No. 19-5516

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

EMW WOMEN'S SURGICAL CENTER, P.S.C., on behalf of itself, its staff, and its patients; ASHLEE BERGIN, M.D., M.P.H., on behalf of herself and her patients; TANYA FRANKLIN, MD, M.S.P.H., on behalf of herself and her patients,

Plaintiffs-Appellees,

v.

ADAM MEIER, in his official capacity as Secretary of Kentucky's Cabinet for Health and Family Services,

Defendant-Appellant,

and

THOMAS B. WINE, et al.,

Defendants.

On Appeal from the United States District Court
for the Western District of Kentucky, No. 3:18-cv-00224-JHM-RSE
Before the Honorable Chief Judge Joseph H. McKinley, Jr.

BRIEF FOR THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, THE AMERICAN MEDICAL ASSOCIATION, THE NORTH AMERICAN SOCIETY FOR PEDIATRIC AND ADOLESCENT GYNECOLOGY, THE NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH, THE AMERICAN COLLEGE OF NURSE-MIDWIVES, AND THE AMERICAN COLLEGE OF OSTEOPATHIC OBSTETRICIANS AND GYNECOLOGISTS AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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September 16, 2019

DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Pursuant to Sixth Cir. R. 26.1, the American College of Obstetricians and Gynecologists, the American Medical Association, the North American Society for Pediatric and Adolescent Gynecology, the National Association of Nurse Practitioners in Women's Health, the American College of Nurse-Midwives, and the American College of Osteopathic Obstetricians and Gynecologists make the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No. The American College of Obstetricians and Gynecologists, the American Medical Association, the North American Society for Pediatric and Adolescent Gynecology, the National Association of Nurse Practitioners in Women's Health, the American College of Nurse-Midwives, and the American College of Osteopathic Obstetricians and Gynecologists are non-profit organizations, with no parent corporations or publicly traded stock.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

None.

Dated: September 16, 2019

/s/ Kimberly A. Parker
KIMBERLY A. PARKER

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The American College of Obstetricians and Gynecologists ("ACOG"), the American Medical Association ("AMA"), the North American Society for Pediatric and Adolescent Gynecology ("NASPAG"), the National Association of Nurse Practitioners in Women's Health ("NPWH"), the American College of Nurse-Midwives ("ACNM"), and the American College of Osteopathic Obstetricians and Gynecologists ("ACOOG") (together, "*Amici*") submit this brief *amici curiae* in support of the Plaintiffs-Appellees.[1]

ACOG is the nation's leading group of physicians providing health care for women. With more than 58,000 members—representing more than 90% of all obstetricians-gynecologists in the United States including ob-gyns in the Commonwealth of Kentucky (hereafter, "Commonwealth" or "Kentucky")—ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring

[1] The parties have consented to the filing of this brief. Pursuant to Federal Rule of Appellate Procedure 29(4)(E), undersigned counsel for *amici curiae* certify that: (1) no counsel for a party authored this brief, in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity—other than *amici curiae*, their members, and their counsel—contributed money intended to fund the preparation or submission of this brief.

access to the full spectrum of evidence-based quality reproductive health care, including abortion care, for all women. ACOG opposes medically unnecessary laws or restrictions that serve to delay or prevent care.

ACOG has previously appeared as *amicus curiae* in various courts throughout the country. ACOG's briefs and guidelines have been cited by numerous courts, including the Supreme Court and this Court, seeking authoritative medical data regarding childbirth and abortion.[2]

[2] *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315 (2016) (citing ACOG and AMA's *amici* brief for academic hospital admitting requirements, medical procedure mortality rate data, and treatment procedures after a miscarriage); *Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG's *amicus* brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's *amicus* brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-178, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as "experts" and repeatedly citing ACOG's *amicus* brief and congressional submissions regarding abortion procedure); *Stuart v. Camnitz*, 774 F.3d 238, 251-252, 255 (4th Cir. 2014) (citing ACOG's and AMA's *amici* brief for medical standards of informed consent in striking North Carolina's mandatory ultrasound display law); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients"); *Women's Med. Prof'l Corp. v. Voinovich*, 130 F.3d 187, 198 n.7 (6th Cir. 1997) (discussion of suction curettage terminology).

AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state, including Kentucky.

ACOG and AMA have submitted briefs *amici curiae* in the Fifth, Eighth, and Eleventh Circuits and in the Supreme Court of Kansas challenging virtually identical dilation and evacuation ("D&E") laws.[3]

NASPAG provides multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive health of youth. NASPAG pursues scientific and educational goals, including to serve and be recognized as the lead provider in pediatric and adolescent gynecological education, research, and clinical care. NASPAG conducts and encourages multidisciplinary and inter-professional programs of medical education and research in the field and advocates for the

[3] *See Hopkins v. Jegley*, No. 17-2879 (8th Cir. Mar. 13, 2018); *Whole Woman's Health v. Paxton*, No. 17-51060 (5th Cir. Apr. 18, 2018); *West Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018); *Hodes & Nauser, MDs, P.A. v. Schmidt*, 440 P.3d 461 (Kan. 2019).

reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based medical practice.

