

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.)

Planned Parenthood Cincinnati Region;)
Planned Parenthood of Central Ohio; Planned)
Parenthood of Greater Cleveland; Preterm;)
Dr. Roslyn Kade; and Dr. Laszlo Sogor,)

Respondents.)

Case No. 2008-1234

Questions of State Law
Certified by the U.S. Court of
Appeals for the Sixth Circuit,
Case Nos. 06-4422 and 06-4423

MERIT BRIEF OF RESPONDENTS

Alphonse A. Gerhardstein (32053)
Jennifer L. Branch (38893)
(COUNSEL OF RECORD)
Gerhardstein & Branch Co. LPA
617 Vine Street, Suite 1409
Cincinnati, Ohio 45202
(513) 621-9100
Fax No. (513) 345-5543
jbranch@gbfirm.com

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David C. Greer (9090)
Bieser, Greer & Landis, LLP
400 National City Center
6 North Main Street
Dayton, OH 45402
(937) 223-3277
Fax No. (937) 223-6339
lcg@bgllaw.com

COUNSEL FOR RESPONDENTS

COUNSEL FOR RESPONDENTS

Benjamin C. Mizer (83089)
(COUNSEL OF RECORD)
Solicitor General
30 East Broad Street
17th Floor
Columbus, Ohio 43215
(614) 466-8980
Fax No. (614) 466-5087
bmizer@ag.state.oh.us

Roger Friedmann (9874)
(COUNSEL OF RECORD)
Assistant Prosecuting Attorney
Hamilton County, Ohio
230 E. Ninth Street, Suite 4000
Cincinnati, Ohio 45202
(513) 946-3025
Fax No. (513) 946-3100
Roger.Friedmann@hcpros.org

COUNSEL FOR PETITIONER,
NANCY H. ROGERS

COUNSEL FOR PETITIONER,
JOSEPH T. DETERS

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INTRODUCTION

The U.S. Court of Appeals for the Sixth Circuit has asked this Court to answer two certified questions of state law regarding the meaning of an unprecedented Ohio law, Ohio House Bill 126 (“H.B. 126” or “Act”), enacted in 2004, which has been codified at R.C. 2919.123. The Act regulates the use of mifepristone (commonly known as RU-486),¹ a medication approved by the Food and Drug Administration (“FDA”) that is used to induce an abortion without a surgical procedure. Since its approval in 2000, nearly one million women in the United States have used mifepristone safely to terminate an early pregnancy.

The Act imposes criminal penalties on a physician who prescribes mifepristone for the purpose of inducing abortion, unless he or she “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:

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. 2919.123(F)(1).

The first certified question before the Court has been stated as follows:

“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?”

The answer to this question is “no.” While the FDA’s Approval Letter (which is included in the Act’s definition of “federal law”) references the use of mifepristone through forty-nine days of pregnancy, the Approval Letter does not limit the use of the drug to that gestational period.

¹ Mifepristone is also sometimes referred to by its commercial name Mifeprex™.

Indeed, no provision of federal law that “governs or regulates” mifepristone limits use of the drug to a specific gestational age range.

The second certified question before the Court has been phrased as follows:

“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?”

The answer to this question is also “no” for a similar reason: while the Approval Letter contains the phrase “for use as *recommended* in the agreed upon labeling text” (emphasis added), the Approval Letter does not require that physicians follow the dosage regimen and protocol discussed in mifepristone’s labeling documents. Again, no provision of federal law that “governs or regulates” mifepristone requires that it be administered with a specific dosage or regimen.

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 provide negative answers to the certified questions presented. This approach is consistent with the plain language of the Act because the “criteria” and “provisions” of federal law – including the FDA’s Approval Letter – do not in any way limit mifepristone’s use to a certain gestational age range or dosage regimen. It is also consistent with the Act’s legislative history. Finally, Planned Parenthood’s construction raises no constitutional concerns and would allow Ohio to implement immediately a first-of-its-kind criminal regulation of abortion.

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.

Petitioner, the Ohio Attorney General (“Petitioner” or “State”), maintains that the Act’s reference to the FDA Approval Letter in its definition of “federal law” draws within the criminal prohibition of the Act not just the Approval Letter, but also an assortment of other documents not enumerated in the Act, but which are referenced in the Approval Letter. Putting aside that the State’s construction poses daunting due process concerns for physicians prescribing mifepristone – because they will never know for certain what other phrases in this long list of documents a prosecutor will translate into a criminal prohibition under the Act – the inescapable fact is that none of these documents, including the Approval Letter, regulate the gestational age or dosage regimen for mifepristone.

This Court should follow the plain language of the Act and reject the State’s interpretation. Such a decision will avoid the inevitable constitutional failings – some of which have already been recognized by the Sixth Circuit and the federal district court – that otherwise would arise.

