

[Cite as *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972.]

**CORDRAY, ATTORNEY GENERAL, ET AL. v. PLANNED PARENTHOOD CINCINNATI
REGION ET AL.**

[Cite as *Cordray v. Planned Parenthood Cincinnati Region*,
122 Ohio St.3d 361, 2009-Ohio-2972.]

*Medicine — Restriction on use of RU-486 abortion pill — R.C. 2919.123 —
Drug-approval letter of Food and Drug Administration.*

(No. 2008-1234 — Submitted March 10, 2008 — Decided July 1, 2009.)

ON ORDER from the United States Court of Appeals for the Sixth Circuit,
Certifying Questions of State Law, Nos. 06-4422 and 06-4423.

SYLLABUS OF THE COURT

The plain language of R.C. 2919.123 mandates that physicians providing mifepristone to patients for the purpose of inducing an abortion do so in accordance with the FDA drug approval letter and the final printed labeling it incorporates, including compliance with the 49-day gestational limitation and the treatment protocols and dosage indications expressly approved by the FDA.

O'DONNELL, J.

{¶ 1} The United States Court of Appeals for the Sixth Circuit has submitted the following two certified questions in accordance with Sup.Ct.Prac.R. XVIII, seeking our answer to these questions of Ohio law:

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

{¶ 3} “2) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so in compliance with the treatment protocols and dosage indications described in the drug’s final printed labeling?” *Planned Parenthood Cincinnati Region v. Strickland* (C.A.6, 2008), 531 F.3d 406, 412.

{¶ 4} The plain language of R.C. 2919.123 mandates that physicians providing mifepristone to patients for the purpose of inducing an abortion do so in accordance with the FDA drug approval letter and the final printed labeling it incorporates, including compliance with the 49-day gestational limitation and the treatment protocols and dosage indications expressly approved by the FDA. Accordingly, we answer these certified questions in the affirmative.

Facts and Procedural History

{¶ 5} In March 1996, the Population Council sponsored a new drug application with the Food and Drug Administration (“FDA”) “for the use of [mifepristone] for the medical termination of intrauterine pregnancy through 49 days’ pregnancy.” In evaluating the safety and efficacy of mifepristone (a drug also known as “RU-486” and its trade name “Mifeprex”) for inducing abortions, the FDA relied on clinical trials involving women with gestational durations of 49 days or less who took 600 mg of mifepristone followed in most cases by a dose of 400 µg of misoprostol two days later. In issuing its September 28, 2000 drug approval letter approving use of mifepristone, the FDA concluded that “adequate information has been presented to approve [mifepristone] for use as recommended in the agreed upon labeling text.”

{¶ 6} Further, in its drug approval letter, the FDA, pursuant to 21 C.F.R. 314.520, imposed an additional restriction that mifepristone “be provided by or under the supervision of a physician who meets the following qualifications:

{¶ 7} “[1.] Ability to assess the duration of the pregnancy accurately.

{¶ 8} “[2.] Ability to diagnose ectopic pregnancies.

{¶ 9} “[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.

{¶ 10} “[4.] Has read and understood the prescribing information of [mifepristone].

{¶ 11} “[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.

{¶ 12} “[6.] Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.

{¶ 13} “[7.] Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.

{¶ 14} “[8.] Must record the [mifepristone] package serial number in each patient’s record.”

{¶ 15} The FDA labeling text referred to in the drug approval letter states, “Mifepristone is indicated for use in the termination of pregnancy (through 49 days’ pregnancy) and has *no other approved indication* for use during pregnancy.” (Emphasis added.) It also explains that treatment with mifepristone requires three office visits by the patient. On day one, the patient takes a single oral dose of 600 mg of mifepristone. On day three, the patient returns to the provider for an oral dose of 400 µg of misoprostol, unless the physician confirms

that the abortion has already occurred. On day 14, the patient again returns for a follow-up visit to ensure that termination of the pregnancy has occurred.

{¶ 16} The FDA-mandated final printed labeling also includes a “Patient Agreement” that requires the patient to affirm that she “believe[s] [that she is] no more than 49 days (7 weeks) pregnant” and a “Prescriber’s Agreement” by which the physician is to indicate that he has met the qualifications for providing mifepristone imposed by the drug approval letter and to agree to administer the drug consistently with listed guidelines.

