IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Planned Parenthood Southwest Ohio Region, *et al.*,	:	Case No. 1:04-CV-493
	:	Chief Judge Susan J. Dlott
Plaintiffs,	:	
	:	ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
v.	:	
Mike DeWine, *et al.*,	:	
Defendants.	:	

This matter is before the Court on the parties' cross-motions for summary judgment (docs. 122 and 124).[1] For the reasons set forth below, the Court **DENIES** Plaintiffs' Motion for Summary Judgment and **GRANTS IN PART** and **DENIES IN PART** Defendants' Motion for Summary Judgment.

I. BACKGROUND

In *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St. 3d 361 (2009), the Ohio Supreme Court considered the scope and meaning of Ohio Rev. Code 2919.123 (the "Act") and succinctly summarized the pertinent facts and procedural history preceding its decision:

> 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

[1]Also pending are Defendants' Motion to Partially Strike the Declaration of Maureen E. Paul (doc. 139) and Plaintiffs' Motion to File Supplemental Declaration of Maureen E. Paul, M.D., M.P.H. (doc. 144). The Court found it unnecessary to rely on Dr. Paul's affidavit in its consideration of the parties' cross-motions for summary judgment. Consequently, Defendants' motion to strike and Plaintiffs' motion for leave are rendered moot.

"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."

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:

"[1.] Ability to assess the duration of the pregnancy accurately.

"[2.] Ability to diagnose ectopic pregnancies.

"[3.] Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

"[4.] Has read and understood the prescribing information of [mifepristone].

"[5.] Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.

"[6.] Must notify the 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.

"[7.] Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.

"[8.] Must record the [mifepristone] package serial number in each patient's record."

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.

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.

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.

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.

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.)

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.

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.
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> 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.

Cordray, 122 Ohio St. 3d at 362-65 (alterations in original).

On appeal from the permanent injunction, the Sixth Circuit *sua sponte* certified two questions of state law to the Ohio Supreme Court seeking an interpretation of the Act. *Planned Parenthood Cincinnati Region v. Strickland*, 531 F.3d 406, 412 (6th Cir. 2008). In *Cordray*, the Ohio Supreme Court issued an opinion stating that "[t]he 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." 122 Ohio St. 3d at 362.

In light of the Ohio Supreme Court's opinion, the Sixth Circuit vacated the permanent injunction issued by this Court in 2006. The Sixth Circuit noted that the preliminary injunction based on the Act's lack of a health or life exception should remain in force and remanded this case back to this Court for consideration of the Ohio Supreme Court's opinion, "as well as issues

identified in [the] previous remand and any other issues that the parties may raise." *Planned Parenthood Southwest Ohio Region v. Strickland*, 331 Fed. App'x 387, 388 (6th Cir. 2009).

Following the Sixth Circuit's remand, both parties moved for summary judgment. Both Plaintiffs and Defendants moved for summary judgment on Plaintiffs' claim that the Act is unconstitutionally vague. (Docs. 122 and 124.) Defendants also moved for summary judgment on Plaintiffs' bodily integrity, health or life exception, and undue burden claims. (Doc. 124).

II. ANALYSIS

A. Legal Standard

Summary judgment is appropriate if "there is no genuine issue as to any material fact" and "the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). On a motion for summary judgment, the movant has the burden of showing that no genuine issues of material fact are in dispute, and the evidence, together with all inferences that can permissibly be drawn therefrom, must be read in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-87 (1986).

The movant may support a motion for summary judgment with affidavits or other proof or by exposing the lack of evidence on an issue for which the nonmoving party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). In responding to a summary judgment motion, the nonmoving party may not rest upon the pleadings but must go beyond the pleadings and "present affirmative evidence in order to defeat a properly supported motion for summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). The nonmoving party must "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2). The Court's task is not "to weigh the evidence and determine the truth of the

matter but to determine whether there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 249. A genuine issue for trial exists when there is sufficient "evidence on which the jury could reasonably find for the [nonmoving party]." *Id*. at 252.

B. Cross-Motions for Summary Judgment on Plaintiffs' Claim that the Act is Unconstitutionally Vague

Both parties move for summary judgment on Plaintiffs' claim that the Act is unconstitutionally vague. Before addressing the parties' motions, the Court will begin by expanding upon this Court's prior opinion declaring the Act void for vagueness.

In 2006, Plaintiffs moved for summary judgment and sought a permanent injunction on the basis that the Act is unconstitutionally vague. (Doc. 69.) Specifically, Plaintiffs argued that the Act was vague because its language requiring physicians to comply with "all provisions of federal law" did not make clear what specific standards physicians must follow in order to prescribe or administer mifepristone without risking prosecution. At that time, the parties fundamentally disagreed on whether the statute's definition of "federal law" incorporated the drug's final printed labeling and, with it, the gestational limitation, treatment protocols, and dosage indications provided therein. Ultimately, this Court held that "the Act is unconstitutionally vague because it is unclear whether 1) the Act's definition of federal law incorporates the [final printed labeling] and 2) if it does, what that incorporation means in terms of lawful prescription of mifepristone." *Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626, 636; Doc. 81 at 15. After declaring the Act void for vagueness, this Court permanently enjoined enforcement of the entire statute. *Id*. at 640; Doc. 81 at 23.