NPWH is a leading national membership organization of nurse practitioners. NPWH's mission is to ensure the provision of quality primary and specialty healthcare to women of all ages by women's health and women's health-focused nurse practitioners. NPWH's mission includes protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs.

ACNM works to advance the practice of midwifery to achieve optimal health for women through their lifespan, with expertise in women's health and gynecologic care. Its members include approximately 7,000 certified nurse-midwives and certified midwives who provide primary and maternity care services to help women of all ages and their newborns attain, regain, and maintain health. ACNM and its members respect each woman's right to dominion over her own health and care, and ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality care.

ACOOG is a non-profit, non-partisan organization committed to excellence in women's health representing over 2,500 providers. ACOOG educates and supports osteopathic physicians to improve the quality of life for women by

promoting programs that are innovative, visionary, inclusive, and socially relevant. ACOOG is likewise committed to the physical, emotional, and spiritual health of women.

SUMMARY OF ARGUMENT

The District Court correctly held that 2018 Kentucky House Bill 454 ("H.B. 454" or "the Act") is facially invalid. H.B. 454 outlaws, with a very limited exception, standard dilation and evacuation ("D&E") abortions. D&E is the predominant and generally safest abortion method beginning early in the second trimester. It is the only outpatient option and accounts for nearly all abortion procedures performed in Kentucky from approximately 15 weeks of pregnancy. Under H.B. 454 clinicians would be forced—under threat of criminal prosecution and potential loss of one's medical license—to first induce fetal demise by performing a medically unnecessary and unreliable procedure, which increases risks without any offsetting medical benefits, on patients seeking D&E abortion.

There is no medical justification for H.B. 454. The Act impermissibly intrudes into the patient-clinician relationship by limiting a clinician's ability to perform the medical treatment that she and her patient decide is best for the patient's particular circumstances and medical interests. Moreover, the Act places clinicians in ethically compromised positions, including the choice between

providing the most appropriate treatment for a particular patient, or disregarding the law in the face of oppressive penalties.

For the above reasons and those discussed below, ACOG, AMA, NASPAG, NPWH, ACNM, and ACOOG urge the court to affirm the District Court's injunction.

ARGUMENT

I. H.B. 454 CRIMINALIZES THE PRIMARY SECOND TRIMESTER ABORTION METHOD IN KENTUCKY WITHOUT SAFE, AVAILABLE, AND RELIABLE ALTERNATIVES

H.B. 454 § 1(2) makes it unlawful for any clinician in Kentucky to perform a D&E abortion without effectuating fetal demise except in the very limited circumstance where such procedure would be necessary "to avert [a patient's] death or for which a delay will create *serious risk of substantial and irreversible* impairment of a *major* bodily function." Ky. Rev. Stat. § 311.720 (emphasis added). The Commonwealth concedes that H.B. 454 effectively outlaws the standard D&E procedure. *See* Appellant's Br. 4; H.B. 454 § 1(2)(a)-(b). Violation of the Act constitutes a Class D felony, with potential jail time, significant fines, and/or loss or suspension of a clinician's medical license. Ky. Rev. Stat. §§ 311.595, 311.606, 532.060(2)(d).

The Act's serious consequences, both for clinicians and their patients, exist despite that D&E is the only abortion method available to nearly all women in Kentucky beginning at approximately 15 weeks last menstrual period ("LMP").[4]

In defending its D&E ban, the Commonwealth proposes three demise methods, which it claims would allow for compliance with the Act: digoxin injection, potassium chloride injection, and umbilical cord transection. Appellant's Br. 33-54. Though it asserts that these methods "are performed regularly, and all of them have been deemed safe and effective in the medical literature," *id.* at 17, they are minority procedures that are fallible, present additional risks to patient health without any offsetting medical benefits, and often are experimental.

A. The Act Proscribes the Safe and Predominant Method of Abortion Beginning Early in the Second Trimester

Some women, in consultation with their clinicians, seek abortion care in the second trimester.[5] Beginning around 15 weeks LMP, abortion is usually performed using the standard D&E method (without fetal demise), which accounts

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[4] *EMW Women's Surgical Ctr., P.S.C. v. Meier*, 373 F. Supp. 3d 807, 826 (W.D. Ky. 2019).

