UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc.;William Richardson, M.D.; and William H. R. Richardson M.D., P.C., doing business in Tucson Women's Center, Plaintiffs, v. Will Humble, Director of the Arizona Department of Health Services, in his official capacity, Defendant.	CV 14-1910 TUC DCB **ORDER**

On March 4, 2014, Plaintiffs filed this Complaint and filed a Motion for Temporary Restraining Order on March 7, 2014. Plaintiffs are Arizona health care providers, who provide surgical and medication abortions. They challenge HR 2036, A.R.S. 36-449.03: Abortion clinics; rules; civil penalties, subsection (E)(6),[1] which mandates: "That any medication, drug or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the United States Food and Drug Administration (FDA) and that is outlined in the final printing labeling instructions[, the FDL,] for that medication, drug or substance." The Director adopted such a regulation on January 27, 2014.

[1]Section 2 of Arizona House Bill 2036, H.R. 2036, 50th Leg., 2d Reg. Sess. (Ariz. 2012).

The law and regulations become effective on April 1, 2014, unless the Court issues a preliminary injunction. The Court denies the Motion for a Preliminary Injunction.

Standard for Preliminary Relief:

According to the Supreme Court, the proper standard for granting or denying a preliminary injunction is as follows:

> A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.

Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008); *see also Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1126–27 (9th Cir.2009) (abandoning the Ninth Circuit's prior preliminary injunction test and applying *Winter*).

Prior to *Winter*, the Ninth Circuit recognized an alternative sliding-scale standard requiring a plaintiff to demonstrate either a combination of probable success on the merits and the possibility of irreparable injury or that serious questions are raised and the balance of hardships tips sharply in his favor. *Taylor v. Westly*, 488 F.3d 1197, 1200-1201 (9th Cir. 2007). Post-*Winter*, the "sliding scale" approach to preliminary injunctions remains only to the extent "'the elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another.'" *Pimentel v. Dreyfus*, 670 F.3d 1096, 1105 -1106 (9th Cir. 2012) (quoting *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011)). Plaintiffs "must establish that irreparable harm is "likely, not just possible," regardless of the strength of Plaintiffs' showing on the other three elements. *Alliance for the Wild Rockies*, 632 F.3d at 1131 (applying *Winters*). The sliding scale supports a preliminary injunction when there are "serious questions going to the merits"[2] and the hardship balance tips sharply toward the plaintiff, assuming the other two

[2]Alternatively, "serious questions," means "'at an irreducible minimum,'" "' a fair chance of success on the merits.'" *Pimentel*, 670 F.3d at 1106 (quoting *Guzman v. Shewry*, 552 F.3d 941, 948 (9th Cir.2009)).

elements of the *Winter* test are also met. *Drakes Bay Oyster Co. v. Jewell*, ___ F.3d ____, 2014 WL 114699 (9th Cir. Jan. 14, 2014) (citing *Alliance*, 632 F.3d at 1131-32)).

HR 2036: RU-486 medication abortion:

The statute and corresponding regulation involves a medication abortion protocol using a combination of two prescription drugs: mifepristone (RU-486 or Mifeprex) and misoprostol (Cytotec). The first drug kills the embryo/fetus and the second causes the uterus to contract and expel the embryo/fetus, completing the abortion.

The protocol mandated by HR 2036 is from 2000, when the FDA approved marketing mifepristone as an abortion-inducing drug and is based on clinical trials from the 1990s. The FDA found RU-486 to be safe and effective through 49 days (7 weeks) lmp (last menstrual period): the patient takes three 200 mg tablets (600 mg) of mifepristone orally at the health center, returns two days later to take two 200 mcg tablets (400 mcg) of misoprostal orally**,** and then has a follow-up visit. A.R.S. 36-449.03(G)(1), Regulation R9-10-1508(G), (J)(3).

