IN THE SUPREME COURT OF OHIO

Nancy H. Rogers, Attorney General; and Joseph T. Deters, as Prosecuting Attorney for Hamilton County, Ohio and as representative of a class of all Prosecuting Attorneys in Ohio,	)	
Petitioners,	)	
v.	)	Case No. 2008-1234
Planned Parenthood Cincinnati Region; Planned Parenthood of Central Ohio; Planned Parenthood of Greater Cleveland; Preterm; Dr. Roslyn Kade; and Dr. Laszlo Sogor,	)	Questions of State Law Certified by the U.S. Court of Appeals for the Sixth Circuit, Case Nos. 06-4422 and 06-4423
Respondents.	)	

PRELIMINARY MEMORANDUM OF RESPONDENTS

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INTRODUCTION

Before this Court is whether to accept two certified questions of state law from the U.S. Court of Appeals for the Sixth Circuit. *See Planned Parenthood Cincinnati Region v. Strickland* (6th Cir. June 23, 2008), Nos. 06-4422, 06-4423, ("Certification Order").[1] Respondents Planned Parenthood Southwest Ohio Region, Planned Parenthood of Central Ohio, Planned Parenthood of Northeast Ohio, Preterm, Dr. Roslyn Kade and Dr. Laszlo Sogor (collectively "Respondents" or "Planned Parenthood")[2] respectfully urge this Court to modify slightly the questions certified by the Sixth Circuit and to accept those modified questions for consideration.

PROCEDURAL HISTORY

This litigation involves a constitutional challenge to a 2004 Ohio law, Ohio House Bill 126 ("H.B. 126" or "Act"), which has been codified R.C. 2919.123, that regulates the use of mifepristone (commonly known as RU-486).[3] Mifepristone is a medication approved by the Food and Drug Administration ("FDA") that is used to induce an abortion without a surgical procedure. H.B. 126 imposes criminal penalties on physicians who prescribe mifepristone for the purpose of inducing abortion, unless the physician "satisfies all the criteria established by federal law" and provides the drug "in accordance with all provisions of federal law." R.C. 2919.123(A). The Act defines "federal law" as:

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[1] *See* Certified copy of order certifying question of state law from United States Court of Appeals for the Sixth Circuit filed in this court on June 25, 2008 referred hereafter as "Certification Order."

[2] Respondents notified the Sixth Circuit in January 2008 of the following changes in Respondents' names: Planned Parenthood Cincinnati Region is now Planned Parenthood Southwest Ohio Region, and Planned Parenthood Greater Cleveland is now Planned Parenthood of Northeast Ohio. Despite this notification, the Sixth Circuit's certification order – and hence the docket in this case – identifies the parties under their previous names. Respondents have kept the caption as it appears on this Court's docket, but in their papers use their current names.

[3] Mifepristone is also sometimes referred to by its commercial name Mifeprex™.

> 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.

Id. 2929.123(F)(1).

Respondents are four health care centers and two physicians who provide medication abortion using mifepristone in accordance with federal law. Almost four years ago, Planned Parenthood sued the Governor, the Attorney General of the State of Ohio, and a defendant class of county prosecuting attorneys represented by the named defendant Joseph Deters, Hamilton County Prosecuting Attorney (collectively "Petitioners" or "State"), in federal court. In early 2007, after taking office, Governor Strickland stated that he did not wish to defend the Act, and the Sixth Circuit allowed him to withdraw his notice of appeal. Therefore, he is not a Petitioner before this Court.

Respondents maintain – and the federal district court agreed – that the Act violates their and their patients' constitutional rights because it is unconstitutionally vague. In addition, if interpreted as the State suggests, the Act has at least three other constitutional problems: (1) it violates a woman's right to bodily integrity under the Fourteenth Amendment to the U.S. Constitution by compelling her to undergo an invasive surgical procedure where an equally safe, if not safer, procedure using medications would otherwise be available to her; (2) it imposes an undue burden on a woman's Fourteenth Amendment right to choose abortion by banning a safe and common method of previability abortion; and (3) it, even if otherwise constitutional, lacks an exception to protect a woman's health. *See Strickland*, Certification Order at 4.

