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IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

ENTERED
AUG 29 2024

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, ET AL.,	:	CASE NO. A 2101148
Plaintiffs,	:	JUDGE ALISON HATHEWAY
-vs.-	:	
OHIO DEPARTMENT OF HEALTH, ET AL.,	:	**DECISION AND ORDER GRANTING PLAINTIFFS' SECOND MOTION FOR PRELIMINARY INJUNCTION**
Defendants.	:	

This matter is before the Court upon Plaintiffs Planned Parenthood of Southwest Ohio ("PPOSW"), Dr. Sharon Liner, and Planned Parenthood of Greater Ohio ("PPGOH"), Julia Quinn, MSN, WHNP-BC Women's Med Group Professional Corporation ("WMGPC") and Preterm-Cleveland's Second Motion for Preliminary Injunction, filed on May 22, 2024. The Court held a Telephone Report on July 9, 2024, where the parties waived oral arguments and agreed to submit on their briefs. Therefore, the Court, having considered the Motion, responsive briefs, and being fully apprised of the relevant facts and laws, finds Plaintiffs' Motion to be well-taken and **GRANTS** the same.

I. BACKGROUND

Dr. Sharon Liner, PPOSW, and PPGOH originally brought this action against Defendants asserting claims for violations of the Ohio Constitution's equal protection and benefit guarantee under Article 1, Section 2, and the Ohio Constitution's protections for individual liberty under Article 1, Sections 1, 2, 16, 20, and 21. Specifically, Plaintiffs sought temporary, preliminary, and permanent injunctive relief and a declaratory

judgment against a ban on the provision of medication abortion via telemedicine, R.C. 2919.124(B) (the "Telemedicine Ban"). After entering a temporary restraining order, this Court issued a preliminary injunction on April 19, 2021 ("PI Order"), prohibiting Defendants from enforcing the Telemedicine Ban until final judgment is entered in this case.

In November 2023, Ohioans voted to enshrine an affirmative right to abortion in the Ohio Constitution. Ohio Const., art. I, § 22 (the "Amendment"). As a result, the Ohio Constitution now explicitly protects every Ohioan's "right to make and carry out [their] own reproductive decisions," including decisions related to abortion. *Id.* at § (A)(5). The Amendment further mandates the following:

> The State shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against either: (1) "[a]n individual's voluntary exercise of this right or (2) [a] person or entity that assists an individual in exercising this right, unless the State can show that it is using the least restrictive means to advance patient health in accordance with widely accepted and evidence-based standards.

Id. at § 22(B).

Because of this Amendment's passage, this Court granted, without opposition from Defendants, Plaintiffs' Motion for Leave to File Amended Complaint. *See* Court's May 14, 2024 Order. Plaintiffs' Amended Complaint adds Julia Quinn, MSN, WHNP-BC; Women's Med Group Professional Corporation ("WMGPC"); and Preterm-Cleveland as additional Plaintiffs. Further, the Amended Complaint challenges two new categories of restrictions on medication abortion, in addition to the Telemedicine Ban: (1) a series of laws that together prohibit qualified and skilled healthcare providers known as advanced practice clinicians ("APCs") from providing medication abortion, regardless of their education, training, and experience, R.C. 2317.56(B), 2919.123, 4723.44(B)(6),

4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm. Code 4723-9-10(K), 4730-2-07(E) (collectively, the "APC Ban") and (2) a ban on prescribing mifepristone – one of two drugs used in the most common medication abortion regimen – for abortion in any way that differs from the formulation set forth in the U.S. Food and Drug Administration's ("FDA") label for the drug, including in otherwise safe, widely-accepted and evidence-based "off-label" formulations, R.C. 2919.123 (the "Evidence-Based Use Ban").

Plaintiffs assert that these statutes are now unconstitutional as a result of the Amendment and seek a second preliminary injunction to enjoin the APC and Evidence-Based Use Bans. Specifically, Plaintiffs argue all three of the Bans unduly burden and discriminate against citizens from making and carrying out their reproductive decisions by limiting access to medication abortion in ways that provide no additional harm reduction and do not reflect the current evidence-based standard of care. In response, the State argues that the Plaintiffs lack standing to bring these claims and that, regardless of standing, the challenged laws fulfill its duty to protect the health and safety of all Ohioans, including those who exercise their right to have an abortion.

