

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

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.

ORDER OF CERTIFICATION TO THE SUPREME COURT OF OHIO

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.¹ 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

¹Ohio 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.²

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

²The 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.

“because 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 "unconstrained 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.” *Arizonans 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:**

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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