THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION CINCINNATI

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, PLANNED PARENTHOOD OF GREATER OHIO, M.D. SHARON LINER, WOMEN'S MED GROUP PROFESSIONAL CORPORATION,

Plaintiffs,

vs.

DAVID YOST, IN THEIR OFFICIAL CAPACITY AS WELL AS THEIR EMPLOYEES, AGENTS, AND SUCCESSORS; MICHAEL O'MALLEY, IN THEIR OFFICIAL CAPACITY AS WELL AS THEIR EMPLOYEES, AGENTS, AND SUCCESSORS; RONALD O'BRIEN, IN THEIR OFFICIAL CAPACITY AS WELL AS THEIR EMPLOYEES, AGENTS, AND SUCCESSORS; JOSEPH DETERS, IN THEIR OFFICIAL CAPACITY AS WELL AS THEIR EMPLOYEES, AGENTS, AND SUCCESSORS; AND MATHIAS HECK JR., IN THEIR OFFICIAL CAPACITY AS WELL AS THEIR EMPLOYEES, AGENTS, AND SUCCESSORS;

Defendants.

Case No.1:19-CV-00118-MRB

Judge Michael R Barrett

PRELIMINARY INJUNCTION

On February 14, 2019, Plaintiffs Planned Parenthood Southwest Ohio Region ("PPSWO"), Planned Parenthood of Greater Ohio ("PPGHO"), Sharon Liner, M.D., and Women's Med Group Professional Corporation (collectively, "Plaintiffs") filed a Complaint (Doc. 1) challenging an Ohio statute that places restrictions on the most common abortion

method used in Ohio for pre-viability, second trimester abortions. With their Complaint, Plaintiffs filed a Motion for a Preliminary Injunction and/or Temporary Restraining Order. (Doc. 4). To preserve the status quo so that the Court could perform the appropriate constitutional and factual inquiries, the Court partially granted the Motion to the extent that it sought temporary relief, and held the portion of the Motion seeking a preliminary injunction in abeyance pending an evidentiary hearing. From April 10 to April 12, 2019, the Court heard the testimony of six medical professionals. The Court will now address Plaintiffs' Motion to the extent that it seeks a preliminary injunction.

I. BACKGROUND

a. The Act

Ohio Senate Bill 145 (S.B. 145 or the Act), 132nd General Assembly (Ohio 2018) (codified at Ohio Rev. Code § 2919.15) was signed into law on December 21, 2018. The Act criminalizes, as of March 22, 2019, the performance of "dismemberment abortions." It states that:

> [n]o person shall knowingly perform or attempt to perform a dismemberment abortion when the dismemberment abortion is not necessary, in reasonable medical judgment, to preserve the life or physical health of the mother as a result of the mother's life or physical health being endangered by a serious risk of the substantial and irreversible physical impairment of a major bodily function.

Ohio Rev. Code § 2919.15(B). Violation of the Act constitutes a fourth-degree felony, punishable by six to eighteen months in prison, and a fine of up to $5,000. Ohio Rev. Code §§ 2919.14(A)(4), 2919.15(C), 2919.18(A)(3)(d). It also subjects physicians to civil liability. *Id.* § 2307.53(A).

The Act supplies the following definition of "dismemberment abortion":

> with the purpose of causing the death of an unborn child, to dismember a *living* unborn child and extract the unborn child one piece at a time from the uterus through use of clamps, grasping forceps, tongs, scissors, or similar instruments that, through the convergence of two rigid levers, slice, crush, or grasp a portion of the unborn child's body to cut or rip it off.

Ohio Rev. Code § 2919.15(A) (emphasis added).[1] "Dismemberment abortion" is not a medical term used by physicians (Keder Direct), but the Parties agree that the term refers to the dilation and evacuation (D&E) abortion procedure. (Doc. 4, PageID 49);(Doc. 25, PageID 253). The Parties also agree that Ohio Rev. Code § 2919.15 contemplates that a physician may legally perform a D&E procedure if the fetus already died *in utero*; if the physician first causes "fetal demise" (*i.e.*, death by injection or umbilical transection) (Doc. 4, PageID 43)(Doc. 25, PageID 253); or, if such a procedure is necessary, "in reasonable medical judgment [of the physician], to preserve the life or physical health of the mother as a result of the mother's life or physical health being endangered by a serious risk of the substantial and irreversible physical impairment of a major bodily function." Ohio Rev. Code § 2919.15(B).

B. Fetal Demise

Plaintiffs argue that, by tacitly creating a fetal demise requirement before D&E may be lawfully performed, the State has essentially banned the most common, available, and safe pre-viability second trimester abortion without a feasible alternative or sufficiently broad medical exception. Although a doctor may legally perform a D&E if he or she first effects "fetal demise" – which can in theory be caused via (1) digoxin injection; (2) potassium chloride injection; and/or (3) umbilical transection – Plaintiffs argue that the fetal demise requirement

[1] The Act "does not prohibit the suction curettage procedure of abortion or the suction aspiration procedure of abortion." *Id.* (codified at Ohio Rev. Code § 2919.15(E)).

places doctors in such an impossible situation that many will abandon the practice of performing otherwise legal, pre-viability second trimester abortions altogether. As will be further described in the factual findings contained in Section II *infra*, Plaintiffs specifically argue that a doctor's inability to effect fetal demise (*i.e.*, a failed attempt to cause death by injection or transection) could place the patient in territory that is hazardous long term, yet insufficiently dire in the short term to trigger the statute's narrow medical exception. Likewise, Plaintiffs argue that the doctor is also placed in criminally dangerous territory, as accidental dismemberment of a living fetus is an inherent risk in at least one fetal demise method proposed by the State. Plaintiffs further argue that, even though the State contends that it would not prosecute accidental dismemberment of a living fetus, nothing prevents the State from taking the contradictory position in the future that even knowing the risk of accidental dismemberment satisfies the Act's *scienter* requirement. Unlike previously enacted partial birth abortion bans, which left other safe, pre-viability second trimester options available, Plaintiffs contend that Ohio doctors performing abortions in the 15-22 week LMP[2] range have no feasible backup option to avoid health risks to patients and legal risks to doctors.

C. Procedural Posture

Plaintiffs take the position that the criminalization of D&E absent pre-abortion fetal demise creates an undue burden on women in Ohio seeking otherwise legal second trimester abortions. In advance of the statute's effective date, Plaintiffs filed on February 14, 2019 a lawsuit asking that this Court declare Ohio Rev. Code § 2919.15 unconstitutional, and to issue an

[2] "LMP" stands for "last menstrual period." According to Plaintiffs and as further discussed below, D&E performed in the 15-18 week LMP range are more severely affected by the Act than the remainder because the medical research on digoxin in particular is silent with respect to its use before 19 weeks. (Doc. 4, PageID 50). In all cases, the medical research is also silent on whether it is safe to administer a second dose of digoxin if the first attempt to cause fetal demise fails.

order preliminarily and permanently enjoining its enforcement. (Doc. 1, PageID 14). Plaintiffs' Complaint was accompanied by their Motion for a Preliminary Injunction and/or Temporary Restraining Order. (Doc. 4).

After expedited briefing which was supported by numerous declarations and supplemental/rebuttal declarations, the Court partially enjoined enforcement of the statute on a temporary basis, and held the remainder of the Motion in abeyance pending an evidentiary hearing. Specifically, the Court temporarily enjoined Defendants, as well as their employees, agents, and successors, and all those acting in active concert with them, from prosecuting or otherwise pursuing legal action against medical professionals based on Ohio Rev. Code § 2919.15, in the following circumstances:

1. Where a physician performs D&E procedure before 18 weeks LMP;
2. Where, during the course of a D&E procedure, a physician accidentally removes fetal parts when intending to comply with demise requirements;
3. Where a physician performs a D&E procedure after an attempted demise procedure fails;
4. Where a physician performs a D&E procedure without demise after making a medical determination that a given patient is not a candidate for a demise procedure, either because a procedure is contraindicated or medically impossible for that patient.

(Doc. 30; 34). The above-referenced temporary restraining ("TRO") order expires on April 18, 2019 (*i.e.*, today). The Court expressed in the TRO that, before entertaining the motion for preliminary injunction, the Court would require an evidentiary hearing. Accordingly, the Court heard evidence from April 10 through April 12, 2019. The following witnesses testified on behalf of Plaintiffs: Dr. Lisa Keder, Dr. Steven Ralston, Dr. Sharon Liner, Dr. Katharine Rivlin, and Dr. Martin Haskell. Dr. Michael Valley testified on behalf of the State.

Before the preliminary injunction hearing, no party asked to consolidate the hearing with the trial on the merits. Therefore, based on the declarations and testimony, the Court makes preliminary findings of fact as set forth in Section II below.

II. FINDINGS OF FACT

a. Parties

Plaintiffs named the Ohio Attorney General, and multiple county prosecutors, as Defendants in this action. Collectively, Defendants are referred to as "the State."

Plaintiffs are abortion providers in Ohio:

1. PPSWO

PPSWO is an Ohio non-profit corporation. It offers surgical abortions, including D&E abortions, at its Cincinnati facility through 21 weeks 6 days LMP. (JX 30, ¶ 3).