A. Abortion in Ohio and Plaintiffs' Medication Abortion Services

Reiterating this Court's findings in its first Preliminary Injunction Entry, Plaintiffs have presented evidence to support the following facts regarding abortion in Ohio and their medication abortion services, which Defendants did not dispute. Plaintiffs state there are two main methods of abortion, medication abortion and procedural abortion, and that both are effective in terminating pregnancy. Currently, medication abortion is available in Ohio up to 10 weeks of pregnancy, and involves patients taking two different medications one to two days apart. Because of current state law requirements, patients

must make two separate visits to a health center to obtain an abortion, at least 24 hours apart: the first for state-mandated informed consent and an ultrasound, and the second for the abortion itself.[1] In the case of medication abortion, the second visit is for the purpose of providing and consumption of the initial medication of the regimen (mifepristone). Patients take the second medication in the regimen (misoprostol) one to two days after the second visit at a location of their choosing, usually at home.

Since state law requires the first visit to be in person with a physician, patients must visit one of Plaintiffs' three surgical facilities in the State that have a physician present at all times: Cincinnati, East Columbus, or Bedford Heights. For patients seeking medication abortion, they have the option for their second visit to return to a surgical facility or to visit one of Plaintiffs' other locations in Dayton or Hamilton (for PPSWO patients) or in Mansfield or Youngstown (for PPGOH patients), where they can video conference with a physician who is at one of the surgical facilities.

Medication abortion, at issue here, and abortion in general, are among the safest treatments in contemporary medical practice. Pl. Ex. 1 ("Grossman Aff."), ¶ 50; *see also* Pl. Ex. 8 ("Grossman 2021 PI Aff."), ¶ 8. Further, many patients, for a variety of reasons, strongly prefer medication abortion over procedural abortion. Pl. Ex. 5 ("Liner Aff."), ¶ 25; Grossman 2021 PI Aff. at ¶¶ 52-53. For instance, patients may prefer medication abortion because they can end their pregnancy at home, when it is the best time for them, and because it allows them more privacy. Grossman 2021 PI Aff. at ¶ 52; Pl. Ex. 10 ("Liner 2021 PI Aff."), ¶ 29. In addition, patients who have experienced sexual assault or abuse

[1] On August 26, 2024, Plaintiffs filed a Notice of Supplemental Authority stating the Franklin County Court of Common Pleas recently issued a preliminary injunction prohibiting the State from enforcing Ohio's 24-hour abortion waiting period, in-person visit requirement, and state-mandated information requirements for abortion. *See Preterm-Cleveland v. Yost*, Franklin C.P. No. 24-CV-2634 (Aug. 23, 2024).

may choose medication abortion to feel more in control of the experience and to avoid re-traumatization from the insertion of instruments into the body – whereas procedural abortions may feel especially traumatic or invasive. Grossman 2021 PI Aff. at ¶ 52; Liner Aff. at ¶25; Pl. Ex. 3 ("Krishen Aff."), ¶ 35. Further, and aside from personal preference, some patients may require medication abortions based on medical contraindications for procedural abortions (e.g., some patients have medical conditions where medication abortion would be significantly safer than procedural abortions, including uterine fibroids, congenital abnormalities, severe obesity, or an extremely flexed uterus). Grossman 2021 PI Aff. at ¶ 53; Liner 2021 PI Aff. at ¶ 29.

B. Challenged Statutes

a. APC Ban

In addition to challenging the Telemedicine Ban, Plaintiffs' Amended Complaint also challenges the APC Ban and the Evidence-Based Use Ban. Because of the APC ban, only physicians can provide abortion care, including medication abortion, in Ohio. *See* R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.41(A)(1); Adm. Code 4723-9-10(K), 4730-2-07(E). Moreover, APCs, which includes Nurse Practitioners ("NPs"), Certified Nurse Midwives ("CNMs"), and Physician Assistants ("PAs"), are expressly prohibited from prescribing any "drug or device to perform or induce an abortion." R.C. 4723.44(B)(6), 4730.02(E), Adm. Code 4723-9-10(K), 4730-2-07(E). Additionally, non-physicians are prohibited from providing, selling, dispensing, or administering mifepristone "for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person." R.C. 2919.123(A). Consequences for violating the APC Ban include criminal

charges, civil penalties, civil forfeiture, and professional sanctions. R.C. 4723.28(B)(30), 4723.99(A), 4730.25(B)(24), 4730.252, 4730.99(A).

