

In the  
**Supreme Court of Ohio**

NANCY H. ROGERS, OHIO ATTORNEY : Case No. 2008-1234  
GENERAL, et al., :  
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 :  
 Petitioners, : On Review of Certified Questions from  
 : The United States Court of Appeals  
 v. : for the Sixth Circuit  
 :  
 :  
 PLANNED PARENTHOOD CINCINNATI : U.S. Court of Appeals Case  
REGION, et al., : Nos. 06-4422/4423  
 :  
 :  
 Respondents. :

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**MERIT BRIEF OF PETITIONER  
OHIO ATTORNEY GENERAL NANCY H. ROGERS**

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ALPHONSE A. GERHARDSTEIN (0032053)  
JENNIFER L. BRANCH (0038893)\*

*\*Counsel of Record*

Gerhardstein & Branch Co., LPA  
617 Vine Street, Suite 1409  
Cincinnati, OH 45202  
513-621-9100

DAVID C. GREER (009090)

Bieser, Greer & Landis LLP  
400 National City Center  
6 North Main Street  
Dayton, OH 45402  
937-223-3277

HELENE T. KRASNOFF

Planned Parenthood Federation of America  
1780 Massachusetts Avenue, NW  
Washington, DC 20036  
202-973-4800

ROGER K. EVANS

Planned Parenthood Federation of America  
434 West 33rd Street  
New York, NY 10001  
212-541-7800

NANCY H. ROGERS (0002375)  
Attorney General of Ohio

BENJAMIN C. MIZER\* (0083089)  
Solicitor General

*\*Counsel of Record*

STEPHEN P. CARNEY (0063460)  
ELISABETH A. LONG (*pro hac* motion  
pending)

Deputy Solicitors

ANNE BERRY STRAIT (0012256)

SHARON A. JENNINGS (0055501)

Assistant Attorneys General

30 East Broad Street, 17th Floor

Columbus, OH 43215

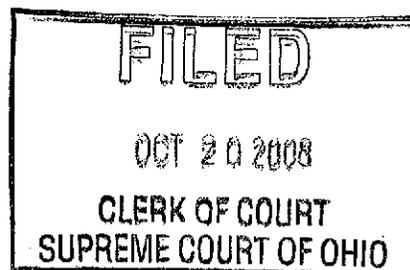
614-466-8980

614-466-5087 fax

[bmizer@ag.state.oh.us](mailto:bmizer@ag.state.oh.us)

Counsel for Petitioner

Ohio Attorney General Nancy H. Rogers



B. JESSIE HILL (0074770)  
Case Western University School of Law  
11075 East Blvd.  
Cleveland, OH 44106  
216-368-0553

JEFFREY M. GAMSO (0043869)  
ACLU of Ohio Foundation, Inc.  
4506 Chester Avenue  
Cleveland, OH 44103  
216-472-2220

Counsel for Respondents  
Planned Parenthood Cincinnati Region, et al.

JOSEPH T. DETERS (0012084)  
Hamilton County Prosecutor

MICHAEL G. FLOREZ (0010693)  
ROGER E. FRIEDMAN (0009874)  
230 E. Ninth Street, Suite 4000  
Cincinnati, OH 45202  
513-946-3229  
513-946-3018 fax

Counsel for Petitioner  
Joseph T. Deters, as Representative of the  
Defendant Class of Ohio Prosecuting  
Attorneys

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## INTRODUCTION

This Court has accepted the request of the U.S. Court of Appeals for the Sixth Circuit to clarify the meaning of an Ohio statute, R.C. 2919.123,<sup>1</sup> that protects the health and safety of women by regulating the use of mifepristone, also known as “RU-486.” Specifically, the statute requires Ohio physicians who use the drug to induce medical abortions to do so only in accordance with “federal law.” R.C. 2919.123 defines “federal law” to include any “drug approval letter” of the U.S. Food and Drug Administration (“FDA”) that governs the use of mifepristone to induce abortions. In September 2000, after considering the new drug application (“NDA”) providing for the use of mifepristone to terminate pregnancies “through 49 days’ pregnancy” and information submitted by the drug’s proponent, the FDA issued a letter (“Approval Letter”) “approv[ing] Mifeprex (mifepristone) Tablets, 200 mg, for use as recommended in the agreed upon labeling text.” Supplement to the Merit Brief of Petitioner Ohio Attorney General Nancy H. Rogers (“Pet’r Supp.”) at S-185. Thus, the FDA approved the drug’s usage for abortions up to a 49-day gestational limit and under the specific protocol outlined in the final printed labeling.

Typically, once the FDA approves a drug for marketing in the United States with respect to one particular use, physicians may then use the drug for other purposes. This practice—called “off-label” use—is generally permissible because the FDA’s jurisdiction does not extend to the actual practice of medicine. Instead, the latter has always been the province of the States. After the FDA finds that a drug is safe for one use, the States are free to authorize or prohibit other uses. Here, Ohio passed legislation doing just that: Ohio decided that, in the interests of

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<sup>1</sup> R.C. 2919.123 was enacted by H.B. 126 of the 125th General Assembly, and will be referred to by its individual subparts or collectively as “the Act.”

women's health and safety, mifepristone should be used to induce abortions only in the manner specifically approved by the FDA, and not for off-label uses.

The certified questions before this Court go to the heart of the Act and the heart of a federal lawsuit challenging Ohio's regulation of mifepristone use as unconstitutionally vague. Respondents, a group of abortion providers and clinics (collectively, "Planned Parenthood"), claim that it is unclear whether R.C. 2919.123 prohibits off-label uses of mifepristone, such as usage after 49 days' gestation or with different protocols. But the language of R.C. 2919.123 is unambiguous. The Act means exactly what it says: Mifepristone may be used in Ohio only in accordance with the gestational limit and treatment protocol specifically approved by the FDA.

The certified questions before this Court ask whether the Act, by defining "federal law" to include the Approval Letter, truly incorporates the 49-day limit and the treatment protocol and dosage requirements referenced in the Approval Letter:

- (1) Does 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?
- (2) Does 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?

App. Ex. 2. The answer to both certified questions is "yes."

## STATEMENT OF THE CASE AND FACTS

### **A. The FDA approved mifepristone for use under certain conditions to induce abortion medically.**

Before the FDA approved mifepristone in September 2000, most first-trimester abortions in this country were "surgical" abortions, performed by vacuum aspiration or suction curettage. *Planned Parenthood Cincinnati Region v. Taft* (6th Cir. 2006), 444 F.3d 502, 505 ("*PPCR I*"). Such surgical abortions have very low complication rates, particularly in early pregnancy.

Mifepristone is a drug that terminates a pregnancy by stopping the production of progesterone, which in turn leads to the detachment of the gestational sac from the uterine wall. It is used to perform medical abortions in combination with a second drug, misoprostol, a prostaglandin that induces contractions to expel the fetus and other tissues from the uterus. *Id.* Mifepristone, despite confusion in some media reports, is not the same as the drug commonly referred to either as emergency contraception or the “morning-after pill.”

The FDA based its decision to approve mifepristone on the results of three large clinical trials. Those clinical trials found that mifepristone is a safe and effective method of inducing abortion up to 49 days’ gestation when it is administered to a carefully selected patient population at a particular dosage, and in combination with misoprostol. *Id.* Those same trials found that the drug’s efficacy greatly decreased, and side effects and adverse events greatly increased, at gestational ages greater than 49 days. *Id.*

The FDA’s Approval Letter noted that the FDA had reviewed and approved the drug on the terms considered in the clinical trials. The Letter expressly referred to those terms and a document known as the “final printed labeling,” which further detailed the protocol for mifepristone use. The Approval Letter said:

This new drug application provides for the use of Mifeprex™ for the medical termination of intrauterine pregnancy ***through 49 days’ pregnancy.***

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to approve Mifeprex™ (mifepristone) Tablets, 200 mg, ***for use as recommended in the agreed upon labeling text.*** The application is approved under 21 CFR 314 Subpart H.

Pet’r Supp. at S-185 (emphasis added). The “agreed upon labeling text” approved by the FDA included the professional labeling, or “package insert,” which described both the 49-day gestational limit and the approved treatment protocol. *Id.* The approved final printed labeling also included a Medication Guide, Pet’r Supp. at S-206, and Patient Agreement, Pet’r Supp. at S-

211, both of which also set forth the 49-day gestational limit and the approved treatment protocol.

The FDA approved mifepristone for use under 21 C.F.R. 314, Subpart H, which allows the FDA to place restrictions on post-approval use of a drug when necessary for safe use. Under 21 C.F.R. 314.520, the FDA specifically placed certain limitations on mifepristone distribution (the “Subpart H restrictions”). Among other things, the Subpart H restrictions require physicians using the mifepristone to read and understand the prescribing information set forth in the drug’s final printed labeling, including an FDA-approved Medication Guide, and also to provide a copy of the Medication Guide and Patient Agreement to each patient. See Pet’r Supp. at S-186. As stated above, the Medication Guide and Patient Agreement expressly state the 49-day gestational limit and the approved protocol. Pet’r Supp. at S-206, S-211.

**B. Ohio passed the Act to ensure that mifepristone could be used in Ohio only under the conditions and circumstances that the FDA considered when it approved the drug.**

As the Sixth Circuit explained in its 2006 opinion in this case, and as no one disputes, doctors generally are allowed—absent some state regulation—to use an FDA-approved drug for off-label uses—that is, for indications and in dosages other than those for which the drug was first expressly approved by the FDA. See *PPCR I*, 444 F.3d at 505. The FDA approves drugs as products for distribution and use in the United States, but does not regulate how the drugs are subsequently used by physicians. Rather, the actual prescribing and use of the drugs is a part of the practice of medicine by doctors, a subject long within the province of state regulation. See *id.* Once the FDA concludes that a drug is safe and effective for one use, each state can decide whether to impose any additional restrictions on that drug’s use.

Soon after the FDA approved mifepristone, some medical providers in Ohio, including Planned Parenthood, began using mifepristone to terminate pregnancies up to 63 days (nine

weeks). They also began to use a much lower dose of mifepristone than called for by the FDA-approved treatment protocol, in conjunction with a much higher dose of the second drug, misoprostol, administered vaginally, as opposed to orally. *Id.* at 505-506.

By 2003, Ohio legislators had become concerned about safety issues surrounding the use of mifepristone and about Ohio's need for a mechanism to limit the drug's use to the terms considered in the FDA's Approval Letter. This concern led to the enactment of R.C. 2919.123, which was passed by Ohio House of Representatives in June 2003, and the Ohio Senate in May 2004. See App. Ex. 6. The Governor signed the Act into law on June 24, 2004.

R.C. 2919.123(A) provides that “[n]o person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion” unless (i) that person is a physician; (ii) the physician “satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions”; and (iii) that physician provides the drug “in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.” R.C. 2919.123(B) further requires physicians to comply with all applicable requirements of federal law regarding follow-up examinations and care. The statute defines the term “federal law” to mean “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 for the purpose of inducing abortions.” R.C. 2919.123(F)(1).

As legislative history confirms, the Act reflects the General Assembly's intent that Ohio doctors prescribe mifepristone for medical abortion only in accordance with the terms of the FDA approval, including the approved indication, treatment protocol, and distribution restrictions set forth in the Approval Letter and the materials referenced in the Letter.

**C. Planned Parenthood sued, claiming, among other things, that the Act is vague in requiring Ohio physicians to comply with the conditions of the FDA Approval Letter.**

Before R.C. 2919.123 even went into effect, Planned Parenthood sued in federal court, seeking injunctive and declaratory relief to prevent the law's enforcement. Planned Parenthood named as defendants Ohio's Governor, Ohio's Attorney General, and the Hamilton County Prosecuting Attorney as the representative of a defendant class of all county prosecutors in Ohio.

In the federal suit, Planned Parenthood alleges that the Act is unconstitutional for four different reasons: the Act is unconstitutionally vague; the Act places an "undue burden" on the right to an abortion; the Act violates a woman's right to bodily integrity; and the Act lacks a health exception. See *PPCR I*, 444 F.3d at 507. After a very short evidentiary hearing, the district court preliminarily enjoined the statute's enforcement solely on the ground that it does not have a health exception. The district court did not address Planned Parenthood's undue burden, bodily integrity, or vagueness arguments. *Id.*

On appeal, the Sixth Circuit vacated the district court's first injunction, finding it too broad, and remanded the case to the district court for further proceedings. *PPCR I*, 444 F.3d at 518. Specifically, the court noted that the U.S. Supreme Court, in the context of a different abortion law that arguably lacked an adequate health exception, had vacated an overbroad injunction of a state law and instructed lower courts to tailor such injunctions to solve only the narrow issue at hand. See *id.*, citing *Ayotte v. Planned Parenthood of N. New England* (2006), 546 U.S. 320. The Sixth Circuit thus vacated the injunction of the entire Ohio law and instructed the district court to determine the appropriate scope of a narrower injunction. *Id.*

The district court then ordered that the parties brief the remand issues. Instead, Planned Parenthood moved for summary judgment on the theory that the Act is unconstitutionally vague. Specifically, Planned Parenthood argued that the statute is unclear as to whether it prohibits off-

label uses or merely restates the restrictions that the FDA imposed as a matter of federal law. The district court concluded that the statute is vague and permanently enjoined the Act's enforcement. *Planned Parenthood v. Taft* (S.D. Ohio 2006), 459 F. Supp. 2d 626, 640.

**D. The federal appeals court asked this Court to determine whether the Ohio law's incorporation of the FDA Approval Letter means that Ohio doctors may prescribe mifepristone only in the dosage referred to, and up to the gestational age referred to, in the Approval Letter.**

Ohio appealed the district court's permanent injunction of the statute. In considering Planned Parenthood's claim that the Act is vague, the Sixth Circuit concluded that this Court is best able to determine the meaning of R.C. 2919.123. The Sixth Circuit issued an order asking this Court to answer two specific questions, quoted above, regarding the statute's meaning and effect. App. Ex. 1. In accordance with Rule XVIII of the Rules of Practice of the Supreme Court of Ohio, this Court accepted the certified questions and ordered the parties to brief the case on the merits. App. Ex. 2.

## ARGUMENT

### **Petitioner Ohio Attorney General's Proposition of Law No. 1:**

*R.C. 2919.123 mandates that doctors in Ohio who perform abortions using mifepristone do so only up to the FDA-approved indication of 49 gestational days.*

The plain language of R.C. 2919.123(A) requires that Ohio physicians who provide medical abortions using mifepristone do so only in accordance with federal law. The Act defines "federal law" to include the FDA Approval Letter. R.C. 2919.123(F). The Approval Letter specifically approved a NDA for the use of mifepristone for medical abortions "through 49 days' pregnancy." Therefore, physicians in Ohio may prescribe the drug only in accordance with the Approval Letter, and that means they can only prescribe the drug up to 49 gestational days. This conclusion is fully supported by the Act's legislative history.

**A. The plain language of R.C. 2919.123 requires physicians in Ohio who perform abortions using mifepristone to do so only up to the FDA-approved indication of 49 gestational days.**

“The paramount consideration in determining the meaning of a statute is legislative intent.” *State v. Jackson*, 102 Ohio St. 3d 380, 2004-Ohio-3206, ¶ 341; accord *Carnes v. Kemp*, 104 Ohio St. 3d 629, 2004-Ohio-7107, ¶ 16. To determine legislative intent, a court must “first review the statutory language.” *State ex rel. Wolfe v. Delaware Cty. Bd. of Elections* (2000), 88 Ohio St. 3d 182, 184, 724 N.E.2d 771. “[W]hen the language of a statute is plain and unambiguous and conveys a clear and definite meaning, there is no need for this court to apply the rules of statutory interpretation.” *State ex rel. Jones v. Conrad*, 92 Ohio St. 3d 389, 392, 2001-Ohio-207. Although “any term left undefined by statute is to be accorded its common, everyday meaning,” *State v. Dorso* (1983), 4 Ohio St. 3d 60, 62, 446 N.E.2d 449, “words and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly.” R.C. 1.42.

The Act requires that any physician using mifepristone to induce an abortion do so “in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.” R.C. 2919.13(A). The statute defines the term “[f]ederal law” in the context of this section to mean “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.” R.C. 2919.13(F)(1) (emphasis added).

The FDA issued its Approval Letter for mifepristone in September 2000, several years before Ohio enacted R.C. 2919.123. The Approval Letter specifically approved mifepristone use in response to a NDA that only sought approval of the drug for use through 49 days’ gestation: “This new drug application provides for the use of Mifeprex™ [mifepristone] for the medical

termination of intrauterine pregnancy through 49 days' pregnancy.” Pet’r Supp. at S-185. The FDA reviewed the drug only in the context of medical abortions performed through 49 gestational days and found the drug to be safe and effective within that time period. Therefore, when the Ohio General Assembly chose to limit the drug’s use to the terms of the Approval Letter, it incorporated that limit—expressly described in the Approval Letter—into Ohio law.

This conclusion is buttressed by the fact that the Approval Letter states that the FDA’s approval of the drug is “for use as recommended in the agreed upon labeling text.” *Id.* The Approval Letter expressly defines that labeling text, better known as the final printed labeling (FPL), to include four documents: the professional labeling (Package Insert), the Medication Guide required under 21 C.F.R. Part 208, the Patient Agreement Form, and the Prescriber’s Agreement Form. *Id.* Three of these documents—the Package Insert, the Medication Guide, and the Patient Agreement—specifically set forth the approved gestational limit of 49 days. The Medication Guide includes a paragraph that states:

**Mifeprex is used to end an early pregnancy.** It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (7 weeks) or less since your last menstrual period began.

Pet’r Supp. at S-206. Further, when a patient signs the Patient Agreement Form, the patient must affirm that she believes that she is not more that 49 days (seven weeks) pregnant. Pet’r Supp. at S-211.

R.C. 2919.123 unambiguously restricts the use of mifepristone for medical abortions in Ohio to the first 49 days of gestation. The mere fact that the statutory language does not expressly mention “49 days” is irrelevant: The statute requires physicians using mifepristone for medical abortions in Ohio to comply with federal law; “federal law” is defined to include the Approval Letter; and the Approval Letter expressly considers and approves the NDA for mifepristone “for the medical termination of intrauterine pregnancy through forty-nine days’

pregnancy.” Therefore, under the plain language of R.C. 2919.123, physicians cannot use mifepristone to induce abortions in Ohio for pregnancies exceeding 49 days.

**B. Even if the plain language of R.C. 2919.123 were ambiguous as to a gestational limitation on abortions using mifepristone in Ohio, legislative history establishes the General Assembly’s intent to prohibit abortions using mifepristone beyond the FDA-approved indication of 49 gestational days.**

The statutory restriction of mifepristone use for medical abortions to the first 49 of gestation is fully supported by the Act’s legislative history. If the language of a statute is ambiguous, this Court may consider relevant legislative history in the course of determining legislative intent. R.C. 1.49(C); see *State v. Jordan* (2000), 89 Ohio St. 3d 488, 492, 733 N.E.2d 601 (“If a statute is ambiguous, the court, in determining the intent of the General Assembly, may consider factors, including ... the legislative history....”). The Act’s legislative history reveals that the Ohio General Assembly’s overriding concern in enacting the statute was to protect women’s health by requiring that Ohio physicians use the drug only in accordance with the FDA-approved indications and requirements.

During the Senate debate of the Act, Sen. Robert Hagan proposed an amendment that would have achieved exactly the result that Planned Parenthood now urges this Court to adopt. Specifically the amendment would have allowed off-label use—*i.e.*, what Planned Parenthood refers to as “evidence-based” use—of mifepristone when certain standards are met:

In line 93, after “(F),” insert: “Nothing in this section shall be construed as prohibiting health care providers from giving, selling, dispensing, administering, or otherwise providing RU-486 (mifepristone) in accordance with evidence-based use of drugs.

[In (G),] [b]etween lines 104 and 105 insert: “(5) “Evidence-based use of drugs” means the use of a drug in a dosage or context that has not been specifically approved for that drug by the United States food and drug administration, if the use of the drug in that dosage or context is supported by adequate study and is recognized as meeting prevailing standards for safe and effective medical care.”

Pet'r Supp. at S-317. In his remarks supporting the proposed amendment, Sen. Hagan noted that some providers were using the drug to induce abortions up to 63 days, under the "evidence based use of medication." Pet'r Supp. at S-465. He argued that many drugs are used "off-label" and that, by adopting the Act without the Amendment, the General Assembly would restrict the mifepristone use in Ohio. Pet'r Supp. at S-464-467.

In response, Sen. Jeff Jacobson spoke against the amendment and expressed his concerns about using the drug other than in accordance with the FDA approval:

But I just ask you to look at one portion of this amendment and then ask yourself whether or not this is something you can in good conscience endorse, and that is the use of drugs, this would say that healthcare providers can allow the use of the drug in a dosage or context that has not been specifically approved for that drug by the United States Food and Drug Administration. Remember why we have RU-486 in the first place; it is because the FDA approved it. And they said how it was to be used, because it is dangerous.

Pet'r Supp. at S-468. After Sen. Hagan made further remarks in support of the amendment, the Senate defeated the amendment by a vote of 22 to 10. Pet'r Supp. at S-317. The Senate then passed the Act in its final form.

This legislative history demonstrates that by defining "federal law" to include the Approval Letter, the General Assembly intended to mandate that physicians performing abortions with mifepristone in Ohio do so only up to the FDA-approved indication of 49 gestational days.

**C. Interpreting R.C. 2919.123 to require only that physicians using mifepristone to induce abortions in Ohio do so in compliance with federal Subpart H requirements would ignore the plain language of the statute and render the Act meaningless.**

Planned Parenthood has argued throughout the federal court proceedings in this case that R.C. 2919.123 should be interpreted to require only that Ohio physicians comply with the specific federal Subpart H requirements listed in the Approval Letter. See Pet'r Supp. at S-186. Subpart H requires, among other things, that every physician who uses mifepristone must read and understand the final printed labeling before using mifepristone, and also must provide each

patient with a copy of the Medication Guide and discuss it with her. Hence, any physician who uses mifepristone in any State must be familiar with the FDA-approved protocol. However, in the absence of an applicable state regulation, such as the Act, a physician would be permitted to use the drug in a different manner.

Planned Parenthood's proposed statutory interpretation is based on circular reasoning: federal law does not prohibit off-label use of drugs, so incorporating "federal law" into the Act's requirements means that the Act does not restrict off-label use. The argument ignores the fact that the statute specifically includes the Approval Letter in the definition of "federal law," and that the Approval Letter specifically approves mifepristone for use in accordance with the 49-day gestational limit and the treatment protocol set forth in the final printed labeling.

Moreover, Planned Parenthood's interpretation would render the statute meaningless. Physicians nationwide are required to comply with the Subpart H distribution restrictions by federal regulations, specifically 21 C.F.R. 314.520. Ohio had no need to pass a statute requiring Ohio physicians to adhere to federal regulations *with which the physicians were already required to comply*. That interpretation would render the statute meaningless in regard to regulating physicians' behavior, contrary to the basic canon that "[i]n enacting a statute, it is presumed that: . . . [t]he entire statute is intended to be effective; . . . [and a] result feasible of execution is intended." R.C. 1.47. "The General Assembly is not presumed to do a vain or useless thing, and . . . when language is inserted in a statute it is inserted to accomplish some definite purpose." *State ex rel. Cleveland Elec. Illum. Co. v. City of Euclid* (1959), 169 Ohio St. 476, 479. If the Act merely required physicians to follow already-binding federal law, then it would have no effect on medical practice in Ohio; at most, the Act would give Ohio parallel enforcement power over existing FDA law.

Instead, the General Assembly expressly included the Approval Letter in the definition of “federal law” in R.C. 2919.123(F). Contrary to Planned Parenthood’s contention, the effect of including the Approval Letter in the definition was to *add* a requirement that the drug only be prescribed in accordance with the provisions of the Approval Letter, thus prohibiting off-label use.

