Case No. 17-51060

United States Court of Appeals

for the

Fifth Circuit

WHOLE WOMAN'S HEALTH, On Behalf of Itself, Its Staff, Physicians and Patients; PLANNED PARENTHOOD CENTER FOR CHOICE, On Behalf of Itself, Its Staff, Physicians, and Patients; PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL HEALTH SERVICES, On Behalf of Itself, Its Staff, Physicians, and Patients; PLANNED PARENTHOOD SOUTH TEXAS SURGICAL CENTER, On Behalf of Itself, Its Staff, Physicians, and Patients; ALAMO CITY SURGERY CENTER, P.L.L.C., On Behalf of Itself, Its Staff, Physicians, and Patients, doing business as Alamo Women's Reproductive Services; SOUTHWESTERN WOMEN'S SURGERY CENTER, On Behalf of Itself, Its Staff, Physicians, and Patients; NOVA HEALTH SYSTEMS, INCORPORATED, On Behalf of Itself, Its Staff, Physicians, and Patients, doing business as Reproductive Services; CURTIS BOYD, M.D., On His Own Behalf and On Behalf of His Patients; JANE DOE, M.D., M.A.S., On Her Own Behalf and On Behalf of Her Patients;

(For Continuation of Caption See Inside Cover)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS, AUSTIN

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND THE AMERICAN MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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Plaintiffs-Appellees,

– v. –

KEN PAXTON, Attorney General of Texas, In His Official Capacity; FAITH JOHNSON, District Attorney for Dallas County, In Her Official Capacity; SHAREN WILSON, Criminal District Attorney for Tarrant County, In Her Official Capacity; ABELINO REYNA, Criminal District Attorney for McLennan County, In His Official Capacity,

Defendants-Appellants.

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that—in addition to the persons and entities listed in the appellees' Certificate of Interested Persons—the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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Planned Parenthood South Texas Surgical Center
Alamo City Surgery Center, P.L.L.C.
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IDENTITY AND INTEREST OF *AMICI CURIAE*

The American College of Obstetricians and Gynecologists ("ACOG") and the American Medical Association (the "AMA") submit this brief *amici curiae* 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 3,092 obstetrician-gynecologists in Texas, ACOG is the leading organization of women's health care providers.

ACOG is dedicated to continuously improving all aspects of healthcare 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 healthcare. ACOG's work has often been cited by federal

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

courts, including the Supreme Court of the United States, as authoritative medical data.[2]

ACOG continues to affirm the legal right of a woman to obtain an abortion and believes women's decisions about whether to have an abortion should be made in consultation with their health care providers and without undue interference by outside parties.[3] While ACOG recognizes and respects that individuals may be personally opposed to abortion, outside parties, including legislators, must not assert their own personal beliefs in a way that compromises patients' access to care.[4] Therefore, it is ACOG's position that 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.

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[2] *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315 (2016) (citing *amici* brief submitted by ACOG, the AMA, and other medical associations in assessing disputed admitting privileges and surgical center requirements); *Hodgson v. Minn.*, 497 U.S. 417, 454 n. 38 (1990) (citing 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 AMA's *amici* 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 *amici* 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).

[3] ACOG, *College Statement of Policy*, *Abortion Policy*, (Jan. 1993, re-aff'd 2014) ("Like 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.").

[4] *See id.*

The AMA is the largest professional association of physicians, residents, and medical students in the United States. The AMA's primary objectives are to promote the science and art of medicine and the betterment of public health. It works relentlessly to advance important issues that protect patients and physicians, including issues related to abortion care. The AMA's members practice in all fields of medical specialization and in every state, including Texas.

SUMMARY OF ARGUMENT

Texas Health and Safety Code § 171.152 (the "D&E Ban") criminalizes the safest and most common method of second-trimester abortion after approximately 15 weeks of gestation—dilation and evacuation ("D&E")—in Texas. D&E accounts for a significant percentage of second-trimester abortions in Texas and is one of the most common methods of abortion provided in the state beginning early in the second trimester.

The State suggests that under the D&E Ban, physicians can still perform D&E so long as they first perform an additional procedure to attempt to cause fetal demise. But this is a false choice. There is no guarantee that any fetal demise procedure will be successful, meaning that no physician can attempt D&E without risking either being unable to complete the procedure—which puts the patient's health at risk—or being subject to criminal penalties under Texas law. If the D&E Ban goes into effect, women in Texas will have limited access to D&E.

The State's suggested workaround of first attempting fetal demise is medically untenable, because those procedures cannot be performed on all patients and have been inadequately studied during the time in which most second-trimester abortions occur. All of the fetal demise procedures introduce serious risks, some of which are life-threatening, to which patients would not otherwise be exposed. Indeed, *amici* are not aware of a single study that supports the State's contention that first inducing fetal demise makes D&E safer. For these and other reasons, the District Court permanently enjoined enforcement of the D&E Ban.

