

In the
Supreme Court of Ohio

NANCY H. ROGERS, OHIO ATTORNEY GENERAL, et al.,
Petitioners,
v.
PLANNED PARENTHOOD CINCINNATI REGION, et al.,
Respondents.

Case No. 2008-1234
On Review of Certified Questions from
The United States Court of Appeals
for the Sixth Circuit
U.S. Court of Appeals Case
Nos. 06-4422/4423

**REPLY BRIEF OF PETITIONER
OHIO ATTORNEY GENERAL NANCY H. ROGERS**

ALPHONSE A. GERHARDSTEIN (0032053)
JENNIFER L. BRANCH (0038893)*
**Counsel of Record*
Gerhardstein & Branch Co., LPA
432 Walnut Street, #400
Cincinnati, OH 45202
513-621-9100

DAVID C. GREER (009090)
Bieser, Greer & Landis LLP
400 National City Center
6 North Main Street
Dayton, OH 45402
937-223-3277

HELENE T. KRASNOFF
Planned Parenthood Federation of America
1780 Massachusetts Avenue, NW
Washington, DC 20036
202-973-4800

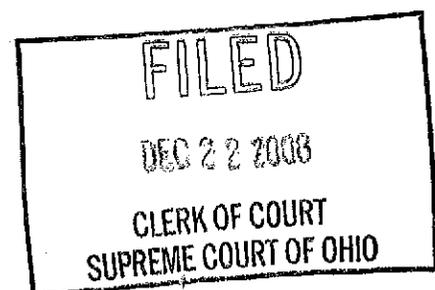
ROGER K. EVANS
Planned Parenthood Federation of America
434 West 33rd Street
New York, NY 10001
212-541-7800

NANCY H. ROGERS (0002375)
Attorney General of Ohio

BENJAMIN C. MIZER* (0083089)
Solicitor General
**Counsel of Record*

STEPHEN P. CARNEY (0063460)
ELISABETH A. LONG (0084128)
Deputy Solicitors
ANNE BERRY STRAIT (0012256)
SHARON A. JENNINGS (0055501)
Assistant Attorneys General
30 East Broad Street, 17th Floor
Columbus, OH 43215
614-466-8980
614-466-5087 fax
bmizer@ag.state.oh.us

Counsel for Petitioner
Ohio Attorney General Nancy H. Rogers



B. JESSIE HILL (0074770)
Case Western University School of Law
11075 East Blvd.
Cleveland, OH 44106
216-368-0553

JEFFREY M. GAMSO (0043869)
ACLU of Ohio Foundation, Inc.
4506 Chester Avenue
Cleveland, OH 44103
216-472-2220

Counsel for Respondents
Planned Parenthood Cincinnati Region, et al.

JOEL J. KIRKPATRICK* (0071924)
**Counsel of Record*
Kirkpatrick Law Offices PC
31800 Northwestern Highway
Suite 350
Farmington Hills, MI 48334
248-855-6010

Mailee R. Smith
Americans United for Life
310 S. Peoria Street
Suite 500
Chicago, IL 60607
312-568-4700

Counsel for Amici Curiae
U.S. Representatives Roscoe Bartlett, et al.

JOSEPH T. DETERS (0012084)
Hamilton County Prosecutor

MICHAEL G. FLOREZ (0010693)
ROGER E. FRIEDMAN* (0009874)
**Counsel of Record*
230 E. Ninth Street, Suite 4000
Cincinnati, OH 45202
513-946-3229
513-946-3018 fax

Counsel for Petitioner
Joseph T. Deters, as Representative of the
Defendant Class of Ohio Prosecuting
Attorneys

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INTRODUCTION

R.C. 2919.123 requires Ohio physicians who use mifepristone to induce medical abortions to do so in accordance with any “drug approval letter” of the U.S. Food and Drug Administration (“FDA”) that governs mifepristone-induced abortions. The FDA’s letter approving mifepristone (“Approval Letter”) specifically contemplates mifepristone use up to a gestational limit of 49 days and under a specific treatment protocol. As the Ohio Attorney General (“State”) argued in its initial merits brief, R.C. 2919.123 requires physicians using mifepristone in Ohio to comply with this gestational limit and treatment protocol, prohibiting “off-label” use of the drug for other purposes and under different protocols. Respondents, a group of abortion providers and clinics (collectively, “Planned Parenthood”), offer no persuasive support for their alternative interpretation of R.C. 2919.123: that the statute only requires compliance with federal regulations governing mifepristone distribution (“Subpart H restrictions”) and does not prohibit off-label mifepristone use in Ohio.