In 2008, on appeal, the Sixth Circuit *sua sponte* certified two questions of state law to the Ohio Supreme Court:

> 1) Does O.R.C. § 2919.123 mandate that physicians in Ohio who perform abortions using mifepristone do so in compliance with the forty-nine-day gestational limit described in the FDA approval letter?
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> 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, 531 F.3d at 412.

In *Cordray*, the Ohio Supreme Court answered both certified questions in the affirmative. The Ohio Supreme Court began its analysis by noting that "[t]he provisions of R.C. 2919.123 are not ambiguous." 122 Ohio St. 3d at 366. First, the court held, the Act's language requiring physicians to comply with "all provisions of federal law" restricts physicians to using mifepristone to induce abortions in accordance with the drug approval letter. *Id.* at 366-67. And, because the FDA "based its approval of mifepristone on its use as recommended in the labeling text," the court found that the drug approval letter incorporates the final printed labeling and, more significantly, the medical regimen described in the final printed labeling. *Id.* at 367.

Turning to the two certified questions, the Ohio Supreme Court determined that the Act prohibits a physician from "knowingly providing mifepristone to induce an abortion beyond the 49th day of pregnancy" because the drug approval letter and the final printed labeling "indicate that the FDA approved the use of mifepristone for use through, but not beyond, the 49th day of pregnancy.'" *Id.* at 367-69. The court also found that 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." *Id.* As interpreted by the Ohio Supreme Court, the Act "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." *Id.* at 362. Knowingly "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." *Id.* at 367.

With this background, and having previously ruled that the Act is unconstitutionally vague, this Court must now determine whether the Ohio Supreme Court's interpretation of the Act in *Cordray* warrants a different conclusion.

1. Plaintiffs' Motion for Summary Judgment on the Void for Vagueness Claim

Plaintiffs renew their Motion for Summary Judgment, arguing that the Act remains unconstitutionally vague even as interpreted by the Ohio Supreme Court. (Doc. 122.) In support of their motion, Plaintiffs advance four separate arguments.

First, Plaintiffs argue that the Act remains vague following *Cordray* because physicians have no advance notice as to what documents have been incorporated by the Act into the criminal law. That is, Plaintiffs argue that the Ohio Supreme Court left open the possibility that the drug approval letter incorporates additional documents that formed the basis of the FDA's approval when it determined that the drug approval letter incorporates the final printed labeling.

Second, Plaintiffs argue that even if the drug approval letter incorporates only the final printed labeling, the Act still is unconstitutionally vague because the final printed labeling is internally contradictory. Plaintiffs point out that the final printed labeling consists of four separate documents: "the professional labeling (or Package Insert), the Medication Guide, the

Patient Agreement, and the Prescriber's Agreement." (Doc. 122-1 at 4 n.2.) Although the Package Insert, Medication Guide, and Patient Agreement "discuss the dosage regimen considered by the FDA in the drug approval process," Plaintiffs contend that the Medication Guide impliedly recognizes a physician's ability to prescribe FDA approved drugs off-label when it states that "[m]edicines are sometimes prescribed for purposes other than those listed in a Medication Guide." (Doc. 122-1 at 14-15) (quoting Medication Guide, Doc. 127-4.) Plaintiffs argue that it is unclear whether physicians are required to comply with the dosage indications and treatment protocols in the Package Insert or whether physicians may prescribe mifepristone off-label, as the Medication Guide seems to imply.

Implicit in Plaintiffs' second argument is the contention that the Ohio Supreme Court's opinion left many questions unanswered. To highlight this point, Plaintiffs' motion proffers three examples from a "multitude of unanswered questions" following *Cordray*:

> [1] Under the Ohio Supreme Court's opinion, it seems that a physician would need to give the woman the second drug involved in the treatment regimen, misoprostol, in the same dosage and manner (*i.e.*, .4 mg taken orally in person) as was done in the clinical trials that formed the basis of the FDA's approval. Does that mean that if a woman failed to return to take the misoprostol, an Ohio physician could be found criminally liable?
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> [2] The current Package Insert instructs physicians that "[b]efore prescribing Mifeprex, [they must] inform the patient about the risk of" certain serious adverse events and "[e]nsure that the patient knows whom to call and what to do" if she has certain problems. While one would hope that all physicians would provide this information, does failure to do so subject Ohio physicians to criminal liability (including the possibility of prison) in addition to whatever civil liability there might be?
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> [3] The Prescriber's Agreement that the FDA requires physicians

> to sign (which is part of the FPL[2]) states that prior to providing mifepristone, the physician must fill out an order form and list on the form each facility that the provider oversees. If the doctor omits a facility from that form, is that doctor criminally liable under the Act?

(Doc. 122-1 at 17) (internal citations omitted) (alterations in original). Plaintiffs argue that *Cordray* leaves these questions unanswered.

