**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF KENTUCKY**
**LOUISVILLE DIVISION**

**CIVIL ACTION NO: 3:18-CV-00224-JHM**

**EMW WOMEN'S SURGICAL CENTER, P.S.C., et al.** **PLAINTIFFS**

**V.**

**ADAM W. MEIER et al.** **DEFENDANTS**

**MEMORANDUM OPINION INCORPORATING FINDINGS OF FACT AND CONCLUSIONS OF LAW**

This matter came before the court for a bench trial that commended on November 13, 2018 and concluded on November 19, 2018. The court has reviewed the parties' post-trial briefs and the evidence at trial, and its findings of facts and conclusions of law are set forth below.

## I. BACKGROUND

### A. Procedural History

Plaintiffs, a Kentucky abortion facility and its two board-certified obstetrician-gynecologists ("OB-GYN") Drs. Ashlee Bergin and Tanya Franklin, challenge the constitutionality of a recently enacted Kentucky abortion law. The law at issue regulates second-trimester abortion procedures and is included in House Bill 454 ("H.B. 454" or "the Act"). Plaintiffs allege that the Act's requirement that Kentucky physicians perform a fetal-demise procedure prior to performing the evacuation phase of a standard Dilation and Evacuation ("D&E") abortion—the principal second-trimester abortion method nationally—is a substantial obstacle to a woman's right to choose a lawful pre-viability second-trimester abortion. As such, Plaintiffs argue H.B. 454 is unconstitutional. More specifically, the individual Plaintiffs assert that, if the Act goes into effect, they will stop performing standard D&E abortions altogether due to ethical and legal concerns regarding compliance with the law, thereby rendering abortions

unavailable in the Commonwealth of Kentucky starting at 15.0 weeks from the date of a woman's last menstrual period ("LMP").[1]

Defendants respond that the Act has neither the purpose nor the effect of placing an undue burden on a woman seeking a second-trimester abortion. Rather, the Defendants contend that H.B. 454 appropriately advances the Commonwealth's interests while leaving open alternative means of obtaining an abortion—specifically, by receiving an additional medical procedure to cause fetal-demise prior to the evacuation phase of a standard D&E. The proposed alternative methods for physicians to induce fetal-demise are threefold: (1) digoxin injection; (2) potassium chloride injection; and (3) umbilical cord transection. The Commonwealth maintains that these procedures are safe, available, and reliable methods for causing fetal-demise. Thus, the Commonwealth claims that H.B. 454 does not operate as an undue burden on a woman's right to a second-trimester pre-viability abortion and is thus a constitutional abortion regulation.

On the day the Act was signed, Plaintiffs filed this lawsuit challenging it as a violation of Plaintiffs' patients' Fourteenth Amendment rights to privacy and bodily integrity. [DN 1 ¶¶ 46–49]. Thereafter, Plaintiffs filed a Motion for a Temporary Restraining Order and Preliminary Injunction and the Court convened a telephonic hearing on the Motion. [DN 6]. During the telephonic hearing, the parties agreed to the entry of a consent order suspending enforcement of the Act until the Court ruled on Plaintiffs' motion for preliminary injunctive relief. [DN 24]. The Court later issued an order requiring the parties to continue abiding by the terms of the consent order until the trial on the merits. [DN 56].

**B. The Act**

H.B. 454 states in relevant part:

[1] Unless otherwise indicated, all references to weeks of pregnancy are LMP.

> No person shall intentionally perform or . . . attempt to perform . . . an abortion on a pregnant woman that will result in the bodily dismemberment, crushing, or human vivisection of the unborn child when the probable post-fertilization age of the unborn child is eleven (11) weeks or greater, except in the case of a medical emergency.

Act, § 1(2)(a)-(b). "Bodily dismemberment, crushing, or human vivisection" is further defined by H.B.454 as any

> procedure in which a person, with the purpose of causing the death of an unborn child, dismembers the living unborn child and extracts portions, pieces, or limbs of the unborn child from the uterus through the use of clamps, grasping forceps, tongs, scissors, or a similar instrument that . . . slices, crushes, or grasps . . . any portion, piece, or limb of the unborn child's body to cut or separate the portion, piece, or limb from the body.

*Id.* § 2(18). A "medical emergency" exception is provided for under this framework. Such an emergency is defined as a condition that "so complicates the medical condition of a pregnant female as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function[.]" K.R.S. § 311.720(9); *see* Act § 1(1)(b). A physician found to be in violation of the Act commits a Class D felony, subjecting him or her to punishment of up to five years' imprisonment, KRS § 532.060(2)(d), and can also expose clinics and physicians to adverse licensing and disciplinary action. *See* KRS § 311.565; KRS § 311.606.

The parties do not dispute that after approximately 15 weeks of pregnancy and before a fetus is viable, the most common second-trimester abortion procedure nationwide is a standard D&E without first inducing fetal-demise. It is also undisputed that the Act prohibits the standard D&E abortion unless fetal-demise occurs before any fetal tissue is removed from the woman.

## II. DISCUSSION

Plaintiffs seek a permanent injunction of H.B. 454. In determining whether a permanent injunction should issue, four considerations are relevant: (1) whether plaintiff showed actual

success on the merits; (2) whether the movant will suffer irreparable injury unless the injunction issues; (3) whether issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of the injunction. *Jolivette v. Husted*, 694 F.3d 760, 765 (6th Cir. 2012) (outlining the permanent injunction factors). The plaintiff bears the burden of persuasion as to each of these four showings. The court will address each showing but first addresses a justiciability question raised by the Commonwealth.