{¶ 17} Since issuing the drug approval letter in September 2000, the FDA has revised it and has twice revised the labeling text for mifepristone. However, none of those revisions or any other action of the FDA has altered the 49-day gestational limitation for administration of mifepristone or modified any of the dosage indications or treatment protocols originally approved by the FDA.

{¶ 18} In general, after the FDA approves a drug for use and absent any state regulation to the contrary, doctors may prescribe that drug for indications, in dosages, and following treatment protocols different from those expressly approved by the FDA in its approval letter, a practice commonly known as “off-label” use. See, e.g., *Planned Parenthood Cincinnati Region v. Strickland* (C.A.6, 2008), 531 F.3d 406, 408; *Planned Parenthood Cincinnati Region v. Taft* (C.A.6, 2006), 444 F.3d 502, 505. Off-label use of drugs approved by the FDA does not violate federal law or FDA regulations, because the FDA regulates the marketing and distribution of drugs, not the practice of medicine. *Id.* Continuing research on the use of mifepristone for inducing abortions led to the development of evidence-based regimens for off-label use of mifepristone in lower dosages (200 mg rather than 600 mg) and beyond the 49-day gestational limitation (up to 63 days of pregnancy) contained in the approval letter and the labeling text it incorporates, as well as varying the route of administration, timing, and dosage of

misoprostol. The FDA has not, however, issued a new drug approval letter approving these uses.

{¶ 19} In 2004, the Ohio General Assembly enacted R.C. 2919.123(A), which provides, “No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the RU-486 (mifepristone) is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.” R.C. 2919.123(F)(1) defines “federal law” to mean “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.” (Emphasis added.)

{¶ 20} Prior to the effective date of R.C. 2919.123, respondents, Planned Parenthood Cincinnati Region and various other abortion providers that use mifepristone to perform abortions in Ohio (collectively, “Planned Parenthood”), filed a complaint in the United States District Court for the Southern District of Ohio challenging the constitutionality of the statute on the grounds that it is void for vagueness, violates their patients’ rights to bodily integrity, lacks an exception to protect the life or health of their patients, and unduly burdens their patients’ right to an abortion. Planned Parenthood sought preliminary and permanent injunctions restraining the state of Ohio from enforcing R.C. 2919.123 and a declaration that the statute violates the right to due process of law.

{¶ 21} The district court determined that Planned Parenthood had shown a strong likelihood of success on the merits of its claim that R.C. 2919.123 unconstitutionally omitted an exception for the health or life of the woman. On appeal, the Sixth Circuit affirmed in part, but, relying on *Ayotte v. Planned Parenthood of N. New England* (2006), 546 U.S. 320, 126 S.Ct. 961, 163 L.Ed.2d 812, the federal appellate court held that the absence of an exception for the life or health of the woman does not necessarily justify an injunction against the entire statute. It therefore remanded the case to the district court to determine the proper scope of the preliminary injunction. *Planned Parenthood Cincinnati Region v. Taft* (C.A.6, 2006), 444 F.3d 502, 511-517.

{¶ 22} On remand, Planned Parenthood moved for a summary judgment and sought a permanent injunction on the basis that R.C. 2919.123 is unconstitutionally vague. Agreeing with Planned Parenthood, the district court declared the statute void for vagueness and permanently enjoined enforcement of the entire statute. *Planned Parenthood Cincinnati Region v. Taft* (S.D. Ohio, 2006), 459 F.Supp.2d 626, 640. The state appealed that decision to the federal appellate court. On appeal, the Sixth Circuit sua sponte certified two questions of state law to this court pursuant to Sup.Ct.Prac.R. XVIII seeking our interpretation of R.C. 2919.123. *Planned Parenthood Cincinnati Region v. Strickland* (C.A.6, 2008), 531 F.3d 406, 412. We agreed to answer both questions. *Rogers v. Planned Parenthood Cincinnati Region*, 119 Ohio St.3d 1440, 2008-Ohio-4487, 893 N.E.2d 512.

Propositions of Law

{¶ 23} In this court, the Ohio Attorney General contends that the plain language of R.C. 2919.123 prohibits physicians from prescribing or providing mifepristone except in accordance with all provisions of federal law governing the use of the drug, including the FDA drug approval letter and the final printed labeling incorporated by that letter, and, by inference, proscribes the off-label use

of mifepristone to induce abortions. Thus, the attorney general urges us to conclude that R.C. 2919.123 incorporates the 49-day gestational limitation on use of the drug and the dosage indications and treatment protocols provided in the final printed labeling as incorporated by the drug approval letter.