Third, Plaintiffs argue that the Act is unconstitutionally vague because the final printed labeling is subject to future revisions. Plaintiffs point out that the FDA has twice revised the final printed labeling since issuing the drug approval letter. Because the Act requires compliance with the drug approval letter, and the drug approval letter requires compliance with the gestational limitation, treatment protocols, and dosage indications contained in the final printed labeling, Plaintiffs argue, the Act's requirements and prohibitions could change with each revision of the final printed labeling, even without any amendment to the Act itself. Plaintiffs argue that this uncertainty fails to give Ohio physicians fair notice of what the Act proscribes.

Fourth, Plaintiffs argue that the Act's failure to define or distinguish the terms "criteria," "specific criteria provisions," and "specific provisions," each of which modifies the defined term "federal law," renders the Act unconstitutionally vague. Because *Cordray* did not address these vague and uncertain terms, Plaintiffs argue that the Act fails to give Ohio physicians fair notice of what it proscribes.

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[2]Plaintiffs refer to the final printed labeling as the "FPL."

2. Defendants' Opposition and Cross-Motion for Summary Judgmenton Plaintiffs' Void for Vagueness Claim

In their opposition to Plaintiffs' motion for summary judgment (doc. 133) and cross-motion for summary judgment (doc. 124[3]), Defendants argue that the Ohio Supreme Court's interpretation of the Act sets forth clear and unambiguous standards of conduct for prescribing and administering mifepristone. Defendants, therefore, seek summary judgment on Plaintiffs' void for vagueness claim.

Defendants urge the Court to read the Act "as though it were written exactly as the [Ohio Supreme Court] has construed it." (Doc. 125 at 17.) As interpreted by the Ohio Supreme Court, Defendants insist that the Act provides physicians with fair notice of what is prohibited: "A physician risks prosecution only if he or she 'knowingly provid[es] mifepristone to induce an abortion beyond the 49th day of pregnancy or . . . knowingly administer[s] it without complying with the dosage requirements and treatment protocols expressly approved by the FDA.'" (Doc. 125 at 18) (quoting *Cordray*, 122 Ohio St. 3d at 368-69) (alterations in Doc. 125.) The "dosage indications" are "600 mg of mifepristone, taken orally, followed two days later by 400 µg of misoprostol, taken orally." (Doc. 133 at 6.) The "treatment protocols" are "set forth clearly in the labeling text (Package Insert), Prescriber's Agreement, Patient Agreement and Medication Guide." (*Id.*) Defendants argue that Plaintiffs can no longer claim that the Act denies fair notice of the standard of conduct for which physicians are to be accountable.

Defendants further argue that "the Act's scienter requirement resolves any remaining

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[3]Defendants' memorandum in support of its Motion for Summary Judgment is filed at doc. 125. Exhibits in support of Defendants' Motion for Summary Judgment are filed at doc. 127-1 through 127-35 and 128-1 through 128-19.

concerns about vagueness." (Doc. 133 at 8.) To violate the Act, "a physician must *knowingly* provide mifepristone in contravention of the FDA-approved protocol." (*Id.*) Although this Court rejected a similar argument in 2006, Defendants insist that *Cordray* has changed the legal landscape:

> When this Court held the Act was unconstitutionally vague, it held that the term "federal law" was ambiguous and that the scienter requirement of the Act did not alleviate the problem because it was dependant on that vague term. The [Ohio Supreme Court] construed "federal law" to "prohibit[] 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 . . . ." Thus, the scienter requirement no longer applies merely to the general term "federal law" under the Act. Reading the Act *as construed by the [Ohio Supreme Court]*, the scienter requirement now applies to two bright line rules: that a physician may not knowingly provide mifepristone past 49 days LMP,[4] and that the physician may not knowingly provide mifepristone using a dosage or treatment regimen that differs from that approved by the FDA.

(Doc. 125 at 20-21) (quoting *Cordray*, 122 Ohio St. 3d at 368-69). Defendants argue that "the Act's scienter requirement vitiates any claim that the Act's purported vagueness could trap an unwary doctor who misunderstands what is prohibited." (Doc. 133 at 8.)

Defendants also address Plaintiffs' argument that the Ohio Supreme Court opened the door to "incorporation" of some or all of the documents mentioned in the drug approval letter. Defendants argue that Plaintiffs are "urging this Court to adopt a nonsensical reading of the Act," a reading which was implicitly rejected by the Ohio Supreme Court in *Cordray*. (*Id.* at 10.) According to Defendants, the Ohio Supreme Court did not open the door to the

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[4]"LMP" means last menstrual period.

incorporation of additional documents; rather, the court found that the drug approval letter incorporates only the final printed labeling, because the drug approval letter makes clear that the FDA's approval of mifepristone was based on its use as recommended in the final printed labeling.