**Petitioner Ohio Attorney General’s Proposition of Law No. 2:**

*R.C. 2919.123 mandates that doctors who perform abortions using mifepristone in Ohio do so only in compliance with the treatment protocol and dosages described in the drug’s FDA-approved labeling.*

For the same reasons that R.C. 2919.123 requires physicians using mifepristone for medical abortions in Ohio to comply with a 49-day gestational limit, it also requires physicians to comply with the treatment and dosage protocol described in the final printed labeling approved by the FDA. The plain language of R.C. 2919.123(A) requires Ohio physicians who provide medical abortions using mifepristone to do so only in accordance with “federal law,” which is defined to include the Approval Letter. R.C. 2919.123(F). The Approval Letter specifically approved a NDA for mifepristone “for use as recommended in the agreed upon labeling text.” Pet’r Supp. at S-185. Physicians in Ohio may prescribe the mifepristone only in accordance with the Approval Letter, and therefore must comply with treatment protocol and dosage requirements in the final printed labeling. This conclusion is fully supported by the legislative history of the Act.

**A. The plain language of R.C. 2919.123 requires physicians who perform abortions using mifepristone in Ohio to do so only in compliance with the treatment protocol described in the drug’s final printed labeling approved by the FDA.**

The plain language of R.C. 2919.123 requires physicians performing abortions using mifepristone in Ohio to comply with the treatment protocol and dosage requirements described in the FDA-approved final printed labeling. To determine the General Assembly’s intent with respect to the Act’s regulation of mifepristone treatment protocols and dosage requirements, this

Court must review the statute's plain language, taking into account any legislative definitions of statutory language. See *Wolfe*, 88 Ohio St. 3d at 184; R.C. 1.42.

As explained above, R.C. 2919.13(A) requires any physician using mifepristone to induce an abortion to comply with all relevant provisions of "federal law," which includes "any [FDA] drug approval letter... that governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortions." R.C. 2919.13(F)(1). The Approval Letter plainly states that the FDA is approving mifepristone "for use as recommended in the agreed upon labeling text." Pet'r Supp. at S-185. The labeling text includes the Package Insert and the Medication Guide, both of which describe the FDA-approved treatment protocol of administering mifepristone 600 mg (3 tablets) orally, followed approximately 48 hours later by misoprostol 400 µg orally to induce contractions and expel the pregnancy. Pet'r Supp. at S-203, S-208.

Although the face of R.C. 2919.123 does not describe specific treatment protocols or dosage requirements, the language of the statute unambiguously restricts a physician's use of mifepristone to induce abortions in Ohio to the terms of the final printed labeling text that were incorporated by reference into the Approval Letter. Therefore, under the plain language of R.C. 2919.123, physicians must comply with the FDA-approved treatment protocol and dosage requirements for mifepristone as set forth in the final printed labeling.

**B. Even if the plain language of R.C. 2919.123 were ambiguous about treatment protocol and dosage requirements for mifepristone-induced abortions in Ohio, legislative history establishes the General Assembly's intent to mandate compliance with the protocol and dosage requirements in the final printed labeling.**

For the reasons explained in the above analysis of the 49-day gestational period, the legislative history of R.C. 2919.123 fully supports the statutory restriction of mifepristone use to FDA-required protocol and dosage requirements. See R.C. 1.49(C) (authorizing courts to consider legislative history when the language of a statute is ambiguous). During legislative

debate of the Act, the Senate considered and rejected Sen. Hagan's proposed amendment to modify the language of the Act to allow for off-label use of mifepristone. Pet'r Supp. at S-317. The Senate's rejection of Sen. Hagan's amendment is consistent with the Ohio General Assembly's overriding concern in enacting R.C. 2919.123: protecting women's health by requiring that Ohio physicians use the drug only in accordance with the FDA-approved indications and requirements.

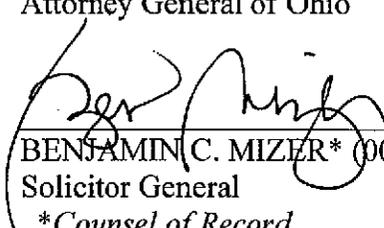
By defining "federal law" to include the Approval Letter, the General Assembly intended to mandate that physicians performing abortions using mifepristone in Ohio do so only in accordance with FDA-approved protocol and dosage requirements.

## CONCLUSION

For the above reasons, Petitioner Attorney General Nancy H. Rogers asks this Court to answer both of the certified questions in the affirmative, as set forth in Petitioner's Proposed Propositions of Law.

Respectfully submitted,

NANCY H. ROGERS (0002375)  
Attorney General of Ohio



BENJAMIN C. MIZER\* (0083089)  
Solicitor General

*\*Counsel of Record*

STEPHEN P. CARNEY (0063460)

ELISABETH A. LONG (*pro hac* motion  
pending)

Deputy Solicitors

SHARON A. JENNINGS (0055501)

ANNE BERRY STRAIT (0012256)

Assistant Attorneys General

30 East Broad Street, 17th Floor

Columbus, Ohio 43215

614-466-8980

614-466-5087 fax

[bmizer@ag.state.oh.us](mailto:bmizer@ag.state.oh.us)

Counsel for Ohio Attorney General  
Nancy H. Rogers

## CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Merit Brief of Petitioner, Ohio Attorney General Nancy H. Rogers, was served by U.S. mail this 20th day of October, 2008, upon the following counsel:

Alphonse A. Gerhardstein  
Jennifer L. Branch  
Gerhardstein & Branch Co., LPA  
617 Vine Street, Suite 1409  
Cincinnati, OH 45202

David C. Greer  
Bieser, Greer & Landis LLP  
400 National City Center  
6 North Main Street  
Dayton, OH 45402  
937-223-3277

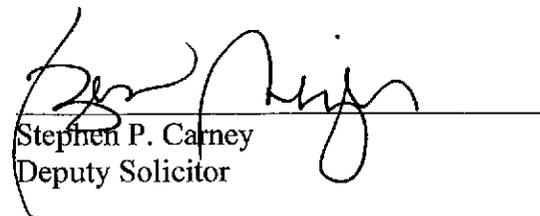
Helene T. Krasnoff  
Planned Parenthood Federation of America  
1780 Massachusetts Avenue, NW  
Washington, DC 20036

Roger K. Evans  
Planned Parenthood Federation of America  
434 West 33rd Street  
New York, NY 10001

B. Jessie Hill  
Case Western University School of Law  
11075 East Blvd.  
Cleveland, OH 44106

Jeffrey M. Gamsco  
ACLU of Ohio Foundation, Inc.  
4506 Chester Avenue  
Cleveland, OH 44103

Roger E. Friedman  
Michael G. Florez  
Hamilton County Prosecutor's Office  
230 E. Ninth Street, Suite 4000  
Cincinnati, OH 45202

  
Stephen P. Carney  
Deputy Solicitor

RECOMMENDED FOR FULL-TEXT PUBLICATION  
Pursuant to Sixth Circuit Rule 206

File Name: 08a0216p.06

**UNITED STATES COURT OF APPEALS**

FOR THE SIXTH CIRCUIT

PLANNED PARENTHOOD CINCINNATI REGION;  
PLANNED PARENTHOOD OF GREATER CLEVELAND;  
PLANNED PARENTHOOD OF CENTRAL OHIO;  
PRETERM; DR. ROSLYN KADE; and DR. LASZLO  
SOGOR,

*Plaintiffs-Appellees,*

v.

TED STRICKLAND, Governor of the State of Ohio,  
*Defendant,*

NANCY H. ROGERS, Interim Attorney General of the  
State of Ohio\*; and JOSEPH T. DETERS, Hamilton  
County, Ohio, Prosecuting Attorney as  
representative of a class of all Prosecuting Attorneys  
in Ohio,

*Defendants-Appellants.*

Nos. 06-4422/4423

08 JUN 23 11:10:00  
RE

Appeal from the United States District Court  
for the Southern District of Ohio at Cincinnati.  
No. 04-00493—Susan J. Dlott, District Judge.

Argued: April 23, 2008

Decided and Filed: June 23, 2008

Before: MOORE, ROGERS, and McKEAGUE, Circuit Judges.

**COUNSEL**

**ARGUED:** Anne Berry Strait, OFFICE OF THE ATTORNEY GENERAL, Columbus, Ohio, for Appellants. Mimi Y.C. Liu, PLANNED PARENTHOOD FEDERATION OF AMERICA, Washington, D.C., for Appellees. **ON BRIEF:** Anne Berry Strait, OFFICE OF THE ATTORNEY GENERAL, Columbus, Ohio, for Appellants. Alphonse A. Gerhardstein, GERHARDSTEIN &

\* Nancy H. Rogers, Interim Attorney General of the State of Ohio, has been automatically substituted for former Attorney General, Marc Dann, pursuant to Fed. R. App. P. 43(c)(2).

BRANCH CO. LPA, Cincinnati, Ohio, Helene T. Krasnoff, PLANNED PARENTHOOD FEDERATION OF AMERICA, Washington, D.C., Roger K. Evans, PLANNED PARENTHOOD FEDERATION OF AMERICA, New York, New York, B. Jessie Hill, CASE WESTERN RESERVE UNIVERSITY, Cleveland, Ohio, Jeffrey M. Gamso, AMERICAN CIVIL LIBERTIES UNION OF OHIO FOUNDATION, Cleveland, Ohio, for Appellees. Mailee R. Smith, Denise M. Burke, Clarke D. Forsythe, AMERICANS UNITED FOR LIFE, Chicago, Illinois, for Amici Curiae.

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**ORDER OF CERTIFICATION TO THE  
SUPREME COURT OF OHIO**

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McKEAGUE, Circuit Judge. On remand from this court's decision in *Planned Parenthood v. Taft*, 444 F.3d 502 (6th Cir. 2006), the district court permanently enjoined the enforcement of Ohio Revised Code ("O.R.C.") § 2919.123 on the basis that it is unconstitutionally vague. The defendants-appellants, Interim Ohio Attorney General, Nancy H. Rogers, and Hamilton County, Ohio, Prosecuting Attorney, Joseph T. Deters, as representative for a class of all Ohio county prosecutors (collectively referred to in this order as the "State"), appealed.<sup>1</sup> On appeal, both the State and Planned Parenthood have presented this court with contrary, yet plausible, interpretations of O.R.C. § 2919.123 that they respectively believe would save the statute from unconstitutionality.

Because neither side addressed the issue of certification in their briefs, we instructed them to discuss at oral argument the propriety of certifying the question of O.R.C. § 2919.123's scope and meaning to the Supreme Court of Ohio. When asked about certification at oral argument, both Planned Parenthood and the State encouraged this court to speculate on how the Supreme Court of Ohio would interpret the statute as opposed to seeking an authoritative interpretation from the Ohio high court via certification. In our opinion, however, the interests of judicial federalism and comity strongly counsel in favor of providing the Supreme Court of Ohio with the opportunity to interpret O.R.C. § 2919.123. Accordingly, we *sua sponte* CERTIFY the questions set forth in § II, B of this order to the Supreme Court of Ohio pursuant to Rule XVIII of the Rules of Practice of the Supreme Court of Ohio. See generally *Elkins v. Moreno*, 435 U.S. 647, 662 (1978) (certifying, *sua sponte*, a question of state law to the Maryland Court of Appeals).

**I. BACKGROUND**

**A. Factual History**

This court's previous opinion set forth the relevant facts as follows:

Until 2000, most first trimester abortions in this country were surgical abortions performed by vacuum aspiration or curettage. In September of 2000, the Food and Drug Administration ("FDA") approved mifepristone [commonly referred to as RU-486], a pill used to induce an abortion without surgical intervention, for manufacture and use in the United States. This approval was based on clinical trials which involved the oral ingestion of 600 mg of mifepristone

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<sup>1</sup>Ohio Governor Ted Strickland initially succeeded his predecessor, Bob Taft, as a defendant-appellant in this action. Subsequent to the filing of this appeal, however, Governor Strickland was granted permission to withdraw as an appellant.

followed two days later by the oral ingestion of 0.4 mg of misoprostol.<sup>2</sup>

Absent state regulation, once a drug has been approved by the FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. This is a widely employed practice known as "off-label" use. Off-label use does not violate federal law or FDA regulations because the FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states. As a result of this research, an off-label protocol was developed consisting of 200 mg of mifepristone administered orally followed one to three days later by 0.8 mg of misoprostol administered vaginally. This regimen is employed up to sixty-three days' gestation and is known as the Schaff protocol after the doctor whose research primarily led to its development.

In 2004, the Ohio General Assembly enacted H.B. 126 ("the Act") to regulate the use of mifepristone in Ohio. Specifically, the Act provides:

No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion . . . unless the person . . . is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.

Ohio Rev. Code Ann. § 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." Ohio Rev. Code Ann. § 2919.123(F). This arguably requires doctors who prescribe mifepristone for the purpose of inducing an abortion to do so only in accordance with the indication, regimen and distribution restrictions approved by the FDA. In other words, the Act arguably prohibits the "off-label" use of mifepristone.

According to the State, the Act was passed because abortion providers in Ohio were openly using the Schaff protocol and "because

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<sup>2</sup>The mifepristone is an abortifacient which terminates the pregnancy by detaching the gestational sac from the uterine wall. The misoprostol is a prostaglandin which induces the contractions necessary to expel the fetus and other products of conception from the uterus.

legislators became aware that several women had died or been severely injured recently as a result of their use of mifepristone.” The State further suggests that Ohio legislators concluded that the FDA had only approved one specific protocol for the administration of mifepristone because that was the only safe and effective protocol. Accordingly, the State argues that [it] banned all other uses of mifepristone to protect Ohio women from unsafe and ineffective mifepristone protocols.

*Taft*, 444 F.3d at 505-06.

While Planned Parenthood previously instructed its doctors that mifepristone could be administered up to sixty-three days’ gestation, its instructions now provide that mifepristone only be administered up to fifty-six days’ gestation. Thus, there can be no debate that physicians in Ohio continue to administer mifepristone beyond the FDA-approved use of forty-nine days’ gestation. These doctors also continue to perform medical abortions using doses of mifepristone that are lower than those approved by the FDA.

## **B. Procedural History**

Section 2919.123 was scheduled to go into effect on September 23, 2004. But, prior to the effective date, Planned Parenthood filed a complaint in United States District Court for the Southern District of Ohio alleging that the statute: (1) is void for vagueness; (2) violates a woman’s constitutional right to bodily integrity by forcing her to undergo a surgical abortion where a medical abortion using mifepristone would be more desirable; (3) lacks the constitutionally-mandated exception for the life and health of the woman; and (4) imposes an undue burden on a woman’s right to an abortion in violation of Supreme Court precedent. On September 22, 2004, the district court issued a preliminary injunction against the State’s enforcement of O.R.C. § 2919.123. *See Planned Parenthood v. Taft*, 337 F. Supp. 2d 1040, 1041 (S.D. Ohio 2004). The district court issued the injunction based on its belief that Planned Parenthood would likely succeed on the merits of its claim that O.R.C. § 2919.123 lacked the constitutionally required exception for the life or health of the woman and that irreparable harm would result from enforcement of the law. *Id.* at 1047-48. The State appealed.

On appeal, we held that the district court erroneously determined that every abortion statute must contain an exception for the life or health of the woman. *Taft*, 444 F.3d at 511. We explained that neither the United States Supreme Court nor this court have announced a per se rule requiring all abortion statutes to contain a life or health exception; rather, each case must be considered on its facts. *Id.* In our prior decision, we went on to examine whether, under the facts of this specific case, the statute was constitutionally infirm because it lacked a health or safety exception. *Id.* at 511-12. With regard to that issue, we agreed with the district court that the record contained “substantial medical authority” in support of Planned Parenthood’s contention that the strictures imposed by O.R.C. § 2919.123 could endanger the life or health of the woman. *Id.* at 513. Relying on the Supreme Court’s recent decision in *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320 (2006), we determined that the absence of a life or health exception did not necessarily justify an injunction against the entire statute. *Id.* at 516-17. Therefore, we remanded the matter to the district court for a determination of the proper scope of the preliminary injunction in light of *Ayotte*, which explained that “we prefer . . . to enjoin only the unconstitutional applications of a statute while leaving other applications in force.” *Ayotte*, 546 U.S. at 327-28.

On remand, Planned Parenthood moved for summary judgment and sought a permanent injunction on the basis that O.R.C. § 2919.123 is unconstitutionally vague. Agreeing with Planned

Parenthood, the district court declared the statute void for vagueness and permanently enjoined the entire statute's enforcement. *Planned Parenthood v. Taft*, 459 F. Supp. 2d 626, 640 (S.D. Ohio 2006). The State has once again appealed.

## II. DISCUSSION

### A. The Propriety of Certification

Rule XVIII of the Rules of Practice of the Supreme Court of Ohio provides the Supreme Court of Ohio with discretion to answer questions of Ohio law certified to it by the federal courts. As a prerequisite to certifying a question, we must determine that "there is a question of Ohio law that may be determinative of the proceeding and for which there is no controlling precedent." R. of Prac. Sup. Ct. Ohio XVIII, § 1. In an opinion exhorting the values of federal court certification where resolution of a question of Ohio law is unclear, the Supreme Court of Ohio has explained that "state[] sovereignty is unquestionably implicated when federal courts construe state law." *Scott v. Bank One Trust Co., N.A.*, 577 N.E.2d 1077, 1080 (Ohio 1991) (per curiam). The *Scott* court further explained that "[c]ertification ensures that federal courts will properly apply state law." *Id.* Echoing similar sentiments regarding the virtues of certification, the United States Supreme Court has recognized that certification of "novel or unsettled questions of state law for authoritative answers by a State's highest court . . . may save time, energy, and resources and help build a cooperative judicial federalism." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 77 (1997) (internal quotations and alterations omitted). Submitting uncertain questions of state law to the state's highest court by way of certification acknowledges that court's status as the final arbiter on matters of state law and avoids the potential for "friction-generating error" which exists whenever a federal court construes a state law in the absence of any direction from the state courts. *See id.* at 79.

Where statutory interpretation is at issue, the United States Supreme Court has instructed the federal courts to employ certification or abstention if the "unconstrued state statute is susceptible of a construction by the state judiciary which might avoid in whole or in part the necessity for federal constitutional adjudication, or at least materially change the nature of the problem." *Bellotti v. Baird*, 428 U.S. 132, 146-47 (1976) (internal quotations omitted). In *Bellotti*, the Court held that the district court erred in failing to order certification and choosing instead to enjoin a Massachusetts statute governing the ability of minors to consent to an abortion. *Id.* at 151. The Court stressed that certification should have been ordered by the lower court because the state law was unclear, and there was no doubt that "adoption of appellant's interpretation would at least materially change the nature of the problem." *Id.* at 147 (internal quotations omitted). Furthermore, the *Bellotti* Court explained that absent an authoritative interpretation by the state court "it is impossible to define precisely the constitutional question presented." *Id.* at 148.

Like the Massachusetts abortion statute involved in *Bellotti*, at the heart of this appeal is the interpretation of a novel and previously uninterpreted state statute. To resolve the issues presented in this case, we must ascertain what O.R.C. § 2919.123 means when it states that physicians who perform abortions using mifepristone must comply with "federal law," as that term is defined in the statute. *See generally Kansas Judicial Review v. Stout*, 519 F.3d 1107, 1120 (10th Cir. 2008) (concluding that certification to the Kansas Supreme Court was appropriate because it was necessary to determine the scope and meaning of a previously uninterpreted state law before addressing whether it was unconstitutionally vague or overbroad). According to the State, by including the approval letter in the statute's definition of "federal law," O.R.C. §2919.123 effectively prohibits physicians from administering mifepristone to women who are beyond forty-nine days' gestation and from using a treatment protocol different from that found in the drug's final printed labeling (i.e., the statute prohibits the off-label use of mifepristone).

Conversely, Planned Parenthood argues that the statute imposes no restrictions on the prescribing practices of physicians; it reads O.R.C. § 2919.123 to require only that physicians who prescribe mifepristone comply with the eight Subpart H requirements set forth in the approval letter because those are the only “requirements” in the letter that refer to physicians. Planned Parenthood further argues that, by its terms, O.R.C. § 2919.123 does not incorporate the treatment protocol set forth in the drug’s final printed labeling.

Planned Parenthood concedes that if its interpretation is adopted, then its claims that the statute is unconstitutional will be rendered moot. However, Planned Parenthood asserts that if the statute is interpreted to mean what the State says it means, then the statute is unconstitutional and was correctly enjoined by the district court. Under the provisions of Rule XVIII and precedent from the United States Supreme Court, certification is appropriate here because the manner in which O.R.C. § 2919.123 is interpreted “may be determinative of the proceeding,” R. Prac. Sup. Ct. Ohio XVIII, § 1, and “might avoid in whole or in part the necessity for federal constitutional adjudication.” *Bellotti*, 428 U.S. at 146-47.

While certainly we are capable of speculating on how the Supreme Court of Ohio would interpret O.R.C. § 2919.123, such “[s]peculation by a federal court about the meaning of a state statute in the absence of prior state court adjudication is particularly gratuitous when . . . the state courts stand willing to address questions of state law on certification.” *Arizonaans for Official English*, 520 U.S. at 79 (internal quotations omitted); *see also Scott*, 577 N.E.2d at 1080 (stating that “certification frees federal courts from having to guess how state courts will decide important questions of state law”) (internal quotations omitted). This is especially true in circumstances like the present case, where the potential for state-federal friction generated by federal court intervention is heightened because O.R.C. § 2919.123 is a novel statute passed pursuant to Ohio’s longstanding power to regulate the practice of medicine within its borders.

#### **B. The Certified Questions of State Law**

For the reasons set forth above, we certify the following questions of state law to the Supreme Court of Ohio pursuant to Rule XVIII of the Rules of Practice of the Supreme Court of Ohio:

- 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?
- 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?

#### **C. The Information Required by Rule XVIII**

Because this court is certifying questions to the Supreme Court of Ohio, we provide the following information in accord with Rule XVIII, § 2(A)-(E).

1. **Name of the case:** Please refer to the caption on page 1 of this order.
2. **Statement of facts:** Please refer to § I of this order for a full recitation of the pertinent facts.

**3. Name of each of the parties:**

**a. Plaintiffs-Appellees:** Planned Parenthood Cincinnati Region; Planned Parenthood of Greater Cleveland; Planned Parenthood of Central Ohio; Preterm; Dr. Roslyn Kade; and Dr. Laszlo Sogor.

**b. Defendants-Appellants:** Nancy H. Rogers, Interim Ohio Attorney General, in her official capacity; Joseph T. Deters as Prosecuting Attorney for Hamilton County, Ohio, and as a representative of a class of all Prosecuting Attorneys in Ohio.