STATEMENT OF THE CASE AND THE FACTS

A. Procedural History

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 Ohio Attorney General, and a defendant class of county prosecuting attorneys represented by the Hamilton County Prosecuting Attorney, in federal court, claiming that the Act was unconstitutional in several respects. The Governor originally defended the Act, but 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. The Hamilton County Prosecuting Attorney

defended the Act through the Sixth Circuit's recent consideration, and therefore, is a Petitioner before this Court. However, he has not filed any papers in this Court, and the Attorney General's brief was not filed on his behalf.

Planned Parenthood's federal lawsuit claims that the Act:

- (1) is unconstitutionally vague;
- (2) 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;
- (3) 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
- (4) even if otherwise constitutional, lacks an exception to protect a woman's health.

(See *Planned Parenthood Cincinnati Region v. Strickland* (C.A.6 June 23, 2008), Nos. 06-4422, 06-4423 ("Certification Order") at 4, Appendix to Merit Brief of Petitioner ("Appx.") Ex. 1.)

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, Appx. Ex. 3.) 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, 126 S. Ct. 961, 163 L.Ed.2d 812, the Sixth Circuit 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* (C.A.6, 2006), 444 F.3d 502, Appx. Ex. 4.)

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. 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, Appx. Ex. 5.) 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, Appx. Ex. 1.) On September 10, 2008, this Court accepted the certified questions and ordered merits briefing. (*See Rogers v. Planned Parenthood Cincinnati Region* (Ohio Sep. 10, 2008), No. 2008-1234, Appx. Ex. 2.)

B. Statement of Facts

1. Mifepristone and Medication Abortion

Mifepristone works to terminate pregnancy by blocking the hormone progesterone, which is needed to maintain a pregnancy. After the patient takes mifepristone, she takes a second medication, a prostaglandin, that causes the cervix to open and the uterus to contract and expel its contents, to complete the abortion process. The prostaglandin most commonly used for this purpose in the United States is misoprostol. Used together, these two medications – mifepristone and misoprostol – safely cause an abortion to occur, and in the overwhelming majority of cases allow the woman to avoid surgical intervention altogether. (PX1008 *Medical Management of Abortion*, ACOG Practice Bulletin No. 67, (Am. Coll. of Obstetricians and Gynecologists, Wash.

D.C.), October 2005 (“ACOG Bulletin”), Supplement to Merit Brief of Petitioner (“Supp.”) 491-502.)

2. FDA Approval of Mifepristone

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, Supp. 192-94.) 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 safe and effective for terminating pregnancies through seven weeks, or forty-nine days, from the first day of a 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 this authority, 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 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 MifeprexTM.

- [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 MifeprexTM package serial number in each patient's record.

(JX2 Approval Letter at 2 (numbers added), Supp. 188.) These are “the criteria established by federal law” and the “provisions of federal law” that regulate how mifepristone is to be provided. R.C. 2919.123(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 JX2 Approval Letter, Supp. 187 and JX9 Revised Approval Letter, Supp. 220.) The FDA Approval Letters do not require 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, Supp. 187.)

3. Evidence-Based Use

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.* (C.A.Fed. 2003), 324 F.3d 1322, 1324 n.1 (per curiam); *Wash. Legal Found. v. Henney* (C.A.D.C. 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, Appx. Ex. 4.) 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).

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, Supp. 218.) And the official Medication Guide for mifepristone (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, Supp. 209.)³

³ The State agrees that there exists no federal statute, rule, or regulation that limits the gestational age for use of mifepristone or requires physicians to follow the FDA-approved dosage regimen

4. Use of Mifepristone Following FDA Approval

After the mifepristone 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 mifepristone is as safe and as effective when given in a lower dosage (200 mg rather than 600 mg). (PX1008 ACOG Bulletin at 2, Supp. 492.) A number of other studies concluded that 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. *Id.* Scientific studies also showed that varying the route of administration significantly decreased the rate of side effects of mifepristone medication abortion. *Id.*

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 8, Supp. 498.)

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, Supp. 378-405; JX38 Medical Abortion Protocol, Planned Parenthood of Greater Cleveland, Supp. 406-29; JX39 Medical Abortion Protocol, Planned Parenthood of Southwest Ohio Region, Supp. 430-31.) 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),

or, indeed, limits evidence-based use of any other FDA-approved drug. (*See* R74 Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. at 24, Supp. 129 ("Plaintiffs also argue that no federal law, rule or regulation prohibits physicians from off-label prescribing. This is true.").)

evidence-based use of mifepristone “has come to be widely employed across the United States.” (*Taft*, 444 F.3d at 506, Appx. Ex. 4.)