On September 22, 2004, the federal district court entered a preliminary injunction against the Act on the ground that Planned Parenthood was likely to succeed on its claim that the Act is unconstitutional for lack of a health exception. *See Planned Parenthood Cincinnati Region v.*

Taft (S.D. Ohio 2004), 337 F. Supp. 2d 1040. On appeal, the Sixth Circuit agreed that the Act is flawed because it lacks a health exception. However, in light of the Supreme Court's holding in *Ayotte v. Planned Parenthood of Northern New England* (2006), 546 U.S. 320, the Court remanded the case to the district court so that it could determine the appropriate scope of preliminary injunctive relief and consider Planned Parenthood's remaining claims. *See Planned Parenthood Cincinnati Region v. Taft* (6th Cir. 2006), 444 F.3d 502.

On remand, Planned Parenthood renewed its request that the district court preliminarily enjoin enforcement of the Act in all its applications. Planned Parenthood also moved for summary judgment on its claim that the Act is unconstitutionally vague, and on September 27, 2006, the district court granted that motion. *See Planned Parenthood Cincinnati Region v. Taft* (S.D. Ohio 2006), 459 F. Supp. 2d 626. Respondents appealed, and on June 23, 2008, rather than rule on the Act's vagueness, the Sixth Circuit, *sua sponte*, asked this Court to answer two questions of state law pursuant to Rule XVIII of the Rules of Practice of this Court. *See Strickland*, Certification Order.

STATEMENT OF FACTS

The FDA approved mifepristone for use in the United States in September 2000 based on the agency's review of three clinical trials that had been completed years earlier and submitted to the FDA with the New Drug Application ("NDA") in 1996. JX3 Package Insert at 3-5, Apx. 192-94.[4] Those trials involved the oral ingestion of 600 mg of mifepristone followed two days later by the oral ingestion of .4 mg of misoprostol. The trials demonstrated that this regimen was

[4] Citations herein are to the Joint Appendix filed by the parties with the U.S. Court of Appeals for the Sixth Circuit. Pursuant to Rule XVIII(4), this Court may request copies of all or any portion of that record be transmitted to it. In addition, to assist the Court, Respondents have attached the FDA's September 2000 approval letter as Exhibit A to this Memorandum.

safe and effective for terminating pregnancies through seven weeks, or forty-nine days, from the first day of the woman's last menstrual period. *Id.*

Mifepristone was approved for use under 21 C.F.R. § 314 Subpart H, which allows the FDA to place restrictions on the post-approval distribution or use of a drug when necessary for safe use. For example, the FDA has the authority to restrict distribution of a drug to "physicians with special training or experience." 21 C.F.R. § 314.520. Using its authority under federal law, the FDA, in its approval letter, imposed the following restrictions on physicians who dispense mifepristone:

> Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:
>
> [1] Ability to assess the duration of the pregnancy accurately.
>
> [2] Ability to diagnose ectopic pregnancies.
>
> [3] Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
>
> [4] Has read and understood the prescribing information of Mifeprex™.
>
> [5] Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.
>
> [6] Must notify the [manufacturer of the drug] in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.
>
> [7] Must report any hospitalization, transfusion or other serious events to [the manufacturer].

[8] Must record the Mifeprex™ package serial number in each patient's record.

JX2 Approval Letter at 2 (numbers added), Apx. 188 (attached hereto as Exhibit A).

Neither the initial FDA approval letter, nor a subsequent letter issued by the FDA, requires prescribers of mifepristone to follow any particular regimen in the provision of mifepristone to their patients. *See id.*, Apx. 187 (Ex. A), and JX9 Revised Approval Letter, Apx. 221. The FDA approval letters do not require, nor even recommend, that physicians follow the regimen used during the clinical trials submitted to the FDA. And while the approval letter notes that the NDA provides for the use of mifepristone through forty-nine days of pregnancy, it does not limit the approval of mifepristone to usage only within this timeframe. JX2 Approval Letter at 1, Apx. 187 (Ex. A).