b. Evidence-Based Use Ban

The Evidence-Based Use Ban, enacted in 2004, prohibits abortion providers from prescribing mifepristone for abortion care in any way that differs from the express terms of mifepristone's final printed labeling as incorporated by the drug's FDA approval letter. R.C. 2919.123. This practice is commonly known as "evidence based" or "off-label" use of a drug. R.C. 2919.123 also reiterates the provision that mifepristone cannot be administered by anyone who is not a licensed physician. R.C. 2919.123(A). Therefore, when prescribing mifepristone for the purpose of inducing an abortion, an Ohio healthcare provider may do so "only by using the dosage indications and treatment protocols expressly approved by the FDA in the drug's printed labeling as incorporated by the drug approval letter." *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972, 911 N.E..2d 871, ¶ 35 (interpreting R.C. 2919.123).

The regimen currently specified on mifepristone's final printed labeling, as approved by the FDA in 2016, is 200 mg of mifepristone taken orally, followed 24 to 48 hours later by 800 mg of misoprostol taken buccally through 70 days from the first day of a pregnant person's last menstrual period ("LMP"). Liner Aff. at ¶ 15, Grossman Aff. at ¶ 67. A violation of 2919.123 is a fourth-degree felony, raising to a third-degree felony for repeat offenses. R.C. 2919.123(D). Physicians or licensed clinicians who do not adhere to the statute may also face sanctions or revocation of their licenses. *Id.* Importantly, these consequences result even when a provider determines, based on the best-available medical evidence, that an off-label use of mifepristone is more medically appropriate for a particular patient.

II. LEGAL STANDARD

A. Preliminary Injunction Standard

To succeed on their motion for preliminary injunction, Plaintiffs must show (1) a substantial likelihood that they will prevail on the merits, (2) that they will suffer irreparable injury if the injunction is not granted, (3) that no third parties will be unjustifiably harmed if the injunction is granted, and (4) that the public interest will be served by the injunction. *de Cavel v. DCHW*, 1st Dist. Hamilton No. C-100221, 2011-Ohio-549, ¶ 7, citing *Procter & Gamble Co. v. Stoneham*, 140 Ohio App.3d 260, 267, 747 N.E.2d 268 (1st Dist. 2000). In addition, Plaintiffs must prove these elements by clear and convincing evidence, or "that measure or degree of proof which will produce in the mind of the trier of facts a firm belief or conviction as to the allegations sought to be established." *Miami Twp. Bd. of Trustees v. Weinle*, 2021-Ohio-2284, 174 N.E.3d 1270, ¶¶ 25-26 (1st Dist.), citing *State v. City of Cincinnati Citizens' Complaint Auth. and Black United Front*, 2019-Ohio-5349, 139 N.E.3d 947, ¶ 21 (1st Dist.), *Cross v. Ledford*, 161 Ohio St. 469, 477, 120 N.E.2d 118 (1954).

Plaintiff and Defendant agree that one purpose of preliminary injunctions is to preserve the status quo. The State argues this Court cannot enjoin the APC and Evidence-Based Use Bans because these statutes were in effect prior to the Amendment's passage. Therefore, the State argues, a preliminary injunction cannot be issued here because these statutes preserve the status quo. However, as Plaintiffs argue, the status quo shifted drastically in December 2023 when the Amendment went into effect. At that time, pre-existing laws that may not have been inflicting constitutionally cognizable harm prior to the Amendment, began to do so once it went into effect. Further, the State ignores that the very nature and purpose of the Amendment was to disrupt the status quo. Ohioans,

through the democratic process, voted to pass the Amendment to enshrine into our Constitution new rights and protections, which immediately nullified the status quo prior to its passage.

B. Ohio's Constitutional Right to Reproductive Freedom

Since the Amendment passed in November 2023, the Ohio Constitution now broadly protects an individual's "right to make and carry out one's reproductive decisions, including but not limited to decisions on...abortion." Ohio Const., art. I, § 22(A)(5). Further, the Amendment states

> The State shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against either: (1) "[a]n individual's voluntary exercise of this right or (2) [a] person or entity that assists an individual in exercising this right, unless the State can show that it is using the least restrictive means to advance patient health in accordance with widely accepted and evidence-based standards.