Amici draw the Court’s attention to several deaths that occurred following a woman having taken mifepristone for medication abortion. See Brief of *Amici Curiae* Members of the U.S. Congress in Support of Petitioners (“*Amici Br.*”) at 13-21. However, *Amici*’s statements misrepresent the facts. It is not true, as they assert, that “at least eight American women have died from mifepristone abortions.” *Id.* at 14. In fact, in its most recent statement on the issue, the FDA reported that six women have died following medication abortion with mifepristone and that one of these deaths “has been determined to be unrelated to an abortion or to the use of Mifeprex and misoprostol.” (JX42 Mifeprex Information at 1, Apr. 10, 2006, Supp. 489.) As to the five remaining deaths, the FDA, which has actually reviewed these cases, has stated that it “do[es] not know whether using Mifeprex or misoprostol caused these deaths.” *Id.*

Undeniably, these rare events were tragic. Planned Parenthood has worked closely with the FDA and the federal Centers for Disease Control to investigate any possible connections between mifepristone medication abortion and these deaths. However, these events have absolutely nothing to do with the certified questions before this Court, and it serves no one’s interest for the facts surrounding these deaths to be flatly misportrayed by *Amici*.

Amici’s brief also ignores the hundreds of thousands of women who have chosen this exceedingly safe method to terminate their pregnancies. The manufacturer of mifepristone explained that between September 2000 and June 2005 alone, more than 460,000 women in the United States had chosen to have a mifepristone medication abortion. (JX23 “Dear Health Care Provider” Letter, July 19, 2005, at 1, Supp. 281.) Today, that number is more than 950,000 women in the United States. See Mifeprex Frequently Asked Questions,

http://www.earlyoptionpill.com/section/faq/#Experience_with_Mifeprex (last visited Nov. 7, 2008). The overwhelming majority of these nearly one million women have followed an evidence-based protocol. (See *Taft*, 444 F.3d at 506, Appx. Ex. 4 (evidence-based use of mifepristone is “widely employed across the United States”); see also JX37 Medical Abortion Protocol, Planned Parenthood of Central Ohio, Supp. 378-405; JX38 Medical Abortion Protocol, Planned Parenthood of Greater Cleveland, Supp. 406-29; JX39 Medical Abortion Protocol, Planned Parenthood Southwest Ohio Region, Supp. 430-51.)

ARGUMENT

Respondents’ Answer to Petitioner’s Proposition of Law No. 1:

O.R.C. § 2919.123 does not 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.

Planned Parenthood urges this Court to find that the Act requires physicians to follow those “criteria” and “provisions” of federal law that, in fact, do regulate who may prescribe mifepristone and how it must be dispensed. This Court should reject the State’s alternative interpretation which would have the Act impose additional requirements derived from words and phrases contained in the FDA Approval Letter, and other documents to which the Approval Letter refers, even though neither those words and phrases nor other documents – nor federal law anywhere – impose those additional requirements.

Planned Parenthood’s common sense interpretation follows the plain language of the Act and comports with legislative intent. While the Approval Letter does note that the manufacturer’s new drug application provided for the use of mifepristone through forty-nine days of pregnancy, federal law – including the Approval Letter – does not in any way limit the drug’s usage to only within this timeframe. Contrary to the State’s suggestion, answering the

certified question in the negative does not render the Act meaningless. In fact, adopting Planned Parenthood’s construction would result in a new, immediately enforceable Ohio criminal statute.

A. Ruling That the Act Does Not Ban the Use of Mifepristone After Forty-Nine Days 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.* (1992), 63 Ohio St.3d 590, 594-95, 589 N.E.2d 1319. In determining legislative intent, the court first looks to the language of the statute. *State ex rel. Burrows v. Indus. Comm’n of Ohio* (1997), 78 Ohio St. 3d 78, 81, 676 N.E.2d 519. “Words used in a statute must be accorded their usual, normal or customary meaning.” *State ex rel. Hawkins v. Pickaway County Bd. of Elections* (1996), 75 Ohio St. 3d 275, 277, 662 N.E.2d 17. If the Court finds that the Act’s language is ambiguous, it may also look to legislative history to determine the intention of the legislature. R.C. 1.49(C). Both the Act’s language and legislative history support Planned Parenthood’s construction.

1. The Plain Language of the Act Supports Planned Parenthood’s Common Sense Interpretation

The Act requires physicians to “satisf[y] all the criteria established by federal law” and provide the drug “in accordance with all provisions of 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.” R.C. 2919.123(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, Supp. 188.) 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] must be provided by or under the supervision of a physician who meets the following qualifications * * *.” (JX2 Approval Letter at 2, Supp. 188 (emphasis added).)

