No. _____

In the Supreme Court of the United States

WILLIAM HUMBLE, DIRECTOR OF THE ARIZONA DEPARTMENT OF HEALTH SERVICES, IN HIS OFFICIAL CAPACITY,
Petitioner,

v.

PLANNED PARENTHOOD ARIZONA, INC.; WILLIAM RICHARDSON, M.D., DBA TUCSON WOMEN'S CENTER; WILLIAM H. RICHARDSON, M.D., P.C., DBA TUCSON WOMEN'S CENTER,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

A plurality of this Court has settled on the appropriate standard for evaluating the constitutionality of abortion regulations: "[o]nly where state regulation imposes an undue burden on a woman's ability to make [the abortion] decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 854 (1992). A State's regulation is invalid if it "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. Federal appellate courts have now reached contrary conclusions regarding how a reviewing court determines whether a facially challenged rational abortion regulation creates a substantial obstacle.

The question presented is whether an abortion regulation that is rationally related to the State's interest in maternal health creates an undue burden and is therefore invalid (a) only when it erects a substantial obstacle to obtaining a previability abortion, as the Fifth and Sixth Circuits held, or (b) when "the extent of the burden a law imposes on a woman's right to abortion" outweighs "the strength of the state's justification for the law," as the Ninth Circuit held in the decision below. (App. 15, 19.)

PARTIES TO THE PROCEEDING

All parties to the proceeding below are included in the caption of the case on the cover page of this brief.

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William Humble, the Director of the Arizona Department of Health Services ("the Department"), petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The Ninth Circuit's opinion (App. 1-27) is reported at 753 F.3d 905 (9th Cir. 2014). The order that the United States District Court for the District of Arizona entered (App. 28-45) is not yet reported but is available at 2014 WL 1377827 (March 31, 2014).

JURISDICTION

The court of appeals' judgment was entered on June 3, 2014. Petitioner invokes this Court's jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

The Fourteenth Amendment to the United States Constitution provides that no State shall "deprive any person of life, liberty, or property, without due process of law."

Arizona Revised Statutes ("A.R.S.") section 36-449.03(E)(6), enacted in 2012, states:

> The director [of the Arizona Department of Health Services] shall adopt rules relating to the abortion procedure. At a minimum these rules shall require . . . [t]hat 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 and that is outlined in the final printing labeling instructions for that medication, drug or substance.

Arizona Administrative Code ("A.A.C.") section R9-10-1508(G), adopted in 2014, states:

> A medical director [of an abortion clinic] shall ensure that any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.

STATEMENT OF THE CASE

This Petition arises out of Respondents' complaint for declaratory relief and preliminary and permanent injunctive relief challenging the constitutionality of the applicable Arizona medication abortion statute and rule. *See* A.R.S. § 36-449.03(G)(1); A.A.C. § R9-10-1508(G) (collectively the "Arizona law"). This case involves irreconcilable lower court interpretations of the "undue burden" standard applicable to state previability abortion regulations. It arises in the context of state laws regulating medication abortion, a method that involves the use of drugs to induce and complete an abortion as an alternative to surgical abortion. The state laws incorporate a Food and Drug Administration approved protocol that Respondents claim imposes an undue burden.

Facing comparable substantive due process challenges to comparable medication abortion laws, the circuits have split based on their different interpretations of the undue burden standard. The Fifth and Sixth Circuits found that Texas and Ohio regulations did not create an undue burden, citing among other things the availability of surgical abortion, a safe and more common method of abortion unaffected by the state laws. But the Ninth Circuit found that Arizona's regulation did create an undue burden, notwithstanding the availability of surgical abortion, after applying the undue burden test in a way that the Fifth and Sixth Circuits did not. Specifically, the Ninth Circuit found that the Arizona law created an undue burden under a weighing test in which it weighed increased costs, delay, and "stigmatization" claimed by Respondents against what it perceived as the State of Arizona's interests in the law. Review is necessary to resolve this circuit split on the way that courts interpret and apply the undue burden standard.

A. Medication Abortion Statutes.

The circuit split implicates Arizona, Texas, and Ohio statutes that require medication abortion providers to follow an FDA-approved protocol. The FDA-approved protocol differs from Respondents' nonapproved (or "off-label") protocol in that the FDA-approved protocol (1) permits medication abortion through the seventh week of pregnancy rather than the ninth week, (2) requires a lower dosage of one drug (misoprostol) and a higher dosage of another drug (mifepristone), and (3) requires the patient to return to the abortion provider to take the second drug. (App. 31.)

The Arizona law does not ban medication abortion and does not affect surgical abortion. Surgical abortion is the most commonly used abortion method in Arizona, including for abortions occurring before the thirteenth week of pregnancy. Arizona Department of Health Services, Abortions in Arizona: 2012 Abortion Report, 23, 29 (Aug. 1, 2013) (stating that in 2012, sixty-eight percent of all abortions performed in Arizona were surgical abortions and indicating that sixty-five percent of abortions performed before thirteen weeks' gestation were surgical abortions), *available at* http://www.azdhs.gov/diro/reports/pdf/2012-arizona-abortion-report.pdf.

The Legislature's stated purpose for the Arizona law is two-fold. First, to "[p]rotect women from the dangerous and potentially deadly off-label use of abortion inducing drugs, such as, for example, mifepristone." Arizona House Bill 2036, H.R. 2036, 50th Leg., 2d Reg. Sess., § 9(B)(2) (Ariz. 2012). Second, "to [e]nsure 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." *Id.* § 9(B)(3).

Numerous legislative findings support this purpose. The Legislature found that the mifepristone use presents significant medical risks to women because of possible infection, sepsis, and hemorrhaging. *Id.* § 9(A)(12). The Legislature also found that "[a]bortion-inducing drugs are associated with increased risk of complications relative to surgical abortions," that "[t]he risk of complications increases with increasing gestational age," and that for medication abortions initiated with mifepristone, there is an increased risk

due to the failure to complete the two-step medication dosage process. *Id.* § 9 (A)(13).[1] The Legislature noted the specific and documented negative outcome statistics cited in the FDA's *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011*. *Id.* § 9(A)(14)-(15). Those negative outcomes include 2207 cases with adverse events, 612 hospitalizations, 339 cases requiring blood transfusions to combat excessive bleeding, 256 infections, 58 ectopic pregnancies, and 14 deaths. *Id.*

B. Respondents' Suit to Enjoin Enforcement of Arizona's Medication Abortion Statute and Related Regulation.

As A.R.S. § 36-449.03 directed, the Department adopted rules to regulate medication abortions consistent with the medication abortion statute enacted in 2012. A.A.C. § R9-10-1508(G).

Before the rules took effect, Respondents filed suit in federal district court seeking to enjoin the Department from enforcing the Arizona law and to have it declared unconstitutional. The district court denied Respondents' motion for a temporary restraining order and preliminary injunction on March 31, 2014. (App. 45.)

