

In the
Supreme Court of Ohio

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

**PRELIMINARY MEMORANDUM OF PETITIONER OHIO ATTORNEY GENERAL
NANCY H. ROGERS IN SUPPORT OF ANSWERING THE CERTIFIED QUESTIONS**

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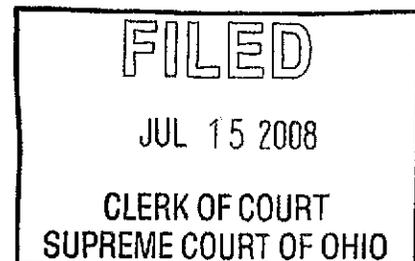
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INTRODUCTION

In this case, a federal appeals court has asked this Court to confirm the meaning of an Ohio law, as that law has been attacked in a federal lawsuit as unconstitutionally vague. The Ohio law, R.C. 2919.123, seeks to protect the health and safety of women by regulating the use of mifepristone, also known as “RU-486.” Specifically, the statute says that the drug may be used in Ohio to induce medical abortions only in accordance with “federal law,” and the term “federal law” is expressly defined to include the “drug approval letter” of the United States Food and Drug Administration (“FDA”). That drug approval letter notes that the “new drug application provides for the use of Mifeprex [the drug’s brand name] for the medical termination of intrauterine pregnancy through 49 days’ pregnancy,” and the letter also states that the FDA has “concluded that adequate information has been presented to approve Mifeprex (mifepristone) Tablets, 200 mg, for use as recommended in the agreed upon labeling text.” Thus, the FDA approved the drug for abortions up to the 49-day gestational limit and for usage under a certain protocol, including a certain dosage. The U.S. Court of Appeals for the Sixth Circuit has asked this Court to answer whether the Ohio law, by citing the approval letter as part of “federal law,” truly incorporates the specific 49-day limit and the dosage and other protocols referenced in the approval letter.

The Court should accept the certified questions, and it should answer them both “yes.” The Sixth Circuit’s questions go to the heart of the statute and also to the heart of Respondents’ challenge, which claims that the Ohio law is unconstitutionally vague. Respondents claim that the law is unclear on whether it prohibits “off-label” uses of this drug, such as usage later in pregnancy with different protocols. Typically, once the FDA approves a drug for one use, doctors may then use the drug for other uses, called “off-label” uses. That is so because States, not the federal government, regulate how doctors may practice medicine. Once the federal

government has found that a drug is safe for one use, its job is done, and the States are then free to allow or prohibit other uses—and here, that is exactly what Ohio has done. Ohio has decided that, in the interests of women’s health and safety, this drug should be used only in the way that the FDA approved, and not for off-label uses.

Respondents insist that the statute is unclear on whether it truly restricts off-label uses—i.e., whether Ohio law incorporates the regimen referenced in the approval letter—but that view is mistaken. Respondents argue that the Ohio law does nothing more than require doctors to follow rules that federal law already requires them to follow, while allowing off-label uses. But, as noted above, the Ohio statute says that the drug may be used only in accordance with federal law, R.C. 2919.123(A), and “federal law” is defined to include “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. 2919.123(F).

While that language is plain, the federal appeals court has asked this Court to clarify what it means. Specifically, the Sixth Circuit has asked the Court to answer two 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 gestation 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?

The Ohio Attorney General (“Ohio”) urges the Court to accept these questions and to answer them both “yes.” On one hand, Ohio acknowledges that such review is unnecessary, and in fact, Ohio argued to the federal court that the language was so straightforward that no certification to this Court was needed. On the other hand, because the federal court has asked, the Court should confirm that Ohio law means what it says: this drug may be used in Ohio only in accordance with the specific FDA-approved gestational limit and treatment protocol.

STATEMENT OF THE CASE AND FACTS

A. **The U.S. Food and Drug Administration 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.*¹

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

The FDA noted in its approval letter that it had reviewed and approved the drugs on those terms, and it expressly referred to those terms and to a document known as the “final printed labeling,” which further details the protocols for using the drug. 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,

¹ Mifepristone, also called RU-486, has been confused in some media reports with a different drug, called emergency contraception or the “the morning-after pill.” The two are different, and R.C. 2919.123 does not regulate emergency contraception.

200 mg, *for use as recommended in the agreed upon labeling text*. The application is approved under 21 CFR 314 Subpart H.