The same cannot be said for the other requirements that the State claims are mandated by the Act, including a forty-nine day gestational limit. The State is correct that the Approval Letter mentions that the manufacturer’s new drug application asked the FDA to consider approval of mifepristone for medication abortion through forty-nine days gestation. *See* Merit Brief of Petitioner Ohio Attorney General Nancy H. Rogers (“Pet’r Merit Br.”) at 9. But there is nothing in federal law – including in the text of the Approval Letter itself – that, in the words of the Act, “governs or regulates” the drug by requiring that it only be used through forty-nine days.⁴

Moreover, the Act itself does not reference any gestational period.⁵ The State dismisses these omissions from the Act’s language as “irrelevant” (Pet’r Merit Br. at 9), but if the Legislature intended that physicians be limited to a certain gestational period, writing a statute that did so clearly would not be difficult. 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

⁴ Likewise, as discussed in response to Petitioner’s Proposition of Law No. 2, *infra*, there is nothing in federal law that requires physicians to follow a specific treatment and dosage regimen.

⁵ Nor does the Act reference a specific treatment and dosage regimen.

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’”).

Amici make the relevant points that the statutory language “is to be examined in light of the ordinary person’s reading of the Act” and that “[h]ere the ‘ordinary person’ is a physician, called upon routinely to prescribe medications in accordance with FDA guidelines.” *Amici Br.* at 11-12. Such a reader would clearly interpret the FDA’s Approval Letter as permitting evidence-based use. Indeed, such readers have uniformly adopted that interpretation.

In short, the Ohio Legislature enacted a law that requires physicians to adhere to the “criteria” and “provisions” of federal law, including those requirements set out in the FDA Approval Letter. Neither federal law nor the Approval Letter limits physicians’ usage of mifepristone to forty-nine days. The plain language of the Act, therefore, does not include a gestational limit, and the first certified question must be answered in the negative.

2. The Act’s Legislative History Comports With Planned Parenthood’s Common Sense Interpretation

This plain reading of the Act is amply supported by its legislative history. In their oral presentations on the floors of the Ohio House and Senate, the key sponsors of the Act, Representative Tom Brinkman and Senator Jim Jordan, stated clearly and unequivocally that the intent of the Act was only to adopt the FDA rules – not to add rules not already imposed by the FDA. (JX41 Transcript of Senate debate re: HB 126 at 1:21, Supp. 460 (Senator Jordan) (the intent of the Act is to “adopt[] the FDA rules”); *id.* at 24:23-25, Supp. 483 (Senator Jordan) (the FDA “put the rules in place”) and 25:5-6, Supp. 484 (Senator Jordan) (“[i]t implements the FDA rules”); *and* JX40 Transcript of House debate re: HB 126) at 1:21-26, Supp. 452 (Representative Brinkman) (“The FDA did require certain common-sense rules and regulations * * * [t]o date, the State of Ohio has not taken action on these FDA regulations.”); *see also* JX41 at 4:20-21,

Supp. 463 (Senator Jordan) (“what we’re doing with this legislation * * * is implementing the FDA rules”); *id.* at 23:13-16, Supp. 482 (Senator Lynn Wachtmann) (“I’d like to remind the Senate what the issue is before us in the form of the bill, and that is to adopt FDA rules here in Ohio regarding this RU-486.”).)

In fact, in introducing the Act on the floors of their respective legislative bodies, the proponents of the Act, Senator Jordan and Representative Brinkman, each read aloud the “common sense rules and regulations” imposed by the Act, *i.e.*, the eight requirements set forth in the first FDA Approval Letter of mifepristone. (JX41 at 1:25-3:3, Supp. 460-62 (Senator Jordan); JX40 at 1:25-3:4, Supp. 452-54 (Representative Brinkman).) Similarly, in his written testimony urging his colleagues in the House Committee to support the Act, Representative Brinkman stated that “House Bill 126 requires the State of Ohio to adopt the federal requirements on RU-486.” (JX28 Minutes and Testimony before the Health Committee of the Ohio House of Representatives re: HB 126 at 1, Supp. 296.) The written testimony then sets forth in detail these “rules for the use of RU-486 [mifepristone]” issued by the FDA, and lists the eight requirements for physicians listed on the original FDA Approval Letter. *Id.*

Representative Brinkman submitted similar written testimony to the Senate Committee. (JX30 Minutes and Testimony before the Senate Health, Human Services and Aging Committee re: HB 126 at 3-4, Supp. 323-24.) Representative Brinkman’s written presentations to the House and Senate committees, his oral testimony on the floor of the House, and Senator Jordan’s oral presentation on the floor of the Senate contain no suggestion whatsoever that the Act was intended to ban evidence-based use of mifepristone or to impose restrictions upon Ohio physicians beyond those established by the FDA.