[5] ACOG, Practice Bulletin No. 135, *Second Trimester Abortion*, 121 Obstetrics & Gynecology 1394, 1394 (2013, reaffirmed 2017) ("Practice Bulletin No. 135") ("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…. The identification of major anatomic or genetic anomalies in the fetus through screening and diagnostic testing most commonly occurs in the second trimester ….").

for approximately 95% of second-trimester abortions nationwide and over 99% of second-trimester abortions in Kentucky.[6]

D&E was developed in the 1970s as a safer alternative to existing abortion methods and is generally considered the safest abortion procedure beginning in the early second trimester.[7] D&E results in fewer medical complications and involves the administration of fewer drugs than alternative procedures.[8] Moreover, D&E is an outpatient procedure that takes approximately ten minutes. By comparison, the less favored alternative to D&E—labor induction—requires a hospital-like facility where drugs are used to induce labor and delivery of a non-viable fetus.[9] Like a standard labor and delivery, the procedure can be expensive, painful, require anesthesia, and last from twelve hours to several days.[10] Although labor induction is generally safe, it typically involves greater costs and risks than D&E: (i) up to 21% of women must undergo an additional surgical procedure to have a retained

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[6] *Id.*; *EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 824 (citing Trial Tr., R.107, PageID ##4643-4645).
[7] *See* Practice Bulletin No. 135, *supra* note 5, at 1395.
[8] *See id*. at 1398.
[9] *Id.* at 1395-1396. Second-trimester abortion can also be completed by hysterectomy or hysterotomy, surgical procedures similar to a caesarean section. But these methods pose much higher risks of complication than D&E and medical abortion and are only used if the latter methods fail. *Id*. at 1396.
[10] *See id.* at 1395-1396.

placenta removed;[11] (ii) uterine rupture, a rare but potentially life-threatening condition, can occur;[12] and (iii) some inductions fail or result in an incomplete abortion, requiring an emergency D&E procedure if infection or heavy bleeding develops.[13] For these reasons, labor induction is rarely used.

B. The Commonwealth's Proposed Demise Methods are Invasive, Additionally Risky, Medically Unnecessary, Experimental, and Unreliable

The Commonwealth contends that providers can comply with H.B. 454 by requiring patients seeking a D&E abortion to first undergo a separate fetal demise procedure. *See* Appellant's Br. 4-5, 34-52; H.B. 454 §1(1)(a), (2)(b). However, there is no universally effective demise method and each of the three options proposed by the Commonwealth presents additional risks to patients without—as ACOG has recognized—evidence of corresponding benefits to justify their use.[14]

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[11] Autry et al., *A Comparison of Medical Induction and Dilation and Evacuation for Second Trimester Abortion*, 187 Am. J. Obstetrics & Gynecology 393, 396-397 (2002); Practice Bulletin No. 135, *supra* note 5, at 1398.

[12] *See* Practice Bulletin No. 135, *supra* note 5, at 1397.

[13] *See id.* at 1396; Autry, 187 Am. J. Obstetrics & Gynecology at 395.

[14] *See* Practice Bulletin No. 135, *supra* note 5, at 1396 ("No evidence currently supports the use of induced fetal demise to increase the safety of second-trimester medical or surgical abortion."); *see also* Society of Family Planning, *Induction of Fetal Demise Before Abortion*, 81 Contraception 462, 463 (2010) ("data remain scarce documenting the effect of [demise] techniques upon the safety of the abortion"); Grimes et al., *Feticidal Digoxin Injection Before Dilation and Evacuation Abortion Evidence and Ethics*, 85 Contraception 140, 140 (2012) (concluding no evidence supports the hypothesis that demise makes D&E easier); Roncari et al., *Inflammation or Infection at the Time of Second Trimester Induced*

1. Digoxin Injections

To attempt fetal demise by injecting digoxin, a clinician must insert a long hypodermic needle to administer the drug transabdominally (through the abdomen into the uterus) or transvaginally (through the vaginal wall or cervix) into the fetus or amniotic sac approximately 24 hours prior to the D&E procedure. Beyond being invasive and painful, digoxin injections are not a feasible demise option in many circumstances for several reasons.

First, digoxin adds risks beyond the minimal risks inherent to a D&E procedure without any benefits. It increases the risk of infection and/or extramural delivery (i.e., delivery outside a medical facility), which has a greater likelihood of the patient hemorrhaging and/or experiencing heightened emotional distress. Moreover, the rate of subsequent hospital admissions, which in one study was six times higher for women who had digoxin than for women who did not, is greater.[15] Digoxin also presents risks of digoxin toxicity (poisoning that can cause irregular

Abortion, 87 Contraception 67, 67 (2013) (noting the usefulness of induced fetal demise remains unknown).