It is standard medical practice in the United States for physicians to prescribe FDA-approved drugs in dosages and for medical indications that were not specifically approved – or even contemplated – by the FDA, particularly where the alternative use is supported by adequate study. *See Allergan, Inc. v. Alcon Labs., Inc.* (Fed. Cir. 2003), 324 F.3d 1322, 1324 n.1 (per curiam); *Wash. Legal Found. v. Henney* (D.C. Cir. 2000), 202 F.3d 331, 333; *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4, at 5 (April 1982) ("accepted medical practice often includes drug use that is not reflected in approved drug labeling"). Such uses are sometimes referred to as "evidence-based" or "off-label" uses.

The Sixth Circuit explained:

> 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.

Taft, 444 F.3d at 505.[5] In fact, in discussing mifepristone, the FDA has made clear that "physicians exercise their judgment in prescribing what they feel is best for the patient, [and] they may decide to use an 'off-label' regimen, rather than the approved regimen." JX8 Mifepristone Questions and Answers at 4, Apx. 219. And, the official Medication Guide (part of the final printed labeling ("FPL")) informs patients that "[m]edicines are sometimes prescribed for purposes other than those listed in a Medication Guide." JX4 Medication Guide at 4, Apx. 209.[6]

Respondents all prescribe mifepristone to induce medication abortion in accordance with evidence-based regimens. *See, e.g.*, JX37 Medical Abortion Protocol, Planned Parenthood of Central Ohio, Apx. 379-406; JX38 Medical Abortion Protocol, Planned Parenthood of Greater Cleveland Protocols, Apx. 407-30; JX39 Medical Abortion Protocol, Planned Parenthood of Southwest Ohio Region, Apx. 431-52. Indeed, in the eight years since the FDA's approval of mifepristone (and much longer since the clinical trials submitted to the FDA were conducted), evidence-based use of mifepristone "has come to be widely employed across the United States." *Taft*, 444 F.3d at 506.

This is because after the clinical trials were submitted to the FDA as part of the drug approval process, a large number of medical studies were conducted about mifepristone medication abortion. These studies concluded that (1) mifepristone is as safe and effective when

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[5] Many states, including Ohio, have recognized the importance of evidence-based uses of medications to the practice of medicine and patient care by, for example, prohibiting insurers that provide coverage for prescription drugs from denying coverage for a drug on the "basis that the drug has not been approved by the [FDA] for the treatment of the particular indication for which the drug has been prescribed." R.C. 1751.66(A).

[6] Even Petitioners have conceded that there exists no federal statute, rule, or regulation that requires physicians to follow the FDA-approved dosage regimen in the provision of mifepristone or, indeed, in the provision of any other FDA-approved drug. *See* R74 Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. at 24 ("Plaintiffs also argue that no federal law, rule or regulation prohibits physicians from off-label prescribing. This is true.").

given in lower dosages (200 mg rather than 600 mg); (2) by varying the dose and route of administration of misoprostol (the second drug used to induce mifepristone medication abortion), mifepristone medication abortion is significantly more effective and can be used later in pregnancy; and (3) varying the route of administration significantly decreased the rate of side effects of mifepristone medication abortion. *See* PX1008 *Medical Management of Abortion*, ACOG Practice Bulletin No. 67, at 19, Apx. 493. These studies have not been submitted to, or reviewed by, the FDA. JX8 Mifepristone Questions and Answers at 4, Apx. 219. However, on the basis of these studies, the American College of Obstetricians and Gynecologists, the leading professional association of physicians who specialize in the health care of women, has given its highest level of recommendation to evidence-based use of mifepristone to induce medication abortion. PX1008 ACOG Bulletin at 19, Apx. 499.

ARGUMENT

I. THIS COURT SHOULD MODIFY SLIGHTLY THE QUESTIONS BEFORE IT

The Sixth Circuit certified two questions of state law to this Court:

> 1) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so in compliance with the forty-nine-day gestational limit described in the FDA approval letter?
>
> 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?

Strickland, Certification Order at 6.