The differences between the FDL, HR 2036, protocol and the current protocol is the availability of medication abortions in the 8th and 9th week of pregnancy, a higher (600 mg versus 200 mg) first dose of mifepristone, the requirement that the second dose of misoprostal be administered at the clinic instead of being taken at home, and the oral administration of two 200 mcg tablets (400 mcg) of misoprostal, as compared to the current buccal, sublingual, administration of one 800 mcg tablet.

On its face, the law reflects a legitimate purpose to: 1) "protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, for example, mifepristone," and 2) "to ensure that physicians abide by the protocol tested and approved by the United States Food and Drug Administration for such abortion-inducing drugs, as outlined in the drug labels." (Response (Doc. 22) at 8 (citing HB 2036, Sec. 9 ¶¶ 25-26). In other words, the primary, if not the sole, purpose of the statute is maternal health.

The government has "a legitimate interest in advancing the state of medical knowledge concerning maternal health and prenatal life[.]" *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 976 (1992).

The government's interest before viability "'may not prohibit any woman from making the ultimate decision to terminate her pregnancy.'" *Gonzales v. Carhart*, 550 U.S. 124, 146 (2007) (quoting *Casey*, 505 U.S. at 879 (plurality opinion). "It also may not impose upon this right an undue burden, which exists if a regulation's 'purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.'" *Id.* (citing *Casey*, 505 U.S. at 878).

"A finding of an undue burden is a shorthand for the conclusion that 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. . . And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." *Casey*, 505 U.S. at 877. The law must be unduly burdensome, i.e., unconstitutional, in a large fraction of relevant cases. *Gonzales*, 550 U.S. at 167-168 (citing *Casey*, 505 U.S. at 895.

In *Gonzales*, the Supreme Court considered the Partial Birth Abortion Ban passed by Congress in 2003, which proscribes performing an "intact" D & C (dilation and cutilage) procedure, but allows D & C procedures where the fetus is removed from the uterus in parts. Admittedly, the regulation did not protect fetal life because it allowed the alternative D&C method of abortion. The sole purpose of the regulation was to send a message of the government's profound respect for the life of the unborn by precluding a method likened to infanticide. *Gonzales*, 550 U.S. at 157-158.[3] The Supreme Court in *Gonzales* assumed *Casey*

[3]"Regulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the

and its progeny to be controlling and found the regulation would be unconstitutional if it "subject[ed] [women] to significant health risks." *Id.* at 161 (quoting *Ayotte v. Planned Parenthood of Northern England*, 546 U.S. 320, 328 (2007) (finding health exception to the parental-involvement statute was necessary "to avert serious and often irreversible damage to pregnant minor's health). And, while the medical evidence suggested that removing the fetus intact is a safer procedure with less potential for tearing and puncturing of the uterus, infection, and other complications, medical evidence showed a "non-intact" D&C procedure never imposes any significant health risks.

The law did not include a health exception. The Court reasoned the premise in *Casey*, that from the inception of the pregnancy, the government has a regulatory interest in protecting the life of the fetus that may become a child, "cannot be set at naught by interpreting Casey's requirement of a health exception so it becomes tantamount to allowing a doctor to choose the abortion method he or she might prefer." "Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession, . . ." *id.* at 158, which in *Gonzales* it did to promote respect for life, including life of the unborn.

The Sixth Circuit in *Planned Parenthood Southwest Ohio v. DeWine*, 696 F.3d 490 (6th Cir. 2012) considered a substantially similar statute to the one presented to this Court. Following *Gonzales*, the Sixth Circuit concluded that the right to choose abortion does not encompass the right to choose a particular abortion method. *Id.* at 514-515. Under Supreme Court precedent the sole question is whether the regulation unduly burdens a woman's right to choose to have an abortion. *Id.* at 516. The court in *DeWine* found that surgical abortions remained a viable alternative to medication abortions and, therefore, the statute passed

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unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose." *Id.* at 146 (quoting *Casey*, 505 U.S. at 877).

constitutional muster. *Id.* Evidence of women's preferences regarding methods was not enough to create a material question of fact pertaining to whether the law imposed a substantial obstacle to a woman's right to choose to have an abortion. *Id.* at 514 n.1, 515-516.