Contrary to the State's assertion, the D&E Ban's requirement of fetal demise before D&E is not justified by a State interest in protecting a fetus from pain. It is well-established and widely accepted within the medical community that a fetus is not capable of perceiving pain at the gestational ages for which abortion is legal in Texas. The State's arguments reflect cherry-picked excerpts from the medical literature and are at odds with the scientific community's consensus.

Finally, the D&E Ban interferes with the physician-patient relationship and places physicians in an ethically untenable position of either (i) denying access to D&E, or (ii) violating the law and risking criminal penalties. Because the D&E Ban restricts access to the safest and the most common method of second-trimester abortion in Texas after approximately 15 weeks of gestation, increases health risks for all Texas women for whom D&E is medically appropriate, does nothing to

protect or advance patient health, and unduly interferes with the physician-patient relationship, the Court should affirm the District Court's decision to permanently enjoin the D&E Ban.

ARGUMENT

I. The D&E Ban Criminalizes the Safest and Most Common Method of Second-Trimester Abortion in Texas After Approximately 15 Weeks of Gestation

A. D&E Is the Safest and Most Common Method of Second-Trimester Abortion in Texas After Approximately 15 Weeks of Gestation

Some women, in consultation with their physicians, decide to obtain an abortion in the second trimester for various reasons.[5] Such procedures are most commonly performed through the D&E method. In performing D&E, a physician dilates a patient's cervix and evacuates the uterus by removing tissue through the cervix and vagina. D&E was developed in the 1970s as a safer alternative to other methods of abortion used at that time.

[5] ACOG, Practice Bulletin No. 135, *Second Trimester Abortion*, 121 Obstetrics & Gynecology 1394, 1394 (2013, re-aff'd 2017) ("Circumstances that can lead to second-trimester abortion include delays in suspecting and testing for pregnancy, delay in obtaining insurance or other funding, and delay in obtaining referral, as well as difficulties in locating and traveling to a provider…[Further,] [t]he identification of major anatomic or genetic anomalies in the fetus through screening and diagnostic testing most commonly occurs in the second trimester," and such conditions include "preeclampsia and preterm premature rupture of membranes.").

More than four decades of data demonstrate that D&E is the safest method of abortion starting early in the second trimester.[6] It results in fewer medical complications than other abortion procedures, such as medical induction.[7] D&E involves the administration of few drugs and does not require hospitalization, which allows more physicians to provide it and makes it more affordable for

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[6] *Id.*

[7] Medical induction involves the administration of drugs to induce contractions and cause a woman to undergo labor. *Id.* at 1395-96. The procedure can involve significant pain, requiring medication and anesthesia, and can last from five hours to several days. *See id.*; ACOG, *Frequently Asked Questions Special Procedures*, (May 2015), https://www.acog.org/Patients/FAQs/Induced-Abortion; *see also* ROA.1601; MAUREEN PAUL ET AL., MANAGEMENT OF UNINTENDED AND ABNORMAL PREGNANCY, 159 (M. Paul et al. eds., 1st ed. 2009). Although medical induction is generally safe, it does involve risks and side effects that D&E does not. For example, medical induction carries a risk of uterine rupture, a rare but potentially life-threatening condition that is more likely to occur in women who have had multiple previous cesarean deliveries. ACOG, *supra* note 5, at 1397. Additionally, approximately five to ten percent of procedures result in retained placenta, a condition which can cause hemorrhaging and requires a surgical intervention. *See id.* at 1398; A.M. Autry et al., *A Comparison of Medical Induction and Dilation and Evacuation for Second-Trimester Abortion*, 187 Am. J. Obstetrics & Gynecology 393, 396 (2002). Because of the complications associated with labor, medical induction occurs in a hospital or hospital-like facility, rather than an outpatient clinic. ACOG, *Frequently Asked Questions Special Procedures*, (May 2015), https://www.acog.org/Patients/FAQs/Induced-Abortion. As a result of these factors, medical induction is far less commonly used to perform second-trimester abortions in Texas and nationwide. Texas Department of State Health Services, *Table 36, Induced Terminations of Pregnancy by Procedure and Post-Fertilization Age, 2015*, https://www.dshs.texas.gov/chs/vstat/vs15/t36.aspx (last updated Mar. 22, 2017) (reporting that medical induction was used to effectuate second-trimester abortion in less than 1% of cases); *see also* ROA.2035 (testimony of Dr. Bhavik Kumar) (noting that patients ultimately opted for D&E instead of medical induction because of the inaccessibility of medical induction services in Texas).

women.[8] Major complications arise in less than one percent of D&E procedures.[9] The procedure can also be completed in approximately ten minutes.[10] For these reasons, D&E constitutes the overwhelming majority of abortions in the United States starting early in the second trimester in the second trimester.[11]