The State ignores all of this legislative history and bases its entire argument that the legislative history supports its interpretation on a single amendment that was rejected in the Ohio Senate. *See* Pet'r Merit Br. at 10-11, 14-15. That amendment, offered by Senator Hagan, would have clarified that the Act does not change existing law which permits evidence-based use of mifepristone. Longstanding precedent holds that an amendment's defeat is irrelevant to the determination of legislative history particularly where – as here – a court cannot determine with any certainty why the amendment was defeated. *See Lockhart v. United States* (2005), 546 U.S. 142, 147, 126 S. Ct. 699, 163 L.Ed.2d 557 (quoting *United States v. Craft* (2002), 535 U.S. 274, 287, 122 S. Ct. 1414, 152 L.Ed.2d 437) (“[F]ailed legislative proposals are ‘a particularly dangerous ground on which to rest an interpretation of a * * * statute.’”); *Broad. Music, Inc. v. Roger Miller Music, Inc.* (C.A.6, 2005), 396 F.3d 762, 774-75, *cert. denied sub nom. Turner v. Roger Miller Music, Inc.* (2005), 546 U.S. 871, 126 S. Ct. 374, 163 L.Ed.2d 162 (“The failure of [a legislature] to enact a particular provision or amendment can be linked to a myriad of hypothetical causes. Absent evidence suggesting otherwise, a court should not assume that any particular cause explains the inaction.”).

It is entirely plausible that the Senators who voted to defeat the Hagan amendment did so because they believed the amendment to be superfluous since the legislation was never intended to ban evidence-based use. Because this Court has no way of determining why the proposed amendment was defeated, it cannot look to its defeat to determine legislative intent. *Craft*, 535 U.S. at 287; *Broad. Music*, 396 F.3d at 774-75.

Indeed, the U.S. Supreme Court has explained that “[t]he views of the opponents of a bill,” such as Senator Hagan, “are not persuasive” because:

In their zeal to defeat a bill, they understandably tend to overstate its reach. The fears and doubts of the opposition are no authoritative guide to the construction of

legislation. It is the sponsors that we look to when the meaning of the statutory words is in doubt.

Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. and Constr. Trades Council (1988), 485 U.S. 568, 585, 108 S.Ct. 1392, 99 L.Ed.2d 645 (quotation and citations omitted). In this case, as discussed above, the Act's sponsors repeatedly stated that the Act was meant to incorporate the requirements placed on mifepristone by the FDA into Ohio law.⁶ Planned Parenthood's construction accomplishes that stated goal.

B. Ruling That the Act Does Not Ban the Use of Mifepristone After Forty-Nine Days Does Not “Render the Act Meaningless”

The State erroneously contends that Planned Parenthood's interpretation of the Act renders it meaningless. *See* Pet'r Merit Br. at 11-12. To the contrary, if the Court answers the certified questions as Planned Parenthood suggests, there would be new criminal penalties – as well as new recordkeeping and reporting requirements that do not exist under federal law – imposed on Ohio physicians who prescribe mifepristone.

In the absence of the Act, there is no governmental entity, including the FDA, that has any enforcement power over physicians in Ohio with respect to the Subpart H requirements set forth in the Approval Letter. It is the responsibility of the manufacturer of mifepristone to ensure that physicians comply with those eight requirements. If the manufacturer found that a physician was not in compliance, it could refuse to provide the drug to the doctor, but there would be no other penalties imposed on the physician under federal law or by the FDA. The FDA does not

⁶ The State cites to a remark made by one of the Act's proponents, Senator Jacobson, regarding the Hagan Amendment. Pet'r Merit Br. at 11. This Court should not rely on this one Senator's isolated statement in opposition to a defeated amendment to determine the intent of the entire Legislature, especially where, as here, the statement has no further support in the record. *State ex rel. Willke v. Taft* (2005), 107 Ohio St. 3d 1, 8, 836 N.E.2d 536, 2005-Ohio-5303; *Nichols v. Villarreal* (1996), 113 Ohio App.3d 343, 349, 680 N.E.2d 1259, (“We must determine the intent of the Ohio General Assembly not from the expressions of a single legislator, but from the expression of the legislative body as a whole.”).

regulate the practice of medicine; its authority to enforce Subpart H requirements is with respect to the manufacturer – *i.e.*, if physicians fail to satisfy the Approval Letter’s requirements, the FDA may withdraw the manufacturer’s approval for the drug. 21 C.F.R. § 314.530(a)(3), (4).

In contrast, under the Act, if an Ohio physician failed to comply with any of the eight “criteria” or “provisions” of federal law that actually do regulate mifepristone use, he or she could be prosecuted for a felony of the fourth degree. R.C. 2919.123(E). And if convicted, he or she would face between 6 and 18 months in jail, a \$5000 fine, or both. R.C. 2929.14(A)(4), 2929.18(A)(3)(d). If the physician previously had been convicted of or pleaded guilty to certain other violations or multiple offenses, the penalty is enhanced to a felony of the third degree, punishable by 1 to 5 years imprisonment, a \$10,000 fine, or both. R.C. 2919.123(E) (as amended by the Act), 2929.14(A)(3) and 2929.18(A)(3)(c). The Act mandates additional penalties including suspension of a physician’s medical license by the State Medical Board for a minimum of one year if a physician is found guilty of more than one violation of the Act. R.C. 4731.22(C) (as amended by the Act).