Of course the same remains true here, the same alternative to medication abortions remains available to women in Arizona: a surgical procedure– vacuum aspiration or suction curettage.

The Fifth Circuit has also considered the constitutionality of a RU-486 regulation that restricts its use to the instructions provided in the FDL. The court explained that when regulating abortion, the legislature need only provide a rational basis for its law. The Court must presume the law to be rational. Any conceivable rationale and even rational speculation suffices as a basis for sate regulatory action, and the legislature need not produce any evidence to sustain the rationality of its statute. *Planned Parenthood v. Abbott*, No. 13-51008, slip op. at 14-17 (5th Cir. March 27, 2014) opinion issued March 27, 2014 (citing *Heller v. Doe*, 509 U.S. 312, 320 (1993); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985), *but see*, *Planned Parenthood v. Van Hollen*, 738 F.3d 786, 787 (7th Cir. 2013) (granting preliminary injunction because evidentiary record was sparse regarding evidence supporting rational basis for imposing admitting privileges requirement on abortion clinics). The Court notes that preliminary injunctions were granted in both *DeWine* and *Abbott*, but these courts ruled preliminarily without the benefit their dispositive rulings afford this Court.

The State follows *DeWine* and *Abbott* and stands on the legislative findings of fact to support the rational basis for HR 2036. Legislative finding #13 reflects that abortion-inducing drugs are associated with increased risk of complications by failure to complete the two-step medication dosage process and findings of fact 14 and 15, reflect various negative outcomes related to medication abortions based on an FDA Mifepristone United States

Postmarketing Adverse Events Summary through 4/30/2011. There is no evidence before the Court regarding any supporting evidence for any asserted legislative fact, but the State bears no such burden.

Plaintiffs have come forward with evidence that reflects medication abortion is extremely safe and safer than the alternative surgical procedure, which is also a very safe procedure. The current medication abortion protocol being precluded by HR 2036 is considered the best practices,"evidence-based"[4] medicine by practicing doctors in Arizona and elsewhere, and endorsed by American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA). *See* (Motion (Doc. 8), Ex. 2: Grossman Decl.¶ 29, 35.) Plaintiffs' evidence reflects there is a clear advantage to the current protocol because it may be used through the 9th week of pregnancy, not just through the 7th week, which is significant because many women do not discover their pregnancies until approximately 49 days, which is the end of 7th week. *Id.* Also, risk factors from medical abortions, such as those cited in the legislative findings from the FDA 2011 report have been reduced or eliminated by the current buccal regimen; medication abortion now has a lower rate of ongoing pregnancies and fewer surgical interventions are necessary to complete the abortion procedure. *Id.* ¶ 33, 43, 44, 46.

This evidence does not, however, suggest that there is no rational basis for the State's regulation. The State need not legislate the best means by which to achieve a goal. There is no least restrictive means component to rational basis review; rational speculation will suffice. An imperfect fit can be rational, and it is not for the Court to "improve" or "cleanse' the legislative process. *Abbott* at 15. Where legislative predictions prove wrong, the legislation can be changed. *Abbott* at 14-15) (citing *Heller v. Doe*, 509 U.S. at 319-321). Importantly, "the determination does not lend itself to an evidentiary inquiry in court, the

[4]Less accurately described as "off-label" use.

state is not required to 'prove' that the objective of the law would be fulfilled." *Id.* at 14 (citing *F.C.C. v. Beach Cmmc'ns, Inc.*, 508 U.S 307, 313 (1993)).

