

by the FDA in the drug’s final printed labeling as incorporated by the drug approval letter.”

Cordray v. Planned Parenthood Cincinnati Region, 911 N.E.2d 871, 879 (Ohio 2009).

The FDA approved mifepristone for use in the United States in September of 2000 based on clinical trials submitted to the FDA in 1996. The treatment regimen specified by the final printed labeling and approval letter calls for the administration of 600 mg of mifepristone orally, followed by the oral ingestion of 0.4 mg of misoprostol two days later, and limits the administration of mifepristone through seven weeks or for the first forty-nine days following the woman’s last menstrual period (“LMP”). Clinical trials subsequently led to the development of an evidence-based protocol calling for a lower dosage of mifepristone that can safely be administered through sixty-three days following the LMP. However, under the Act, any physician employing the evidence-based protocol—also referred to as an off-label mifepristone abortion—is subject to criminal prosecution and disciplinary action, including suspension or revocation of their medical license. O.R.C. § 2919.123(E). The Act contains no exception to protect the health or the life of the patient.

Prior to the Act’s enforcement, Plaintiffs and/or their predecessors—physicians and organizations providing abortions to their patients—brought this action pursuant to 42 U.S.C. § 1983 to obtain declaratory relief that the Act is unconstitutional and injunctive relief barring its enforcement. Specifically, Plaintiffs challenged the constitutionality of the statute on the grounds that it (1) is unconstitutionally vague, (2) violates a patient’s right to bodily integrity by compelling surgery in circumstances where medical abortion would otherwise be desired or appropriate treatment, (3) lacks the constitutionally-mandated exception to allow otherwise restricted practices where they are necessary to preserve a women’s health or life, and (4) imposes an undue burden on a patient’s right to choose abortion by prohibiting a safe and

common method of pre-viability abortion. Three of Plaintiffs' claims have been litigated to final judgment in Defendants' favor.

The only claim remaining in this action is whether the Act is unconstitutional due to its failure to include an exception to its restrictions where necessary to protect a woman's life or health. The Court previously granted Plaintiffs' motion for a preliminary injunction on their life/health exception claim, which remains in effect to the extent that enforcement of the Act "prohibits off-label mifepristone abortions that are 'necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.'" (Order Clarifying the Scope of the Preliminary Injunction 7, Doc. 158 at PageID 2619.) Plaintiffs maintain that for women with specified medical conditions, including some of Plaintiffs' patients, the Act subjects them to significant health risks. Specifically, Plaintiffs contend that surgical abortions are difficult if not impossible for women with particular medical conditions and "[i]f these woman cannot avail themselves of an alternative evidence-based regimen of mifepristone medication after 49 days LMP, their only alternative is to undergo an invasive medical procedure that carries significantly more risk to their health or lives, or to forgo abortion and carry an unwanted pregnancy." (Doc. 179 at PageID 2783.) Plaintiffs claim the Act is unconstitutional as applied to these women and seek relief in the form of a permanent injunction enjoining Defendants from enforcing the Act where necessary in appropriate medical judgment for the preservation or life of the woman.

II. DEFENDANT'S MOTION TO DISMISS

Defendant has filed a Motion to Dismiss this action for lack of subject matter jurisdiction and for failure to state a claim on which relief may be granted, pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) respectively. As discussed below, the Court finds Defendant's motion to be without merit.

A. Subject Matter Jurisdiction

Defendant first argues that the Second Amended Complaint should be dismissed pursuant to Fed. R. Civ. Pro. 12(b)(1) because the Court lacks subject matter jurisdiction. It is Defendant's position that Plaintiffs lack standing to bring the life/health exception claim and that the complaint is not ripe for review.

1. Standing

Defendant contends that the complaint should be dismissed because, as Defendant sees it, the speculative and hypothetical nature of Plaintiffs' allegations deprives them of standing to bring the claim. Specifically, Defendant claims that Plaintiffs' theory of harm impermissibly "relies on a highly attenuated chain of possibilities." (Doc. 184 at PageID 2794–95 (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. ___, 133, S.Ct. 1138, 1148 (2013))).