{¶ 24} According to Planned Parenthood, neither the FDA’s approval letter nor any other provision of federal law prohibits abortion providers from using mifepristone to induce abortions beyond the 49th day of pregnancy or from following any evidence-based regimens for administering mifepristone not expressly approved by the FDA. Because the FDA regulates the marketing and distribution of drugs, not the practice of medicine, the approval letter does not “govern” or “regulate” a physician’s off-label use of mifepristone. Planned Parenthood further argues that the General Assembly could expressly prohibit the off-label use of drugs approved by the FDA, as it did in the case of certain anabolic steroids. It maintains that the General Assembly chose not to prohibit the off-label use of mifepristone but instead codified the physician-qualification, reporting, and recordkeeping requirements as specified in the FDA’s drug approval letter. Finally, Planned Parenthood contends that adopting the attorney general’s interpretation of R.C. 2919.123 would render the statute unconstitutional because abortion providers would have no advance notice of what documents referred to by the drug approval letter have been incorporated by the statute into the criminal law and because prohibiting the evidence-based use of mifepristone would infringe on the rights of women by requiring them to undergo a surgical procedure when a noninvasive one is available.

{¶ 25} We are therefore called upon to interpret the scope and meaning of R.C. 2919.123 with respect to physicians who perform abortions using mifepristone.

Law and Analysis

{¶ 26} In construing R.C. 2919.123, “ ‘our paramount concern is the legislative intent in enacting the statute.’ ” *State v. Buehler*, 113 Ohio St.3d 114, 2007-Ohio-1246, 863 N.E.2d 124, at ¶ 29, quoting *State ex rel. Steele v. Morrissey*, 103 Ohio St.3d 355, 2004-Ohio-4960, 815 N.E.2d 1107, at ¶ 21. “ ‘In determining this intent, we first review the statutory language, reading words and phrases in context and construing them according to the rules of grammar and common usage.’ ” *Id.*, quoting *Steele* at ¶ 21; R.C. 1.42. If the statutory text is unambiguous, we apply it. *State v. Hairston*, 101 Ohio St.3d 308, 2004-Ohio-969, 804 N.E.2d 471, at ¶ 13.

Statutory Restriction on the Use of Mifepristone

{¶ 27} The provisions of R.C. 2919.123 are not ambiguous. It allows physicians to provide or prescribe mifepristone to a patient to induce an abortion only if “the physician provides the RU-486 (mifepristone) * * * in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.” Pursuant to R.C. 2919.123(F)(1), “ ‘Federal law’ means * * * *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.” (Emphasis added.) Accordingly, the statute restricts physicians to using mifepristone to induce abortions in accordance with the FDA’s drug approval letters governing or regulating mifepristone for that purpose.

{¶ 28} In approving mifepristone for use, the FDA imposed postapproval restrictions “to assure safe use of the drug product” pursuant to its authority under 21 C.F.R. 314.520. In its brief, Planned Parenthood admits that “the FDA, in its Approval Letter, imposed * * * restrictions on physicians who dispense mifepristone,” explaining that mifepristone “must be provided by or under the supervision of a physician who meets” the qualifications that appear in the drug approval letter. These qualifications govern and regulate the use of mifepristone

to induce abortions by mandating that physicians who do not meet these qualifications may not provide mifepristone to induce abortions. Further, the drug approval letter refers to the labeling text, which includes the Prescriber's Agreement, which requires physicians to agree to comply with the postapproval restrictions imposed by the FDA. Therefore, we conclude that the drug approval letter in this case "governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortions." R.C. 2919.123(F)(1).

**Administration of Mifepristone in Accordance with the
FDA Approval Letter**

{¶ 29} A physician provides mifepristone in accordance with the drug approval letter by administering the drug in conformity with the medical regimen approved by the FDA in that letter. R.C. 2919.123 thus requires physicians in Ohio to conform their use of mifepristone for the purpose of inducing abortions to any gestational limit, dosage indications, or treatment protocols set forth in the drug approval letter.