[15] Dean et al., *Safety of Digoxin for Fetal Demise Before Second-Trimester Abortion by Dilation and Evacuation*, 85 Contraception 144 (2012); Diedrich & Drey, *Induction of Fetal Demise Before Abortion: SFP Guideline 20101*, 81 Contraception 462 (2010).

heartbeat), consumptive coagulopathy (a condition affecting the blood's ability to clot),[16] infection,[17] vomiting,[18] and nausea.[19]

Second, digoxin injections fail to cause demise in up to approximately 20% of cases.[20] Following a failed digoxin attempt, the patient's cervix will already be dilated, and at that point, delaying the D&E procedure to re-attempt fetal demise exposes the patient to further risks of infection and extramural delivery. But it is extremely unlikely that a clinician in this situation could certify that the patient's health is so gravely endangered that the Act's narrow exception is met.[21] To comply with the Act, the clinician would thus have to attempt demise again and wait another 24 hours for it to possibly take effect. *Amici* are not aware of any guidelines regarding the safety or efficacy of administering repeat digoxin

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[16] *See* Society of Family Planning, 81 Contraception at 463, 469.
[17] Practice Bulletin No. 135, *supra* note 5, at 1396 (noting that a retrospective cohort study reported increased infection after digoxin use); *see also* Dean, 85 Contraception at 145 (finding infection to be a primary outcome of retrospective cohort study on digoxin use to induce demise prior to D&E).
[18] Trial Tr., R.106, PageID ##4472-4473, 4490.
[19] Trial Tr., R.103, PageID #3989.
[20] *See, e.g.*, *EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 818 (citing Trial Tr., R.106, PageID #4391; Trial Tr., R.107, PageID ##4675-4676; Trial Tr., R.103, PageID #3911). Society of Family Planning, 81 Contraception at 467 (retrospective cohort study finding 8% failure rate for intra-amniotic digoxin and 4% failure rate among women for intrafetal digoxin); Grimes, 85 Contraception at 140 (finding up to 70% failure rate for digoxin injections depending on dose and administration); Gariepy et al., *Transvaginal Administration of Intraamniotic Digoxin Prior to Dilation and Evacuation*, 87 Contraception 76 (2013) (finding digoxin administration unsuccessful in 8% of prospective study participants).
[21] *See* Trial Tr., R.107, PageID #4684.

injections. Accordingly, such an additional attempt would be untested, prolong the procedure, compound costs, and potentially expose the patient to unknown risks.

Third, in addition to being experimental in cases of repeat doses, digoxin injections on patients below 18 weeks LMP would also be untested. There is no data establishing the safety or reliability of digoxin use on women with pregnancies before 18 weeks LMP—roughly half of Kentucky's D&E patients.[22] Thus, attempting a digoxin injection at such gestations would subject women to a procedure with risks that have not been quantified and an unknown likelihood of effectiveness.

Fourth, digoxin injections are not feasible for all patients. They can be contraindicated for women with certain cardiac conditions, such as arrhythmias, and may not be possible for women with common features such as a long cervix, uterine fibroids, obesity,[23] or certain placental or fetal positioning.[24] While a minority of clinicians outside Kentucky may attempt digoxin injections in certain circumstances at later gestations[25] to ensure compliance with intact dilation and extraction laws, if digoxin fails, results in complications, or is against a patient's

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[22] *EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 818 (citing Trial Tr., R.107, PageID #4678).
[23] Gariepy, 87 Contraception at 76.
[24] *See EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 818 (citing Trial Tr., R.106, PageID ##4387-4388; Trial Tr., R.107, PageID #4661; Trial Tr., R.102, PageID ##3793-3794; Trial Tr., R.103, PageID #3969).
[25] Davis, R.106, PageID ##4373-4374.

medical interests, clinicians can immediately complete a standard D&E abortion without fear of liability. Under H.B. 454, however, clinicians in these situations would be forced to choose among attempting a second, untested injection contrary to the patient's best interests; waiting for the patient's health to decline severely to the point where the clinician believes the narrow health exception applies; or complete the D&E without demise, protecting the patient's health but subjecting themselves to criminal liability and the loss/suspension of their medical license.

2. Potassium Chloride Injections

To attempt fetal demise by potassium chloride ("KCl"), a clinician must use a ten- to twenty-centimeter long needle to inject the drug through the woman's abdomen, uterus, amniotic sac, and into the fetal heart (intracardiac) or umbilical vein. KCl injections are technically challenging and require expensive, hospital-grade ultrasound equipment. KCl procedures are not taught in OB-GYN residencies or family planning fellowships, and are generally only covered in subspecialty fellowships, like maternal fetal medicine programs, that require years of additional training.[26] *Amici* are not aware of any facilities, in Kentucky or elsewhere in the U.S., that offer KCl training to practicing clinicians.[27]

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[26] *See EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 819-820 (citing Trial Tr., R.106, PageID ##4418-4419, 4555-4556; Trial Tr., R.107, Page ID ##4661-4662; Trial Tr., R.102, Page ID #3801; Trial Tr., R.103, PageID ##3977, 4129-4130, 4184-4185).

[27] *See id.* at 820 (citing Trial Tr., R.107, PageID ##4732-4733).