Article III, § 2 of the Constitution limits the federal judicial power to the adjudication of cases and controversies. One component of the case-or-controversy requirement is standing, which requires a plaintiff to satisfy three elements. "First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (internal citations and quotation marks omitted). Second, a causal connection must exist between the injury and the disputed conduct. In other words, the injury must be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." *Id.* (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976)). Finally, it must be likely that the injury will be redressed by a favorable decision. *Id.*

The Court has previously determined that Dr. Kade—the former medical director of the Planned Parenthood affiliate in Cincinnati and Plaintiff Dr. Kress’s predecessor in this action—had standing to challenge the Act on behalf of herself and her patients. The Court reasoned that as the director of Planned Parenthood Dr. Kade administered off-label medical abortions with mifepristone in a manner prohibited by the Act and that Dr. Kade faced prosecution if she continued her practice. On this basis, the Court found that she had standing to bring a pre-enforcement challenge. Observing the consistency with which courts have held that physicians whose conduct is regulated by an abortion statute have standing to challenge those statutes on behalf of their patients, the Court also found that Dr. Kade had standing to enforce her patients’ rights.

Nevertheless, Defendant cites *Clapper v. Amnesty Int’l USA*, 568 U.S. ___, 133 S.Ct. 1138, 1148 (2013), for the proposition that Plaintiffs’ theory of harm impermissibly “relies on a highly attenuated chain of possibilities.” In *Clapper*, the Supreme Court considered a pre-enforcement challenge to provisions of the Foreign Intelligence Surveillance Act, which authorizes the surveillance of non-United States individuals reasonably believed to be located outside the United States to acquire foreign intelligence information. The respondents in that case—attorneys and organizations whose work allegedly requires them to engage in communications with individuals targeted by the act—argued that they could establish standing based upon the “objectively reasonable likelihood that their communications with their foreign contacts will be intercepted under [50 U.S.C.] § 1881a at some point in the future.” *Id.* at 1143. The Supreme Court held that the respondents failed to establish injury in fact, finding that respondents’ theory of harm rested on a highly attenuated chain of possibilities. The Court noted that:

Respondents' argument rests on their highly speculative fear that: (1) the Government will decide to target the communications of non-U.S. persons with whom they communicate; (2) in doing so, the Government will choose to invoke its authority under § 1881a rather than utilizing another method of surveillance; (3) the Article III judges who serve on the Foreign Intelligence Surveillance Court will conclude that the Government's proposed surveillance procedures satisfy § 1881a's many safeguards and are consistent with the Fourth Amendment; (4) the Government will succeed in intercepting the communications of respondents' contacts; and (5) respondents will be parties to the particular communications that the Government intercepts.

Id. at 1148. Importantly, the Court found it speculative that the Government would target communications to which the respondents are parties, as the act "expressly provides that respondents, who are U.S. persons, cannot be targeted for surveillance under § 1881a." *Id.*

By contrast, Plaintiffs here are indisputably targeted by the Act. The Act in this case specifically targets persons who "knowingly give, sell, dispense, administer, otherwise provide or prescribe RU-486 (mifepristone) to another for the purposes of inducing an abortion" beyond the patient's forty-ninth day of pregnancy or in a manner other than the dosage indications and treatment protocols expressly approved by the FDA in the drug's final printed labeling.

Plaintiffs allege that they provided medication-based, off-label abortions beyond the forty-ninth day of pregnancy prior to the Act, that they would continue to use the banned protocol but for the Act, and that they fear prosecution if they continue to do so. The Court finds these allegations distinguishable from *Clapper* and sufficient to establish standing to challenge the Act.

The Court also finds that Dr. Kress has standing to enforce his patients' rights. In order to establish third-party standing, a plaintiff must have suffered an injury in fact and share a close relationship with the third-parties who face an obstacle inhibiting them from bringing the claim on their own behalf. *Kowalski v. Tesmer*, 543 U.S. 125, 129–30 (2004). As the Court noted in finding that Dr. Kress's predecessor had standing to challenge the Act on behalf of her patients,

physicians may bring suit on behalf of their patients due to: 1) the close relationship between women and their physicians; 2) the fact that in the context of an abortion regulation, women's due process rights are inextricably bound up with the activity that a physician plaintiff wishes to pursue; and 3) the fact that women are faced with several obstacles to asserting their own rights. *Planned Parenthood Cincinnati Reg.*, 337 F. Supp. 2d 1040, 1045 (S.D. Ohio 2004). *See also Singleton v. Wulff*, 428 U.S. 150, 118 (1976) ("it is generally appropriate to allow a physician to assert the rights of women patients as against governmental interference with the abortion decision"); *Planned Parenthood of Wisc., Inc. v. Van Hollen*, 738 F.3d 786, 793 (7th Cir. 2013) ("the cases are legion that allow an abortion provider . . . to sue to enjoin as violations of federal law . . . state laws that restrict abortion"); *Planned Parenthood Se., Inc. v. Bentley*, 951 F. Supp. 2d 1280, 1284 (M.D. Ala. 2013) ("federal courts routinely recognize an abortion provider's standing to assert the claims of its patients") (collecting cases).

Having determined that Dr. Kress has third party standing to assert the rights of his patients, as well as standing to assert his own rights, the Court dispenses with further inquiry into the remaining Plaintiffs. *See Carey v. Population Servs. Int'l*, 431 U.S. 678, 682 (1977) (ending the standing inquiry after determining that one party had standing); *Taft*, 337 F. Supp. 2d at 1045 (same).

2. Ripeness

Defendant next contends that Plaintiffs' claim is not ripe. In order for this Court to have jurisdiction over the subject matter of a claim, the claim must be ripe for judicial review. *Bigelow v. Mich. Dep't of Natural Res.*, 970 F.2d 154, 160 (6th Cir. 1992). The ripeness doctrine operates to "ensure that courts decide only existing, substantial controversies, not hypothetical questions or possibilities." *Norton v. Ashcroft*, 298 F.3d 547, 554 (6th Cir. 2002)

(citations omitted). In determining whether or not a claim is ripe for adjudication, the Court considers two basic questions: (1) is the claim fit for judicial decision in the sense that it arises in a concrete factual context and concerns a dispute that is likely to come to pass and (2) what is the hardship to the parties of withholding court consideration? *Warshak v. United States*, 532 F.3d 521, 525 (6th Cir. 2008) (internal quotation marks and citations omitted).

In *Gonzales v. Carhart*, 550 U.S. 124 (2007), the Supreme Court specified that an as-applied challenge is the preferred mechanism for challenging a statute's lack of a health exception. The Court noted that such a challenge requires a showing that "in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used." *Id.* at 167. Citing *Gonzales*, as well as *Richmond Med. Ctr. For Women v. Herring*, 570 F.3d 165 (4th Cir. 2009), Defendant argues that Plaintiffs' claim lacks the specificity necessary to enable the Court to adjudicate the constitutional challenge. Specifically, Defendant contends that Plaintiffs fail to allege discrete and well-defined instances in which the life/health exception is likely to apply or that any harm has occurred or is sufficiently likely to occur in the future.

In *Richmond*, the Fourth Circuit upheld a Virginia Act criminalizing intact dilation and extraction ("D & E") abortions, a procedure in which the fetus is terminated after its "entire head is outside the body of the mother or, in a breach delivery, its trunk past the navel is outside the body of the mother." *Id.* at 169 (internal citation and quotation marks omitted). Although similar in many respects to the federal partial birth abortion law upheld in *Gonzales*, the Virginia law does not exclude accidental intact D & E abortions—that is, where the physician intends to perform a standard D & E abortion, but the fetus emerges beyond the anatomical landmarks identified in the act. The plaintiff physician in that case testified that "in less than 0.5% of cases,

the fetus is presented in a breach position and accidentally emerges intact up to its head, at which point the head becomes lodged in the cervix.” *Id.* at 175. Failure to use the banned procedure in this circumstance, the plaintiff testified, would risk the life of the mother. However, because a physician will not know at the onset of the standard procedure whether an accidental intact D & E procedure will become necessary, the plaintiff argued that if the act were to take effect his only option would be to cease performing the standard D & E procedure or to violate the act. *Id.* at 171. On this basis, the plaintiff argued the act was facially unconstitutional because it imposed an undue burden on a woman’s decision to have an abortion using the standard D & E procedure.

The Fourth Circuit disagreed, noting that—unlike the Ohio Act in the instant case—the Virginia law includes an exception enabling a doctor to take any step within reasonable medical judgment necessary to prevent the mother’s death. *Id.* at 175, 178. In light of the plaintiff’s testimony that the circumstances in which the intact procedure was necessary presented a risk to the woman’s life, the *Richmond* court found “little or no evidence in the record suggesting the inevitability of the ‘accidental’ intact D & E abortion that would violate the Virginia Act.” *Id.* at 175. The Fourth Circuit found the possibility that such a circumstance might arise in a rare case to be insufficient to find the statute facially invalid. *Id.* To the extent that the plaintiff purported to bring an as-applied challenge—as Plaintiffs have in the instant case—the court determined that the plaintiff failed to present the concrete facts necessary to create a live case or controversy. Specifically, the record contained “no concrete factual circumstance to which [the plaintiff] can claim the Act applies unconstitutionally,” as the plaintiff failed to indicate that he had any particular patient in mind “nor any discrete factual circumstance that is detailed by medical records or other similarly concrete evidence.” *Id.* at 180. Furthermore, because the plaintiff

testified that the circumstances are unique in each of his cases, he could not determine how the act might generally apply.