The district court found that the State's adoption of the FDA-approved protocol for medication abortions did not create a substantial obstacle to a woman's right to obtain a first trimester abortion because surgical abortion—the safe and most common method of first

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[1] Respondents' off-label protocol allows dosages of misoprostol to be self-administered at home. (App. 31.)

trimester abortion—remained readily available. (App. 42-43.) The district court concluded that because the Arizona law did not create a substantial obstacle to a woman's right to obtain an abortion in a large fraction of relevant cases, the law did not impose an undue burden. (App. 42.)

Respondents filed an interlocutory appeal the following day. The Ninth Circuit granted Respondents' "emergency motion for an injunction pending appeal" and, after briefing and oral argument, reversed the district court's denial of the motion for a temporary restraining order and preliminary injunction. (App. 27.)

C. The Ninth Circuit's Analysis of the Likelihood of Success on the Merits.

In assessing Respondents' likelihood of success on the merits, the Ninth Circuit panel assumed without deciding that the Arizona law satisfied rational-basis review. (App. 19.) Accordingly, it addressed only the undue burden analysis, i.e., whether the Arizona law created a substantial obstacle to a woman's right to choose to have an abortion. (*Id*.) Toward that end, the panel recited the applicable rule set forth in *Planned Parenthood of Southeast Pennsylvania v. Casey*, 505 U.S. 833, 895 (1992), that "in order to show an undue burden, plaintiffs must show that, 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 undergo an abortion." (App. 19 [internal quotation marks omitted].)

However, the panel did not resolve the likelihood of success on the merits by addressing whether the

Arizona law created a substantial obstacle for a large fraction of the women whom it affected. Instead, expressly noting that its analysis conflicted with the recent Fifth and Sixth Circuit decisions in *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 748 F.3d 583 (5th Cir. 2014), and *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490 (6th Cir. 2012), the panel applied a weighing test of its own invention, "compar[ing] the extent of the burden a law imposes on a woman's right to abortion with the strength of the state's justification for the law." (App. 15.) Elaborating, the panel opined that "[t]he more substantial the burden, the stronger the state's justification for the law must be to satisfy the undue burden test; conversely, the stronger the state's justification, the greater the burden may be before it becomes 'undue.'" (*Id.*) Accordingly, the panel concluded that it "must weigh the burdens against the state's justification, asking whether and to what extent the challenged regulation actually advances the state's interests." (*Id.* at 16.)

Applying its newly developed weighing test, the Ninth Circuit held that the district court abused its discretion when it found that Respondents were unlikely to succeed on the merits of their undue burden claim. Shifting the burden to the state, the Ninth Circuit disregarded the legislative findings as unsupported and found that the state did not establish that the Arizona law furthered any interest in women's health. (App. 20.) The court then examined three types of burdens discussed in *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 541-43 (9th Cir. 2004), and asserted that they existed in this case based on what the panel characterized as Respondents'

"uncontroverted" written submissions: increased costs and inconvenience, deterrence and delay that increase health risks, and "stigmatizing of abortion practice and usurping of providers' ability to exercise medical judgment." (App. 21.) Through this analysis the Ninth Circuit concluded that Respondents had "introduced uncontroverted evidence that the Arizona law substantially burdens women's access to abortion services, and Arizona has introduced no evidence that the law advances in any way its interest in women's health." (App. 24.) Based on what it derived from the materials that Respondents had attached to their complaint and their preliminary injunction motion, the Ninth Circuit held that "the burden imposed by the Arizona law is undue within the meaning of *Casey* and *Gonzales* [*v. Carhart*, 550 U.S. 124 (2007)]." (App. 24.)

D. Stay of the Mandate.

The Ninth Circuit has stayed the mandate pending the filing of the state's Petition, but the interim emergency injunction remains in effect. Accordingly, the Arizona law is not currently being implemented.

REASONS FOR GRANTING THE PETITION

The Ninth Circuit's new weighing test created a circuit split and considerable confusion concerning the application of this Court's substantive due process doctrine as it applies to state regulation of abortion. The Ninth Circuit acknowledged that its decision conflicts with *Abbott* and *DeWine*, neither of which "compare[d] the extent of the burden a law imposes on a woman's right to abortion with the strength of the state's justification for the law" in deciding whether

that law creates an undue burden under *Casey*. (App. 15.)

The panel recognized that "the Fifth and Sixth Circuits consider the state's justification only for the very limited purpose of applying rational-basis review" and do not consider "whether the regulation has been shown actually to advance the state's legitimate interests." (App. 18.) The panel then concluded that *Abbott* and *DeWine* were "inconsistent with the undue burden test as articulated and applied in *Casey* and *Gonzales*" because "[t]he Fifth and Sixth Circuits' approach fails to recognize that the undue burden test is context-specific, and that both the severity of a burden and the strength of the state's justification can vary depending on the circumstances." (App. 19.)

As those statements indicate, the circuits are now interpreting *Gonzales* and *Casey* in irreconcilable ways and applying different analyses to determine whether an abortion regulation creates an unconstitutional undue burden. These divergent views of this Court's undue burden framework have resulted in contrary outcomes in cases challenging comparable abortion regulations. Moreover, the Ninth Circuit's analysis implicitly expands the established right to choose to have a previability abortion to include the right to choose the abortion method, even where a regulation does not affect the most commonly used, safe method and without evidence that the regulation will prevent a large fraction of women whom the Arizona law affects from obtaining an abortion. This Court should grant review to resolve the circuit split and clarify that Arizona's regulation of medication abortions is valid under *Casey*'s undue burden standard.

Although the Ninth Circuit has remanded this case for entry of a preliminary injunction, the Court has recognized that "there is no absolute bar to review of nonfinal judgments of the lower federal courts" and that the interlocutory character affects only the prudential calculus of whether certiorari should be granted. *See, e.g., Mazurek v. Armstrong*, 520 U.S. 968, 971-75 (1997) (per curiam) (summarily reversing an interlocutory order where the Ninth Circuit clearly erred in its application of *Casey*'s undue burden test and its erroneous decision would have immediate consequences in the case before it as well as in the other States in the Ninth Circuit). When "there is some important and clear-cut issue of law that is fundamental to the further conduct of the case and that would otherwise qualify as a basis for certiorari, the case may be reviewed despite its interlocutory status." Robert L. Stern et al., *Supreme Court Practice*, 259 (8th ed. 2002). Indeed, this Court has granted review of interlocutory court of appeals decisions innumerable times.[2]

This case warrants the Court's immediate review for the reasons that the Court found compelling in *Mazurek*. First, like the Ninth Circuit determination that the Court reversed in *Mazurek*, 520 U.S. at 971, the Ninth Circuit decision here did not apply the undue burden test that *Casey* requires and its erroneous standard will govern the district court's determination on remand. Second, like the Ninth Circuit's order in

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[2] Recent examples include *Cutter v. Wilkinson*, 125 S. Ct. 2113 (2005); *Norfolk S. Ry. v. Kirby*, 125 S. Ct. 385 (2004); *Jones v. R.R. Donnelly & Sons Co.*, 541 U.S. 369 (2004); and *Gratz v. Bollinger*, 539 U.S. 244 (2003).