Moreover, KCl injections are difficult regardless of method or gestational age. They require injection into an extremely small space, while the fetus and patient may be moving.[28] Intracardiac KCl injections in the later second trimester are further complicated by the thickening of the fetal chest wall, requiring more finesse to introduce the needle into the moving fetal heart. While a clinician attempting an intracardiac KCl injection who misses could potentially attempt to cause demise by injection into the chest cavity (intrathoracic injection), *Amici* are not aware of any medical study on the efficacy of intrathoracic injection to cause demise. Such injections are less effective, increase procedure time, and typically require exposing the patient to a higher dose of potentially lethal KCl than injections into the fetal heart or umbilical cord.

Moreover, if a clinician accidentally introduces KCl into the patient's circulatory system, she can suffer cardiac arrest.[29] KCl use also exposes patients to risks of intraamniotic infection or chorioamnionitis, a bacterial infection affecting the membranes surrounding the fetus;[30] uterine atony that can cause hemorrhage; pain; and nausea.[31] Lastly, like the Commonwealth's other proposed demise

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[28] Trial Tr., R.103, PageID ##4186-4187.
[29] Coke et al., *Maternal Cardiac Arrest Associated with Attempted Fetal Injection of Potassium Chloride*, 13 Int'l J. Obstetric Anesthesia 287 (2004).
[30] Society of Family Planning, 81 Contraception at 468-469 (noting KCl injections have caused infection).
[31] Trial Tr., R.103, PageID ##4194, 4198.

methods, KCl injections can be infeasible due to fairly common features, such as uterine fibroids, obesity, cesarean-section scaring, and fetal and uterine positioning.[32]

3. Umbilical Cord Transections

Attempting fetal demise by transecting the umbilical cord ("UCT") requires that a clinician rupture the amniotic membrane and insert an instrument into the uterus to attempt to grasp and sever the umbilical cord.[33] UCT is technically challenging and unreliable.

UCT is far from a dependable demise method. Rupturing the amniotic membrane causes the amniotic fluid to drain, the uterus to immediately contract, and the fetal tissue, placenta, and umbilical cord to compress into a single mass.[34] Without the amniotic fluid, the procedure cannot be easily guided by ultrasound imaging. As a result, locating the umbilical cord requires blindly fishing around the woman's uterus to locate and transect a cord that is "roughly the width of a piece of yar[n]" and that cannot be reliably distinguished from other tissue.[35]

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[32] *See EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 820 (citing Trial Tr., R.106, PageID ##4423, 4551-4552; Trial Tr., R.103, PageID ##4187-4189).
[33] Trial Tr., R.106, PageID #4434.
[34] *Id.*
[35] *EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 821 (citing Trial Tr., R.106, PageID #4434); Trial Tr., R.106, PageID #4436.

Critically, it is probable that a clinician will grasp fetal tissue instead of or with the cord, thus violating the Act's language.[36]

Attempting UCT not only presents risks of liability, but also increases risks to patient health. Additional passes of instruments through the cervix and into the uterus to attempt to locate the cord prolong the procedure and carry risks of blood loss, infection, and uterine perforation.[37] If a clinician begins the procedure but ultimately determines that transection is not possible—such as when the cord is blocked by the fetus or is too small to be identified—the patient is left with a ruptured amniotic membrane, creating a high risk of infection, bleeding, and extramural delivery. While it would be medically imperative to proceed with the D&E procedure at such point, the clinician would be forced to either violate the Act or wait for the patient's health to further decline so as to invoke the emergency exception. Even if the UCT was successful, waiting for demise once the cord has been transected can as much as double the D&E procedure's length (not including time spent locating and transecting the cord), during which time the patient may

[36] *See* Trial Tr., R.107, PageID #4814.
[37] *See* Tocce et al., *Umbilical Cord Transection to Induce Fetal Demise Prior to Second-Trimester D&E Abortion*, 88 Contraception 712, 714-715 (2013) (complications resulting from UCT included blood loss, hemorrhaging, cervical lacerations, and the need for intravenous antibiotics).

experience increased blood loss and anesthesia exposure, all without any medical need.[38]

Not only is UCT particularly difficult to perform in earlier stages of the second trimester, but it is hardly researched.[39] *Amici* are familiar with only one study on transection, which analyzes procedures performed by just two providers in a single setting.[40] The study lacks a control group and "does not provide the type or quality of evidence that warrants reaching generalized conclusions about the feasibility or reliability of [UCT]."[41] Because it is impossible to perform a UCT without the potential for violating the Act, the procedure failing, and jeopardizing patient health, UCT is not a medically acceptable means of compliance.