B. It Is Medically Inappropriate to Require Physicians to Attempt Fetal Demise

The State suggests that D&E could still be available under the D&E Ban so long as physicians first cause fetal demise. The State argues that physicians can induce fetal demise by: digoxin injection; potassium chloride injection; or "umbilical cord transection." As discussed below, all of these procedures pose serious health risks to the patient which do not accompany a D&E procedure,[12] and none offer any counterbalancing medical benefit. *Amici* are not aware of any

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[8] *See* ACOG, *supra* note 5, at 1398.
[9] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125(1) Obstetrics & Gynecology 175, 181 (2015).
[10] ROA.1601.
[11] National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States*, at 2-18, https://doi.org/10.17226/24950 (2018) ("D&E is usually the medically preferred method of abortions at 14 weeks' gestation or later. The alternative–induction–is more painful, slower, and more expensive.").
[12] While the State alleges that there have been no complications arising from induced fetal demise in the past five years, App. Br. at 33, complications are not reported on such a granular level. For example, government statistics report complication type, but not the precise cause of complications. *See* Texas Department of State Health Services, *Table 33, Induced Terminations of Pregnancy by Complications, 2015*, https://www.dshs.texas.gov/chs/vstat/vs15/t33.aspx (last updated Feb. 15, 2018).

medical literature that concludes attempting fetal demise enhances the safety of D&E.[13] To the contrary, each procedure is contraindicated for certain groups of patients, and some can result in labor and extramural delivery.[14] Far from advancing women's health, the D&E Ban is a medically inappropriate, politically-generated proscription against the safest method of abortion.

1. *Injecting Digoxin*

To attempt to cause fetal demise by injecting digoxin, a physician injects the drug directly into the fetus or, if that is not possible, into the amniotic fluid. Digoxin injections are difficult to administer, because a physician must use a spinal needle under ultrasound guidance to inject the drug through the patient's abdomen, vaginal wall, or vagina and cervix.

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[13] ACOG, *supra* note 5, at 1396; *see also* Society of Family Planning, *Induction of Fetal Demise Before Abortion*, 81 Contraception 462, 463 (2010) ("Although numerous methods have been used over the years to achieve fetal demise, data remain scarce documenting the effect of these techniques upon the safety of the abortion itself."); David A. Grimes et al., *Feticidal Digoxin Injection Before Dilation and Evacuation Abortion Evidence and Ethics*, 85 Contraception 140, 140 (2012) (noting that while some physicians claim fetal demise makes D&E easier, there is no evidence to support this hypothesis); Danielle Roncari et al., *Inflammation or Injection at the Time of Second Trimester Induced Abortion*, 87 Contraception 67, 67 (2013) (noting that the usefulness of induced fetal demise remains unknown).

[14] Danielle Roncari et al., 87 Contraception at 68; *see also* Gillian Dean et al., *Safety of Digoxin for Fetal Demise Before Second-Trimester Abortion by Dilation and Evacuation*, 85 Contraception 144, 148 (2012) (finding that digoxin before D&E is associated with increased rates of spontaneous abortion and recommending that digoxin injections not be administered prior to D&E).

First and foremost, injecting digoxin cannot justify the D&E Ban, because it is not medically appropriate for all women. The procedure is contraindicated for women who are obese,[15] or who have anatomical variations such as a long cervix or fibroids. Digoxin injections also pose risks for women who do not fall into any of these patient groups, including infection that can create risks to their health.[16] Further, accidental absorption of the drug into a woman's circulation can result in toxicity or can cause consumptive coagulopathy, a condition affecting the blood's ability to clot.[17]

Even when digoxin is not contraindicated, it cannot justify the D&E Ban, because it does not cause fetal demise in all cases.[18] Various studies, as well as

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[15] Aileen M. Gariepy et al., *Transvaginal Administration of Intraamnitoic Digoxin Prior to Dilation and Evacuation*, 87 Contraception 76, 76 (2013) (finding that when digoxin is injected under a transabdominal approach, it is difficult for the physician to accomplish on obese patients).

[16] ACOG, s*upra* note 5, at 1396 (noting that a retrospective cohort study reported increased odds of infection after digoxin use); *see also* Gillian Dean et al., 85 Contraception at 145 (finding infection to be a primary outcome of their retrospective cohort study on digoxin use to induce fetal demise prior to D&E); MAUREEN PAUL ET AL., s*upra* note 7, at 168 ("Any procedure associated with transabdominal needle placement into the uterine cavity can result in maternal infection.").

[17] *See* Society of Family Planning, *supra* note 13, at 463, 469.