2. Sharon Liner, M.D.

Dr. Liner is a physician licensed to practice medicine in Ohio. Dr. Liner serves as the Medical Director of PPSWO and provides abortions at its Cincinnati facility through 21 weeks 6 days LMP. (*Id.)*

3. PPGOH

PPGHO is an Ohio non-profit corporation. PPGOH offers surgical abortions, including D&E abortions at two Ohio clinics. At its Columbus facility, PPGOH offers D&E through 19 weeks 6 days LMP. At its Bedford Heights facility near Cleveland, PPGOH offers D&E through 18 weeks 6 days LMP. (JX 29, ¶ 10).

4. Women's Med Group Professional Corporation

Plaintiff Women's Med Group Professional Corporation owns and operates the Women's Med Center of Dayton (Women's Med), which provides surgical abortions, including D&E, through 21 weeks 6 days LMP or to 450 grams estimated fetal weight. (JX 31, ¶¶ 1, 11).

b. Witnesses

1. Dr. Lisa Keder

Lisa Keder, M.D., is a board-certified obstetrician-gynecologist (OB/GYN) practicing in the state of Ohio. She is a professor and Vice Chair of the Ohio State University Wexner Medical Center's Department of OB/GYN and Division Director for General OB/GYN. In addition to overseeing gynecologic services and general obstetrics services, Dr. Keder provides full-scope OB/GYN care to patients. Dr. Keder teaches medical students and residents based on the national OB/GYN curriculum. Dr. Keder is a contract physician at PPGOH, where she provides patient care, including abortions. She previously served as the Director of Planned Parenthood of Central Ohio (now merged into PPGOH). Dr. Keder has provided thousands of abortions in Ohio throughout her career, including D&Es. She has published multiple peer reviewed articles on contraception and family planning. Dr. Keder received a medical degree from the Ohio State University College of Medicine and completed a four-year OB/GYN residency and a two-year fellowship in Family Planning and Contraception at the University of Pittsburgh. She also has a Master's in Public Health (MPH) from the University of Pittsburgh.

Plaintiffs offered Dr. Keder as an expert qualified in OB/GYN, including the provision of abortion care and second-trimester abortions in Ohio, as well as OB/GYN resident training and the training required to provide abortion care in Ohio. (Keder Direct; JX-23 (Keder CV)).

2. Dr. Steven Ralston

Steven J. Ralston, M.D., M.P.H., is a board-certified OB/GYN and board-certified maternal-fetal medicine (MFM) specialist. Dr. Ralston is the Chair of OB/GYN at Pennsylvania Hospital in Philadelphia, Pennsylvania. He is also a Clinical Professor of OB/GYN at the University of Pennsylvania. Dr. Ralston provides direct care to patients as an MFM specialist and supervises MFM fellows, OB/GYN residents, and medical students. As an MFM specialist, Dr. Ralston is skilled in ultrasound and intrauterine needle-based procedures, including injections of potassium chloride (KCl), in which he trains MFM fellows. Dr. Ralston received his medical degree from Columbia University, completed an OB/GYN residency at Yale University, and completed his MFM fellowship at Tufts University. Dr. Ralston also received a MPH from Boston University. He has served on the Committee on Ethics for the American College of Obstetricians and Gynecologists (ACOG), the Committee on Bioethics of the American Academy of Pediatrics, and the Ethics Committee of the American Society of Reproductive Medicine.

Dr. Ralston has authored dozens of peer-reviewed clinical research articles and ethics opinions that set national standards of practice. Dr. Ralston provides full-scope OB/GYN care to patients, including D&Es and other abortions. Plaintiffs offered Dr. Ralston as an expert qualified on fetal development, specifically on fetal pain, as well as maternal fetal medicine, advanced intrauterine needle-based procedures including fetal KCl injection, and the training required to perform such injections. (Ralston Direct; JX-28 (Ralston CV)).

3. Dr. Sharon Liner

Sharon Liner, M.D., is a family physician licensed to practice medicine in Ohio. For the last 12 years, Dr. Liner has served as Director of Surgical Services of PPSWO in

Cincinnati, as well as Medical Director since October 2018. In her roles, Dr. Liner supervises physicians and residents, assists in developing and implementing PPSWO policies and procedures, and provides direct care services to women, including D&E procedures and other abortions. Dr. Liner has been working as a physician at PPSWO since 2004. She earned her medical degree from Michigan State University and completed Family Medicine residency at the University of Cincinnati. (Liner Direct; JX-30 ¶¶ 1-3 (Liner Decl.)).

Dr. Liner is also a Plaintiff in this action.

4. Dr. Katharine Rivlin

Katherine Rivlin, M.D., is a board-certified OB/GYN licensed to practice in the state of Ohio. Dr. Rivlin practices and serves on the faculty of the Ohio State University Wexner Medical Center, and she works as a staff physician at PPGOH. Dr. Rivlin provides prenatal care, comprehensive gynecological care, and gynecological surgery. She also conducts clinical research in abortion and contraception. Dr. Rivlin earned her medical degree from the University of Mississippi and completed an OB/GYN residency at New York University Medical Center. She completed a fellowship in Family Planning at Columbia University Medical Center, during which time she also completed a MPH in epidemiology. Dr. Rivlin provides medication and surgical abortions in Ohio, including D&E. (Rivlin Direct; JX-29 ¶¶ 1-2 (Rivlin Decl.)).

5. Dr. W.M. Martin Haskell

W.M. Martin Haskell, M.D., is a licensed family physician in the state of Ohio. He is the sole shareholder of WMGPC, which owns and operates Women's Med Center of Dayton (WMCD). Dr. Haskell is the Medical Director of WMCD, where he supervises physicians and clinicians and provides direct reproductive healthcare to patients. Dr. Haskell has trained physicians in abortion care. He received a medical degree from the University of

Alabama and completed an anesthesia internship at the University Hospital in Alabama. Dr. Haskell received 18 months of residency training in general surgery and two years of family practice residency training at the University of Cincinnati. Dr. Haskell has provided thousands of abortions since 1978, including D&E procedures, until his recent retirement. (Haskell Direct; JX-31 ¶¶ 1, 3-5 (Haskell Decl.)).

6. Dr. Michael Valley (State's Witness)

Michael Valley, M.D. currently practices obstetrics and gynecology and urogynecology in a private practice in Minnesota, where he is licensed to practice medicine. He completed a residency in obstetrics and gynecology. Dr. Valley performs D&Es but limits this practice to demised fetuses. (JX 24, ¶ 1; Valley Direct).

Dr. Valley estimates that he has performed five to ten D&E procedures over the course of his career, all of which were performed on patients who had already miscarried before he began the procedure. (Valley Cross). The most recent D&E procedure that Dr. Valley performed was at least five years ago. (Valley Cross). Dr. Valley has never used digoxin injections, KCl injections, or umbilical cord transections (UCT) to attempt fetal demise prior to performing an abortion. (Valley Cross). Dr. Valley does not hold himself out as an expert on fetal development, fetal neurology, or D&E abortion procedures.

c. Abortion in Ohio

Considering the fact that abortion "procedures seek to terminate a potential human life, [this] discussion may seem clinically cold or callous to some, perhaps horrifying to others." *Stenberg v. Carhart*, 530 U.S. 914, 923, 120 S. Ct. 2597, 2605 (2000). As the Supreme Court has observed, however, "[t]here is no alternative way . . . to acquaint the reader with the

technical distinctions among different abortion methods and related factual matters, upon which the outcome of this case depends." *Id*. For that reason, drawing upon the testimony and related medical texts, this Court shall describe the relevant methods of performing abortions in technical detail.

1. First Trimester

Most Ohio women who undergo abortions do so during the first trimester of pregnancy, which lasts until 13 weeks LMP. (JX 36). The testimony establishes that legal abortion is a common and safe medical procedure; that it is generally safer for a woman than carrying a pregnancy to term; and that the complication rate for abortion is low. (Keder Direct; Ralston Cross).

First-trimester abortions do not involve the dismemberment of a living fetus. In the first trimester, clinicians can induce abortions through medication, or alternatively, can suction the uterus to remove the fetus all at once and without the need for piece-by-piece removal. (JX 22, ¶ 18). In the first trimester of pregnancy, abortions in Ohio are performed using either medical or surgical means. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct). Medication abortion, which is accomplished through the ingestion of medications in the form of pills, is available up to 10 weeks LMP in Ohio. (Keder Direct; Liner Direct; Haskell Direct). Surgical abortion in the first trimester is performed by using suction aspiration to empty the uterus. (Keder Direct; Liner Direct; Haskell Direct).

2. Second Trimester

Starting at approximately 15 weeks LMP, suction alone is no longer sufficient to evacuate the uterus. (Keder Direct; Liner Direct). Therefore, beginning around 15 weeks LMP, physicians routinely use a combination of suction and surgical instruments to remove the fetus

and other products of conception from the uterus. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct). This procedure is commonly referred to as a D&E. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct).