{¶ 30} The FDA drug approval letter states that the "new drug application provides for the use of [mifepristone] for the medical termination of intrauterine pregnancy through 49 days' pregnancy." The FDA concluded on review of the application that "adequate information has been presented to approve [mifepristone] for use as recommended in the agreed upon labeling text." Thus, the FDA based its approval of mifepristone on its use as recommended in the labeling text, thereby incorporating that text into its letter of approval. The FDA labeling text specifically provides that "[m]ifepristone is indicated for use in the termination of pregnancy (through 49 days' pregnancy) and has no other approved indication for use during pregnancy." The drug approval letter and the labeling text indicate that the FDA approved the use of mifepristone for use through, but not beyond, the 49th day of pregnancy ("dated from the first day of the last menstrual period"). Administering mifepristone to induce an abortion

beyond the 49th day of pregnancy would not be in accordance with the drug approval letter.

{¶ 31} Similarly, the drug approval letter, by incorporating the labeling text, provides a specific dosage indication and treatment protocol: 600 mg of mifepristone, taken orally, followed when necessary by an oral dose of 400 µg of misoprostol two days later. Using any other dosage indication or treatment protocol would not be in accordance with the drug approval letter.

{¶ 32} Therefore, R.C. 2919.123 mandates that physicians providing mifepristone to patients for purposes of inducing an abortion do so in accordance with the FDA drug approval letter. The FDA approved the use of mifepristone through the 49th day of pregnancy pursuant to a medical regimen in which the woman receives an oral dose of 600 mg of mifepristone followed by an oral administration of 400 µg of misoprostol two days later. Because the FDA does not approve the use of mifepristone beyond the 49th day of pregnancy or using any other dosage amount or treatment protocol, providing mifepristone for the purpose of inducing an abortion beyond the 49th day or using any other dosage indications or treatment protocols would not be in accordance with the drug approval letter and is therefore prohibited by R.C. 2919.123.

{¶ 33} Planned Parenthood argues that a physician has the authority to prescribe a drug for off-label use in the practice of medicine. Off-label use is defined by the federal courts as the prescription of drugs for indications, in dosages, and following treatment protocols different from those expressly approved by the FDA. *Planned Parenthood Cincinnati Region v. Strickland*, 531 F.3d at 408; *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d at 505. However, the General Assembly has specifically restricted the use of mifepristone to physicians who satisfy all criteria established by federal law in order to provide mifepristone and who provide it in accordance with all provisions of federal law that govern mifepristone for inducing abortions. It has also specifically defined

“federal law” as used in R.C. 2919.123 to include the FDA drug approval letter. The September 28, 2000 drug approval letter incorporates the final printed labeling.

{¶ 34} Other drugs have been similarly restricted in Ohio. See R.C. 3719.06(B) (providing that “[n]o licensed health professional * * * shall prescribe, administer, or personally furnish a schedule III anabolic steroid for the purpose of human muscle building or enhancing human athletic performance and no pharmacist shall dispense a schedule III anabolic steroid for either purpose, unless it has been approved for that purpose under the ‘Federal Food, Drug, and Cosmetic Act’ ”); Ohio Adm.Code 4731-11-04(C)(2) (prohibiting the use of a schedule III or IV controlled substance for purposes of weight reduction unless, among other requirements, “[t]he controlled substance is prescribed strictly in accordance with the F.D.A. approved labeling”).

{¶ 35} Thus, pursuant to R.C. 2919.123, a physician may provide mifepristone for the purpose of inducing an abortion only through the patient’s 49th day of pregnancy and only by using the dosage indications and treatment protocols expressly approved by the FDA in the drug’s final printed labeling as incorporated by the drug approval letter.

Conclusion

{¶ 36} The Ohio Constitution vests the General Assembly, and not this court, with the legislative powers of government. Our role, in exercise of the judicial power granted to us by the Constitution, is to interpret the law that the General Assembly enacts. Because we conclude that the plain language of R.C. 2919.123 prohibits a physician from knowingly providing mifepristone to induce an abortion beyond the 49th day of pregnancy or from knowingly administering it without complying with the dosage indications and treatment protocols expressly approved by the FDA in the drug approval letter and the final printed labeling, we answer both certified questions in the affirmative.

So answered.

LUNDBERG STRATTON and CUPP, JJ., concur.

MOYER, C.J., concurs in syllabus and judgment.