[18] *See, e.g.*, *id.* at 467 (reporting that in a retrospective cohort study, there was an eight percent failure rate among women who received intra-amniotic digoxin and a four percent failure rate among women who received various doses of intrafetal digoxin); David A. Grimes et al., *supra* note 13, at 140 ("[D]igoxin injection may fail to achieve its primary objective: from zero percent to seventy percent of first injections are unsuccessful in causing fetal demise, depending on dose and route of administration."); Aileen M. Gariepy et al., *Transvaginal Administration of*

experts in this case, have acknowledged that digoxin injections have a five to ten percent failure rate.[19] The State's *amici* effectively concede this risk and argue that physicians can cure it by administering a second dose of digoxin should the first dose fail.[20] However, *amici* are unaware of any evidence-based guidelines regarding administration of repeat injections of digoxin. Nor are there any reported studies about the risks to women of using multiple digoxin injections should a first dose fail.[21]

Even when successful, digoxin works slowly and can take up to 24 hours to cause fetal demise. Because overnight dilation is not an essential part of D&E before approximately 18 weeks of gestation, it is typically a one-day procedure. A woman required to receive a digoxin injection would thus have to go to an

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Intraamniotic Digoxin Prior to Dilation and Evacuation, 87 Contraception 76 (2013) (finding in a prospective study, digoxin administration was unsuccessful in eight percent of participants).

[19] *See supra* note 18; ROA.1935-36 (testimony of Dr. Mark D. Nichols); ROA.2099 (testimony of Dr. Robin Wallace); ROA.2214-15 (testimony of Dr. Amna Dermish); ROA.2779 (testimony of Dr. Eduardo Aquino).

[20] Brief for the Attorneys General of the States of Louisiana, et al. as *Amici Curiae* Supporting Appellants, *Whole Woman's Health, et al., v. Paxton, et al.*, (No. 17-51060) (Mar. 5, 2018), at *15.

[21] Physicians that refuse to administer multiple injections of digoxin in the absence of it being adequately studied will be faced with no good choices, as they will either need to perform D&E without first inducing fetal demise in violation of the D&E Ban, refuse to perform the abortion altogether, or recommend one of the other two fetal demise procedures that are not widely available in Texas and would cause further delay and expense to the woman. *See* ROA.1938 (testimony of Dr. Mark D. Nichols).

additional appointment at a clinic in advance of her abortion, unless she would have otherwise already required advance dilation.[22] As a result, the D&E Ban would create an additional barrier to abortion for Texas women, who already must make multiple trips to a clinic to obtain an abortion, and whose ability to access abortion has already been seriously curtailed by clinic closures and various state restrictions on abortions.

Further, digoxin injections would be more difficult to administer in the early stages of the second trimester, when most D&Es occur, due to the small size of the fetus. *Amici* are not aware of any reported studies that show the effects of the drug prior to 18 weeks, making it impossible for physicians to determine whether the procedure is appropriate or safe for patients in that stage of pregnancy.[23] It is

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[22] The D&E Ban further increases the burden faced by a woman who already must make multiple trips to a clinic in order to receive an abortion in Texas. On the first visit, a woman must receive an ultrasound and state-mandated counseling. TEX. HEALTH & SAFETY CODE ANN. §§ 171.011-.012 (Lexis 2017). A woman then must wait 24 hours before making a second visit to receive abortion care. *Id.* However, because causing fetal demise by digoxin injection can take up to 24 hours, a woman would be required to then make a third trip to complete the D&E, which would not otherwise be necessary. As one expert testified, it is usually difficult for a woman to make multiple trips as is, because they may need to arrange for child care, time off work, and the necessary financing, which often requires several weeks of saving up. ROA.2021 (testimony of Dr. Bhavik Kumar).

[23] The State quibbles that the "[t]he district court also never explained why a procedure . . . at 18 weeks suddenly becomes dangerous and experimental at 17 weeks," App. Br. at 36. This criticism fails on two fronts. First, it misrepresents the number of weeks, and thus the range of gestational development, at issue. D&E procedures are common beginning at 15 weeks. Second, it is widely recognized that a fetus changes rapidly from one week to the next, and that determining

highly inappropriate to require physicians to perform a procedure that is medically unnecessary and for which the risks, complication rates, and efficacy are unknown.[24]

2. *Injecting Potassium Chloride*

To attempt to cause fetal demise by injecting potassium chloride, a physician must inject potassium chloride directly into a fetal heart using a spinal needle under the guidance of an advanced ultrasound machine. Injecting potassium chloride is not a meaningfully available method of fetal demise in Texas: it carries extreme health risks, must be performed in a hospital setting by physicians who have specialized training, and is very difficult to administer.