Mazurek, 520 U.S. at 975, the Ninth Circuit has stayed implementation of Arizona's law and its decision will have consequences in the eight other States in the Ninth Circuit. Granting review is even more compelling here than in *Mazurek* because the Ninth Circuit's new weighing test created a circuit split.

I. This Court Should Grant Review to Resolve the Circuit Split Concerning the Correct Application of the Undue Burden Standard.

A. The Fifth and Sixth Circuits Recognized that an Abortion Regulation that Is Rationally Related to the State's Interest in Protecting Maternal Health Is Valid if It Does Not Impose an Undue Burden on a Woman's Right to Choose an Abortion.

The Fifth and Sixth Circuits upheld medication abortion statutes that are comparable to the Arizona law, rejecting the same substantive due process arguments that Respondents made in the case below. Those courts interpreted this Court's precedent as requiring two determinations in facial challenges to previability abortion regulations: (1) whether the challenged statute has a rational basis and, if so, (2) whether it creates a substantial obstacle to obtaining an abortion for a large fraction of the women whom the statute affects. *Abbott*, 748 F.3d at 590; *DeWine*, 696 F.3d at 514.

Specifically, the undue burden analysis in the Fifth and Sixth Circuits turned on whether the medication abortion law created a substantial obstacle for a large fraction of women who seek an abortion during their eighth and ninth weeks of pregnancy and who prefer

medication abortion over surgical abortion. *Abbott*, 748 F.3d at 604; *DeWine*, 696 F.3d at 514-15.

In the Fifth and Sixth Circuit decisions, the courts did not require the States to prove that their laws advanced maternal health and did not weigh the State's interests against the affected women's burdens. Rather, the decisions presume that the substantial obstacle requirement formulated in *Casey* has already balanced the State's interest in rational abortion regulation against the due process right to choose to have an abortion. *See also Cook v. Gates*, 528 F.3d 42, 55 (1st Cir. 2008) ("[I]n *Casey*, the Supreme Court reaffirmed a woman's fundamental right to choose to have an abortion but applied the 'undue burden' test which balanced the state's legitimate interest in potential human life against the extent of the imposition on the woman's liberty interest.") (internal citation omitted).

Applying principles set forth in *Gonzales*, the Fifth and Sixth Circuits correctly determined that restrictions on medication abortion cannot create a substantial obstacle under *Casey* if the more common surgical method remains available, unless the party challenging the ban can show that a large fraction of women whom the regulation affects cannot undergo surgical abortion. *See Abbott*, 748 F.3d at 604-05 (holding no substantial obstacle where Planned Parenthood had not clearly defined the conditions in which medication abortion was necessary to avert medical risk during the eighth or ninth week and experts disagreed whether medication abortions were "actually safer" for women who had conditions that purportedly heightened the risks of surgical abortion);

DeWine, 696 F.3d at 508 (quoting the district court's conclusion, which it affirmed, that the medication abortion statute did not create an undue burden "because 'it is undisputed that the Act does not impact the[ ] ability to choose a safe, commonly used method of abortion,' i.e., a surgical abortion"); *id.* at 515 ("[T]he [United States Supreme] Court has not expressly endorsed an approach that would protect the right to choose *a particular method* of abortion"); *id.* at 515-16 (stating that some women's preference for medication abortion over surgical abortion does not support "the conclusion that the unavailability of a [medication] abortion would create a *substantial obstacle* for a large fraction of women in deciding whether to have an abortion").

Both *Abbott* and *DeWine* found that the continuing availability of surgical abortion defeated a claim of facial invalidity under the "substantial obstacle" analysis because Planned Parenthood could not show that a large fraction of women who cannot obtain a medication abortion in the relevant two-week period cannot safely obtain a surgical abortion. *Abbott*, 748 F.3d at 604; *DeWine*, 696 F.3d at 515-16. To the contrary, the court in *DeWine* observed that the attestations from nine women who could not obtain medication abortions undermined the substantial obstacle showing because all nine women were able to obtain surgical abortions. *Id*. at 516. That conclusion logically follows the premise that an obstacle is substantial only if it prevents a large fraction of affected women from exercising the choice to undergo an abortion, as opposed to preventing them from choosing the *method* of abortion. When all nine women

whom the regulation affected were able to obtain a safe abortion, the obstacle was necessarily insubstantial.

B. The Ninth Circuit Incorrectly Applied a Weighing Test of Its Own Making Rather than *Casey*'s Undue Burden Test.

Rejecting the Fifth and Sixth Circuits' interpretation of *Casey* and *Gonzales* that resulted in those courts upholding medication abortion statutes similar to the Arizona law, the Ninth Circuit found that Arizona's law was unconstitutional because the State did not demonstrate that its interests in protecting maternal health outweighed the burdens that the Arizona law created. Under the Ninth Circuit's formulation, courts must now address factors that this Court neither discussed nor applied in *Casey* and *Gonzales*: (1) the strength of the State's justification for the regulation, (2) the extent to which the regulation advances the statute's purpose, (3) the relative degree to which the regulation obstructs a woman's ability to choose to have an abortion (as opposed to simply whether the obstacle is substantial), and (4) a determination of whether the first two factors outweigh the third. (App. 15-16.)

Here, assuming that the medication abortion regulation was rational and addressing those additional factors, the Ninth Circuit appears to have concluded that the State's justification was entitled to no weight at all because (in its view) the State did not provide evidence that the Arizona law furthers any interest in women's health. (App. 19-21.) As its opinion notes, the State relied on legislative findings that explained the statute's rationale and purposes. (App. 20.) Under the rational-basis test, the State may rely

on legislative findings to support its argument that the Arizona law furthers the State's legitimate interest in protecting maternal health. *See Heller v. Doe*, 509 U.S. 312, 320 (1993) ("A State . . . has no obligation to produce evidence to sustain the rationality of a statutory classification.").

The court went on to examine the obstacles that the Arizona law created, stating that they "substantially burden[ed] women's access to abortion services" in terms of increased costs and inconvenience, deterrence and delay, and "stigmatizing of abortion practice and usurping of providers' ability to exercise medical judgment." (App. 20-21.) But the court did not conclude those obstacles were "substantial," nor did it examine whether the Arizona law prevented a large fraction (or any) of the women whom the law affected from exercising the right to obtain an abortion.[3] Rather than following *Casey*, the court decided that increased costs, delay, and deterrence in obtaining an abortion were more significant than the Arizona Legislature's justification for the regulation and therefore held that the Arizona law was unconstitutional. (App. 16 ["[W]e must weigh the burdens against the state's justification, asking whether and to what extent the challenged regulation actually advances the state's interest."]), (App. 24 [finding the burdens "undue within the meaning of *Casey*"]).