3. D&E

D&E is the only outpatient abortion procedure available to women in Ohio beginning at approximately 15 weeks LMP. (Keder Direct; Liner Direct; Haskell Direct; Rivlin Direct). D&E has two steps: (1) dilation of the cervix and (2) piece by piece removal of the fetus, placenta and uterine lining with surgical instruments and suction. (JX 22, ¶¶ 20-21). Dr. Keder explained that, during the first step, clinicians place laminaria into the patient's cervix, which slowly absorb water and dilate the cervix over a period of about 24 hours. Because the cervical opening is smaller than the fetus, and the cervix is dilated only enough to be able to safely complete the procedure, separation or disarticulation of the fetal tissue usually occurs as the physician uses instruments to bring the tissue through the cervix. (Keder Cross). In the second step, Dr. Keder testified that clinicians may further dilate the cervix before removing the fetus with a combination of surgical instruments and suction. Specifically, the physician uses forceps or other surgical instruments in conjunction with suction to remove the fetus and other contents of the uterus. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct). During her testimony, Dr. Keder admitted that a fetus is not removed intact during a D&E. She testified that clinicians often detach limbs and other fetal parts while completing a D&E procedure. (Keder Cross). The evacuation process typically takes about 10 minutes. (Keder Direct; Haskell Cross).

Dr. Keder testified that the D&E steps occur over two visits to an abortion clinic. (Keder Direct). Dr. Keder agreed in her testimony that D&Es involve risks of infection, hemorrhage, cervical laceration, uterine perforation, and other complications. She believed that

the rate of these complications, which she estimated at less than one percent for each complication, was acceptable to continue performing the procedure. (Keder Cross). By way of contrast, Dr. Keder testified that a cesarean section has a 1 to 2 percent risk of infection but cesarean sections are an acceptable medical procedure. (Keder Direct).

Based on the record before the Court, D&E procedures are considered safe. (Keder Direct; Rivlin Direct; Ralston Cross). Major complications occur in fewer than 1% of second-trimester abortions performed by D&E. (Keder Direct). Furthermore, while abortion is generally a safe procedure for the woman, rates of complications increase with gestational age. From 1998-2010, the mortality rate for abortions at or less than 8 weeks LMP was 0.3 for every 100,000 abortions and 0.5 for abortions between 9-13 weeks LMP. This rate increased to a rate of 2.5 for abortions between 14-17 weeks LMP and increased to a rate of 6.7 for abortions at or after 18 weeks LMP. JX 1, Table 2. The rate increases to 10.4 per 100,000 procedures for abortions at or after 21 weeks LMP, which is higher than the 8.8 mortality rate for pregnancies. (*Compare* JX 8 at 1063 *with* JX 1 at 5).

The D&E procedure is distinct from a dilation and extraction (D&X) procedure, also known as "intact D&E," which involves dilating the cervix sufficiently to remove the fetus intact to a defined anatomical landmark. The D&X procedure is banned under the Federal Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531; *see Gonzales v. Carhart*, 550 U.S. 124, 168 (2007), and by separate provisions of the Ohio Revised Code § 2919.151. Prior to S.B. 145, those laws did not prohibit the D&E procedure at issue in this case. *See Gonzales*, 550 U.S. at 135; Ohio Rev. Code §2919.15(A)(1); *Women's Med. Prof'l Corp. v. Taft*, 353 F.3d 436 (6th Cir. 2003).

4. Alternatives to D&E

Other than D&E, the only abortion methods available after 15 weeks LMP are induction abortion and hysterotomy; the latter is similar to a Caesarian-section procedure. (Keder Direct; Rivlin Direct). Both procedures are rare and available only in a hospital setting. (Keder Direct; Rivlin Direct). Furthermore, induction abortions are much riskier than D&E procedures. (Keder Direct). They require a woman to go through labor and delivery, and thus must be performed in an inpatient setting. (Keder Direct; Liner Direct; Valley Cross). They take at least eight hours and may take up to several days to complete. (Keder Direct). Up to 33% of women who undergo induction abortions have a retained placenta and require surgery. (JX-22 ¶ 25 (Keder Decl.)). Other risks include infection (Valley Cross), cervical bleeding, failure to fully pass the pregnancy, and hemorrhage (Keder Direct). Because they are performed in hospital settings, induction procedures are far more expensive than clinic-based D&E abortions. (Keder Direct). They are also generally not available in Ohio, as very few hospitals in Ohio perform abortions, and even then, in only very limited medical situations. (Keder Direct; Haskell Direct; Rivlin Direct).

5. Fetal Demise

D&E need not necessarily be performed by dismembering a living fetus. Some doctors choose to kill the fetus, using digoxin, before performing the surgical dismemberment and evacuation. *Gonzales*, 550 U.S. at 136. Nationally, however, most doctors do not currently attempt to induce fetal demise prior to a D&E. (Keder Direct). According to a recent study of second-trimester abortion in the U.S., 74% of clinicians who provide D&Es after 18 weeks LMP do not cause demise before the procedure. (Keder Direct; Valley Cross; JX-37 at 4 (White et al., *Second-Trimester Surgical Abortion Practices in the United States* (White Study))). Of the

providers who did routinely induce demise, 70% began at 20 weeks' gestation or greater. (JX-37 at 4 (White Study)).[3] Some doctors have claimed anecdotally that administration of digoxin makes D&E easier to perform, as demise softens the fetal tissue, but some scientific literature disputes such claims. (JX-3 at 4 (Jackson et al., *Digoxin to Facilitate Law Second-Trimester Abortion: A Randomized, Masked, Placebo-Controlled Trial* (Jackson Study)); JX-9 at 4-5 (Gariepy et al., *Transvaginal Administration of Intraamniotic Digoxin Prior to Dilation and Evacuation* (Gariepy Study))).

Notwithstanding the varying practices in the medical community regarding pre-D&E fetal demise, the State asserts that all physicians can avoid criminal liability under S.B. 145 by inducing fetal demise before carrying out the evacuation part of the D&E procedure, proposing three means of doing so: injection of digoxin, injection of potassium chloride (KCl), or umbilical cord transection (UCT). (Doc. 25, PageID 255); (Valley Direct).

a. Digoxin

Digoxin is a medication that causes the fetal heart to stop beating. (Valley Direct; Keder Direct). Beginning at 18 or 20 weeks LMP, some, but not all, physicians attempt to induce

[3] The evidence suggests that, of the doctors who performed fetal demise prior to enactment of Ohio Rev. Code §2919.15, they likely started doing so to avoid violating the partial birth abortion ban. Specifically, following the enactment of the partial birth abortion (D&X) bans, some doctors who provided D&E procedures began attempting demise starting at later gestations (18 or 20 weeks LMP) to avoid accidentally violating the bans while attempting to perform a D&E. (Keder Direct; Haskell Direct; Rivlin Direct; Liner Direct). This is less of a concern today, because many doctors have found they can reliably avoid violating those bans without performing demise. Thus, some doctors have trended away from digoxin use. (Keder Direct).

Additionally, advancements in medical research have uncovered additional concerns about the risks digoxin presents to patients. (Keder Direct). Consistent with these developments, current Planned Parenthood Federation of America (PPFA) guidelines permit, but do not mandate, digoxin use after 18 weeks LMP. (Liner Redirect).

demise by injecting digoxin either into the fetus (intrafetal) or into the amniotic fluid (intraamniotic). (Keder Direct; Liner Direct; Haskell Direct). Digoxin procedures can be technically challenging for the physician. (Keder Direct; Liner Direct). Although intrafetal injections have higher effectiveness rates than intraamniotic injections, intrafetal injections are more challenging. (Keder Direct).

Physicians at PPGOH never use digoxin to attempt fetal demise before completing a D&E procedure, and physicians at PPSWO and WMCD use digoxin to attempt fetal demise beginning at 18 weeks, and in some cases beginning at 20 weeks. (Keder Direct; Rivlin Direct; Haskell Direct; Liner Direct).

Physicians who administer digoxin do so by using a 3.5-inch spinal needle to inject the drug transabdominally (through the woman's abdomen into the uterus) or transvaginally (through the woman's vaginal wall or the cervix into the uterus). (Keder Direct; Liner Direct; Haskell Direct). When it works, digoxin can take up to 24 hours to be effective. (Valley Direct; Keder Direct; Liner Direct). Therefore, physicians who attempt to cause demise with digoxin generally do so the day before the scheduled D&E procedure. (Keder Direct; Liner Direct; Haskell Direct). [4]

In response to questioning from the Court, the Parties' witnesses agreed that digoxin creates risks of infection and extramural delivery (*i.e.*, delivery of a non-viable fetus outside a health care facility). (Keder Court Examination; Valley Court Examination; *See* JX-14 at 3 (Tocce et al., *Umbilical Cord Transection to Induce Fetal Demise Prior to Second-Trimester*

[4] The State proposes that digoxin could be administered the same day as the cervix is dilated. Therefore, digoxin administration would not necessarily increase the number of patient visits, a point that Plaintiffs do not appear to dispute.