Id. at § 22(B).

Interpreting voter-enacted constitutional provisions requires Ohio courts to "consider how the language would have been understood by the voters who adopted the amendment." *State v. Yerkey*, 171 Ohio St.3d 367, 2022-Ohio-4298, 218 N.E.3d 749, ¶ 9, quoting *Castleberry v. Evatt*, 147 Ohio St. 30, 33, 67 N.E.2d 861 (1946). From Plaintiffs' perspective, the text of the Amendment is clear and straight forward. The State, however, believes this Court should examine the context surrounding the passage of the Amendment. Specifically, the State claims the purpose of the Amendment was to restore the pre-*Dobbs* regime.[2] This Court may have been inclined to examine the context surrounding the Amendment's passage if the language of the Amendment was unclear or

[2] In *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), the U.S. Supreme Court held that the United States Constitution does not confer a right to abortion, overturning *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992) – which is the "pre-*Dobbs*" regime the State refers to that allowed the APC and Evidence-Based Use Bans.

ambiguous, but it is not. *Id.*, citing *City of Centerville v. Knab*, 162 Ohio St.3d 623, 2020-Ohio-5219, 166 N.E.3d 1167, ¶ 22 (where a provision's language is unclear or ambiguous, courts may consider the "history of the amendment and the circumstances surrounding its adoption, the reason and necessity of the amendment, the goal the amendment seeks to achieve, and the remedy it seeks to provide").

The Amendment's language plainly establishes that it offers greater protection of individuals' rights to make their own reproductive choices than those adopted by the U.S. Supreme Court in *Roe* and *Casey*, which make up the pre-*Dobbs* regime the State references. *See Roe v. Wade*, 410 U.S. 113 (1973); *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). In fact, the Amendment could have followed the language from either of those cases, but it did not. Indeed, prior to the Amendment's passage, Ohio Attorney General Dave Yost himself recognized that the Amendment's plain text "creates a new, legal standard that goes beyond what *Roe* and *Casey* said" and gives "greater protection to abortion to be free from regulation than at any point in Ohio's history."[3] The State now attempts to argue that Yost's statement was published prior to an "October wave of reassurances to the public that no such broader effects arose from the Amendment." Def. Memo. in Opp. at 19. This "wave," the State argues, suggested that the Amendment could restore *Roe*. Even if true, which the State fails to provide support for this claim, and had Yost changed his mind because of an "October wave of reassurances to the public that no such broader effects arose from the Amendment" nothing prevented him from providing another analysis or opinion on the matter. But he did not.

[3] *Issue 1 on the November 2023 Ballot: A Legal Analysis by the Ohio Attorney General*, at 3, 5-6 (Oct. 5, 2023), https://www.ohioattorneygeneral.gov/SpecialPages/FINAL-ISSUE-1-ANALYSIS.aspx.

Thus, the Amendment explicitly sets an applicable legal standard – one that places a stringent burden on the State. Under the Amendment, patient health is the only state interest that an abortion regulation may constitutionally advance. Therefore, any restrictions on abortion must be narrowly tailored to further protect patient's health *and* such restrictions must be the least restrictive means to advance the patient's health "in accordance with widely accepted and evidence-based standards."

III. LAW AND ANALYSIS

A. Plaintiffs Are Substantially Likely to Succeed on Their Claims

1. *Plaintiffs are substantially likely to prevail against Defendants' threshold challenges to their standing and the availability of relief they seek.*

Defendants have reiterated some of the same standing arguments that this Court addressed in its first preliminary injunction order. Defendants again argue that, to the extent Plaintiffs bring claims on behalf of their patients, those claims are barred because Plaintiffs lack third-party standing. As pointed out by Plaintiffs, the new Amendment confers standing to those persons or entities whose rights are burdened, penalized, prohibited, or interfered with. Ohio Const., art. I, § 22(B). Here, Plaintiffs are the "persons or entities" who are assisting patients seeking abortions, but whose rights are burdened, penalized, prohibited, or interfered with because of the Bans. Thus, Plaintiffs have shown they have standing to bring these claims on their own; Plaintiffs need not make an argument that they have third-party standing. The challenged statutes restrict and criminally penalize abortion care that Plaintiffs are now constitutionally able to provide, causing damages which they now seek relief from.