These questions reflect several factual inaccuracies about the provision of mifespristone. As described in detail in the Statement of Facts, *supra*, the FDA's approval letter does not require that physicians act "in compliance" with any gestational "limit." *See* JX2 Approval Letter at 1, Apx. 187 (Ex. A). While the approval letter notes that the new drug application

provides for the use of mifepristone through forty-nine days of pregnancy, it does not "limit" the approval of mifepristone to usage only within this timeframe. *Id.* Indeed, a physician who prescribes mifepristone after forty-nine days gestation is still "in compliance" with all FDA rules. Similarly, a physician who uses a dosing regimen different from that described in the FPL is still "in compliance" with all FDA rules. *See Taft*, 444 F.3d at 505 ("Off-label use does not violate federal law or FDA regulations . . .").

Accordingly, Respondents respectfully request that this Court modify the questions as follows to correct these inaccuracies and proceed to answer these modified questions:

> 1) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so only through the forty-nine-day gestational period referenced in the FDA approval letter's description of the new drug application for mifepristone?
>
> 2) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone use the treatment protocols and dosage indications described in the drug's final printed labeling?

See, e.g., Estate of Monahan v. Am. States Ins. Co. (2001), 93 Ohio St. 3d 1449 (Lundberg Stratton, J.) (indicating that she would answer a question certified by a federal court, but "would answer the question as modified in the preliminary memorandum" of one of the parties); *see also Houston v. Wilkinson* (2001), 93 Ohio St. 3d 1449 (Cook, J.) (indicating that she would accept jurisdiction from an order certifying a conflict, but would address a modified version of the certified question); *Layne v. Ohio Adult Parole Auth.* (Ohio 2001), 93 Ohio St. 3d 1448 (Cook, J.) (same).

II. THIS COURT SHOULD ACCEPT THE QUESTIONS AS MODIFIED AND ANSWER THOSE QUESTIONS IN THE NEGATIVE BECAUSE A NEGATIVE ANSWER COMPORTS WITH LEGISLATIVE INTENT AND WILL RESOLVE THE CONSTITUTIONAL QUESTIONS PENDING IN FEDERAL COURT, END THE LITIGATION, AND ALLOW H.B. 126 TO BE ENFORCED

In essence, the Sixth Circuit has asked this Court to determine what the Act's reference to "any drug approval letter" in its definition of "federal law" means. Planned Parenthood urges this Court to find that the Act requires physicians to follow those requirements actually contained in the FDA's approval letter. This approach follows the plain language of the statute and comports with legislative intent. Moreover, it raises no constitutional issues, and therefore, would end this litigation and allow H.B. 126 to take effect and be enforced.

In contrast, Petitioners maintain that the Act's reference to "drug approval letter" requires Respondents to comply with myriad other rules that are not required by federal law, are not mandated by that letter, and are not identified in the Act. This is because Petitioners construe the Act's reference to the drug approval letter to incorporate matters discussed in documents mentioned in that letter, of which there are many. This interpretation is not only unsupported by the language of the Act; it creates a criminal prohibition implicating the exercise of constitutional rights that is the paradigm of an unconstitutionally vague statute. Should this Court agree with Petitioners' interpretation, not only will Planned Parenthood's vagueness challenge ensue and H.B. 126 remain enjoined, but its other three constitutional claims will also remain to be litigated in federal court, perhaps for years to come.

A. Answering the Modified Questions in the Negative is in Accordance with the Legislative Intent of the Act

This Court has explained that the paramount concern in construing the language of a statute must be the intent of the legislature in enacting the statute. *State v. S.R.*, 63 Ohio St. 3d (1992) 590, 594-95. In determining legislative intent, the court first looks to the language of the

statute. *State ex rel. Burrows v. Indust. Comm'n of Ohio* (1997), 78 Ohio St. 3d 78, 81. "Words used in a statute must be accorded their usual, normal or customary meaning." *Hawkins v. Pickaway County Bd. of Elections* (1996), 75 Ohio St. 3d 275, 277.