FDA Approval Letter, Sept. 28, 2000, at 1 (emphasis added). The “agreed upon labeling text” approved by the FDA letter included the professional labeling or “package insert,” which spelled out both the 49 day gestational limit and the approved treatment protocol. The approved final printed labeling also included a Medication Guide and Patient Agreement which again set forth the 49 day limit along with the approved treatment protocol.

The FDA was sufficiently concerned about mifepristone’s safety that it approved the drug for use under 21 CFR 314 Subpart H, which allows the FDA to place restrictions on post-approval use of a drug when necessary for safe use. Specifically, under 21 CFR 314.520, the FDA placed certain limitations on the distribution of the drug (the “Subpart H restrictions”), including requirements that the doctors who use the drug to read and understand the prescribing information about the drug as set forth in the drug’s final printed labeling, including an FDA-approved Medication Guide, and that the doctors provide a copy of the Medication Guide and Patient Agreement to each patient. Both of these documents expressly set forth the gestational limit of 49 days and the approved protocol.

B. Ohio passed a law 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 an earlier 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, i.e., 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. Off-label use is allowed, from the federal perspective, because the FDA approves only the drugs as products, and the FDA does not regulate the practice of medicine by doctors, as the latter is left to the States. See *id.* So once a drug is considered safe and effective for one use, the FDA’s job is

done, and it is each State's job to determine whether, in its regulation of the practice of medicine, any other restrictions are called for.

Soon after the FDA approved mifepristone, some medical providers in Ohio began expanding the use of mifepristone to terminate pregnancies up to 63 days (9 weeks). They also began using a much lower dose of mifepristone than called for by the FDA-approved treatment protocol, and instead used 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 the safety issues surrounding the drug and about the need for Ohio to have a mechanism to enforce the terms of the FDA approval. The result was H.B. 126 of the 125th General Assembly ("the Act"), which passed by a large margin in the Ohio House in June 2003, and in the Ohio Senate in May 2004.

As the legislative history confirms, the Act demonstrates the General Assembly's intent that mifepristone be prescribed in Ohio for medical abortion only in accordance with the FDA approval, including the approved indication, treatment protocol, and distribution restrictions set forth in the FDA Approval Letter and the materials referenced in the Letter. First, R.C. 2919.123(A) provides that no person shall knowingly give, sell or dispense, administer, otherwise provide, or prescribe mifepristone to another for the purpose of inducing an abortion, unless the person who provides or prescribes the drug is a physician, that 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 finally that the 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). In the State’s view, this means that the statute limits the use of mifepristone in Ohio to all the parameters of the FDA approval, while, as explained below, Respondents claim that the law does not include all the terms referenced in the letter. But no one disputes that, as a general rule, Ohio may, as part of its power to regulate the practice of medicine, prohibit off-label uses of drugs.

C. Some medical providers sued, claiming, among other things, that the Ohio law is vague in saying that Ohio doctors must follow the FDA approval letter’s conditions.

The Governor signed the Act into law on June 24, 2004. Before the law went into effect, a group of clinics and providers (together, “Planned Parenthood”), sued in the U.S. District Court for the Southern District of Ohio, Western Division, seeking injunctive and declaratory relief preventing the law’s enforcement. The defendants included 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, but the sole issue in the current federal appeal is its claim that the law is unconstitutionally vague. The other issues involve an alleged “undue burden” on the right to an abortion, an alleged violation of a right to bodily integrity, and an objection to the lack of a health exception in the law. The district court first enjoined the statute’s enforcement solely on the grounds that it does not have a health exception. The district court did not address the undue burden, bodily integrity, or vagueness arguments.

On appeal, the Sixth Circuit vacated the first injunction, finding it too broad, and it 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 had, in the context of a different abortion law that arguably lacked an adequate health exception, 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 Northern New England*, 546 U.S. 320 (2006) (“*Ayotte*”). 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.

The district court then ordered that the parties brief the remand issues. Instead, Planned Parenthood moved for summary judgment on the theory that the statute is unconstitutionally vague. Specifically, Planned Parenthood argued that the statute is unclear on whether it prohibits off-label uses, or whether it merely restates the restrictions that the FDA imposed as a matter of federal law. The district court decided that the statute is vague, and it permanently enjoined the statute’s enforcement. *Planned Parenthood v. Taft* (S.D. Ohio 2006), 459 F. Supp. 2d 626, 640.