Plaintiffs specifically challenge the correctness of all the legislative findings of fact, *id.* ¶¶ 36-48. But, it is not enough that the legislature may have incorrectly predicted that a law will benefit the community. *Abbott* at 14. Plaintiffs strongest argument is that the risks associated with medication abortions, relied on by the State as the reason for adopting the FDL protocol, have been substantially reduced or eliminated by the sublingual administration of one 800 mcg tablet of misoprostol, which will be precluded under HR 2036. Additionally, the FDL protocol requires a dose of mifepristone three times higher than necessary. To prevail, however, Plaintiffs must show more than a disagreement that the MDL is a less safe protocol, *Gonzales*, 550 U.S. at 162-64, and more than simply an imperfect fit, *Heller*, 509 U.S. at 321. Where reasonable minds can disagree, there is a rational basis, *Beach Commc'ns*, 508 U.S. at 315.

Before turning to the undue burden analysis, the Court notes that the *DeWine* court concluded there can be no separate constitutionally asserted violations under the equal protection clause or of the right to bodily-integrity because under *Casey* the test for the constitutionality of a law regulating abortion is undue burden. In other words, these claims become "part and parcel" of the "undue-burden framework," subject to rational basis review. *DeWine*, 696 F.3d at 507-508. The Court must also consider the Plaintiffs' claim that the statute is void for vagueness.

Plaintiffs assert that the express language of the statute lends itself to two different interpretations. First, the statute requires that "any medication, drug or other substance used to induce an abortion" be administered in compliance with the "protocol" that is authorized by the FDA and that is outlined in the FDL "for that medication, drug or substance." A.R.S. § 36-449.03(E)(6). Misoprostol is such a drug and has been approved by the FDA only for use on ulcers. *Cf. Cline v. Oklahoma Coalition for Reproductive Justice*, 313 P.3d 253, 260

(Okla. 2013) (finding state statute substantially similar to Arizona's law prohibits the use of misoprostol to induce abortions because express language reflected legislative intent to reach all abortion-inducing drugs, including misoprostol). Therefore, physicians will believe the use of misoprostal is precluded because it has not been approved as an abortifacient.

Second, Plaintiffs present evidence that the FDA does not approve or authorize drug protocols. It's approval allows drug manufacturers to advertise and promote the drug for a particular use. (Motion (Doc. 8), Ex. 3: Rarick ¶ 8.) The FDL is an informational document that provides physicians with guidance about how to use a drug based on use information prepared and submitted by the drug sponsor to the FDA. *Id.* ¶ 11. The FDA requires FDL updates for safety, but not for new uses. *Id.* ¶ 12.

After a drug is approved by the FDA, physicians generally do and are generally expected to use it "off-label,"or more accurately described: "evidence based" use. This is considered: "Good medical practice and the best interests of the patient" and physicians are required to use legally available drugs, biologics and devices according to their best knowledge and judgment. *Id.* ¶ 18. (citing FDA Information Sheet, *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices*," *see also Cline*, 313 P.3d at 260 (finding FDA-approved labeling is "not intended to limit or interfere with the practice of medicine nor to preclude physicians of medicine from using their best judgment in the interest of the patient") (citing FDA Drug Bulletin 12:4-5, 59 Fed. Reg. 59,820, 59, 821 (Nov. 18, 1994);*Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir.1989) (rejecting argument that Medicaid could rely on FDA approval statement in limiting coverage of AZT as reasonable because FDA approval not intended to interfere with practice of medicine nor preclude physicians from using their best judgment in the best interest of patient).

Plaintiffs assert that a physician knowledgeable regarding the FDA approval process will be confused in regard to the statute's requirement to administer the drug under the

protocol authorized by the FDA because no such protocol exists, and therefore, believe they cannot use RU-486 under any circumstances.

The State submits any confusion or ambiguity in the statute is clarified by legislative fact #9, which expressly and specifically defines the, "as approved by the FDA and outlined in the FDL," protocol for mifepristone to consist of: 1) three 200 mg tablets of mifepriston taken orally, followed by two 200 mcg tablets of misopristol taken orally. This Court finds there is little likelihood Plaintiffs will prevail on the vagueness challenge. The finding of fact #9 expresses the clear legislative intent to preclude the use of these two drugs, except for by giving: 1) three 200 mg tablets of mifepriston to be taken orally, followed by two 200 mcg tablets of misoprostol to be taken orally. For example, the current protocol of administering only one 200 mg tablet of mifepriston is precluded. Likewise, the current protocol of administering, buccally, one 800 mcg of misoprostol is precluded.