Potassium chloride injections are much more difficult and risky to administer than digoxin. During the second trimester, the fetal heart is smaller than a dime. Successfully injecting potassium chloride is very challenging to accomplish, even by trained physicians who have undergone the necessary

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gestational age is vital for the timing of appropriate care. ACOG, Committee Opinion No. 700, *Methods for Estimating the Due Date*, at 2 (May 2017); KEITH L. MOORE, ET AL., THE DEVELOPING HUMAN CLINICALLY ORIENTED EMBRYOLOGY 92 (ElSevier, 10th ed. 2016). The State's expert recognized this as well. ROA.2819 (testimony of Dr. Colleen Malloy). Likewise, risks inherent to abortion care vary based on gestational age. A digoxin injection administered before 18 weeks of gestation, whether by one week or three weeks, does not necessarily carry the same risk/benefit analysis as digoxin injections administered after 18 weeks.

[24] David A. Grimes et al., *supra* note 13, at 142 ("The risk/benefit equation argues against routine feticidal digoxin injection. . . . [F]eticidal injection of digoxin should be offered only in the context of a formal research study.").

additional training. Training in the safe administration of potassium chloride is not part of standard ob-gyn curricula and, as a result, few physicians are qualified to perform the procedure.

Potassium chloride injections also pose risks that can be severe. For example, injections that are administered incorrectly can have a devastating impact on a woman's health, including infection of varying degrees or cardiac arrest.[25] Because of the risks associated with injecting potassium chloride into a woman's body, physicians must rely on advanced ultrasound technology that is typically available only in hospitals. Because clinics are generally unable to afford such equipment, few physicians are trained in its administration, and because injecting potassium chloride carries high risks for patients, it is rarely used outside the maternal-fetal medicine context.

3. *"Umbilical Cord Transection"*

To attempt to cause fetal demise by umbilical cord transection, a physician attempts to sever the umbilical cord by first rupturing the amniotic membrane by inserting a suction tube or other instrument, such as forceps, into the uterus and, if possible, grasping the umbilical cord to sever it. Such a procedure is not a viable alternative to D&E. Attempting to sever an umbilical cord is technically

[25] Society of Family Planning, *supra* note 13, at 468-69 (noting that potassium chloride injections have caused maternal cardiac arrest and infection).

challenging, rarely used, and unpredictable. The initial act of rupturing the amniotic membrane causes amniotic fluid to drain, which immediately causes the uterus to compress. This makes it difficult to identify the cord, which at 17 weeks of gestation is only about 8.5 millimeters in diameter, or less than half the diameter of a dime,[26] and increases the likelihood that the physician's instruments will injure the woman undergoing the procedure. Additionally, the procedure's success depends in large part on the placement of the umbilical cord inside the uterus. If the umbilical cord is blocked by the fetus, it may be difficult and risky for a physician to attempt to reach it, and the physician may determine that it is not possible to proceed.

Attempting to transect the umbilical cord involves inherent risks that D&E does not. If a physician begins the procedure but ultimately determines that transection is not possible, the patient is left with a ruptured amniotic membrane, creating a high risk of infection. The procedure can also create blood loss, placental separation, contractions, infection, and increase the risk of uterine perforation.[27]

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[26] C. Barbieri et. al, *Sonographic Measurement of the Umbilical Cord Area and the Diameters of its Vessels During Pregnancy*, 32(3) J. Obstet. & Gynaecol. 230, 233 (2012).

[27] Kristina Tocce et al., *Umbilical Cord Transection to Induce Fetal Demise Prior to Second-Trimester D&E Abortion*, 88 Contraception 712, 714 (2013) (noting complications resulting from UCT included blood loss, hemorrhaging, and cervical lacerations, as well at the use of iv antibiotics in some cases).

Similar to injection-based methods of attempting to cause fetal demise, attempting to sever an umbilical cord is more difficult to perform in the earlier stages of pregnancy and has hardly been researched.[28] *Amici* are not aware of any studies regarding attempted transection in the early weeks of the second trimester. *Amici* are aware of only one study on transection later in the second trimester, and reliance on that study is problematic, because it followed only two providers in a single setting and therefore is not generalizable.[29] It also lacked a control group and did not evaluate how much time or how many passes it took those physicians to successfully complete the procedure.[30]

In addition to the procedures above, the State alleges that physicians could utilize a suction technique to cause fetal demise in abortions that occur before seventeen weeks of gestation.[31] However, suction is not medically appropriate for all patients, and some physicians do not use it at all during the second trimester. The D&E Ban would prevent physicians from utilizing the safest and most appropriate procedure for their individual patients.

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[28] Society of Family Planning, *supra* note 13, at 463, 466 (noting that umbilical cord transection has not been investigated rigorously nor described recently in the medical literature as a technique before abortion).
[29] Kristina Tocce et al., 88 Contraception at 712.
[30] *Id.*
[31] App. Br. at 34.