D. The federal appeals court has now 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 fetal age referred to, in the federal approval letter.

Ohio again appealed. The Sixth Circuit, in addressing Planned Parenthood’s claim that the statute is vague, determined that this Court could best determine the statute’s meaning. Consequently, the Sixth Circuit issued an order asking this Court to answer the two specific questions (quoted above at 2) regarding the statute’s meaning and effect. That certification order was filed with this Court on June 25, 2008, triggering this Court’s preliminary consideration of whether to answer the federal court’s questions. As explained below, the State urges the Court to accept the certification, and to answer both questions “yes.”

THIS COURT SHOULD ANSWER THE CERTIFIED QUESTIONS

Although the State urges the Court to accept the federal court's invitation, it is obliged to note that such certification is unneeded here. That is so because the statute's meaning is plain, as detailed in the merits section below, and because the underlying federal appeal involves *solely* a vagueness challenge, not any other substantive challenge to the law. For this reason, when the federal court asked the parties at oral argument whether it should certify questions to this Court, the State initially opposed certification.

Nevertheless, the State now urges the Court to answer the certified questions for the simple reason that the federal court has asked, and if there is any doubt about the statute's meaning—even if there ought not be, in the State's view—then this Court can and should clarify the State's meaning. As the federal court noted in its order certifying the questions, certification helps to reduce the “potential for friction-generating error” that exists whenever a federal court reviews a state law that has not yet been reviewed by state courts. *Planned Parenthood Cincinnati Region v. Strickland* (6th Cir.), 2008 U.S. App. Lexis 13232, *10. As long as the federal court feels uncertain about addressing the Ohio law without this Court's guidance, then the safer course is for this Court to accept the certification and prevent any mistake or confusion about the meaning of state law.

Moreover, this Court's review might prove especially useful here because this Court is especially attuned to the principle that Ohio's General Assembly does not enact laws that are meaningless. R.C. 1.47 (“In enacting a statute, it is presumed that . . . the entire statute is intended to be effective.”); *State ex rel. Cleveland Elec. Illum. Co. v. City of Euclid* (1959), 169 Ohio St. 476, 479 (“when language is inserted in a statute it is inserted to accomplish some definite purpose.”). Here, that canon is critical because, as detailed below, Planned Parenthood's view is that the statute merely tells doctors to follow federal rules that they already must follow

as a matter of federal law; they insist that the Ohio statute does not add the additional restriction of prohibiting off-label uses. But the Assembly would not likely have passed this law merely to duplicate existing federal law, as opposed to invoking the State's right to regulate doctors and making a real difference by passing the law.

In sum, although certification is not needed, the Court should nevertheless accept the certified questions and answer them for the federal court. And as explained below, the Court should answer both questions "yes."

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 forty-nine gestational days.

R.C. 2919.123(A) requires that Ohio physicians who provide medical abortions using mifepristone do so only in accordance with federal law. The statute defines “federal law” to include the FDA Approval Letter. R.C. 2919.123(F). Therefore, physicians in Ohio may prescribe the drug only in accordance with the Approval Letter, and so can only prescribe the drug up to 49 gestational days.

In the Approval Letter, the FDA specifically approved the drug to be used in response to an application that only sought approval for use through 49 days’ gestation: “This new drug application provides for the use of Mifeprex for the medical termination of intrauterine pregnancy **through 49 days’ pregnancy.**” Thus, that timeframe was the context in which the FDA found the drug to be safe and effective, so when Ohio chose to limit the drug’s use to the terms of the Approval Letter, that incorporates that limit—expressly stated in the Letter—into Ohio law. In addition, the Approval Letter provides that:

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 final printed labeling (FPL) [including the professional labeling (Package Insert), the Medication Guide required for this product under 21 CFR Part 208, the Patient Agreement Form, and the Prescriber’s Agreement Form] must be identical to the submitted draft labeling. . .

Approval Letter at 1 (emphasis added). The agreed labeling (sometimes referred to as the “final printed labeling”) includes the Package Insert, the Medication Guide, and the Patient Agreement. Each of these documents specifically sets forth the approved gestational limit of 49 days. The Medication Guide includes a paragraph that states:

Mifeprex is used to end 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.

Further, by signing the Patient Agreement, the patient herself agrees that she believes that she is not more than 49 days (7 weeks) pregnant.