**4. Names, Addresses, and Telephone Numbers of Counsel for Each Party:**

**a. Plaintiffs-Appellees' Counsel:**

Ms. Mimi Y.C. Liu  
Ms. Nicole G. Berner  
Planned Parenthood Federation of  
America  
1780 Massachusetts Ave., N.W.  
Washington, D.C. 20036  
(202) 973-4862

Mr. Jeffrey M. Gamso  
American Civil Liberties Union  
of Ohio Foundation  
4506 Chester Ave.  
Max Wohl Civil Liberties Center  
Cleveland, OH 44103-2136  
(216) 472-2220

Mr. Roger K. Evans  
Planned Parenthood Federation of  
America  
434 W. 33rd St.  
New York, NY 10001-0000  
(212) 541-7800

Ms. B. Jessie Hill  
Case Western Reserve  
University School of Law  
11075 East Boulevard  
Cleveland, OH 44106-0000  
(216) 368-0553

Ms. Jennifer L. Branch  
Mr. Alphonse A. Gerhardstein  
Gerhardstein & Branch  
617 Vine St.  
Suite 1409 Enquirer Building  
Cincinnati, OH 45202-0000  
(513) 621-9100

**b. Defendants-Appellants' Counsel:**

Ms. Anne Berry Strait  
Office of the Attorney General  
Court of Claims Defense Section  
150 E. Gay St.  
23rd Floor  
Columbus, OH 43215  
(614) 466-7447

Mr. Roger Friedmann  
Assistant Prosecuting Attorney  
Hamilton County, Ohio  
230 E. Ninth St.  
Suite 4000  
Cincinnati, OH 45202  
(513) 946-3025

Ms. Sharon A. Jennings  
Office of the Attorney General  
30 E. Broad St.  
15th Floor State Office Tower  
Columbus, OH 43215  
(614) 466-2872

Mr. Michael G. Florez  
Assistant Prosecuting Attorney  
Hamilton County, Ohio  
230 E. Ninth St., Suite 4000  
Cincinnati, OH 45202  
(513) 946-3229

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*Planned Parenthood Cincinnati Region  
et al. v. Strickland et al.*

Page 8

Ms. Holly J. Hunt  
Office of the Attorney General  
Constitutional Offices Section  
30 E. Broad St.  
17th Floor  
Columbus, OH 43215  
(614) 466-2872

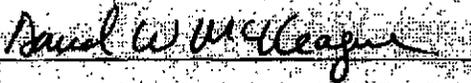
**5. Designation of Moving Party:** Although neither side has sought certification, we designate Interim Ohio Attorney General, Nancy H. Rogers, and Hamilton County, Ohio, Prosecuting Attorney, Joseph T. Deters, as representative for a class of all Ohio prosecuting attorneys— who have been collectively referred to throughout this order as the “State”—as the moving parties.

**D. Instructions to the Clerk**

In accordance with Rule XVIII, § 3 of the Rules of Practice of the Supreme Court of Ohio, Mr. Leonard Green, Clerk of the United States Court of Appeals for the Sixth Circuit, is hereby instructed to serve copies of this certification order upon counsel for the parties and to file this certification order under the seal of this court with the Supreme Court of Ohio, along with appropriate proof of service.

**III. CONCLUSION**

For the foregoing reasons, we **CERTIFY** questions of state law to the Supreme Court of Ohio. It is further ordered that the district court’s injunction against the enforcement of O.R.C. § 2919.123 remain in full force and effect pending further order of this court.

  
\_\_\_\_\_  
David W. McKeague  
United States Court of Appeals for the Sixth Circuit

Nancy H. Rogers, Ohio Attorney General,  
et al.

Case No. 2008-1234

ENTRY

v.

Planned Parenthood Cincinnati Region  
et al.

This cause came before the Court on the certification of a state law question from the United States Court of Appeals for the Sixth Circuit. Upon review of the preliminary memoranda pursuant to S.Ct.Prac.R. XVIII(6),

It is determined that the Court will answer the following questions:

- 1) Does 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?
- 2) Does 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?

It is further ordered by the Court that petitioner shall file their merit brief within 40 days of the date of this entry and the parties shall otherwise proceed in accordance with S.Ct.Prac.R. VI, and S.Ct.Prac.R. XVIII(7).

Upon consideration of the motions for admission pro hac vice of Roger K. Evans and Helene K. Krasnoff by Jennifer Branch,

It is ordered by the Court that the motions for admission pro hac vice are granted.

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THOMAS J. MOYER  
Chief Justice

**EXHIBIT 2**

LEXSEE 337 FSUPP2D 1040

**PLANNED PARENTHOOD CINCINNATI REGION, et al., Plaintiffs,  
v. BOB TAFT, et al., Defendants.**

Case No. C-1-04-493

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DIS-  
TRICT OF OHIO, WESTERN DIVISION**

*337 F. Supp. 2d 1040; 2004 U.S. Dist. LEXIS 20373*

September 22, 2004, Decided

**SUBSEQUENT HISTORY:** Amended by, Motion denied by, Motion granted by, Injunction granted at *Planned Parenthood Cincinnati Region v. Taft*, 2004 U.S. Dist. LEXIS 19933 (S.D. Ohio, Oct. 1, 2004)

Affirmed in part and vacated in part by, Remanded by *Planned Parenthood Cincinnati Region v. Taft*, 439 F.3d 304, 2006 U.S. App. LEXIS 4459 (6th Cir.) (6th Cir. Ohio, 2006)

Affirmed in part and vacated in part by, Remanded by *Planned Parenthood Cincinnati Region v. Taft*, 2006 U.S. App. LEXIS 9207 (6th Cir.) (6th Cir. Ohio, 2006)

**DISPOSITION:** Defendant Allen's Motion To Dismiss denied. Plaintiffs' Motion for Preliminary Injunction granted. Court enjoined Defendants from enforcing Act.

**COUNSEL:** [\*\*1] For Planned Parenthood Cincinnati Region, Plaintiff: Alphonse Adam Gerhardstein, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jennifer Lynn Branch, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Nicole G Berner, Planned Parenthood Federa-

tion of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Washington, DC, Roger K Evans, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, New York, NY.

For Planned Parenthood of Greater Cleveland, Alphonse Adam Gerhardstein, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jennifer Lynn Branch, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Nicole G Berner, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Washington, DC, Roger K Evans, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, New York, NY.

For Planned Parenthood of Central [\*\*2] Ohio, Alphonse Adam Gerhardstein, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jennifer Lynn Branch, Laufman & Gerhardstein, LEAD AT-

TORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Nicole G Berner, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Washington, DC, Roger K Evans, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, New York, NY.

For Preterm, Beatrice Jessie Hill, Case Western Reserve University School of Law, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH.

For Roslyn Kade, Alphonse Adam Gerhardstein, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jennifer Lynn Branch, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Nicole G Berner, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Washington, DC, Roger K Evans, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, New York, NY.

Laszlo Sogor, Alphonse Adam Gerhardstein, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Jeffrey M Gamso, Legal Director, ACLU of Ohio, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cleveland, OH, Jennifer Lynn Branch, Laufman & Gerhardstein, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Cincinnati, OH, Nicole G Berner, Planned Parenthood Federation of America, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Washington, DC, Roger K Evans, Planned Parenthood Federation of America,

LEAD ATTORNEY, ATTORNEY TO BE NOTICED, New York, NY.

For Bob Taft, Defendant: Holly J Hunt, Ohio Attorney General - 1, Constitutional Offices Section, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Columbus, OH, Sharon A Jennings, Ohio Attorney General - 2, Chief Counsel's Staff Section, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Columbus, OH, Anne Berry Strait, Court of Claims Defense - 1, ATTORNEY TO BE NOTICED, Columbus, OH.

For Jim Petro, Holly J Hunt, Ohio Attorney General - 1, Constitutional Offices Section, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Columbus, OH, Sharon A Jennings, Ohio Attorney General - 2, Chief Counsel's Staff Section, LEAD ATTORNEY, ATTORNEY TO BE NOTICED, Columbus, OH, Anne Berry Strait, Court of Claims Defense - 1, ATTORNEY TO BE NOTICED, Columbus, OH.

Michael K Allen, Kathleen McGarvey Hidy, Hamilton County Prosecutor's Office, ATTORNEY TO BE NOTICED, Cincinnati, OH, Tamara Susan Sack, Hamilton County Prosecutor's Office - 1, ATTORNEY TO BE NOTICED, Cincinnati, OH.

**JUDGES:** District Judge Susan J. Dlott.

**OPINION BY:** Susan J. Dlott

**OPINION**

[\*1042] ORDER GRANTING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND DENYING DEFENDANT ALLEN'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT

This matter comes before the Court on Plaintiffs' Motion for Preliminary Injunction (doc. # 2) and Defendant Michael K. Allen's

Motion To Dismiss This Action Under Federal *Rule 12(b)* (doc. # 28). Plaintiffs Planned Parenthood Cincinnati Region, Planned Parenthood of Central Ohio, Planned Parenthood of Greater Cleveland, and Preterm ("Planned Parenthood") filed both the original Complaint (doc. # 1) and the Motion for Preliminary Injunction (doc. # 2) on August 2, 2004. For the reasons set forth below, the Court **GRANTS** Plaintiffs' Motion.

## I. BACKGROUND

[\*\*5] Plaintiffs Planned Parenthood, Dr. Sogor, and Dr. Kade (collectively, "Plaintiffs"), brought this action challenging the constitutionality of Ohio's recently enacted *H.B. 126* ("the Act"), which is scheduled to take effect on September 23, 2004. The Act regulates the use of mifepristone, commonly known as RU-486, which is a drug used for medical abortion. Specifically, the Act provides:

No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion . . . unless the person . . . is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion *in accordance with all provisions of federal law* that govern the use of RU-486 (mifepristone) for inducing abortions.

§ 2919.123(A) (emphasis added).

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 ad-

ministration of [\*\*6] the United States that governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortion's." See § 2919.123(F). Violators of the Act are deemed "guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree," and repeat offenders are guilty of a felony in the third degree. See § 2919.123(E). Further, the Act provides that offenders who are doctors are "subject to sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license" *Id.* Finally, the Act requires the state medical board to revoke, suspend, reprimand, or refuse to grant a certificate to any doctor who enters a plea of guilty or is found guilty of violating any state law regulating the distribution of any drug. See § 4731.22(B)(3). *Section 4731.22(B)(3)* clearly applies to doctors found guilty of violating *Section 2919.123(A)* for unlawfully prescribing mifepristone.

Plaintiffs moved for a preliminary injunction "restraining defendants, their employees, agents, and successors, and all others acting in concert or participation with them, from enforcing [\*\*7] the provisions of H.B. 126" (doc. # 2, at 1). Plaintiffs [\*1043] named as defendants Bob Taft, the Governor of Ohio, and Jim Petro, the Attorney General of Ohio, in their official capacities, and Michael K. Allen, as Prosecuting Attorney for Hamilton County, Ohio, and as a representative of a class of all prosecuting attorneys in Ohio. On August 23, 2004, Plaintiffs filed a Motion for Certification of Defendant Class (doc. # 10), requesting that the Court certify a defendant class consisting of all county prosecuting attorneys in Ohio and appoint Michael K. Allen as the defendant class representative.<sup>1</sup> In challenging the Plaintiffs' Motion for Preliminary Injunction, Defendants argue that Plaintiffs' Motion should be denied because Plaintiffs lack standing to bring this suit, and Defendant Allen moves to Dismiss on the same ground.

1 The Court has not had sufficient time to conduct a hearing on the Motion for Class Certification, as requested by both parties, before entering this Order. The Court intends to hold a hearing on the Motion for Class Certification following the entering of this Order and, if appropriate, to amend this Order consistent with its findings on class certification. As a provisional measure, the Court orders Defendant Attorney General Petro to send notice of this Order to all 88 members of the proposed defendant class described in Plaintiffs' Motion for Class Certification within 48 hours of entry of this Order.

## [\*\*8] II. JURISDICTION AND STANDING

The Court conducted a hearing on the Motion for Preliminary Injunction on September 13 and 14, 2004. Following Opening Statements on September 13, 2004, the Court expressed its concerns about Planned Parenthood's standing. On the morning of September 14, 2004, before the Court convened, Plaintiffs filed an Amended Complaint (doc. # 18) adding Dr. Laszlo Sogor and Dr. Roslyn Kade ("Plaintiff Physicians") as Plaintiffs. On September 14, 2004, Defendants requested a continuance of the hearing, arguing that: 1) because the Amended Complaint added plaintiffs, it rendered the Motion for Preliminary Injunction before the Court "stale" such that there was no pending Motion for Preliminary Injunction before the Court; and 2) because Planned Parenthood filed the Amended Complaint during the hearing and Defendants had not had time to read it or respond to it, Defendants were thereby prejudiced.

The Court held that the Amended Complaint related back to the time of the filing of the stale.<sup>2</sup> The original Complaint, and that the Motion for Preliminary Injunction was therefore not Court then proceeded with the hearing.

Consequently, the Court will consider [\*\*9] the Amended Complaint to be the relevant complaint for purposes of the Motion for Preliminary Injunction.

2 The Court offered to extend the time for the hearing if Defendants requested more time to prepare for and respond to the Amended Complaint, which Defendants did not.

Generally, this Court has federal question jurisdiction to consider a case, such as this one, where Plaintiffs challenge an alleged deprivation of a Constitutional right by a State law. See 28 U.S.C. §§ 1331, 1343(a)(3), and 1343(a)(4). Nevertheless, this Court would lack jurisdiction to proceed if, as Defendants contend, Plaintiffs lack standing to pursue this case. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992). Thus, this Court must consider Plaintiffs' standing before reaching the merits of Plaintiffs' Motion for Preliminary Injunction.

Defendants cite *Women's Medical Prof. Corp. v. Taft*, 114 F. Supp. 2d 664 (S. D. Ohio 2000) and *Women's Medical Prof. Corp. v. Voinovich*, 911 F. Supp. 1051 (S.D. Ohio 1995), [\*\*10] *aff'd*, 130 F.3d 187 (6th Cir. 1997), *cert denied*, 523 U.S. 1036, 140 L. Ed. 2d 496, 118 S. Ct. 1347 (1998), for the proposition that the Court must evaluate [\*1044] the standing of each individual plaintiff and that each plaintiff must establish standing in its or his/her own right. Contrary to Defendants' assertion, in both of these cases, once the court determined that at least one plaintiff physician had standing, the court dispensed with a standing inquiry regarding the other plaintiffs and permitted all plaintiffs to proceed. See *WMPC v. Taft*, 114 F. Supp. 2d at 668; *WMPC v. Voinovich*, 911 F. Supp. at 1059. Thus, if the Court determines that any one of the Plaintiffs has standing, the Court has jurisdiction and may proceed with the case. See *Carey v. Population Services International*, 431 U.S. 678,

682, 52 L. Ed. 2d 675, 97 S. Ct. 2010 (1977) (recognizing that when at least one plaintiff has standing to challenge all aspects of claims, a court need not determine the standing of other plaintiffs).

Defendants also contend that in order to establish standing, each Plaintiff must submit factual evidence for the Court to examine to determine if each of the Plaintiffs has met the standing [\*\*11] requirements. Defendants would be correct if the Court were determining standing for the purposes of a final judgment on the merits. See *Lujan*, 504 U.S. at 561; see also *Okpalobi v. Foster*, 190 F.3d 337, 350 (5th Cir.1999) (controverted factual allegations supporting standing must be supported by evidence in cases proceeding to final judgment). When court considers whether a plaintiff has standing to request a preliminary injunction or whether plaintiff has standing pursuant to a motion to dismiss, however, standing is determined by analyzing the material allegations in the complaint, which must be accepted as true. See *Okpalobi*, 190 F.3d at 350 (courts analyze standing for both motions for preliminary injunction and motions to dismiss based on the material allegations of the complaint); see also *Haskell v. Washington Tp.*, 864 F.2d 1266, 1276 (6th Cir. 1988) (reversing district court's grant of defendant's motion to dismiss on grounds that plaintiff lacked standing because allegations in complaint were sufficient to establish standing). The Court therefore determines whether Plaintiffs have standing for purposes of [\*\*12] both the Motion for Preliminary Injunction and Allen's Motion to Dismiss by considering the allegations in Plaintiffs' Amended Complaint.

Standing involves two levels of inquiry: 1) whether the plaintiff has shown that a "case or controversy" exists, which can be shown by proving actual injury or injury in fact likely to be redressed by a favorable decision; and 2) whether the plaintiff is the proper proponent of the rights on which the action is based. See

*Planned Parenthood Ass'n of Cincinnati Inc. v. City of Cincinnati*, 822 F.2d 1390, 1394 (6th Cir. 1987). The Court will first consider the standing of the Physician Plaintiffs.

Dr. Kade is the medical director of Plaintiff Planned Parenthood Cincinnati Region and also has a private practice in Cincinnati. (Doc. # 18, P 10.) As part of her duties at PPCR, Dr. Kade performs evidence-based medical abortions with mifepristone, which Defendants contend is prohibited by the Act. (Kade Affidavit, PP 6,8.) If, after the Act took effect, Dr. Kade continued her practice of providing evidence-based abortions using mifepristone, Defendants would have authority to prosecute her under the Act, and Dr. Kade has attested that [\*\*13] she fears such prosecution. (Id. at P 11.) Thus, Dr. Kade has clearly alleged a case or controversy with Defendants regarding an injury likely to be redressed by a favorable decision. Thus, because Dr. Kade faces a direct risk of enforced prosecution by Defendants under the Act, she has standing to bring a pre-enforcement challenge to the Act. See *WMPC v. Taft*, 114 F. Supp. 2d at 667-68; *WMPC v. Voinovich*, 911 F. Supp. at 1058.

[\*1045] Dr. Kade has also asserted standing to enforce her patients' rights. Courts have consistently held that physicians whose conduct is regulated by an abortion statute have standing to challenge those statutes on behalf of themselves and their patients. See, e.g., *Singleton v. Wulff*, 428 U.S. 106, 118, 49 L. Ed. 2d 826, 96 S. Ct. 2868 (1976); see also *Planned Parenthood of Wisconsin v. Doyle*, 162 F.3d 463, 465 (7th Cir. 1998) (Posner, J.) ("the standing of the physician plaintiffs, and of Planned Parenthood as the owner of abortion clinics in Wisconsin, to maintain this suit is not open to question.") Physicians may bring suit on behalf of their patients due to: 1) the close relationship between women and their physicians; 2) [\*\*14] the fact that in the context of abortion regulation, women's due process rights are inextricably bound up with the activity that

a physician plaintiff wishes to pursue; and 3) the conclusion that women are faced with several obstacles to asserting their own rights. See *Singleton*, 428 U.S. at 117; see also *WMPC v. Taft*, 114 F. Supp. 2d at 668; *WMPC v. Voynovich*, 911 F. Supp. at 1058. All of these factors are present here.

The Court therefore finds that Dr. Kade has both individual and third-party standing and thus dispenses with inquiry into the remaining Plaintiffs' standing. Plaintiffs have made sufficient allegations in their complaint regarding standing both to withstand Allen's Motion to Dismiss and to allow the Court to proceed to the merits of Plaintiffs' Motion for Preliminary Injunction.

### III. LEGAL STANDARD

*Federal Rule of Civil Procedure 65* authorizes the Court to grant a preliminary injunction. When deciding whether to issue a preliminary injunction, the Court considers four factors: "(1) whether the movant has a 'strong' likelihood of success on the merits; (2) whether the movant would otherwise suffer irreparable [\*\*15] injury; (3) whether issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of a preliminary injunction." *Leary v. Daeschner*, 228 F.3d 729, 736 (6th Cir. 2000).

### IV. ANALYSIS

Plaintiffs challenge the Act on the following grounds: "the Act is unconstitutionally vague; the Act violates their patients' right to bodily integrity by compelling surgery in circumstances where a medical abortion [as opposed to surgical abortion] would otherwise be the desired or appropriate treatment; the Act lacks the constitutionally-mandated exception to allow otherwise restricted practices where they are necessary to preserve a woman's life or health; and, the Act imposes an undue burden on their patients' right to choose abortion by

prohibiting a safe and common method of pre-viability abortion." (See doc. # 2, at 1)

Plaintiffs allege that because of the former factors, Plaintiffs have a strong likelihood of success on the merits. Further, Plaintiffs allege that Planned Parenthood, Plaintiff Physicians, and their patients would face irreparable injury if the Act takes effect. (Id. at 18-19.) [\*\*16] Specifically, Plaintiffs argue that because the Act is unconstitutionally vague, Plaintiff Physicians would be left to guess about whether they may legally provide medical abortions in certain instances. (Id. at 18.) Specifically, Plaintiffs state that Planned Parenthood and the Plaintiff Physicians have been providing medical abortions using an evidence-based protocol of mifepristone.<sup>3</sup> [\*1046] (See doc. # 18, PP 6-11.) This evidence-based protocol differs in several respects from the protocol which the FDA tested and on which it based its approval of mifepristone, including the dose of mifepristone and the dose and administration of its companion drug, misoprostol, and also allows for a medical abortion later in the term of pregnancy.<sup>4</sup> Plaintiffs note that the Act provides that physicians may prescribe mifepristone only in accordance with federal law, and that the Act includes the FDA approval letter within its definition of federal law. However, Plaintiffs also note that the FDA approval letter does not require physicians to adhere to any particular protocol, although the documents on the final printed labeling do discuss only the protocol that was tested by the FDA. (Id. at P 38.) Thus, [\*\*17] Plaintiffs argue that it is unclear whether the Act's inclusion of the FDA approval letter in the definition of federal law renders it illegal for a physician to prescribe the evidence-based protocol of mifepristone. Consequently, Plaintiffs argue that Plaintiff Physicians would face the threat of possible criminal prosecution and loss or suspension of their medical licenses if they continue to prescribe the evidence-based protocol of mifepristone. (Id. at P 53.) Plaintiffs also argue that Plaintiff Physicians' patients would face irreparable

harm because the Act may force some women seeking an abortion to forego medical abortion and undergo either surgical abortion or other more invasive procedures, which may be both riskier and more costly for a particular woman. (See doc. # 2, at 18-19.)

3 Or in the case of Planned Parenthood of Central Ohio, intended to switch to an evidence-based protocol, but suspended those preparations due to uncertainty regarding the meaning of the Act. (See doc. # 18, P 8.)

4 The evidence-based protocol for medical abortion consists of a single oral dose of 200 mg of mifepristone followed by a single dose of .6 mg misoprostol administered vaginally, and is effective for medical abortion through at least 63 days after a woman's last menstrual period ("LMP"). The protocol for medical abortion that the FDA tested and on which it based its approval of mifepristone consisted of three oral doses of 200 mg of mifepristone followed by a single dose of .4 mg misoprostol also taken orally, through 49 days LMP.

#### **[\*\*18] A. Strong Likelihood Of Success On The Merits**

Though Plaintiffs bring four constitutional challenges to the Act, this motion can be resolved based upon just one of those: "the Act lacks the constitutionally-mandated exception to allow otherwise restricted practices where they are necessary to preserve a woman's life or health." (See doc. # 2, at 1.) As Plaintiffs note, a long line of Supreme Court authority mandates and reaffirms that the *Due Process Clause of the Constitution* requires that every statute regulating abortion include an exception for those situations where necessary, in appropriate medical judgment, to preserve the life and health of the mother. See *Stenberg v. Carhart*, 530 U.S. 914, 930-31, 147 L. Ed. 2d 743, 120 S. Ct. 2597 (2000); *Roe v. Wade*, 410

*U.S. 113, 163-65, 35 L. Ed. 2d 147, 93 S. Ct. 705 (1973)* (striking down statute prohibiting abortion except where necessary to save a woman's life, and holding that post-viability, a state may regulate abortion except where it is necessary in appropriate medical judgment to preserve the life *and health* of the mother) (emphasis added); see also *Planned Parenthood v. Casey*, 505 U.S. 833, 846, 879-80, 120 L. Ed. 2d 674, 112 S. Ct. 2791 (1992) (affirming that [**\*\*19**] *Roe* "forbids a State to interfere with a woman's choice to undergo an abortion procedure if continuing her pregnancy would constitute a threat to her health.") This health exception is required both post and pre-viability. See *Carhart*, 530 U.S. at 930.

[\*1047] Defendants argue, citing *Carhart*, that a health exception is required only where substantial medical authority supports the proposition that banning a particular procedure could endanger a woman's health. Defendants argue further that Plaintiffs "cannot sustain their burden" of showing that an abortion using mifepristone in a manner prohibited by the Act is ever necessary in appropriate medical judgment for the preservation of the life or health of the mother. Defendants therefore conclude that the Act does not require a health exception and is constitutional.

Defendants' arguments are misplaced. In *Carhart*, the Court considered a plaintiff's challenge to a Nebraska statute banning partial birth abortion. The Court held that the statute was unconstitutional both because it placed an undue burden on a woman's right to a pre-viability abortion, and because it lacked a health exception (the Nebraska statute [**\*\*20**] contained only a "mother's life" exception). Like Defendants here, Nebraska argued that the statute did not require a health exception because there were alternative methods of abortion and the ban would create no risk to women's health, *Id.* at 931. The Court rejected this argument because "[Nebraska] fail[ed] to demonstrate that banning D & X without a

health exception may not create significant health risks for women, because the record shows that significant medical authority supports the proposition that in some circumstances, D & X would be the safest procedure." *Id.* at 932.