O'CONNOR and LANZINGER, JJ., concur in part and dissent in part.

PFEIFER, J., dissents.

O'CONNOR, J., concurring in part and dissenting in part.

{¶ 37} I concur in the court's judgment that R.C. 2919.123 prohibits a physician from knowingly providing mifepristone to induce an abortion beyond the 49th day of pregnancy because, pursuant to 21 C.F.R. 314.520, the FDA restricted the use of mifepristone to women who certify by executing a patient agreement that they believe that they are no more than 49 days pregnant. I dissent from the holding that R.C. 2919.123 prohibits all off-label uses of the drug.

A

{¶ 38} R.C. 2919.123 permits the administration of mifepristone to induce abortion in accordance with federal law, including the FDA's approval letter and package-labeling materials. It forbids the administration of mifepristone to women who are past the 49-day gestational limit. When the FDA concludes that a drug product can be safely used only if distribution or use is restricted, it can require such postmarketing restrictions as are needed to ensure safe use. Relying on this authority, described in 21 C.F.R. 314.520, the FDA set forth the following specific restrictions in its approval letter on the use of mifepristone:

{¶ 39} 1. The drug must be administered by a qualified physician.

{¶ 40} 2. The physician must provide each patient with a Medication Guide and Patient Agreement.

{¶ 41} 3. The physician must fully explain the procedure to each patient.

{¶ 42} 4. The physician must give the patient an opportunity to read and discuss both the Medication Guide and the Patient Agreement.

{¶ 43} 5. *The physician must obtain the patient's signature on the Patient Agreement and must sign it as well.*

{¶ 44} The Patient Agreement requires the patient to certify that she believes that she is no more than 49 days pregnant. In requiring a patient to sign the patient agreement, the FDA prohibits the use of mifepristone outside of the 49-day gestational period. It is the requirement of the patient agreement that indicates the limitation on the use of mifepristone. I thus concur with this result reached by the majority.

B

{¶ 45} Despite agreeing that the FDA has limited the use of mifepristone and that the General Assembly has enacted that limitation into law, I dissent from the majority's conclusion that R.C. 2919.123 prohibits all off-label uses of the drug.

{¶ 46} R.C. 2919.123 requires that for the purpose of abortion, mifepristone must be administered by a qualified physician in accordance with federal law, including the FDA's drug-approval letter and labeling materials. The majority relies on language in the drug-approval letter that states, "Mifepristone is indicated for use in the termination of pregnancy (through 49 days' pregnancy) and has no other approved indication for use during pregnancy" to conclude that use of mifepristone after the 49-day limit is not in accordance with the drug-approval letter and therefore violates R.C. 2919.123. By approving the use of mifepristone for the purpose of abortion during the first 49 days of pregnancy, however, the FDA did not prohibit doctors from varying the administration, timing, or dosage of the drug.

{¶ 47} It is well accepted that after the FDA approves a drug for use, doctors may prescribe the drug for off-label uses. 12 FDA Drug Bulletin

(Apr.1982) 4, quoted in *Weaver v. Reagen* (C.A.8, 1989), 886 F.2d 194, 198 (“ ‘Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling’ ”). See also *Planned Parenthood Cincinnati Region v. Taft* (C.A.6, 2006), 444 F.3d 502, 505; *Klein v. Biscup* (1996) 109 Ohio App.3d 855, 863–864, 673 N.E.2d 225. Indeed, the Eighth District Court of Appeals recognized that “ ‘FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.’ ” *Id.* at 863, quoting *Weaver*, 886 F.2d at 198. “Thus, the decision whether to use a drug for an off-label purpose is a matter of medical judgment, not of regulatory approval.” *Id.* at 864.

{¶ 48} The law recognizes that medical judgments are best left to the sound discretion of those with the education, training, and experience to make the best-informed decisions – physicians. “Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment.” United States Food and Drug Administration, Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators 1998 Update, available at <http://www.fda.gov/oc/ohrt/irbs/offlabel.html>. Although doctors and other health-care professionals are not immune from valid limitations on the practice of medicine, those limitations must be imposed properly.