D&E Abortion (Tocce Study II) ("[W]omen who received digoxin experienced higher rates of infection[.]").[5] Extramural delivery is a result of the fact that digoxin causes demise, which accelerates delivery. (Haskell Cross). Digoxin has also been shown to increase risks of digoxin toxicity, cardiac distress, rupture of membranes, damage to maternal vessels, and bleeding. (Keder Direct). When attempting digoxin, a doctor can accidentally hit an artery and cause bleeding, or puncture the small intestine introducing infection into the uterus. (Haskell Direct).

One large, retrospective study of digoxin use found a 1.9% extramural delivery rate for women who received digoxin prior to an abortion, as compared to a 0% rate for those who did not. (JX-6 at 5 (Tocce et al., *Feasibility, Effectiveness and Safety of Transvaginal Digoxin Administration Prior to Dilation and Evacuation*)). Dr. Haskell testified that between 25 and 100 patients have experienced extramural deliveries or threatened extramural deliveries since WMCD began using digoxin. (Haskell Cross).

Extramural deliveries create risks of hemorrhage; they can also be stressful and even emotionally and physically traumatic to patients. (Haskell Direct; Rivlin Direct). Clinics that use digoxin beginning at 18 weeks LMP typically have a rotating call system with physicians and other staff available overnight so a patient can receive an emergency D&E at the outpatient facility if she shows signs of extramural delivery. (Rivlin Direct; Liner Direct; Haskell Direct). However, such programs are not feasible at facilities like PPGOH, where only a few doctors provide part-time care and maintain full practices elsewhere. (Rivlin Direct). Some PPGOH providers already participate in overnight calls at their other practices. (Rivlin Direct).

[5] However, witnesses also agreed that risks of infection and extramural delivery likewise exist when performing D&E without fetal demise.

Digoxin also presents side effects such as nausea and vomiting and can be painful and anxiety-producing for the patient. (Liner Direct). There is no evidence that digoxin makes the D&E procedure safer. (Keder Direct; JX-4 at 9 (Diedrich & Drey, *Induction of Fetal Demise Before Abortion* (SFP Guidelines))). The Society for Family Planning (SFP) has concluded that there are documented risks to digoxin use prior to D&E without a corresponding increase in safety to the woman that would justify subjecting her to those risks. (Keder Direct; Valley Cross; JX-4 at 8-9 (SFP Guidelines)). Likewise, ACOG has concluded that there is no evidence that digoxin increases the safety of abortion procedures. (Keder Direct; JX-35 at 3 (ACOG Practice Bulletin)).

There is virtually no data addressing the use of digoxin in women with pregnancies before 18 weeks LMP—when most D&Es occur in Ohio. (Keder Direct, Liner Direct, Rivlin Direct). Digoxin use prior to 18 weeks LMP would be experimental and entail subjecting women to a procedure with risks that have not yet been quantified. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct).

At all gestational ages, digoxin injections may not be possible for a variety of reasons, such as maternal health conditions, anatomical characteristics, or contraindications. (Valley Cross; Keder Direct; Liner Direct; Rivlin Direct). In a study on digoxin cited by the State, women were excluded for several contraindications, including renal failure and hyperthyroidism. (Valley Direct; JX-3 at 2 (Jackson Study)). Digoxin injections can be dangerous for women with certain cardiac conditions (Keder Direct; Liner Direct; Haskell Direct) or allergies (Haskell Direct; Valley Cross). Digoxin injections are less likely to be successful or achievable for women with obesity (Valley Cross; Haskell Direct; Liner Recross), a history of cesarean sections (Haskell Direct), or uterine fibroids. (Keder Direct; Liner Recross).

Obesity and uterine fibroids are common in Ohio. (Keder Direct; Rivlin Direct). Fetal positioning can also make digoxin administration difficult or impossible. (Keder Direct).

Importantly, digoxin fails to cause demise in up to 10% of cases. (Keder Direct; Rivlin Direct; Haskell Direct). A study cited by the State found that intraamniotic injections had a failure rate of 31%, and the average failure rate of all digoxin injections was 6.6%. (Valley Cross; JX-5 at 3 (Molaei et al., *Effectiveness and Safety of Digoxin to Induce Fetal Demise Prior to Second-Trimester Abortion* (Molaei Study))). The two testifying doctors who use digoxin beginning after 18 weeks LMP reported multiple digoxin failures at their clinics. (Haskell Cross; Liner Direct).

A physician cannot determine in advance if a digoxin injection will fail to cause demise. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct; Valley Cross). The physician would only learn that there was a demise failure when he or she was about to start the evacuation portion of the D&E procedure, approximately 24 hours after the digoxin injection. (Keder Direct; Liner Direct; Haskell Direct). At that point, the woman's cervix would be dilated and her amniotic sac, or membranes, may be ruptured. (Keder Direct).

b. KCl

Fetal potassium chloride injections offer another alternative method to fetal demise. To effect fetal demise via KCl injection, maternal fetal medicine (MFM) specialists administer KCl directly into the fetal heart (intracardiac) to cause fetal demise. (Keder Direct; Ralston Direct). None of the Plaintiffs' providers use KCl prior to a D&E, nor do they possess the requisite training and skill to do so. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct). This testimony is supported by the medical literature:

> Potassium chloride achieves its effect by disrupting the balance of intra- and extracellular potassium ions, decreasing the conduction of action potentials in cardiac myocytes, thus leading to bradycardia and, eventually, asystole. Because it must be administered by intracardiac injection for maximum effect on the myocardium, KCl injection requires more technical skill than intrafetal or intra-amniotic digoxin injection [51].

(JX-4 (*Induction of fetal demise before abortion)*).

When attempting fetal demise with KCl, the intent is to inject it directly into the fetal heart, causing asystole (cessation of cardiac activity). (Valley Direct; Ralston Direct). If the fetal heart is missed, intrathoracic injections may also be successful. (Valley Direct).[6] The procedure typically takes 15 to 20 minutes. (JX-27 ¶ 28 (Ralston Decl.)). If the physician reaches the fetal heart, demise occurs in about two minutes and the physician thereafter completes the evacuation procedure. (JX-11 at 2 (Pasquini et al., *Intracardiac Injection of Potassium Chloride as Method for Feticide*)).

Physicians who administer KCl injections do so by using a needle to inject the drug transabdominally (through the woman's skin, fat, muscle, abdominal cavity, and then the amniotic sac, fetus, and fetal heart) to attempt to cause fetal demise. (Ralston Direct). The fetal heart is a very small, moving target that the specialist must reach. (Ralston Direct). Intracardiac KCl injections become even more difficult when maternal health conditions, such as obesity, uterine fibroids, muscular tumors, or scar tissue, block the uterus. (Ralston Direct). At earlier gestational ages, KCl injections are particularly difficult because of the small fetal heart/thorax,

[6] However, intrathoracic injections are less effective in causing demise. (Ralston Direct). They typically require a higher dosage of KCl, presenting greater risks to the woman. (Valley Cross; Ralston Direct). Like intracardiac KCl injections, the skills needed for intrathoracic injections are beyond that of a typical OB/GYN and much greater than that required for amniocentesis. (Ralston Direct).

which may be a moving target due to patient movement. (Ralston Direct). At later gestations, the additional tissue and increased fetal movement complicate the procedure. (Ralston Direct). If administered incorrectly, KCl injections can cause maternal cardiac arrest. (Valley Cross; Keder Direct; Ralston Direct). KCl injections also pose additional health risks to women, including the risk of infection, bleeding, and accidental bowel perforation, which can cause sepsis. (Ralston Direct).

Intracardiac KCl injections are technically challenging, requiring years of specialized training only available through a three-year MFM subspecialty fellowship undertaken after completion of a four-year OB/GYN residency. (Keder Direct; Liner Direct; Ralston Direct). It is one of the more difficult procedures that MFM specialists perform. (Ralston Direct). In fact, even some MFM fellows do not receive KCl training. (Valley Cross). Others cannot develop the advanced spatial recognition and fine motor skills necessary to accomplish a KCl injection. (Ralston Direct). Of the 20 to 40 MFM fellows or junior faculty members that Dr. Ralston has trained in KCl, 5 to 10 were unable to master the procedure. (Ralston Direct). In the studies relied on by the State, all KCl procedures were completed by MFM specialists. (Ralston Direct).

There is no process or structure in place by which a practicing doctor in Ohio, particularly a non-OB/GYN, could become trained in KCl injections to cause demise. (Liner Direct; Keder Direct). Proficiency in KCl injections requires that a physician first achieve competency in amniocentesis, potentially requiring performing hundreds of such procedures. (Ralston Direct). During his MFM fellowship, Dr. Ralston observed KCl procedures approximately a dozen times himself before attempting to perform one under supervision, even after having performed other intrauterine needle-based procedures. (Ralston Direct). To learn KCl, a doctor in Ohio would have to apply and gain admission to a three-year MFM fellowship

program. (Liner Direct; Keder Direct). MFM specialties require prior OB/GYN certification. (Liner Direct; Ralston Direct). Therefore, doctors in Ohio who are not OB/GYNs, like Dr. Liner, would have to complete a total of seven additional years of education and training to earn an MFM accreditation. (Liner Direct).

