*i.e.*, the gestational limit for all D&Es in Alabama), the mortality rate for abortion is significantly lower than the mortality rate from childbirth.[23]

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courts are required to "consider the burdens a law imposes on abortion access together with the benefits those laws confer." *Whole Woman's Health*, 136 S. Ct. at 2309 (citing *Casey*, 505 U.S. at 887-98). The District Court, like other district courts around the country that have considered challenges to abortion restrictions since the Supreme Court decided *Whole Women's Health*, properly weighed the burden on women seeking an abortion against the State's purported justification for the law. *See, e.g., Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, 273 F. Supp. 3d 1013, 1021 (S.D. Ind. 2017) (balancing benefits and burdens in considering requirement that women delay abortion by 18 hours after obtaining ultrasound); *Hopkins v. Jegley*, 267 F. Supp. 3d 1024, 1064 (E.D. Ark. 2017) (balancing benefits and burdens in considering D&E ban); *June Med. Servs. LLC v. Gee*, No. 16-00444-BAJ-RLB, 2017 U.S. Dist. LEXIS 191938, at *46-47 (M.D. La. Nov. 15, 2017) (recognizing the applicability of undue burden balancing test in considering D&E ban); *Whole Women's Health v. Paxton*, No. A-17-CV-690-LY, 2017 U.S. Dist. LEXIS 195268, at *32-36 (W.D. Tex. Nov. 22, 2017) (balancing benefits and burdens in considering D&E ban).

[21] Appellants' Appendix Doc. 139 at 70.

[22] Practice Bulletin 135*; see also* Grimes et al., *Mid-Trimester Abortion by Dilation and Evacuation: A Safe and Practical Alternative*, 296 New. Eng. J. Med. 1141 (1977).

[23] *See, e.g.*, Grossman et al., *Complications After Second Trimester Surgical and Medical Abortion*, 16 Reproductive Health Matters 173, 173 (2008); Elizabeth G.

Moreover, D&E is the fastest and most cost effective method of second-trimester abortion.[24] While some women visit their physicians the day prior to the D&E procedure to take medication or begin cervix dilation, D&E can typically be

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Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion & Childbirth in the United States,* 119 Obstetrics & Gynecology 215, 216 (Feb. 2012) ("The risk of death associated with child birth was approximately 14 times higher than that with abortion"); *see also* Raymond et al., *Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States*, 90 Contraception 476-79 (Nov. 2014) (finding that "such travel [to the abortion clinic] may impose a great risk of death than the abortion itself").

The State's *amici curiae* suggest that the Ban is necessary because D&E is supposedly unsafe. To support their argument, the State's *amici* rely on ACOG's submission in *Gonzales*. *See* Brief for Association of Pro-life Obstetricians and Gynecologists and American College of Pediatricians as *Amici Curiae* Supporting Defendants-Appellants Seeking Reversal, *West Alabama Women's Ctr. v. Miller*, No. 17-15208-FF, at 16-18 (11th Cir. Jan. 30, 2018). But the State's *amici* mischaracterize ACOG's submission in that case. *Gonzales* involved a challenge to the Partial-Birth Abortion Ban Act of 2003, which prohibited physicians from performing "intact" D&E procedures. ACOG submitted a brief addressing the health risks that ban posed to women. ACOG's brief recognized that, in certain circumstances and for certain patients, intact D&E is a safer procedure than standard D&E. *See* Brief for the American College of Obstetricians and Gynecologists as *Amicus Curiae* Supporting Respondents, *Gonzales v. Carhart*, 550 U.S. 124 (2007) (Nos. 05-380, 05-1382), 2006 WL 2867888. Contrary to assertions by the State's *amici*, ACOG's brief in *Gonzales* did not mean that standard D&E procedures are *unsafe*; rather, ACOG's submission noted that there can be safety advantages to performing intact D&E (which has been outlawed and is thus not available to Alabama women). As set forth in this brief, standard D&E is a very safe and common second-trimester abortion procedure.