II. Scientific Evidence Establishes that a Fetus Cannot Experience Pain Prior to 24 Weeks of Gestation

A. The Human Fetus Does Not Have the Capacity to Experience Pain During the Period in which Abortions Are Legal in Texas

The State's argument that a fetus can feel pain during the time when abortion is permissible in Texas has been roundly rejected by the scientific community. The widely-accepted scientific consensus is that (1) the human fetus does not develop the physical ability to perceive pain before at least 24 weeks, as even the basic anatomical structures necessary for transmission of signals from peripheral neural receptors to the brain have not yet developed; and (2) the capacity for conscious perception of pain does not develop until at least the third trimester, months after abortion is no longer available under Texas law.[32] This conclusion has been re-affirmed multiple times, including by the Royal College of Obstetricians and Gynecologists in March 2010[33] and researchers from the University of Siena in Siena, Italy, in 2012.[34]

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[32] TEX. HEALTH & SAFETY CODE ANN. § 171.044 (Lexis 2017).

[33] Royal College of Obstetricians and Gynecologists, *Fetal Awareness: Review of Research and Recommendations for Practice* 11 (Mar. 2010) [hereinafter *RCOG*] ("The lack of cortical connections before 24 weeks … implies that pain is not possible until after 24 weeks" and "[e]ven after 24 weeks, there is continuing development and elaboration of intracortical networks").

[34] Bellieni & Buonocore, *Is Fetal Pain A Real Evidence?*, 25 J. Maternal-Fetal & Neonatal Med. 1203, 1205 (2012) ("Our data show that there is consistent evidence of the possibility for the fetus to experience pain in the third trimester, and this evidence is weaker before this date and null in the first half of pregnancy."). *See also* Susan J. Lee et al., *Fetal Pain: A Systematic*

A fetus does not develop the connections necessary to transmit signals from peripheral sensory nerves to the brain until at least 24 weeks of gestation.[35] Moreover, the fetal brain lacks the ability to transmit or process those signals, because the structures of the brain that permit those functions do not develop until at least 24 weeks of gestation.[36] As a result, a fetus does not have the physiological capacity to perceive pain until *at least* 24 weeks of gestation, at which point abortion is already prohibited under Texas law.[37]

The perception of pain requires more than just the mechanical transmission and reception of signals within the brain; it is "an emotional and psychological experience that requires conscious recognition of a noxious stimulus."[38] The capacity for such conscious recognition does not develop until the third trimester at

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Multidisciplinary Review of the Evidence, 294 JAMA 947, 52 (2005) (concluding after review of available peer-reviewed journals analyzing fetal pain that a human fetus probably does not have the capacity to experience pain until 29 weeks of gestation at the earliest).

[35] ACOG, Wisconsin Section, *20-Week Abortion Ban Legislation*, 1 https://images.magnetmail.net/images/clients/ACOG/attach/WI_IssuePaper20WeekAbortionBan_updated.pdf.

[36] RCOG, *supra* note 33, at 11 ("Connections from the periphery to the cortex are not intact before 24 weeks of gestation."); Stuart W.G. Derbyshire, *Can Fetuses Feel Pain?*, 332 BMJ 909, 912 (2006) (stating that the "neuroanatomical system for pain can be considered complete by 26 weeks' gestation").

[37] RCOG, *supra* note 33, at 11 ("The lack of cortical connections before 24 weeks … implies that pain is not possible until after 24 weeks.").

[38] Lee et al., 294 JAMA at 952; *see also* Derbyshire, 332 BMJ at 912 ("A developed neuroanatomical system is necessary but not sufficient for pain experience"); RCOG, *supra* note 33, at 6, 10 (discussing definition of pain).

the earliest, months after the point in which abortions are no longer permitted under Texas law.[39] Indeed, there is good evidence that the neural circuitry necessary to distinguish touch from "nociception" (i.e., painful touch) does not develop until 35-37 weeks of gestation, which is late in the third trimester.[40]

B. The State Failed to Cite Any Credible Scientific Evidence of Fetal Pain Early in the Second Trimester

The State argues that the D&E Ban is justified in part by its interest in prohibiting a procedure that, according to the State, "has the potential to cause excruciating pain to a developing fetus."[41] This stated interest is entirely unfounded and is based on bad science. There is no credible scientific evidence that fetuses can feel pain before 24 weeks of gestation.

The State bases its argument on the testimony of its expert, Dr. Malloy, whose practice does not involve the study of fetal pain. Dr. Malloy is Board Certified in neonatal-perinatal medicine and pediatrics, not gynecology or

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[39] Lee et al., 294 JAMA at 947, 952; Bellieni & Buonocore, 25 J. Maternal-Fetal & Neonatal Med. at 1205; *see also* RCOG, *supra* note 33, at 11 ("[T]he fetus is sedated by the physical environment of the womb and usually does not awaken before birth."); Derbyshire, 332 BMJ at 912 (concluding that "it is not possible for a fetus to experience pain").