Despite Dr. Valley's representations to the contrary, KCl injections are not akin to amniocentesis; they are more complex. (Ralston Direct). During an amniocentesis, a physician inserts a needle into the large, immobile amniotic sac, with the primary concern being avoiding the much smaller fetus. (Ralston Direct). A KCl injection, by contrast, requires the physician to identify the precise location and angle at which to insert the needle to reach the very small and moving fetal heart. (Ralston Direct). In any event, amniocentesis is not taught in current OB/GYN training programs. (Ralston Direct; Keder Direct; Valley Cross).

Additionally, KCl procedures require high resolution ultrasound machines that provide detailed imagery and fine delineation of fetal structure. (Ralston Direct; Haskell Direct and Cross). (See also JX-14) ("Although intrathoracic KCl is highly effective, it requires additional training and a high level of ultrasonography skills and equipment")). These machines are not currently available in Plaintiffs' facilities and can cost up to $250,000 (Ralston Direct; Haskell Direct).

Ultimately, Ohio providers testified that they would be unable to perform KCl injections, because of their lack of experience and adequate equipment. (Liner Direct; Haskell Direct). While KCl is an alternative to digoxin and UCT, the use of KCl to cause demise by Ohio's abortion providers in outpatient facilities is not practicable and would be unsafe for patients. (Ralston Direct).

c. Umbilical Transection

Umbilical cord transection offers another alternative to cause fetal demise. In a transection, a clinician inserts a surgical instrument or suction into the uterus, grasps the umbilical cord, and transects (i.e., cuts) it. Dr. Keder testified that the transection interrupts the blood flow into the fetus, causing the fetus to die. (Keder Direct). None of Plaintiffs' providers use this procedure to cause demise prior to a D&E. (Keder Direct; Liner Direct; Rivlin Direct; Haskell Direct).

Fetal demise follows within minutes of the cord transection, averaging three and a half minutes in one study of the procedure, with an upper limit of 11 minutes. (JX 14 at 714). Dr. Keder agreed that 95 percent of umbilical cord transections in that study caused fetal demise within seven minutes. (Keder Cross).

To transect the cord as envisioned by the State, the physician must rupture the amniotic membranes, grasp the cord with instruments, and divide it. (Keder Direct; Liner Direct; Rivlin Direct). Rupturing the amniotic membranes causes the amniotic fluid to drain from the uterus. (Keder Direct). The physician would then have to wait for cessation of fetal heart tones, which can take up to 11 minutes. (Keder Direct).

The statute provides no guidance, or forgiveness, for accidentally grasping fetal tissue. This is a risk because the physician often cannot see the umbilical cord on ultrasound once the amniotic fluid is drained. (Liner Direct; Rivlin Direct). Without amniotic fluid, the uterus contracts and the fetal tissue, placenta, and cord become compressed into a single mass that is difficult to image on an ultrasound. (Keder Direct; Liner Direct). In such circumstances, there is no way to reliably distinguish the cord from fetal tissue on an ultrasound. (Keder Direct; Liner Direct). This is a particularly significant issue earlier in pregnancy, when the cord is

smaller and thus harder to locate. (Keder Direct; Liner Direct; Rivlin Direct). In response to questioning from the Court, Dr. Valley expressed the view that UCT is the least practicable of the State's three proposed demise methods because of the difficulty in visualizing the procedure on an ultrasound. (Valley Court Examination). The fetus may also drop down when the amniotic fluid is drained, blocking the cervix and preventing the physician from reaching the cord. (JX-22 ¶ 43 (Keder Decl.)).

UCT subjects women to health risks over and above the risks associated with the D&E procedure itself. (Keder Direct; Rivlin Direct). Additional passes of surgical instruments through the cervix and into the uterus to try to locate the cord presents risks of lacerations (Valley Cross), blood loss, uterine perforation, infection (Rivlin Direct), and hemorrhage (Haskell Direct). This is contrary to OB/GYN training, which teaches that doctors should use as few intrauterine passes as possible to minimize the risk of infection or trauma. (Keder Direct). In some instances, performing a UCT requires a physician to reach higher up into the uterine cavity than would otherwise be necessary for a D&E procedure, violating a basic principle of safe D&E performance. (Haskell Direct). UCT also prolongs procedure time for the woman as the physician would need to wait up to 11 minutes after transecting the cord for fetal demise to occur. (Keder Direct; Liner Direct; Rivlin Direct). Any time a surgical procedure is elongated, additional risks are created for the patient. (Valley Cross). Specifically with respect to UCT, during the time the physician waits to confirm fetal demise, the patient would be exposed to additional anesthesia, which increases risks to the patient (Valley Cross; Ralston Direct), and potentially further blood loss (Rivlin Direct).

Furthermore, Dr. Haskell testified that, in 1999, he had performed around 3,000 late-term D&E procedures with only 3 major complications, which equates to a 0.1 percent

complication rate. However, he also testified that these late term D&E procedures averaged 15 minutes, but could take as long as 30 or 45 minutes. (Haskell Cross). Additionally, Dr. Haskell testified that the late term D&E procedures could involve up to 50 passes of the instruments in order to completely remove the fetus and placenta. (Haskell Cross).

At the time the physician is attempting to locate and transect the cord, the woman's cervix will have been dilated, her amniotic sac will have ruptured, and instruments will have already been introduced into the uterus in an attempt to locate the cord. (Keder Direct; Rivlin Direct). Failing to complete the procedure at that point subjects the patient to risks of infection, bleeding, and extramural delivery. (Keder Direct). It is in the best interest of the patient to complete the evacuation procedure as quickly and as safely as possible in order to minimize these risks. (Rivlin Direct).

The inability to effectively visualize the uterine contents also exposes doctors to the risk of violating the statute each time a cord transection is attempted. (Keder Direct; Liner Direct). It is highly likely that a doctor will grasp fetal tissue instead of the cord, violating the express language of S.B. 145. (Keder Direct). The State's witness also recognized this as a potential consequence of UCT. (Valley Cross).

Finally, the Court would note that UCT is minimally researched. (Keder Direct; Liner Direct). The single study discussing the use of routine UCT as a method of inducing fetal demise was a retrospective study based on the charts of one clinic. (Keder Direct; JX-14 at 2 (Tocce Study II)). The foregoing study noted that "[t]here are no published studies to date which specifically examine the characteristics of UCT as a method of inducing fetal demise prior to D&E." (JX-14 at 4).

6. Fetal Pain

Fetal demise would ensure that the fetus cannot perceive pain as it is being dismembered. Dr. Valley testified that the medical literature has not reached a conclusion on fetal pain, and that the issue is disputed. However, the general consensus of the medical community is that fetal pain is not possible before at least 24 weeks LMP, when neural connections to the cortex develop, because a functioning cortex is necessary for pain perception. (Ralston Direct). An article published by the Society of Family Planning explained that:

> [T]he best indicator as to when a fetus has potentially the capacity to experience pain is the development of the thalamocortical axons, which do not occur until at least 29 weeks of gestational duration; however, their functionality within the intrauterine environment has not been determined.

(JX-4 (*Induction of fetal demise before abortion)*).

Every major medical organization that has examined the issue of fetal pain has reached similar conclusions, including ACOG and the Royal College of Obstetricians and Gynecologists (RCOG). (Valley Cross; Ralston Direct). RCOG's 2010 report on fetal pain reviewed "all . . . evidence of relevance to fetal awareness and pain," (JX-38 at 9 (Royal College of Obstetricians and Gynecologists, *Fetal Awareness: Review of Research and Recommendations for Practice* (RCOG, *Fetal Awareness*))), including information from over 50 papers pertaining to functional development and how this evidence may be interpreted (JX-38 at 13 (RCOG, *Fetal Awareness*)). Several peer-reviewed studies have reached similar conclusions. (Ralston Direct; JX-39 at 15-16 (Apkarian et al., *Human Brain Mechanisms of Pain Perception and Regulation in Health and Disease*); JX-40 at 5-7 (Kostovic & Jovanov-Milosevic, *The Development of Cerebral Connections During the First 20-45 Weeks' Gestation*)).

The Royal College of Obstetricians and Gynecologists does note a minority position within their members. In 2007, those minority members submitted a report stating, "We are deeply concerned that the RCOG failed to give full information to the House of Commons Select Committee . . . since 1997 the RCOG has consistently denied that foetuses can feel pain earlier than 26 weeks, without acknowledging that *amongst experts in this field there is no consensus*. Professor Anand is a world authority in the management of neonatal pain and has put forward a cogent argument suggesting that the RCOG position is based on a number of false or uncertain presuppositions." (JX 38 at 1 (emphasis added)).

However, even independent of the majority and minority positions on fetal pain, the medical literature and Plaintiffs' expert's clinical observations also suggest that a fetus 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. (Ralston Direct; JX-42 at 4 (Rigatto et al., *Fetal Breathing and Behavior Measured Through a Double-Wall Plexiglass Window in Sheep*); JX-43 at 3 (Derbyshire, *Can Fetuses Feel Pain*?); JX-44 at 10 (Mellor et al., *The Importance of 'Awareness' for Understanding Fetal Pain*)). In performing procedures that would cause pain to a conscious person, Dr. Ralston has never witnessed a fetus react in a way that would indicate reception to pain. (Ralston Direct).