A tenable reading of the former statement might imply, as Defendants argue, that a health exception is required only where it is evident that the banned or regulated method of abortion is necessary at times to preserve the health and safety of the mother. Significantly; however, even if the Court intended to modify the mandatory health exception, the Court clearly placed the burden of proof not, as Defendants desire, upon a plaintiff to prove that a health exception is necessary, but rather upon a defendant to show that a ban or regulation would never cause any risk to [\*\*21] a mother's health. Even if this Court were inclined to so read Stenberg-- which it is not--Plaintiffs have still shown a strong likelihood of success on the merits because it is highly unlikely that Defendants will be able to prove that there are no circumstances in which the Act's regulation of mifepristone would cause significant health risks. Plaintiffs have already presented expert medical testimony at the hearing that there are women who have medical conditions that render surgical abortion riskier than the evidence-based protocol for medical abortion, which Defendants argue is prohibited under the Act. (Tr. 9/13/04, Schaff test., 52:1-58:25; Tr. 9/14/04, Sogor test., 23:15-25:5)

Also, despite the former analysis of Defendants' argument, the Court finds that the appropriate reading of Carhart -- and the one consistent with Supreme Court precedent -- is that a health exception is always required. Indeed, the Carhart Court expressed the health exception requirement as an independent proposition in several other places in the opinion while the scope of the necessary health exception is debated -- not only by the parties here but also by lower federal courts' case law [\*\*22] -- this

Court need not reach this question because the Act lacks *any* exception for the life or health of the mother. Consequently, Plaintiffs have likelihood of success on the merits that the Act violates the *Due Process Clause* and is unconstitutional.

### **B. Irreparable Injury**

Because this Court has found that the Act threatens or impairs Plaintiffs' patients' constitutional right to Due Process, [\*1048] the Court must find that Plaintiffs and their patients' will suffer an irreparable injury if the preliminary injunction does not issue. See *ACLU of KY v. McCreary County, Kentucky*, 354 F.3d 438, 445 (6th Cir. 2003), citing *Elrod v. Burns*, 427 U.S. 347, 373, 49 L. Ed. 2d 547, 96 S. Ct. 2673 (1976) (affirming district court's grant of preliminary judgment for plaintiffs who alleged violation of their *First Amendment* rights); see also *Overstreet v. Lexington-Fayette Urban County Gov't*, 305 F.3d 566, 578 (6th Cir. 2002) ("courts have also held that 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.") Thus, this factor of the preliminary injunction inquiry [\*\*23] weighs in favor of granting Plaintiffs' Motion for Preliminary Injunction.

### **C. Substantial Harm to Others**

Because Plaintiffs have shown a substantial likelihood of success on the merits on the ground that the Act is unconstitutional, "no substantial harm to others can be said to inhere in its enjoinder." See *Deja Vu of Nashville, Inc. v. Metropolitan Gov't of Nashville*, 274 F.3d 377, 400 (6th Cir. 2001), citing *Connection Distrib. Co. v. Reno*, 154 F.3d 281, 288 (6 Cir. 1998). Thus, this factor of the preliminary injunction inquiry weighs in favor of granting Plaintiffs' Motion for Preliminary Injunction.

### **D. Public Interest**

"It is always in the public interest to prevent violation of a party's constitutional rights." *Id.*, at 400, citing *G & V Lounge, Inc. v. Michigan Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994). Thus, the public interest factor of the preliminary injunction inquiry also weighs in favor of granting Plaintiffs' Motion for Preliminary Injunction.

## V. CONCLUSION

Because Plaintiffs have demonstrated a strong likelihood of success on the merits regarding an alleged violation of [\*\*24] their constitutional rights, the other factors to consider in granting a preliminary injunction automatically weigh in Plaintiffs' favor. Because Plaintiffs have made sufficient allegations in their complaint to establish standing, and because all four factors to consider in issuing a preliminary injunction weigh heavily in favor of doing so, this Court **DENIES** Defendant Allen's Motion To Dismiss (doc. # 28) and **GRANTS** Plaintiffs' Motion for Preliminary Injunction (doc. # 2). The Court hereby **ENJOINS** Defendants from enforcing the Act.

IT IS SO ORDERED.

Susan J. Dlott

United States District Judge

444 F.3d 502, \*, 2006 U.S. App. LEXIS 9207, \*\*;  
2006 FED App. 0129A (6th Cir.), \*\*\*

LEXSEE 444 F3D 502

**PLANNED PARENTHOOD CINCINNATI REGION, et al., Plaintiffs-Appellees, v. BOB TAFT, et al., Defendants-Appellants.**

No. 04-4371

**UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT**

**06a0129a.06 444 F.3d 502; 2006 U.S. App. LEXIS 9207; 2006 FED App. 0129A (6th Cir.)**

**December 7, 2005, Argued**

**April 13, 2006, Decided**

**April 13, 2006, Filed**

**SUBSEQUENT HISTORY:** Summary judgment granted by, Injunction granted at, On remand at *Planned Parenthood Cincinnati Region v. Taft*, 2006 U.S. Dist. LEXIS 69964 (S.D. Ohio, Sept. 27, 2006)

**PRIOR HISTORY:** [\*\*1] Appeal from the United States District Court for the Southern District of Ohio at Cincinnati. No. 04-00493--Susan J. Dlott, District Judge.

*Planned Parenthood Cincinnati Region v. Taft*, 439 F.3d 304, 2006 U.S. App. LEXIS 4459 (6th Cir.) (6th Cir. Ohio, 2006)

*Planned Parenthood Cincinnati Region v. Taft*, 2004 U.S. Dist. LEXIS 19933 (S.D. Ohio, Oct. 1, 2004)

*Planned Parenthood Cincinnati Region v. Taft*, 337 F. Supp. 2d 1040, 2004 U.S. Dist. LEXIS 20373 (S.D. Ohio, 2004)

**COUNSEL:** ARGUED: Anne Berry Strait, OFFICE OF THE ATTORNEY GENERAL, CHARITABLE LAW SECTION, for Appellants.

Nicole G. Berner, PLANNED PARENTHOOD FEDERATION OF AMERICA, Washington, D.C., for Appellees.

ON BRIEF: Anne Berry Strait, OFFICE OF THE ATTORNEY GENERAL, CHARITABLE LAW SECTION, Columbus, Ohio, Sharon A. Jennings, Holly J. Hunt, OFFICE OF THE ATTORNEY GENERAL OF OHIO, CONSTITUTIONAL OFFICES SECTION, Columbus, Ohio, for Appellants.

Nicole G. Berner, PLANNED PARENTHOOD FEDERATION OF AMERICA, Washington, D.C., Alphonse A. Gerhardstein, GERHARDSTEIN, BRANCH & LAUFMAN, Cincinnati, Ohio, Roger K. Evans, Mimi Y.C. Liu, PLANNED PARENTHOOD FEDERATION OF AMERICA, New York, New York, Jeffrey M. Gamso, AMERICAN CIVIL LIBERTIES UNION OF OHIO FOUNDATION, Cleveland, Ohio, Jessie Hill, CASE WESTERN RESERVE UNIVERSITY SCHOOL OF LAW, Cleveland, Ohio, for Appellees.

Peter O. Safir, Kelly A. Falconer, COVINGTON & BURLING, Washington, D.C., for Amicus Curiae.

**JUDGES:** Before: MOORE, ROGERS, and McKEAGUE Circuit Judges. McKEAGUE, J., delivered the [\*\*2] opinion of the court, in

which ROGERS, J., joined. MOORE, J., delivered a separate opinion concurring in part.

**OPINION BY: McKEAGUE**

**OPINION**

[\*505] [\*\*\*2] **AMENDED OPINION**

McKEAGUE, Circuit Judge. This matter is before the court on Plaintiffs' petition for panel rehearing. Upon consideration of the relevant briefs and the record, we vacate our prior opinion, *Planned Parenthood v. Taft*, 439 F.3d 304 (6th Cir. 2006), and replace it with this amended opinion. Plaintiffs challenge an Ohio statute which prohibits the off-label use of the abortion drug mifepristone (more commonly known as RU-486). The district court granted a preliminary injunction enjoining enforcement of the statute on two alternative grounds. The State timely filed an interlocutory appeal. For the following reasons, we hold that the district court's primary holding was error, but affirm the reasoning of the district court's alternative holding. Nevertheless, we vacate the district court's order in part and remand for consideration of the appropriate scope of injunctive relief in light of the United States Supreme Court's recent decision in *Ayotte v. Planned Parenthood of Northern New England*, U.S. , 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006). [\*\*\*3]

**I.**

Until 2000 most first trimester abortions in this country were surgical abortions performed by vacuum aspiration or curettage. In September of 2000, the Food and Drug Administration ("FDA") approved mifepristone, a pill used to induce an abortion without surgical intervention, for manufacture and use in the United States. This approval was based on clinical trials which involved the oral ingestion of 600 mg of mifepristone followed two days later by the oral ingestion of 0.4 mg of misoprostol.<sup>1</sup> Upon examining the results of these trials, the FDA concluded that this regimen was a safe and ef-

fective method of medical abortion when employed up through forty-nine days' gestation. Consequently, the FDA approved the use of mifepristone. The FDA labeling and approval letter indicated that the appropriate treatment regimen was to administer 600 mg of mifepristone orally followed by 0.4 mg of misoprostol administered orally two days later and that mifepristone was not to be administered after forty-nine days' gestation.

1 The mifepristone is an abortifacient which terminates the pregnancy by detaching the gestational sac from the uterine wall. The misoprostol is a prostaglandin which induces the contractions necessary to expel the fetus and other products of conception from the uterus.

[\*\*4] Absent state regulation, once a drug has been approved by the FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. This is a widely employed practice known as "off-label" use. Off-label use does not violate federal law or FDA regulations because the FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states. Subsequent to the clinical trials relied upon by the FDA, other trials were conducted experimenting with different possible regimens for administering mifepristone and misoprostol. As a result of this research, an off-label protocol was developed consisting of 200 mg of mifepristone administered orally followed [\*506] one to three days later by 0.8 mg of misoprostol administered vaginally. This regimen is employed up to sixty-three days' gestation and is known as the Schaff protocol after the doctor whose research primarily led to its development. The Schaff protocol is the method of medical (i.e., non-surgical) abortion recommended by the National Abortion Federation and Planned Parenthood Federation of America and has come to be widely [\*\*5] employed across the United States.<sup>2</sup>

2 After this appeal was briefed, the American College of Obstetricians and Gynecologists (ACOG) issued a practice bulletin stating that compared with the FDA protocol the Schaff protocol is "associated with a decreased rate of continuing pregnancies, decreased time to expulsion, fewer side effects, improved complete abortion rates, and lower cost for women with pregnancies up to 63 days' gestation." The previous relevant ACOG practice bulletin from 2001 had only recommended using the FDA protocol and specifically stated that medical abortion should not be performed after forty-nine days' gestation.

[\*\*3] In 2004, the Ohio General Assembly enacted H.B. 126 ("the Act") to regulate the use of mifepristone in Ohio. Specifically, the Act provides:

No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion . . . unless the person . . . is a physician, the physician [\*\*6] satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.

*Ohio Rev. Code Ann. § 2919.123(A)*. The Act defines "federal law" as, "any law, rule, or regulation of the United States or any drug ap-

proval 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." *Ohio Rev. Code Ann. § 2919.123(F)*. This arguably requires doctors who prescribe mifepristone for the purpose of inducing an abortion to do so only in accordance with the indication, regimen and distribution restrictions approved by the FDA. In other words, the Act arguably prohibits the "off-label" use of mifepristone.

According to the State, the Act was passed because abortion providers in Ohio were openly using the Schaff protocol and "because [\*\*7] legislators became aware that several women had died or been severely injured recently as a result of their use of mifepristone." <sup>3</sup> The State further suggests that Ohio legislators concluded that the FDA had only approved one specific protocol for the administration of mifepristone because that was the only safe and effective protocol. Accordingly, the State argues that they banned all other uses of mifepristone to protect Ohio women from unsafe and ineffective mifepristone protocols.

3 The record in this case does not contain any indication that any woman died or was severely injured as a result of an off-label mifepristone protocol. The only source cited did indicate that one death had been reported, but that was due to the fact that mifepristone was administered to a woman with an ectopic pregnancy. All parties unequivocally agree that mifepristone is contraindicated for ectopic pregnancies at any gestational age. Two cases of severe bacterial infection and one heart attack were also reported in women who had taken mifepristone, but no causal link was established.

[\*\*8] The Act was scheduled to go into effect on September 23, 2004. Dr. Roslyn Kade, Dr. Laszlo Sogor, and various Planned [\*\*507] Parenthood chapters in Ohio (collectively,

"Plaintiffs") brought this action challenging the constitutionality of the Act on the grounds that it (1) is unconstitutionally vague, (2) violates a patient's right to bodily integrity by compelling surgery in circumstances where a medical abortion would otherwise be the desired or appropriate treatment, (3) lacks the constitutionally-mandated exception to allow otherwise restricted practices where they are necessary to preserve a woman'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. Plaintiffs named as defendants Bob Taft, the Governor of Ohio, and Jim Petro, the Attorney General of Ohio, in their official capacities, and Michael K. Allen, as Prosecuting Attorney for Hamilton County, Ohio, and as a representative of a class of all prosecuting attorneys in Ohio (collectively, "the State").

Before the Act went into effect, Plaintiffs moved for a preliminary injunction. A two-day evidentiary hearing was held in which [\*\*9] each side was allotted a total of three hours to present testimony and cross-examine opposing witnesses. Plaintiffs presented the expert testimony of Dr. [\*\*\*4] Eric Schaff and Dr. Laszlo Sogor. The State presented the testimony of Dr. Susan Crockett. The district court granted the motion for a preliminary injunction on the basis that Plaintiffs had established a strong likelihood of prevailing on their third argument, that the statute needs a health or life exception. The district court did not address the other three arguments. The State timely filed an interlocutory appeal.

## II.

The Sixth Circuit's review of a district court's grant of a preliminary injunction is limited to an abuse of discretion standard. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 387 F.3d 522, 532 (6th Cir. 2004); *ACLU v. Taft*, 385 F.3d 641, 645 (6th Cir. 2004); *United States v. Edward Rose & Sons*, 384 F.3d 258,

261 (6th Cir. 2004); *Sec'y of Labor v. 3Re.com, Inc.*, 317 F.3d 534, 537 (6th Cir. 2003). The district court's determination will be disturbed only if it relied upon clearly erroneous findings of fact, improperly [\*\*10] applied the governing law, or used an erroneous legal standard. *Nightclubs, Inc. v. City of Paducah*, 202 F.3d 884, 888 (6th Cir. 2000). Under this standard, the court must review the district court's legal conclusions de novo and its factual findings for clear error. *Taubman Co. v. Webfeats*, 319 F.3d 770, 774 (6th Cir. 2003).

## III.

The district court held that "a long line of Supreme Court authority mandates and reaffirms that the *Due Process Clause of the Constitution* requires that every statute regulating abortion include an exception for those situations where necessary, in appropriate medical judgment, to preserve the life and health of the mother." These cases are said to impose a "per se" requirement on all abortion statutes.<sup>4</sup> The State argues that the requirement of a health or life exception does not apply to every single statute which regulates abortion, but only to those statutes which regulate abortion in a manner which might actually endanger women's health or lives. The district court offered little analysis to support its adoption of a per se requirement, [\*508] and close scrutiny of the case law reveals that no such blanket requirement [\*\*11] has been imposed.

4 Other circuits have made reference to a "per se" requirement but with inconsistent meanings. See *Richmond Med. Center for Women v. Hicks*, 409 F.3d 619, 625 (4th Cir. 2005); *Reproductive Health Services of Planned Parenthood v. Nixon*, 429 F.3d 803, 805-06 (8th Cir. 2005); *Planned Parenthood v. Wasden*, 376 F.3d 908, 922 (9th Cir. 2004).

In *Planned Parenthood v. Casey* the Supreme Court reaffirmed three basic principles

which were originally set forth in *Roe v. Wade*: (1) previability a woman has a right to obtain an abortion without the state imposing an undue burden on her decision, (2) postviability the state may restrict abortion except when a woman's health or life is in danger, and (3) throughout a pregnancy the state has legitimate interests in protecting both "the health of the woman and the life of the fetus that may become a child." *Planned Parenthood v. Casey*, 505 U.S. 833, 846, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992). The [\*\*12] Court later clarified that a state may not restrict abortion procedures which are necessary to preserve the health or life of the mother at any time during a pregnancy. *Stenberg v. Carhart*, 530 U.S. 914, 930, 120 S. Ct. 2597, 147 L. Ed. 2d 743 (2000) ("Since the law requires a health exception in order to validate even a postviability abortion regulation, it at a minimum requires the same in respect to previability regulation.").

The State's challenge to the district court's use of a per se requirement is a conflation of two similar, but separate, arguments. The first argument is that a previability regulation must only have a health or life exception if the lack of such an exception imposes an undue burden. The second is that there is no blanket requirement anywhere in the case law that every single regulation which affects abortion must have a health or life exception. The State's briefing varies between treating these two propositions as separate arguments, treating them as the same argument simply restated in different terms, and treating the second proposition as the logical result of the first proposition. [\*\*\*5] This creates confusion because although the arguments are closely [\*\*13] related, it is not correct to say that a previability regulation must only have a health or life exception if the lack of such an exception imposes an undue burden, for reasons explained below, while it is correct to say that there is no per se requirement for a health or life exception in all abortion statutes. The best way to avoid

this confusion is to address each proposition separately.

According to the State, *Casey* mandates that all statutes affecting previability abortions are evaluated using the undue burden standard, including to determine whether such a statute must contain a health or life exception. Therefore, the State argues such an exception is only necessary if the absence of an exception would impose an undue burden. While the State's construction of *Casey* might be plausible in the absence of any subsequent relevant case law, the Supreme Court has since made it abundantly clear that the necessity and adequacy of a health or life exception is a question entirely separate from the undue burden analysis. See *Carhart*, 530 U.S. at 930. In *Carhart* the Court struck down the statute at issue as it related to previability abortions on the basis [\*\*14] that it imposed an undue burden. *Id.* However, it unequivocally stated that the statute needed a health exception and the lack of that exception was a separate and independent basis for striking down the statute. *Id.*; see also *Ayotte v. Planned Parenthood of Northern New England*, U.S. , 126 S. Ct. 961, 969, 163 L. Ed. 2d 812 (2006) . This analysis dooms the State's argument that a health or life exception is only necessary if its absence would impose an undue burden.

The next component of the State's argument is a direct challenge to the district court's imposition of a per se requirement. The Supreme Court cases the district [\*509] court cited contain only one statement which offers textual support for a per se requirement. In *Casey* the Court stated that the second essential holding of *Roe v. Wade* was "a confirmation of the State's power to restrict abortions after fetal viability, if the law contains exceptions for pregnancies which endanger the woman's life or health." *Casey*, 505 U.S. at 846. However, this lone statement must be read in the context of the many other statements in *Casey*, *Carhart*, and *Ayotte* [\*\*15] which frame the same general

principle in slightly, but significantly, different terms. For example, the *Casey* Court stated that "the essential holding of *Roe* forbids a State to interfere with a woman's choice to undergo an abortion procedure if continuing her pregnancy would constitute a threat to her health." *Id.* at 880; see also *Carhart*, 530 U.S. at 931 ("The governing standard requires an exception where it is necessary, in appropriate medical judgment for the preservation of the life or health of the mother."); *Ayotte*, 126 S. Ct. at 967 ("Our precedents hold, that a State may not restrict access to abortions that are necessary, in appropriate medical judgment, for preservation of the life or health of the mother."). The latter, more predominant, way the health or life exception requirement is expressed indicates that a statute which regulated abortion, but did not pose any significant risk to a woman's health or life, would not violate the health or life exception requirement.

Furthermore, the Supreme Court's *application* of the health or life exception requirement further undermines the slender textual support for [\*\*16] a per se requirement. In *Carhart*, the Court invalidated Nebraska's ban on partial-birth abortion because although it contained a life exception, it did not contain a health exception. *Carhart*, 530 U.S. at 930-38. The language throughout the opinion shows that before coming to this conclusion the Court carefully considered whether a health exception was necessary. *Id.* at 934-37 ("We find these eight arguments insufficient to demonstrate that Nebraska's law needs no health exception." "Given these medically related evidentiary circumstances, we believe the law requires a health exception."). If an abortion statute is per se unconstitutional without a health or life exception, the Court would only have had to note that the statute at issue regulated abortion and that it did not have a health exception. Those two facts alone (neither of which was disputed) would have been sufficient to find a constitutional violation. Both the Court's predominant discussion of the health or life exception re-

quirement and its application demonstrate that there is no such per se requirement.

[\*\*6] Neither can support for a per se requirement be found in any of [\*\*17] the cases from other circuits cited in the briefs. Although the First Circuit has stated that a health or life exception is a per se requirement, in the same case it went on to observe that all three times an abortion statute has been challenged in the Supreme Court, "the Court has indicated that an exception must be provided *when the restriction would place a woman's health at risk.*" *Planned Parenthood of Northern New England v. Heed*, 390 F.3d 53, 59-60 (1st Cir. 2004) (emphasis added), *vacated and remanded on other grounds sub nom. Ayotte v. Planned Parenthood of Northern New England*, U.S. , 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006). Since the court expressed the requirement both ways and did not examine the issue in detail, its commentary is not helpful one way or the other.

At first glance, it appears that the Ninth Circuit has followed a per se approach because it has stated that "an adequate [\*510] health exception . . . is a *per se* constitutional requirement." *Planned Parenthood v. Wasden*, 376 F.3d 908, 922 (9th Cir. 2004). However, the context shows that the Ninth Circuit was not imposing a per se requirement [\*\*18] as the district court did here, but rather holding that determining whether a health or life exception is constitutionally necessary "requires an analysis separate from any undue burden inquiry." *Id.* The Ninth Circuit's use of the phrase "per se requirement" describes the fact that the health or life exception requirement is separate and distinct from the undue burden standard. See *id.* The *Wasden* court does *not* use the phrase "per se requirement" the same way that the parties and the district court in this litigation have used it, which is to refer to the proposition that every law which affects abortion must contain a health or life exception. Consequently, *Wasden* does not support a per

se requirement that all abortion statutes must have a health or life exception.

The Fourth and Eighth Circuits have also stated that the health or life exception requirement is a "per se constitutional rule." *Richmond Med. Center for Women v. Hicks*, 409 F.3d 619, 625 (4th Cir. 2005); *Reproductive Health Services of Planned Parenthood v. Nixon*, 429 F.3d 803, 805-06 (8th Cir. 2005); *Carhart v. Gonzales*, 413 F.3d 791, 796 (8th Cir. 2005). [\*\*19] However, once again the context indicates that neither circuit was embracing the test employed by the district court in this case. *Nixon*, 429 F.3d at 805-06; see also *Hicks*, 409 F.3d at 625-26; *Gonzales*, 413 F.3d at 796-97. Neither were these courts using the phrase "per se rule" in the same sense as the Ninth Circuit. The cases decided by the Fourth and Eighth Circuits involved statutes banning partial birth abortion which were similar to the statute struck down by the *Carhart* Court for lack of a health exception. The Fourth Circuit case was decided first and used the phrase "per se constitutional rule" to describe the fact that the Supreme Court had already determined that statutes banning partial birth abortions were required to contain a health exception as well as a life exception. *Hicks*, 409 F.3d at 625-26. The Fourth Circuit concluded that the body of medical evidence relevant to whether substantial medical authority indicated that a ban of partial birth abortion created a significant health risk did not need to be "reproduced in every subsequent challenge to a partial birth abortion statute lacking a health [\*\*20] exception." *Id.* The Eighth Circuit reached the same conclusion and referred to the "per se rule" that a partial birth abortion ban must contain a health exception (at least until a state is able to demonstrate that medical procedures have advanced to the point where the *Carhart* Court's conclusion is no longer valid). *Nixon*, 429 F.3d at 805-06; *Gonzales*, 413 F.3d at 796-97.