**A. Standing**

As a preliminary matter, the Commonwealth asserts that EMW lacks standing to challenge the constitutionality of H.B. 454. Ordinarily, a party cannot claim standing to vindicate constitutional rights of some third party, in this case the patients of EMW. *Singleton v. Wulff*, 428 U.S. 106, 114 (1976). However, this general rule has exceptions. Without engaging in a lengthy analysis about the relationship between EMW and its patients, it is enough to state that it is well-established that it is "appropriate to allow a physician to assert the rights of women patients as against governmental interference with the abortion decision . . . ." *Id.* at 118; *see also Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1396 (6th Cir. 1987) (holding that Planned Parenthood and its Medical Director had standing to assert the third-party rights of their patients because the patients' rights are "inextricably bound up with the activity the . . . clinic desires to pursue and seemingly would not be asserted as effectively by the third parties who actually possess those rights") (internal quotation marks omitted); *Northland Family Planning Clinic, Inc. v. Cox*, 487 F.3d 323, 328 (6th Cir. 2007) (adjudicating physicians' and clinics' claims on behalf of their abortion patients); *Women's Med. Prof. Corp. v. Voinovich*, 130 F. 3d 187, 191–92 n.3 (6th Cir. 1997) (same).

**B. Permanent Injunction – Success on the Merits**

To be entitled to permanent injunctive relief, Plaintiffs must first show they succeeded on the merits of their constitutional challenge to the Act.

**1. Legal Framework**

**a. The Undue Burden Test**

In the nearly half century since *Roe v. Wade* recognized the Fourteenth Amendment right to decide whether or not to terminate a pregnancy, the Supreme Court has addressed abortion regulations on several occasions. This court's decision is controlled by the precepts articulated in those opinions. Specifically, three basic principles arising from *Planned Parenthood of Southeastern Pa. v. Casey* guide this court. 505 U.S. 833 (1992). In that case, the Supreme Court affirmed the essential holding of *Roe*. *Id.* at 846.

> First is a recognition of the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State. Before viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure. Second is a confirmation of the State's power to restrict abortions after fetal viability, if the law contains exceptions for pregnancies which endanger the woman's life or health. And third is the principle that the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child.

*Id.* In this case the Court turns its focus to the first and third principles.

According to this framework, before viability, a state may not forbid elective abortion entirely. *See Gonzales v. Carhart*, 550 U.S. 124, 146 (2007) (quoting *Casey*, 505 U.S. at 879); *see also Stenberg v. Carhart*, 530 U.S. 914, 921 (2000). Further, a state "may not impose upon this right an undue burden, which exists if a regulation's 'purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.'" *Gonzales*, 550 U.S. at 146 (quoting *Casey*, 505 U.S. at 878). But a state is not left with no power to regulate. Rather, "[r]egulations which do no more than create a structural mechanism by which the State . . . may express profound respect for the life of the unborn are permitted, if they are not a substantial

obstacle to the woman's exercise of the right to choose." *Id.* (quoting *Casey*, 505 U.S. at 877) (internal quotation marks omitted).

In 2016 the Supreme Court elaborated on pre-viability regulations. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016). The Court reiterated that "a statute which, while furthering [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." *Id.* at 2309 (quoting *Casey*, 505 U.S. 877) (internal quotation marks omitted). Specifically, *Casey* "requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." *Id.* The determination of whether a state regulation is a substantial obstacle—and therefore an undue burden—must be assessed in relation to the benefits that the regulation provides. *Id.* Where a regulation's burdens exceed its benefits, the regulation constitutes a substantial obstacle to a woman's choice and cannot withstand constitutional challenge. *Id.*

**b. Second-Trimester Abortion Jurisprudence**

Plaintiffs rely heavily on two Supreme Court cases in which the Court reviewed laws intended to ban Dilation and Extraction ("D&X") abortions, otherwise known as partial-birth abortions. *See Stenberg v. Carhart*, 530 U.S. 914 (2000); *Gonzales v. Carhart*, 550 U.S. 124 (2007). Both cases are instructive. Nebraska's statute in *Stenberg* was found to be unconstitutional because the language of the law was such that it prohibited not only D&X abortions, but also could be read to ban the standard D&E abortion. *See Stenberg*, 530 U.S. at 930 ("[I]t 'imposes an undue burden on a woman's ability' to choose a D&E abortion, thereby unduly burdening the right to choose abortion itself.") (quoting *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833,

874 (1992)). In striking down the Nebraska law, the Court elaborated that using the challenged law,

> some present prosecutors and future Attorneys General may choose to pursue physicians who use [the standard] D&E procedures, the most commonly used method for performing previability second trimester abortions. All those who perform abortion procedures using that method must fear prosecution, conviction, and imprisonment. The result is an undue burden upon a woman's right to make an abortion decision.

*Id.* at 945–46. Seven years later, the Supreme Court upheld a federal statute specifically aimed at D&X abortion procedures because the more narrowly-written law "allows, among other means, a commonly used and generally accepted method, so it does not construct a substantial obstacle to the abortion right." *Gonzales*, 550 U.S. at 165. The "other means" and "generally accepted method" the Supreme Court refers to is the standard D&E procedure without fetal-demise.

At least ten states other than Kentucky have enacted fetal-demise laws similar to the H.B. 454. In many of those states, similar challenges to that here have been raised.[2] In Alabama, the Eleventh Circuit upheld a permanent injunction granted by the district court enjoining Alabama from enforcing a similar fetal-demise law. *See West Ala. Women's Ctr. v. Miller*, 299 F. Supp. 3d 1244 (M.D. Ala. 2017), *aff'd*, *West Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018). The district court concluded that the law at issue imposed an undue burden on women seeking pre-viability D&E abortions and was thus unconstitutional. *Id.*

In Arkansas, a federal district court issued a preliminary injunction to enjoin a similar fetal-demise law. The court found that if the law were to go into effect, the fraction of women for whom the law is relevant would immediately lose the right to obtain a pre-viability abortion anywhere in the state after 14 weeks. *Hopkins v. Jegley*, 267 F. Supp. 3d 1024 (E.D. Ark. 2017).