II. MEDICAL CONSENSUS ESTABLISHES FETAL PAIN IS NOT POSSIBLE DURING THE RELEVANT GESTATIONAL PERIOD

In asserting an interest in avoiding "fetal pain," the Commonwealth attempts to manufacture medical uncertainty where none exists. *See* Appellant's Br. 4, 10-11. The clearly established medical consensus is that fetal pain perception is not

[38] Trial Tr., R.106, PageID ##4435-4437.
[39] Society of Family Planning, 81 Contraception at 463, 466 (noting UCT has not been "investigated rigorously" nor "described recently in the medical literature as a technique before abortion").
[40] Tocce, 88 Contraception at 713-714.
[41] *EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 821 (citing Trial Tr., R.102, PageID #3809); Tocce, 88 Contraception at 713.

possible before *at least* 24 weeks LMP, which is well after 21.6 weeks when EMW stops performing abortions.[42] Every major medical organization that has examined the issue of fetal pain—and several peer-reviewed studies—have reached the same conclusion.[43]

The medial consensus is that fetal pain perception is not possible before 24 weeks LMP, because the circuitry required to experience pain is simply not developed in earlier gestations. Pain perception requires an intact neural pathway from the periphery of the body (the skin), through the spinal cord, into the thalamus (the gray matter in the brain that relays sensory signals) and on to regions of the cerebral cortex.[44] These neural connections do not develop until after at least 24 weeks LMP, and the cerebral cortex does not fully mature until after

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[42] *See EMW Women's Surgical Ctr., P.S.C.*, 373 F. Supp. 3d at 823.

[43] *See* ACOG, *Facts Are Important - Fetal Pain* (July 2013), https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactAreImportFetalPain.pdf; Royal College of Obstetricians and Gynaecologists, *Fetal Awareness: Review of Research and Recommendations for Practice* (Mar. 2010) (concluding fetal pain is not possible before 24 weeks gestation, based on expert panel review of over 50 papers in medical and scientific literature); Kostovic & Jovanov-Milosevic, *The development of cerebral connections during the first 20-45 weeks' gestation*, 11 Seminars in Fetal & Neonatal Medicine 415 (2006); Apkarian et al., *Human brain mechanisms of pain perception and regulation in health and disease*, 9 Eur. J. Pain 463 (2005); Lee et al., *Fetal Pain: A Systematic Multidisciplinary Review of the Evidence*, 294 JAMA 947 (2005).

[44] *See, e.g.*, Apkarian et al., 9 Eur. J. Pain at 463-484; Tracey & Mantyh, *The Cerebral Signature for Pain Perception and Its Modulation*, 55 Neuron 377 (2007); Key, *Why fish do not feel pain*, 3 Animal Sentience 1 (2016).

birth.[45] Additionally, medical literature shows that a fetus likely cannot experience pain at any gestational age, because it is kept in a sleep-like state by environmental factors in the uterus, including certain hormones and low oxygen levels.[46]

III. H.B. 454 INTRUDES ON THE PATIENT-CLINICIAN RELATIONSHIP

The application of a clinician's sound medical judgement is the cornerstone of the patient-clinician relationship. ACOG's *Code of Professional Ethics* states that "the welfare of the patient must form the basis of all medical judgments. … The obstetrician-gynecologist should … exercise all reasonable means to ensure that the most appropriate care is provided to the patient."[47] AMA's *Code of Medical Ethics* similarly states that "[p]atients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment."[48]

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[45] Kostovic & Jovanov-Milosevic, 11 Seminars in Fetal & Neonatal Medicine 415.
[46] *See* ACOG *Facts Are Important - Fetal Pain* 10-11, *supra* note 43; Rigatto et al., *Fetal breathing and behavior measured through a double-wall Plexiglass window in sheep*, 61 J. Applied Physiol. 160 (1986); Derbyshire, *Can fetuses feel pain*?, 332 BMJ 909 (2006); Mellor et al., *The importance of 'awareness' for understanding fetal pain*, 49 Brain Research Reviews 455 (2005).
[47] ACOG, *Code of Professional Ethics of the American College of Obstetricians and Gynecologists* 2 (Dec. 2015) ("ACOG Code of Ethics"), http://www.acog.org/About-ACOG/ACOG-Departments/Committees-and-Councils/Volunteer-Agreement/Code-of-Professional-Ethics-of-the-American-College-of-Obstetricians-and-Gynecologists.
[48] AMA, *Code of Medical Ethics, Chapter 1: Ethics of Patient-Physician Relationships*, § 1.1.3(b), *https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview* (last visited Sept. 16, 2019).