[24] Practice Bulletin 135.

done outpatient (in a health care provider's office or clinic) and typically takes only ten to fifteen minutes.[25]

B. SB 363 Mandates a Potentially Harmful One-Size-Fits-All Procedure.

SB 363 prohibits physicians from performing standard D&E by requiring them to effect "fetal demise" prior to removing the fetus through D&E.[26] The State argues that Alabama women have regular access to three methods that induce fetal demise: umbilical cord transection, digoxin injection, and potassium chloride injection.[27] None of these procedures, or any other fetal demise technique, have been shown to increase the safety of second-trimester abortion.[28] Though some physicians might find it medically appropriate to employ these procedures on a case-by-case basis, all three procedures are extremely difficult and invasive, do not always work, are not appropriate for all patients, and could impose significant risks to the patient, illustrating how the Ban's interference with the medical judgment of health care providers obstructs abortion care and endangers women's health.[29]

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[25] ACOG, *Frequently Asked Questions, Induced Abortion* (2015), http://www.acog.org/Patients/FAQs/Induced-Abortion; Appellants' Appendix Doc. 139 at 70-71.

[26] Ala. Code § 26-23G-1 et seq.

[27] State Br. at 15.

[28] Practice Bulletin 135 ("No evidence currently supports the use of induced fetal demise to increase the safety of second-trimester medical or surgical abortion").

[29] ACOG recognizes that physicians sometimes recommend fetal demise when treating their abortion patients and asserts that such treatment decisions must be left to a patient and her physician. SB 363 obstructs that important policy goal and

i. Umbilical Cord Transection

Umbilical cord transection is a technically challenging procedure in which a physician dilates the woman's cervix, uses an ultrasound machine to locate the umbilical cord, and then perforates the amniotic membrane to ideally cut the cord and cause the heart to stop.[30] Physicians are forced to locate and then transect the umbilical cord, which can be thin, flaccid, and difficult to locate.[31] As the amniotic fluid drains, the uterus and its contents become compressed and physicians using this technique struggle to identify the umbilical cord from other tissues and structures.[32] With the contents of the uterus collapsed together, it can be difficult or even impossible for a physician using an instrument to distinguish the cord from the fetus and other uterine contents. Even when a physician is able to successfully perform umbilical cord transection, the patient may suffer a number of significant

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interferes with physicians' ability to engage in ethical, shared decision-making with their patients.

[30] Appellants' Appendix Doc. 139 at 73-74.

[31] As explained by the District Court, "before the amniotic membrane is punctured, the physician is readily able to visualize the fetus and the umbilical cord due to the contrast on the ultrasound between the amniotic fluid and the uterine and fetal tissue. However, when the amniotic membrane is punctured at the beginning of the procedure, the amniotic fluid drains from the uterus. Once the fluid has drained, it is much more difficult to visualize the location of the umbilical cord because the contrast dissipates along with the amniotic fluid." *Id*. at 74-75.

[32] *Id.* at 75.

health risks, including blood loss, placental separation, contractions, infection, and uterine perforation.[33]

In addition, the likelihood of these serious risks has been inadequately studied.[34] Given the potentially severe medical consequences and the lack of understanding as to the safety of this procedure, the State's expectation that physicians will use this technique imposes significant health risks for women without any medical benefit.

ii. Digoxin and Potassium Chloride Injections

The two remaining methods, digoxin injections and potassium chloride injections, require the physician to insert "a long surgical needle through the patient's skin, abdomen, and uterine muscle, in order to inject [the named chemical] into the fetus."[35] Both procedures are invasive, and because they are completed without anesthesia, the procedures are painful for women.[36] Like umbilical cord

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[33] *Id.* at 76-79.

[34] *Id.* at 79-82.

[35] *Id.* at 92; *see also id.* at 85.

[36] *Id.* at 85, 92-93. Though State's *amici* attempt to justify the Ban under the theory that a fetus can feel pain, the State has not defended the Ban on these grounds. Even if the State had asserted such a theory, it would have been baseless. As the District Court recognized, fetal pain is not a "biological possibility" at the gestational stages at issue here. *Id.* at 64, n.18. Indeed, a fetus is incapable of experiencing pain until after viability. *See* ACOG, *Facts are Important, Fetal Pain*, https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/ FactAreImportFetal Pain.pdf (July 2013). "Rigorous scientific studies have found that the connections necessary to transmit signals from the peripheral

transection, neither of these methods can be relied upon to achieve fetal demise in every case.[37]