The Court finds *Richmond* distinguishable from the instant case. Plaintiffs have identified discrete factual circumstances in which they claim the banned protocol is required. According to Plaintiffs, the Act is unconstitutional as applied to women with anomalies of the reproductive and genital tract, such as large uterine fibroids and cervical stenosis, which make accessing the pregnancy inside the uterus difficult or impossible. *See Planned Parenthood v. DeWine*, No. 1:04-cv-493, 2011 WL 9158009, at *16 (S.D. Ohio May 29, 2011) (noting that both parties in this action “are able to articulate the discrete instances in which an off-label mifepristone abortion may be medically necessary”). Furthermore, the articulated circumstances are not hypothetical, as Plaintiffs have alleged and the record includes testimony that they have patients with the specified conditions. (Doc. 179 at PageID 2783; Trans. Pr. Hearing 12, Doc. 38 at PageID 786.) Finally, there is no uncertainty as to how the Act would operate in this case. Because the Act prohibits mifepristone abortions after forty-nine days LMP, women with the specified conditions would be forced to undergo a surgical abortion, which Plaintiffs claim carries significantly more risk to their health or lives.

Accordingly, the Court finds *Richmond* to be distinguishable from the instant case and otherwise insufficient to dismiss Plaintiffs’ claim as unripe. To require that Plaintiffs identify a particular patient with large uterine fibroids or cervical stenosis seeking a medical abortion between forty-nine and sixty-three days LMP in order to state a justiciable claim—as Defendant asks the Court to do¹—ignores not only the reality of the factual circumstances in which this

¹ Defendant argues that “Plaintiffs’ claim is unripe because they fail to specify any woman who has sought, or is likely to seek, an abortion from Plaintiffs under circumstances that would render the Act unconstitutional.” (Reply p. 9, Doc. 191 at PageID 2879.) In other words, Defendant contends that “Plaintiffs do not allege that any woman

action arises, but also the hardship to Plaintiffs if review is delayed. Cases such as this are the very reason why courts permit physicians to bring actions on behalf of their patients in the first place. *See Singleton*, 428 U.S. at 117 (recognizing the “imminent mootness” of any individual woman’s claim as an obstacle in support of permitting physicians to assert the rights of women patients against governmental interference with the abortion decision). *Cf. Gonzales*, 550 U.S. at 189 (Ginsburg, J., dissenting) (“Surely the Court cannot mean that no suit may be brought until a woman’s health is immediately jeopardized by the ban A woman suffering from medical complications needs access to the medical procedure at once and cannot wait for the judicial process to unfold.”) (internal quotation marks and citations omitted).

For the above reasons, the Court finds Defendant’s motion without merit and denies the Motion to Dismiss with respect to Defendant’s standing and ripeness challenges.

B. Health or Life Exception Claim

Having found that the Court has subject matter jurisdiction over Plaintiffs’ claim, the Court must next determine if the complaint fails to state a claim upon which relief may be granted, as Defendant argues.

1. Standard

Federal Rule of Civil Procedure 12(b)(6) allows a party to move to dismiss a complaint for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). A district court “must read all well-pleaded allegations of the complaint as true.” *Weiner v. Klais and Co., Inc.*, 108 F.3d 86, 88 (6th Cir. 1997). However, this tenet is inapplicable to legal

who faces such risk has ever, or is likely to, come to one of their clinics from 50-63 days pregnant seeking an abortion. Plaintiffs’ assertion that some of their patients suffer from medical conditions that would make a mifepristone abortion ‘safer’ is potentially relevant *if* such a patient were pregnant and *if* she wanted an abortion and *if* she came to the clinic between 50-63 days and *if* her medical condition were such that any alternative would expose her to significant health risks. Plaintiffs do not plead that a woman meeting all of these necessary conditions, has obtained, or is likely to seek, an abortion from Plaintiffs’ clinics.” (*Id.* at 5; Doc. 191 at PageID 2875.)