With regard to Plaintiffs' proffered examples in connection with their second argument, Defendants contend that these are merely hypotheticals "that have not arisen and are not likely to arise with respect to the parties before the court." (*Id.* at 15.) Even so, Defendants insist that the examples are easily answered by *Cordray*. In their first example, Plaintiffs asked:

> [1] Under the Ohio Supreme Court's opinion, it seems that a physician would need to give the woman the second drug involved in the treatment regimen, misoprostol, in the same dosage and manner (*i.e.*, .4 mg taken orally in person) as was done in the clinical trials that formed the basis of the FDA's approval. Does that mean that if a woman failed to return to take the misoprostol, an Ohio physician could be found criminally liable?

(Doc. 122-1 at 17.) Defendants argue that the answer is "no." According to Defendants, the Act only prohibits a physician from knowingly prescribing mifepristone contrary to the final printed labeling. "Thus, if a physician provided mifepristone on day one, and the woman failed to appear for her appointment on day three, the physician would not have 'knowingly' violated the Act." (Doc. 133 at 15.) Defendants then add, "[a] physician could only be found criminally liable under the Act if he or she knew that the patient was not coming back." (*Id.*)

In their second example, Plaintiffs asked:

> [2] The current Package Insert instructs physicians that "[b]efore prescribing Mifeprex, [they must] inform the patient about the risk of" certain serious adverse events and "[e]nsure that the patient knows whom to call and what to do" if she has certain problems. Revised Package Insert, April 22, 2009 at 2 (Exhibit B). While one

> would hope that all physicians would provide this information, does failure to do so subject Ohio physicians to criminal liability (including the possibility of prison) in addition to whatever civil liability there might be?

(Doc. 122-1 at 17) (alterations in original.) Defendants argue that the answer is "yes." According to Defendants, if a physician knowingly fails to adhere to the treatment protocols contained in the final printed labeling, including the requirement that physicians discuss the risks of mifepristone and obtain informed consent from the patient, the physician certainly would be liable under the Act.

In their third example, Plaintiffs asked:

> [3] The Prescriber's Agreement that the FDA requires physicians to sign (which is part of the FPL) states that prior to providing mifepristone, the physician must fill out an order form and list on the form each facility that the provider oversees. If the doctor omits a facility from that form, is that doctor criminally liable under the Act?

(*Id.*) Defendants insist that "the answer is, clearly, 'no.'" (Doc. 133 at 17.) According to Defendants, *Cordray* makes clear that physicians are required to follow only the "medical regimen" and "treatment protocols" found in the final printed labeling. Defendants argue that this example underscores the futility in Plaintiffs argument, as this scenario is "highly unlikely to lead to prosecution." (*Id.*) In sum, Defendants argue that "none of [Plaintiffs'] hypothetical questions demonstrate either that the Act is vague or that the [Ohio Supreme Court] did not construe the Act with enough specificity to put physicians on notice of what is prohibited." (*Id.* at 18.)

Next, Defendants dispute Plaintiffs' argument that the final printed labeling is internally inconsistent. Defendants readily acknowledge that the Medication Guide mentions that some

medicines are prescribed off-label. However, Defendants insist that "[w]arning patients about off-label use does not endorse off-label use." (Doc. 133 at 14.) Defendants insist that Plaintiffs' reading of the Medication Guide is also contradicted by the holding in *Cordray*, which requires that physicians adhere to the gestational limitation, treatment protocols and dosage indications set forth in the drug approval letter and final printed labeling. Defendants argue this sentence was taken out of context in Plaintiffs' brief and does not render the final printed labeling internally inconsistent or the Act unconstitutionally vague.

Defendants then argue that the possibility of future revisions to the final printed labeling does not render the Act unconstitutional. Defendants first note that the previous revisions to the final printed labeling have not altered the 49-day gestational limitation for the administration of mifepristone, nor have the revisions modified any of the dosage indications or treatment protocols contained in the final printed labeling. Defendants insist that future revisions to the gestational limitation, treatment protocols, or dosage indication would not render the Act unconstitutionally vague. Defendants argue that physicians administering mifepristone would certainly be aware of these "well publicized" changes and would simply need to change their protocols in order to adapt to the revisions. Furthermore, Defendants argue, the Act's scienter requirement insulates physicians who are not made aware of any changes to the final printed labeling.

Finally, Defendants argue that the Act is not unconstitutionally vague simply because it fails to define or distinguish between the terms "criteria," "specific criteria provisions," and "specific provisions," all of which modify the term "federal law." Following *Cordray*, Defendants argue, the term "federal law" is clearly defined and the terms modifying "federal

law" should be given their plain meaning.

3. Following *Cordray*, the Act is not unconstitutionally vague.

For the purpose of determining whether the Act is unconstitutionally vague, this Court "must take the statute as though it read[s] precisely as the highest court of the State has interpreted it." *Kolender v. Lawson*, 461 U.S. 352, 355 n.4 (1983) (quoting *Wainwright v. Stone*, 414 U.S. 21, 22-23 (1973), in turn quoting *Minnesota ex rel. Pearson v. Probate Court*, 309 U.S. 270, 273 (1940)). As construed by the Ohio Supreme Court in *Cordray*, the Act is not void for vagueness.