While not required, the Court believes that Plaintiffs have third-party standing to assert their patients' rights under the Amendment, as indicated in its previous order. In

its first preliminary injunction order, this Court found that abortion providers and clinics, the exact Plaintiffs in this case, have third-party standing to raise constitutional claims on behalf of their patients. The Court finds the same to still be true today.

2. *Plaintiffs are substantially likely to succeed on their claim that the aforementioned statues will violate their and their patients' newly enshrined constitutional right to reproductive freedom.*

The Amendment grants sweeping protections ensuring reproductive autonomy for patients in Ohio. Plaintiffs have provided substantial evidence to prove by clear and convincing evidence that the Bans at issue here violate these newly enshrined rights in a manner that is not the least restrictive, and actually causes harm to Plaintiffs' patients. The State fails to make any argument that these statutes are the least restrictive means to advance patient health and are in accordance with widely accepted and evidence-based standards of care.

a. APC Ban

While APCs are prohibited from prescribing medications used in medication abortions (mifepristone and misoprostol) for abortion purposes, nothing in Ohio law prevents APCs from legally prescribing these same medications for *other* purposes, including miscarriage management. Grossman Aff. ¶ 32. APCs are highly skilled, comprehensively regulated, and qualified health professionals, subjected to rigorous education and certification requirements and delegated broad authority by the State Medical Board of Ohio (for PAs) and the Ohio Board of Nursing (for NPs and CNMs). Pl. Ex. 7 ("Spetz Aff."), ¶¶ 19-22, 90-95; Grossman Aff. at ¶ 20. Specific to Ohio, APCs collaborate with physicians under standard care agreements, which does not require physicians to be physically present when APCs provide care but allows for physician supervision and consultation as necessary. Pl. Ex. 6 ("Quinn Aff."), ¶ 8.

Studies show that APCs can provide medication abortion at least as safely as physicians and have shown no difference in outcome between a medication abortion provided by an APC and one provided by a physician. Grossman Aff. at ¶ 23, Spetz Aff. at ¶ 84. In fact, no evidence shows that if patients receive medication abortions from an APC they have a higher risk of experiencing complications than if they received medication abortions from a physician. Grossman Aff. at ¶ 23, Spetz Aff. at ¶¶ 84-85. Therefore, multiple professional organizations, including the American College of Obstetricians and Gynecologists, the American Public Health Association, the World Health Organization, and the National Academies of Sciences, Engineering, and Medicine, support the provision of medication abortion by appropriately trained APCs. Grossman Aff. at ¶¶ 24-25, Spetz Aff. at ¶¶ 72-78. Studies recognized by the FDA "found no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion between" physicians and APCs providing the drug. Grossman Aff. at ¶ 28. Because of these studies, even the FDA does not require provision of mifepristone under physician supervision. *Id.*

Despite these findings, the APC ban prohibits APCs from prescribing medication to induce an abortion. Again, neither this Ban nor other Ohio law prohibits APCs from legally prescribing the same medications for other purposes, including miscarriage management. This is so even though miscarriage management requires essentially the same clinician skill and knowledge and carries the same risk to patients as medication abortion. Grossman Aff. at ¶ 32. Further, this prohibition forces patients to rely exclusively on physicians to provide them with medication abortion care in Ohio. Grossman Aff. at ¶ 32. Consequently, this limits the number of available medication abortion appointments, the timing of such appointments, and the number of sites where

medication abortions are offered. Grossman Aff. at ¶¶ 43-44; Pl. Ex. 2 ("Haskell Aff."), ¶ 18; Pl. Ex. 4 ("Lewis Aff."), ¶¶ 18-20; Krishen Aff. at ¶ 15. Not only are parents required to make arrangements for missed work or childcare, but they must also overcome "heightened financial and logistical burdens associated with increased travel," which are further exacerbated for low-income patients, patients with children, and patients in unstable living situations (i.e., those experiencing homelessness or intimate partner violence). Liner Aff. at ¶¶ 21-22, 47; Grossman Aff. at ¶¶ 43-48.