By criminalizing the most predominant method of second trimester abortion beginning at approximately 15 weeks LMP, H.B. 454 wrongfully intrudes on that relationship by substituting the clinician's medical judgment with that of the Kentucky legislature.[49]

A. Legislation That Intrudes on the Patient-Clinician Relationship is Antithetical to the Practice of Medicine

While some regulation of medical practice is necessary to protect patient safety, legislation that substitutes a clinician's sound medical judgment with that of a legislative agenda impermissibly interferes with the patient-clinician relationship.[50]

Proper, effective medical practice requires that clinicians have the authority to consider appropriate courses of treatment and discuss those options with their patients openly, honestly, and confidentially. Laws should not interfere with a clinician's ability to determine and counsel her patient according to the best available medical evidence and the clinician's medical judgment developed through years of training and on the job experience. "Laws that require physicians to give, or withhold, specific information when counseling patients, or that

[49] *See* Joffe, R.107, PageID #4826.
[50] *See id.* PageID #4815 ("[T]he fact that physicians are forced to act contrary to their patient's best medical interest and without the voluntary and informed consent is inconsistent with the way that doctor/patient relationships ought to be.")

mandate which tests, procedures, treatment alternatives or medicines physicians can perform, prescribe, or administer are ill-advised."[51]

Both within and outside Kentucky, all but a small percentage of abortions beginning around 15 weeks LMP are performed by D&E.[52] Contrary to the Commonwealth's assertion that mandating fetal demise before a clinician can perform D&E is "safe and effective,"[53] there is good reason that, in consultation with their patients, clinicians almost always perform D&E as the Commonwealth attempts to proscribe it: it is generally the safest and most accessible method of second trimester abortion, there is no medical benefit to first attempting to cause demise, and such attempts are not always feasible or successful.[54] H.B. 454

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[51] ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013, amended and reaffirmed July 2019), https://www.acog.org/-/media/Statements-of-Policy/Public/89LegislativeInterference2019.pdf?dmc=1&ts=20190916T1842004040; ACNM, *ACNM Opposes State Legislative Threats to Abortion* Care (Mar. 2019) ("Our code of ethics mandates that we engage in a process of non-coercive, evidence-based informed consent, and shared decision making. Therefore, we object to any legislation and/or regulation that interferes with the patient-provider relationship."), https://www.midwife.org/acnm/files/cclibraryfiles/filename/000000007327/ACNM%20Opposition%20Statement%20to%20Threats%20to%20Abortion%20Care%20March%202019.pdf.

[52] Practice Bulletin No. 135, *supra* note 5, at 1394.

[53] Appellant's Br. 17.

[54] Grimes et al., *Mifepristone and Misoprostol Versus Dilation and Evacuation for Midtrimester Abortion: A Pilot Randomized Controlled Trial*, 111 Obstetrics & Gynecology 148 (Feb. 2004); Practice Bulletin No. 135, *supra* note 5, at 1398.

criminalizes the most appropriate procedure chosen by clinicians and their patients in nearly all cases.

B. H.B. 454 Mandates a Potentially Harmful One-Size Fits All Procedure

Far from advancing women's health, H.B. 454 undermines the patient-clinician relationship by eliminating the clinician's ability to suggest and the patient's ability to consent to what is a simpler, safer form of second trimester abortion for all but a small percentage of patients. As set forth *supra,* none of the proposed fetal demise procedures has been shown to maintain, let alone increase, the safety of second-trimester abortion.[55]

Though some clinicians might find it medically appropriate—upon review of a patient's individualized medical circumstances—to recommend demise on a case-by-case basis, medical consensus is clear that all three procedures can be more difficult and increase complication risks. Criminalizing the clinician's ability to consider and prescribe the optimal form of treatment, in consultation with her patient, obstructs sound medical care and endangers a woman's health.[56]

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[55] Practice Bulletin No. 135, *supra* note 5, at 1396.

[56] *Amici* recognize some physicians—leveraging the full range of appropriate procedures for a second trimester abortion—may recommend fetal demise when treating the particular medical circumstances unique to an individual client. That treatment decision is made properly when appropriately considering the range of potential procedures, between a patient and her clinician. H.B. 454 obstructs that important policy goal and interferes with the ability of the patient and physician to engage in ethical, shared decision-making.

IV. H.B. 454 PLACES CLINICIANS IN ETHICALLY COMPROMISED POSITIONS

Every person has the right to access the "best available, scientifically based health care."[57] Accordingly, clinicians are ethically bound to "exercise all reasonable means to ensure" their patients receive "the most appropriate" and effective care.[58] A foundation of medical ethics is that "the welfare of the patient must form the basis of all medical judgments."[59]

These principles are reflected in the central tenants of ethical medical care including beneficence, nonmaleficence, and autonomy. Beneficence obligates clinicians to provide medical care that "is likely to benefit the patient."[60] Nonmaleficence compels physicians "not to harm or cause injury"—in other words, to "'do no harm.'"[61] Respect for autonomy encompasses a patient's right to freely and knowingly make her own healthcare decisions.[62]