{¶ 49} Because the FDA’s approval of the use of mifepristone within the 49-day gestational limit does not prohibit off-label use of the drug, other uses are also in accordance with federal law. If the legislature intended to forbid all off-label uses of mifepristone, it could have expressly done so. Instead, it limited the use of the drug to those uses that are in accordance with federal law. Thus, I would hold that although R.C. 2919.123 restricts the delivery of the drug to women no more than 49 days pregnant because of the FDA’s required patient

agreement, I do not agree that the statute prohibits all off-label use of mifepristone. Accordingly, I concur in part and dissent in part.

LANZINGER, J., concurs in the foregoing opinion.

PFEIFER, J., dissenting.

{¶ 50} R.C. 2919.123 states, among other things, that mifepristone may not be prescribed other than “in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions.” The majority opinion, in syllabus law, considers this provision a “mandate” that mifepristone may be prescribed only subject to a 49-day gestational limitation. I do not read R.C. 2919.123 so narrowly.

{¶ 51} First, and obviously, the plain language of R.C. 2919.123 does not mention a 49-day gestational limitation.

{¶ 52} Second, federal law does not specifically limit the use of mifepristone, because the FDA does not regulate the practice of medicine. *Southard v. Temple Univ. Hosp.* (2001), 566 Pa. 335, 341, 781 A.2d 101, quoting *In re Orthopedic Bone Screw Prods. Liab. Litigation* (E.D.Pa., Mar. 8, 1996), 1996 WL 107556, quoting *Klein v. Biscup* (1996), 109 Ohio App.3d 855, 864, 673 N.E.2d 225 (“The courts further recognized that the FDA does not regulate the practice of medicine, and therefore the ‘ “decision whether or not to use a drug for an off-label purpose is a matter of medical judgment[,] not of regulatory approval.” ’ ”).

{¶ 53} The drug-approval letter in this case, which is defined by R.C. 2919.123(F)(1) as “federal law,” states that mifepristone is approved for use and that its use is indicated “for the medical termination of intrauterine pregnancy through 49 days’ pregnancy.” Neither the approval letter nor any other federal law prohibits the off-label use of mifepristone. To the contrary, off-label use of medications is accepted, perhaps even necessary. *State Bd. of Registration for*

Healing Arts v. McDonagh (Mo.2003), 123 S.W.3d 146, 150, citing 21 U.S.C. 396 and *Buckman Co. v. Plaintiffs' Legal Commt.* (2001), 531 U.S. 341, 350-351, 121 S.Ct. 1012, 148 L.Ed.2d 854, and fn. 5 (“non-FDA-approved, or ‘off-label,’ use of medications by physicians is not prohibited by the FDA and is generally accepted in the medical profession”); *Southard*, 566 Pa. at 340, 781 A.2d 101, quoting *Buckman*, 531 U.S. at 350, citing James M. Beck and Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions* (1998), 53 Food and Drug L.J. 71, 76-77 (“The United States Supreme Court recently recognized that off-label use ‘is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine’ ”).

{¶ 54} Third, the General Assembly could have specifically banned the off-label use of mifepristone, as it banned particular off-label uses of certain steroids. See R.C. 3719.06(B). But it didn’t.

{¶ 55} Nothing in the plain language of R.C. 2919.123 mandates that the use of mifepristone be limited to the first 49 days of pregnancy. I dissent.

Richard Cordray, Attorney General, Benjamin C. Mizer, Solicitor General, Stephen P. Carney and Elisabeth A. Long, Deputy Solicitors, and Anne Berry Strait and Sharon A. Jennings, Assistant Attorneys General, for petitioner.

Gerhardstein & Branch Co., L.P.A., Alphonse A. Gerhardstein, and Jennifer L. Branch; and Bieser, Greer & Landis, L.L.P., and David C. Greer, for respondents.

Planned Parenthood Federation of America, Helene T. Krasnoff, and Roger K. Evans, for respondents Planned Parenthood Southwest Ohio Region, Planned Parenthood of Central Ohio, Planned Parenthood of Northeast Ohio, Dr. Roslyn Kade, and Dr. Laszlo Sogor.

B. Jessie Hill, Case Western Reserve University School of Law, Cooperating Counsel for the ACLU of Ohio; and ACLU of Ohio Foundation, Inc., and Jeffrey M. Gamso, for respondent Preterm.

Kilpatrick Law Offices, P.C., and Joel J. Kirkpatrick; and Mailee R. Smith, Americans United for Life, for amici curiae members of the United States Congress, in support of the Ohio Attorney General.