As a result of the difficulties this Ban creates, patients may be delayed past the gestational age limit for medication abortion entirely. Grossman Aff. at ¶ 52, Krishen Aff. at ¶ 30, Lewis Aff. at ¶ 23. Therefore, to obtain an abortion, "such patients will either need to have a procedural abortion, contrary to their preference or medical indication; leave the State to get the medication abortion they desire, as some of Dr. Liner's patients have done; or may even be forced to carry a pregnancy to term against their will." Pl. Memo. in Support at 12, Liner Aff. at ¶ 26; *see also* Grossman Aff. at ¶ 52. Ultimately, patients are being forced to remain pregnant against their will, causing further physiological stressors and emotional distress. Krishen Aff. at ¶ 29, Grossman Aff. at ¶ 54, Liner Aff. at ¶ 24. While abortion overall is extremely safe, the risks do increase as the pregnancy progresses, which means patients are subjected to those heightened risks if and when they do obtain abortion care. Grossman Aff. at ¶ 50, Haskell Aff. at ¶ 18, n. 1.

Lastly, the APC Ban harms not only patients, but the patients' providers and staff. Plaintiffs assert they are committed to providing timely, compassionate, patient-centered care, but the APC Ban causes emotional distress and psychological harm to providers because they are forced to turn away patients they would otherwise be able to serve and

witness their patients face significant and unnecessary hurdles to get the care they need and deserve. *See* Krishen Aff. at ¶ 31, Quinn Aff. at ¶ 23.

In response, the State argues that the "plain text of the Amendment supports Ohio's requirement that only physicians prescribe abortion-inducing drugs." Def. Memo. in Opp. at 22. That is false. The portion of the Amendment the State cites to in support of this argument is referencing post-viability abortion. Specifically, the Amendment provides that "abortion may be prohibited after fetal viability" *unless* "in the professional judgment of the pregnant patient's treating physician it is necessary to protect the pregnant patient's life or health." Ohio Const., art I, § 22(B). This language the State cites to says nothing about preventing licensed, qualified APCs from providing pre-viability abortions, which would include medication abortions. Actually, the Amendment protects all persons and entities assisting a pregnant person in obtaining an abortion – the Amendment's protections are not limited to physicians. *See* Ohio Const., art. I, § 22(B)(2).

Medical evidence and medical consensus show that APCs can (and do in many other states) provide medication abortion just as safely and effectively as physicians. The State provided no evidence or argument to refute this fact. Further, even if the State did provide such evidence or argument, the State did not even address how the categorical ban on several types of highly trained, well-credentialed, competent clinicians from providing medication abortion care within their scope of practice constitutes the "least restrictive means" of advancing patient health as is now constitutionally required. However, Plaintiffs have provided extensive credible evidence to show, by clear and convincing evidence, that they are substantially likely to succeed on their claim that the APC Ban violates Ohioans' constitutional right to abortion. The record establishes that

the APC Ban serves no medical purpose and does nothing to advance patient health. Rather, the APC Ban actually risks harming patient health and well-being.

b. Evidence-Based Use Ban

Ohio does not typically restrict off-label use of drugs. Plaintiffs provided two instances, which the State does not dispute, where Ohio does restrict off-label use of drugs: (1) the use of mifepristone for abortion care and (2) the use of certain Schedule III anabolic steroids. R.C. 3719.06(B), *see also* Spetz Aff. at ¶ 40. In fact, "evidence-based" or "off-label" use of medications is a common and essential part of medical practice as it allows providers to care for patients according to the best medical practice. Grossman Aff. at ¶ 59; Liner Aff. at ¶¶ 7, 13. Strikingly, Ohio law does not impose these restrictions on the off-label use of mifepristone for purposes other than abortion, including miscarriage management. Haskell Aff. at ¶ 22; Lewis Aff. at ¶ 24.

Further, "providers outside of Ohio prescribe mifepristone for off-label use in accordance with evidence-based standards of care." *See* Grossman Aff. at ¶¶ 17, 61. Plaintiffs have provided testimony that shows how the standard of medical care can, and in this case does, differ from FDA labeling. Specific to mifepristone, in 2000 the FDA approved a 600 mg dosage of mifepristone for abortion. *Id.* at ¶¶ 64-65. However, by the time mifepristone was available in the United States, "research had conclusively demonstrated that a lower dosage of mifepristone (when combined with a different dosage and manner of administering misoprostol) was equally effective through 63 days LMP." *Id.* at ¶ 66. Because of this research, abortion providers offered their patients a formulation that differed from the FDA label at the time when mifepristone was readily available. *Id.* In 2016, and through reliance on this evidence-based regimen, the FDA approved several changes to mifepristone labeling. *Id.* at ¶ 67. However, Ohio's Evidence-

Based Use Ban prohibits Ohio providers from prescribing mifepristone based on these research advances, including additional evidence that has emerged since 2016.