In arguing that R.C. 2919.123 allows for off-label mifepristone use in Ohio, Planned Parenthood disregards the statute’s plain language and instead employs circular reasoning to urge this Court to answer the certified questions in the negative. According to Planned Parenthood, because federal law and the FDA do not generally prohibit off-label use of FDA-approved drugs, then Ohio’s law allowing physicians to prescribe mifepristone only in accordance with the terms of the FDA’s approval—which include a gestational limit and treatment protocol—similarly must not prohibit off-label mifepristone use in Ohio. To the contrary, R.C. 2919.123’s plain language prohibits off-label mifepristone use by requiring Ohio physicians to adhere to the FDA-approved gestational limit and treatment protocol.

Unable to overcome the statute’s plain meaning, Planned Parenthood assigns too much weight to ambiguous statements made by the bill’s sponsors in an attempt to distract the Court

from legislative history supporting the State's interpretation of R.C. 2919.123. Specifically, Planned Parenthood attempts to undermine a crucial piece of the statute's legislative history: the proposal, debate, and defeat of an amendment that, if adopted, would have allowed so-called "evidence-based" mifepristone use in Ohio. But Planned Parenthood offers no sound reason why a member would have offered this amendment if the legislation did not already prohibit off-label mifepristone use. Instead, Planned Parenthood now asks this Court to read R.C. 2919.123 as if the General Assembly *had* adopted the amendment to safeguard off-label mifepristone use in Ohio. In fact, as Bill Analyses authored by the Ohio Legislative Service Commission ("LSC") make clear, the General Assembly enacted legislation that restricts off-label use by requiring Ohio physicians to comply with the FDA's conditions for mifepristone use. Contrary to Planned Parenthood's assertions, the legislative history underscores the statute's plain language, confirming that R.C. 2919.123 allows Ohio physicians to use mifepristone to induce abortions *only* under the conditions noted in the Approval Letter.

Ultimately the Court need not reach the legislative history, however, because R.C. 2919.123's plain language answers the certified questions before this Court: Ohio physicians may use mifepristone to induce abortions only up to the FDA-approved indication of 49 gestational days and under the treatment protocol described in the FDA-approved final labeling. The Court should therefore answer both certified questions in the affirmative.

ARGUMENT

Petitioner Ohio Attorney General's Proposition of Law No. 1:

R.C. 2919.123 mandates that doctors in Ohio who perform abortions using mifepristone do so only up to the FDA-approved indication of 49 gestational days.

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

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

Read together, the two certified questions ask this Court to decide a single issue: What does R.C. 2919.123 require of Ohio physicians using mifepristone to perform abortions? The statute's plain language answers that question: R.C. 2919.123 requires physicians to use mifepristone only as approved by the FDA—that is, only in accordance with the gestational limit and treatment protocol described in the FDA's Approval Letter. This interpretation is consistent with the statute's legislative history. Accordingly, this Court should answer both certified questions in the affirmative.

A. The statute's plain language requires Ohio physicians to comply with the FDA-approved gestational limit and treatment protocol.

The certified questions at heart ask what the General Assembly accomplished by defining “federal law” in R.C. 2919.123 to include the FDA's Approval Letter. Planned Parenthood argues that because federal law does not generally prohibit off-label use of FDA-approved drugs and the Approval Letter does not specifically prohibit off-label mifepristone use, then Ohio's law must not prohibit off-label mifepristone use. The problem with this argument is that the General Assembly expressly defined the term “federal law” to include not only federal statutes and rules, but also the Approval Letter. R.C. 2919.123(F)(1). The fact that federal law does not prohibit off-label use or regulate physicians is precisely why Ohio enacted the statute—to require Ohio physicians to use mifepristone only as specifically contemplated in the Approval Letter. The

Approval Letter identifies a gestational limit and incorporates mifepristone's final printed labeling ("FPL"), which repeatedly sets forth the protocol for mifepristone use. Supplement to Merit Br. of Pet'r Ohio Att'y General Nancy H. Rogers ("Supp.") at S-195. By enacting R.C. 2919.123, the General Assembly made both the gestational limit and treatment protocol requirements for using mifepristone in Ohio.