When this Court last addressed Plaintiffs' vagueness claim, it was unclear whether the Act required that physicians "prescribe mifepristone only according to the FDA-approved protocol or whether they [could] lawfully prescribe an evidence-based protocol." *Planned Parenthood Cincinnati Region*, 459 F. Supp. 2d at 637; Doc. 81 at 17. In *Cordray*, the Ohio Supreme Court resolved this issue by concluding that the Act prohibits off-label use of mifepristone. The court summarized the Act's prohibitions as follows:

> [T]he 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.

Cordray, 122 Ohio St. 3d at 368-69. The court summarized the dosage indications and treatment protocols provided in the final printed labeling as follows:

> [The final printed labeling] 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.

Id. at 363. Following *Cordray*, this Court finds that the Act provides doctors "of ordinary intelligence a reasonable opportunity to know what is prohibited." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

Even so, the Court must address some of Plaintiffs' contentions. Plaintiffs contend that the Act denies physicians fair notice of what conduct is prohibited because the final printed labeling could be revised and, consequently, the Act's requirements and prohibitions could change without any action by the legislature to change the language of the Act itself. Plaintiffs successfully argued this position to the Court in 2006. At that time, however, it was unclear what the final printed labeling required in terms of lawful prescription of mifepristone. This Court found that the possibility of future revisions to the final printed labeling only compounded the Act's vagueness. Because *Cordray* makes clear that the Act proscribes off-label use of mifepristone, and because the previous revisions have not altered the gestational limitation, treatment protocols or dosage indications, the Court cannot now say that the Act denies physicians fair notice. As to the possibility of future revisions, the Ohio Supreme Court correctly pointed out that "[o]ther drugs have been similarly restricted in Ohio." *Cordray*, 122 Ohio St. 3d at 368 (citing Ohio Rev. Code § 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 Admin.

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")). That the final printed labeling of mifepristone might at some point in the future be revised in a manner that might be difficult to reconcile with the Ohio Supreme Court's decision in *Cordray* does not now present a live justiciable controversy regarding the Act's constitutionality. The Court will not speculate whether such a revision will or could ever occur.

Plaintiffs also contend that following *Cordray*, the drug approval letter arguably incorporates additional documents that formed the basis of the FDA's approval, many of which discuss different gestational ages and dosage indications. Plaintiffs argue that it is unclear with which of those documents physicians are required to comply. Plaintiffs also argue that the final printed labeling is internally inconsistent because the Medication Guide states that medicines are sometimes prescribed off-label. Plaintiffs' arguments are unavailing. Both arguments are incompatible with the Ohio Supreme Court's holding that the Act expressly requires physicians to comply with the gestational limitation, treatment protocols, and dosage indications in the final printed labeling. With respect to the incorporation of additional documents, although the Ohio Supreme Court did not explicitly state that only the final printed labeling was incorporated into the drug approval letter, that conclusion logically follows from the court's holding and this Court finds as such.

Plaintiffs also argue that the Act's failure to define or distinguish the terms "criteria," "specific criteria provisions," and "specific provisions" renders the Act unconstitutionally vague, even after *Cordray*. In 2006, this Court found the terms "particularly troubling because they

modify the term 'federal law,'" and at that time the definition of the term "federal law" was unclear. Since then, the Ohio Supreme Court has defined what the Act means when it states that physicians must provide mifepristone in accordance with federal law. As the United States Supreme Court has explained, "[c]ondemned to the use of words, we can never expect mathematical certainty from our language." *Grayned*, 408 U.S. at 110. With this point in mind, this Court is of the opinion that, although the specific terms may not be defined with "meticulous specificity, ... it is clear what the ordinance as a whole prohibits." *Id.*

The same logic applies to Plaintiffs' examples of "unanswered questions" following *Cordray*. Plaintiffs' examples, roughly stated, reduce to the assertion that the final printed labeling contains many statements, and it is unclear whether a physician's failure to comply with each and every one of those statements will lead to prosecution under the Act. Doubtless, both the Act and *Cordray* leave marginal questions unanswered; however, the Court is confident that physicians have fair notice of what conduct is prohibited. The Act's scienter requirement further blunts any notice concerns.

As interpreted, the Act now sets forth "relatively clear guidelines as to prohibited conduct" and provides doctors "of ordinary intelligence a reasonable opportunity to know what is prohibited." *See Gonzales v. Carhart*, 550 U.S. 124, 149 (2007). Furthermore, given the Act's scienter requirement, a physician will not face liability if he or she prescribes mifepristone in contravention to the FDA-approved protocol by mistake. Therefore, the Act cannot be described as "a trap for those who act in good faith." *Gonzales*, 550 U.S. at 149-50 (quoting *Colautti v. Franklin*, 439 U.S. 379, 395 (1979)).

The Court **DENIES** Plaintiffs' Renewed Motion for Summary Judgment (doc. 122) and

GRANTS Defendants' Motion for Summary Judgment (doc. 124) as to Plaintiffs' claim that the Act is unconstitutionally vague.