Digoxin injections are risky, unreliable, and not suitable for all women. The risks of conducting this procedure include infection, digoxin toxicity, delivery outside the health care facility, vomiting, nausea, and pain.[38] In addition, physicians cannot accurately predict how long it will take for digoxin injections to become effective (or if they will be effective at all).[39] When effective, digoxin can take up to 24 hours to stop the fetal heartbeat, which in turn could delay the procedure and require a patient to make multiple trips to her physician.[40] However, the State's expert, Dr. Joseph Biggio, testified in the preliminary hearing before the trial court

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sensory nerves to the brain, as well as the brain structures necessary to process those signals, do not develop until at least 24 weeks of gestation." *Id*. Moreover, the perception of pain is an "emotional and psychological experience that requires conscious recognition of a noxious stimulus." *Id.* (citing Royal College of Obstetricians and Gynaecologists, *Fetal Awareness: Review of Research and Recommendations for Practice*, https://www.rcog.org.uk/globalassets/documents/guidelines/rcogfetalawarenesswpr0610.pdf (Mar. 2010)). Evidence shows that a fetus does not develop the "neural circuitry necessary to distinguish touch from painful touch" until late in the third trimester. *Id*. Because the necessary connections and structures are undeveloped, fetal pain is not possible at the gestational ages at issue here, and is entirely irrelevant to an analysis of the Ban.

[37] Appellants' Appendix Doc. 139 at 89-91, 93-95.

[38] *See* Appellants' Appendix Doc. 54-5 ¶¶ 21, 24, 26, 28, 29.

[39] Appellants' Appendix Doc. 139 at 92.

[40] *Id.*

that this method achieves fetal demise only "between 90 and 95 percent" of the time—*i.e.*, it doesn't work between 5-10% of the time.[41] Where the initial injection of digoxin is unsuccessful, a second injection could be attempted, but there have been no studies conducted that establish the appropriate dosage or potential risks of this second injection.[42] The Ban provides no guidance on how a doctor should deal with this scenario, and, in any event, a woman should not have to undergo such inherently unreliable and unpredictable measures to exercise her constitutional right to an abortion.

A number of obstacles can prevent physicians administering digoxin to an individual patient. For example, Dr. Biggio agreed that "obesity could present an obstacle" to a digoxin injection,[43] and that "it will not be possible, for reasons of fetal positioning, uterine anatomy, to do an intrafetal digoxin injection on every patient."[44]

Potassium chloride injections are similarly untenable and unreliable. Potassium chloride can cause the fetal heart to stop almost immediately if

[41] Motion Hearing Transcript Vol. II, *West Alabama Women's Ctr. v. Miller*, No. 2:15-cv-497-MHT (M.D. Ala. Oct. 5, 2016) ("Biggio") at 113:20-24.

[42] Appellants' Appendix Doc. 139 at 93-94.

[43] Biggio at 143:9-11.

[44] *Id.* at 143:5-8.

administered directly into the fetal heart.[45] But the fetal heart is smaller than a dime during the second trimester, and this direct insertion can be very difficult to accomplish by even trained physicians.[46] The consequences of missing the heart and inadvertently injecting potassium chloride into the woman's bloodstream or elsewhere can be severe, including cardiac arrest.[47] In addition, potassium chloride injections carry risks even when properly performed, including intramniotic infection and sepsis.[48] The added degree of risk for these women—who would be detrimentally affected by the Ban—remains unknown.[49] Further, as with digoxin injections, potassium chloride injections are not an alternative for a number of women. As Dr. Biggio testified, fetal positioning, obesity, and fibroids can present an obstacle to the successful injection of potassium chloride.[50]

The potassium chloride injection method is further complicated by the difficulty of the procedure. As the State has conceded, the procedure is "generally

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[45] Appellants' Appendix Doc. 139 at 85.

[46] *Id.* at 86. As the District Court recognized, the physicians who administer these injections "are maternal-fetal-medicine fellows, who complete three years of highly supervised training to specialize in high-risk pregnancies." *Id.* at 87.

[47] *See* Appellants' Appendix Doc. 54-5 ¶ 30.