Planned Parenthood argues that the State therefore is wrong to say R.C. 2919.123 would be meaningless unless it imposes the gestational limit and protocol restrictions. Merit Br. of Resp'ts Planned Parenthood Cincinnati Region et al. ("Planned Parenthood Br.") at 17. As an alternative, Planned Parenthood advocates a so-called "common sense" interpretation of R.C. 2919.123, reading the statute only to give Ohio a mechanism for enforcing federal Subpart H restrictions that otherwise would be enforceable only by mifepristone manufacturers. *Id.* at 11. But Planned Parenthood misses the point of the State's argument: Planned Parenthood cannot pick and choose which parts of the Approval Letter with which R.C. 2919.123 requires compliance. By requiring compliance with federal law and defining "federal law" to include the Approval Letter, R.C. 2919.123 *both* gives Ohio a mechanism for enforcing the Subpart H restrictions *and* requires physicians to comply with the FDA-approved gestational age *and* treatment protocol. Planned Parenthood offers no principled reason why this Court should read R.C. 2919.123 to impose only some of the Approval Letter's requirements—namely, the Subpart H restrictions.

The State's interpretation of R.C. 2919.123 does not, as Planned Parenthood claims, improperly read words into the statute by interpreting "federal law" to include the final printed labeling referenced in the Approval Letter. Once again, Planned Parenthood engages in circular reasoning, claiming that Ohio law must not prohibit off-label mifepristone use because the

“provisions” and “criteria” of federal law do not prohibit off-label use. Planned Parenthood Br. at 19-21. In fact, R.C. 2919.123 plainly requires compliance “with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions,” R.C. 2919.123(A), and defines “federal law” to include “any law, rule or regulation of the United States *or any drug approval letter of the food and drug administration,*” R.C. 2919.123(F)(1) (emphasis added). In addition to stating the Subpart H requirements, the Approval Letter and every document published as part of that letter prominently discuss the FDA-approved gestational limit and treatment protocol. The FDA incorporated the FPL in the Approval Letter and indicated in every document comprising the FPL that it was approving mifepristone use in treatments up to 49 gestational days and under a specific protocol. Supp. at S-185, S-206, S-211. Recognizing the possibility of off-label mifepristone use, the General Assembly enacted R.C. 2919.123 to require as a matter of Ohio law that Ohio physicians comply with the gestational limit and treatment protocol considered by the FDA. R.C. 2919.123 thus reflects the General Assembly’s intent *both* to give Ohio power to enforce physicians’ compliance with Subpart H regulations *and* to confine mifepristone use to the terms considered by the FDA.

Even though Planned Parenthood sought and secured a permanent injunction of R.C. 2919.123 for vagueness, it now claims that the statute’s plain meaning is clear. Planned Parenthood insists that the statute does nothing more than allow Ohio to enforce federal Subpart H restrictions, and it contends that reading the statute to do anything more would render it unconstitutionally vague. Planned Parenthood Br. at 23-24. To survive a vagueness challenge, a statute must be sufficiently clear that persons of ordinary intelligence can steer between lawful and unlawful conduct, but it need not be drafted with mechanical precision. *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972) (“Condemned to the use of words, we can never expect

mathematical certainty from our language.”). Although the General Assembly could have expressly written the gestational limit and treatment protocol into the statute, rather than incorporating these limitations by reference to the Approval Letter, legislatures are not obligated to draft statutes in the clearest possible way to avoid a finding of ambiguity. Even if R.C. 2919.123 could have been more artfully drafted, its plain meaning is obvious: The statute’s definition of “federal law” makes it sufficiently clear that Ohio physicians must comply with the gestational limit and treatment protocol contemplated by the FDA.