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[3] Indeed, in *Casey*, this Court held that the increased burdens of cost and delay that could result from a law requiring a 24-hour waiting period did not constitute an undue burden. 505 U.S. at 874, 886.

The Fifth and Sixth Circuits' application of the undue burden test rests on a fundamentally different interpretation of *Casey* and *Gonzales* than the Ninth Circuit's interpretation of the undue burden test under that precedent. Courts within the Fifth and the Sixth Circuit will necessarily apply the undue burden standard in a way that conflicts with decisions by courts within the Ninth Circuit. Because these two different applications of this Court's precedent cannot be harmonized, this Court should grant review.

Review is also warranted because the Ninth Circuit found that the Arizona law was invalid even though it did not affect the availability of surgical abortions and there was no dispute that this alternative, safe method of abortion remained available to Arizona women. In *Gonzales*, this Court stated that when a statute "allows, among other means, a commonly used and generally accepted method" of abortion, "it does not construct a substantial obstacle to the abortion right." 550 U.S. at 165. In contrast to the Ninth Circuit, the Fifth and Sixth Circuits relied on the availability of surgical abortions in determining that the plaintiffs had not demonstrated that the regulation of medication abortions imposed an undue burden.

The Ninth Circuit held that "[t]he availability of on-label medication abortions during the first seven weeks of pregnancy, and of surgical abortions thereafter . . . does not preclude a finding of undue burden." (App. 25.)[4] That would be true under the Fifth and Sixth Circuit's approach only if Planned Parenthood had

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[4] "On-label" refers to the FDA-approved protocol that abortion providers must follow under the Arizona regulation.

shown that the Arizona law would actually prevent a large fraction of women who would otherwise undergo a medication abortion during the eighth or ninth week of pregnancy from obtaining a surgical abortion in the same time frame (or at any time up to the point of viability). The Ninth Circuit's conclusion instead rested on Planned Parenthood's attestations that the regulation would cause "a significant increase in the cost of medication, and that many women will be delayed in, or deterred from, seeking an abortion if the evidence-based regimen is foreclosed to them." (App. 25.)[5] That conclusion is supportable only under the Ninth Circuit's approach, where these considerations can outweigh the State's purportedly "non-existent" health and safety objectives, even if *all* women who cannot obtain a medication abortion can still obtain a surgical abortion. (App. 25.)

Put more starkly, the Fifth and Sixth Circuits held that a substantial obstacle is one that prevents a substantial fraction of women whom the regulation affects from exercising their right to choose to have an abortion; while the Ninth Circuit held that an obstacle is substantial if it increases the costs, inconvenience, or undesirability of exercising the right—unless the government has a strong enough justification to outweigh such considerations and regardless whether it prevents *any* woman affected by the statute from actually obtaining an abortion. The Ninth Circuit's application of the undue burden test, which ignores the availability of a safe alternative to the regulated

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[5] The Ninth Circuit employed the phrase "evidence-based regimen" to refer to the off-label regimen that permits medication abortion through the ninth week of pregnancy.

abortion procedure, is irreconcilable with the Fifth and Sixth Circuits' application of the undue burden test. Because the Ninth Circuit's approach significantly alters and expands the meaning of an "undue burden" under *Casey*, this Court should grant the state's petition for writ of certiorari.

C. The Seventh Circuit's Application of the Undue Burden Standard Further Demonstrates that This Court's Review Is Necessary to Clarify the Undue Burden Standard's Correct Application.

In support of its decision to apply a weighing test to the undue burden analysis, the Ninth Circuit also relied on *Planned Parenthood of Wisconsin, Inc. v. Van Hollen*, 738 F.3d 786 (7th Cir. 2013), stating that the *Van Hollen* court "adopted an approach much like ours in *Eden*." (App. 18.)[6] To the extent that the Seventh Circuit's majority supports applying a weighing test, the concurrence further demonstrates that the Ninth Circuit erred in applying a weighing test instead of the undue burden test.

In *Van Hollen*, the Seventh Circuit addressed a law that required an abortion clinic's doctors to have admitting privileges at a hospital within thirty miles of the abortion clinic. 738 F.3d at 787, 798. Wisconsin enacted the law on a Friday and required compliance by the following Monday. *Id.* at 788. The *Van Hollen*

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[6] The Ninth Circuit did not adopt a weighing test in *Eden*. Instead, the court found that where "a purported health regulation fails to rationally promote an interest in maternal health on its face," the regulation fails rational-basis review and "the undue burden standard is not triggered at all." *Eden,* 379 F.3d at 540.

majority affirmed the district court's granting of a preliminary injunction, holding that the law imposed an undue burden because "the medical grounds thus far presented . . . are feeble, yet the burden great *because of the state's refusal to have permitted abortion providers a reasonable time within which to comply*." *Id.* at 798 (emphasis added). Accordingly, although the *Van Hollen* majority suggested that applying the undue burden test involved weighing the State's interest against the burden that the law imposed, it focused more on the unreasonable amount of time within which the doctors would have been required to comply than it did on whether the admitting privileges requirement itself presented an undue burden. *Id.* at 789 ("The impossibility of compliance with the statute even by doctors fully qualified for admitting privileges is a compelling reason for the preliminary injunction, albeit a reason that diminishes with time.").

Judge Manion concurred in part and in the judgment, agreeing that the court should affirm the district court's preliminary injunction because the doctors were not given a reasonable amount of time to obtain admitting privileges. 738 F.3d at 799. However, his analysis did not incorporate any weighing of interests against burdens. Relying on *Gonzales*, he articulated the appropriate standard: "[L]egislation regulating abortion must pass muster under rational basis review *and* must not have the 'practical effect of imposing an undue burden' on the ability of women to obtain abortions." *Id*. at 799 (quoting *Karlin v. Foust*, 188 F.3d 446, 481 (7th Cir. 1999)). Judge Manion specifically noted that the government need not prove that the law advances women's health; rather, the State's legitimate interest "'may be based on rational

speculation unsupported by evidence or empirical data.'" *Id.* at 800 (quoting *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993)). Judge Manion further noted that this Court "has rejected as misguided arguments that an abortion law is unconstitutional because the medical evidence contradicts the claim that the law has any medical basis." *Id.* (citing *Mazurek*, 520 U.S. at 971-75). Based on the appropriate undue burden standard, Judge Manion concluded that "Wisconsin's admitting privileges requirement is rationally related to the State's legitimate interests and should not create an undue burden to Wisconsin women's right to abortion." *Id.* at 807.