C. Defendants' Motion for Summary Judgment on Plaintiffs' Bodily Integrity Claim

Defendants move for summary judgment on Plaintiffs' claim that the Act violates a woman's right to bodily integrity because it compels surgical abortion in circumstances where medical abortion would otherwise be desired or appropriate treatment. (Doc. 124.) Defendants argue that the Act does not infringe upon the right to bodily integrity, and that the undue burden standard set forth in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), represents the proper framework for analyzing Plaintiffs' challenge to the Act.

The Supreme Court has long recognized a substantive due process right to bodily integrity. Generally, the right has been employed to protect against nonconsensual intrusions into one's body. *See, e.g.*, *Rochin v. California*, 342 U.S. 165 (1952) (finding that detainee's bodily integrity was violated when police ordered doctors to pump his stomach to obtain evidence of drugs); *Winston v. Lee*, 470 U.S. 753 (1985) (holding that surgical removal of potential evidence from an individual's body without individual's consent is an unconstitutional intrusion upon bodily integrity); *Riggins v. Nevada*, 504 U.S. 127 (1992) (finding that forced administration of antipsychotic medication during trial violated substantive due process); *Washington v. Harper*, 494 U.S. 210, 229 (1990) (noting that "forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty."). The right to bodily integrity has also been held to protect the right to refuse unwanted lifesaving medical treatment. *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261 (1990).

Plaintiffs claim that the Act infringes upon a woman's right to bodily integrity because it

forces some "women seeking an abortion to have an invasive surgical procedure in a clinic setting when they would prefer an alternative, private, safe method using medications." (Doc. 134 at 30.) However, Plaintiffs' claim is not on the same footing as the forced, involuntary invasions of bodily integrity outlined above, principally because the Act does not force women to undergo any procedure, surgical or otherwise. When broken down, Plaintiffs' argument appears to be this: by prohibiting off-label use of mifepristone, the Act leaves women with gestational durations exceeding 49-days with no other option but a surgical abortion to terminate their pregnancies. While this may be true, it does not change the fact that the Act itself does not compel women to undergo surgery to terminate a pregnancy.

To be clear, an abortion law that places restrictions on certain procedures can pose an unconstitutional undue burden on a woman's right to choose to have an abortion. *See Stenberg v. Carhart*, 530 U.S. 914 (2000). The undue burden inquiry is, however, separate and apart from the bodily integrity analysis and the abortion restriction at issue here is appropriately addressed in terms of an undue burden. Plaintiffs here have not alleged any facts sufficient to state a claim that the Act violates a woman's right to bodily integrity under established precedent. Therefore, the Court **GRANTS** Defendants' Motion for Summary Judgment as to Plaintiffs' bodily integrity claim.

D. Defendants' Motion for Summary Judgment on Plaintiffs' Health or Life Exception Claim

Defendants next move for summary judgment on Plaintiffs' claim that the Act is unconstitutional because it lacks an exception to protect the health or life of the mother. Defendants argue that (1) the Supreme Court's decision in *Gonzales v. Carhart*, 550 U.S. 124 (2007), requires that the Court employ the undue burden standard in connection with the health

or life exception claim and (2) the Act is not facially invalid because the absence of a health or life exception does not amount to an undue burden on a woman's right to choose an abortion. The Court will address each argument in turn.

In *Gonzales*, the Supreme Court upheld as constitutional the federal partial-birth abortion statute, 18 U.S.C. § 153, even though the statute lacks an exception to preserve the health of the woman. 550 U.S. at 168. The Court analyzed the necessity of a health exception within the undue burden framework, framing the argument as "whether [a statute] has the effect of imposing an unconstitutional burden on the abortion right because it does not allow use of the barred procedure where 'necessary, in appropriate medical judgment, for the preservation of the . . . health of the mother.'" *Id.* at 161 (quoting *Ayotte*, 546 U.S. at 327-28). The Court then provided the standard it would use to make this determination: the lack of a health exception "would be unconstitutional . . . if it 'subject[ed] [women] to significant health risks.'" *Id.* (quoting *Ayotte*, 546 U.S. at 328).

The Court determined that the federal partial-birth abortion statute's lack of a health exception did not impose an undue burden on the abortion right because the record revealed "medical uncertainty over whether the Act's prohibition creates significant health risks." *Id.* at 164. Because there was medical disagreement on this central factual question, the Court determined that the statute could survive a facial challenge: "The Act is not invalid on its face where there is uncertainty over whether the barred procedure is ever necessary to preserve a woman's health." *Id.* at 166-67. The Court further noted that an as-applied challenge would be the preferred mechanism for challenging the federal partial-birth abortion statute's lack of a health exception:

> This is the proper manner to protect the health of the woman if it can be shown that in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used. In an as-applied challenge the nature of the medical risk can be better quantified and balanced than in a facial attack.

Id. at 167.