B. The statute’s plain language is fully supported by its legislative history, which reflects the General Assembly’s intent to require Ohio physicians to comply with the FDA-approved gestational limit and treatment protocol.

Although Planned Parenthood attempts to marshal additional legislative history in support of its “common sense” interpretation of R.C. 2919.123, Planned Parenthood Br. at 11, legislative history fully supports the State’s reading of the statute and therefore also requires an affirmative response to the certified questions.

1. As shown by its rejection of an amendment that would have protected off-label mifepristone use, the General Assembly intended to require compliance with the FDA-approved gestational limit and treatment protocol.

As the State’s initial merits brief explains, the Ohio Senate specifically rejected Sen. Robert Hagan’s amendment, which would have protected off-label mifepristone use in Ohio. See Merit Br. of Pet’r Ohio Att’y General Nancy H. Rogers at 10-11. The bill’s sponsor, Sen. Jeff Jacobson, spoke against the Hagan amendment, clarifying that the bill’s objective was to limit mifepristone use in Ohio to the terms of the FDA’s approval:

. . . [A]sk yourself whether or not this is something you can in good conscience endorse, and that is the use of drugs, this would say that healthcare providers can allow the use of the drug in a dosage or context that has not been specifically approved for that drug by the United States Food and Drug Administration. Remember why we have RU-486 in the first place; it is because the FDA approved it. And they said how it was to be used, because it is dangerous. It is dangerous to women in that some women have died.

Supp. at S-468. Sen. Jacobson openly objected to language that would allow Ohio physicians to use mifepristone “in a dosage or context that has not been specifically approved for that drug by the [FDA].” *Id.*

Planned Parenthood unsuccessfully attempts to blunt the impact of this legislative history by erroneously asserting that the Court cannot consider the General Assembly’s rejection of an amendment when determining legislative intent. Planned Parenthood cites several cases for the proposition that courts cannot use evidence of an amendment’s defeat to understand legislative intent. Planned Parenthood Br. at 16-17. These cases, however, did not hold that courts cannot consider such evidence of legislative intent. Rather, in each case cited by Planned Parenthood, a court declined to consider an amendment’s defeat as evidence of legislative intent when “several equally tenable inferences may be drawn from an amendment’s defeat.” *United States v. Craft* (2002), 535 U.S. 274, 287 (internal quotation and citation omitted); see *Broad. Music, Inc. v. Roger Miller Music, Inc.* (6th Cir. 2005), 396 F.3d 762, 774; see also *Lockhart v. United States* (2005), 546 U.S. 142, 147. By contrast, in *Franklin Federal Savings Bank v. Office of Thrift Supervision* (6th Cir. 1991), 927 F.2d 1332, the Sixth Circuit found that debate about an amendment that would have addressed exactly the kind of transaction involved in the lawsuit was the most persuasive legislative history available. *Id.* at 1340. “In the course of the floor debate, representatives expressed their understanding of what the statutory language meant. The debate is useful to us because it reveals a shared understanding of a particular text.” *Id.* at 1340-41.

In this case, the General Assembly actively debated the Hagan amendment, and the legislative record reveals a shared understanding of what Sen. Jacobson’s bill and Sen. Hagan’s amendment would accomplish—the bill would prohibit off-label mifepristone use in Ohio and

the Hagan amendment would preserve off-label use. Sen. Hagan explained to the Ohio Senate that Sen. Jacobson's proposed legislation would "deviate from the way medicine is practiced in this country and in Ohio," Supp. at S-464, and consequently interfere with women's "freedoms to make [their] own decisions" by restricting mifepristone use in Ohio, *id.* at S-466. In response, Sen. Jacobson opposed the amendment because it would allow Ohio physicians to use mifepristone "in a dosage or context that has not been specifically approved for that drug by the [FDA]." *Id.* at S-468. No one voiced a contrary opinion about the effect the Hagan amendment would have on the proposed legislation. See Supp. at S-464–S-470. The reasons why Sen. Hagan offered the amendment and the Senate defeated it are not hypothetical; they were stated on the record. Both Sen. Hagan and Sen. Jacobson understood that the proposed legislation before the General Assembly would impact the legality of off-label mifepristone use in Ohio, and they conveyed this fact to the entire Senate through debate.