Accordingly, based on the record medical literature, the Court finds it unlikely that pre-viability fetuses feel pain. The Court recognizes, however, the State's interest in legislating in this area to prevent even the possibility.

7. Informed Consent and Other Ohio Regulations

Abortion care in Ohio is extensively regulated. (Keder Direct). Women must attend a counseling visit at least 24 hours before the procedure for a legally mandated ultrasound,

during which the doctor must describe the fetal development and inform the patient in writing if a fetal heartbeat was detected. (Keder Direct). This requirement adds a third day to an already two-day D&E procedure and creates an obstacle for many patients, some of whom are from rural areas and must travel long distances to a clinic, taking time off from work or school. (Keder Direct). Ohio has banned all abortions after 22 weeks LMP (Keder Direct) and D&X procedures at any gestational age. It requires that each clinic have a written transfer agreement with a hospital located within 30 miles. Ohio Admin. Code § 3701-83-19(E); Ohio Rev. Code Ann. § 3702.303. The Court takes judicial notice that Ohio has just enacted a law banning all abortions after a fetal heartbeat is detected, which would effectively ban most abortions in the State. S.B. 23, 133rd Gen. Assmb. (Ohio 2019).

III. ANALYSIS

As final relief, Plaintiffs seek an Order from this Court declaring Ohio Rev. Code § 2919.15 unconstitutional on its face, and a permanent injunction barring its enforcement. The purpose of a preliminary injunction is to preserve the *status quo* prior to entry of the final order. *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996). In considering a preliminary injunction, the court considers four elements: "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (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." *City of Pontiac Retired Emples. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (per curiam). "These four considerations are factors to be balanced, not prerequisites that must be met." *Kessler v. Hrivnak*, No. 3:11-cv-35, 2011 U.S. Dist. LEXIS 57689, at *8-9 (S. D. Ohio May 31,

2011). "Although no one factor is controlling, a finding that there is simply no likelihood of success on the merits is usually fatal." *Id*.

a. Likelihood of Success

The law is well settled that women possess a fundamental constitutional right of access to abortions. *Roe v. Wade*, 410 U.S. 113, 153-54, 93 S. Ct. 705, 727, 35 L. Ed. 2d 147 (1973). However, the right to terminate a pregnancy is not absolute: "[A] state may regulate abortion before viability as long as it does not impose an 'undue burden' on a woman's right to terminate her pregnancy." *Women's Med. Prof'l Corp. v. Taft*, 353 F.3d 436, 443 (6th Cir. 2003) (quoting *Planned Parenthood v. Casey*, 505 U.S. 833, 876 (1992)). The undue burden test was recently summarized by the Supreme Court as follows: "there exists an undue burden on a woman's right to decide to have an abortion, and consequently a provision of law is constitutionally invalid, if the purpose or effect of the provision is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2300 (2016) (quotation marks omitted). In other words, a regulation of abortion method is constitutional if it (1) imposes no undue burden, and (2) is rationally related to a legitimate state interest, such as the interest in regulating the medical profession and promoting respect for life, including the life of the unborn. *Gonzales*, 550 U.S. at 158. The Court will begin by assessing the "purpose" of Ohio Rev. Code § 2919.15; thereafter, the Court will assess its effect.

1. Purpose of the Act

"One requirement that *Casey* and its progeny establish . . . is that a state regulation that applies to pre-viability stage abortions must have a legitimate or valid purpose

other than simply reducing the number of abortions." *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1318 (11th Cir. 2018). Here, the statute at issue describes in detail the nature of the D&E procedure. Based on the language contained in the statute, this Court concludes that the General Assembly's "description of the prohibited abortion procedure demonstrates [its] rationale for the [prohibition]," *i.e.*, to end a practice that many would find inhumane. *See Gonzales*, 550 U.S. at 156. Consistent with that end, the State represents that legitimate governmental interests justify the statute's limitations on D&E procedures, "as Ohio seeks to promote respect for life, protect the medical community, and eliminate the possibility for pain for the unborn child." (Doc. 25, PageID 254).

Initially, the Court would observe that the weight of medical authority supports Plaintiffs' contention that – in the period where D&E procedures are performed in Ohio – a fetus lacks the necessary connections between its nerves and the cortex to perceive pain. Regardless, the unlikelihood of fetal pain at the relevant gestational age does little if anything to diminish the legitimacy of the State's proffered interests in enacting Ohio Rev. Code § 2919.15. The Supreme Court has held that "[n]o one would dispute that, for many, D&E is a procedure itself laden with the power to devalue human life." *Gonzales*, 550 U.S. at 158. Although context shows that the Supreme Court was referring to intact D&E, or partial birth abortion, the D&E procedure at issue here is just as laden with the power to devalue human life as partial birth abortion. Dismemberment, limb by limb, occurs in both procedures. Indeed, Justice Ginsburg has noted that both methods are equally gruesome. *Id.* at 182.

In light of the above, this Court holds that, even in the absence of fetal pain, the State's proffered rationale for the statute is supported by legitimate governmental interests. Specifically, the act of tearing a living fetus apart could "coarsen" society and the medical

profession "to the humanity of not only newborns, but all vulnerable and innocent human life, making it increasingly difficult to protect such life." *Id.* at 157. Furthermore, "[u]nder [Supreme Court] precedents it is clear the State has a significant role to play in regulating the medical profession." *Id*. at 156. In the context of abortion, the State's interest is especially clear because of the convergence of legal, medical, and moral considerations. The dignity of the medical profession teeters in the balance. While the feasibility (or lack thereof) of the State's alternatives is discussed below, the Court holds that the State's interest in protecting human life and the dignity of the medical profession is legitimate.

2. Effect of the Act

Even where the government acts with a legitimate purpose, a statute governing abortion may still be unconstitutional in effect. *Hellerstedt*, 136 S. Ct. at 2309 (citing *Casey*, 505 U.S. at 877, 112 S. Ct. at 2820; *see also Gonzales*, 550 U.S. at 161 ("The Act's furtherance of legitimate government interests bears upon, but does not resolve, . . . whether the Act has the effect of imposing an unconstitutional burden on the abortion right . . . ."). Whether the statute, in effect, causes an undue burden depends in part on the type of constitutional challenge mounted—facial or "as applied."

a. Facial Challenge

Plaintiffs challenge Ohio Rev. Code § 2919.15 on its face. Initially, the Court would note that, in *Gonzales*, the Supreme Court expressed disfavor for pre-enforcement facial challenges to abortion statutes. 550 U.S. at 168. Specifically, in reviewing the federal ban on partial birth abortion, the Supreme Court stated:

> It is neither our obligation nor within our traditional institutional role to resolve questions of constitutionality with respect to each

> potential situation that might develop. "[I]t would indeed be undesirable for this Court to consider every conceivable situation which might possibly arise in the application of complex and comprehensive legislation." *United States* v. *Raines*, 362 U.S. 17, 21, 80 S. Ct. 519, 4 L. Ed. 2d 524 (1960) (internal quotation marks omitted). For this reason, "[a]s-applied challenges are the basic building blocks of constitutional adjudication."

Id. However, this Court is not convinced that *Gonzales'* preference for as-applied challenges precludes an inquiry into the facial constitutionality of Ohio Rev. Code § 2919.15 in this case. Plaintiffs argue that, unlike the ban on partial birth abortion at issue in *Gonzales*, where alternatives to D&X existed, Ohio's D&E ban absent successful fetal demise leaves physicians with no realistic alternatives. Plaintiffs essentially contend that a ban on D&E paralyzes physicians and in turn their patients in 100% of pre-viability, second trimester cases, because requiring that the doctor first ensure fetal demise forces them to assume risks (such as the need to employ experimental procedures) that leave them with no other choice but to abandon D&E altogether— and again, no alternatives (induction, hysterotomy, etc.) are available in the outpatient setting. Accordingly, the issue Plaintiffs present is sweeping enough in nature, such that the Court will entertain the facial challenge.

b. Large Fraction

The standard for establishing undue burden in the specific context of facial challenges to abortion statutes "has been a subject of some question." *Gonzales*, 550 U.S. at 167 (comparing *Ohio* v. *Akron Center for Reproductive Health*, 497 U.S. 502, 514, 110 S. Ct. 2972, 111 L. Ed. 2d 405 (1990) ("[B]ecause appellees are making a facial challenge to a statute, they must show that no set of circumstances exists under which the Act would be valid" (internal quotation marks omitted)), with *Casey*, 505 U.S., at 895, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (opinion of the Court) (indicating a spousal-notification statute would impose an undue

burden "in a large fraction of the cases in which [it] is relevant" and holding the statutory provision facially invalid)). However, the Parties generally agree that *Casey*'s "large fraction" standard applies. (Defendants' Opp., Doc. 25, PageID 266); (Plaintiffs' Reply, Doc. 28, PageID 559). *Accord*: *Cincinnati Woman's Servs. v. Taft*, 468 F.3d 361, 367 (6th Cir. 2006) (holding that to prevail a plaintiff must show that "in a large fraction of the cases in which [the abortion restriction] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion").