[48] *See* Motion Hearing Transcript Vol. I, *West Alabama Women's Ctr. v. Miller*, No. 2:15-cv-497-MHT (M.D. Ala. Oct. 4, 2016) at 29; Appellants' Appendix Doc. 81-6 at 463, 468 (describing identification of sepsis in a patient following a feticidal injection).

[49] Appellants' Appendix Doc. 139 at 89.

[50] *Id*. at 89-91.

only performed by specialists."[51] Dr. Biggio underscored this fact, agreeing that "additional training is required before an OB-GYN could perform intracardiac KCl injections,"[52] and that it is not "standard for OB-GYNs to learn how to do intracardiac KCl" at the University of Alabama.[53] Indeed, Dr. Biggio testified that he was not aware of a single clinic or medical school in Alabama where outside physicians could get that training.[54] Even assuming a woman could find a clinic that performed this procedure, the associated risks and high failure rates make it an impractical and unreliable replacement to the stand-alone D&E method.

Unequivocally, the interventions mandated by the Alabama legislature are misguided and against forty years of well-documented medical research. The legislature presents procedures that create risks to the patient as solutions to complying with the Ban. By presenting these fetal demise methods, the State purports to show that second-trimester abortions would remain available in Alabama under the Ban. However, the overwhelming medical evidence shows that the Ban imposes significant health risks for women, and that the State's proposed methods are not, in fact, a feasible way of complying with the Ban.

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[51] State Br. at 32.

[52] Biggio at 138:19-22.

[53] *Id.* at 140:1-3.

[54] *Id*. at 141:23-25.

C. The Ban Gives No Guidance for an Unsuccessful Fetal Demise.

SB 363 fails to address a scenario in which an attempted fetal demise is unsuccessful. None of the demise procedures cited by the State provide a means to ensure fetal demise in all cases. Because the parameters of the "health exception" discussed below are unclear, physicians will be unsure of whether they must again try to induce fetal demise. The Ban's silence leaves the physician, and the patient, in an even more precarious position, and could ultimately result in physicians refusing to attempt the procedure.

These concerns are not academic. The suggested fetal demise procedures are unpredictable and have relatively high failure rates, and it is unclear how a physician should or could proceed following a failed fetal demise attempt. ACOG is not aware of any evidence-based guidelines regarding the proper course of action for a doctor who has attempted to use digoxin and found that it did not work. Moreover, Dr. Biggio testified that he knew of no studies testing "the efficacy of a second digoxin injection."[55] Additionally, patients for whom umbilical cord transection is unsuccessful will be left with ruptured amniotic membranes, creating a high risk of infection, but the Ban would prohibit the physician from completing the abortion. In other words, the Ban could prevent physicians from providing patients the treatment they need to avoid life threatening infections.

[55] Biggio at 142:17-25.

Faced with this situation, many Alabama physicians would likely not be willing to attempt fetal demise and will simply refuse to provide D&E procedures. As the District Court recognized, many physicians would not rely upon methods that could cause harm to their patients.[56] The Ban's restrictions on D&E, combined with this lack of guidance, thus obstructs a physician's ability to provide their patient with proper treatment.

D. The Ban's "Health Exception" Does Not Adequately Protect Patients.

SB 363 contains a health exception that applies when a physician, in reasonable medical judgment, determines that "the [woman] has a condition that so complicates her medical condition that it necessitates the abortion of her pregnancy to avert serious risk *of substantial and irreversible impairment of a major bodily function*."[57] According to the State, this exception cures the one-size-fits-all nature of the Ban that subjects patients to unnecessary and significant health risks.[58] Not so.

As noted above, the fetal demise procedures offered by the State are unreliable and highly risky. The Ban's so-called "health exception" does not cure these

[56] *See* Appellants' Appendix Doc. 139 at 125 ("The medical directors of both clinics…testified that, if forced to induce fetal-demise before every D&E, they would stop performing second-trimester abortions in order to comply with their ethical obligation of beneficence--doing what is in the best interest of patients.").

[57] Ala. Code § 26-23G-2(6) (emphasis added).