In light of this evidence, Planned Parenthood's contention that "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" could not be more misleading. Planned Parenthood Br. at 16. Once again, Planned Parenthood relies on circular reasoning: If the General Assembly defeats a proposed amendment that would create an exception to an activity prohibited by a bill, then enacts the bill, does that mean the General Assembly did not enact the prohibition to which the amendment proposed an exception? Planned Parenthood offers no persuasive reason why the General Assembly would reject the Hagan amendment if it did not intend to prohibit off-label mifepristone use. The General Assembly did want to give Ohio a mechanism to enforce the Subpart H restrictions, as Planned Parenthood argues, but it *also* wanted to ban off-label mifepristone use.

Planned Parenthood is trying to pick and choose the components of legislative history most favorable to its argument, urging this Court simultaneously to ignore Sen. Sen. Jacobson's remarks about the Hagan amendment and to rely on his remarks supporting Planned Parenthood's statutory interpretation. As Planned Parenthood correctly observes, the Court "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." *Nichols v. Villareal* (1996), 113 Ohio App. 3d 343, 349; see Planned Parenthood Br. at 17 n.6. Debate of the Hagan amendment and information provided by the LSC, as described below, demonstrate that the members of the General Assembly had a shared understanding that R.C. 2919.123 would restrict mifepristone use in Ohio to the FDA-approved gestational limit and treatment protocol.

2. Ohio Legislative Service Commission analyses acknowledge that the Act specifically contemplates a 49-day gestational limit and indicate that the Act does more than require compliance with federal Subpart H restrictions.

The LSC wrote numerous Bill Analyses—summaries provided to members of the General Assembly to assist their understanding of legislation—of the proposed legislation, noting in each the 49-day gestational limit for mifepristone use. See LSC, Bill Documents, <http://www.lsc.state.oh.us/billdocuments.html> ("Bill analyses explain, in detail, the contents of each version of a bill as it advances through the legislative process."); see also LSC, A Guidebook for Ohio Legislators 60 (10th ed. 2007-2008), available at <http://www.lsc.state.oh.us/guidebook/guidebook07.pdf> ("A bill analysis does not present arguments for or against a bill, nor does it discuss any political implications of passing or defeating a bill. However, because it contains an impartial and nonpartisan description of a bill's contents, it is useful in understanding the bill.") The LSC repeatedly described the terms of the Approval Letter, explaining: "In issuing its approval, the FDA specified that the drug for use in the termination of early pregnancy, defined as 49 days (seven weeks) or less." Bill Analysis of

H.B. 126, 125th General Assembly (As Passed by the General Assembly), Supp. at S-371; Bill Analysis of H.B. 126, 125th General Assembly (As Passed by the House), Supp. at S-351 (same); Bill Analysis of H.B. 126, 125th General Assembly (As Reported by S. Health, Human Services, Aging), Supp. at 360-61 (same); see Bill Analysis of H.B. 126, 125th General Assembly (As Reported by H. Health), Supp. at S-347-48 ([FDA] restrictions provide that the drug may be used only for the medical termination of intrauterine pregnancy through 49 days (seven weeks) pregnancy.”)

“Although this Court is not bound by [LSC] analyses, we may refer to them where we find them helpful and objective.” *Meeks v. Papadopoulos* (1980), 62 Ohio St. 2d 187, 191. In this case, LSC’s analyses are both objective and helpful indicators of the legislators’ shared understanding. They demonstrate not only the General Assembly’s specific intent to incorporate the FDA’s “restrictions” confining mifepristone use to a gestational limit, but also the General Assembly’s more general intent to accomplish more by enacting R.C. 2919.123 than merely giving Ohio a mechanism to enforce the Subpart H restrictions.

3. Planned Parenthood’s claim that mifepristone use is safe and effective does not undermine the General Assembly’s legitimate concerns about mifepristone use, which motivated the enactment of R.C. 2919.123.

