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

PLANNED PARENTHOOD CINCINNATI REGION, *et al.*,	:	Case No. 1:04-CV-493
Plaintiff,	:	
	:	Chief Judge Susan J. Dlott
v.	:	
	:	ORDER CLARIFYING THE SCOPE
MIKE DEWINE, *et al.*,	:	OF THE PRELIMINARY
	:	INJUNCTION
Defendants.	:	

This matter is before the Court on the parties' request for clarification of the scope of a preliminary injunction issued by the Court on September 22, 2004, which was later affirmed in part and vacated in part by the Sixth Circuit in *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502 (6th Cir. 2006). (Docs. 153, 154, 155, 156, and 157). Having reviewed and carefully considered the decision in *Planned Parenthood Cincinnati Region*, the Court concludes that the preliminary injunction, as narrowed by the Sixth Circuit, enjoins the application of Ohio Revised Code ("O.R.C.") § 2919.123 only insofar as it prohibits off-label mifepristone abortions that are "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *See Planned Parenthood Cincinnati Region*, 444 F.3d at 511. To the extent that Plaintiffs now seek a broader injunction, that request is **DENIED**.

I. Background

A brief review of the procedural history of this case is necessary to an understanding of the issues now before the Court. At its core, this case involves the constitutionality of O.R.C. § 2919.123 (the "Act"), which regulates the use of mifepristone (commonly known as "RU-486")

to provide medical abortions. Specifically, the Act bars Ohio physicians from administering or prescribing RU-486 to induce an abortion unless the drug is provided to a patient "in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone)." O.R.C. § 2919.123(A). The Act defines "federal law" as "any law, rule, or regulation of the United States or any drug approval letter of the food and drug administration of the United States that governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortions." O.R.C. § 2919.123(F)(1). Because the Act requires doctors who prescribe RU-486 to do so only in accordance with the indication, regimen, and distribution restrictions approved by the FDA, the Act prohibits "off-label"[1] use of RU-486.

On August 2, 2004, Plaintiffs filed their original Complaint and Motion for Preliminary Injunction, challenging the constitutionality of the Act on the following grounds: (1) that it is unconstitutionally vague; (2) that it violates a patient's right to bodily integrity by compelling surgery in circumstances where medical abortion would otherwise be desired or appropriate treatment; (3) that it lacks the constitutionally mandated exception to allow otherwise restricted practices where they are necessary to preserve a women's health or life; and (4) that it imposes an undue burden on a patient's right to choose abortion by prohibiting a safe and common method of pre-viability abortion. On September 22, 2004, after a two-day evidentiary hearing, this Court determined that Plaintiffs had shown a strong likelihood of success on the merits of their claim that the Act unconstitutionally omitted an exception for the health or life of the woman. *See Planned Parenthood Cincinnati Region v. Taft*, 337 F. Supp. 2d 1040 (S.D. Ohio

[1] "Off-label" use refers to the practice of prescribing a drug for indications, regimens, and in dosages other than those expressly approved by the FDA.

2004). The Court granted Plaintiffs' request for a preliminary injunction against enforcement of the Act in its entirety.

Defendants appealed the preliminary injunction. The Sixth Circuit agreed that Plaintiffs had shown a strong likelihood of success on the merits of their claim that the Act unconstitutionally omitted an exception for the health or life of the woman. *See Planned Parenthood Cincinnati Region*, 444 F.3d at 511-517. But, the Sixth Circuit determined that the absence of an exception for the health or life of the woman "did not necessarily justify an injunction against the entire statute." *Id*. The Sixth Circuit vacated this Court's order in part, "leaving the preliminary injunction undisturbed insofar as it prohibits unconstitutional applications of the statute." *Id*. at 517. The Sixth Circuit remanded the case for further proceedings and directed this Court to "determine whether a broader injunction is still required by considering the legislative intent and the Plaintiffs' as-yet-unaddressed vagueness, bodily integrity, and undue burden claims." *Id*.

On remand, Plaintiffs moved for summary judgment and a permanent injunction on the basis that the statute was unconstitutionally vague. This Court granted Plaintiffs' motion for summary judgment and, on September 27, 2006, permanently enjoined enforcement of the statute.

Defendants again appealed. The Sixth Circuit *sua sponte* issued an order certifying two questions to the Ohio Supreme Court: "(1) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so in compliance with the forty-nine-day gestational limit described in the FDA approval letter?" and (2) "Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so in compliance

with the treatment protocols and dosage indications described in the drug's final printed labeling?" *Planned Parenthood Cincinnati Region v. Strickland*, 531 F.3d 406, 412 (6th Cir. 2008). The Sixth Circuit made clear that the injunction against enforcement of the Act, based on the Act's vagueness, remained in full force while the Ohio Supreme Court considered the certified questions. *Id*. at 414.

On July 1, 2009, the Ohio Supreme Court answered both certified questions in the affirmative, finding that the "plain language of [the Act] mandates that physicians providing mifepristone to patients for the purpose of inducing an abortion do so in accordance with the FDA drug approval letter and the final printed labeling it incorporates, including compliance with the 49-day gestational limitation and the treatment protocols and dosage indications expressly approved by the FDA." *Cordray, et al., v. Planned Parenthood Cincinnati Region, et al.*, 122 Ohio St. 3d 361, 362 (2009).