Initially, the Court would note – as it did in the TRO – that other courts that have reviewed state statutes similar to the one at issue here have declared them unconstitutional. *See, e.g.*, *Williamson*, 900 F.3d at 1310; *Whole Woman's Health v. Paxton*, 280 F. Supp. 3d 938 (W.D. Tex. 2017). However, the State has argued since the inception of this litigation that the *Paxton* court's decision was based on a mistaken belief, in reliance on *Hellerstedt*, that the challenged legislation must always confer "medical benefits" on a woman to be constitutional. Specifically, the State argues that an analysis of "medical benefits" applies only where a state cites health/safety reasons as its legitimate governmental purpose for legislating, and such a rationale was not offered by the State here. In other words, if a state offers such a rationale, then it must back it up with health-based evidence. In light of the Supreme Court's opinions predating *Hellerstedt*, the Court generally agrees, as it is skeptical that *Hellerstedt* meant to require a medical or health "benefit" to the woman for every restriction on pre-viability abortion, regardless of the subject matter of the legislation. That said, the Court believes that the *Paxton* court would have reached the same result with or without a "medical benefit" analysis because, at the end of the day, it determined that the legislation at issue burdened a "large fraction" of

women. *Paxton*, 280 F. Supp. 3d at 952. The State's argument is noted, but the Court still treats *Paxton* as persuasive authority.

Also, the Court must address the State's argument that the Court must defer to the State's factfinding in this case. The Court disagrees. The Act includes no legislative factfinding. Even if it had, such factfinding is not entitled to "[u]ncritical deference." *Gonzales*, 550 U.S. at 166. Courts "retain[] an independent constitutional duty to review factual findings where constitutional rights are at stake." *Id*. at 165. The Court will thus preliminarily weigh the evidence presented in this case.

Here, Plaintiffs presented significant, credible evidence via declaration and at the evidentiary hearing supporting that the Act's implicit fetal demise requirement causes an undue burden to a large fraction of women. Each of the State's suggested demise options have serious drawbacks, that vary depending on the gestational age and size of the fetus. While these gestational periods are certainly discussed in each of the parties' position papers, they are not addressed in the Act, which is technically silent on the issue of fetal demise. The most obvious issues linked to gestational age/size are the unstudied nature of digoxin prior to 19 weeks, and the failure rate that exists post-19 weeks; the highly specialized skill, training, knowledge and equipment required for KCl injections, which are rendered even more difficult where fetal size is small; and the risk of grasping fetal material in the UCT procedure, which is particularly likely when the umbilical cord is small.

Furthermore, of the above methods, digoxin is the only method being used in Ohio clinics with any degree of regularity – generally, to avoid accidentally violating the partial birth abortion ban – but it simply cannot be used in all pre-viability, second trimester abortions. The Court has preliminarily found that: (1) digoxin may be contraindicated due to, *inter alia*,

patient allergies, patient cardiac issues, or gestational age (*i.e.*, there is no research regarding the safety/efficacy of digoxin prior to 19 weeks, making its administration arguably experimental); (2) digoxin may be difficult or impossible to administer into the amniotic fluid/fetus with a needle due to patient obesity or fibroids, which is a common issue for women seeking D&E; (3) medical literature supports that digoxin fails up to 10% of the time, and there is no research on whether it is safe to administer a second dose of digoxin to effect demise. The existence of potassium chloride and UCT, as either primary or backup demise methods, does not offer an acceptable safety net that would allow doctors to move forward. Potassium chloride is dangerous to the woman, so it is imperative that the target (a small fetal heart or thorax) not be missed. Accordingly, the administration of potassium chloride is a precise procedure requiring that a maternal fetal medicine specialist use advanced ultrasound technology that exists only in hospitals. Contrary to Dr. Valley's testimony, the Court is not persuaded that the skill or equipment to perform potassium chloride injections in the outpatient setting can be readily obtained.[7] UCT is also not a feasible primary or backup option, because it requires that the amniotic sac be punctured and that the cord be located without accidentally dismembering the fetus, which is not always possible due to diminished ultrasound clarity and fetal positioning. The State claims that it would not prosecute such accidental dismemberments, but "[m]id-

[7] Drs. Ralston and Valley clearly approach the issues from different perspectives. This does not automatically disqualify either witness' testimony if such testimony is supported by the medical and scientific record. It is the court's job to determine the persuasiveness of the testimony and evidence. Dr. Ralston's testimony was supported by theories and techniques that have been medically and scientifically tested and subjected to peer review published literature. The known and potential rates of error for injections is likewise well published, and his testimony is in accordance research generally accepted by the medical community. While Dr. Valley's testimony has limited support, Dr. Ralston's opinions on fetal pain and needle procedures are shared by a much broader expanse of the medical and scientific community, and is therefore more persuasive in the Court's determination of the issues.

litigation assurances are all too easy to make and all too hard to enforce, which probably explains why the Supreme Court has refused to accept them." *Williamson*, 900 F.3d at 1328 (citing *Stenberg*). Indeed, nothing prevents the State from later taking the position that *scienter* to violate the Act is present when a physician even attempts UCT, because the substantial risk of dismemberment is always there. Finally, abandoning the D&E mid-procedure is also not an option, because the cervix has already been dilated. Sending the patient home without completing the D&E creates a significant risk of extramural delivery.

In the face of the foregoing complications, the State points to the statute's medical exception to rebut Plaintiffs' undue burden argument. However, the medical exception is narrowly drafted at best, and unconstitutionally vague at worst.[8] The exception states that D&E may be performed if it is necessary "in reasonable medical judgment [of the physician], to preserve the life or physical health of the mother as a result of the mother's life or physical health being endangered by a serious risk of the substantial and irreversible physical impairment of a major bodily function." Ohio Rev. Code § 2919.15(B) (emphases added). This exception does not adequately resolve the quandary faced by physicians presented with the failure of a demise procedure: at what point in the process does a physician determine the existence of a "serious risk" of "substantial and *irreversible* physical impairment of a major bodily function" – when the demise attempt first fails? After a second, experimental attempt is made? After the physician engages in an undefined wait-and-see period during which his or her patient is experiencing blood loss while anesthesia wears off? Doctors who take early action will be the subject of

[8] To be clear, the Court is not passing on the issue of vagueness at this time. Based on the testimony of Plaintiffs' witnesses, however, the Court has significant concerns regarding the potential vagueness of the medical exception that the Court will consider before entering final judgment in this case.

opinionated second-guessing (and potential prosecution), while procrastination increases the risk of harm to the patient. In the case of digoxin failures, doctors would thus be forced to choose between: violating the law and proceeding with the evacuation procedure; attempting a second digoxin injection or demise method, which attempts are untested and additionally risky (Keder Direct); allowing the patient to deteriorate to the point where the physician felt that the exception applied (JX-22 ¶ 35 (Keder Decl.)); or abandoning the patient, in contravention of professional and ethical responsibilities (Rivlin Direct), despite the risks attendant to having already dilated the patient's cervix. Digoxin is the most feasible of the three methods (where a patient is even a candidate for it), yet the worst-case scenario still lurks at the outset of every D&E because the doctor has no safety valve or backup to select if digoxin fails. The medical exception is inadequate. *Casey*, 505 U.S. at 879 (citing *Roe v. Wade*, 410 U.S. 113, 164-65, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973));*Stenberg v. Carhart*, 530 U.S. 914, 854, 120 S. Ct. 2597, 2612 (2000).

The Court thus concludes, based on the current record, that Plaintiffs are likely to succeed on the merits. While the Court is cognizant of the Supreme Court's warning in *Gonzales* that lower courts are not to declare legislation unconstitutional after focusing on "every conceivable situation" that could arise, the Court does not believe that that warning applies here. In *Gonzales*, a feasible backup procedure was available. 550 U.S. at 165 ("Alternatives are available to the prohibited procedure. As we have noted, the Act does not proscribe D&E."). No such backup procedure exists here. D&E is the only pre-viability second trimester abortion method available in the outpatient setting in Ohio. Without the option of selecting a different method, or the ability to rely on a sufficiently broad medical exception, physicians who perform D&E are presented with a series of demise options that layer risks on top of existing risks (particularly where demise fails after the first attempt), forcing doctors who perform D&E down

a path of no return should they be unable to effect pre-D&E demise. The literature supports that failure to cause demise could arise for at least 10% of women who are even candidates for digoxin; trying a second injection or demise method is experimental; and abandoning D&E, and releasing the still-pregnant patient with a dilated cervix, creates the risk of extramural delivery. To avoid this scenario, doctors may be forced to demur from performing pre-viability, second trimester abortions altogether. *Stenberg v. Carhart*, 530 U.S. 914, 945-46, 120 S. Ct. 2597, 2617 (2000). The Act thus burdens a "large fraction" of women seeking pre-viability, second trimester abortion.

The Court could consider a different conclusion had the State sought through the Act to require fetal demise after 18 weeks LMP, when the medical literature supports usage of digoxin; used language similar to Ohio's partial birth abortion ban, which only requires that demise be "attempted,"[9] thus eliminating the medical quandary inherent to making a second, experimental demise attempt; and included a medical exception broad enough to provide doctors the ability to use their judgment when demise fails without fear of prosecution. However, the Act as written, combined with the record evidence regarding the science currently at the disposal of Ohio physicians practicing in the outpatient setting, makes it unlikely that the can State overcome Plaintiffs' challenge. [10]

[9] See Ohio Rev. Code § 2919.151(G).