[40] Lorenzo Fabrizi, *A Shift in Sensory Processing that Enables the Developing Human Brain to Discriminate Touch from Pain*, 21 Current Biology 1552, 1552 (2011) (concluding that "specific neural circuits necessary for discrimination between touch and nociception emerge from 35-37 weeks gestation in the human brain"); *see also* Lee et al., 294 JAMA at 950.

[41] App. Br. at 24.

obstetrics.[42] She has no experience studying fetal development, and she has never treated fetuses previability, including performing surgery or other procedures.[43] She has never published a peer-reviewed article concerning fetal pain.[44]

Dr. Malloy bases her opinions on fetal pain largely on her care of prematurely-delivered infants.[45] But Dr. Malloy conceded that she is not aware of any studies or articles that conclude that a pre-22 week fetus would feel pain in the same way that a premature infant would.[46] To the contrary, she conceded that there are numerous articles and studies (including materials that she relied on in completing her expert report) that contradict this assumption.[47]

Because Dr. Malloy was unable to rely on her own experience concerning fetal pain, she relied on cherry-picked articles and researchers, including Dr. K.S. Anand, who Dr. Malloy characterized as the "guru" of the fetal pain rhetoric that has been adopted by the State.[48] Like Dr. Malloy, Dr. Anand has not conducted any primary research on pain perception: he is "a pediatrician who has conducted

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[42] *See* Expert Report of Colleen Ann Malloy, M.D. at 8 (Sept. 20, 2017).
[43] *See* ROA.2818, 2840.
[44] ROA.2859.
[45] ROA.2829.
[46] ROA.2846.
[47] ROA.2850; *see* Lee et al., 294 JAMA at 947; Stuart W.G. Derbyshire, *Feotal Pain?*, 24(5) Best Practice & Research Clin. Ob. & Gyn. 647 (2010).
[48] ROA.2823.

research on pain in general, focusing primarily on infants."[49] As a result of his lack of credibility, Dr. Anand's purported expertise regarding fetal pain perception has been soundly rejected by federal courts.[50]

In short, the State was unable to provide credible evidence to support its assertion that a fetus is capable of feeling pain early in the second trimester.

III. The D&E Ban Places Physicians in an Ethically Compromising Position

ACOG and the AMA are committed to the right of every woman to access the "best available, scientifically-based health care."[51] For women who seek second-trimester abortion, the best available scientifically-based health care includes D&E. The D&E Ban makes it illegal for physicians to act in accordance with their ethical obligations to their patients.

A. The Ethical Dilemma

To comply with the D&E Ban, physicians must either deny access to the safest and most common form of second-trimester abortion in Texas after approximately 15 weeks of gestation, or attempt one of three understudied,

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[49] *Planned Parenthood Fed'n v. Ashcroft*, 320 F. Supp. 2d 957, 999 (N.D. Cal. 2004), *rev'd on other grounds by Gonzales v. Carhart*, 550 U.S. 124 (2007).
[50] *Id*. at 999-1000 (declining to give Dr. Anand's testimony any weight greater than that of others who have reviewed the scientific literature and reached different conclusions).
[51] ACOG, *Statement of Policy*, *Global Women's Health and Rights* (July 2012, re-aff'd), http://www.acog.org/-/media/Statements-of-policy/public/2012GlobalWmHlthRights.pdf.

unnecessary, and risk-increasing procedures to induce fetal demise. In some instances, physicians will determine that inducing fetal demise prior to D&E is medically inappropriate for a particular patient. In such cases, the physician would be forced to either deny the patient the safest procedure available or risk incurring criminal penalties for violating the law. In making this determination, the D&E Ban creates a conflict between the physician's professional and ethical obligations.

Physicians are ethically required to exercise all reasonable means to ensure their patients receive the most appropriate and effective care.[52] These ethical obligations are expressed through the principles of beneficence, non-maleficence, and patient autonomy.[53] Beneficence requires physicians to act in a way that is likely to benefit patients.[54] Non-maleficence directs physicians to refrain from acting in ways that might harm patients unless the harm is justified by concomitant benefits.[55] If a physician determines that it is in a patient's best interest to undergo D&E without first attempting fetal demise but is nonetheless forced to attempt the

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[52] ACOG, *Code of Professional Ethics of the American College of Obstetricians and Gynecologists*, at 1-2 (2011), https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20180104T2059488380; *see also* American Medical Association, *Principles of Medical Ethics, Chapter 1: Opinions on Patient-Physician Relationships*, § 1.1.3(b) (2016).

[53] ACOG, Committee Opinion No. 390, *Ethical Decision Making in Obstetrics & Gynecology*, at 1 (Dec. 2007, re-aff'd 2016); American Medical Association, *Principles of Medical Ethics*, (June 2001).

[54] ACOG, Committee Opinion No. 390, at 3.

[55] *Id.*

procedure, the physician cannot fulfill their duties of beneficence and non-maleficence.