[2] There have been no legal challenges raised to the fetal-demise laws in Mississippi and West Virginia. The North Dakota clinic's lawyers are waiting for a decision from the Eighth Circuit on the challenge to similar legislation in Arkansas.

Arkansas appealed the district court's grant of the preliminary injunction to the Eighth Circuit which heard oral arguments on December 13, 2018.

The Kansas Court of Appeals affirmed a district court's grant of a temporary injunction that enjoined fetal-demise legislation like that at issue here. *Hodes & Nauser MDs, P.A. v. Schmidt*, 368 P.3d 667 (Kan. Ct. App. 2016) (en banc). The Court of Appeals concluded that, "[g]iven the additional risk, inconvenience, discomfort, and potential pain associated with these [fetal-demise] alternatives, some of which are virtually untested, . . . banning the standard D&E, a safe method used in about 95% of second-trimester abortions, is an undue burden on the right to abortion." *Id.* at 678.

In Ohio, a federal district court issued a temporary restraining order, pending an evidentiary hearing on the motion for a preliminary injunction, as to fetal-demise legislation. *Planned Parenthood S.W. Ohio Region v. Yost*, No. 1:19-CV-00118 (S.D. Ohio March 26, 2019) (DN 34). In issuing that order, the court stated that the "weight of legal authority favors" the plaintiffs. *Id.* at 8. That court held an evidentiary hearing as to the preliminary injunction beginning April 10, 2019. On April 18, 2019, the federal district court granted in part a motion for preliminary injunction finding that the plaintiffs were likely to succeed on the merits. *Planned Parenthood S.W. Ohio Region v. Yost*, 2019 WL 1758488, at *16 (S.D. Ohio Apr. 18, 2019). The court concluded that the fetal-demise legislation burdened a large fraction of women seeking pre-viability, second trimester abortions and was likely unconstitutional as written. *Id.*

In Louisiana, a similar suit has been filed over House Bill 1081 and other abortion regulations passed by the Louisiana legislature. *June Med. Servs. LLC v. Gee*, No. 3:16-CV-0444 (M.D. La. July 1, 2016).

An Oklahoma state district court enjoined enforcement of fetal-demise legislation in 2015. *Nova Health Sys. v. Pruitt*, No. CV-2015-1838 (Okla. Cty. Dist. Ct. Oct. 28, 2015). The court considered the Supreme Court's precedents in *Stenberg* and *Gonzales* and stated that those opinions weighed the state's asserted interests but still found the previous ban on D&E abortions to be unconstitutional. *Id.* slip op. at 7–8. The court ruled that the state's asserted interests were legitimate but likely did not justify the law's burden on a woman's right to terminate a pre-viability pregnancy. *Id.* slip op. at 8. Accordingly, the court granted a temporary injunction preventing the law from taking effect. *Id.* slip op. at 12.

Finally, in Texas, a federal district court held a bench trial and issued a permanent injunction foreclosing enforcement of a law that imposed civil and criminal penalties on physicians who performed standard D&E abortions without first ensuring fetal-demise. *Whole Woman's Health v. Paxton*, 280 F. Supp. 3d 938 (W.D. Tex. 2017). That court assumed, without finding, that the interests asserted by Texas were legitimate but also that "requiring a woman to undergo an unwanted, risky, invasive, and experimental procedure in exchange for exercising her right to choose an abortion" constituted a substantial burden. *Id.* at 953. Consequently, the court concluded the law was facially unconstitutional and declared it void. *Id.* at 954. The State appealed that decision to the Fifth Circuit which heard oral arguments on November 5, 2018. On March 13, 2019, the Fifth Circuit panel issued a stay, explaining that the court would not resolve the appeal until the Supreme Court disposes of a Louisiana abortion case concerning admitting privileges before it on writ of certiorari. *Whole Woman's Health v. Paxton*, No. 17-51060 (5th Cir. 2019) (Doc. No. 00514871170).

In *Paxton*, the court aptly summarized a district court's role when faced with such a decision: "Once the Supreme Court has defined the boundaries of a constitutional right, a district

court may not redefine those boundaries. Further the role of the district court is to preserve a right, not to search for a way to evade or lessen the right." *Paxton*, 280 F. Supp. 3d at 945. As such, the *Stenberg* and *Gonzales* decisions control, and the evolving fetal-demise litigation in the lower courts inform this constitutional challenge. Just as the law at issue in *Paxton*, H.B. 454 "has the undisputed effect of banning the standard D&E procedure when performed before fetal demise," because of the extensive burdens that accompany the law. *Id.* The Supreme Court's determination that "laws with the effect of banning the standard D&E procedure result in an undue burden upon a woman's right to have an abortion and are therefore unconstitutional" is binding. *Id.*

**2. The Interests of the Commonwealth of Kentucky**

One requirement that *Casey* and its progeny establish for pre-viability regulations is that a state regulation of the abortion procedure must be substantiated by a legitimate or valid purpose. The Commonwealth argues that H.B. 454 protects the ethics, integrity, and reputation of the medical community and expresses respect for the dignity of human life—interests, it notes, advanced by the federal law upheld in *Gonzales*. [DN 119 at 4]. Plaintiffs do not dispute the legitimacy of those interests. [DN 118 at 30 n.32].

Indeed, the Supreme Court said in no uncertain terms that "the government 'has an interest in protecting the integrity and ethics of the medical profession.'" *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997)). The Court also reaffirmed that "the State, from the inception of the pregnancy, maintains its own regulatory interest in protecting the life of the fetus that may become a child[.]" *Id.* at 158.

But the fact that the Act furthers legitimate state interests does not end this constitutional inquiry. Even though the act may further a legitimate state interest, a pre-viability abortion restriction must still survive the undue burden test. *See Whole Woman's Health v. Hellerstedt*, 136

S. Ct. 2292, 2309 ("[A] statute which, while furthering [the interest in potential life or some other] valid interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.") (citing *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 877 (1992)); *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1320–21 (11th Cir. 2018). The court now considers the burden imposed on women.