Thus, the Act does far more than simply “give Ohio parallel enforcement power over existing FDA law.” Pet’r Merit Br. at 12. It creates stringent new criminal requirements and penalties on Ohio physicians who prescribe mifepristone.⁷ It seems highly unlikely that one of those doctors – who prior to the Act, could only lose his or her ability to prescribe mifepristone if he or she failed to satisfy the eight requirements in the Approval Letter, but now would face a felony conviction, significant time in prison, and stringent fines – would call the Act “meaningless.”

⁷ The Act also imposes new and more onerous recordkeeping and reporting requirements than those imposed by federal law, the FDA, or the drug’s manufacturer. *See* R.C. 2919.123(C).

Respondents' Answer to Petitioner's Proposition of Law No. 2:

O.R.C. § 2919.123 does not 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.

The State's argument with respect to the dosage regimen is even more dubious than with respect to the forty-nine day period. That is because while at least the Approval Letter includes the words "through 49 days pregnancy," it is completely silent as to any treatment protocol or dosage regimen. (See JX 2 Approval Letter, Supp. 187-89.) Thus, the State resorts to arguing that because the Approval Letter mentions "the agreed upon labeling text" (*id.*) and the final printed label ("FPL") mentions the dosage regimen used in the clinical trials, the Act limits physicians to that regimen. This Court should reject Petitioners' construction because in addition to being unsupported by the Act's plain language and legislative history, as discussed in response to Proposition of Law No. 1, *supra*,⁸ it violates two additional rules of statutory construction: (1) it would impermissibly require the Court to read words into the statute that are not there; and (2) it would render several provisions of the Act meaningless.⁹

A. The State's Construction Impermissibly Reads Words Into the Act

The State asks this Court to find that the Act requires that, under penalty of criminal prosecution, Ohio physicians must follow the "treatment and dosage protocol" described in the mifepristone product labeling documents. Pet'r Merit Br. at 13. This construction violates the plain language of the Act because there are no "criteria" or "provisions" of federal law that

⁸ Again, the only legislative history cited by the State in support of its construction is the rejection of Senator Hagan's amendment. See Pet'r Merit Br. at 14-15. As discussed in detail in response to Proposition of Law No. 1, *supra*, the rejection of this amendment does not support the State's construction, especially given that the Act's sponsors never suggested that the Act was intended to ban evidence-based use. To the contrary, they repeatedly stated that the purpose of the Act was to "implement[] the FDA rules." (JX41 at 4:20-21, Supp. 463 (Senator Jordan).)

⁹ In addition, as explained in Proposition of Law No. 3, *infra*, the State's construction renders the Act impermissibly vague.

require a physician to follow any dosage or treatment protocol when prescribing mifepristone. Nor is there 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 [mifepristone],” R.C. 2919.123(F)(1) (emphasis added), so as to require a certain dosage or treatment protocol. Indeed, the Approval Letter does not even mention a dosage or treatment protocol at all.

Under established canons of statutory construction, this Court may not read language into the Act that does not appear in its text. *Vought Indus., Inc. v. Tracy* (1995), 72 Ohio St.3d 261, 265, 648 N.E.2d 1364, 1367 (“There is no authority under any rule of statutory construction to add to, enlarge, supply, expand, extend or improve the provisions of the statute to meet a situation not provided for.”) (quotation and citation omitted). This Court’s “obligation is to apply the statute as written.” *Id.*

As written, the Act requires physicians to follow the “criteria” and “provisions” of federal law, including the Approval Letter for mifepristone. There is nothing in federal law or the Approval Letter that requires the use of – or even mentions – any treatment protocol or dosage.¹⁰ Thus, if the Act were interpreted (as the State urges) to require physicians to comply with the dosage regimen and indications mentioned in the FPL, the Court would have to “extend the law by implication or inference and recognize[] [language] * * * not expressed.” *Carrel v. Allied Products Corp.* (1997), 78 Ohio St.3d 284, 288, 677 N.E.2d 795. This it cannot do. *Id.*; *see also Cleveland Elec. Illuminating Co. v. Cleveland* (1988), 37 Ohio St.3d 50, 524 N.E.2d 441, 445.

¹⁰ To the contrary, in publicly answering questions about mifepristone, the FDA has made clear its position that “[b]ecause physicians exercise their judgment in prescribing what they feel is best for the patient, they may decide to use an ‘off-label’ regimen, rather than the approved regimen.” (JX 8 FDA Mifepristone Questions and Answers 4/17/2002 at 4, Supp. 218.)