Even as Planned Parenthood attempts to discredit Amici’s data about mifepristone-related deaths, they acknowledge that some deaths have occurred, and those deaths are relevant to the certified questions because they support the General Assembly’s justifiable concerns about limiting mifepristone use to the terms of the FDA’s approval. As Planned Parenthood acknowledges, the General Assembly has authority to enact laws prohibiting off-label use of a drug, such as mifepristone, and has exercised this authority in the past. Planned Parenthood Br. at 21 n.11 (“[T]o be clear, there is no dispute about whether the State may regulate evidence-based use of FDA-approved drugs. Clearly it can.”); see, *e.g.*, R.C. 3719.06 (prohibiting off-

label prescriptions of anabolic steroids for athletic enhancement). Evidence of patient deaths that *may* have been related to off-label mifepristone use is relevant to the questions before this Court because it demonstrates one of the General Assembly's reasons for enacting R.C. 2919.123—even if it were later decided that the deaths were not related to mifepristone use.

Planned Parenthood devotes an extensive section of its merits brief to arguing that using mifepristone at longer gestations and under different protocols is safe and effective, implying that the General Assembly had no reason to prohibit off-label use of the drug. Specifically, Planned Parenthood claims that “a number of 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.” Planned Parenthood Br. at 9. In support of this argument, Planned Parenthood relies on an outdated American College of Obstetrics and Gynecology (“ACOG”) Bulletin, which cited the results of several now-outdated studies as grounds for approving an “evidenced-based regimen” involving the vaginal administration of misoprostol. *Medical Management of Abortion*, ACOG Practice Bulletin No. 67 (Oct. 2005), Supp. at S-491-502.

But Planned Parenthood fails to mention that Planned Parenthood itself has abandoned the ACOG protocol in the wake of medical evidence indicating a possible relationship between the protocol and several deaths from toxic-shock infections immediately following abortions. Planned Parenthood now uses a different protocol involving the buccal administration of misoprostol—placing misoprostol between a patient's tongue and cheek and allowing it to slowly dissolve—when using mifepristone to induce abortions. See Supp. at 385-86 (Planned Parenthood of Central Ohio's Medical Abortion Protocol, as revised in March 2006); 413 (Planned Parenthood of Greater Cleveland's Medical Abortion Protocol, as implemented in

March 2006), 439-40 (Planned Parenthood Southwest Ohio Region’s Medical Abortion Protocol, as revised in March 2006). This protocol is being subjected to medical studies only now. The fact that even Planned Parenthood found reason to be concerned about its original off-label protocol for mifepristone abortions suggests that the General Assembly’s concerns were well-founded.

Considered together, this legislative history supports the State’s interpretation of R.C. 2919.123 and reveals that Planned Parenthood’s “common sense interpretation” does not appeal to the common sense at all.

C. Planned Parenthood’s third proposition of law improperly asks this Court to decide issues beyond the scope of the certified questions.

Planned Parenthood’s Proposition of Law No. 3 asks this Court to consider issues beyond the scope of the certified questions this Court agreed to answer under S.Ct.Prac.R. XVIII(6). According to Planned Parenthood, the Court should answer the certified questions in the negative because doing so will resolve Planned Parenthood’s constitutional concerns and therefore end the federal litigation in this case. In other words, Planned Parenthood argues that if this Court answers the certified questions “no,” the federal case will end because this Court will have agreed that any other statutory reading would be unconstitutional.¹ According to Planned

¹ Planned Parenthood inaccurately states that the Sixth Circuit has already “agreed that [R.C. 2919.123] is flawed because it lacks a health exception.” Planned Parenthood Br. at 4. The Sixth Circuit did acknowledge that Planned Parenthood met its initial burden—for preliminary injunction purposes—of showing that the Due Process Clause might require a health exception in this statute. *Planned Parenthood Cincinnati Region v. Taft* (6th Cir. 2006), 439 F.3d 304, amended by *Planned Parenthood Cincinnati Region v. Taft* (6th Cir. 2006), 444 F.3d 502. However, the Sixth Circuit then reversed and remanded, instructing the district court to enter a more narrowly drawn preliminary injunction pending a full trial on the merits of the health exception claim and Planned Parenthood’s other constitutional claims. *Id.* at 505. That trial has not yet occurred, and the issue of whether the statute needs a health exception remains unresolved.