[10] The State cites Plaintiffs' ability to comply with this court's TRO as evidence that statute does not impose an undue burden. The difficulty in this logic is that the Court's TRO dealt with and addressed, on a temporary basis, the readily apparent flaws in the legislation. Based on the record before the Court, the Act as written presents substantial obstacles to a large fraction of Plaintiffs' patients, as evidenced by the experimental aspect of the pre-18 week demise procedures cited by the Court.

As for the preliminary remedy: the Parties at various points have suggested that the Court consider at least partial preliminarily relief, as opposed to wholesale relief for the opposing side. The Court construes these requests as triggering the Supreme Court's requirement to determine whether "finely drawn" relief is appropriate and possible. *Ayotte v. Planned Parenthood*, 546 U.S. 320, 331, 126 S. Ct. 961, 969 (2006). In *Ayotte*, the Supreme addressed "three interrelated principles [that] inform [courts'] approach to remedies":

> First, the Court seeks to avoid "nullify[ing] more of a legislature's work than is necessary," because doing so "frustrates the intent of the elected representatives of the people." *Id*. For this reason where partial, rather than facial, invalidation is possible, it is the "required course." *Id*. Second, the Court noted that "mindful that our constitutional mandate and institutional competence are limited, we restrain ourselves from rewriting state law to conform it to constitutional requirements even as we strive to salvage it." *Id*. This consideration counsels in favor of looking to how clearly the court has "already articulated the background constitutional rules at issue and how easily we can articulate the remedy." *Id*. Thus where the Court has established a bright line constitutional rule, it is more appropriate to invalidate parts of the statute that go beyond the constitutional line, whereas "making distinctions in a murky constitutional context, or where line-drawing is inherently complex, may call for a 'far more serious invasion of the legislative domain' than we ought to undertake." *Id*. at 330 (quoting *United States v. Nat'l Treasury Employees Union*, 513 U.S. 454, 479 n.26, 115 S. Ct. 1003, 130 L. Ed. 2d 964 (1995)). Finally, the Court considers legislative intent, and inquires whether the legislature would prefer to have part of the statute remain in force. *Id*. At the same time, however, the Court is "wary of legislatures who would rely on our intervention," because where states merely cast as wide a net as possible and leave it to the courts to determine the permissible extent of a statute's reach, they run the risk of delegating legislative authority to the judiciary. *Id*.

Northland Family Planning Clinic, Inc. v. Cox, 487 F.3d 323, 333-34 (6th Cir. 2007) (quoting *Ayotte*).

Here, the Court will begin with the first and third considerations. While Plaintiffs seek facial relief, and the Court has deemed Plaintiffs likely to prevail on their facial challenge to

the statute, the Court nonetheless has concerns about entering a full injunction based on an expedited record developed without discovery. The Court construes *Ayotte* and *Northland Family Planning* as permitting, and in some situations requiring, partial interim relief. *See Taft*, 444 F.3d at 517. And the Court believes that partial interim relief is supported by the statute's legislative intent. Indeed, the Court has little doubt that the Ohio General Assembly would rather have part of its statute survive than see it entirely enjoined, particularly where the Court has not yet reached final resolution on the merits. This intent is evidenced by the State's papers, where it invites the Court to "craft a remedy," as well as the Act's severability section. *See* Ohio Rev. Code § 2919.205. While the Court does not wish to encourage the State to cast the widest net possible, at the end of the day, a partial injunction will end dismemberment of living fetuses in cases where demise can be performed safely and non-experimentally. Such a result aligns with the intent of the State's elected representatives.

The second consideration looks to whether drawing such lines is even practicable. Initially, the Court would note that "there is a meaningful distinction between partially invalidating or severing a statute (the course preferred under *Ayotte*), and adopting a narrowing construction[.]" *Id*. at 335. "It may well be that a strained narrowing construction has more potential to amount to judicial rewriting of the statute than does partial invalidation, even though the two appear to be closely related." *Id*. Regardless, "if either of these more limited remedies is available, they [are the] preferred course." *Id*. Here, the Court is navigating the constitutional boundaries of an unwritten part of the statute. Specifically, fetal demise is not even mentioned in the Act. Thus, it would not be accurate to state that the Court is "invalidating" a portion of the Act, the way some courts might "invalidate" a subsection of a statute requiring spousal notice (for example) based a "bright line" constitutional rule. Instead, any grant of partial relief here

would require the Court to engage in a narrowing construction, where it becomes more and more difficult to avoid judicial rewriting. However, this will be a graver concern once the Court reaches the final merits of this case. At present, however, the record before the Court enables it to preliminarily identify specific categories of criminal prosecutions that must be enjoined to avoid running afoul of the Constitution. The Court's ability to identify these categories suggests that a limited remedy is indeed available, so, as reflected in Section V below, the Court will enter a partial preliminary injunction.

b. Irreparable Harm/Harm to Others

The Court will apply the same analysis here that it applied at the TRO phase. "[A] plaintiff can demonstrate that a denial of an injunction will cause irreparable harm if the claim is based upon a violation of the plaintiff's constitutional rights." *Overstreet v. Lexington-Fayette Urban Cty. Gov't*, 305 F.3d 566, 578 (6th Cir. 2002). *Accord*: *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of [constitutional] freedoms … unquestionably constitutes irreparable injury."). While physicians do not possess a constitutional right to perform abortions, they do generally have standing to assert constitutional challenges on behalf of their patients in the abortion context. *Planned Parenthood of Greater Ohio v. Hodges*, No. 16-4027, 2019 U.S. App. LEXIS 7200, at *8 (6th Cir. Mar. 12, 2019) (*en banc*). As the Court has preliminary found that the Act creates an undue burden to a "large fraction" of women seeking a pre-viability, second trimester abortion, particularly in the 15-18 week range, the second and third factors weigh in favor of Plaintiffs.

c. Public Interest

"The public interest is promoted by the robust enforcement of constitutional rights," *Am. Freedom Def. Initiative v. Suburban Mobility Auth. for Reg'l Transp.*, 698 F.3d 885, 896 (6th Cir. 2012), and it is in the public's interest to uphold those rights if they are being denied "absent medical or other legitimate concerns." *Doe v. Barron*, 92 F. Supp. 2d 694, 697 (S.D. Ohio 1999). Because the record at this juncture supports that the Act creates an undue burden to a large fraction of women seeking a pre-viability, second trimester abortion, a preliminary injunction serves the public interest.

IV. BOND

The Court waives the bond requirement of Rule 65(c) of the Federal Rules of Civil Procedure. *Moltan Co. v. Eagle-Picher Indus., Inc.*, 55 F.3d 1171, 1176 (6th Cir. 1995) (district court has discretion to issue preliminary injunction with no bond); *Roth v. Bank of the Commonwealth*, 583 F.2d 527, 539 (6th Cir. 1978) (same).

V. CONCLUSION

The Motion (Doc. 4) for preliminary injunction is **GRANTED IN PART**. Consistent with the above, the Court declines to enjoin Defendants from enforcing Ohio Rev. Code § 2919.15 in its entirety. Each side has asked this Court, in the alternative, to enter a partial injunction. (Defendants' Opp., Doc. 25, PageID 258) (inviting Court to "craft a remedy"); (Plaintiffs' Reply, Doc. 28, PageID 560) (including alternative request for partial injunction if the Court disinclined to grant wholesale relief to Plaintiffs). Therefore, the Court **ORDERS** as follows: Defendants David Yost, Michael O'Malley, Ronald O'Brien, Joseph Deters, and Mathias Heck, in their respective official capacities, as well as their employees, agents, and successors, and all those acting in active concert with them, are **PRELIMINARILY**

ENJOINED from prosecuting or otherwise pursuing legal action against medical professionals based alleged violations of Ohio Rev. Code § 2919.15 accruing during the pendency of this Court's temporary and preliminary orders, in the following circumstances:

1. Where a physician performs D&E procedure before 18 weeks LMP;

2. Where, during the course of a D&E procedure, a physician accidentally removes fetal parts when intending to comply with demise requirements;

3. Where a physician performs a D&E procedure after an attempted demise procedure fails;

4. Where a physician performs a D&E procedure without demise after making a medical determination that a given patient is not a candidate for a demise procedure, either because a procedure is contraindicated or medically impossible for that patient.

Based on the text of the statute, it is the Court's understanding that a physician may perform a D&E procedure if such a procedure is necessary, "in reasonable medical judgment [of the physician], to preserve the life or physical health of the mother as a result of the mother's life or physical health being endangered by a serious risk of the substantial and irreversible physical impairment of a major bodily function," Ohio Rev. Code § 2919.15; thus, these circumstances are already covered by the statute and need not be included in the above preliminary injunction. Indeed, no party requested that such language be included in the Order.

Consistent with the above, there is no requirement of a bond. This Order is effective upon entry.

IT IS SO ORDERED.

s/*Michael R. Barrett*
Hon. Michael R. Barrett
United States District Judge