Thus, the disagreement between the *Van Hollen* majority and the concurrence about the appropriate test to apply to determine the validity of abortion regulations further demonstrates that this Court should grant review.

II. The Ninth Circuit's Application of a Weighing Test to Invalidate Arizona's Abortion Law Is Contrary to This Court's Precedent.

The Ninth Circuit's weighing test for assessing the validity of abortion-related regulations finds no support in this Court's precedents. The undue burden test adopted, explained, and applied in *Casey* simply asks whether the requirement is "likely to prevent a significant number of women [affected by the regulation] from obtaining an abortion." 505 U.S. at 893. It does not call for weighing the extent to which the law advances the state's interest against the burdens the law imposes. Later cases applying the undue burden test, such as *Mazurek* and *Gonzales*, confirm that the test asks only whether the regulation

creates a substantial obstacle to obtaining an abortion and does not call for weighing relative interests and burdens.

Justice O'Connor, writing for the plurality, set out and clarified the undue burden test, recognizing that most of the Court's abortion decisions reflected this approach and overruling portions of previous decisions that were inconsistent with the undue burden standard. *Casey*, 505 U.S. at 874 (noting that a law which "has the incidental effect of making it more difficult or more expensive to procure an abortion" is valid if it "serves a valid purpose" and that a law is invalid "[o]nly where state regulation imposes an undue burden" and listing the Court's opinions supporting this standard); *id.* at 875 (stating that "[n]ot all governmental intrusion is of necessity unwarranted" and that the Court's decisions that struck down abortion regulations that in "no real sense deprived women of the ultimate decision" went too far). The plurality clarified what is meant by an undue burden: "A finding of an undue burden is 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." *Id.* at 877. In applying the undue burden standard to the spousal notification requirement, the plurality found that it was invalid because it was "likely to prevent a significant number of women from obtaining an abortion." *Id.* at 893.

The Ninth Circuit did not apply *Casey*'s undue burden standard. It did not conclude that Arizona's regulation of medication abortions was likely to prevent any woman from obtaining an abortion. Under

Casey, a regulation creates an undue burden if "in a large fraction of cases in which [it] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." 505 U.S. at 895. Because the Arizona law regulating medication abortion is designed to foster the health of a woman seeking an abortion and does not impose an undue burden on her right to obtain an abortion, the Ninth Circuit erred in finding the law was invalid. *Casey* does not support the application of a weighing test.

The post-*Casey* cases confirm this. In *Mazurek*, the Court reversed the Ninth Circuit's determination that a law requiring physicians to perform abortions could be unconstitutional even though the district court had found "that there was insufficient evidence in the record that the requirement posed a substantial obstacle to a woman seeking an abortion." 520 U.S. at 972 (internal quotation marks omitted). The plaintiffs argued that the physician-only law must have an invalid purpose because evidence demonstrated that physician assistants could perform first-trimester abortions as safely as physicians. *Id.* at 973. The Court rejected that argument, finding that it was foreclosed by *Casey*, which emphasized that States have "'broad latitude to decide that particular functions may be performed only by licensed professionals, *even if an objective assessment might suggest that those same tasks could be performed by others.*'" *Id.* (quoting *Casey*, 505 U.S. at 885) (emphasis added in *Mazurek*).

Like the decision that this Court reversed in *Mazurek*, the decision below erroneously refused to apply *Casey*'s undue burden test. This Court should likewise reverse the Ninth Circuit's decision here.

Finally, in *Gonzales*, the Court held that the ban on partial-birth abortions was not facially unconstitutional. 550 U.S. at 166-67. In doing so, the Court reiterated the appropriate standard for evaluating an abortion regulation's facial validity: "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 interest in regulating the medical profession . . . ." *Id.* at 158. The Court also held that a statute "does not construct a substantial obstacle to the abortion right" when that statute "allows, among other means, a commonly used and generally accepted method" of abortion. *Id.* at 165. The Court concluded that 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, given the availability of other abortion procedures that are considered to be safe alternatives." *Id.* at 166-67.

Under *Gonzales*, the Ninth Circuit should have found that Arizona's regulation of medication abortion was facially valid because to the extent that it restricts some women from obtaining a medication abortion, the Arizona law does not affect a woman's right to obtain a surgical abortion, which is the most common method and is indisputably safe. Instead, the Ninth Circuit brushed aside this precedent by characterizing the burden in *Gonzales* as "slight" (because the banned method was similar to the remaining available method) and characterizing the government's countervailing interest in fetal life as "sufficient to justify the burden." (App. 25.) This Court should grant review to clarify that States are accorded broad latitude to regulate in

the interest of protecting maternal health and that abortion regulations are valid unless they place a substantial obstacle on a woman's ability to obtain a safe abortion.

CONCLUSION

This Court should grant the Petition for Writ of Certiorari.

Respectfully submitted,

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APPENDIX

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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 14-15624
D.C. No. 4:14-cv-01910-DCB

[Filed June 3, 2014]

PLANNED PARENTHOOD ARIZONA, INC.; WILLIAM RICHARDSON, M.D., DBA Tucson Women's Center; WILLIAM H. RICHARDSON, M.D., P.C., DBA Tucson Women's Center,
Plaintiffs-Appellants,

v.

WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity,
Defendant-Appellee.

OPINION

Appeal from the United States District Court
for the District of Arizona
David C. Bury, District Judge, Presiding

Argued and Submitted
May 13, 2014—San Francisco, California

Filed June 3, 2014

Before: Susan P. Graber, William A. Fletcher, and Richard A. Paez, Circuit Judges.

Opinion by Judge W. Fletcher

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OPINION

W. FLETCHER, Circuit Judge:

Plaintiffs Planned Parenthood Arizona, Inc., Dr. William Richardson, and Tucson Women's Center appeal the district court's denial of their motion for a

preliminary injunction. Plaintiffs seek to enjoin enforcement of an Arizona statute, Ariz. Rev. Stat. § 36-449.03(E)(6), and its implementing regulation, Ariz. Admin. Code § R9-10-1508(G), which restrict the manner in which certain medications may be used to perform abortions. The district court denied the preliminary injunction because it found that plaintiffs had not shown a likelihood of success on the merits. We reverse.

I. Background

"Before 2000, most first-trimester abortions were surgical, performed by a procedure commonly known as vacuum aspiration or suction curettage." *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 494 (6th Cir. 2012). In 2000, the Federal Drug Administration ("FDA") first approved the use of medications to perform abortions. *Id.*

A. Medication Abortion Regimens

The far-and-away most common method of medication abortion employs a combination of two prescription drugs, mifepristone (sometimes known as RU-486) and misoprostol. Mifepristone ends pregnancy by blocking the hormone progesterone, thereby causing the fertilized egg to detach from the uterine wall. Misoprostol causes the uterus to contract and expel its contents. In 2000, the FDA approved mifepristone for use in medication abortions under the brand name Mifeprex. The approved drug label for Mifeprex described an "on-label" regimen requiring a woman to take 600 milligrams of mifepristone orally at a clinic, return to the clinic two days later to take 400 micrograms of misoprostol orally, and return again for

a follow-up visit. These three clinic visits are in addition to the visit Arizona law requires for a woman to receive an in-person consultation with her doctor at least twenty-four hours before an abortion. *See* Ariz. Rev. Stat. § 36-2153. Clinical evidence submitted by Mifeprex's manufacturer established this on-label regimen to be safe and effective through seven weeks of pregnancy, or 49 days from the woman's last menstrual period ("LMP"). The FDA has approved misoprostol only for the treatment of stomach ulcers.