If the Legislature had wanted to ban evidence-based use, as the State contends, it could easily have made this requirement clear. Ohio Adm. Code Section 4731:11-04(2), for example, requires prescriptions of controlled substances used for weight reduction to be “strictly in accordance with the F.D.A. approved labeling.”¹¹ By contrast, the Act makes no reference whatsoever to the dosage regimen in the product labeling.¹² Because the Approval Letter does not require a specific treatment protocol or dosage, this Court should answer the certified question in the negative.

B. It is the State – And Not Planned Parenthood – Who Asks This Court to Render Provisions of the Act Meaningless

The State points out to this Court that in enacting a statute, it is presumed that the entire statute is intended to be effective and each provision is intended to accomplish some purpose. *See* Pet’r Merit Br. at 12 (citing R.C. 1.47 and *State ex rel. Cleveland Elec. Illum. Co. v. City of Euclid* (1959), 169 Ohio St. 476, 479, 159 N.E.2d 756). Planned Parenthood agrees. Yet it is the State’s construction – and not Planned Parenthood’s – that renders several provisions of the Act meaningless.

The Act requires physicians to comply with both the “criteria established by federal law that a physician must satisfy in order to provide * * * mifepristone” and the “provisions of federal law that govern the use of * * * mifepristone.” R.C. 2919.123(A). As explained in *Response to Proposition of Law No. 1, supra*, the first four requirements in the Approval Letter

¹¹ To be clear, there is no dispute about whether the State may regulate evidence-based use of FDA-approved drugs. Clearly it can (subject to any constitutional limitations). The question for this Court is whether the plain language of the Act (or if necessary, its legislative history), can be understood to do that.

¹² The State argues that “The Act means exactly what it says: Mifepristone may be used in Ohio only in accordance with the gestational limit and treatment protocol specifically approved by the FDA.” Pet’r Merit Br. at 2. This statement is quite stunning because, of course, the Act does not “exactly” say anything about a gestational limit or treatment protocol. Indeed, the Act is completely silent as to those requirements that the State now seeks to impose.

are “criteria * * * a physician must satisfy” to provide mifepristone, and the second four requirements in the Approval Letter are “provisions * * * that govern the use” of mifepristone.

In contrast, the State has argued that the Act has “two separate mandates.” (R74 Defs.’ Mem. in Opp’n to Pls.’ Mot. for Summ. J. at 13, Supp. 118.) First, it claims that all eight requirements in the Approval Letter are the “criteria established by federal law.” *Id.* Second, it maintains that the Act’s reference to “all provisions of federal law that govern the use of * * * mifepristone” means that physicians must follow what is laid out in the FPL. *Id.* However, Petitioners’ interpretation would render the “criteria” requirement meaningless (or duplicative) because the FPL itself includes the eight requirements from the Approval Letter. (See JX6 Prescriber’s Agreement, Supp. 212-13.)¹³ Thus, in addition to all of the other reasons set forth herein, this Court should adopt Planned Parenthood’s interpretation because it better gives effect to the provisions of Act.

Respondents’ Proposition of Law No. 3:

Finding that O.R.C. § 2919.123 does not mandate that physicians in Ohio who perform abortions using mifepristone do so only within a specific gestational period or according to a certain treatment protocol and dosage indication will fully resolve this litigation and allow O.R.C. § 2919.123 to be enforced.

In determining legislative intent, this Court may also consider the consequences of a particular construction. R.C. 1.49(E); *see also Bailey v. Republic Engineered Steels, Inc.* (2001), 91 Ohio St. 3d 38, 40, 741 N.E.2d 121 (“In determining legislative intent when faced with an ambiguous statute, the court may consider several factors, including * * * the consequences of a particular construction.”) (citations omitted). More on point here, this Court has repeatedly held that every reasonable construction must be resorted to in order to save a statute from

¹³ Similarly, the State’s interpretation renders R.C. 2919.123(B) meaningless because the FPL also includes the information related to “follow-up examinations or care” that the State claims that the Act requires.

unconstitutionality. *See, e.g., Brookbank v. Gray* (1996), 74 Ohio St. 3d 279, 287, 658 N.E.2d 724 (“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, 67 N.E.2d 439 (“[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); *see also Clark v. Martinez* (2005), 543 U.S. 371, 380-81, 125 S.Ct. 716, 160 L.Ed.2d 734 (“[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 * * *”).

Adopting the State’s interpretation of the Act will lead directly to this result: a multitude of constitutional problems to be litigated in the pending federal court case from which the certified questions have arisen.¹⁴ 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, Appx. Ex. 5.) Putting aside that none of these documents are mentioned in the Act or are otherwise part of federal law, adopting this expansive and elastic approach to statutory interpretation would render the Act unconstitutional in several ways.