**3. Burden on Women**

Plaintiffs outline in detail all of the burdens attendant to the proposed fetal-demise procedures. As a summation of all the problems with the proposed fetal-demise procedures, Plaintiffs offered the testimony of Dr. Franklin, one of the named Plaintiffs. Dr. Franklin explained that because of the burdens the Act would impose, both ethically and legally, she and her colleague Dr. Bergin will stop performing standard D&E abortions if the Act goes into effect. Such a decision by these doctors would render abortions unavailable within the state of Kentucky to women who are 15 weeks pregnant.

The Commonwealth, in contrast, says the Act does not impose the burdens articulated by Plaintiffs because there are three methods by which abortion providers can safely and reliably cause fetal-demise before performing a D&E procedure: (1) digoxin injection; (2) potassium chloride injection; and (3) umbilical cord transection. It is necessary to discuss each of the Commonwealth's proposed methods of fetal-demise to explain why each is an unusable workaround.

**a. Digoxin Injections**

The Commonwealth's first proposed method is the use of digoxin injections—the least technically challenging but also the least reliable. To inject digoxin, physicians begin by using an ultrasound machine to visualize the woman's uterus and the fetus. The physician then inserts a

long surgical needle through the patient's skin, abdomen, and uterine muscle, to inject digoxin into the fetus. Although such injections are not terribly difficult to perform, as it can also be administered into the amniotic fluid, it is still not a feasible option for fetal-demise for several reasons.

First, and most importantly, digoxin injections are not reliable for inducing fetal-demise. When injected into the fetus or amniotic fluid, digoxin has a failure rate ranging between 5% and 20%. Tr. Vol. I 62:5–13 [DN 106]; Tr. Vol. II 53:6–54:18 [DN 107]; Tr. Vol. IV 41:10–13 [DN 103]. If the first dose of digoxin fails to cause fetal-demise, the Act would require an abortion provider to either inject a second dose or try an alternative method of fetal-demise. There is no medical literature on the proper dosage for a second digoxin injection or the potential risks associated with another injection. Tr. Vol. I. 66:16–67:2 [DN 106]; Tr. Vol. II 56:8–21 [DN 107]; Tr. Vol. III-B 102:5–19 [DN 102]. As such, successive digoxin injections would subject a patient seeking a D&E to an experimental medical procedure. Tr. Vol. I 67:3–9 [DN 106].

Second, a variety of factors affect whether a provider is actually able to inject digoxin into the fetus or amniotic fluid—placental positioning, fetal positioning, obesity, and the presence of uterine fibroids or cesarean-section scars can make such injections more difficult, if not impossible, to administer. Tr. Vol. I 58:21–59:13 [DN 106]; Tr. Vol. II 39:1–19 [DN 107]; Tr. Vol. III-B 103:12–15, 104:3–13 [DN 102]; Tr. Vol. IV 99:17–24 [DN 103]. Further, digoxin cannot be administered to women with known contraindications. Tr. Vol. I 59:24–61:22 [DN 106].

Third, digoxin injections are essentially experimental for women before 18 weeks of pregnancy, and about 50% of second-trimester abortions in Kentucky are performed before 18 weeks of pregnancy. *See* PX 128 (summarizing data of EMW's second-trimester abortion procedures); Tr. Vol. II 56:22–24 [DN 107]. The vast majority of studies on digoxin injections

focus on pregnancies at or after 18 weeks. Only a few studies include cases of women at 17 weeks of pregnancy and no study has been done on the efficacy, dosage, or safety of digoxin injections before 17 weeks of pregnancy. Tr. Vol. I 67:25–68:9 [DN 106]; Tr. Vol. IV 114:23–115:3 [DN 103]. Consequently, requiring digoxin use before 18 weeks would force patients to undergo an experimental and potentially harmful medical procedure without any associated benefits.

Fourth, digoxin injections subject patients to increased health risks. The parties' experts agreed that digoxin injections are associated with heightened risks of infection, extra mural delivery, vomiting, and hospitalization, compared to standard D&E alone. The best studies submitted to the judicial record support this conclusion about the relative safety of digoxin injections. The court finds that even when administered successfully after 18 weeks, digoxin injections carry the abovementioned significant, added health risks to the standard D&E procedure.

Finally, additional logistical and emotional burdens are associated with a digoxin injection. Digoxin works slowly—sometimes taking up to 24-hours if effective—requiring physicians to administer the injection the day before the scheduled D&E. As such, mandating a digoxin injection prolongs the length of a D&E abortion from one day to two, requiring a woman to pay additional costs—child care, transportation, overnight travel, and others—to have the procedure. This burden, of having to make multiple trips for the procedure, is especially pronounced for low-income women. Although Plaintiffs do not keep financial records for D&E abortion patients, the court heard testimony about the poverty levels in Kentucky, Tr. Vol. III-A 27:13–29:16 [DN 108], and the poverty rates among abortion patients nationally. *Id.* 33:20–35:3. The court is willing to draw the conclusion that many of the women receiving abortions at EMW are low-income and will suffer adverse economic consequences if the D&E procedure is prolonged to two days. *Id.* 35:12–25. Additionally, there are emotional burdens associated with digoxin

injections. Any needle procedure, particularly one with a large needle and no correlative medical benefit, will cause emotional distress for some patients. Tr. Vol. I 120:16–121:4 [DN 106].

Because of the unreliability of the procedure, unknown risks associated with second doses, unknown risks for women before 18 weeks of pregnancy, additive risk of complications, increased travel burden, and the pain and invasiveness of the procedure, the court finds that a digoxin injection is not a feasible method of inducing fetal-demise before performing the evacuation phase of a D&E abortion. The court concludes that in all instances the procedure would create a substantial obstacle to a woman's right to an abortion.