When the FDA approved mifepristone for use in abortions, it imposed restrictions on mifepristone's marketing and distribution—but not on its use—under the FDA's "Subpart H" regulations. *See* 21 C.F.R. § 314.520. These restrictions require the manufacturer to distribute mifepristone only to doctors who sign an agreement "stating that he or she possesses the necessary qualifications and will adhere to the other requirements." One Subpart H restriction requires doctors to agree to provide each patient "a copy of the Medication Guide and Patient Agreement" and obtain the patient's signature on the Patient Agreement. In the Patient Agreement, the patient attests that she "understand[s]" the steps involved in the on-label regimen. The patient agrees to "follow my provider's advice about when to take each drug." The Subpart H restrictions, Medication Guide, and Patient Agreement do not require doctors to administer mifepristone according to the on-label regimen. *Cline v. Okla. Coal. for Reprod. Justice*, 313 P.3d 253, 261 n.17 (Okla. 2013) (per curiam).

By the time the FDA approved Mifeprex's label, studies already showed that a different regimen for

medication abortion was safe and effective through nine weeks of pregnancy, or 63 days LMP (instead of 49 days LMP). This regimen requires taking 200 milligrams (instead of 600 milligrams) of mifepristone orally at the clinic, taking 800 micrograms of misoprostol two days later at home (instead of at the clinic) by dissolving the drug between the cheek and gum, and then returning to the clinic for a follow-up visit. Consistent with common terminology, we call this off-label regimen the "evidence-based" regimen. Dr. Richardson states in a sworn declaration that "virtually all abortion providers" now use the evidence-based regimen. He further states, "Few if any [providers] use the [on-label] method." The American College of Obstetricians and Gynecologists strongly favors the evidence-based regimen over the on-label regimen. Brief for American College of Obstetricians & Gynecologists and the American Medical Ass'n as Amici Curiae at 7–8. Notably, the district court found that the evidence-based regimen is

> considered the best practices . . . by practicing doctors. . . . [T]here 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 [the] 7th week. . . . Also, risk factors from medical abortions . . . have been reduced or eliminated by the current [evidence-based] regimen; medication abortion now has a lower rate of ongoing pregnancies and fewer surgical interventions are necessary to complete the abortion procedure.

Medication abortions now account for 41 percent of all first-trimester abortions performed at Planned Parenthood clinics nationwide. In 2012 in Arizona, 43 percent of all abortions performed during the first nine weeks of pregnancy were medication abortions. Plaintiffs presented uncontroverted evidence in the district court that many women who choose medication abortion strongly prefer it over surgical abortion. Medication abortion is less invasive than surgical abortion, which is a particularly important consideration for survivors of rape or sexual abuse. Further, some women have medical conditions that make medication abortion significantly safer than surgical abortion. The district court found that "medication abortion is extremely safe and safer than the alternative surgical procedure, which is also a very safe procedure."

Since the FDA approved mifepristone in 2000, there have been eight known deaths from infection in women using earlier off-label regimens (a fatality rate of less than 0.0005 percent). The FDA investigated these eight cases and found no causal connection between the infections and the use of mifepristone or misoprostol. A study conducted in 2013 surveyed the most recent six years of data and found no infection-related deaths out of 711,556 medication abortions performed under the current evidence-based regimen. James Trussell et al., *Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion*, 89 Contraception 193, 195 (2014).

The on-label regimen fails to terminate the pregnancy in about 1 percent of cases, and as many as 8 percent of women following the on-label regimen

require surgical-abortion procedures to stop heavy bleeding caused by the medications. The evidence-based regimen fails in about 0.5 percent of cases, and fewer than 2 percent of women require subsequent surgical-abortion procedures. Because of the larger dose of mifepristone required by the on-label regimen, the drugs for the on-label regimen cost $160 more than for the evidence-based regimen. The on-label regimen also increases costs by requiring an additional clinic visit. Finally, the evidence-based regimen allows women to take misoprostol in their homes, eliminating the risk that they will pass their pregnancies, a process involving heavy bleeding and cramping, during their trip home from the second clinic visit.

B. FDA Approval

When the FDA approves a drug, it does so on the basis of evidence of clinical trials submitted by the drug's manufacturer. The FDA generally does not conduct its own trials. According to plaintiffs' expert Dr. Lisa Rarick, who participated as an FDA official in the approval process for mifepristone, the FDA "does not authorize protocols for drugs . . . . Rather, approval of [a drug] allows the drug sponsor to advertise and promote the drug for a particular use." The drug's manufacturer also submits a proposed label for approval. The label "provides physicians with guidance about how to use a drug in accordance with how the drug sponsor requested and received FDA approval for its use." The label "does not impose binding obligations on physicians." The "FDA does not require a manufacturer to update a drug's [label] for new uses or protocols," and there rarely are sufficient economic incentives for the manufacturer to do so.

According to Dr. Rarick, the FDA "neither prohibit[s] nor discourage[s]" off-label use of FDA-approved drugs. In fact, "the FDA has repeatedly acknowledged that off-label use is common and is sometimes required by good medical practice." In a 1982 "FDA Drug Bulletin," the FDA stated:

> The [Federal Food, Drug, and Cosmetic] Act does not . . . limit the manner in which a physician may use an approved drug. 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. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.
>
> . . . Valid new uses for drugs already on the market are often . . . confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to [the] FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

12 FDA Drug Bulletin 5 (1982). The FDA has consistently maintained that position. *See* U.S. Food & Drug Admin., *"Off-Label" and Investigational Use of*

Marketed Drugs, Biologics, and Medical Devices - Information Sheet (Aug. 10, 2011), http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm. Off-label use of drugs is especially common in pediatrics, oncology, and gynecology and obstetrics.

C. Arizona Legislation

In 2012, the Arizona legislature passed House Bill 2036, a collection of statutory amendments regulating abortion. The amendment at issue in this case regulates medication abortion. It provides:

> The director [of the Arizona Department of Health Services] shall adopt rules relating to the abortion procedure. At a minimum these rules shall require . . . [t]hat 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 [F]ood and [D]rug [A]dministration and that is outlined in the final printing labeling instructions for that medication, drug or substance.