Autonomy recognizes that patients have ultimate control over their bodies and a right to a meaningful choice when making medical decisions. The principle also requires physicians to honor and respect patient decisions about the course of their care.[56] This principle illustrates the injustice of the D&E Ban, where the law would prevent a physician from offering a patient D&E, even though it may be the safest method available.

ACOG and the AMA recognize that attempting fetal demise may be appropriate in some cases for some patients. While some physicians may view fetal demise as beneficial to the performance of D&E in some circumstances for some patients, this approach has not been widely adopted throughout the medical community. The decision to attempt fetal demise is one that must be left to a physician's medical judgment based on each patient's circumstances. All three procedures that can be used to attempt fetal demise do not always work, are not appropriate for all patients, and pose health risks. It is, therefore, imperative that physicians be permitted to consider a patient's health to determine whether attempting fetal demise in a particular instance is safe and appropriate, as what is medically suitable for one patient may not be the best course of action for another.

[56] *Id.*

B. The D&E Ban Will Limit Women's Access to D&E In Texas

The D&E Ban will directly cause many physicians in Texas to stop offering D&E services. Three abortion providers in this case alone testified that they will discontinue performing second-trimester D&E if they are required to always ensure fetal demise beforehand. Because it is unknown how many more physicians will cease to offer D&E and since medical induction is not commonly performed in Texas, access to second-trimester abortion care will be significantly hindered.

An additional concern is the risk that women will resort to measures outside of a medical setting to obtain an abortion. Historical data show that where access is limited, women often resort to unsafe means to end an unwanted pregnancy, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, and reliance on unqualified abortion providers.[57] Today, approximately 21 million women worldwide obtain unsafe abortions each year, resulting in approximately 50,000 maternal deaths annually.[58]

[57] ACOG, Committee Opinion No. 613, *Increasing Access to Abortion*, at 2 (Nov. 2014, re-aff'd 2017).
[58] *Id.*

In Texas, it has been reported that a higher percentage of women attempted self-induced abortion than women nationally.[59] These women achieved self-induction primarily through home remedies or medication obtained from Mexico without a prescription.[60] The increased number of obstacles women face to obtain abortion care in Texas, coupled with the drastic reduction of Texas open abortion facilitates, means that more women may consider or attempt self-induction if the D&E Ban goes into effect.[61]

ACOG and the AMA oppose laws that interfere with patients' ability to be treated according to the best currently available medical evidence and physicians' medical judgment.[62] As the Supreme Court has consistently articulated, laws

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[59] Texas Policy Evaluation Project, *Texas Women's Experiences Attempting Self-Induced Abortion in the Face of Dwindling Options*, at 1 (Nov. 2015) https://ibisreproductivehealth.org/sites/default/files/files/publications/TxPEP_Texas%20womens%20experiences%20self%20induction_ResearchBrief_17Nov2015.pdf.

[60] *Id.* at 2-3.

[61] *Id.* at 1.

[62] ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship*, (May 2013).

> 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 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.

regulating abortion care that unduly interfere with a physician's ability to act in the best interest of his or her patient should be struck down.[63]

C. The D&E Ban Improperly Intrudes Into the Patient-Physician Relationship

The D&E Ban creates a dangerous precedent of empowering legislators to interfere with individualized medical determinations and care in ways that increase, rather than reduce, medical risks. Political considerations, especially those which have no scientific basis, should not restrict physicians' ability to exercise sound medical judgment and provide patients with a full range of safe and quality care.

* * *

Id.

[63] *See Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).

CONCLUSION

For all of the reasons stated above, the D&E Ban should not be implemented. This Court should affirm the District Court's permanent injunction.

Dated: April 18, 2018

Respectfully submitted,

FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP

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CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2018, I electronically filed a true and correct copy of the foregoing *Amici Curiae* Brief with the Clerk of the Court by using the appellate CM/ECF system, which will send notification of such filing to all registered users of the CM/ECF system.

Dated: April 18, 2018

/s/ Janice M. Mac Avoy
Janice M. Mac Avoy

CERTIFICATE OF COMPLIANCE

I hereby certify that (i) required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; (ii) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1; and (iii) the document has been scanned with the most recent version of commercial virus-scanning software and was reported free of viruses.

I further certify that this brief complies with: (i) the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,473 words, excluding the parts of the brief exempted by Rule 32(f); and (ii) the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Times New Roman) using Microsoft Word (the same program used to calculate the word count).

Dated: April 18, 2018

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United States Court of Appeals

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April 19, 2018

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No. 17-51060 Whole Woman's Health, et al v. Ken Paxton, et al
USDC No. 1:17-CV-690

Dear Ms. Mac Avoy,

The following pertains to your brief electronically filed on April 18, 2018.

You must submit the 7 paper copies of your brief required by 5TH CIR. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1.

Sincerely,

LYLE W. CAYCE, Clerk

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