The Act requires physicians to comply with "federal law." R.C. 2919.123(A). The Act defines "federal law" as including "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." *Id.* 2929.123(F)(1).

This Court should interpret the Act according to its plain meaning, *i.e.*, under Ohio law, physicians must comply with the requirements placed on them by federal law, including the FDA's approval letter for mifepristone. That letter places eight requirements on physicians. JX2 Approval Letter at 2, Apx. 188 (Ex. A). The first four requirements are "criteria established by federal law that a physician must satisfy in order to provide . . . mifepristone." R.C. 2919.123(A). The second four requirements are "provisions of federal law that govern the use of . . . mifepristone." *Id.* It is clear from the language of the approval letter that these eight requirements are indeed intended to be requirements: "[Mifepristone] <u>must be provided</u> by or under the supervision of a physician <u>who meets the following qualifications</u> . . . ." JX2 Approval Letter at 2, Apx. 188 (Ex. A) (emphasis added).

The same cannot be said for the many other requirements that the State claims are mandated by the Act. There is simply nothing in the approval letter that requires physicians to adhere to any gestational limit, product labeling, treatment protocols, or dosage indications. Moreover, the Act itself does not reference any gestational period, product labeling, treatment protocols, or dosage indications. If the Ohio Legislature intended that physicians be limited to a certain gestational period or a certain dosing regimen, writing a statute that did so clearly would

not be difficult.[7] But the plain language of the Act does not state that physicians must follow a specific regimen or a certain gestational limit.

The common sense interpretation proposed by Planned Parenthood not only comports with the plain language of the Act; it is also consistent with its legislative history. *See* R.C. 1.49(c) (in construing a statute, this Court may also look to legislative history to determine the intent of the legislature). On numerous occasions, the key sponsors of the Act, Representative Tom Brinkman and Senator Jim Jordan, stated clearly and unequivocally that the intent of the Act was to adopt the FDA rules – not to add new rules in addition to those imposed by the FDA. *See, e.g.*, JX41 Transcript of Senate debate re: H.B. 126 at 1:21, Apx. 461 (Senator Jordan) (the intent of the Act is to "adopt[] the FDA rules"); *id.* at 25:5-6, Apx. 485 (Senator Jordan) ("[it] implements the FDA rules"); *and* JX40 Transcript of House debate re: H.B. 126 at 1:21-26, Apx. 453 (Representative Brinkman) (Ohio has not yet "taken action on these FDA regulations").

B. Answering the Modified Questions in the Negative Will Fully Resolve This Litigation and Allow H.B. 126 to be Enforced

Both federal courts and this Court have repeatedly held that every reasonable construction must be resorted to in order to save a statute from unconstitutionality. *See, e.g., Clark v. Martinez* (2005), 543 U.S. 371, 380-81 ("[W]hen deciding which of two plausible statutory constructions to adopt, a court must consider the necessary consequences of its choice. If one of them would raise a multitude of constitutional problems, the other should prevail . . . ");

[7] In fact, the Ohio Legislature has banned the off-label use of certain steroids. *See* R.C. 3719.06(3)(b) (providing that "[n]o licensed health professional . . . shall prescribe, administer, or personally furnish a schedule III anabolic steroid for the purpose of human muscle building or enhancing human athletic performance and no pharmacist shall dispense a schedule III anabolic steroid for either purpose, unless it has been approved for that purpose under the 'Federal Food, Drug, and Cosmetic Act'").

Brookbank v. Gray (1996), 74 Ohio St. 3d 279, 287 ("Where reasonably possible, a statute should be given a construction which will avoid rather than a construction which will raise serious questions as to its constitutionality.") (citation and quotation omitted); *Chambers v. Owens-Ames-Kimball Co.* (1946), 146 Ohio St. 559, 566 ("[I]t is a well-recognized rule that courts should, if possible, give a statute such construction as will avoid conflict with constitutional requirements and will permit it to operate lawfully and constitutionally.") (citations omitted). In contrast to this principle, answering the certified questions affirmatively – as the State proposes – would raise numerous constitutional problems and result in additional litigation in federal court.