**b. Potassium Chloride Injections**

The Commonwealth's second proposed fetal-demise method is the intra-fetal or intra-cardiac injection of potassium chloride. Like digoxin injections, physicians administering potassium chloride injections begin by using an ultrasound machine to visualize the patient's uterus and fetus. The physician then inserts a long surgical needle through the woman's skin, abdomen, and uterine muscle, and then into either the fetus or, more specifically, the fetal heart. When the injection is administered directly to the fetal heart, fetal-demise is achieved almost immediately. However, based on the evidence, the court finds that potassium chloride injections are not a feasible method of causing fetal-demise before standard D&E procedures for several reasons.

First, and most importantly, injecting potassium chloride requires great technical skill and is an extremely challenging procedure to perform. Tr. Vol. I 228:18–231:12 [DN 106]. A provider's goal is to inject the substance directly into the fetal heart, which at approximately 15–16 weeks is about the size of a dime. Even around 20–22 weeks, the fetal heart remains very small, about the size of a quarter. *Id.* at 212:6–12; *see also id.* at 88:1–3; Tr. Vol. IV 23:13–18, 317:17–

20 [DN 103]. It is undisputed that Plaintiffs have not been trained to perform this procedure. Tr. Vol. II 39:20–25 [DN 107]; Bergin Depo., 120:1–12, 121:4–13 [PX 420]. Intra-fetal and intra-cardiac potassium chloride injections are not taught in OB-GYN residencies or in family-planning fellowships, such as the ones Plaintiffs completed. Tr. Vol. I 88:4–13 [DN 106]; Tr. Vol. II 39:20–40:12, 40:2–22 [DN 107]; Tr. Vol. III-B 111:7–9 [DN 102]; Tr. Vol. IV 107:5–7, 314:18–315:17 [DN 103]. In fact, these injections are generally only taught in subspecialist fellowship programs, such as maternal-fetal medicine ("MFM") and reproductive endocrinology and infertility fellowships. Tr. Vol. I 88:14–89:5, 226:24–227:17 [DN 106]; Tr. Vol. II 40:1–12 [DN 107]; Tr. Vol. IV 259:21–260:12 [DN103]. These fellows go through several years of highly supervised and specialized training. The injection is typically used by such subspecialists for selective reduction of pregnancies in women with multiple gestations. Tr. Vol. I 88:24–89:5 [DN 106].

It would be impossible for Plaintiffs to receive this specialized training within Kentucky because no hospital in the Commonwealth offers this type of training. Tr. Vol. II 110:19–111:4 [DN 107]. Even if this subspecialist training were available in Kentucky, the Plaintiff's expert, Dr. Lynn Simpson, credibly testified that it could take years to see enough patients and perform enough supervised injections to be competent to perform the procedure. Tr. Vol. I 244:25–245:22 [DN 106]; Tr. Vol. IV 315:18–316:17 [DN103]. Based on the length of time it would take to learn the procedure and the lack of training available within the Commonwealth, the court finds that Plaintiffs have no practical way to learn how to perform this procedure safely.

Second, as with digoxin, potassium chloride injections are not a feasible method because they cannot be completed on every woman seeking a standard D&E. Obesity, fetal and uterine position, cesarean-section scar tissue, and uterine fibroids may complicate or even prevent

completely the administration of the injections in many women. Tr. Vol. I 94:7–12, 222:6–223:15 [DN 106]; Tr. Vol. IV 317:21–319:9 [DN 103]. Further, as conceded by the Commonwealth's expert, a correctly-administered potassium chloride injection cannot be relied upon to cause fetal-demise in every single case. Tr. Vol. IV 96:4–11 [DN 103].

Finally, again, like digoxin, potassium chloride injections carry serious health risks to the woman. Such injections increase the risk of uterine or other internal organ perforation as well as the risk of infection. Tr. Vol. I 94:13–95:1, 232:20–234:10 [DN 106]; *see e.g.*, Tr. Vol. III-B 114:21–116:3 [DN 102]. An additional risk associated with this procedure is the potential harmful effect on the woman's heart—because potassium chloride has harmful effects on the heart, inadvertently injecting it into the woman's circulation can cause cardiac arrest, though there is only a single documented case. *See e.g.*, Tr. Vol. I 95:2–16 (discussing PX 19) [DN 106]. These risks would only be exacerbated by untrained physicians performing the potassium chloride procedure.

As with digoxin injection, potassium chloride injection is an unnecessary and potentially harmful medical procedure with no counterbalancing medical benefit for the woman. This procedure is technically very challenging and carries with it serious health risks for the woman. Additionally, there is no practical way for Plaintiffs to receive adequate training so that they may perform these injections competently. This being the case, the court finds potassium chloride injection to be an unworkable method for physicians attempting to induce fetal-demise before performing the evacuation phase of a standard D&E abortion in Kentucky. To the extent such an injection could or would be used, the court finds that, like a digoxin injection, the procedure would create a substantial obstacle to a woman's right to an abortion based on the significant health risks associated therewith.

### c. Umbilical Cord Transection

The Commonwealth's final proposed method of fetal-demise is umbilical cord transection. To perform this procedure, the provider dilates the woman's cervix enough to allow the passage of instruments to transect the cord. Once the cervix is dilated, the physician uses an ultrasound for guidance and punctures the amniotic membrane, causing the amniotic fluid to drain from the uterus. Then, the physician inserts an instrument into the uterus, locates, and grasps the cord and, with another instrument, cuts the cord. Tr. Vol. I 105:2–108:9 [DN 106]; Tr. Vol. II 46:14–47:10 [DN 107]. At this stage in the second-trimester, the umbilical cord is about the width of a piece of yarn. Tr. Vol. I 105:20–24 [DN 106]. The physician then waits for the fetal heartbeat to stop, which generally occurs within 10 minutes. The physician then may perform the evacuation phase of the standard D&E. Several factors render this procedure an unworkable method for inducing fetal-demise.

First, several aspects of the procedure make cord transection a technically difficult procedure—lack of visualization following the rupture of the amniotic sac, the shrinking size of the uterus, and the small size of the umbilical cord. As to the lack of visualization, before the amniotic sac is punctured, the physician can easily visualize the fetus and umbilical cord due to the contrast on the ultrasound between those components and the amniotic fluid. However, once a physician ruptures the amniotic sac and the fluid begins to drain, they can no longer rely on an ultrasound image to visualize the different components of the fetus and guide the instruments to the cord—the provider essentially performs the transection blind. Tr. Vol. I 106:8–14 [DN 106]; Tr. Vol. II 47:4–7, 50:14–25 [DN 107]. Also, because of the rupturing of the amniotic sac, the uterus begins to contract bringing the fetus and the umbilical cord together, no longer separated by the buoyant amniotic fluid. Thus, the physician must identify, reach, and cut the cord with a

surgical instrument without visualization or space between different types of tissue. This poses another hurdle for the provider because if they cut fetal tissue instead of, or in addition to the cord, they have arguably violated the Act. Tr. Vol. 1 106:24–107:6 [DN 106]; Tr. Vol. II 47:23–48:9 [DN 107]. Finally, the blind procedure and close nature of all the uterine materials make locating the umbilical cord, roughly the width of a piece of yard, technically very difficult. Tr. Vol. I 105:20–24 [DN 106].

Second, cord transection is not a feasible method for fetal-demise because it is essentially an experimental procedure that carries no medical benefits to the patient. The Commonwealth claims that cord transection is a viable, safe option to cause fetal-demise based on a single study—a retrospective case series without any control group. Tr. Vol. I 109:22–112:7 [DN 106]. In addition to providing a low level of evidence, the study only looked at umbilical cord transections performed by two providers at a single location. Tr. Vol. III-B 118:10–119:11 [DN 102]. The study does not provide the type or quality of evidence that warrants reaching generalized conclusions about the feasibility or reliability of umbilical cord transection, particularly in light of the serious risks that are outlined below. *Id.* at 119:12–16.

Umbilical cord transection carries serious health risks, including blood loss, infection, and uterine injury. A physician may have to make multiple passes into the uterus while attempting to locate the umbilical cord. In doing so, each pass increases the risk of infection and uterine damage. Tr. Vol I 107:7–108:2 [DN 106]; Tr. Vol. II 51:7–10 [DN 107]. As performing cord transection involves blindly searching for the umbilical cord, the risk of these complications would be in addition to the risks inherent to the standard D&E alone. Additionally, while locating and transecting the cord, then waiting for the fetal heart to stop, the uterus will be contracting and the

placenta will begin to separate and bleeding will occur. Tr. Vol. I 107:15–21 [DN 106]; Tr. Vol. II 47:1–22, 51:4–7 [DN 107].

For the reasons set out above, the court finds that umbilical cord transection as a method of fetal-demise prior to the evacuation phase of a standard D&E would impose a substantial obstacle to a woman's right to pre-viability abortion.

**4. Balancing of Benefits and Burdens – Application of the Undue Burden Test**

As stated above, to determine whether a law regulating abortion constitutes an undue burden on the right to terminate a pregnancy pre-viability, the court must balance the state's interests underlying a law against the obstacles imposed by the law to women's access to abortion. Where a regulation's burdens exceed its benefits, the regulation constitutes a substantial obstacle to a woman's choice—such a regulation cannot withstand constitutional challenge. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016).

Having just outlined the burdens associated with the Act, it is necessary to further discuss one of the Commonwealth's asserted interests and correlative benefit. The Commonwealth asserts that its interest in fetal dignity is bolstered because, according to its expert witness, the fetuses subjected to standard D&E abortions can feel pain.

The court heard testimony from competing experts, Dr. Colleen Malloy for the Commonwealth and Dr. Steven Ralston for the Plaintiffs. Dr. Malloy is employed as a neonatologist at Northwestern University. Importantly, Dr. Malloy has never performed a procedure on a pregnant woman or a fetus. Tr. Vol. IV 201:6–14 [DN 103]. Dr. Malloy testified that a fetus can certainly feel pain by 22 weeks and possibly as early as 15 weeks. *Id.* at 150:16–19, 159:13–22. Dr. Malloy described the onset of fetal pain as a dimmer switch turning on gradually over the course of the fetus's development. *Id.* at 150:23–151:21. In other words, she

explained, though developing neural elements necessary for pain perception may be immature, they are not inactive. Dr. Malloy testified that two organizations share her opinion with respect to fetal pain—the American Academy of Pro-Life Obstetricians and Gynecologists and the Christian Medical and Dental Association. *Id.* 159:23–160:4.

Dr. Ralston, a well-credentialed MFM who chairs the OB-GYN Department at the University of Pennsylvania, testified that the overwhelming medical consensus is contrary to that of Dr. Malloy—that fetal pain perception is impossible before 24 weeks. *Id.* at 270:11–285:9. Dr. Ralston expressly testified that Dr. Malloy's opinion "is a minority outlier opinion." *Id.* at 274:13–22. In support of this conclusion, Dr. Ralston cited several organizations that share his opinion, including the Royal College of Obstetricians and Gynecologists and the American College of Obstetricians and Gynecologists, two reputable medical organizations. *Id.* at 310:4–311:118. Dr. Ralston explained that this consensus is based on the understanding in the scientific community that fetal pain perception requires consciousness, which in turn requires two elements absent in a fetus before 24 weeks: intact connections from the periphery to the thalamus and then to the cortex, and a sufficiently developed cerebral cortex. *Id.* at 270:11–285:12, 310:4–312:9, 340:5–15. Dr. Ralston testified that the existence of a developed cortex and intact neurocircuitry—the above listed connections—are necessary for any degree of pain perception, thus refuting Dr. Malloy's dimmer switch theory. Further, Dr. Ralston testified that evidence suggests pain perception is unlikely at any point during pregnancy due to factors that preclude consciousness in utero. *Id.* at 285:15–297:3, 340:5–23.

Based on Dr. Ralston's credible testimony, the extensive studies cited therein, and the consensus of the vast majority of the medical community, the court concludes that it is very unlikely that a fetus can feel pain before 24 weeks. Because H.B. 454 concerns second-trimester

abortions performed between 15 and 21.6 weeks, fetal pain is not a concern. The Commonwealth's argument that H.B. 454 provides a benefit of preventing fetal pain from the standard D&E abortion fails.

Still yet, the Commonwealth asserted two interests advanced by the Act that were recognized as legitimate in *Gonzales*—protecting the ethics, integrity, and reputation of the medical community and expressing respect for the dignity of human life even in the absence of fetal pain. However, Kentucky cannot pursue these interests in a way that completely denies women the constitutionally protected right to terminate a pregnancy before the fetus is viable. Here, the Commonwealth avers that its interests are sufficiently strong to justify the burdens the Act would impose on Kentucky women because they would retain the ability to terminate pregnancy at or after 15 weeks by first undergoing a fetal-demise procedure. However, the Commonwealth's argument is premised on the idea that it is feasible for Plaintiffs to safely and reliably utilize the three proposed fetal-demise methods examined above. For the reasons discussed above—the methods' associated risks, technical difficulty, untested nature, time and cost associated with performing them, and the lack of training opportunities—the court concludes on the current record that the proposed fetal-demise methods are not feasible for inducing fetal-demise before standard D&E at EMW. *See W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1327 (11th Cir. 2018) (concluding that based on the findings the proposed fetal-demise methods place a substantial obstacle in the path of a woman's right to a pre-viability abortion). Consequently, if the court were to allow the Act to go into effect, Kentucky women would lose their right to pre-viability abortion access at or after 15 weeks. The Supreme Court specifically addressed such a scenario and held that "[b]efore viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to

elect the procedure." *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 846 (1992). Consequently, the Commonwealth's interests, while legitimate, are not sufficient to justify such a substantial obstacle to the constitutionally protect right to terminate a pregnancy before viability.

**5. Intent Requirement**

The scienter requirement does not save the Act from its constitutional shortcomings. The Commonwealth contends that the intent requirement in H.B. 454 shields from liability physicians who unintentionally cut fetal tissue when attempting to comply with the Act. Specifically, the Commonwealth argues that because of this intent requirement, "there can be no criminal penalties when a physician performs a D&E procedure under a good-faith, but mistaken, belief that fetal demise has occurred." [DN 119 at 35]. But this assurance leaves the provider at the mercy of a prosecutor's discretion. The provider would face this risk every time they performed a fetal-demise procedure, particularly umbilical cord transection. Given that a prosecution and conviction could impose upon a physician a criminal sentence of up to five years imprisonment and other potential disciplinary and licensing action, it is unsurprising that Dr. Franklin testified that she would stop performing D&E abortions after 15 weeks if the Act went into effect. This deterrence of physicians, like Dr. Franklin, from providing D&E abortions thereby denies Kentucky women access to pre-viability abortions.

**6. Large Fraction Test**

To prevail on the facial challenge to H.B. 454, Plaintiffs must demonstrate that "in a large fraction of cases in which [the provision at issue] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 895 (1992). In the large-fraction test, the court uses as the denominator those cases in which the law at issue is relevant which is a narrower class than "pregnant women" or "the class

of women seeking abortions." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2320 (2016) (quoting *Casey*, 505 U.S. at 894–95). As such, the court rejects the Commonwealth's argument that the denominator should be all women seeking abortions, not just women seeking a D&E abortion.

The court makes the following findings of fact regarding the fraction of women effected by the Act. EMW is the sole licensed outpatient abortion facility located in Kentucky. Each year, EMW provides more than 3,000 abortions. PX 120. During 2016, 17.47% of those abortions were performed by the standard D&E procedure. PX 120; PX 129. Standard D&E accounts for over 99% of second-trimester abortions in Kentucky. Tr. Vol. II 21:21–23:6 [DN 107]; PX 120. The only alternatives to D&E—induction of labor or hysterotomy—are rare and must be performed in a hospital setting. Tr. Vol. I 36:1–38:22 [DN 106]. A strong majority of standard D&Es currently occur from 15.0 to 17.0 weeks LMP. PX 128. Of the 537 D&Es reported by EMW Louisville in 2016, 57.9% took place during these earliest weeks of the second-trimester. *Id.*

The court determines that H.B. 454 is relevant for all Kentucky women who select standard D&E through the second-trimester and that the Act causes an undue burden for a large fraction of these women. In Kentucky in 2016, 537 women had a standard D&E. PX 129. H.B.454 would unduly burden 100% of these women because, if the Act goes into effect, standard D&E abortions will no longer be performed in the Commonwealth due to ethical and legal concerns regarding compliance with the law.

The Commonwealth argues that if the court uses as the denominator only the women seeking a second-trimester D&E abortion, the Act still does not affect a large fraction of women because not all women who seek a D&E abortion will find the Act to be a substantial obstacle. The Commonwealth claims that because not all women will suffer the complications associated

with the fetal-demise procedures, the large fraction test is not met. [DN 119 at 40–41]. However, the court finds that under the Act, all women seeking a second-trimester abortion at and after 15 weeks would have to endure a medically unnecessary and invasive procedure that may increase the duration of an otherwise one-day standard D&E abortion. Further, the court heard testimony that the individual providers will no longer continue to offer standard D&Es if the Act goes into effect. That is a substantial obstacle and it affects all such women.

