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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

PLANNED PARENTHOOD CINCINNATI REGION, et al.,
Plaintiffs-Appellees,

v.

BOB TAFT, et al.,
Defendants-Appellants.

No. 04-4371

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

Argued: December 7, 2005

Decided and Filed: February 24, 2006

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

COUNSEL

ARGUED: Anne Berry Strait, OFFICE OF THE ATTORNEY GENERAL, CHARITABLE LAW SECTION, Columbus, Ohio, 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.

McKEAGUE, J., delivered the opinion of the court, in which ROGERS, J., joined. MOORE, J. (p. 13), delivered a separate opinion concurring in part.

OPINION

McKEAGUE, Circuit Judge. 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 (2006).

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.[1] Upon examining the results of these trials, the FDA concluded that this regimen was a safe and effective 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.

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 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 employed across the United States.[2]

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.

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[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.

[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.

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 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 legislators became aware that several women had died or been severely injured recently as a result of their use of mifepristone."[3] 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. Therefore, they banned all other uses of mifepristone to protect Ohio women from unsafe and ineffective mifepristone protocols.

The Act was scheduled to go into effect on September 23, 2004. Dr. Roslyn Kade, Dr. Laszlo Sogor, and various Planned 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 each side was allotted a total of three hours to present testimony and cross-examine opposing witnesses. Plaintiffs presented the expert testimony of Dr. 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 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).

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[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.

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.[4] 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, and close scrutiny of the case law reveals that no such blanket requirement has been imposed.

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 (1992). The 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 (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. This creates confusion because although the arguments are closely 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 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 (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 court cited contain only one statement which

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[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).

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* 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 ("[T]he 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 ("[O]ur 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 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 requirement and its application demonstrate that there is no such per se requirement.

Neither can support for a per se requirement be found in any of 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 (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 "[a]n adequate 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 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). 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 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 se requirement that all abortion statutes contain a health or life exception regardless of whether the statute endangers the health of life of the woman. *See id.* at 919-20.

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 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 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 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, 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.

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 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.[5] 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.[6]

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

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[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.

[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 uncontested.

> 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 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 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 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 safety of abortion procedures. *See Mazurek v. Armstrong*, 520 U.S. 968, 973 (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.

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 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 for all medically foreseeable circumstances or conditions.[7]

[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

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 expert 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 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 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.[8] 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 of discretion. 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).

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

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by the State on the narrow issue which became the central focus.

[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.

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 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.

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, 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 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 (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 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 (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 "[i]f 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 injunctive relief," namely the prohibition of the statute's unconstitutional applications. *Id.* at 964, 969. 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 (2003); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 382-83 (1992); *see also Branch v. Smith*, 538 U.S. 254, 265 (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 (2005) (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 (1908) — "insofar as it restrain[ed] 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*, — U.S. —, 126 S. Ct. 361 (2005); *PACCAR Inc. v. TeleScan Techs., L.L.C.*, 319 F.3d 243, 258 (6th Cir. 2003) (affirming in 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 a preliminary injunction prohibiting enforcement of three statutory sections only "insofar as it applie[d] 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 (1977) (per curiam) (noting that the injunction "appear[ed] 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 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.[9] *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*, — F.3d —, 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).

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 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 determination that Plaintiffs had established a strong likelihood of succeeding on the merits

[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.

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.

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 though IV of the majority opinion. I also agree that in light of *Ayotte v. Planned Parenthood of Northern New England*, — U.S. —, 126 S. Ct. 961 (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 excluded 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 view, we cannot say that the presence of a different view by itself proves the contrary." *Stenberg v. Carhart*, 530 U.S. 914, 937 (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 have been sufficient to defeat 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.