Without the Evidence-Based Use Ban, Plaintiffs would be able to provide mifepristone to their patients for medication abortion beyond 70 days LMP – which is consistent with the best-available medical evidence. Haskell Aff. at ¶ 27, Liner Aff. at ¶ 17, Lewis Aff. ¶ 26, Krishen Aff. at ¶ 34. The best-available medical evidence shows that mifepristone can be used safely and effectively for medication abortions beyond 70 days LMP. Grossman Aff. at ¶¶ 69-70, Liner Aff. at ¶ 16. Numerous reasons exist as to why patients beyond 70 days LMP may choose or need medication abortion over procedural abortion. *See supra* at 4-5. Plaintiffs argue this Ban in no way advances patient health, and even if it did, it would not be the least restrictive means of doing so. Plaintiffs argue instead that the Ban actively harms patient health. Similar to the APC Ban, the State's response contains no evidence to support a categorical ban on off-label use of mifepristone for abortion. Again, Ohio law does not restrict off-label use of mifepristone for purposes other than abortion, including miscarriage management. Further, the State fails to provide support for or make any argument that the Ban advances patient health. Plaintiffs have shown by clear and convincing evidence that they are substantially likely to prevail on their claim that the Evidence-Based Use Ban violates Ohioan's constitutional right to reproductive freedom.

B. Plaintiffs and Their Patients Will Suffer Irreparable Harm Absent Relief

Because Plaintiffs have shown a substantial likelihood they will succeed on their claims that they and their patients' constitutional rights are being violated, a finding of irreparable harm is warranted. "[I]mpair[ment]" of a constitutional right "mandates a

finding of irreparable injury." *Magda v. Ohio Elections Comm'n.*, 2016-Ohio-5043, 58 N.E.3d 1188, ¶ 38 (10th Dist.), citing *Bonnell v. Lorenzo*, 241 F.3d 800, 809 (6th Cir. 2001). The record demonstrates that without preliminary relief, Plaintiffs will still be limited in their ability to provide reproductive care to their patients, contrary to the Amendment's broad protections. Additionally, patients all across the state will still be irreparably harmed by obstacles to care and regulations that are more restrictive than the Amendment allows. These current regulations require many patients to travel significantly farther to obtain an abortion and cause unnecessary harm by burdening them with excessive financial, physical, and emotional costs. Each day these Bans remain in place, Plaintiffs' and their patients continue to suffer irreparable harm.

C. No Third Parties Will Be Harmed and the Public Interest Will Be Served by an Injunction

No third parties would be harmed if the Bans are enjoined. Plaintiffs have provided ample evidence to show that not only is abortion common, safe, and effective beyond 70 days LMP, but trained APCs can safely and effectively provide abortion, as well. An injunction will not harm Defendants nor any other third party. Rather, these Bans remaining in place continue to impair patient health and well-being, while also violating Ohioans' constitutional rights. Additionally, the public interest will be served by an injunction, not only because it will prevent future constitutional violations, but also because the public interest is served when the Ohio Constitution is properly applied.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction is hereby **GRANTED.** All Defendants and their officers, successors, agents, servants, employees, attorneys and those persons in active concert or participation with them are

PRELIMINARILY ENJOINED from enforcing R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4739.39(B)(2), 4730.42(A)(1), and Adm. Code 4723-9-10(K) and 4730-2-07(E) until final judgment is entered in this case. Additionally, the Court's first Entry Granting Plaintiffs' Motion for a Preliminary Injunction, filed on April 20, 2021, shall remain in effect until final judgment is entered in this case, as stated in that order. Lastly, because Defendants face no risk of financial loss from the injunction, and in light of the Plaintiffs' role as nonprofit health care providers, the Court hereby sets Plaintiffs' Civ. R. 65(C) bond requirement at $0.00.

IT IS SO ORDERED.

Judge Alison Hatheway