First, as the district court found, adopting the State’s interpretation, instead of clarifying the reach of H.B. 126, would “render the Act all the more uncertain,” *id.* at 637, and therefore,

¹⁴ Planned Parenthood outlines the federal constitutional issues here for the Court’s benefit in considering how to answer the certified questions. However, these federal constitutional issues remain pending in the federal courts, and by outlining them here, Planned Parenthood is not seeking to litigate them in this Court.

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, Supp. 187-89.) 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, Supp. 190-213; JX9 Revised Approval Letter, Nov. 15, 2004, Supp. 220-22; JX10-12 Revised Package Insert, Medication Guide and Patient Agreement, Nov. 15, 2004, Supp. 223-41; JX19-21 Revised Package Insert, Medication Guide and Patient Agreement, July 19, 2005, Supp. 258-77.) 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, Appx. Ex. 5.)

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 would fail 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, 92 S.Ct. 2294, 33 L.Ed.2d 222. 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, Supp. 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 years of age and who also smoke 10 or more cigarettes per day” should be “treated with caution.” (JX3 Package Insert, Supp. 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?

Answering the certified questions as the State suggests does not answer any of these – or a myriad of other – questions raised by the State’s construction. It, therefore, would not cure the Act’s vagueness.

Second, in addition to the Act’s vagueness problems, answering the certified questions in the affirmative leads to the other constitutional problems identified by Planned Parenthood in its complaint. That is, if women in Ohio must ingest three times the amount of mifepristone that

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* Statement of the Case and the Facts, *supra* (outlining Respondents’ 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, Appx. Ex. 4.)

This Court can fulfill its duty to employ a statutory construction that avoids unconstitutionality by answering the certified questions as Planned Parenthood proposes. This common sense approach comports with the plain language of the Act and is consistent with its legislative history. Moreover, adopting Planned Parenthood’s construction would allow this 2004 criminal prohibition to take effect and be enforceable in Ohio. In contrast, answering the questions as the State proposes will result in numerous constitutional problems that will remain to be litigated for years to come. Therefore, this Court should agree with Planned Parenthood and find that the Act does not mandate a certain gestational limit or dosage regimen for the use of mifepristone for medication abortion.

CONCLUSION

For the foregoing reasons, this Court should answer the certified questions in the negative.

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Respectfully submitted,

By AA Gerhardstein

Alphonse A. Gerhardstein (32053)
Jennifer L. Branch (38893) (COUNSEL OF RECORD)
Gerhardstein & Branch Co. LPA
617 Vine Street, Suite 1409
Cincinnati, Ohio 45202
(513) 621-9100
Fax No. (513) 345-5543
JBranch@gbfirm.com

David C. Greer (9090)
Bieser, Greer & Landis LLP
400 National City Center
6 North Main Street
Dayton, OH 45402-1908
(937) 223-3277
Fax No. (937) 223-6339
dcg@bgllaw.com

Attorneys for Respondents,

Helene T. Krasnoff
Planned Parenthood Fed. of America
1110 Vermont Avenue, N.W., Suite 300
Washington, D.C. 20005
(202) 973-4800
Fax No. (202) 296-3480
helene.krasnoff@ppfa.org

Roger K. Evans
Planned Parenthood Fed. of America
434 West 33rd Street
New York, New York 10001
(212) 541-7800
Fax No. (212) 247-6811
roger.evans@ppfa.org

Attorneys for Respondents Planned Parenthood Southwest
Ohio Region, Planned Parenthood of Central Ohio, Planned
Parenthood of Northeast Ohio, Dr. Roslyn Kade, and Dr.
Laszlo Sogor,

and

B. Jessie Hill (74770)
Cooperating Counsel for the ACLU of Ohio
Case Western Reserve University, School of Law
11075 East Blvd.
Cleveland, Ohio 44106
(216) 368-0553
Fax No. (216) 368-2086
jessie.hill@case.edu

Jeffrey M. Gamso (43869)
Legal Director
ACLU of Ohio Foundation, Inc.
4506 Chester Avenue
Cleveland, Ohio 44103
(216) 472-2220
Fax No. (216) 472-2210
jmgamso@acluohio.org

Attorneys for Respondent Preterm

CERTIFICATE OF SERVICE

I certify that on the 18th day of November, 2008, a true and correct copy of this Merit Brief of Respondents was sent by electronic mail and U.S. Mail to the following counsel of record for Petitioners:

Benjamin C. Mizer (83089)
Solicitor General
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
(614) 466-8980
Fax No. (614) 466-5087
bmizer@ag.state.oh.us

Roger Friedmann (9874)
Assistant Prosecuting Attorney
Hamilton County, Ohio
230 E. Ninth Street, Suite 4000
Cincinnati, Ohio 45202
(513) 946-3025
Fax No. (513) 946-3100
Roger.Friedmann@hcpros.org



Alphonse A. Gerhardstein
COUNSEL FOR RESPONDENTS