On August 6, 2009, in light of the Ohio Supreme Court's opinion, the Sixth Circuit vacated the permanent injunction issued on September 27, 2006 and held that the preliminary injunction issued on September 22, 2004 "remains in force per [the April 13, 2006] order." *Planned Parenthood Southwest Region, et al. v. Strickland, et al.*, 331 F. App'x 387, 388 (6th Cir. 2009). The Sixth Circuit then remanded the case "for consideration of the Ohio Supreme Court's opinion as well as issues identified in our previous remand and any other issues that the parties may raise." *Id*.

Following the Sixth Circuit's remand, both parties moved for summary judgment. (Docs. 122, 124.) Before the Court could rule on those motions, at a status conference on January 12, 2011, Plaintiffs requested clarification of the scope of the preliminary injunction following the

Sixth Circuit's remand. Because the parties have vastly different opinions on the issue, the Court asked the parties to file briefs setting forth their respective positions.

II. Discussion

At issue is the scope of the preliminary injunction issued by the Court on September 22, 2004, that was affirmed in part and vacated in part by the Sixth Circuit on April 13, 2006. Plaintiffs contend that the scope of the preliminary injunction, which enjoined Defendants from enforcing any provision of the Act, remains undisturbed. Defendants argue that the Sixth Circuit's April 13, 2006 decision narrowed the preliminary injunction to enjoin only those particular applications of the Act that would pose a significant risk to a woman's health or life.

Although the Court acknowledges the legitimacy of both parties' interpretation, the Court believes that the Sixth Circuit's April 13, 2006 decision in *Planned Parenthood Cincinnati Region* narrowed the scope of the preliminary injunction. In that decision, the Sixth Circuit agreed with this Court's finding that the Act "may not constitutionally omit a health or life exception." *Planned Parenthood Cincinnati Region*, 444 F.3d at 505. Citing *Stenberg v. Carhart*, 530 U.S. 914 (2000), the Sixth Circuit set forth the legal standard to determine whether a statute must contain a health or life exception:

> [W]here substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health[,] [*Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992)] requires the statute to include a health exception when the procedure is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.

Planned Parenthood Cincinnati Region, 444 F.3d at 511. With respect to the Act, the Sixth Circuit concluded:

> [T]he evidence presented to the district court established at least as persuasive a case as that presented in *Carhart* that the abortion regulation at issue could pose a significant health risk to women with particular medical conditions. Consequently, the district court's ruling that Plaintiffs established a strong likelihood of prevailing on the merits has not been shown to be erroneous.

Id. at 514.

Although the evidence supported a finding that the Act unconstitutionally omitted a health or life exception, the Sixth Circuit took issue with the scope of the preliminary injunction in light of the Supreme Court's decision in *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320 (2006). In *Ayotte*, the Supreme Court held that when an abortion statute lacks a constitutionally necessary health exception, "invalidating the statute entirely is not always necessary or justified, for lower courts may be able to render narrower declaratory and injunctive relief," namely the prohibition of the statute's unconstitutional applications. 546 U.S. at 323, 331. Having determined that the lower courts "need not have invalidated the law wholesale," the Supreme Court vacated the First Circuit's opinion affirming the district court's permanent injunction; the case was remanded to the district court to determine whether the statute's legislative intent would allow for a narrower injunction prohibiting the statute's unconstitutional applications. *Id.* at 331-32.

In its analysis of *Ayotte*, the Sixth Circuit made note of the fact that the Supreme Court did not vacate the underlying injunction itself, stating, "[t]his silence as to the injunction is significant because the Court has not hesitated to vacate all or part of an injunction explicitly when it so desires." *Id*. at 516. Recognizing that *Ayotte* did not institute a "new automatic-vacature rule," the Sixth Circuit found it appropriate to simply "adhere to the usual approach to overbroad injunctions." *Id*. The usual approach, the Sixth Circuit observed, is to "vacate an

injunction only insofar as it is too broad, leaving the balance intact." *Id*. "In light of this well-established method of dealing with overbroad injunctions," the Sixth Circuit determined that the proper course was to vacate in part this Court's order, affirm the preliminary injunction "insofar as it prohibits unconstitutional applications of the Act," and vacate the preliminary injunction "insofar as it prohibits constitutional applications of the Act." *Id*. at 517-18. On remand, the Sixth Circuit ordered this Court to "determine whether a broader injunction is still required by considering the legislative intent and the Plaintiffs' as-yet-unaddressed vagueness, bodily integrity, and undue burden claims." *Id*. at 517.

In the wake of the Sixth Circuit's decision, the preliminary injunction remained in place only "insofar as it prohibits unconstitutional applications of the Act." *Id*. at 517-18. The only "unconstitutional applications" considered by the Sixth Circuit at that time dealt with the Act's lack of a health or life exception. Consequently, this Court must conclude that the Sixth Circuit's April 13, 2006 decision narrowed the scope of the preliminary injunction to enjoin application of the Act only insofar as it prohibits off-label mifepristone abortions that are "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *See id.* at 511. To conclude otherwise would be contrary to the explicit terms of that order.

To the extent that Plaintiffs' argument seeks a broader injunction based on Plaintiffs' health or life exception claim or Plaintiffs' remaining three claims, the Court **DENIES** that request. The preliminary injunction at issue, as narrowed by the Sixth Circuit, has been in force since the Sixth Circuit's remand on August 6, 2009 and, given that the Court is close to ruling on the motions for summary judgment, the Court believes it is unnecessary to broaden the scope of

the preliminary injunction at this time.

IT IS SO ORDERED.

s/Susan J. Dlott

Chief Judge Susan J. Dlott
United States District Court