conclusions, or legal conclusions couched as factual allegations, which are not entitled to an assumption of truth. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To withstand a dismissal motion, a complaint “does not need detailed factual allegations,” but it must contain “more than labels and conclusions [or] a formulaic recitation of the elements of a cause of action.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). “[T]he complaint must contain either direct or inferential allegations respecting all material elements to sustain a recovery under some viable legal theory.” *Harvard v. Wayne Cty.*, 436 F. App’x 451, 457 (6th Cir. 2011) (internal quotation or citation omitted). “Factual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555. The Court does not require “heightened fact pleading of specifics, but only enough facts to state a claim for relief that is plausible on its face.” *Id.* at 570. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

2. Analysis

The lack of a life or health exception in an abortion statute imposes an unconstitutional burden on a woman’s right to abortion if it subjects a woman to significant health risks. *Gonzales*, 550 U.S. at 161 (quoting *Ayotte v. Planned Parenthood N. New Eng.*, 546 U.S. 320, 328 (2006)). As noted above, a pre-enforcement as-applied challenge to an abortion statute’s failure to protect the health of a mother may be maintained upon a showing that “in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the act must be used.” *Id.* at 167.

In this case, Defendant first contends that Plaintiffs fail to allege that the Act subjects women to a significant health risk. Citing *Women’ Med. Prof’l Corp. v. Taft*, 353 F.3d 436 (6th

Cir. 2003) and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), Defendant maintains that Plaintiffs are required to demonstrate a risk of harm “that is both ‘serious’ and longstanding, if not ‘irreversible.’” (Motion to Dismiss 13–14, Doc. 184 at PageID 2806–2807.)

Defendant’s argument is without merit, as it conflates the statutory language of health exceptions upheld in these cases with the standard applicable to Plaintiffs’ claim. For example, in *Taft*, the Sixth Circuit considered the constitutionality of a health exception to an Ohio statute restricting partial-birth abortions. The statutory exception in that case permitted the restricted procedure when “necessary, in reasonable medical judgment, to preserve the life or health of the mother as a result of the mother’s life or health being endangered by a serious risk of the *substantial and irreversible impairment of a major bodily function.*” *Taft*, 353 F.3d at 444 (quoting Ohio Rev. Code Ann. § 2919.11(B)(C)) (emphasis added). Although the Sixth Circuit upheld the statute, it did so after interpreting the exception to “allow[] physicians to perform the partial birth procedure whenever the procedure is necessary to protect the mother from significant health risks,” noting that the Fourteenth Amendment requires nothing more. *Id.* at 445 (“Ohio’s maternal health exception is valid because it permits the partial birth procedure when necessary to prevent significant health risks. The Fourteenth Amendment, as applied in *Casey* and *Carhart*, requires nothing more.”). Similarly, in *Casey*, the Supreme Court considered a Pennsylvania statute’s health exception which also used permitted a restricted procedure to avoid “serious risk of *substantial and irreversible impairment of a major bodily function.*” *Casey*, 505 U.S. at 879. The Court upheld the exception, deferring to the lower courts’ statutory interpretation that the act does “not in any way pose a significant threat to the life or health of a woman.” *Id.* at 880. Because Defendant’s argument misstates the standard applicable to Plaintiffs’ claim it does not provide a basis for dismissal.

Defendant otherwise contends that Plaintiffs fail to state a claim because they fail to allege discrete and well-defined instances in which the procedure must be used. However, the Court has already determined that Plaintiffs have alleged discrete and well-defined instances in rejecting Defendant's ripeness challenge. In short, Plaintiffs claim that certain specified medical conditions make surgical abortion difficult or impossible. Under the Act, these women would not have access to evidence-based or off-label mifepristone abortions after forty-nine days LMP, leaving them to choose between carrying an unwanted pregnancy or undergoing a surgical procedure. As this Court and the Sixth Circuit have previously observed, in these circumstances the Act could subject these women to significant health risks. *See Taft*, 444 F.3d at 514 ("the evidence presented to the district court established . . . that the abortion regulation at issue could pose a significant health risk to women with particular medical conditions"); *Taft*, 337 F. Supp. 2d. at 1047 ("Plaintiffs have already presented expert medical testimony . . . that there are women who have medical conditions that render surgical abortion riskier than the evidence-based protocol for medical abortion."). The Court finds these allegations to be sufficient to state a plausible claim for relief and to survive Defendant's Motion to Dismiss.

III. CONCLUSION

For the above reasons, the Defendant's Motion to Dismiss (Doc. 184) is **DENIED**.

IT IS SO ORDERED.

S/Susan J. Dlott
Chief Judge Susan J. Dlott
United States District Court