Ariz. Rev. Stat. § 36-449.03(E)(6). Defendant William Humble, Director of Arizona's Department of Health Services, adopted an implementing regulation as required by the amendment. Ariz. Admin. Code § R9-10-1508(G). The regulation had an effective date of April 1, 2014. We refer to the amendment and regulation collectively as "the Arizona law."

The legislature described its purpose in passing the Arizona law as "[p]rotect[ing] women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, for example, mifepristone" and "[e]nsur[ing] that physicians abide

by the protocol tested [sic] and approved by the United States Food and Drug Administration for such abortion-inducing drugs." The legislative findings describe various health risks from the use of mifepristone, including risks of infection and hemorrhage. The district court found that the Arizona legislature provided no "supporting evidence for any asserted legislative fact." The court observed that "the risks associated with medication abortions, relied on by the State as the reason for adopting the [on-label] protocol, have been substantially reduced or eliminated" by the evidence-based regimen.

D. Challenge to the Arizona Law

There are currently ten abortion providers in Arizona, located in three of the state's fifteen counties. Planned Parenthood Arizona, Inc. ("PPAZ"), provides abortions at its clinics in Glendale, Tempe, Tucson, and Flagstaff. PPAZ performs medication abortions according to the evidence-based regimen. The Glendale, Tempe, and Tucson clinics provide both surgical and medication abortions. The Flagstaff clinic provides only medication abortions. PPAZ's Flagstaff clinic is the only abortion provider in northern Arizona. The next closest provider is in Glendale, which is located, on average, 160 miles from locations in northern Arizona; it is 372 miles away from some locations. In 2013, PPAZ provided 6,667 abortions for women through 63 days LMP. Thirty-eight percent were medication abortions. Twenty-six percent of these medication abortions occurred after 49 days LMP. Because they occurred after 49 days LMP, such abortions would not have been available if PPAZ had been required to follow the on-label regimen.

PPAZ's Flagstaff clinic used to provide medication abortions through an advanced practice clinician instead of a doctor, but Arizona banned that practice in 2011. The Flagstaff clinic could not provide abortions of any kind until February 2014, when it found a doctor to perform medication abortions. During the period when the Flagstaff clinic could not perform abortions, significantly fewer women in northern Arizona obtained abortions than before 2011.

Dr. Richardson owns and operates Tucson Women's Center, where he provides surgical and medication abortions. Dr. Richardson performs medication abortions according to the evidence-based regimen. In 2013, he provided abortions to 932 women, 660 of whom were nine weeks pregnant (63 days LMP) or less. Of those 660 women, 43 percent chose medication abortion.

PPAZ, Dr. Richardson, and Tucson Women's Center sued Director Humble in his official capacity, seeking declaratory and injunctive relief against the Arizona law. For convenience, we refer to the defendant as "Arizona." Plaintiffs brought their claims on behalf of themselves, their patients, and the physicians they employ. *See Isaacson v. Horne*, 716 F.3d 1213, 1221 (9th Cir. 2012), *cert. denied*, 134 S. Ct. 905 (2014). Plaintiffs moved for a preliminary injunction, asserting that the Arizona law is unconstitutionally vague, violates women's fundamental rights to abortion and bodily integrity, and violates equal protection. The district court denied the motion. It found that the evidence-based regimen "is considered the best practices," and that Arizona had not presented any evidence to support its legislative findings or to show

that the law actually advances women's health. It treated these findings as legally irrelevant. It held that the Arizona law is not vague and does not violate equal protection or a woman's right to bodily integrity. It held further that the law rationally advances Arizona's interest in women's health and does not impose an undue burden on Arizona women's right to abortion.

Plaintiffs timely appealed and filed an emergency motion for an injunction pending appeal. A motions panel of this court enjoined enforcement of the Arizona law pending appeal and expedited the appeal. *See Planned Parenthood of Ariz., Inc. v. Humble*, No. 14-15624 (9th Cir. Apr. 8, 2014) (order granting emergency injunction).

II. Discussion

A. Standard for Preliminary Injunctions

We review the district court's denial of a preliminary injunction for abuse of discretion. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). Reliance "on an erroneous legal standard" is an abuse of discretion. *Id.* (internal quotation marks omitted). We review the district court's legal conclusions de novo and its factual findings for clear error. *Id.*

"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). "'[S]erious questions going to the merits' and a balance of hardships that tips sharply

towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Alliance for the Wild Rockies*, 632 F.3d at 1135. "[T]he deprivation of constitutional rights 'unquestionably constitutes irreparable injury.'" *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

B. Success on the Merits

1. Interpretation of the Arizona Law

The parties disagree about the correct interpretation of the Arizona law. Plaintiffs argue that, under a proper reading of its text, the law flatly prohibits all medication abortions. Arizona disagrees. It argues that the law allows medication abortions, but only if they are performed in accordance with the on-label regimen. We need not resolve this dispute. We assume for the purposes of our analysis that Arizona's interpretation of the law is correct.

2. Undue Burden

Plaintiffs argue that the Arizona law is unconstitutional because it imposes an undue burden on a woman's right to abortion. *See Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 876 (1992). In *Casey*, a plurality of the Supreme Court rejected both strict scrutiny and rational-basis review of abortion regulations, holding instead that laws regulating pre-viability abortions are unconstitutional if they impose an "undue burden" on a woman's right to abortion. *Id.* at 876. *Casey* recognized that states have legitimate "interests in maternal health and protecting

fetal life [that] can, in some circumstances, justify regulations of abortion." *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 539 (9th Cir. 2004). The undue burden test seeks to balance those interests with a woman's fundamental right to abortion. *See id.* The only interest Arizona asserts in this case is its interest in women's health.

Our undue burden analysis starts with *Casey*'s plurality opinion. *See Isaacson*, 716 F.3d at 1222 n.8. The plurality explained, "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." *Casey*, 505 U.S. at 877. Of the four Supreme Court cases addressing abortion since *Casey*, only *Gonzales v. Carhart*, 550 U.S. 124 (2007), provides meaningful guidance on how to apply *Casey*'s undue burden test. *Cf. Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 323 (2006) (addressing only the scope of equitable relief); *Stenberg v. Carhart*, 530 U.S. 914, 938 (2000) (interpreting a statute in a way that the state conceded imposed an undue burden); *Mazurek v. Armstrong*, 520 U.S. 969, 972 (1997) (per curiam) (addressing the evidence required to support a finding of improper legislative purpose). *Gonzales* emphasized the balance struck by *Casey*, holding that a state may "regulat[e] the medical profession in order to promote respect for life," so long as the state does not act irrationally or "impose an undue burden" on a woman's right to abortion. 550 U.S. at 158. It held that a court reviewing an abortion regulation "must determine whether the [regulation] furthers the legitimate interest of the Government in protecting the life of the fetus that may become a child." *Id.* at 146.