Parenthood, this Court can now save everyone significant time and trouble by answering the certified questions “no.”

Planned Parenthood’s approach suffers from several flaws. First, Planned Parenthood is asking the Court to consider issues beyond the scope of the certified questions, essentially urging the Court to resolve the constitutional questions at issue in the underlying federal action (even though Planned Parenthood chose the federal forum). This Court agreed to answer two certified questions about the statute’s meaning, and therefore should “issue a written opinion stating the law governing the . . . questions certified,” consistent with S.Ct.Prac.R. XVIII(8). Second, Planned Parenthood improperly invokes the principal of judicial economy as a basis for asking the Court to ignore the statute’s plain language. See *State v. Elam* (1994), 68 Ohio St. 3d 585, 587 (“Where the wording of a statute is clear and unambiguous, this court’s only task is to give effect to the words used.”). Third, Planned Parenthood relies heavily on statements in the district court’s decision, which is itself the subject of the current federal appeal, and essentially asks this Court to adopt those statements. In other words, Planned Parenthood wants this Court to provide the result that Planned Parenthood has been unable to achieve thus far in the federal litigation—an interpretation that would gut the statute’s meaning.

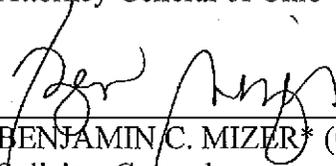
While the State, too, would like to see this litigation resolved, the State cannot agree that this Court should end the litigation by writing a decision that ignores R.C. 2919.123’s plain language. Accordingly, consistent with the statute’s plain language and legislative history, the Court should answer both certified questions in the affirmative and avoid considering issues beyond the scope of those questions.

CONCLUSION

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

Respectfully submitted,

NANCY H. ROGERS (0002375)
Attorney General of Ohio



BENJAMIN C. MIZER* (0083089)
Solicitor General
**Counsel of Record*

STEPHEN P. CARNEY (0063460)

ELISABETH A. LONG (0084128)

Deputy Solicitors

SHARON A. JENNINGS (0055501)

ANNE BERRY STRAIT (0012256)

Assistant Attorneys General

30 East Broad Street, 17th Floor

Columbus, Ohio 43215

614-466-8980

614-466-5087 fax

bmizer@ag.state.oh.us

Counsel for Petitioner

Ohio Attorney General Nancy H. Rogers

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Reply Brief of Petitioner, Ohio Attorney General Nancy H. Rogers, was served by U.S. mail this 22nd day of December, 2008, upon the following

counsel:

Alphonse A. Gerhardstein
Jennifer L. Branch
Gerhardstein & Branch Co., LPA
617 Vine Street, Suite 1409
Cincinnati, OH 45202

David C. Greer
Bieser, Greer & Landis LLP
400 National City Center
6 North Main Street
Dayton, OH 45402

Helene T. Krasnoff
Planned Parenthood Federation of America
1780 Massachusetts Avenue, NW
Washington, DC 20036

Roger K. Evans
Planned Parenthood Federation of America
434 West 33rd Street
New York, NY 10001

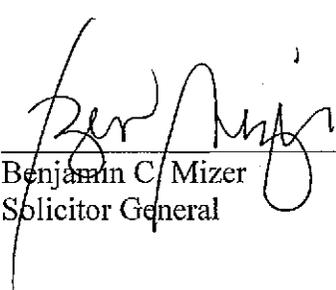
B. Jessie Hill
Case Western University School of Law
11075 East Blvd.
Cleveland, OH 44106

Jeffrey M. Gamso
ACLU of Ohio Foundation, Inc.
4506 Chester Avenue
Cleveland, OH 44103

Roger E. Friedman
Michael G. Florez
Hamilton County Prosecutor's Office
230 E. Ninth Street, Suite 4000
Cincinnati, OH 45202

Joel Kirkpatrick
Kirkpatrick Law Offices PC
31800 Northwestern Highway
Suite 350
Farmington Hills, MI 48334

Mailee R. Smith
Americans United for Life
310 S. Peoria Street
Suite 500
Chicago, IL 60607



Benjamin C. Mizer
Solicitor General