[58] *See* State Br. at 15 & 43-44.

problems because it is clearly not intended to encompass the inherent risks of fetal demise procedures, such as added pain, infections, blood loss, and increased anesthesia exposure. If those risks fell within the Ban's limited health exception, fetal demise procedures would never be required. Instead, the statute requires that women first be subjected to the numerous and serious risks and burdens inherent in these procedures. It is only once the patient has suffered those risks and burdens that the exception may apply.

Regardless of whether any particular woman wants or needs to undergo one of the suggested fetal demise procedures, it is indisputable that the procedures are not medically appropriate for all women. The choice should be left to the patient and her physician.

II. The Ban Creates an Ethical Dilemma for Physicians.

In invading the patient-physician relationship and imposing significant health risks on the patient, the Ban leaves physicians in an ethically compromising position.

On the one hand, physicians are exposed to a civil suit or criminal penalties for violating the law by performing a D&E without first inducing fetal demise, including a fine of up to $10,000, imprisonment for up to two years, or both.[59] On the other hand, the medical profession is bound by ethical principles of beneficence, non-maleficence, and patient autonomy. The AMA Code of Medical Ethics requires

[59] Ala. Code §§ 26-23G-5, 7.

that doctors "provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment."[60] ACOG's Code of Ethics further requires obstetrician-gynecologists to "exercise all reasonable means to ensure that the most appropriate care is provided to the patient."[61] As noted above, physicians must also respect a patient's autonomous choices, including the patient's ability to freely choose specific treatment.[62] In the case of second-trimester abortions, an overwhelming majority of women choose D&E over other abortion procedures.[63]

SB 363's blanket requirement that a physician must perform the demise methods detailed above, irrespective of the physician's medical judgment and the patient's circumstances, is contrary to these long-established ethical requirements.

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[60] AMA Code of Medical Ethics § 1.1.3(b).

[61] ACOG, *Code of Professional Ethics of the American College of Obstetricians and Gynecologists* (2011), at 2 ("ACOG Code of Ethics"), https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20170403T2158227311.

[62] ACOG, *Committee on Ethics, Committee Opinion, Ethical Decision Making in Obstetrics and Gynecology* (Dec. 2007), http://www.acog.org/Clinical Guidance-And-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Decsion-making-in-Obstetrics-and-Gynecology.

[63] Practice Bulletin 135 (nationally D&E accounts for 95% of all second-trimester abortions); *see also* Grimes et. al., *Mifepristone and misoprostol,* 111 Obstetrics & Gynecology at 153 (2004) (finding that the "failed feasibility trial" suggests most women prefer D&E and were therefore unwilling to participate in a randomized trial which may result in a different abortion procedure).

Physicians must be able to make treatment decisions based on their patient's individual needs. They should not be forced to adjust patient care to accommodate the legislature's political preferences.

III. SB 363 Opens the Door to Improper Regulation of the Patient-Physician Relationship.

SB 363, if upheld, would create dangerous precedent for legislatures to interject their political views into the patient-physician relationship. Such political considerations should not restrict physicians' ability to exercise sound medical judgment and provide patients with a full range of quality care where, as here, the law offers no benefit to the patient and obstructs the availability of a safe and otherwise common procedure. The Ban opens the door to legislatures across the country picking and choosing which medical procedures they deem suitable, regardless of the physician's determination to the contrary. Such decisions should be left to medical professionals dedicated to ensuring the highest quality of care for their patients.

CONCLUSION

For all of the reasons stated above, SB 363 unduly interferes with the patient-physician relationship and imposes significant health risks on women in Alabama. This Court should uphold the District Court's injunction because it impermissibly interferes with the patient-physician relationship and threatens the health of women in the state by compelling physicians to use riskier and medically unnecessary second-trimester abortion methods.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the typeface requirements of Federal Rules of Appellate Procedure 32(a)(5) and the type styles requirements of Federal Rules of Appellate Procedure 32(a)(6) because it has been prepared in 14-point Times New Roman, a proportionally spaced typeface.

I further certify that this brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 32(a)(7)(B) and 29(a)(5) because it contains 5,772 words, excluding parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word.

Dated: March 15, 2018

/s/ Andrew B. Cashmore
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CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2018, I caused to be electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit through the Court's CM/ECF system, which will serve an electronic copy on all counsel of record. I further certify that I will cause an original and seven copies of this brief to be filed with the Court at the directive of the Clerk of the Court.

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