Because the Act affects all second-trimester D&E abortion procedures in Kentucky, the relevant class of women here consists of all women in Kentucky who are 15 to 21.6 weeks pregnant and seek an outpatient second-trimester D&E abortion. Plaintiffs successfully demonstrated that H.B. 454 would operate as an undue burden for a large fraction of women for whom the provision is an actual, rather than irrelevant, restriction.

**7. Out-of-State Abortion Clinics**

The Commonwealth made an argument at trial that the existence of out-of-state abortion clinics would provide a workaround if EMW were to stop performing D&E abortions. This argument is frivolous and can be addressed succinctly. The Commonwealth cannot enact unconstitutional laws and expect other states to compensate for its constitutional infirmity. *Jackson v. Women's Health Org. v. Currier*, 760 F.3d 448, 457 (5th Cir. 2014) ("[A] state cannot lean on its sovereign neighbors to provide protection of its citizens' federal constitutional rights"), *cert. denied*, 136 S. Ct. 2536 (2016); *see also EMW Women's Surgical Ctr., P.S.C. v. Glisson*, No. 3:17-CV-00189, 2018 WL 6444391, at *26 (W.D. Ky. Sept. 28, 2018) (stating that "the availability of abortion services in other states does not cure the infirmities presently imposed by Kentucky law"). Therefore, the availability of the standard D&E procedure in neighboring states is irrelevant and in no way affects this constitutional challenge.

For the foregoing reasons, Plaintiffs successfully showed that H.B. 454 operates as an undue burden on a woman's right to a second-trimester pre-viability abortion—an unconstitutional enactment under current precedent. As such, Plaintiffs satisfied the first of the four requirements for a permanent injunction.

**C. Permanent Injunction – Irreparable Harm**

As discussed above, Plaintiffs successfully showed the Act will operate as a substantial obstacle to a woman's right to an abortion before the fetus reached viability—a violation of a woman's Fourteenth Amendment rights to privacy and bodily integrity. "[I]f it is found that a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated." *Am. Civil Liberties Union of Ky. V. McCreary Cty.*, 354 F.3d 438, 445 (6th Cir. 2003). Thus, enforcement of H.B. 454 will cause immediate and irreparable harm to Plaintiffs' patients' constitutional rights as a matter of law. *See Whole Women's Health v. Paxton*, 264 F. Supp. 3d 813, 824 (W.D. Tex. 2017) ("The court concludes that Plaintiffs have established that absent a temporary restraining order they will suffer irreparable harm by being unable to access the most commonly used and safest previability-second-trimester-abortion procedure[.]"); *Hopkins v. Jegley*, 267 F. Supp. 3d 1024, 1068–69 (E.D. Ark. 2017) (concluding that enforcement of the D&E mandate would inflict irreparable harm on the plaintiff and his patients "as there is no adequate remedy at law").

If a permanent injunction does not issue, the fraction of women for whom H.B. 454 is relevant would immediately suffer irreparable harm by losing the right to obtain a pre-viability abortion anywhere in the Commonwealth of Kentucky after 15 weeks. As such, the second requirement for a permanent injunction is satisfied.

**D. Permanent Injunction – Remaining Factors**

Having shown success on the merits and irreparable harm to the clinic's patients, Plaintiffs must also show that the requested injunction would not cause substantial harm to others and that the public interest would be served by issuance of the injunction. *Jolivette v. Husted*, 694 F.3d 760, 765 (6th Cir. 2012). Plaintiffs do so easily. As to the harm to others, if an injunction does not issue, Kentucky women would lose the right to obtain a pre-viability abortion anywhere in the Commonwealth beginning at 15 weeks. If an injunction does issue, an unconstitutional law passed by Kentucky legislators will not go into effect. Accordingly, substantial harm to others will not result if the injunction issues. Finally, as to the public interest, it is well-established that the public has no interest in the enforcement of an unconstitutional law. *See, e.g.*, *G & V Lounge, Inc. v. Michigan Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994); *see also Am. Freedom Def. Initiative v. Suburban Mobility Auth. For Reg'l Transp.*, 698 F.3d 885, 896 (6th Cir. 2012) ("The public interest is promoted by the robust enforcement of constitutional rights[.]").

## III. CONCLUSION

In reaching this decision, the court was guided by Supreme Court precedent and lower courts' opinions resolving challenges to similar legislation. As appropriately stated by the Eleventh Circuit, "[i]n our judicial system, there is only one Supreme Court, and we are not it. As one of the 'inferior Courts,' we follow its decisions.'" *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1329 (11th Cir. 2018) (citing U.S. Const. art. III § 1).

The Supreme Court's holdings in *Stenberg* and *Gonzales* direct a single result—the Commonwealth's interests in protecting the reputation of the medical community and expressing respect for fetal life, while legitimate, are insufficient to allow a law that would act as a de facto ban on a woman's right to an abortion after 15 weeks to go into effect. The Commonwealth's legitimate interests do not allow the imposition of an additional required medical procedure—an

invasive and risky procedure without medical necessity or benefit to the woman—prior to the standard D&E abortion. Here, Kentucky's legitimate interests must give way to the woman's right. The Act, like the one at issue in *Paxton*, "does more than create a structural mechanism by which the [Commonwealth] expresses profound respect for the unborn. The Act intervenes in the medical process of abortion prior to viability in an unduly burdensome manner." 280 F. Supp. 3d 938, 954 (W.D. Tex. 2017).

Because H.B. 454 "has the effect of placing a substantial obstacle in the path of a woman's choice[, it] cannot be considered a permissible means of serving its legitimate ends." *Planned Parenthood v. Casey*, 505 U.S. 833, 877 (1992). H.B. 454 is facially unconstitutional for the foregoing reasons. Accordingly, the court declares the Act void and will permanently enjoin the Commonwealth from enforcing the Act.

Joseph H. McKinley Jr., District Judge
United States District Court

May 8, 2019

cc: counsel of record