The Tenth Circuit has also faced the issue of whether a particular abortion statute needed

to contain a health or life exception. *Planned Parenthood v. Owens*, 287 F.3d 910 (10th Cir. 2002). The statute at issue required a forty-eight hour waiting period after parental notification. *Id.* at 920. The Tenth Circuit concluded that an exception was necessary based on the observation that experts from both sides agreed that there were medical emergencies which could arise which would endanger the health or life of a minor if she could not obtain an abortion before the expiration of the waiting period. *Id.* The court's discussion of whether the statute at issue could affect the health or life of a minor is an implicit rejection of a per [\*\*21] se requirement that all abortion statutes contain a health or life exception regardless of whether the statute endangers the health or life of the woman. See *id.* at 919-20.

[\*\*7] [\*511] In light of the way the Supreme Court has both expressed and applied the health or life exception requirement, the district court's holding that the requirement is a per se rule was erroneous. Consequently, it is necessary to consider the district court's alternative holding.

#### IV.

The district court held that Plaintiffs had established a significant likelihood of prevailing on the merits even if there is no per se requirement. The district court held that at a minimum the Supreme Court case law requires the State to demonstrate that there are no circumstances under which a statute would result in significant health risks in order to preserve a statute from being held unconstitutional due to lack of a health or life exception. The State challenges both the district court's placement of the burden of proof on the State and the district court's conclusion that the evidence submitted at the preliminary injunction hearing was sufficient to show a substantial likelihood that the Act [\*\*22] must contain a health or life exception. We find that there is no need to address the burden of proof issue because the evidence

submitted was sufficient to merit the district court's conclusion as to the necessity of a health or life exception regardless of which party had the burden of proof.

The legal standard for determining when a statute which affects abortion must contain a health or life exception was succinctly set forth by the *Carhart* Court.

By no means must a State grant physicians unfettered discretion in their selection of abortion methods. But where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health *Casey* 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.

*Carhart*, 530 U.S. at 938 (internal quotations and citations omitted). An exception is constitutionally necessary where substantial medical authority indicates that a banned procedure would be safer than the other available procedures, not just when banning the procedure subjects [\*\*23] a woman to risks from the pregnancy itself. *Id.* at 931. As emphasized previously by this circuit, an exception is only necessary (and must only cover) circumstances where a statute poses a *significant* health risk. *Id.*; *Women's Medical Pro. Corp. v. Taft*, 353 F.3d 436, 448-49 (6th Cir. 2003). Finally, an adequate showing of a significant health risk in certain circumstances is sufficient to require an exception even if those circumstances rarely occur. *Carhart*, 530 U.S. at 934 ("The State cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it."); *see also Ayotte*, 126 S. Ct. at 967.

At the preliminary injunction evidentiary hearing Plaintiffs introduced expert testimony from two doctors which established that, if enforced, the statute would result in significant risk to women's health in particular, albeit narrow, circumstances. They pointed to the fact that the statute prohibits the use of mifepristone for a medical abortion after seven weeks' gestation although many doctors would offer a mifepristone medical abortion as an option up to nine weeks' gestation [\*\*24] pursuant to the Schaff protocol in the following specific circumstances where other alternatives pose a significant risk to a woman's health: a bicornuate (i.e. divided) uterus, extreme flexion of the uterus, large uterine fibroids, cervical stenosis, female genital mutilation, [\*512] and other abnormalities of the female genital tract. While Plaintiffs' experts did not challenge the fact that for most women surgical abortion is an alternative which does not present any more risk than medical abortion, they testified that for some women these health conditions make surgical abortion significantly more risky. For such women, a medical abortion using mifepristone would pose significantly less risk than undergoing a surgical abortion.

[\*\*\*8] The State's expert, Dr. Crockett, stated in her affidavit that when surgical abortion is contraindicated because of a woman's medical condition, a mifepristone medical abortion is also contraindicated because surgical abortion is necessary in the small percentage of cases in which the mifepristone medical abortion fails. However, Dr. Crockett did not, either in her affidavit or hearing testimony, contradict Plaintiffs' experts' testimony that certain [\*\*25] medical conditions render a surgical abortion more risky than a *successful* mifepristone medical abortion. An unsuccessful medical abortion would place a woman in the same position she would be in if a medical abortion was not available. Moreover, the record indicates that a mifepristone medical abortion would be successful at least ninety percent of the time.<sup>5</sup> In light of the uncontested facts,

Dr. Crockett's sworn statement is unavailing. She is essentially asserting that no patient should be permitted to choose a less risky medical abortion over what both parties agree may be a significantly more risky surgical abortion for that patient simply because of a ten percent or less chance that the surgical abortion might be necessary anyway if the medical abortion fails. This is the only evidence the State proffered at the preliminary injunction stage which addresses Plaintiffs' experts' testimony that in some circumstances a surgical abortion poses significantly greater risk than a medical abortion.<sup>6</sup>

5 The precise efficacy rate of the Schaff protocol at various gestational ages has been vigorously disputed. However, the highest failure rate claimed by the State is ten percent.

[\*\*26]

6 Since the State did not present any other evidence on this point, the list of circumstances enumerated by Plaintiffs' experts under which surgical abortion can be significantly more risky is untested.

The State also points to the cross-examination of Plaintiff's expert, Dr. Schaff, who agreed that a medical abortion can be safely performed using the drug methotrexate (which is not regulated by the Act) instead of mifepristone. However, on re-direct Dr. Schaff explained that while methotrexate is an excellent drug, using it for a medical abortion is far less safe than mifepristone. He explained the reason for this as follows:

Methotrexate again is a cancer agent [in addition to being used for medical abortions] because it stops cells dividing. It's not selective. It stops all cells that are rapidly dividing. An embryo or early pregnancy is rapidly dividing, and that's why it works to end an early

pregnancy. But it also is toxic to all cells in the body; that's why it also works as a cancer chemotherapeutic agent.

The State offered no testimony or other evidence at the [\*\*27] preliminary injunction hearing refuting Dr. Schaff's opinion that using methotrexate for a medical abortion poses greater health risks than using mifepristone.

Both of Plaintiffs' experts testified that there are no other drugs besides methotrexate and mifepristone which can be used to perform a medical abortion. While Dr. Crockett asserted that there are a variety of other ways to evacuate a uterus medically besides using mifepristone, this assertion [\*513] is irrelevant because mifepristone is not used to evacuate the uterus; it is used to terminate the pregnancy. Misoprostol (which is not regulated by the Act) is then administered to evacuate the uterus. The State did not provide any evidence that any drug other than methotrexate would be available for performing medical abortions between seven and nine weeks' gestation if the Act took effect. Consequently, the medical authority available at the preliminary injunction phase of this case permitted the finding that using mifepristone is the safest available method of medical abortion and that in some circumstances a medical abortion using mifepristone would pose significantly less risk to the health or life of a discrete class of women [\*\*28] than a surgical abortion.

In its appellate brief, the State points to a case in which the Supreme Court upheld a statute which allowed only doctors (and not physician assistants) to perform abortions in spite of evidence that this regulation might not have been necessary to accomplish its stated purpose of increasing the [\*\*\*9] safety of abortion procedures. *See Mazurek v. Armstrong*, 520 U.S. 968, 973, 117 S. Ct. 1865, 138 L. Ed. 2d 162 (1997). The State argues that there is even

more reason to uphold the statute at issue here because there is evidence that the statute is necessary to make abortion procedures safer. Regardless of the accuracy of the State's characterization of the evidence, the argument misses the mark. The issue of whether a statute is justified as a safety measure in general is not dispositive. As long as there are certain circumstances in which a statutorily-banned procedure is significantly safer, the statute must contain a health or life exception. The *Mazurek* case sheds no light on this issue because there was no indication or argument that the statute considered there would create a significant risk to any woman's health or life. *See Mazurek*, 520 U.S. 968, 117 S. Ct. 1865, 138 L. Ed. 2d 162. [\*\*29]

The State goes on to make various arguments which can each be disposed of briefly. First, the State emphasizes that surgical abortion is a safe and available alternative. While true in the vast majority of situations, this is not dispositive because it does not address the expert testimony that there are some circumstances in which the surgical option is considerably more risky for some women. Next, the State points to the absence of any studies which show that a mifepristone medical abortion is the safest procedure under particular circumstances. However, the Supreme Court has made it clear that such studies are not necessary where there is expert testimony that a restricted procedure is safer than the alternatives. *Carhart*, 530 U.S. at 936-37. The State goes on to claim that Plaintiffs' own expert's testimony shows that using mifepristone to induce medical abortions past seven weeks' gestation is dangerous. This argument is unsupported in the record. According to the State, Dr. Schaff's testimony indicates that his protocol is not as safe or effective as the FDA-approved protocol. Putting aside the accuracy of this statement (which is contested), the relative efficacy [\*\*30] and safety of the two mifepristone protocols has nothing to do with whether a health or life exception is required. To answer this question the

court must examine the difference between the safety of the banned procedure (mifepristone medical abortion) and the safety of other available procedures (surgical abortion or methotrexate medical abortion) after seven weeks' gestation. The State does not point to any evidence which demonstrates that there is an alternative abortion procedure which is available after seven week's gestation which is as safe or safer than a mifepristone medical abortion [\*514] for all medically foreseeable circumstances or conditions.<sup>7</sup>

7 The lack of such evidence at the preliminary injunction stage does not necessarily indicate that there is no such authority in the vast store of medical knowledge. Procedural factors inherent in the preliminary injunction determination—such as the compressed time frame in which to present testimony related to four complex constitutional issues, a relatively short period of time to prepare for the hearing, and the lack of available discovery—may well have had a role in the dearth of evidence introduced by the State on the narrow issue which became the central focus.

[\*\*31] The evidence presented at the preliminary injunction stage does not adequately support the State's claim that the Act may constitutionally omit a health or life exception. In *Carhart* the Supreme Court ruled that a health or life exception was necessary where the record demonstrated: (1) that the banned abortion procedure significantly obviated health risks in particular circumstances, (2) there was "a highly plausible record-based explanation of why that might be so," (3) there was conflicting expert testimony over whether the banned procedure was safer, and (4) there was an absence of any clinical studies relevant to the issue. *Carhart*, 530 U.S. at 936-37. For purposes of determining whether to grant a preliminary injunction in this case, all of these requirements have been met. There was uncontroverted ex-

pert evidence that the restricted abortion procedure obviated health risks in particular circumstances. The testimony of Plaintiffs' experts provided an explanation of why this might be the case. As this explanation was both uncontradicted and facially reasonable, it can be fairly characterized as "highly plausible." At the preliminary injunction hearing the [\*\*32] State did not effectively contest Plaintiffs' evidence that the banned procedure could be safer than other available procedures. Finally, as in *Carhart*, here there were no clinical studies relevant to this particular issue. Accordingly, the 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 [\*\*\*10] district court's ruling that Plaintiffs established a strong likelihood of prevailing on the merits has not been shown to be erroneous.

## V.

During the evidentiary hearing on the preliminary injunction, the district court recognized the State's witness, Dr. Crockett, as an expert in the areas of obstetrics, gynecology and the FDA approval process but refused to allow Dr. Crockett to testify as an expert regarding medical and surgical abortion or the critical review of medical literature.<sup>8</sup> The State argues that refusing to recognize Dr. Crockett as an expert on medical and surgical abortion because she did not perform elective abortion procedures was an abuse [\*515] of discretion. [\*\*33] The State argues that performing elective abortion procedures is not a prerequisite to being an expert on such procedures and points out that such a rule would make it extremely difficult for governmental entities to secure the services of expert witnesses in such cases. The practical point is well taken, and the legal principle is sound. As with any other procedure or topic, an individual can acquire expertise regarding elective abortion procedures through a

variety of means other than actually performing the precise procedure at issue. *See, e.g., Berry v. City of Detroit*, 25 F.3d 1342, 1350 (6th Cir. 1994) (observing that an aeronautical engineer would be qualified to testify about the flight of a bumblebee based on general flight principles even if he had never actually seen a bumblebee).

8 The State has not appealed the district court's order refusing to recognize Dr. Crockett as an expert in the critical review of medical literature. Although that order has not been placed before us, the only reason the district court gave for her ruling was that Dr. Crockett did not have any specific training in the critical review of medical literature beyond the training incorporated in her general medical school and residency training. This ruling ignored Dr. Crockett's testimony that her residency program at Georgetown University put particular emphasis on training residents in the critical review of medical literature, that she had taught classes on the subject, that she had done extensive reading and self-education on the subject, and that she had critically reviewed medical literature for the FDA. If these qualifications are not sufficient to demonstrate expertise, this court is hard-pressed to imagine what qualifications would suffice.

[\*\*34] Furthermore, the record is far from clear as to whether the district court judge even based her ruling solely on the fact that Dr. Crockett did not perform elective abortions. The district judge explicitly stated that whether a doctor performs elective abortions "has nothing to do with my recognizing someone as an expert or not. The only thing, I'm not looking at their point of view; I'm just looking at the experience and qualifications they need to be designated by the Court as an expert." (JA 594.) Nevertheless, viewing the record as a whole, there is some merit to the State's argument that

in spite of what the district court said, the only conceivable reason for failing to recognize Dr. Crockett as an expert on elective medical and surgical abortion was, in fact, because she does not perform elective abortions. While the district court will have to resolve this issue at the trial on the merits, this court need not resolve this issue now because Dr. Crockett's proffered testimony, even if admitted into evidence, would not have been sufficient to defeat Plaintiffs' motion for a preliminary injunction.

Dr. Crockett's proffered testimony addressed two topics. First, she criticized [\*\*35] the studies relied upon by Plaintiffs' experts to show the efficacy of the Schaff protocol as compared to the FDA-approved protocol. Dr. Crockett opined that Dr. Schaff's studies manipulated the numbers to make his protocol appear more effective than the FDA protocol. However, whether the Schaff protocol is effective ninety-five percent of the time (as asserted by Plaintiffs) or ninety percent of the time (as asserted by the State) does not determine whether the Act must contain a health or life exception. Second, Dr. Crockett opined that the lower dosage of mifepristone used in the Schaff protocol might only be effective because of the larger dosage of misoprostol used. This point is also not related to the central issue. Since Dr. Crockett's proffered testimony does not affect the issue on appeal, there is no reason to scrutinize the district court's evidentiary ruling.

[\*\*\*11] VI.

The State's final argument is that the district court erred by enjoining the entire Act, including the reporting and record-keeping provision which Plaintiffs do not argue is unconstitutional. The State has *not* argued that even if the Act was required to contain a health or life exception, [\*\*36] the preliminary injunction should have only enjoined those particular applications of the Act which would have posed a significant risk to a woman's health or life. At the time this case was briefed and argued, there

was not any concrete support for such an argument. However, after oral argument was heard in this case, the Supreme Court held that when an abortion statute lacks a constitutionally necessary health or life exception, a narrow injunction prohibiting only unconstitutional [\*\*516] applications of the statute should be employed where such an approach is not contrary to legislative intent. *Ayotte v. Planned Parenthood of Northern New England*, U.S. , 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006).

Plaintiffs claim that the State's severability argument with respect to the reporting and record-keeping provision of the Act is not properly raised on appeal because it was not adequately presented to the trial court. In spite of the State's protestations to the contrary, Plaintiffs are correct that the State waived its severability argument at the preliminary injunction stage. However, this issue is intertwined with the broader issue of whether the scope [\*\*37] of the preliminary injunction was appropriate in light of the *Ayotte* decision. Although the State did not pose this broader challenge, it can hardly be faulted for failing to raise an argument before there was legitimate legal support for such an argument. Regarding an argument as waived under such circumstances would be both inequitable and counterproductive. *Hormel v. Helvering*, 312 U.S. 552, 557-59, 61 S. Ct. 719, 85 L. Ed. 1037 (1941) (noting an efficiency rationale for addressing waived issues where intervening case authority might change the result). Parties would be forced to either litter their pleadings with every argument which might conceivably be adopted during the pendency of a proceeding or forgo the benefit of any new relevant case law.

In *Ayotte*, the Supreme Court held that "if enforcing a statute that regulates access to abortion would be unconstitutional in medical emergencies," then "invalidating the statute entirely is not always necessary or justified." 126 S. Ct. at 964. Instead, "lower courts may be able to render narrower declaratory and injunc-

tive relief," namely the prohibition of the statute's unconstitutional applications. *Id.* at 964, 969. [\*\*38] Invalidating the statute *in toto* is still appropriate, however, if the legislature would "prefer[] no statute at all to a statute enjoined in [this] way." *Id.* at 969. The Court vacated the First Circuit's opinion affirming the district court's order granting a permanent injunction and remanded the case for the lower courts in the first instance to determine the legislative intent. *Id.* at 966, 969. Notably, the Court did *not* vacate the underlying injunction itself. This 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. *E.g.*, *Scheidler v. Nat'l Org. for Women, Inc.*, 537 U.S. 393, 411, 123 S. Ct. 1057, 154 L. Ed. 2d 991 (2003); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 382-83, 112 S. Ct. 2031, 119 L. Ed. 2d 157 (1992); *see also Branch v. Smith*, 538 U.S. 254, 265, 123 S. Ct. 1429, 155 L. Ed. 2d 407 (2003).

Given the absence of a new automatic-vacatur rule in *Ayotte*, it is appropriate simply to adhere to the usual approach to overbroad injunctions. *Cf. United States v. Booker*, 543 U.S. 220, 125 S. Ct. 738, 769, 160 L. Ed. 2d 621 (2005) [\*\*39] (instructing the courts of appeals to use "ordinary prudential doctrines" when applying *Booker* to cases pending on direct appeal). The courts' practice has long been to vacate an injunction only insofar as it is too broad, leaving the balance intact. *E.g.*, *Morales*, 504 U.S. at 382-83 (vacating in part an injunction prohibiting state officers from enforcing state law - under the doctrine of *Ex Parte Young*, 209 U.S. 123, 28 S. Ct. 441, 52 L. Ed. 714 (1908)--"insofar as it restrained the operation of state laws" that the officers had not threatened to enforce); *Tumblebus Inc. v. Cranmer*, 399 F.3d 754, 768 (6th Cir.) (vacating and remanding for further factfinding one part of a preliminary injunction while affirming the other part), *cert. denied*, [\*\*517] U.S. , 126 S. Ct. 361, 163 L. Ed. 2d 68 (2005); *PACAAR Inc. v. Telescan Techs., L.L.C.*, 319

*F.3d* 243, 258 (6th Cir. 2003) (affirming in [\*\*12] part and vacating in part a preliminary injunction where "the scope of the injunction [was] too broad"); *Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1244, 1253 (6th Cir. 1997) (vacating [\*\*40] a preliminary injunction prohibiting enforcement of three statutory sections only "insofar as it applied to" one section); *Sheeran v. American Commercial Lines, Inc.*, 683 F.2d 970, 981 (6th Cir. 1982) (generally affirming a preliminary injunction but modifying it as to one defendant and vacating it as to another); *Blaylock v. Cheker Oil Co.*, 547 F.2d 962, 966 (6th Cir. 1976) (vacating one provision of a preliminary injunction while affirming three others); *see also Branch*, 538 U.S. at 265 (affirming one basis of an injunction but vacating an alternative ground). Although it went unmentioned in *Ayotte*, the Supreme Court has even employed this approach in the context of an injunction prohibiting the enforcement of an abortion regulation. *Guste v. Jackson*, 429 U.S. 399, 400, 97 S. Ct. 657, 50 L. Ed. 2d 638 (1977) (per curiam) (noting that the injunction "appeared to extend to the entire statute" and vacating the injunction "insofar as it bars enforcement of the 'informed consent' requirements").

In light of this well-established method of dealing with overbroad injunctions, the proper course is to vacate in part the district court's [\*\*41] order, leaving the preliminary injunction undisturbed insofar as it prohibits unconstitutional applications of the statute. On remand, the district court must 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.<sup>9</sup> *Ayotte*, 126 S. Ct. at 969 (explaining that if the legislature "preferred no statute at all to a statute enjoined" in its unconstitutional applications, then "consistency with legislative intent requires invalidating the statute *in toto*"); *Planned Parenthood Fed'n of America, Inc. v. Gonzales*, 435 F.3d 1163, 2006 WL 229900, at \*17-20 (9th Cir. 2006) (noting

that the court might have been able to draft a narrowly drawn injunction consistent with the legislative intent if the statute's only constitutional infirmity was the lack of a health exception but ultimately invalidating the entire statute because it was also unconstitutionally vague and imposed an undue burden).

9 Nothing in our decision today prohibits consideration on remand of the changed stance of the American College of Obstetricians and Gynecologists, which now supports the mifepristone protocol at issue in this case.

[\*\*42] VII.

The only aspect of the district court's preliminary injunction analysis which the State challenges is its conclusion that Plaintiffs established a strong likelihood of prevailing on the merits. The State has not questioned the district court's conclusion that the remaining preliminary injunction factors of irreparable injury, the interests of third parties, and the public interest also weighed in favor of granting the preliminary injunction. The district court's primary basis for concluding that Plaintiffs had established a strong likelihood of success on the merits was the conclusion that every statute which regulates abortion must contain a health or life exception. This holding was error. However, the district court alternatively held that Plaintiffs were likely to succeed on the merits even if the health or life exception requirement was not a per se requirement because substantial medical evidence had been presented that the Act could [\*518] pose a significant risk to women's health or lives. Based on the evidence presented at the preliminary injunction stage, this conclusion was not an abuse of discretion. Consequently, there is no basis for overturning the district court's [\*\*43] determination that Plaintiffs had established a strong likelihood of succeeding on the merits of their claim that the Act is unconstitutional because it lacks a health or life exception. However, in light of *Ayotte*,

the validity of the broad preliminary injunction entered by the district court must be reconsidered. For the reasons discussed above, this court need not address the merits of the State's remaining claims of error. The district court's order is AFFIRMED in part and VACATED in part. We AFFIRM the preliminary injunction insofar as it prohibits unconstitutional applications of the Act, but VACATE the preliminary injunction insofar as it prohibits constitutional applications of the Act. The case is REMANDED for the district court to determine the appropriate scope of preliminary injunctive relief consistent with this opinion.

**CONCUR BY: KAREN NELSON MOORE**  
(In Part)

**CONCUR**

[\*\*\*13] CONCURRENCE

KAREN NELSON MOORE, Circuit Judge, concurring in part. Because I agree that Plaintiffs have satisfied the preliminary-injunction standard of demonstrating a strong likelihood of prevailing on the merits, I join Parts I through IV of the majority opinion. I also agree that in light [\*\*44] of *Ayotte v. Planned Parenthood of Northern New England*, U.S. , 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006), the preliminary injunction should be vacated in part and the case remanded to the district court to reconsider the scope of the injunction. Thus, I join Parts VI and VII. Finally, I join Part V only insofar as it recognizes that the district court's limitation of the state's expert-witness testimony is irrelevant to the outcome of this appeal. This irrelevance is precisely why I cannot, however, endorse the majority's needless dicta on the merits of the evidentiary question.