The State maintains that "the exact form of the FPL, including the package insert, the Medication Guide, the Patient Agreement, and the Prescriber's Agreement, are clearly made a part of the approval of the drug," and therefore, also part of the Act's definition of "federal law." *Taft*, 459 F. Supp. 2d at 635. Putting aside that none of these documents are mentioned in the Act or are otherwise part of federal law, this expansive and elastic approach to statutory interpretation renders the Act unconstitutional in several ways.

First, as the district court found, Petitioners' interpretation, instead of clarifying the reach of H.B. 126, "render[s] the Act all the more uncertain," *id.* at 637, and therefore, vague "as a matter of law." *Id.* at 640. Indeed, taken to its logical conclusion, the State's interpretation would subject physicians to potentially limitless requirements, the bounds of which they could never divine. *Id.* at 635-37. This is because the FDA approval letter does not just mention the FPL – it references more than 90 separate documents that were submitted to the FDA between 1996 and 2000 as part of the approval process. JX2 Approval Letter, Apx. 187-89 (Ex. A). Each of these documents, in turn, contains pages upon pages of discussion of a broad array of subjects.

Moreover, most of the documents in the FPL – including the package insert, the Medication Guide, the Patient Agreement, and the FDA approval letter itself – have been revised, some of them more than once, since the drug's initial approval in September 2000. *See, e.g.,* JX3-6 Package Insert, Medication Guide and Patient Agreement, Apx. 190-213; JX9 Revised Approval Letter, Nov. 15, 2004, Apx. 221-23; JX10-12 Revised Package Insert, Medication Guide and Patient Agreement, Nov. 15, 2004, Apx. 224-42; JX19-21 Revised Package Insert, Medication Guide and Patient Agreement, July 19, 2005, Apx. 259-78. The Act nowhere makes clear, and the State has not said, which versions of these documents – which are subject to future revisions as well – are to be incorporated into Ohio law by the Act. Therefore, as the federal district court explained, the State's "interpretation, which would permit the Act's requirements and prohibitions to change without any amendment to the Act or notice to physicians it regulates, is particularly troublesome from a fair warning perspective." *Taft*, 459 F. Supp. 2d at 637 n.10.

Even if the Act's prohibitions extended only to the FPL – a limitation for which there is no logical basis on the face of the Act or under the State's novel interpretation – the Act fails to satisfy the constitutional demands of due process because it does not provide physicians with "a reasonable opportunity to know what is prohibited, so that [they] may act accordingly." *Grayned v. City of Rockford* (1972), 408 U.S. 104, 108. The questions raised by "incorporation" of the FPL into the Act's definition of federal law are not limited to the two certified to this Court. Rather, questions abound. A few examples:

- Must physicians follow the regimen set forth in the FPL when prescribing misoprostol, the second medication used to induce medication abortion, when the Act itself says that it is a law regulating mifepristone?

- The Prescriber's Agreement that the FDA requires physicians to sign states that prior to providing mifepristone, the physician must fill out an order form and list on the form each facility that the provider oversees. JX6 Prescriber's Agreement, Apx. 212. If the doctor omits a facility from that form, is that doctor criminally liable under the Act?
- The Package Insert says that women who are "more than 35 and who smoke 10 or more cigarettes per day" should be "treated with caution." JX3 Package Insert, Apx. 197. Can a physician be thrown in jail if a jury determines that he or she did not treat a woman over 35 who smokes with the appropriate level of caution?[8]

Second, in addition to the Act's vagueness problems, answering the certified questions in the affirmative leads to the other constitutional problems identified by Respondents in their complaint. That is, if women in Ohio must ingest three times the amount of mifepristone than has been proven safe and effective and are forced after forty-nine days to undergo a surgical procedure when a safe – and perhaps safer – procedure using medications would otherwise be available, their rights under the Fourteenth Amendment to the U.S. Constitution are infringed. *See* Procedural History, *supra* (outlining Respondents' constitutional claims). Indeed, the Sixth Circuit has already recognized that prohibiting evidence-based use of mifepristone likely infringes upon the constitutionally protected rights of women with health conditions that make surgical abortion more dangerous. *See Taft*, 444 F.3d at 511-14. To avoid all of these