The Court turns to the undue burden balancing test prescribed in *Casey*. Defendants explain that a common alternative method of abortion is available: a surgical procedure commonly known as vacuum aspiration or suction curettage. Before 2000, this was the mainstay first-trimester abortion procedure. "[S]urgical abortions in the first trimester are extremely safe and, for most healthy women, can take less than five to ten minutes at an outpatient clinic, usually with only local anesthesia and often sedation. Briefly, a surgical abortion is performed by inserting a speculum into the woman's vagina, dilating the cervix, and then inserting a tube into her uterus that empties the contents by suction. Side effects include bleeding and cramping. Surgical abortions have been performed for decades, and the mortality rate is extremely low at roughly .1 per 100,000." *DeWine*, 695 F.3d at 493. Currently, vacuum aspiration or suction curettage remains the most common first trimester abortion procedure, with RU-486 being used by approximately 41 percent of women. (Reply (Doc. 24), Ex. 2L Kress Decl. ¶ 6.)

Plaintiffs assert the FDL protocol precluding medication abortions in the 8th and 9th week of pregnancy imposes an undue burden on some women who, for medical reasons, can not safely have a surgical abortion. These medical conditions include the following:**:** anomalies of the reproductive and genital tract, large uterine fibroids, female genital mutilation, vaginismus, or cervical stenosis, severe obesity or extremely flexed uterus. *Id.* ¶ 21. Some women have psychological conditions that make a medication abortion better than a surgical abortion, including: those who fear surgical procedures, victims of rape, or women who have experienced sexual abuse or molestation. *Id.* ¶ 20. A medication abortion is substantially similar to a miscarriage and, consequently, less traumatic than a surgical proceeding to terminate a pregnancy. *Cf.*, *Gonzales*, 550 U.S. at 159-160 (discussing psychological implications of abortion method in the context of "intact" D&C as most potentially traumatic because it is like infanticide). The statute does not contain a health exception allowing these women to obtain medication abortions at the 8 and 9 gestational stage in their pregnancies. Plaintiffs assert the statute is unconstitutional because it lacks a health exception for these women. Additionally, as for these women who do not discover their pregnancy until late in the 8th week,[5] they are banned from choosing to have an abortion if a surgical proceeding is precluded by their medical condition.

Plaintiffs submit evidence supporting their assertion that in respect to all women seeking medication abortions, the FDL protocol is an undue burden because it increases cost, will result in unavailability of medication abortions due to clinic shut downs, and other burdens which have generally not been held substantial obstacles to a women's access to abortion. *Abbott* at 27 n. 15 (citing *DeWine*, 696 F.3d at 514-15 relying on *Casey*, 505 U.S. at 885-886, 901). The State's response is simple: there is little substantive difference between the two medication abortion protocols, and in every instance except perhaps for

[5]Many women do not detect pregnancy until close to 49 days LMP: week seven (43 days through 49 days). (Motion (Doc. 8), Ex. Grossman Decl. ¶ 34.)

women with certain medical conditions, women are free to obtain a safe and readily available method of abortion: vacuum aspiration or suction curettage.

The Sixth Circuit found evidence that women preferred one method of abortion over another was not sufficient to even raise a triable question of fact. To create a substantial obstacle to the abortion right, the law must "impose an undue burden on 'a woman's ability to make th[e] decision to have an abortion.'" *DeWine*, 696 F.3d at 514. The court considered whether in a large fraction of the cases in which the law is relevant, it will operate as a substantial obstacle to a woman's choice to have an abortion. The answer was no. In a large fraction of cases, the law will simply change the method of abortion. *Id.* at 514-515. The Court realizes that the evidence in this case may differ from the evidence presented to the Sixth Circuit, but the principals and logic remain the same. Given the ready availability of a safe alternative method of abortion, Plaintiffs have a difficult evidentiary burden to establish HR 2036 is a substantial obstacle to a woman's right to obtain a first trimester abortion in Arizona.