Plaintiffs presented significant evidence on the safety benefits of the banned abortion procedure. The state attempted to counter this evidence with the testimony of its expert witness, Dr. Susan Crockett, but the district court ex-

cluded some of her testimony. The state now appeals this evidentiary ruling. The Supreme Court has instructed us that in these circumstances, Dr. Crockett's testimony is irrelevant: "Where a significant body of medical opinion believes a procedure may bring with it greater safety for some patients and explains the medical reasons supporting that [\*\*45] view, we cannot say that the presence of a different view by itself proves the contrary." *Stenberg v. Carhart*, 530 U.S. 914, 937, 120 S. Ct. 2597, 147 L. Ed. 2d 743 (2000). Because Plaintiffs presented "a significant body of medical opinion" supporting their position, Dr. Crockett's "different view" could not have affected the merits. *Id.*; *Richmond Med. Ctr. for Women v. Hicks*, 409 F.3d 619, 625 n.1 (4th Cir. 2005) ("Even if we assumed without deciding that the district court abused its discretion in excluding the Commonwealth's opinion evidence, the consideration of that evidence would not change our result."), *petition for cert. filed*, 74

U.S.L.W. 3352 (U.S. Dec. 1, 2005) (No. 05-730). Thus, it matters not a whit that the testimony was excluded. *See FED. R. EVID. 103(a)* ("Error may not be predicated upon a ruling which admits or excludes evidence unless a substantial right of the party is affected . . .").

Presumably in recognition of *Stenberg*, the majority states that "this court need not resolve this issue now because Dr. Crockett's proffered testimony, even if admitted into evidence, would not [\*\*46] have been sufficient to defeat [\*519] Plaintiffs' motion for a preliminary injunction." Majority Op. at 10. It reiterates that "there is no reason to scrutinize the district court's evidentiary ruling." *Id.* Unfortunately, the majority ignores its own advice, as it proceeds to "scrutinize" the evidentiary ruling even though "there is no reason" to do so. Because the evidentiary issue has no impact on the outcome of this appeal, I do not join the majority's dicta regarding this evidence.

## LEXSEE

**PLANNED PARENTHOOD CINCINNATI REGION, et al., Plaintiffs,  
v. BOB TAFT, et al., Defendants.**

**Case No. C-1-04-493**

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DIS-  
TRICT OF OHIO, WESTERN DIVISION**

*459 F. Supp. 2d 626; 2006 U.S. Dist. LEXIS 69964*

**September 27, 2006, Filed**

**SUBSEQUENT HISTORY:** Question certified by *Planned Parenthood Cincinnati Region v. Strickland*, 2008 U.S. App. LEXIS 13232 (6th Cir.), 2008 FED App. 216P (6th Cir.) (6th Cir. Ohio, 2008)

**PRIOR HISTORY:** *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 2006 U.S. App. LEXIS 9207 (6th Cir.) (6th Cir. Ohio, 2006)

**COUNSEL:** [\*1] For Planned Parenthood Cincinnati Region, on behalf of themselves, their staff, and their patients, Planned Parenthood of Greater Cleveland, on behalf of themselves, their staff, and their patients, Planned Parenthood of Central Ohio, on behalf of themselves, their staff, and their patients, Dr. Roslyn Kade, on behalf on themselves, their staff, and their patients, Dr Laszlo Sogor on behalf of themselves, their staff, and their patients, Plaintiffs: Alphonse Adam Gerhardstein, Jennifer Lynn Branch, Gerhardstein Branch & Laufman Co. LPA, Cincinnati, OH; Jeffrey M Gamso, Legal Director, ACLU of Ohio, Cleveland, OH; Nicole G Berner, Planned Parenthood Federation of America, Washington, DC; Roger K Evans, Planned Parenthood Federation of America, New York, NY.

For Preterm, on behalf of themselves, their staff, and their patients, Plaintiff: Alphonse Adam Gerhardstein, Gerhardstein Branch & Laufman Co. LPA, Cincinnati, OH; Beatrice Jessie Hill, Case Western Reserve University School of Law, Cleveland, OH; Jeffrey M Gamso, Legal Director, ACLU of Ohio, Cleveland, OH.

For Bob Taft, in his official capacity, Governor of Ohio, Jim Petro, in his official capacity, Attorney General of [\*\*2] Ohio, Defendants: Holly J Hunt, Sharon A Jennings, Ohio Attorney General, Columbus, OH; Anne Berry Strait, Court of Claims Defense - 1, Columbus, OH.

For Joseph Deters, Defendant: Michael Gerard Florez, Assistant Prosecutor, Hamilton County Ohio, Cincinnati, OH; Roger Edward Friedmann, Cincinnati, OH.

**JUDGES:** Susan J. Dlott, United States District Judge.

**OPINION BY:** Susan J. Dlott

**OPINION**

[\*628] ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND ENJOINING DEFENDANTS

This matter comes before the Court on remand from the United States Court of Appeals for the Sixth Circuit and on Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the Alternative, Renewed Motion for Preliminary Injunction ("SJ Motion") (doc. # 69). For the reasons that follow, the Court **GRANTS** Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the Alternative, Renewed Motion for Preliminary Injunction ("SJ Motion") (doc. # 69) and **PERMANENTLY ENJOINS** Defendants from enforcing any provisions of Ohio's H.B. 126 ("the Act").

## I. PROCEDURAL HISTORY & BACKGROUND

Plaintiffs filed both their original Complaint (doc. # 1) and their original Motion for Preliminary Injunction [\*\*3] ("PI Motion") (doc. # 2) on August 2, 2004, and filed an Amended Complaint on September 13, 2004 (doc. # 18). On September 22, 2004, this Court entered its Order granting Plaintiffs' motion for a preliminary injunction (docs. ## 26 and 41).<sup>1</sup> On September 22, 2004, Defendants filed an interlocutory appeal of this Court's order. On February 15, 2006, the Sixth Circuit issued its Opinion affirming in part and vacating in part this Court's Order granting the preliminary injunction, and remanded the case to this Court to determine the appropriate scope of preliminary injunctive relief in light of the Sixth Circuit's opinion. (See doc. # 60.) On April 13, 2006, the Sixth Circuit issued an amended judgment to the same effect. (Doc. # 66); see also *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006).

<sup>1</sup> On October 2, 2004, the Court issued an Amended Order correcting a typographical error in the original Order. (See Doc. # 41.)

On March 16, 2006, this Court set a [\*\*4] schedule for the parties' remand briefing re-

garding the scope of the preliminary injunction. (See doc. # 63.) Instead of limiting their briefing to the scope of the preliminary injunction, however, Plaintiffs filed the instant consolidated SJ Motion requesting both summary judgment and a permanent injunction, or, only in the alternative, [\*\*629] a renewed preliminary injunction which, as before, enjoins the entire Act. The Court held oral argument on that Motion on June 26, 2006.

### A. The Parties

Plaintiffs in this case are Planned Parenthood Southwest Ohio Region<sup>2</sup>, Planned Parenthood of Central Ohio, Planned Parenthood of Greater Cleveland, and Preterm (collectively "Planned Parenthood"), and Doctors Sogor and Kade ("Plaintiff Physicians") on behalf of themselves and their patients (all collectively, "Plaintiffs"). Defendants are Bob Taft, the Governor of Ohio, and Jim Petro, the Attorney General of Ohio, in their official capacities, and Joseph Deters,<sup>3</sup> as Prosecuting Attorney for Hamilton County, Ohio, and as a representative of a class of all prosecuting attorneys in Ohio (collectively, "Defendants").<sup>4</sup>

<sup>2</sup> Plaintiff Planned Parenthood Southwest Ohio Region was previously named Planned Parenthood Cincinnati Region. The Complaint was filed in the entity's former name, but this Court has since received plaintiff's Notice of Change in Plaintiff's Name (doc. # 49).

[\*\*5]

<sup>3</sup> Pursuant to *Federal Rule of Civil Procedure 25(d)*, Plaintiffs moved for and were granted leave to substitute the newly elected Hamilton County Prosecutor, Joseph Deters, for the originally named Defendant Prosecutor Michael Allen (docs. ## 48,51).

<sup>4</sup> On August 23, 2004, Plaintiffs filed a Motion for Certification of Defendant Class (doc. # 10), requesting that the Court certify a defendant class consisting

of all county prosecuting attorneys in Ohio and appoint Michael K. Allen as the defendant class representative. This Court certified that Defendant Class on December 1, 2004. (See doc. # 46).

### B. The Challenged Act

Plaintiffs brought this action challenging the constitutionality of the Act, which was to take effect on September 23, 2004. The Act regulates the use of mifepristone, commonly known as RU-486, which is a drug used for medical abortion. Specifically, the Act provides:

No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing [\*\*6] an abortion . . . unless the person . . . is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion *in accordance with all provisions of federal law* that govern the use of RU-486 (mifepristone) for inducing abortions.

§ 2919.123(A) (emphasis added). 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." See § 2919.123(F)(1).

The Act provides that those who violate its provisions are guilty of a felony (of varying

degrees) and requires state licensing boards to discipline doctors who enter a plea of guilty to or are found guilty of violating the law. Specifically, violators of the Act are deemed "guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree," and repeat offenders are guilty of [\*\*7] a felony in the third degree. See § 2919.123(E). Further, the Act provides that offenders who are doctors are "subject to sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license." Id. Finally, [\*630] the Act requires the state medical board to revoke, suspend, reprimand, or refuse to grant a certificate to any doctor who enters a plea of guilty or is found guilty of violating any state law regulating the distribution of any drug. See § 4731.22(B)(3). Section 4731.22(B)(3) clearly applies to doctors found guilty of violating Section 2919.123(A) for unlawfully prescribing mifepristone.

### C. Plaintiffs' Original Motion for a Preliminary Injunction

Originally, Plaintiffs moved for a preliminary injunction "restraining defendants, their employees, agents, and successors, and all others acting in concert or participation with them, from enforcing the provisions of H.B. 126." (See doc. # 2 at 1). Plaintiffs challenged the Act on the following grounds: "the Act is unconstitutionally vague; the Act violates their patients' right to bodily integrity by compelling [\*\*8] surgery in circumstances where a medical abortion [via mifepristone, and as opposed to surgical abortion] would otherwise be the desired or appropriate treatment; the Act lacks the constitutionally-mandated exception to allow otherwise restricted practices where they are necessary to preserve a woman's life or health; and, the Act imposes an undue burden on their patients' right to choose abortion by prohibiting a safe and common method of pre-viability abortion." (See doc. # 2, at 1.)

In ruling on Plaintiff's PI Motion, this Court described Plaintiffs' arguments as follows<sup>5</sup>: "Plaintiffs allege that because of the former factors [see supra former paragraph], Plaintiffs have a strong likelihood of success on the merits. Further, Plaintiffs allege that Planned Parenthood, Plaintiff Physicians, and their patients would face irreparable injury if the Act takes effect. (Id. at 18-19.) Specifically, Plaintiffs argue that because the Act is unconstitutionally vague, Plaintiff Physicians would be left to guess about whether they may legally provide medical abortions in certain instances. (Id. at 18.) Specifically, Plaintiffs state that Planned Parenthood and the Plaintiff [\*\*9] Physicians have been providing medical abortions using an evidence-based protocol of mifepristone.<sup>6</sup> (See doc. # 18, PP 6-11.) This evidence-based protocol differs in several respects from the protocol which the FDA tested and on which it based its approval of mifepristone ["FDA-approved protocol"], including the dose of mifepristone and the dose and administration of its companion drug, misoprostol, and also allows for a medical abortion later in the term of pregnancy.<sup>7</sup> Plaintiffs note that the Act provides [\*631] that physicians may prescribe mifepristone only in accordance with federal law, and that the Act includes the FDA approval letter within its definition of federal law. However, Plaintiffs also note that the FDA approval letter does not require physicians to adhere to any particular protocol, although the documents on the final printed labeling do discuss only the protocol that was tested by the FDA. (Id. at P 38.) Thus, Plaintiffs argue that it is unclear whether the Act's inclusion of the FDA approval letter in the definition of federal law renders it illegal for a physician to prescribe the evidence-based protocol of mifepristone. Consequently, Plaintiffs argue that [\*\*10] Plaintiff Physicians would face the threat of possible criminal prosecution and loss or suspension of their medical licenses if they continue to prescribe the evidence-based protocol of mifepristone. (Id. at P 53.) Plaintiffs also argue that Plaintiff

Physicians' patients would face irreparable harm because the Act may force some women seeking an abortion to forego medical abortion and undergo either surgical abortion or other more invasive procedures, which may be both riskier and more costly for a particular woman. (See doc. # 2, at 18-19.)" (See doc. # 41-2 at 8-9.)

5 The following recitation of Plaintiffs' arguments for a preliminary injunction is excerpted from this Court's Order granting Plaintiff's motion for a preliminary injunction (doc. # 41-2.)

6 Or in the case of Planned Parenthood of Central Ohio, intended to switch to an evidence-based protocol, but suspended those preparations due to uncertainty regarding the meaning of the Act. (See doc. # 18, P 8.)

7 The evidence-based protocol for medical abortion [that Planned Parenthood and Plaintiff Physicians used at the time of the PI Motion] consists of a single oral dose of 200 mg of mifepristone followed by a single dose of .8 mg misoprostol administered vaginally, and is effective for medical abortion through at least 63 days after a woman's last menstrual period ("LMP"). The protocol for medical abortion that the FDA tested and on which it based its approval of mifepristone consisted of three oral doses of 200 mg of mifepristone followed by a single dose of .4 mg misoprostol also taken orally, through 49 days LMP. [Planned Parenthood now offers two variations of their former evidence-based protocol. (Doc. # 69 at 6 n.5.) For the purposes of this memorandum, the court will not distinguish between the different evidence-based protocols and will use the same term, "evidence-based protocol," to refer to all of them.]

[\*\*11] This Court held that Plaintiffs had demonstrated a strong likelihood of success on the merits of their claimed violation of their constitutional rights on two alternative grounds: 1) the Act lacked any health exception, which this Court construed as a per se requirement under Supreme Court precedent for statutes regulating abortion; and 2) evidence presented at the hearing on the PI Motion demonstrated that there were women for whom the evidence-based protocol for medical abortion was safer than surgical abortion. (*Id.* at 10-11.) Having so found, the Court also found that the other factors to be considered for a preliminary injunction necessarily weighed in its favor. (*Id.* at 12-13.) The Court therefore entered an order enjoining Defendants from enforcing any provisions of the Act. (*Id.* at 13.)

#### D. The Sixth Circuit's Decision on Appeal

On appeal, the Sixth Circuit held that this Court erred in holding that all statutes regulating abortion, including the Act, must contain a per se health exception. The Sixth Circuit described the proper legal standard as follows:

where substantial medical authority supports the proposition that banning a particular abortion [\*\*12] procedure could endanger women's health *Casey* 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. An exception is constitutionally necessary where substantial medical authority indicates that a banned procedure would be safer than the other available procedures, not just when banning the procedure subjects a woman to risks from the pregnancy itself. As emphasized previously by this circuit, an exception is only necessary (and

must only cover) circumstances where a statute poses a *significant* health risk. Finally, an adequate showing of a significant health risk in certain circumstances is sufficient to require an exception even if those circumstances rarely occur.

*Planned Parenthood Cincinnati Region*, 444 F.3d at 511.

The Sixth Circuit held that, despite having misread the law, this Court was nevertheless correct to enjoin the Act because "[a]t the [PI Motion] evidentiary hearing Plaintiffs introduced expert testimony from two doctors which established that, if enforced, the statute would result in significant [\*632] risk to women's [\*\*13] health in particular, albeit narrow, circumstances." *Id.* at 511. The Sixth Circuit concluded that "the 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.

The Sixth Circuit thus remanded the case to this Court "for consideration of the appropriate scope of injunctive relief in light of the United States Supreme Court's recent decision in *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320, 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006)." In *Ayotte*, the Supreme Court held that "[g]enerally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of a statute while leaving other applications in force, or to sever its problematic portions while [\*\*14] leaving the remainder intact." *Ayotte*, 126 S. Ct. at 967. The Sixth Circuit clarified that in light of *Ayotte*,

this Court should "leav[e] the preliminary injunction undisturbed insofar as it prohibits unconstitutional applications of the statute." It also held that "[o]n remand, the district court must 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." *Planned Parenthood Cincinnati Region*, 444 F.3d at 517.

On remand, however, Plaintiffs seek either summary judgment and a *permanent* injunction of the Act for unconstitutional vagueness, or, in the alternative, a renewed preliminary injunction based on its other constitutional arguments that enjoins the entire Act. The self-dubbed State Defendants (Attorney General Petro and Governor Robert Taft) filed a Memorandum in Opposition to Plaintiff's SJ Motion (doc. # 74), which Defendant Deters joined on behalf of himself and the other Defendant County Prosecuting Attorneys (see doc. # 76).

## II. JURISDICTION

This Court has federal question jurisdiction [\*\*15] to consider a case, such as this one, where the plaintiffs challenge an alleged deprivation of a Constitutional right by a State law. See 28 U.S.C. §§ 1331, 1343(a)(3), and 1343(a)(4).

## III. PLAINTIFF'S SJ MOTION

### A. Motion for Summary Judgment

Plaintiffs move for summary judgment on their claim that the Act is impermissibly vague and thereby violates Plaintiffs' right to due process under the *Fourteenth Amendment*. If this Court grants summary judgment to Plaintiffs, they also request that the Court permanently enjoin the Act.

#### 1. Legal Standard

Summary judgment is appropriate if no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. See *Fed. R. Civ. P. 56(c)*. On a motion for summary judgment, the movant has the burden of showing that no genuine issue of material facts are in dispute, and the Court must read the evidence, together with all inferences that can permissibly be drawn therefrom, in the light most favorable to the party opposing the motion. See *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-87, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). [\*\*16]

[\*633] The moving party may support a motion for summary judgment with affidavits or other proof or by exposing the lack of evidence on an issue for which the nonmoving party will bear the burden of proof at trial. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). In responding to a summary judgment motion, the nonmoving party may not rest upon the pleadings but must go beyond the pleadings and "present affirmative evidence in order to defeat a properly supported motion for summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). The nonmoving party "must set forth specific facts showing there is a genuine issue for trial." *Fed. R. Civ. Pro. 56(e)*. The task of the Court is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 249. A genuine issue for trial exists when the evidence is not "so one-sided that one party must prevail as a matter of law." *Id.* at 252.

#### 2. Analysis

##### a. Plaintiffs' Argument that the Act is Unconstitutionally Vague

The question [\*\*17] of whether the Act is unconstitutionally vague is a question of law and therefore can be resolved on summary

judgment. See *U.S. v. Namey*, 364 F.3d 843, 844 (6th Cir. 2004).

"It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108, 92 S. Ct. 2294, 33 L. Ed. 2d 222 (1972). As the Grayned court explains:

Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

*Id.* at 108-09 (1972). Thus, the *Due Process* clause of the *Fourteenth Amendment* [\*\*18] prohibits laws so vague that persons of ordinary intelligence must guess at their meaning. See *Smith v. Goguen*, 415 U.S. 566, 573 n.8, 94 S. Ct. 1242, 39 L. Ed. 2d 605 (1974) (citations omitted). Also, "[t]he [vagueness] doctrine incorporates notions of fair notice or warning. Moreover, it requires legislatures to set reasonably clear guidelines for law enforcement officials and triers of fact in order to prevent 'arbitrary and discriminatory enforcement.'" *Id.* at 572-73.

Significantly, criminal statutes that implicate the exercise of constitutionally protected rights are subject to a more stringent vagueness test. See *Colautti v. Franklin*, 439 U.S. 379, 386, 391, 99 S. Ct. 675, 58 L. Ed. 2d 596 (1979); *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499, 102 S. Ct. 1186, 71 L. Ed. 2d 362 (1982). The Supreme Court has held that "the right of privacy, implicit in the liberty secured by the *Fourteenth Amendment* 'is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.'" *Colautti*, 439 U.S. at 386 (citing *Roe v. Wade*, 410 U.S. 113, 153, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973)). Thus, the Act, which implicates the exercise of that constitutionally [\*\*19] protected right, is subject to a more stringent vagueness test.

First, in their SJ Motion, Plaintiffs argue that the Act violates their due process rights because it is unconstitutionally vague on its face. Plaintiffs argue that the undefined and ambiguous terms render the Act unconstitutionally vague. Specifically, Plaintiffs argue that

It is unclear from the face of the Act what is meant by the requirements that physicians who provide mifepristone to induce medication [sic] abortion comply with "all criteria established by federal law" and [act] in accordance with "all provisions of federal law that govern use" of the drug. It is also unclear whether these requirements differ in any way from the requirements that the physicians satisfy "all the *specified* criteria established by federal law" and that the physicians provide mifepristone in accordance with "the *specified* provisions of federal law."

Doc. # 69 at 7 (emphasis in original). Plaintiffs note that the Act does not define nor distinguish the terms "criteria," "specific criteria," "provisions," and "specific provisions," each of which modifies the defined term "federal law." As Plaintiffs point out, [\*\*20] in construing statutory language, "significance and effect should, if possible, be accorded to every word, phrase, sentence and part of an act." See *Sarmiento v. Grange Mut. Cas. Co.*, 106 Ohio St. 3d 403, 2005 Ohio 5410, 835 N.E.2d 692, 698 (Ohio 2005). Plaintiffs argue that because the Act fails to define these different modifying terms, it is thus "unclear from the face of the Act what is meant by the requirements that physicians who provide mifepristone to induce medication abortion comply with 'all criteria established by federal law,' and in accordance with 'all provisions of federal law that govern use' of the drug," as well as what it means for a physician to satisfy "all the specified criteria established by federal law," and provide mifepristone only in accordance with "the specified provisions of federal law." (Doc. # 69 at 7 (emphasis added).) Plaintiffs conclude that "[t]hese vague and uncertain terms fail to give fair notice of what the Act proscribes and leave the door open for arbitrary and discriminatory enforcement of the Act," (id. at 7-8) thereby violating Plaintiffs' due process rights.

The Court agrees that the statute provides no bases for distinguishing between [\*\*21] these phrases or knowing in what way they modify the Act's definition of federal law. The Act's vague terms are particularly troubling because they modify "federal law," the defined term with which physicians must comply or face criminal penalty.

Second, in their Reply, Plaintiffs make an even more persuasive argument that the Act is vague. Plaintiffs argue that Defendants' counterarguments regarding the plain meaning of the Act further reveal and compound the Act's vagueness. (Doc. # 74 at 14-15.)<sup>8</sup> To address Plaintiffs' [\*635] persuasive rebuttal, the

Court must first address Defendants' counterargument.

8 Plaintiffs also argue that Defendants' interpretation of the Act "would require the Court to read language into the Act that does not appear in its text." (Doc. # 77 at 6.) Plaintiffs cite *Vought Indus., Inc. v. Tracy*, 72 Ohio St. 3d 261, 1995 Ohio 18, 648 N.E. 2d 1364 (Ohio 1995), for the proposition that "[t]here is no authority under any rule of statutory construction to add to, enlarge, supply, expand, extend or improve the provisions of the statute to meet a situation not provided for." (Id. at 7 (citing *Vought*, 648 N.E. 2d at 1367).) And, Plaintiffs argue that the legislative history does not support Defendants' construction of the Act. Plaintiffs conclude that for all of these reasons, it would be improper for this Court to accept Defendants' construction of the statute. The Court need not consider Plaintiffs' alternative arguments as it finds Defendants' counterarguments regarding the Act's plain meaning to be unavailing.

[\*\*22] In their Opposition to Plaintiffs SJ Motion, Defendants argue that the act is not vague and that from the Act's "plain language," it is clear that the Act prohibits physicians from prescribing the evidence-based protocol. Specifically, Defendants assert that it is clear that the Act "restricts the use of mifepristone to induce abortions in Ohio to the FDA approved indications and treatment regimen, as set forth in the approval letter and [the final printed labeling instructions ("FPL")]." (Doc. # 74 at 2.) At another point in their Opposition, Defendants contend that in addition to the approval letter and "the exact form of the FPL, including the package insert, the Medication Guide, the Patient Agreement, and the Prescriber's Agreement, are clearly made a part of the approval of the drug" and therefore also part of the definition of federal law with which physi-

cians must comply. (Id. at 15 (emphasis added).) In sum, Defendants argue that 1) by including the FDA approval letter in its definition of federal law, the Act also incorporates by reference into that definition the requirements of all of the documents referred to in the Approval Letter (such as the FPL) and some [\*\*23] of the documents that *those* documents refer to; and 2) the Approval Letter clearly limits physicians to prescribing FDA-approved protocol, and hence, so does the Act.

First, in rebutting Defendants' argument, Plaintiffs argue that it is far from clear that the Act's definition of federal law includes the FPL. As Plaintiffs point out, while the Act's definition of federal law specifically mentions the FDA approval letter, the Act itself does not. Thus, from the face of the Act (in its definition of federal law), there is no reason to believe that the Act includes the FPL as part of federal law with which physicians must comply. As Defendants argue, however, because the approval letter, which within the Act's definition of federal law, references the FPL, arguably, the FPL and other documents which the approval letter mentions are incorporated by reference into the Act's definition of federal law by reference.

The Court finds however, that even if it were clear from the face of the Act that the FPL is part of the definition of federal law -- which it is not -- it is still not clear either what the approval letter requires regarding the FPL or what the FPL itself requires regarding [\*\*24] acceptable dosage protocols. Most notably, it is unclear from the text of the approval letter whether, as Defendants submit, it mentions the FPL to limit physicians' prescription of mifepristone to the FDA-approved protocol. The approval letter states in relevant part that "[t]he final printed labeling (FPL) . . . must be identical to the submitted draft labeling . . . submitted September 27, 2000." (JX2.) The approval letter further provides that "[m]arketing the product with FPL that is not

identical to the approved labeling text *may* render the product misbranded and an unapproved new drug." (Id.) Thus, while the approval letter mentions the FPL, it seems to do so only to regulate the conduct of manufacturers and distributors of mifepristone, not physicians who prescribe mifepristone. On the other hand, the approval letter also states that "[t]his new drug application provides for the use of [mifepristone] for the medical termination of intrauterine pregnancy through 49 days' pregnancy. We have . . . concluded that adequate information [\*636] has been presented to approve [mifepristone] [t]ablets, 200 mg, for use as recommended in the agreed upon labeling text." The [\*\*25] former language could indeed be read to limit physicians' prescription of mifepristone to the FDA-approved protocol, but it is far from clear that it does so. And, as Plaintiffs point out, neither the former language, nor any other language in the approval letter, nor the Act itself, nor the Food and Drug Act *specifically prohibits* physicians from prescribing an evidence-based protocol of mifepristone. (See JX1, JX2 and JX9.) Thus, the Act is unconstitutionally vague because it is unclear whether 1) the Act's definition of federal law incorporates the FPL, and 2) if it does, what that incorporation means in terms of lawful prescription of mifepristone.

Second, in arguing that Defendants' reading of the Act underscores its vagueness, Plaintiffs point out that under Defendants' reading of the statute, physicians may only prescribe mifepristone in accordance with the FPL, as well as "*the approved indication, treatment regimen, and distribution restrictions set forth in the FDA Approval Letter and the materials incorporated therein.*" (Doc. # 69 at 13, citing Defs. Resp (doc. # 74) at 6 (emphasis added).) Plaintiffs point out that this reading arguably also requires [\*\*26] physicians to adhere to the requirements of more than 90 separate documents that were submitted to the FDA as part of the approval process, as well as numerous federal regulations, all of which are referred to in the

approval letter.<sup>9</sup> (Doc. # 69 at 13.) Plaintiffs argue further that under the State's reading of the Act, "all of these [90-plus] documents and regulations could potentially be construed as 'materials incorporated therein,' thereby becoming requirements subject to criminal prosecution under the Act." (Id.) Moreover, Plaintiff notes that many of these materials -- including the approval letter itself, the FPL, and the Mifeprex package insert, medication guide, and patient agreement, which are all specifically mentioned in the approval letter -- have been revised or reissued since the FDA issued its initial approval letter. (*Compare* JX 2 and JX 9; JX 3-6 and JX 10-12.) Plaintiffs submit that under Defendants' reading of the Act, it is unclear with which of the referenced documents, and with which *version* of those documents, physicians are required to comply under the Act. Plaintiffs conclude that Defendants' reading of the Act, if accepted, would [\*\*27] place Plaintiffs "in the untenable position of not knowing which statements contained in this voluminous series of documents they are bound to follow in order to avoid facing criminal prosecution." (Id.) Plaintiffs conclude that Defendants' reading of the Act is further evidence of its vagueness.

9 Defendants argue that those 90-plus separate documents are clearly *not* intended to be considered part of the Act's definition of federal law because all the approval letter does is "acknowledge receipt" of those documents. (See doc. # 74 at 14-15.) Defendants' argument is inconsistent with their argument that the Act's reference to the approval letter incorporates by reference the FPL, the package insert, the Medication Guide, the Patient Agreement, and the Prescriber's Agreement. The approval letter's reference to those 90-plus documents that they received and reviewed in approving mifepristone arguably does incorporate the contents and requirements of those

documents into the FDA approved regimen.

[\*\*28] The Court agrees with Plaintiffs. As Plaintiffs point out, under Defendants' reading of the Act, the Act's requirements and prohibitions could change over time, without any action by the legislature to change the language of the Act itself. In response to this criticism, Defendants argue [\*637] that because the physicians whose conduct it regulates, "practice in a very particularized area of medicine," they "can certainly be expected to be familiar with the prescribing information about mifepristone, including the FDA approved indications and regimen." (See doc. # 74 at 17.) Defendants cite *Fleming v. U.S. Dept. of Agric.*, 713 F.2d 179, 184 (6th Cir. 1983), for the principle that "when the persons affected by the regulation[] are a select group with specialized understanding of the subject being regulated the degree of definiteness required to satisfy due process concerns is measured by the common understanding and commercial knowledge of the group." (See doc. # 74 at 17 (quoting *Fleming*, 713 F.2d at 184).) Although Defendants' citation is correct, their argument misses the point. The question here is not, as Defendants suggest, whether physicians regulated [\*\*29] by the Act are able to understand "the prescribing information for mifepristone, including the FDA approved indications and regimen." (See doc. # 74 at 17.) Rather, the question is whether such physicians can understand whether, under the Act's definition of federal law, they must prescribe mifepristone only according to the FDA-approved protocol or whether they may lawfully prescribe an evidence-based protocol.

Plaintiffs argue that for all of the above reasons, Defendants' reading of the Act renders it more variable -- and thus vaguer -- over time. The Court agrees. Defendants' interpretation of the Act does render the Act all the more uncertain. What is most significant, however, is that Defendants' interpretation of the Act, particularly in terms of its incorporation by reference

of the FPL in the definition of federal law, is tenable. That is to say, the parties' briefs demonstrate that the Act is susceptible to *at least* two equally good faith and plausible, but contradictory, legal interpretations. Thus, the Act fails "to set reasonably clear guidelines for law enforcement officials and triers of fact," and thereby risks "arbitrary and discriminatory enforcement." See *Goguen*, 415 U.S. at 573. Moreover, given this Court's own struggle in divining the meaning of the Act, as well as that of the parties' highly competent lawyers, the Court is convinced that the physicians regulated by the Act, untrained in the law, could not possibly be expected to understand its requirements and prohibitions. Thus, the Act fails to give those subject to criminal punishment under the Act a "reasonable opportunity to [\*\*30] know what is prohibited." <sup>10</sup> See *Grayned*, 408 U.S. at 108, and therefore fails to provide fair notice. See *id.* Because the Act fails to meet either major due process requirement, the Court holds that the Act is unconstitutionally vague.

10 The Court notes that Defendants' interpretation, which would permit the Act's requirements and prohibitions to change without any amendment to the Act or notice to the physicians it regulates, is particularly troublesome from a fair warning perspective.

**b. Defendants' Alternative Argument Regarding the [\*\*31] Act's "Knowingly" Requirement**

Defendants argue that, even if the Court finds, as it has, that the Act is unconstitutionally vague, the Act's "knowingly" requirement cures the Act's vagueness. Defendants cite *Village of Hoffman Estates* for the principle that a scienter requirement "mitigates a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." (Doc. # 74 at 20 (citing *Village of Hoffman Estates*, 455 U.S. at 499).)

Although Defendants are correct that the Act includes a scienter requirement, [\*638] their argument is nonetheless unavailing. The Act provides, in relevant part, that:

A person who gives, sells, dispenses, administers, otherwise provides or prescribes RU-486 (mifepristone) to another as described in division (A) of this section **shall not be prosecuted** based on a violation of the criteria contained in this division **unless the person knows** that . . . the person did not satisfy all the specified criteria established by federal law, or that the person did not provide the RU-486 (mifepristone) in accordance with the specified provisions of federal law, whichever is applicable. [\*\*32]

§ 2919.123(A) (emphasis added). As highlighted above, the Act conditions a violator's prosecution on his knowledge that he failed to satisfy the specified criteria of federal law or that he did not provide mifepristone in accordance with the specified provisions of federal law.

However, the Act's scienter requirement is irrelevant because it is dependent upon the vague term "federal law." Contrary to Defendants' assertion, *Village of Hoffman Estates* provides only that "a scienter requirement may mitigate a law's vagueness." *Village of Hoffman Estates*, 455 U.S. at 499 (emphasis added). As Plaintiffs point out, "a scienter requirement applied to an element that is itself vague does not cure the provision's overall vagueness." See, e.g., *Planned Parenthood Federation of Am., Inc. v. Gonzales*, 435 F.3d 1163, 1184 (9th Cir. 2006). Here, the Act's knowingly requirement does just that: it applies to the vague definition of federal law. As this Court has held that the Act is unconstitutionally vague due to its uncer-

tain definition of "federal law," the Act's knowingly requirement, which applies to that vague term, does not cure the Act's [\*\*33] unconstitutionality vagueness.

**c. Plaintiffs' Alternative Argument Regarding the Construction of the Act Cannot Save the Act from Unconstitutionality**

The Court is not persuaded by Plaintiffs' alternative argument that the Court could save the Act by construing the Act to do "nothing more than incorporate into the Ohio code the specific requirements imposed by federal law on prescribers of mifepristone, including the eight requirements set forth in the FDA Approval letter." (Doc. # 69 at 17.) In so arguing, Plaintiffs necessarily conclude that the Approval letter itself has a clear meaning. As explained above, the Court disagrees.

The Court is well aware of the Supreme Court's directive that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." See *Chapman v. U.S.*, 500 U.S. 453, 464, 111 S. Ct. 1919, 114 L. Ed. 2d 524 (1991). However, the Supreme Court has also explained that while the "canon of construction that a court should strive to interpret a statute in a way that will avoid an unconstitutional construction is useful in close cases . . . it is not a license for the judiciary to rewrite language enacted by the legislature." *Id.* (citations [\*\*34] omitted).

This is not a close case. Here, despite having reviewed and re-reviewed the Act, the Court finds that Plaintiffs' alternative interpretation of the Act is no more reasonable (nor unreasonable) than Defendants'. Indeed, the Court finds that several other interpretations of the Act are also plausible. As such, the Court cannot agree that Plaintiffs' reading of the statute "would cure the constitutional defects created by the State's extreme interpretation," (*id.* at 18.). The Court would have to rewrite language enacted by the legislature to give the Act one definite meaning. The Court therefore holds

that the statute [\*639] cannot be saved from unconstitutionality by Plaintiffs' alternative argument.

**B. No Portion of the Act is Severable and the Act Must be Enjoined in its Entirety**

Because the Court has determined that summary judgment should be granted to Plaintiffs and that a permanent injunction of the Act is necessary, the Court need not consider Plaintiffs' alternative argument regarding the appropriate scope of the *preliminary* injunction. However, the Court must still consider the appropriate scope of the *permanent* injunction. See *Ayotte*, 126 S. Ct. at 967. [\*\*35] As the *Ayotte* Court explained, "when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of the statute while leaving other applications in force." The *Ayotte* Court also pointed out that in so doing, "a court cannot 'use its remedial powers to circumvent the intent of the legislature.'" *Id.* at 968.

Thus, this Court must determine whether there are constitutional portions of the Act that may remain in force. See *id.* at 967. As the Court has determined that the Act's criminal provisions are unconstitutionally vague in all of their potential applications, the only question that remains is whether the Act's physician qualifications, recordkeeping and reporting requirements are severable from the remainder of the requirements. In so deciding, the Court must remain mindful that [its] constitutional mandate and institutional competence are limited," and "restrain [itself] from 'rewrit[ing] state law to conform it to constitutional requirements' even as we strive to salvage it." *Id.* at 968.

The question of whether portions [\*\*36] of the Act can be severed from the Act's unconstitutional portions is a question of Ohio law. See *Leavitt v. Jane L.*, 518 U.S. 137, 139, 116 S. Ct. 2068, 135 L. Ed. 2d 443 (1996). The Court

must remain mindful that [its] constitutional mandate and institutional competence are limited," and "restrain [itself] from 'rewrit[ing] state law to conform it to constitutional requirements' even as we strive to salvage it." *Id.* at 968.

The Act itself contains no severability provision. *Ohio Revised Code* § 1.50, however, provides:

If any provision of a section of the Revised Code or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the section or related sections which can be given effect without the invalid provision or application, and to this end the provisions are severable.

*Ohio Rev. Code* § 1.50. Thus, in Ohio, there is a presumption of statutory severability. *Id.*; see also *Women's Med. Prof. Corp. v. Voinovich*, 130 F.3d 187, 202 (6th Cir. (Ohio) 1997). Ohio courts employ the following test for determining whether an unconstitutional [\*\*37] provision may in fact be severed:

(1) Are the constitutional and the unconstitutional parts capable of separation so that each may read and may stand by itself? (2) Is the unconstitutional part so connected with the general scope of the whole as to make it impossible to give effect to the apparent intention of the Legislature if the clause or part is stricken out? (3) Is the insertion of words or terms necessary in order to separate the constitutional part from the unconstitutional part, and to give effect to the former only?

*Women's Med. Prof. Corp. v. Voinovich*, 130 F.3d at 202.

[\*640] Defendants argue that the Act's physician qualifications and recordkeeping and reporting requirements can be severed from the rest of the Act and therefore should not be enjoined. Plaintiffs counter that those portions of the Act cite to, and therefore are inextricably bound up with, the portion of the Act that is unconstitutionally vague. Plaintiffs conclude that the recordkeeping and reporting requirements as well as the physician qualifications are therefore also unenforceable and must be enjoined.

The Act's physician qualification requirement provides that: "[n]o person [\*\*38] shall knowingly . . . prescribe RU-486 (mifepristone) . . . unless the person . . . is a physician . . . satisfy[ing] all the criteria established by federal law." *Ohio Rev. Code* § 2919.123(A) (emphasis added). The Act's reporting and recordkeeping provisions provide: [i]f a physician provides RU-486 (mifepristone) to another for the purpose of inducing an abortion *as authorized under division (A)*" of the Act, the physician must report to the state medical board certain serious health events suffered by his patient following her use of mifepristone, *id.* at § 2919.123(C)(1) (emphasis added), and that "[n]o physician who provides RU-486 (mifepristone) to another for the purpose of inducing an abortion *as authorized under division (A)* of [the Act] shall knowingly fail to file a report required under division (C)(1)." *Id.* at § 2919.123(C)(2) (emphasis added).

It is clear that the Act's physician qualifications and recordkeeping and reporting requirements are dependent upon, and therefore inextricably bound up with, the unconstitutional portions of the Act found in § 2919.123(A) and (F)(1). As such, these requirements are not capable of separation so that [\*\*39] each may read and may stand by itself. See *Women's Med. Prof. Corp. v. Voinovich*, 130 F.3d at

202. The Court therefore holds that no portion of the Act may be severed and that the Act must be enjoined in its entirety.

#### IV. CONCLUSION

Having found as a matter of law that the Act is unconstitutionally vague and that no portion of it can be severed, the Court hereby: 1) **GRANTS** Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the

Alternative, Renewed Motion for Preliminary Injunction (doc. # 69) in so far as it requests summary judgment on the vagueness issue; and 2) **PERMANENTLY ENJOINS** Defendants from enforcing any provisions of the Act.

IT IS SO ORDERED.

s/Susan J. Dlott

United States District Judge

# AN ACT

To amend sections 4729.29, 4731.22, and 4731.223 and to enact section 2919.123 of the Revised Code regarding the provision or use of RU-486 (mifepristone) for an abortion.

*Be it enacted by the General Assembly of the State of Ohio:*

SECTION 1. That sections 4729.29, 4731.22, and 4731.223 be amended and section 2919.123 of the Revised Code be enacted to read as follows:

Sec. 2919.123. (A) No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the RU-486 (mifepristone) is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions. A person who gives, sells, dispenses, administers, otherwise provides, or prescribes RU-486 (mifepristone) to another as described in division (A) of this section shall not be prosecuted based on a violation of the criteria contained in this division unless the person knows that the person is not a physician, that the person did not satisfy all the specified criteria established by federal law, or that the person did not provide the RU-486 (mifepristone) in accordance with the specified provisions of federal law, whichever is applicable.

(B) No physician who provides RU-486 (mifepristone) to another for the purpose of inducing an abortion as authorized under division (A) of this section shall knowingly fail to comply with the applicable requirements of any federal law that pertain to follow-up examinations or care for persons to whom or for whom RU-486 (mifepristone) is provided for the purpose of inducing an abortion.

(C)(1) If a physician provides RU-486 (mifepristone) to another for the

purpose of inducing an abortion as authorized under division (A) of this section and if the physician knows that the person who uses the RU-486 (mifepristone) for the purpose of inducing an abortion experiences during or after the use an incomplete abortion, severe bleeding, or an adverse reaction to the RU-486 (mifepristone) or is hospitalized, receives a transfusion, or experiences any other serious event, the physician promptly must provide a written report of the incomplete abortion, severe bleeding, adverse reaction, hospitalization, transfusion, or serious event to the state medical board. The board shall compile and retain all reports it receives under this division. Except as otherwise provided in this division, all reports the board receives under this division are public records open to inspection under section 149.43 of the Revised Code. In no case shall the board release to any person the name or any other personal identifying information regarding a person who uses RU-486 (mifepristone) for the purpose of inducing an abortion and who is the subject of a report the board receives under this division.

(2) No physician who provides RU-486 (mifepristone) to another for the purpose of inducing an abortion as authorized under division (A) of this section shall knowingly fail to file a report required under division (C)(1) of this section.

(D) Division (A) of this section does not apply to any of the following:

(1) A pregnant woman who obtains or possesses RU-486 (mifepristone) for the purpose of inducing an abortion to terminate her own pregnancy;

(2) The legal transport of RU-486 (mifepristone) by any person or entity and the legal delivery of the RU-486 (mifepristone) by any person to the recipient, provided that this division does not apply regarding any conduct related to the RU-486 (mifepristone) other than its transport and delivery to the recipient;

(3) The distribution, provision, or sale of RU-486 (mifepristone) by any legal manufacturer or distributor of RU-486 (mifepristone), provided the manufacturer or distributor made a good faith effort to comply with any applicable requirements of federal law regarding the distribution, provision, or sale.

(E) Whoever violates this section is guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree. If the offender previously has been convicted of or pleaded guilty to a violation of this section or of section 2919.12, 2919.121, 2919.13, 2919.14, 2919.151, 2919.17, or 2919.18 of the Revised Code, unlawful distribution of an abortion-inducing drug is a felony of the third degree.

If the offender is a professionally licensed person, in addition to any other sanction imposed by law for the offense, the offender is subject to

sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license, including the sanctioning provided in section 4731.22 of the Revised Code for offenders who have a certificate to practice or certificate of registration issued under that chapter.

(F) As used in this section:

(1) "Federal law" means 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.

(2) "Personal identifying information" has the same meaning as in section 2913.49 of the Revised Code.

(3) "Physician" has the same meaning as in section 2305.113 of the Revised Code.

(4) "Professionally licensed person" has the same meaning as in section 2925.01 of the Revised Code.

Sec. 4729.29. (A) Divisions (A) and (B) of section 4729.01 and section 4729.28 of the Revised Code do not do either of the following:

(1) Apply to a licensed health professional authorized to prescribe drugs or prevent a prescriber from personally furnishing the prescriber's patients with drugs, within the prescriber's scope of professional practice, that seem proper to the prescriber.

(2) Apply to the sale of oxygen, peritoneal dialysis solutions, or the sale of drugs that are not dangerous drugs by a retail dealer, in original packages when labeled as required by the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

(B) When a prescriber personally furnishes drugs to a patient pursuant to division (A)(1) of this section, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes.

When personally furnishing to a patient RU-486 (mifepristone), a prescriber is subject to section 2919.123 of the Revised Code. A prescription for RU-486 (mifepristone) shall be in writing and in accordance with section 2919.123 of the Revised Code.

Sec. 4731.22. (A) The state medical board, by an affirmative vote of not fewer than six of its members, may revoke or may refuse to grant a certificate to a person found by the board to have committed fraud during

the administration of the examination for a certificate to practice or to have committed fraud, misrepresentation, or deception in applying for or securing any certificate to practice or certificate of registration issued by the board.

(B) The board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend an individual's certificate to practice, refuse to register an individual, refuse to reinstate a certificate, or reprimand or place on probation the holder of a certificate for one or more of the following reasons:

(1) Permitting one's name or one's certificate to practice or certificate of registration to be used by a person, group, or corporation when the individual concerned is not actually directing the treatment given;

(2) Failure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease;

(3) Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug;

(4) Willfully betraying a professional confidence.

For purposes of this division, "willfully betraying a professional confidence" does not include providing any information, documents, or reports to a child fatality review board under sections 307.621 to 307.629 of the Revised Code and does not include the making of a report of an employee's use of a drug of abuse, or a report of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by that section upon a physician who makes either type of report in accordance with division (B) of that section. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised Code.

(5) Making a false, fraudulent, deceptive, or misleading statement in the solicitation of or advertising for patients; in relation to the practice of medicine and surgery, osteopathic medicine and surgery, podiatric medicine and surgery, or a limited branch of medicine; or in securing or attempting to secure any certificate to practice or certificate of registration issued by the board.

As used in this division, "false, fraudulent, deceptive, or misleading statement" means a statement that includes a misrepresentation of fact, is

likely to mislead or deceive because of a failure to disclose material facts, is intended or is likely to create false or unjustified expectations of favorable results, or includes representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established;

(7) Representing, with the purpose of obtaining compensation or other advantage as personal gain or for any other person, that an incurable disease or injury, or other incurable condition, can be permanently cured;

(8) The obtaining of, or attempting to obtain, money or anything of value by fraudulent misrepresentations in the course of practice;

(9) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony;

(10) Commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed;

(11) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a misdemeanor committed in the course of practice;

(12) Commission of an act in the course of practice that constitutes a misdemeanor in this state, regardless of the jurisdiction in which the act was committed;

(13) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a misdemeanor involving moral turpitude;

(14) Commission of an act involving moral turpitude that constitutes a misdemeanor in this state, regardless of the jurisdiction in which the act was committed;

(15) Violation of the conditions of limitation placed by the board upon a certificate to practice;

(16) Failure to pay license renewal fees specified in this chapter;

(17) Except as authorized in section 4731.31 of the Revised Code, engaging in the division of fees for referral of patients, or the receiving of a thing of value in return for a specific referral of a patient to utilize a particular service or business;

(18) Subject to section 4731.226 of the Revised Code, violation of any provision of a code of ethics of the American medical association, the American osteopathic association, the American podiatric medical association, or any other national professional organizations that the board

specifies by rule. The state medical board shall obtain and keep on file current copies of the codes of ethics of the various national professional organizations. The individual whose certificate is being suspended or revoked shall not be found to have violated any provision of a code of ethics of an organization not appropriate to the individual's profession.

For purposes of this division, a "provision of a code of ethics of a national professional organization" does not include any provision that would preclude the making of a report by a physician of an employee's use of a drug of abuse, or of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by that section upon a physician who makes either type of report in accordance with division (B) of that section. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised Code.

(19) Inability to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

In enforcing this division, the board, upon a showing of a possible violation, may compel any individual authorized to practice by this chapter or who has submitted an application pursuant to this chapter to submit to a mental examination, physical examination, including an HIV test, or both a mental and a physical examination. The expense of the examination is the responsibility of the individual compelled to be examined. Failure to submit to a mental or physical examination or consent to an HIV test ordered by the board constitutes an admission of the allegations against the individual unless the failure is due to circumstances beyond the individual's control, and a default and final order may be entered without the taking of testimony or presentation of evidence. If the board finds an individual unable to practice because of the reasons set forth in this division, the board shall require the individual to submit to care, counseling, or treatment by physicians approved or designated by the board, as a condition for initial, continued, reinstated, or renewed authority to practice. An individual affected under this division shall be afforded an opportunity to demonstrate to the board the ability to resume practice in compliance with acceptable and prevailing standards under the provisions of the individual's certificate. For the purpose of this division, any individual who applies for or receives a certificate to practice under this chapter accepts the privilege of practicing in

this state and, by so doing, shall be deemed to have given consent to submit to a mental or physical examination when directed to do so in writing by the board, and to have waived all objections to the admissibility of testimony or examination reports that constitute a privileged communication.

(20) Except when civil penalties are imposed under section 4731.225 or 4731.281 of the Revised Code, and subject to section 4731.226 of the Revised Code, violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board.

This division does not apply to a violation or attempted violation of, assisting in or abetting the violation of, or a conspiracy to violate, any provision of this chapter or any rule adopted by the board that would preclude the making of a report by a physician of an employee's use of a drug of abuse, or of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by that section upon a physician who makes either type of report in accordance with division (B) of that section. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised Code.

(21) The violation of any abortion rule adopted by the public health council pursuant to section 3701.341 of the Revised Code;

(22) Any of the following actions taken by the agency responsible for regulating the practice of medicine and surgery, osteopathic medicine and surgery, podiatric medicine and surgery, or the limited branches of medicine in another jurisdiction, for any reason other than the nonpayment of fees: the limitation, revocation, or suspension of an individual's license to practice; acceptance of an individual's license surrender; denial of a license; refusal to renew or reinstate a license; imposition of probation; or issuance of an order of censure or other reprimand;

(23) The violation of section 2919.12 of the Revised Code or the performance or inducement of an abortion upon a pregnant woman with actual knowledge that the conditions specified in division (B) of section 2317.56 of the Revised Code have not been satisfied or with a heedless indifference as to whether those conditions have been satisfied, unless an affirmative defense as specified in division (H)(2) of that section would apply in a civil action authorized by division (H)(1) of that section;

(24) The revocation, suspension, restriction, reduction, or termination of clinical privileges by the United States department of defense or department

of veterans affairs or the termination or suspension of a certificate of registration to prescribe drugs by the drug enforcement administration of the United States department of justice;

(25) Termination or suspension from participation in the medicare or medicaid programs by the department of health and human services or other responsible agency for any act or acts that also would constitute a violation of division (B)(2), (3), (6), (8), or (19) of this section;

(26) Impairment of ability to practice according to acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances that impair ability to practice.

For the purposes of this division, any individual authorized to practice by this chapter accepts the privilege of practicing in this state subject to supervision by the board. By filing an application for or holding a certificate to practice under this chapter, an individual shall be deemed to have given consent to submit to a mental or physical examination when ordered to do so by the board in writing, and to have waived all objections to the admissibility of testimony or examination reports that constitute privileged communications.

If it has reason to believe that any individual authorized to practice by this chapter or any applicant for certification to practice suffers such impairment, the board may compel the individual to submit to a mental or physical examination, or both. The expense of the examination is the responsibility of the individual compelled to be examined. Any mental or physical examination required under this division shall be undertaken by a treatment provider or physician who is qualified to conduct the examination and who is chosen by the board.

Failure to submit to a mental or physical examination ordered by the board constitutes an admission of the allegations against the individual unless the failure is due to circumstances beyond the individual's control, and a default and final order may be entered without the taking of testimony or presentation of evidence. If the board determines that the individual's ability to practice is impaired, the board shall suspend the individual's certificate or deny the individual's application and shall require the individual, as a condition for initial, continued, reinstated, or renewed certification to practice, to submit to treatment.

Before being eligible to apply for reinstatement of a certificate suspended under this division, the impaired practitioner shall demonstrate to the board the ability to resume practice in compliance with acceptable and prevailing standards of care under the provisions of the practitioner's certificate. The demonstration shall include, but shall not be limited to, the

following:

(a) Certification from a treatment provider approved under section 4731.25 of the Revised Code that the individual has successfully completed any required inpatient treatment;

(b) Evidence of continuing full compliance with an aftercare contract or consent agreement;

(c) Two written reports indicating that the individual's ability to practice has been assessed and that the individual has been found capable of practicing according to acceptable and prevailing standards of care. The reports shall be made by individuals or providers approved by the board for making the assessments and shall describe the basis for their determination.

The board may reinstate a certificate suspended under this division after that demonstration and after the individual has entered into a written consent agreement.

When the impaired practitioner resumes practice, the board shall require continued monitoring of the individual. The monitoring shall include, but not be limited to, compliance with the written consent agreement entered into before reinstatement or with conditions imposed by board order after a hearing, and, upon termination of the consent agreement, submission to the board for at least two years of annual written progress reports made under penalty of perjury stating whether the individual has maintained sobriety.

(27) A second or subsequent violation of section 4731.66 or 4731.69 of the Revised Code;

(28) Except as provided in division (N) of this section:

(a) Waiving the payment of all or any part of a deductible or copayment that a patient, pursuant to a health insurance or health care policy, contract, or plan that covers the individual's services, otherwise would be required to pay if the waiver is used as an enticement to a patient or group of patients to receive health care services from that individual;

(b) Advertising that the individual will waive the payment of all or any part of a deductible or copayment that a patient, pursuant to a health insurance or health care policy, contract, or plan that covers the individual's services, otherwise would be required to pay.

(29) Failure to use universal blood and body fluid precautions established by rules adopted under section 4731.051 of the Revised Code;

(30) Failure of a collaborating physician to fulfill the responsibilities agreed to by the physician and an advanced practice nurse participating in a pilot program under section 4723.52 of the Revised Code;

(31) Failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised

Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file;

(32) Failure of a physician supervising a physician assistant to maintain supervision in accordance with the requirements of Chapter 4730. of the Revised Code and the rules adopted under that chapter;

(33) Failure of a physician or podiatrist to enter into a standard care arrangement with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with whom the physician or podiatrist is in collaboration pursuant to section 4731.27 of the Revised Code or failure to fulfill the responsibilities of collaboration after entering into a standard care arrangement;

(34) Failure to comply with the terms of a consult agreement entered into with a pharmacist pursuant to section 4729.39 of the Revised Code;

(35) Failure to cooperate in an investigation conducted by the board under division (F) of this section, including failure to comply with a subpoena or order issued by the board or failure to answer truthfully a question presented by the board at a deposition or in written interrogatories, except that failure to cooperate with an investigation shall not constitute grounds for discipline under this section if a court of competent jurisdiction has issued an order that either quashes a subpoena or permits the individual to withhold the testimony or evidence in issue;

(36) Failure to supervise an acupuncturist in accordance with Chapter 4762. of the Revised Code and the board's rules for supervision of an acupuncturist;

(37) Failure to supervise an anesthesiologist assistant in accordance with Chapter 4760. of the Revised Code and the board's rules for supervision of an anesthesiologist assistant;

(38) Assisting suicide as defined in section 3795.01 of the Revised Code.

(C) Disciplinary actions taken by the board under divisions (A) and (B) of this section shall be taken pursuant to an adjudication under Chapter 119. of the Revised Code, except that in lieu of an adjudication, the board may enter into a consent agreement with an individual to resolve an allegation of a violation of this chapter or any rule adopted under it. A consent agreement, when ratified by an affirmative vote of not fewer than six members of the board, shall constitute the findings and order of the board with respect to the matter addressed in the agreement. If the board refuses to ratify a consent agreement, the admissions and findings contained in the consent agreement shall be of no force or effect.

If the board takes disciplinary action against an individual under

division (B) of this section for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the disciplinary action shall consist of a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice. Any consent agreement entered into under this division with an individual that pertains to a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of that section shall provide for a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice.

(D) For purposes of divisions (B)(10), (12), and (14) of this section, the commission of the act may be established by a finding by the board, pursuant to an adjudication under Chapter 119. of the Revised Code, that the individual committed the act. The board does not have jurisdiction under those divisions if the trial court renders a final judgment in the individual's favor and that judgment is based upon an adjudication on the merits. The board has jurisdiction under those divisions if the trial court issues an order of dismissal upon technical or procedural grounds.

(E) The sealing of conviction records by any court shall have no effect upon a prior board order entered under this section or upon the board's jurisdiction to take action under this section if, based upon a plea of guilty, a judicial finding of guilt, or a judicial finding of eligibility for intervention in lieu of conviction, the board issued a notice of opportunity for a hearing prior to the court's order to seal the records. The board shall not be required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.

(F)(1) The board shall investigate evidence that appears to show that a person has violated any provision of this chapter or any rule adopted under it. Any person may report to the board in a signed writing any information that the person may have that appears to show a violation of any provision of this chapter or any rule adopted under it. In the absence of bad faith, any person who reports information of that nature or who testifies before the board in any adjudication conducted under Chapter 119. of the Revised Code shall not be liable in damages in a civil action as a result of the report or testimony. Each complaint or allegation of a violation received by the board shall be assigned a case number and shall be recorded by the board.

(2) Investigations of alleged violations of this chapter or any rule adopted under it shall be supervised by the supervising member elected by the board in accordance with section 4731.02 of the Revised Code and by

the secretary as provided in section 4731.39 of the Revised Code. The president may designate another member of the board to supervise the investigation in place of the supervising member. No member of the board who supervises the investigation of a case shall participate in further adjudication of the case.

(3) In investigating a possible violation of this chapter or any rule adopted under this chapter, the board may administer oaths, order the taking of depositions, issue subpoenas, and compel the attendance of witnesses and production of books, accounts, papers, records, documents, and testimony, except that a subpoena for patient record information shall not be issued without consultation with the attorney general's office and approval of the secretary and supervising member of the board. Before issuance of a subpoena for patient record information, the secretary and supervising member shall determine whether there is probable cause to believe that the complaint filed alleges a violation of this chapter or any rule adopted under it and that the records sought are relevant to the alleged violation and material to the investigation. The subpoena may apply only to records that cover a reasonable period of time surrounding the alleged violation.

On failure to comply with any subpoena issued by the board and after reasonable notice to the person being subpoenaed, the board may move for an order compelling the production of persons or records pursuant to the Rules of Civil Procedure.

A subpoena issued by the board may be served by a sheriff, the sheriff's deputy, or a board employee designated by the board. Service of a subpoena issued by the board may be made by delivering a copy of the subpoena to the person named therein, reading it to the person, or leaving it at the person's usual place of residence. When the person being served is a person whose practice is authorized by this chapter, service of the subpoena may be made by certified mail, restricted delivery, return receipt requested, and the subpoena shall be deemed served on the date delivery is made or the date the person refuses to accept delivery.

A sheriff's deputy who serves a subpoena shall receive the same fees as a sheriff. Each witness who appears before the board in obedience to a subpoena shall receive the fees and mileage provided for witnesses in civil cases in the courts of common pleas.

(4) All hearings and investigations of the board shall be considered civil actions for the purposes of section 2305.252 of the Revised Code.

(5) Information received by the board pursuant to an investigation is confidential and not subject to discovery in any civil action.

The board shall conduct all investigations and proceedings in a manner

that protects the confidentiality of patients and persons who file complaints with the board. The board shall not make public the names or any other identifying information about patients or complainants unless proper consent is given or, in the case of a patient, a waiver of the patient privilege exists under division (B) of section 2317.02 of the Revised Code, except that consent or a waiver of that nature is not required if the board possesses reliable and substantial evidence that no bona fide physician-patient relationship exists.

The board may share any information it receives pursuant to an investigation, including patient records and patient record information, with law enforcement agencies, other licensing boards, and other governmental agencies that are prosecuting, adjudicating, or investigating alleged violations of statutes or administrative rules. An agency or board that receives the information shall comply with the same requirements regarding confidentiality as those with which the state medical board must comply, notwithstanding any conflicting provision of the Revised Code or procedure of the agency or board that applies when it is dealing with other information in its possession. In a judicial proceeding, the information may be admitted into evidence only in accordance with the Rules of Evidence, but the court shall require that appropriate measures are taken to ensure that confidentiality is maintained with respect to any part of the information that contains names or other identifying information about patients or complainants whose confidentiality was protected by the state medical board when the information was in the board's possession. Measures to ensure confidentiality that may be taken by the court include sealing its records or deleting specific information from its records.

(6) On a quarterly basis, the board shall prepare a report that documents the disposition of all cases during the preceding three months. The report shall contain the following information for each case with which the board has completed its activities:

- (a) The case number assigned to the complaint or alleged violation;
- (b) The type of certificate to practice, if any, held by the individual against whom the complaint is directed;
- (c) A description of the allegations contained in the complaint;
- (d) The disposition of the case.

The report shall state how many cases are still pending and shall be prepared in a manner that protects the identity of each person involved in each case. The report shall be a public record under section 149.43 of the Revised Code.

- (G) If the secretary and supervising member determine that there is clear

and convincing evidence that an individual has violated division (B) of this section and that the individual's continued practice presents a danger of immediate and serious harm to the public, they may recommend that the board suspend the individual's certificate to practice without a prior hearing. Written allegations shall be prepared for consideration by the board.

The board, upon review of those allegations and by an affirmative vote of not fewer than six of its members, excluding the secretary and supervising member, may suspend a certificate without a prior hearing. A telephone conference call may be utilized for reviewing the allegations and taking the vote on the summary suspension.

The board shall issue a written order of suspension by certified mail or in person in accordance with section 119.07 of the Revised Code. The order shall not be subject to suspension by the court during pendency of any appeal filed under section 119.12 of the Revised Code. If the individual subject to the summary suspension requests an adjudicatory hearing by the board, the date set for the hearing shall be within fifteen days, but not earlier than seven days, after the individual requests the hearing, unless otherwise agreed to by both the board and the individual.

Any summary suspension imposed under this division shall remain in effect, unless reversed on appeal, until a final adjudicative order issued by the board pursuant to this section and Chapter 119. of the Revised Code becomes effective. The board shall issue its final adjudicative order within sixty days after completion of its hearing. A failure to issue the order within sixty days shall result in dissolution of the summary suspension order but shall not invalidate any subsequent, final adjudicative order.

(H) If the board takes action under division (B)(9), (11), or (13) of this section and the judicial finding of guilt, guilty plea, or judicial finding of eligibility for intervention in lieu of conviction is overturned on appeal, upon exhaustion of the criminal appeal, a petition for reconsideration of the order may be filed with the board along with appropriate court documents. Upon receipt of a petition of that nature and supporting court documents, the board shall reinstate the individual's certificate to practice. The board may then hold an adjudication under Chapter 119. of the Revised Code to determine whether the individual committed the act in question. Notice of an opportunity for a hearing shall be given in accordance with Chapter 119. of the Revised Code. If the board finds, pursuant to an adjudication held under this division, that the individual committed the act or if no hearing is requested, the board may order any of the sanctions identified under division (B) of this section.

(I) The certificate to practice issued to an individual under this chapter

and the individual's practice in this state are automatically suspended as of the date of the individual's second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, or the date the individual pleads guilty to, is found by a judge or jury to be guilty of, or is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state or treatment or intervention in lieu of conviction in another jurisdiction for any of the following criminal offenses in this state or a substantially equivalent criminal offense in another jurisdiction: aggravated murder, murder, voluntary manslaughter, felonious assault, kidnapping, rape, sexual battery, gross sexual imposition, aggravated arson, aggravated robbery, or aggravated burglary. Continued practice after suspension shall be considered practicing without a certificate.

The board shall notify the individual subject to the suspension by certified mail or in person in accordance with section 119.07 of the Revised Code. If an individual whose certificate is automatically suspended under this division fails to make a timely request for an adjudication under Chapter 119. of the Revised Code, the board shall ~~enter~~ do whichever of the following is applicable:

(1) If the automatic suspension under this division is for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the board shall enter an order suspending the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, imposing a more serious sanction involving the individual's certificate to practice.

(2) In all circumstances in which division (1)(1) of this section does not apply, enter a final order permanently revoking the individual's certificate to practice.

(J) If the board is required by Chapter 119. of the Revised Code to give notice of an opportunity for a hearing and if the individual subject to the notice does not timely request a hearing in accordance with section 119.07 of the Revised Code, the board is not required to hold a hearing, but may adopt, by an affirmative vote of not fewer than six of its members, a final order that contains the board's findings. In that final order, the board may order any of the sanctions identified under division (A) or (B) of this section.

(K) Any action taken by the board under division (B) of this section resulting in a suspension from practice shall be accompanied by a written statement of the conditions under which the individual's certificate to practice may be reinstated. The board shall adopt rules governing conditions to be imposed for reinstatement. Reinstatement of a certificate suspended

pursuant to division (B) of this section requires an affirmative vote of not fewer than six members of the board.

(L) When the board refuses to grant a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate.

(M) Notwithstanding any other provision of the Revised Code, all of the following apply:

(1) The surrender of a certificate issued under this chapter shall not be effective unless or until accepted by the board. Reinstatement of a certificate surrendered to the board requires an affirmative vote of not fewer than six members of the board.

(2) An application for a certificate made under the provisions of this chapter may not be withdrawn without approval of the board.

(3) Failure by an individual to renew a certificate of registration in accordance with this chapter shall not remove or limit the board's jurisdiction to take any disciplinary action under this section against the individual.

(N) Sanctions shall not be imposed under division (B)(28) of this section against any person who waives deductibles and copayments as follows:

(1) In compliance with the health benefit plan that expressly allows such a practice. Waiver of the deductibles or copayments shall be made only with the full knowledge and consent of the plan purchaser, payer, and third-party administrator. Documentation of the consent shall be made available to the board upon request.

(2) For professional services rendered to any other person authorized to practice pursuant to this chapter, to the extent allowed by this chapter and rules adopted by the board.

(O) Under the board's investigative duties described in this section and subject to division (F) of this section, the board shall develop and implement a quality intervention program designed to improve through remedial education the clinical and communication skills of individuals authorized under this chapter to practice medicine and surgery, osteopathic medicine and surgery, and podiatric medicine and surgery. In developing and implementing the quality intervention program, the board may do all of the following:

(1) Offer in appropriate cases as determined by the board an educational and assessment program pursuant to an investigation the board conducts under this section;

(2) Select providers of educational and assessment services, including a quality intervention program panel of case reviewers;

(3) Make referrals to educational and assessment service providers and approve individual educational programs recommended by those providers. The board shall monitor the progress of each individual undertaking a recommended individual educational program.

(4) Determine what constitutes successful completion of an individual educational program and require further monitoring of the individual who completed the program or other action that the board determines to be appropriate;

(5) Adopt rules in accordance with Chapter 119. of the Revised Code to further implement the quality intervention program.

An individual who participates in an individual educational program pursuant to this division shall pay the financial obligations arising from that educational program.

Sec. 4731.223. (A) As used in this section, "prosecutor" has the same meaning as in section 2935.01 of the Revised Code.

(B) Whenever any person holding a valid certificate issued pursuant to this chapter pleads guilty to, is subject to a judicial finding of guilt of, or is subject to a judicial finding of eligibility for intervention in lieu of conviction for a violation of Chapter 2907., 2925., or 3719. of the Revised Code or of any substantively comparable ordinance of a municipal corporation in connection with the person's practice, or for a second or subsequent time pleads guilty to, or is subject to a judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the prosecutor in the case, on forms prescribed and provided by the state medical board, shall promptly notify the board of the conviction or guilty plea. Within thirty days of receipt of that information, the board shall initiate action in accordance with Chapter 119. of the Revised Code to determine whether to suspend or revoke the certificate under section 4731.22 of the Revised Code.

(C) The prosecutor in any case against any person holding a valid certificate issued pursuant to this chapter, on forms prescribed and provided by the state medical board, shall notify the board of any of the following:

(1) A plea of guilty to, a finding of guilt by a jury or court of, or judicial finding of eligibility for intervention in lieu of conviction for a felony, or a case in which the trial court issues an order of dismissal upon technical or procedural grounds of a felony charge;

(2) A plea of guilty to, a finding of guilt by a jury or court of, or judicial finding of eligibility for intervention in lieu of conviction for a misdemeanor committed in the course of practice, or a case in which the trial court issues an order of dismissal upon technical or procedural grounds of a charge of a misdemeanor, if the alleged act was committed in the course of practice;

(3) A plea of guilty to, a finding of guilt by a jury or court of, or judicial finding of eligibility for intervention in lieu of conviction for a misdemeanor involving moral turpitude, or a case in which the trial court issues an order of dismissal upon technical or procedural grounds of a charge of a misdemeanor involving moral turpitude.

The report shall include the name and address of the certificate holder, the nature of the offense for which the action was taken, and the certified court documents recording the action.

SECTION 2. That existing sections 4729.29, 4731.22, and 4731.223 of the Revised Code are hereby repealed.

SECTION 3. Section 4731.22 of the Revised Code is presented in this act as a composite of the section as amended by both Am. Sub. H.B. 474 and Sub. S.B. 179 of the 124th General Assembly. The General Assembly, applying the principle stated in division (B) of section 1.52 of the Revised Code that amendments are to be harmonized if reasonably capable of simultaneous operation, finds that the composite is the resulting version of the section in effect prior to the effective date of the section as presented in this act.

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*Speaker* \_\_\_\_\_ *of the House of Representatives.*

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*President* \_\_\_\_\_ *of the Senate.*

Passed \_\_\_\_\_, 20\_\_\_\_

Approved \_\_\_\_\_, 20\_\_\_\_

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*Governor.*

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

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*Director, Legislative Service Commission.*

Filed in the office of the Secretary of State at Columbus, Ohio, on the  
\_\_\_\_ day of \_\_\_\_\_, A. D. 20\_\_\_\_.

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*Secretary of State.*

File No. \_\_\_\_\_ Effective Date \_\_\_\_\_

**§ 314.445 Guidelines.**

(a) The Food and Drug Administration prepares guidelines under § 10.90(b) to help persons comply with requirements in this part.

(b) The Center for Drug Evaluation and Research will maintain and make publicly available a list of guidelines that apply to the Center's regulations. The list states how a person can obtain a copy of each guideline. A request for a copy of the list should be directed to the CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

[50 FR 7493, Feb. 22, 1985, as amended at 55 FR 11581, Mar. 29, 1990; 56 FR 3776, Jan. 31, 1991]

**Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses**

SOURCE: 57 FR 58958, Dec. 11, 1992, unless otherwise noted.

**§ 314.500 Scope.**

This subpart applies to certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

[57 FR 58958, Dec. 11, 1992, as amended at 64 FR 402, Jan. 5, 1999]

**§ 314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.**

FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiological, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval under this section will be

subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome. Postmarketing studies would usually be studies already underway. When required to be conducted, such studies must also be adequate and well-controlled. The applicant shall carry out any such studies with due diligence.

**§ 314.520 Approval with restrictions to assure safe use.**

(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:

- (1) Distribution restricted to certain facilities or physicians with special training or experience; or
- (2) Distribution conditioned on the performance of specified medical procedures.

(b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

**§ 314.530 Withdrawal procedures.**

(a) For new drugs approved under §§ 314.510 and 314.520, FDA may withdraw approval, following a hearing as provided in part 15 of this chapter, as modified by this section, if:

- (1) A postmarketing clinical study fails to verify clinical benefit;
- (2) The applicant fails to perform the required postmarketing study with due diligence;
- (3) Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the drug product;
- (4) The applicant fails to adhere to the postmarketing restrictions agreed upon;
- (5) The promotional materials are false or misleading; or
- (6) Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.