[8] Given that the State's interpretation raises more questions than it answers, if this Court disagrees with Planned Parenthood's interpretation, it should find that it is unable to determine what the Act means and therefore, cannot answer the certified questions. *See Taft*, 459 F. Supp. at 638 (finding that the Act has no clear meaning because in addition to the interpretations advanced by the parties, "several other interpretations of the Act are also plausible" and "[t]he Court would have to rewrite language enacted by the legislature to give the Act one definite meaning").

constitutional problems and allow H.B. 126 to take effect, this Court should agree with Respondents and answer the certified questions in the negative.

CONCLUSION

For the foregoing reasons, this Court should adopt the modified questions proposed by Planned Parenthood and answer those questions in the negative.

Dated: July 15, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on the 15 th day of July, 2008, a true and correct copy of this Preliminary Memorandum of Respondents was sent by U.S. Mail to the following counsel of record for Petitioners:

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Exhibit A

NDA 20-687

SEP 28 2000

Population Council
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New York, NY 10021

Dear Ms. Arnold:

Please refer to your new drug application (NDA) dated March 14, 1996, received March 18, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MIFEPREX™ (mifepristone) Tablets, 200 mg.

We acknowledge receipt of your submissions dated April 19, June 20, July 25, August 15 and September 16 and 26, 1996; January 30, March 31, July 28, August 5, September 24, November 26, 1997; January 30 (2), February 19, April 27, June 25, October 26, December 8, 1998; February 8 and 22, March 31, April 28, May 10 and 20, June 3 (2), 15, 23, 25, and 30, July 14 (2) and 22, August 3, 13, 18 and 30, September 3, 8, 13 and 30, October 5, 26 and 28, November 16 and 29 (2), December 6, 7 and 23, 1999; and January 11, 21 and 28 (2), February 16 and 24; March 3, 6, 9, 10, 30 and 31 (2), April 20, May 3, 11 and 17, June 22 and 23, July 11, 13, 25 and 27, August 18, 21 and 24, September 8, 12; 15 (2), 19 (2), 20, 21, 22, 26 (2), and 27 (2), 2000. Your submission of March 30, 2000 constituted a complete response to our February 18, 2000 action letter.

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

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to approve Mifeprex™ (mifepristone) Tablets, 200 mg, for use as recommended in the agreed upon labeling text. The application is approved under 21 CFR 314 Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced regulations.

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 (Package Insert, Medication Guide, Patient Agreement Form, and the Prescriber's Agreement Form submitted September 27, 2000; and the immediate container and carton labels submitted July 25, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative

purposes, this submission should be designated "FPL for approved NDA 20-687." Approval of this submission by FDA is not required before the labeling is used.

Under 21 CFR 314.520, distribution of the drug is restricted as follows:

Mifeprex™ must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex™.
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.
- Must record the Mifeprex™ package serial number in each patient's record.

With respect to the aspects of distribution other than physician qualifications described above, the following applies:

- Distribution will be in accordance with the system described in the March 30, 2000 submission. This plan assures the physical security of the drug product and provides specific requirements imposed by and on the distributor including procedures for storage, dosage tracking, damaged product returns, and other matters.

We also note the following Phase 4 commitments, specified in your submission dated September 15, 2000. These commitments replace all previous commitments cited in the September 18, 1996 and the February 18, 2000 approvable letters. These Phase 4 commitments are:

1. A cohort-based study of safety outcomes of patients having medical abortion under the care of physicians with surgical intervention skills compared to physicians who refer their patients for surgical intervention. Previous study questions related to age, smoking, and follow-up on day 14 (compliance with return visit) will be incorporated into this cohort study, as well as an audit of signed Patient Agreement forms.

2. A surveillance study on outcomes of ongoing pregnancies.

You have agreed to provide the final Phase 4 protocols for these studies within six months.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call [redacted]

Sincerely,

/S/

Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL