Nos. 06-4422 & 06-4423

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PLANNED PARENTHOOD CINCINNATI REGION, *et al*.,

Plaintiff-Appellees,

v.

TED STRICKLAND, Governor of Ohio, *et al*.,

Defendant-Appellants.

On Appeal from the Southern District of Ohio, No. 04-00493

BRIEF OF *AMICI CURIAE* UNITED STATES SENATOR AND REPRESENTATIVES IN SUPPORT OF DEFENDANT-APPELLANTS AND REVERSAL OF THE SOUTHERN DISTRICT OF OHIO

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

The constitutionality of the Food & Drug Administration's (FDA) protocol for the administration of RU-486, or mifepristone, has been called into question in this case. *Amici Curiae* Senator Tom A. Coburn, M.D. (OK), and Representatives Roscoe Bartlett (MD),[2] John Boehner (OH),[3] Steve Chabot (OH), Trent Franks (AZ), Jim Jordan (OH), Patrick McHenry (NC),[4] Joseph Pitts (PA), Jean Schmidt (OH), Chris Smith (NJ),[5] and Mark Souder (IN),[6] are United States Senators and Representatives who support adherence to the FDA protocol, at a minimum, for the administration of mifepristone. *Amici* have a strong interest in the proper interpretation and administration of a federal law.

Additionally, *Amici* Congressmen Souder and McHenry have a particular interest in ensuring that adolescents and adult women are protected from the

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[1] According to Fed. R. App. P. 29, Counsel for *Amici* has contacted the parties and has obtained consent to file this brief.

[2] Lead Sponsor of H.R. 63, the RU-486 Suspension and Review Act.

[3] House Minority Leader.

[4] Vice Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources.

[5] Chairman of the House Pro-Life Caucus.

[6] Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources.

medical risks associated with mifepristone. These *Amici* participated in the May 17, 2006, hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, which heard extensive evidence demonstrating the life-threatening risks associated with mifepristone. The Committee's October 2006 Staff Report, which concluded that mifepristone should be withdrawn from the market, is attached as an Appendix to this brief.

The other *Amici*, though not members of the House Subcommittee, share their colleagues' interest in the constitutionality of the FDA protocol and their interest in ensuring that women are protected from the medical risks of mifepristone.

For these reasons, *Amici* urge this Court to reverse the lower court's decision and uphold the constitutionality of OHIO REV. CODE § 2919.123.

SUMMARY OF ARGUMENT

Abortion-related legislation is historically treated differently by courts than non-abortion-related legislation. Thus, an examination of U.S. Supreme Court and lower federal court jurisprudence regarding alleged vagueness of abortion-related legislation is proper. OHIO REV. CODE § 2919.123 (the Act, or § 2919.123) is not void for vagueness in the context of such decisions. The FDA's protocol is clear to both parties, and physicians routinely prescribe medications in accordance with federal law. In addition, a reading of the Act as a whole leads to the FDA-approved mifepristone label, which sets out the FDA protocol. It is also important that the Act is directed at protecting women, does not suffer from the "double ambiguities" contained in other abortion regulations, and contains a scienter requirement, which saves the Act from a vagueness challenge. There is no risk that physicians will be "chilled" from prescribing mifepristone.

In addition, the severe medical risks of mifepristone underscore the importance of the Act. These risks demonstrate the danger of off-label use of mifepristone and the need for the standard of care found in § 2919.123.

ARGUMENT

I. OHIO REV. CODE § 2919.123 IS NOT VAGUE UNDER CONTROLLING ABORTION JURISPRUDENCE

In order to survive a vagueness challenge, a statute must "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that

he may act accordingly." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). However, the Constitution does not require that statutory language provide "mathematical certainty." *Id.* at 110. Instead, a statute is not vague if it is clear what the statute "as a whole prohibits." *Id.*

In the context of § 2919.123—an abortion-related statute—it is necessary to examine how courts have specifically treated vagueness challenges to abortion-related laws. Examining both U.S. Supreme Court and lower federal court jurisprudence reveals that § 2919.123 withstands a vagueness challenge.

A. U.S. Supreme Court Precedent Demonstrates That Abortion-Related Statutes Are Not Unconstitutional Unless Doubly Ambiguous And Lacking A Scienter Requirement.

The Supreme Court has squarely addressed criminal vagueness issues on only a few occasions.[7] Thus, the following cases bear weight when examining the alleged vagueness of abortion-related statutes.

In *U.S. v. Vuitch*, the Court heard the appeal of a defendant who had been indicted for producing and attempting to produce an abortion in violation of a D.C. statute. 402 U.S. 62, 67 (1971). A district judge ruled the law unconstitutionally vague, in part because of the "ambivalent and uncertain word 'health'" in the

[7] For example, while *Stenberg v. Carhart* involved the language of Nebraska's partial-birth abortion statute, the Court utilized the undue burden standard and did not address whether the law was "vague." *See generally Stenberg*, 530 U.S. 914 (2000). Furthermore, that statute banned a certain form of abortion, while there is no ban at all in § 2919.123.

statute's exception clause. *Id*. at 68. The judge stated that there was "no indication whether it include[d] varying degrees of mental as well as physical health." *Id*. at 71.

The Supreme Court disagreed. *Id*. at 71-72. While the legislative history and House Report provided no guidance, one district court judge had construed the word to also include mental health. *Id*. The Court concluded that that construction accorded with the general usage and modern understanding of the word "health," noting that the consideration of "whether a particular operation is necessary for a patient's physical or mental health is *a judgment that physicians are obviously called upon to make routinely* …." *Id*. at 72 (emphasis added).

The Court affirmed this position in *Doe v. Bolton*, 410 U.S. 179 (1973), the companion case of *Roe v. Wade*, 410 U.S. 113 (1973). The appellants challenged as vague a provision making it a crime to perform an abortion unless the abortion was "necessary." *Doe*, 410 U.S. at 191. The Court concluded that "[t]he vagueness argument is set at rest by the decision in *United States v. Vuitch*." *Id*. (citation omitted). The Court stated, "[w]hether, in the words of the Georgia statute, 'an abortion is necessary' is a professional judgment that the Georgia physician *will be called upon to make routinely*." *Id*. at 192 (emphasis added).

The Court agreed with the district court that medical judgment may be exercised in light of a number of factors, but stated that such factors allow the

physician the room necessary to "make his best medical judgment." *Id*.[8] However, the Court also noted that such "room [] *operates for the benefit, not the disadvantage*, of the pregnant woman." *Id*. (emphasis added).

Finally, in *Colautti v. Franklin*, the Court examined a Pennsylvania statute criminalizing the failure to utilize a prescribed technique when the fetus "is viable" or when there is "sufficient reason to believe that the fetus may be viable." 439 U.S. 379, 381 (1979). The Court began by explaining the Court's understanding of "viability" in *Roe*, *Doe*, and *Planned Parenthood of Central Missouri v. Danforth*.[9] *Id*. at 386-88.

The Court then concluded that the statute included a *double ambiguity*. First, it was unclear whether the statute imported a purely subjective standard (*i.e*., was based upon the physician's judgment, skill, and training), or a mixed subjective and objective standard (*i.e*., was based upon the physician's judgment, skill, and training, but in addition was based upon another's judgment, which may trump the physician's judgment). Second, it was unclear whether the phrase "may

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[8] *But see Webster v. Reprod. Health Serv*., 492 U.S. 490, 519-20 (1989) (stating that the Court was satisfied that a provision *regulating the discretion* of the physician "permissibly furthers the State's interest in protecting potential human life…."). The Court further stated that the Missouri statute in question was "designed to ensure that abortions are not performed where the fetus is viable—*an end which all concede is legitimate*—and that is *sufficient to sustain its constitutionality*." *Id.* at 520 (emphasis added).

[9] *Danforth*, 428 U.S. 52 (1976).

be viable" simply referred to viability as outlined in *Roe* and *Danforth*, or instead referred to a "gray" area prior to viability. *Id*. at 391.

It was "[*b]ecause of the double ambiguity*" that the Pennsylvania statute was distinguishable from the statutes upheld in *Vuitch* and *Doe*. *Id*. at 393-94 (emphasis added). This double ambiguity was compounded by the strict liability nature of the statute, subjecting a physician to potential criminal liability without regard to fault. *Id*. at 394. Because the statute lacked a scienter requirement, the Court concluded that the provision directing a physician to determine whether a fetus "may be viable" was "little more than a 'trap set for those who act in good faith.'" *Id*. at 395 (citation omitted). The Court concluded that the fact that physicians may disagree as to the viability of a fetus, in combination with the strict liability nature of the statute, could have a chilling effect on the willingness of physicians to perform abortions near the point of viability. *Id*. at 396.

In addition, the Court found the statute's standard of care provision impermissibly vague. *Id*. at 397. Specifically, that standard required physicians to employ an abortion technique offering the greatest possibility of fetal survival, provided that another technique was not necessary to preserve the life or health of the mother. *Id*. It was unclear whether the statute permitted the physician to consider his duty to the patient to be greater than that to the fetus, or whether the physician must make a "trade-off" between the mother's health and the chance of

fetal survival. *Id*. at 400. The Court stated that when "conflicting duties of this magnitude are involved, the State, at the least, must proceed with greater precision before it may subject a physician to possible criminal sanctions." *Id*. at 400-01. The lack of a scienter requirement also "exacerbate[d] the uncertainty of the statute." *Id*. at 401.

As demonstrated in Part I.C., *infra*, § 2919.123 suffers from none of the defects of the statute in *Collautti*. It contains a scienter requirement and a clear objective standard.

B. Lower Federal Court Decisions Also Demonstrate That Abortion-Related Statutes Are Not Unconstitutional Unless Doubly Ambiguous And Lacking A Scienter Requirement.

Literally hundreds of vagueness challenges have been launched against abortion-related legislation; thus, *Amici* present a cross-section of federal court decisions applying a vagueness standard to abortion-related laws.[10]

[10] Vagueness challenges obviously require case-by-case analyses. Therefore, some abortion-related cases are fairly inapplicable, such as cases examining the First Amendment rights of protestors. Furthermore, the different results in different cases are compounded by different Circuits' use of the "invalid in all its applications" facial validity standard in *U.S. v. Salerno*, 481 U.S. 739 (1987), as opposed to the "large fraction" standard in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). As such, *Amici* examine cases bearing a direct significance to the case at hand.

The Sixth Circuit

The most appropriate starting point is this Circuit's opinion in *Women's Medical Professional Corporation v. Voinovich*. 130 F.3d 187 (6th Cir. 1997), *cert. denied*, 523 U.S. 1036 (1998). In *Voinovich*, this Circuit examined a partial-birth abortion ban adopted by Ohio. *Id*. at 190. After setting forth the standard for vagueness challenges in *Grayned*, this Circuit explained that the Supreme Court stated that a "statute is void only if it is so vague that 'no standard of conduct is specified at all.'" *Id*. at 197 (quoting *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971)). This Circuit went on to declare that perhaps the most important consideration is whether a law threatens to inhibit the exercise of constitutionally protected rights. *Id*.

This Circuit further explained that the term "scienter" means "knowingly," requiring that a defendant have some degree of guilty knowledge or culpability in order to be found criminally liable for an act. *Id*. at 203. As in *Colautti*, the partial-birth abortion ban at issue contained both subjective and objective elements—a "dual standard … [with] no scienter requirement." *Id*. at 204. This Circuit concluded that *Colautti* is "strongly indicative of the Court's view that in this area of law, scienter requirements are particularly important." *Id*. at 205. Because the lack of a scienter requirement was compounded by the dual

subjective-objective standard and combined with strict liability, this Circuit concluded it could have a chilling effect. *Id*.

The Circuit also made some important contrasts between the Ohio law and the provisions upheld in *Planned Parenthood v. Casey*. *Id*. at 208. The Ohio law *banned* certain abortions, while the *Casey* provisions "only" *delayed* abortions. *Id*. The Court also noted that under the provisions litigated in *Casey*, "a woman would still be *free to choose* to have an abortion." *Id*. (emphasis added).[11]

The Fourth Circuit

In *Greenville Women's Clinic v. Commissioner, S.C. Department of Health and Environmental Control*, the Fourth Circuit examined regulations establishing standards for licensing abortion clinics. 317 F.3d 357, 359 (4th Cir. 2002), *cert. denied*, 538 U.S. 1008 (2003). The plaintiffs challenged a number of provisions as vague, including the following:

- granting the governing department the discretion to impose any penalty within the possible range of penalties;
- requiring the abortionists to be "properly qualified by training and experience to perform pregnancy termination procedures;" and
- stating that "conditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the [governing department]."

[11] Before striking down the law, this Court went on to examine *Colautti*, *Doe*, and *Vuitch*, discussed *supra*.

Id. at 365.

Acknowledging that the provisions fell short of mathematical precision, the Fourth Circuit concluded that a "reasonable person, *reading the regulation in its entirety and in the context of South Carolina statutes*, would be able to interpret the regulation and determine what is required and what conduct is prohibited." *Id*. at 366 (emphasis added). For example, in examining the provision requiring physicians to be "properly qualified," the Court outlined that physicians *routinely* hold themselves out as trained and experienced in given areas, and that such a standard is *routinely* applied in the medical field. *Id*. The court added, "we can expect abortion clinics to consult relevant legislation in advance of action or to seek clarification from appropriate administrative sources when necessary." *Id*. at 367.

The Seventh Circuit

Karlin v. Foust involved a challenge to Wisconsin's law requiring physicians to obtain the informed consent of women before performing an abortion. 188 F.3d 446, 453 (7th Cir. 1999). The court first examined the law's medical emergency provision, which contained no scienter requirement, meaning a physician was liable without regard to his or her good faith attempt to comply with the law. *Id*. at 459. The court explained that it was the first court to squarely address whether an objective standard is unconstitutionally vague. *Id*. at 460.

The court began with an examination of the basic facts and holdings of the Sixth Circuit's decision in *Voinovich*, disagreeing with this Circuit's interpretation of *Colautti* as suggesting that an abortion statute with an objective standard is vague without a scienter requirement. *Id*. at 462.[12] Instead, the Seventh Circuit concluded that *Colautti* only indicated that a scienter requirement could potentially save an already vague statute from being struck for vagueness. *Id*. at 463 (citing *Colautti*, 439 U.S. at 396; *Hoffman Estates v. Flipside, Hoffman Estates, Inc*. 455 U.S. 489, 499 (1982)).

Because the court concluded that *Colautti* does not suggest that a properly worded mixed standard is void for vagueness, it refused to find an objective standard alone *per se* unconstitutional. *Id*. at 463. Instead, the "central principle established in *Colautti* is that an abortion statute that imposes liability on a physician for erroneous medical determinations is void for vagueness only if it leaves physicians uncertain as to the relevant legal standard under which their medical determinations will be judged." *Id*.

The court further distinguished the holdings in *Voinovich* by pointing out that that case involved a *dual objective-subjective standard*, meaning the Sixth

[12] The court also explained that the Third Circuit's decision in *Planned Parenthood v. Casey* illustrated that a statute containing a subjective standard alone will not be found void for vagueness. *Karlin*, 188 F.3d at 461 n.10 (citing *Casey*, 947 F.2d 682 (3rd Cir. 1991), *aff'd in part & rev'd in part*, 505 U.S. 833).

Circuit did not pass on the constitutional sufficiency of an objective standard alone. *Id*. On the other hand, the Wisconsin statute at issue involved no such uncertainty because it clearly indicated that the standard to which it held physicians was an objective one. *Id*. at 464.

After a thorough analysis of the medical emergency provision in question, including a discussion of the physicians' relevant discretion,[13] the court concluded that the provision provided "fair warning" to physicians and provided for "fair enforcement" by authorities[14] because 1) the standard clearly conveyed to physicians that their emergency medical determinations would be judged on an objective basis; 2) physicians are accustomed to having their medical decisions adjudged under an objective standard; and 3) this same objectivity provided an adequate safeguard against any risk of arbitrary and unfair enforcement.[15] *Id*. at 464-68.

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[13] "[A]ssessing the seriousness of a risk to a patient's health and the necessity of immediate treatment is something that physicians are called upon to do routinely under an objective standard…." *Id.* at 464-65.

[14] "Just as [the provision's] 'reasonable medical judgment' standard clearly provides the standard to which physicians must conform their conduct, that same standard provides the guideline pursuant to which prosecutors, state licensing authorities, and civil plaintiffs can seek to hold physicians liable for erroneous medical determinations." *Id.* at 466.

[15] The court also explained that any chilling effect would be minimal, because physicians were already subject to financial liability at tort law. *Id*. at 467. There were no criminal penalties under the provision.

The Seventh Circuit next examined the plaintiffs' claim that the law failed to adequately convey what information a physician was to provide to a woman. *Id*. at 471. The court noted that the Supreme Court "has recognized the propriety of strict liability without any element of scienter in statutes that are 'regulatory' in nature or designed to protect the 'public welfare.'" *Id*. at 476. The purpose of such laws is to impose a high standard of care upon entities who have assumed responsibilities "*vis a vis* the public at large." *Id*. at 477. The court concluded that because of the state's legitimate interest in ensuring that women made informed abortion choices, it was perfectly reasonable to hold physicians to a strict liability standard in order to encourage physicians to truly ensure women receive that information. *Id*.

The court took special note that physicians are highly trained, intelligent persons, and that it was "simply not that difficult" to ascertain what information the law required them to disseminate. *Id*. With a "minimum amount of diligence," a physician would have no difficulty complying. *Id*.

The Eighth Circuit

In *Fargo Women's Health Organization v. Schafer*, the Eighth Circuit analyzed the term "medical emergency" in North Dakota's informed consent statute in a similar fashion to the courts above. 18 F.3d 526 (8th Cir. 1994). The

Circuit concluded that a reference to a physician's clinical judgment along with the inclusion of a scienter requirement saved North Dakota's statute. *Id*. at 534-35. The court went on to explain that "medical emergency" was not vague when viewed in light of the purpose section of the act, which made clear that the state intended to protect maternal health. *Id*. at 535. The court's "common sense interpretation" of the statute "easily" led it to conclude that physicians were fully capable of understanding the statute's requirements. *Id*.[16]

In *Reproductive Health Services of Planned Parenthood of the St. Louis Region, Inc. v. Nixon*, the Circuit echoed that "concern is lessened if [a] statute contains a scienter requirement." 428 F.3d 1139, 1143 (8th Cir. 2005). While acknowledging that physicians may have difficultly determining what the Missouri informed consent statute at issue mandated, the "core mandate" of the statute was clear and constitutional. *Id*. at 1144.[17]

[16] *See also Planned Parenthood of Minn./S.D. v. Rounds*, 372 F.3d 969, 974 (8th Cir. 2004) ("When both sides agree to the meaning of a particular word, we do not see how either side can say, in good faith, that it was unable to understand the meaning of that word.").

[17] Because the constitutional question was "close," the Circuit court upheld the lower court's initial preliminary injunction, but required that the lower court narrow its overly broad injunction. *Nixon, 423 F.3d* at 1145.

C. U.S. Supreme Court And Lower Federal Court Jurisprudence Support The Constitutionality Of § 2919.123.

Under the guidance of the aforementioned Supreme Court and lower federal court jurisprudence, the constitutionality of § 2919.123 should be upheld. Section 2919.123(A) provides that physicians must provide mifepristone "in accordance with all provisions of federal law." OHIO REV. STAT. §2919.123(A). "Federal law" means "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*. at 2919.123(F)(1). As this Court is well aware, the Plaintiffs claim that it is unclear "whether the Act's inclusion of the FDA approval letter in the definition of federal law renders it illegal for a physician to prescribe" the protocol they prefer to prescribe. *See Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626, 631 (S.D. Ohio 2006).

The mifepristone label[18] accompanying the drug explains in unambiguous words that it "is indicated for the medical termination of intrauterine pregnancy through 49 days' pregnancy."[19] Under the heading "Dosage and Administration,"

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[18] The District Court refers to this label as the "final printed labeling instructions," or "FPL." *See Taft*, 459 F. Supp. 2d at 635.

[19] *MIFEPREX™ (mifepristone) Tablets, 200 mg For Oral Administration Only* (mifepristone label), at: http://www.fda.gov/Cder/foi/label/2000/20687lbl.htm (last visited Feb. 13, 2007). This label is easily accessible on the FDA's website.

the label explains that treatment requires three office visits by the patient and may only be administered in a clinic, medical office, or hospital under the supervision of a physician. The label then states that on Day One, three 200 mg tablets are taken in a single oral dose; on Day Three, the patient returns and, unless an abortion has occurred and is confirmed, the patient takes two more tablets orally. The label also provides that on Day 14, the patient is to return for a follow-up visit in order to confirm that a complete termination has occurred. In addition, the label's title states "for oral administration only."

The Plaintiffs are not "confused" by the FDA's protocol. Even the lower court explicitly stated that the FDA protocol "that the FDA tested and on which it based its approval of mifepristone consisted of three oral doses of 200 mg of mifepristone followed by a single dose of .4 mg misopristol also taken orally, through 49 days LMP." *Id*. at 630 n.7. Thus, the Plaintiffs are not confused with regard to the exact protocol outlined by the FDA. *See Rounds*, 372 F.3d at 974 (stating that when both sides agree to a meaning of a word, neither side can argue it is vague). Instead, the Plaintiffs only argue that it is unclear whether the Act includes the FDA protocol in its definition of federal law. As is demonstrated below, the Plaintiffs are merely grabbing at straws in order to defend their

preferred—and untested and unapproved—protocol. The Plaintiffs are folding a substantive dispute into a vagueness claim.

Physicians are called upon on a daily basis to provide prescriptions for a variety of medications. Likewise, physicians routinely provide those prescriptions in accordance with federal guidance and FDA-approved labeling. It is not confusing that FDA protocol and labeling for any drug would be included in a definition of federal law. The "routineness" of a practice is constantly cited in decisions upholding challenged abortion laws. *See Doe*, 410 U.S. at 192; *Vuitch*, 402 U.S. at 72; *Greenville Women's Clinic*, 317 F.3d at 366; *Karlin*, 188 F.3d at 464-65. In the same way, § 2919.123 should be upheld, because the routine nature of the required actions negate any vagueness claims.

Furthermore, § 2191.123 is to be examined in light of the ordinary person's reading of the Act. Here, the "ordinary person" is a physician, called upon routinely to prescribe medications in accordance with FDA guidelines. As noted in *Greenville Women's Clinic*, we can expect a physician to consult relevant legislation and FDA protocol in advance of an action, or to seek clarification from appropriate administrative sources when necessary. *See Greenville Women's Clinic*, 317 F.3d at 367. Physicians are intelligent and highly trained and should have no difficulty complying with § 2919.123 after a "minimum amount of diligence." *See Karlin*, 188 F.3d at 477.

Even if physicians routinely fail to follow the protocol outlined in FDA-approved labels, the provisions of § 2919.123 itself provide guidance as to what is included in "federal law." Section 2919.123(B) provides that no physician "shall knowingly fail to comply with the applicable requirements of any federal law *that pertain to follow-up examinations.*…" OHIO REV. CODE § 2919.123(B) (emphasis added). As demonstrated above, the mifepristone label unambiguously pertains to follow-up care. Thus, when taken "as a whole,"[20] the text of § 2919.123 points to the mifepristone label, which clearly sets forth the required FDA protocol.

In examining the whole of the law, it is also important to note that the law is aimed at the protection of women. *See* Part II. and Appendix, *infra*. Because the Act does not ban or restrict access to abortion or an abortion method, the exercise of a constitutional right is not threatened.[21] *See Voinovich*, 130 F.3d at 197. As discussed by this Circuit in *Voinovich*, the Act can be compared to the provisions upheld in *Casey*, because women are still free to choose to have an abortion. *Id*. at 208. Because of its protective purpose, the Act "operates for the benefit, not the disadvantage," of women. *Doe*, 410 U.S. at 192.

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[20] *See Grayned*, 408 U.S. at 110; *Greenville Women's Clinic*, 317 F.3d at 366; *Nixon*, 428 F.3d at 1144.

[21] Restricted access does not equate to threatened Constitutional rights. *See*, *e.g*., *Mazurek v. Armstrong*, 520 U.S. 968 (1997) (reaffirming *Conn. v. Menillo*, 423 U.S. 9 (1975)).

Because the Act is not aimed at protecting potential human life and is instead exclusively focused on protecting the health of women, there are no "conflicting duties" that require greater precision in wording the statute. *See Colautti*, 439 U.S. at 400-01. As in *Fargo*, the Act is not vague in view of the light of its purpose: to protect maternal health. *Fargo*, 18 F.3d at 535. In a discussion of strict liability, the court in *Karlin* explained that a state's legitimate interest in protecting women made it perfectly reasonable to hold physicians to a strict liability standard in order to truly protect women. *Karlin*, 188 F.3d at 477. As in *Webster*, protecting the health of women is "an end which all concede is legitimate," and thus regulating physicians' mere preferences in drug administration permissibly furthers the State's interest. *Webster*, 492 U.S. at 519-20.

Moreover, the Act does not suffer from the "double ambiguity" or "dual standard" present in *Colautti* or *Voinovich*. Instead, the Act sets out the specific standard to be followed: the person prescribing must be a physician, must satisfy all criteria established in federal law to prescribe mifepristone, and must act in accordance with federal law governing the use of mifepristone.[22] OHIO REV. CODE

[22] Even if it is argued that this is an entirely objective standard, the purely objective standard in *Karlin* was upheld. *See generally Karlin*, 188 F.3d 446. Furthermore, the Act is "saved" by its scienter requirement. *Id*. at 463. *See infra* this section.

§ 2919.123. Furthermore, a physician is only liable if he "knowingly"[23] fails to comply with the statute. Thus, any claimed ambiguity is offset by the inclusion of this scienter requirement,[24] and the Act survives the Plaintiff's vagueness challenge.

Finally, the enforcement of § 2919.123 poses no occasion for a "chilling effect." At the very least, if a physician is concerned about whether or not his actions may be illegal, he can always fall back on the clearly approved dosage and administration instructions in the drug's label. While the Plaintiffs refer to a "voluminous series of documents they are bound to follow,"[25] these documents as well as the approved FDA protocol are summarized in the drug's label. If physicians abide by the drug's label, there is no need to fear prosecution. For the same reason, the Act poses no threat of arbitrary enforcement, as officials can require no more than what is in the drug's label. *See Karlin*, 188 F.3d at 464-68.

For all of these reasons, § 2919.123 provides a "reasonable opportunity to know what is prohibited" and is not so vague that "no standard of conduct is

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[23] *See* OHIO REV. CODE §§ 2919.123(A), 2919.123(B), and 2919.123(C)(2). This Circuit defines "scienter" as "knowingly," meaning § 2919.123's scienter requirement is unarguably present. *Voinovich*, 130 F.3d at 203.

[24] As discussed throughout Part I.A. and Part I.B., *supra*, the inclusion of a scienter requirement is weighed heavily in examining the constitutionality of a statute.

[25] *See Taft*, 459 F. Supp. 2d at 636.

specified at all." *Grayned*, 408 U.S. at 108; *Voinovich*, 130 F.3d at 197. Therefore, § 2919.123 cannot be held void for vagueness.

II. THE SEVERE MEDICAL RISKS OF MIFEPRISTONE UNDERSCORE OHIO'S COMPELLING INTEREST IN § 2919.123

The courts' jurisprudence on vagueness—the last vestige for striking down laws that might be politically "unpopular" to some—underscores a tendency by some courts to significantly weigh the political, medical, and sociological implications when evaluating abortion legislation. Given that tendency, this Circuit must be fully informed of the need for legislation in this case.

To date, at least eight American women have died from mifepristone abortions. As detailed below, the dangerous risks of mifepristone demand strict adherence to the FDA-approved protocol. Off-label use of mifepristone is deadly, and the necessity of § 2919.123 is obvious.

A. The Use Of Mifepristone Presents Significant Medical Risks To Women.

1. Death by C. sordellii bacterial infection

From September 2003 through June 2005, the FDA reported four U.S. deaths due to *C. sordellii* bacterial infection in women, ages 18-34, who had undergone mifepristone abortions.[26] All four patients were two months pregnant

[26] *Sepsis and Medical Abortion*, at: http://www.fda.gov/cder/drug/advisory/mifeprex.htm (last visited Feb. 12, 2007); *Emerging Clostridial Disease Workshop* (CDC-FDA-NIH Transcript May 11,

and received the off-label dosages and vaginal administration preferred by the Plaintiffs. All died within five to seven days following receipt of mifepristone, with identical clinical signs of shock, absence of fever, increase in leukocytes and red blood cells, and decrease in plasma volume. The time from hospital admission to death was a matter of hours, and one woman collapsed and died before reaching the hospital.[27]

These deaths demonstrated that severe infection occurs unpredictably, is difficult to identify, and is difficult to treat due to the absence of usual symptoms of infection (*e.g.*, fever). Once identified, it can result in death in a matter of hours.[28]

2006), at: http://www.fda.gov/cder/meeting/clostridia_disease.htm (last visited Feb. 19, 2007) (CDC Workshop).

[27] Fischer et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medical Abortion*, N.E. J. MED. 353:2352-60 (2005); CDC Workshop, *supra*, at 79-82, 104-105; Gary & Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifeprestone as an Abortifacient*, ANNALS OF PHARM. (Feb. 2006).

[28] Miech, *Patholphysicology of Mifepristone-Induced Septic Shock Due to Clostridium sordellii*, ANNALS OF PHARM. (Sept. 2005); Statement by Donna Harrison, M.D., for *RU-486: Demonstrating a Low Standard for Women's Health?*, Hearing before the Committee on Government Reform, House of Representatives (May 17, 2006), Serial No. 109-202, at: http://www.gpoaccess.gov/congress/index.html (last visited Feb. 16, 2007); Fischer, *supra*, at 2356, 2358; Gary-Harrison, *supra*.

Multiple species of *Clostridium*, including *sordellii* (*C. sordellii*), are found in 8-18% of all women.[29] Yet *C. sordellii* is usually suppressed by a normally functioning immune system, and therefore infection in healthy, young women is very rare and "occurs primarily among patients with serious underlying immunoconditions."[30] However, these four U.S. women were reported by the Centers for Disease Control (CDC) and FDA as having been previously healthy, without any underlying immunoconditions.[31] They had no risk factors predisposing them to infection or death—especially from a bacteria that rarely affects humans with a normal immune system.[32]

Medical literature explains that this phenomenon occurs because mifepristone can prevent the proper functioning of the immune system and cause fatal toxic shock.[33] Mifepristone blocks receptors that play a necessary role in the

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[29] Fischer, *supra*, at 2358; CDC Workshop, *supra*, at 93, 107.

[30] CDC Workshop, *supra*, at 76-77, 93, 115; Meich, *supra*, at 1484; Harrison, *supra*, at 139; Calhoun & Harrison, *Challenges to the FDA Approval of Mifepristone*, ANNALS OF PHARM. 166 (Jan. 2004); Fischer, *supra*, at 2356.

[31] Fischer, *supra*, at 2352-53, 2356; CDC Workshop, *supra*, at 79; Harrison, *supra*, at 139.

[32] Harrison, *supra*, at 135.

[33] Webster & Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glococorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, J. ENDOCRIN. 181, 207-21 (2004); Miech, *supra*; Gary-Harrison, *supra*; Harrison, *supra*; CDC Workshop, *supra*, at 76-121.

immune system's response to bacteria. Combined with the mifepristone effects of a softened, open cervix and lack of protective mucous, this impairment of the immune system allows *C. sordellii* to enter the uterus and multiply. Once established in the uterus, it secretes lethal toxins, which break down G-proteins, the molecular switches that activate the functions necessary for cellular immune responses.[34]

In addition, mifepristone blocks the hypothalamic-pituitary-adrenal (HPA) axis, which controls an essential aspect of the body's immune system. When the proper functioning of the HPA axis is prevented, dangerous levels of excess cytokines, or proteins, are released.[35] The combined entrance of excess cytokines and lethal toxins into the circulatory system causes toxic shock syndrome, multiple organ failure, and, ultimately, death.[36] This causal chain between mifepristone and death by toxic shock syndrome has been demonstrated in multiple animal models of septic shock,[37] ***where the mortality rate increased from 13% to 100% in mifepristone-treated animals***.[38]

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[34] Miech, *supra*, at 1484; CDC Workshop, *supra*, at 109.

[35] McGregor, *Response to letter to the editor*, CONTRACEPTION 74, 174-77 (2006).

[36] CDC Workshop, *supra*, at 108-10, 115, 118; Miech, *supra*; Gary-Harrison, *supra*; Webster-Sternberg, *supra*.

[37] CDC Workshop, *supra*, at 91, 108, 115.

In the deaths of the four U.S. women, the symptoms appeared four to five days after receipt of mifepristone.[39] While most drugs are metabolized and eliminated from the body in a few hours, mifepristone has an unusually long half-life of 30 hours. It thus takes four to five days to remove 95% of mifepristone from the body, and in some women, it can take up to 18 days.

Furthermore, because mifepristone abortions typically involve severe cramping, women are frequently prescribed codeine. Codeine competes with mifepristone for the enzyme that breaks down mifepristone, thereby prolonging the drug's lengthy presence in the uterus. *C. sordellii* then has enough time to establish itself, multiply, and secrete lethal, immunity-impairing toxins, contributing to the onset of fatal toxic shock. [40]

Medical scholarship, scientific data, and cases of recent fatalities in the U.S. support the conclusion that abortion by mifepristone presents a significant risk of death.[41] In short, mifepristone's anti-progesterone mechanism makes the uterus "a

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[38] Sternberg, *Proceedings of the Nat'l Acad. Sci.* 86: 2374-78 (1989); Harrison, *supra*, at 135, 138.

[39] Fischer, *supra*, at 2352-53.

[40] CDC Workshop, *supra*, at 79, 89, 105-06.

[41] Letter from Donna Harrison, M.D., to Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy and Human Resources, at Q.1(b) (Souder letter); Harrison, *supra*, at 138-39.

fertile medium of dead fetal tissue surrounded by an endometrium that lacks normal innate immune responses"[42] and an "ideal bacterial culture for *C. sordellii*."[43] Mifepristone's blockage of the HPA axis, combined with exposure to *C. sordellii*, places women in a vulnerable state. The blockage of glucocorticoid receptors prohibits the body from protecting itself from the lethal toxins excess cytokines. As a result, the body undergoes fatal toxic shock.

2. Other life-threatening infections

Through July 2005, the FDA reported at least 46 cases of life-threatening infections requiring hospitalization. Reported cases included septic shock, toxic shock syndrome, adult respiratory distress syndrome from sepsis, *Escheria coli* sepsis, group B Streptococcus septicemia, disseminated intravascular coagulopathy (DIC) with heptic and renal failure, and severe pelvic infection. Four of these cases required ICU hospitalization. An additional 14 patients were treated for pelvic infections as outpatients. Severe pelvic infection also presents an increased risk of subsequent ectopic pregnancy, tubal occlusion with subsequent infertility, and chronic pelvic pain from adhesive disease.[44]

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[42] Gary-Harrison, *supra*, at 109.

[43] CDC Workshop, *supra*, at 109.

[44] Gary-Harrison, *supra*, at 192-93; Harrison, *supra*, at 141; Medwatch Adverse Event Reports, *Individual Safety Report nos. 3803789-5, 4327968-6, 4411599-3,*

3. Massive hemorrhage

The FDA has reported that at least 116 women have required blood transfusions for massive bleeding after mifepristone abortions, with at least 54 losing over one-half of their blood volume. These women would have died without immediate access to sophisticated emergency facilities equipped to perform large blood transfusions. Medical research has shown that one to two of every 1,000 women who undergo mifepristone abortions will require emergency blood transfusion for massive hemorrhage. Because no risk factors have been identified, it is impossible to predict or prevent massive hemorrhage from mifepristone abortion.[45]

4. Further dangers specifically associated with off-label use

Ectopic pregnancy is an absolute contraindication to mifepristone,[46] and the only way it can be discovered is by ultrasound.[47] Because symptoms of ectopic

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4199811-X, 3915940-9, & 3943786-2 (FDA Office of Postmarking Drug Risk Assessment).

[45] Harrison, *supra*, at 136, 141-42; Gary-Harrison, *supra*, at 192; Paul et al., *A Clinician's Guide to Medical and Surgical Abortion* 202 (1999).

[46] Gary-Harrison, *supra*, at 195.

[47] Calhoun-Harrison, *supra*, at 165.

pregnancy mimic the symptoms of completed mifepristone abortions, ectopic pregnancies go easily undiagnosed.[48]

Improper screening and failure to follow FDA protocol requiring follow-up care place the lives of women with unknown ectopic pregnancies at even greater risk of death by ruptured ectopic pregnancy. The FDA has reported that at least 17 women have had undetected ectopic pregnancies during mifepristone administration, eleven of which resulted in ectopic rupture. One of these eleven women bled to death—a death which would not have occurred if the ectopic pregnancy had been properly diagnosed.[49] The absence of ultrasound use and follow-up care also increases the risk of retained tissue, thereby increasing the risk of infection.[50]

In addition, disregard for mifepristone's failure rate increases medical risk. It is generally understood that the percentage of incomplete mifepristone abortions requiring emergency surgical intervention increases with gestational age. Mifepristone's failure rate is 8% at 49 days gestation, 17% at 50-56 days gestation,

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[48] Medical Management of Abortion, *ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician Gynecologists* 26(4):1-20 (2001); Calhoun-Harrison, *supra*, at 165.

[49] Gary-Harrison, *supra*, at 192-93; Medwatch, *supra*, *Individual Safety Report no. 3806144-7*.

[50] Calhoun-Harrison, *supra*, at 165.

and 23% at 57-63 days gestation. Abdominal pain, nausea, diarrhea, and vaginal bleeding also increase with increasing gestational age.[51] Despite these known statistics, the Plaintiffs continue to advocate use of mifepristone past the FDA's 49-day protocol.

B. Mifepristone Offers No Net Therapeutic Benefits Over The Safer Alternatives.

1. Risk of death from C. sordellii bacterial infection

In 30 years, there have been no reported deaths from *C. sordellii* following surgical abortion. At less than eight weeks gestation, it has been reported that the rate of death from infection by all causes, except *C. sordellii,* is 0.1 per 100,000 surgical abortions, which means that the risk of death from *C. sordellii* after a mifepristone abortion is at the very least ten times the risk of death from all other types of bacterial infection in surgical abortion procedures.[52] In addition, the risk of death from *C. sordellii* after mifepristone abortion is ***fifty times the risk of death*** from *C. sordellii* after surgical abortion.[53]

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[51] Calhoun-Harrison, *supra*, at 165; Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, N.E. J. MED. 338:1241-47 (1998).

[52] Calhoun-Harrison, *supra*, at 165; Greene, *Fatal Infections Associated with Mifepristone-Induced Abortion*, N.E. J. MED. 353; 22 (Dec. 1, 2005).

[53] Harrison, *supra*, at 135, 141; Fisher, *supra*, at 2358; Souder Letter, *supra*, at Q.1(b).

2. Risk of hemorrhage

The risk of hemorrhage from mifepristone is much greater than the risk of hemorrhage from surgical abortion.[54] A study specifically comparing the outcomes of surgical and mifepristone abortions found that, of the women who required surgery to complete an abortion after receiving mifepristone, 12.5% also underwent emergency surgery for acute bleeding. In contrast, no women in the surgical abortion group required emergency surgery for acute bleeding.[55]

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Statistics demonstrate that both surgical abortion and childbirth are safer alternatives to mifepristone abortion. One scientific study has also revealed that mifepristone abortions fail more often than surgical abortion, have more subsequent bleeding for a longer duration of time, require more emergency surgical intervention, and are more painful than surgical abortions.[56] Thus, mifepristone does not offer women any net therapeutic benefit; rather, it exposes women to greater medical risk.

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[54] Harrison, *supra*, at 136, 142-44; Souder Letter, *supra*, at Q.1(b), 2, 5, 7.

[55] Jensen et. al, *Outcomes of Suction Curettage and Mifepristone Abortions in the United States: A Prospective Comparison Study*, CONTRACEPTION 59-153-59 (1999).

[56] *Id.;* Souder Letter, *supra*, at Q.5.

The foregoing medical evidence, along with the discussion presented in the Appendix, demonstrates that the federal protocol makes sense medically and serves to protect women's health and establish a uniform standard for the administration of mifepristone. Section 2919.123 is thus directly and strongly related to protecting women's health by requiring that Ohio providers follow the standard of care in the federal protocol.

CONCLUSION

The decision of the Southern District of Ohio should be reversed.

Respectfully Submitted,

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February 24, 2007

CERTIFICATE OF COMPLIANCE

Counsel for *Amici Curiae* hereby certifies that the foregoing Brief of *Amici Curiae* complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,947 words, excluding the parts of the brief exempted

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PROOF OF SERVICE

I hereby certify that on February 26, 2007, I served two paper copies of the foregoing Brief of *Amici Curiae* to counsel listed below by depositing said copies in U.S.P.S. first-class mail, postage paid.

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