Defendants argue that following *Gonzales*, a health or life exception is only necessary if the absence of an exception would impose an undue burden on the right to choose abortion. Defendants insist that the Act's lack of a health or life exception does not place an undue burden on the right to choose abortion because, like the situation in *Gonzales*, medical uncertainty exists regarding whether access to an off-label mifepristone abortion is ever necessary to avoid significant health risks to women. Defendants contend that women who suffer from medical complications that make surgical abortion risky could obtain a medical abortion using the drug methotrexate, or they could choose to maintain the pregnancy. Defendants also question whether this Court's can consider Plaintiffs' challenge to the Act at all, based on the *Gonzales* Court's admonition of facial challenges to the federal partial-birth abortion statute.

Plaintiffs counter that summary judgment is inappropriate because issues of fact remain as to whether the Act subjects women to significant health risks. In support of their position, Plaintiffs point out that both this Court and the Sixth Circuit previously found that the Act could pose significant health risks to women with certain medical conditions, including women with "a bicornuate (i.e., divided) uterus, extreme flexion of the uterus, large uterine fibroids, cervical stenosis, female genital mutilation, and other abnormalities of the female genital tract." (Doc. 134 at 43) (quoting *Planned Parenthood Cincinnati Region*, 444 F.3d 502 at 511-12.) Plaintiffs argue that there is no "medical uncertainty" on this point. Plaintiffs insist that summary

judgment is premature and unwarranted, pointing out that the *Gonzales* decision "came only after [the Supreme Court] reviewed the evidence that had been offered on this issue at three different trials on the merits as well as an extensive legislative history." (*Id*. at 39.) Plaintiffs therefore insist that there are contested factual issues concerning the health risks associated with the Act's prohibition of off-label mifepristone abortions which preclude summary judgment.

The Court finds that *Gonzales* does not serve as a basis for summary judgment on Plaintiffs' health or life exception claim. While *Gonzales* makes clear that the need for a health exception is analyzed through the undue burden framework, *Gonzales* reaffirms that a regulation "would be unconstitutional . . . if it 'subject[ed] [women] to significant health risks.'" *Id.* (quoting *Ayotte*, 546 U.S. at 328). Here, whether the Act subjects women to significant health risks remains, at a minimum, a disputed issue of material fact. This Court previously found that the Act could pose significant health risks to women. *See Planned Parenthood Cincinnati Region v. Taft*, 337 F. Supp. 2d 1040 (S.D. Ohio 2004); Doc. 36. The Sixth Circuit agreed, finding that evidence submitted at the preliminary injunction phase suggested that the Act "could pose a significant health risk to women with particular medical conditions." *Planned Parenthood Cincinnati Region,* 444 F.3d at 514. Defendants argue that medical disagreement exists over the need for a health or life exception, and yet Defendants also concede that surgical abortions pose greater risks for women with medical complications. (Doc. 138 at 12.) These contentions are, at a minimum, laden with contested factual issues that cannot be resolved in Defendants' favor on summary judgment.

Moreover, *Gonzales* does not address Plaintiffs' claim that the Act requires an exception

to protect the woman's life, because the federal statute at issue in *Gonzales* contains a life exception. *See* 18 U.S.C. § 1531(a) ("This subsection does not apply to a partial-birth abortion that is necessary to save the life of a mother ..."). Thus, the Supreme Court's "precedent pertaining to the life exception remains unchanged" by *Gonzales*, *see Northland Family Planning Clinic, Inc. v. Cox*, 487 F.3d 323, 340 (6th Cir. 2007), and the necessity of an exception to protect a woman's life will need to be addressed going forward.

As to the propriety of entertaining a facial challenge to the Act, *Gonzales* does not require dismissal. In *Gonzales*, the Supreme Court rejected a facial challenge to the federal partial-birth abortion statute prohibiting the intact dilation and evacuation procedure. Critical to the Court's holding was the conflicted factual record, which cast doubts about the medical need for a health exception. After evaluating the evidence adduced at three separate trials, the Court found medical "uncertainty over whether the barred procedure [was] ever necessary to preserve a woman's health." *Gonzales*, 550 U.S. at 166-67. The Court further concluded, "[i]n these circumstances the proper means to consider [health] exceptions is by as-applied challenge." *Gonzales*, 550 U.S. at 167. Defendants argue that this statement requires dismissal of Plaintiffs' health or life exception claim. This Court disagrees. At this stage of the litigation, unlike the situation in *Gonzales*, this Court is without the benefit of full evidence. The current record indicates, and Defendants concede, that surgical abortions pose greater risks for women with medical complications. (Doc. 138 at 12.) Additionally, both parties are able to articulate the discrete instances in which an off-label mifepristone abortion may be medically necessary. (*See* doc. 125 at 31-32; doc. 134 at 13.) In combination, these facts cast doubt on a suggestion that *Gonzales* renders Plaintiffs' challenge to the Act improper. Therefore, the Court **DENIES**

Defendants' Motion for Summary Judgment as to Plaintiffs' claim that the Act lacks an exception for the health or life of the woman.