The remaining question is whether the 8th and 9th week limitation in HR 2036 is a substantial obstacle for some women with certain medical conditions, who cannot safely undergo the alternative surgical procedure. To prevail on this claim if the statute is, otherwise, constitutional, the Plaintiffs must establish that the lack of a health exception imposes a significant health risk. *Gonzales*, 550 U.S. at 161. It is not enough to show that there is simply a medical disagreement as to whether prohibiting medication abortions in the 8th and 9th week of pregnancy would actually impose a significant health risk. *Id.* at 162-164. At this time, Plaintiffs proffer no more than a list of medical conditions, without any explanation regarding significant health risks. More importantly, Plaintiffs should have brought an "as-applied challenge, which is the proper means for challenging the lack of an exception to the regulations at issue, 'the nature of the medical risk can be better quantified and balanced than in a facial attack.'" *Abbott* at 33 (citing *Gonzales*, 550 U.S. at 167).

Conclusion:

Given the rational basis analysis applicable in this case and the availability of a safe and common method of abortion for women in the first trimester of pregnancy, the Court finds that it is not likely the Plaintiffs will prevail on the merits of their Complaint.

For these same reasons the Court finds that Plaintiffs are not likely to suffer irreparable harm in the absence of preliminary relief. In the context of irreparable harm, the Court has considered that some women, especially those in Flagstaff, will have greater difficulty securing medication abortions when the law is implemented. Women in northern Arizona, who are eight and nine weeks pregnant, will have to travel several hundred extra miles and may have to secure overnight lodging to obtain a surgical procedure because the clinic in Flagstaff only provides medication abortions. If the Flagstaff clinic closes entirely, all women in northern Arizona will have to do the same to obtain any abortion procedure. As for all women throughout the state, medication abortions will cost more and require more time and effort to secure. Women will have to make two trips to the clinic, instead of one. This obviously increases the difficulty in obtaining the procedure because it requires them to twice take off work, get day care, etc. Whether or not these factors are substantial obstacles to abortion remains to be seen, but based on the limited record before the Court they do not qualify as irreparable harm. These type of burdens may become substantial obstacles in the aggregate, (Reply (Doc. 28) at 14 (citation omitted), but in and of themselves are not sufficient to tip the balance of equity for Plaintiffs. Because the Court finds it unlikely that Plaintiffs will prevail on the merits of the constitutional claims, it rejects that notion as irreparable injury. *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (finding a violation of constitutional rights 'unquestionably constitutes irreparable injury). Accordingly, the Court finds that the injunction is not in the public interest. *Cf., Sammartano v. First Judicial District Court*, 303 F.3d 959, 974 (9th Cir. 2002) (describing public interest in protecting constitutional right under the First Amendment).

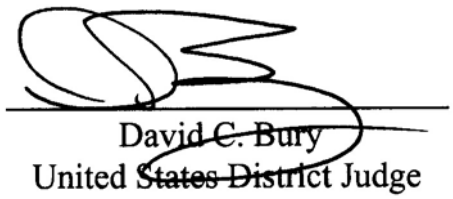
The Court finds that the Plaintiffs are not entitled to preliminary relief because they have not established serious questions going to the merits nor that the hardship balance tips sharply towards them.

Accordingly,

IT IS ORDERED that the Motion for Temporary Restraining Order/Motion for Preliminary Injunction (Doc. 14) is DENIED.

IT IS FURTHER ORDERED that the Court shall set a Scheduling Conference, pursuant to Fed. R. Civ. P. 16.

DATED this 31st day of March, 2014.



David C. Bury
United States District Judge