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[57] ACOG, *Statement of Policy, Global Women's Health and Rights* 1 (July 2012, reaffirmed July 2018), https://www.acog.org/-/media/Statements-of-Policy/Public/88GlobalWmHlthRights2018.pdf?dmc=1&ts=20190905T1826368160.
[58] ACOG Code of Ethics, *supra* note 47, at 2.
[59] *Id.* at 2.
[60] ACOG, *Committee Opinion: Ethical Decision Making in Obstetrics and Gynecology* 3 (2007, reaffirmed 2019) ("ACOG, *Ethical Decision Making*"), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co390.pdf?dmc=1&ts=20190905T2001520928; *see also* ACNM, *Code of Ethics with Explanatory Statements*, § 3, https://www.midwife.org/acnm/files/ACNMLibraryData/UPLOADFILENAME/000000000293/Code-of-Ethics-w-Explanatory-Statements-June-2015.pdf.
[61] ACOG, *Ethical Decision Making* 3; ACNM, *Code of Ethics with Explanatory Statements*, § 3.
[62] *Id.*

In opposition to these principles, H.B. 454 places clinicians in ethically compromised positions.

First, to comply with H.B. 454, a clinician who determines that D&E is the best available treatment must nevertheless perform a superfluous fetal demise procedure. This procedure presents "no benefit to the patient"[63] and involves unjustified health risks—including being experimental in certain circumstances.[64] The law's imposition of such treatment conflicts with principles of medical ethics.[65] And H.B. 454's medical emergency exception provides little comfort. The exception covers just a fraction of patients, and clinicians—who promise to "do no harm" to their patients—should not be forced to wait until a woman is on the brink of "substantial and irreversible impairment of a major bodily function"[66] before providing medical care.[67]

Second, H.B. 454 requires clinicians to indiscriminately deny access to D&E, regardless of the patient's individual needs. Where D&E is the proper treatment, and especially in Kentucky where there are no non-D&E options after 15 weeks LMP, clinicians are faced with a circumstance where they are unable to

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[63] ACOG Code of Ethics, *supra* note 47, at 2 ("It is unethical to prescribe, provide, or seek compensation for therapies that are of no benefit to the patient.").
[64] *Supra* Section I.B.
[65] ACOG Code of Ethics, *supra* note 47, at 2; Davis, R.106, PageID #4452; Joffe, R.107, PageID #4819.
[66] Ky. Rev. Stat. § 311.720(9).
[67] *See West Ala. Woman's Ctr.*, 900 F.3d at 1329.

provide the most appropriate and effective treatment for that individual patient.[68] Prohibiting clinicians from providing the most appropriate and effective treatment for each patient contradicts medical ethics.

Third, H.B. 454 undermines patient autonomy. Even where a patient does not want to be subjected to additional, risk-enhancing, experimental procedures, because of the legal limitations imposed by H.B. 454, a physician must reject the patient's choice—or face substantial penalties. But refusing the patient's preferred treatment infringes upon the patient's right to choose her own medical treatment.[69]

Fourth, but far from least, H.B. 454 places clinicians in the untenable situation of choosing between providing the best available medical care and risking substantial criminal and professional penalties. Clinicians who violate H.B. 454 are subject to a felony charge, up to five years imprisonment, and adverse licensing and disciplinary action.[70] While D&E in the second trimester is overwhelmingly

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[68] *See* ACOG Code of Ethics, *supra* note 47, at 2; AMA, *Code of Medical Ethics Opinions, Chapter 1: Ethics of Patient-Physician Relationships*, *supra* note 48 at § 1.1.1.

[69] Joffe, R.107, PageID #4827. Similarly, the dearth of literature surrounding the fetal demise options renders physicians unable to provide direct information regarding the procedures' risks, undermining important ethical requirements such as informed consent. *See* ACOG, *Committee Opinion: Informed Consent* 1 (2009, reaffirmed 2015), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20190905T2028490803; *see also* AMA, *Code of Medical Ethics Opinions, Chapter 2: Ethics of Consent, Communication & Decision Making*, *supra* note 48 at § 2.1.1 ("Informed consent to medical treatment is fundamental in both ethics in law."); Joffe, R.107, PageID #4826.

[70] Ky. Rev. Stat. §§ 311.565, 311.606, 532.060(2)(d).

the most appropriate medical treatment for patients, clinicians cannot abide by their ethical duty to "place [the] patient['s] welfare above the physician's own self-interest"[71] without subjecting themselves to criminal liability and the suspension or loss of their license. H.B. 454 accordingly pits the welfare of the patient against a clinician's desire to avoid severe retribution—a burdensome ethical dilemma.

CONCLUSION

For the foregoing reasons, *Amici* urge the Court to affirm the District Court's decision.

Respectfully submitted,

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[71] AMA, *Code of Medical Ethics Opinions, Chapter 1: Ethics of Patient-Physician Relationships*, *supra* note 48 at § 1.1.1.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1) and 29(a)(4), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(f) and 29(a)(5), the brief contains 6,034 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word for Office 365 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Kimberly A. Parker
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September 16, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of September, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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