E. Defendants' Motion for Summary Judgment on Plaintiffs' Undue Burden Claim

As discussed in the previous section of this opinion, *Gonzales* makes clear that the need for a health exception is analyzed through the undue burden framework. And, based on the present record, contested factual issues remain regarding whether the Act's lack of a health or life exception constitutes an undue burden on a woman's right to choose abortion. To the extent that Plaintiffs assert an undue burden claim separate and apart from the health or life exception claim, the Court will address this claim and Defendants' motion for summary judgment below.

Plaintiffs argue that the Act's restrictions unduly burden the abortion right because: (1) by prohibiting off-label use of mifepristone, the Act essentially bans a safe and common method of abortion for women with gestational durations between 50 and 63 days LMP; (2) the cost of a mifepristone abortion will increase because the FDA-approved protocol requires additional clinic visits and a higher dosage of mifepristone than is currently being administered using an off-label regimen; and (3) women will be denied the "ability to have a safe, private procedure that they feel very strongly is the best way for them to manage their own bodies." (Doc. 134 at 41.)

Defendants move for summary judgment on this claim, arguing that the Act does not place a substantial obstacle in the path of a woman seeking an abortion. Defendants argue that the Act does not "ban" a particular method of abortion; rather, the Act restricts the administration of mifepristone to the FDA approved labeling and allows women to "obtain safe and effective on-label mifepristone abortions up to 49 days LMP." (Doc. 138 at 12.) Defendants point out that surgical abortion remains a safe and effective alternative to mifepristone abortion

for women with gestational durations between 50 and 63 days LMP. Defendants do not dispute that the Act may require additional clinic visits and a higher dosage of mifepristone than is currently being administered off-label. But, Defendants argue that increased expense and inconvenience related to obtaining a mifepristone abortion does not, as a matter of law, amount to an undue burden on the abortion right.

The Supreme Court has made clear that the state may not place an undue burden on a woman's decision to have an abortion before viability. *See Casey*, 505 U.S. at 874. An undue burden exists if "a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Id* at 877. Even viewing the evidence in the light most favorable to Plaintiffs, it is clear that the record does not create a triable issue of material fact as to whether the Act has the effect of creating a substantial obstacle to the abortion right. There is no evidence that the Act would impose an undue burden on "a woman's ability to make th[e] decision to have an abortion." *Id*. at 874. Rather, the evidence suggests that for women with gestational durations of 49 days or less, the Act's restrictions may require additional clinic visits and a higher dose of mifepristone than is administered off-label. While an additional clinic visit and a higher dose of medication may increase the cost of the procedure, *Casey* instructs that "[t]he fact that a law ... has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Id*. at 874.

As for women with gestational durations beyond 49 days, it is undisputed that the Act does not impact their ability to choose a safe, commonly used method of abortion. Plaintiffs acknowledge that first trimester surgical abortions are "very safe " for women without medical

complications. (Doc. 134 at 12.) The record also indicates that surgical abortions are the most common first trimester abortion method in Plaintiffs' clinics. (*See* Doc. 134-1 at 17) ("In 2009, thirty-one percent of all of the women who came to Plaintiffs' clinics who were eligible for either medication or surgical abortion chose a medication abortion."). The conclusion that the Act does not impose an undue burden is further supported by evidence introduced in the most recent round of briefing. In January, Plaintiffs submitted affidavits from nine women who claim to be unduly burdened by the Act's restrictions. (*See* Docs. 153-5 through 153-13.) Each woman underwent a surgical abortion at one of Plaintiffs' clinics, and each woman testified that she would have preferred to have a medical abortion using mifepristone.[5] (*See id.*) The fact that each of these women were able to obtain an abortion using a safe, commonly used procedure convinces the Court that the Act does not create a substantial obstacle to the abortion right.

Therefore, the Court **GRANTS** Defendants' Motion for Summary Judgment (doc. 124) as to Plaintiffs' claim that the Act imposes an undue burden on a patient's right to choose abortion.

III. CONCLUSION

For the foregoing reasons, the Court **DENIES** Plaintiffs' Renewed Motion for Summary Judgment (doc. 122), the Court **DENIES** Defendants' Motion for Summary Judgment (doc. 124) as to Plaintiffs' claim that the Act unconstitutionally lacks an exception for the health or life of the woman, and the Court **GRANTS** Defendants' Motion for Summary Judgment as to

[5]One affiant, Leslie Doe, submitted an affidavit on behalf of her minor child. *See* Doc. 153-6.

Plaintiffs' claims that the Act is unconstitutionally vague, that the Act violates a woman's right to bodily integrity, and that the Act imposes an undue burden on a patient's right to choose abortion. The Court **DENIES AS MOOT** Defendants' Motion to Partially Strike the Declaration of Maureen E. Paul (doc. 139) and Plaintiffs's Motion to File Supplemental Declaration of Maureen E. Paul, M.D., M.P.H. (doc. 144).

IT IS SO ORDERED.

_____s/Susan J. Dlott____________
Chief Judge Susan J. Dlott
United States District Court