Therefore, by defining “federal law” to include the FDA Approval Letter, R.C. 2919.123 mandates that doctors in Ohio who perform abortions using mifepristone do so only up to the FDA-approved indication of forty-nine gestational days.

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

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

By including the Approval Letter in the definition of “federal law,” R.C. 2919.123 also requires doctors to use mifepristone only in compliance with the treatment protocol set forth in the final printed labeling.

As explained above, the Approval Letter plainly states that the drug is being approved “for use as recommended in the agreed upon labeling text.” This labeling text includes the Package Insert and the Medication Guide. Both of these documents explain the FDA approved treatment protocol of mifepristone 600 mg (3 tablets) orally, followed approximately 48 hours later by misoprostol 400 µg orally to induce contractions and expel the pregnancy.

The federal Subpart H requirements already require every doctor to read and understand these documents before he may use mifepristone; he is further required to provide each patient with a copy of the Medication Guide and discuss it with her. Hence, every doctor who uses mifepristone, in all 50 States, must be familiar with the FDA-approved protocol.

Planned Parenthood is mistaken in arguing that the inclusion of the Approval Letter in the statutory definition of “federal law” means only that Ohio doctors must comply with federal law

in general. Planned Parenthood argues that because federal law does not prohibit off-label use of drugs, the result is that the Ohio statute, by incorporating federal law, does not restrict off-label use either. But that argument fails to explain why Ohio passed this law at all. It makes sense to accept that Ohio passed this law pursuant to its undisputed power to prohibit off-label uses of FDA-approved drugs. As the Sixth Circuit noted in *PPCR I*, the FDA regulates only marketing and distribution of drugs, not doctors' medical practices, so once the FDA has approved a drug, physicians can use it off-label for other purposes. That does not mean that the States cannot restrict off-label use, of course, because the States regulate the practice of medicine.

Thus, the only plausible reason for Ohio to have passed this law is that Ohio sought to invoke its right to regulate doctors and to prohibit off-label uses. Otherwise, the statute would be meaningless in regard to regulating doctors' 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 Ohio law merely told doctors to follow already-binding federal law, then it would have no effect at all on doctors' practice; at most, it would give Ohio parallel enforcement power over existing FDA law.

Planned Parenthood unsuccessfully seeks to avoid this result by arguing that Ohio's incorporation of the Approval Letter carries real meaning because it serves to require that doctors follow the eight specific Subpart H restrictions that are listed in the Approval Letter. But codifying this list into state law still does not require anything new of Ohio doctors, as again, federal law already requires doctors to follow those restrictions. See 21 CFR 314.520. In other

words, doctors in all 50 States must follow the eight specific Subpart H restrictions, so Planned Parenthood's alternate view still means that Ohio's statute does not ask Ohio's doctors to do anything differently from Michigan or Pennsylvania doctors.

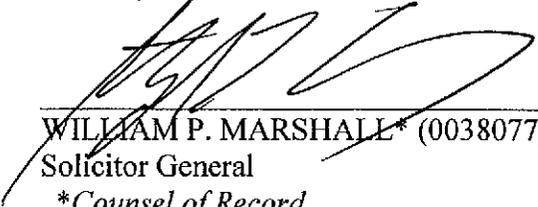
By contrast, the State's reading of the statute does require Ohio doctors to act differently from their counterparts in the other 49 States, as Ohio doctors must stick to the FDA-approved protocols and may not try off-label uses, even if the FDA would otherwise allow them to as a matter of federal law. In other words, Ohio doctors may provide mifepristone to terminate pregnancies only up to the 49-day gestational limit, and they may do so only in accordance with the approved treatment protocol, including the dosage and other relevant protocols.

CONCLUSION

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

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Preliminary Memorandum of Petitioner, Ohio Attorney General Nancy H. Rogers in Support of the Certified Questions was served by U.S. mail this 15th of July, 2008, upon the following counsel:

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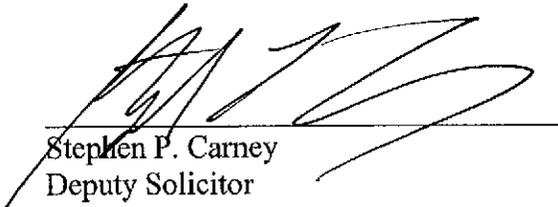
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