The analysis in both *Casey* and *Gonzales* focused on state laws purporting to advance the state's interest in fetal life. Here, however, the Arizona law purports to advance Arizona's interest in women's health. We wrote in *Eden*,

> [*Casey*'s] application of the "undue burden" standard is often not extendable in obvious ways to the context of a law purporting to promote maternal health.
>
> In the context of a law purporting to promote fetal life, whatever obstacles that law places in the way of women seeking abortions logically serve the interest the law purports to promote—fetal life—because they will prevent some women from obtaining abortions. By contrast, in the context of a law purporting to promote maternal health, a law that is poorly drafted or which is a pretext for anti-abortion regulation can both place obstacles in the way of women seeking abortions *and* fail to serve the purported interest very closely, or at all.

379 F.3d at 539–40 (citations omitted).

In *Eden*, we described our approach to applying *Casey*'s undue burden test. Under *Eden*, we compare the extent of the burden a law imposes on a woman's right to abortion with the strength of the state's justification for the law. *See id.* at 542. The more substantial the burden, the stronger the state's justification for the law must be to satisfy the undue burden test; conversely, the stronger the state's justification, the greater the burden may be before it becomes "undue." On one extreme, *Eden* described

cases where "a purported health regulation fails to rationally promote an interest in maternal health on its face." *Id.* at 540. In such a case, the regulation fails even rational-basis review, and "the undue burden standard is not triggered at all." *Id.* On the other extreme, laws that are "harmless" or that have only an "incidental effect" on abortion require little justification. *Mazurek*, 520 U.S. at 972; *Casey*, 505 U.S. at 874. In cases between those two extremes, we must weigh the burdens against the state's justification, asking whether and to what extent the challenged regulation actually advances the state's interests. If a burden significantly exceeds what is necessary to advance the state's interests, it is "undue." *See* Webster's Third New Int'l Dictionary 2492 (1993) (defining "undue" as "excessive" or "unwarranted").

Our approach in *Eden* follows from *Casey*, in which the plurality wrote that "*[u]nnecessary* health regulations that have the purpose *or* effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." 505 U.S. at 878 (emphasis added); *see Eden*, 379 F.3d at 542 (relying on evidence that a regulation was "unnecessary as a matter of public health"). Whether a regulation is necessary depends on whether and how well it serves the state's interest. "[T]he means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it." *Casey*, 505 U.S. at 877. The same is true for laws purporting to protect women's health: they "must be calculated" to advance women's health, "not hinder it." *Id.*

Under this approach, the plurality in *Casey* upheld a law requiring, with some exceptions, minors to get consent from their parents before obtaining an abortion. *Id.* at 899. The plurality did so based on the state's "quite reasonable assumption that minors will benefit from consultation with their parents and that children will often not realize that their parents have their best interests at heart." *Id.* at 895. At the same time, a majority of the Court struck down a law requiring married women to get consent from their husbands. *Id.* at 887–95. The Court distinguished parental consent from spousal consent based on the state's comparatively weaker justification in the second instance. While the state could assume that minors might not realize their own best interests, it could not "adopt a parallel assumption about adult women." *Id.* at 895.

Similarly, the Court in *Gonzales* upheld the federal Partial-Birth Abortion Ban Act of 2003 only after finding that the Act would advance the state's interest in fetal life by "encourag[ing] some women to carry the[ir] infant to full term, thus reducing the absolute number of late-term abortions." 550 U.S. at 160. Importantly for this case, *Gonzales* held that a court applying the undue burden test should not "place dispositive weight on [legislative] findings. The Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake. . . . Uncritical deference to [the legislature's] factual findings in these cases is inappropriate." *Id.* at 165–66.

In *Planned Parenthood of Wisconsin, Inc. v. Van Hollen*, 738 F.3d 786 (7th Cir. 2013), the Seventh

Circuit adopted an approach much like ours in *Eden*. The court affirmed a preliminary injunction against a Wisconsin law that required abortion providers' doctors to have admitting privileges at a hospital within thirty miles of the provider's clinic. *See id.* at 787, 798. The state's only justification for the law was protection of women's health. *Id.* at 789. As in *Eden*, the Seventh Circuit analyzed whether the Wisconsin law actually advanced that interest and found, on the record before it, that the law did not. *See id.* at 789–91, 797–98. The court wrote, "The cases that deal with abortion-related statutes sought to be justified on medical grounds require not only evidence . . . that the medical grounds are legitimate but also that the statute not impose an 'undue burden' on women seeking abortions. The feebler the medical grounds, the likelier the burden, even if slight, [is] to be 'undue' in the sense of disproportionate or gratuitous." *Id.* at 798 (citations omitted).

The district court in this case did not cite or discuss our decision in *Eden*. It relied instead on decisions of the Fifth and Sixth Circuits. *See Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, No. 13-51008, 2014 WL 1257965, at *7–8 (5th Cir. Mar. 27, 2014); *DeWine*, 696 F.3d at 513–18 (opinion of McKeague, J.). In applying the undue burden test, the Fifth and Sixth Circuits consider the state's justification only for the very limited purpose of applying rational-basis review. Once an abortion regulation survives rational-basis review, these circuits pay no attention to whether the regulation has been shown actually to advance the state's legitimate interests. In *Abbott*, the Fifth Circuit held that courts may not consider the strength of the state's

justification, stating that an abortion regulation need only be supported by "rational speculation." 2014 WL 1257965, at *7–8 (internal quotation marks omitted). In *DeWine*, the Sixth Circuit analyzed whether an Ohio abortion regulation was an undue burden without considering the strength of the state's justification for the regulation. 696 F.3d at 513–18.

We conclude that *Abbott* and *DeWine* are inconsistent with the undue burden test as articulated and applied in *Casey* and *Gonzales*. The Fifth and Sixth Circuits' approach fails to recognize that the undue burden test is context-specific, and that both the severity of a burden and the strength of the state's justification can vary depending on the circumstances. *See Eden*, 379 F.3d at 541 (citing *Casey*, 505 U.S. at 901). We adhere to the approach in *Eden* and *Van Hollen*, which requires us to weigh the extent of the burden against the strength of the state's justification in the context of each individual statute or regulation.

We assume without deciding that the Arizona law passes rational-basis review and move directly to the application of the undue burden test. *See Eden*, 379 F.3d at 540–41. In order to show an undue burden, plaintiffs must show that, "'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 undergo an abortion.'" *Id.* at 539 (quoting *Casey*, 505 U.S. at 895) (alteration in *Eden*). We limit our inquiry to "the group for whom the law is a restriction, not the group for whom the law is irrelevant." *Casey*, 505 U.S. at 894. Under this limitation, we address the burden on women who, in the absence of the Arizona law, would

receive medication abortions under the evidence-based regimen. *See id.* at 894–95.

We start with the strength of Arizona's justification for the law. On the record before us, Arizona has presented no evidence whatsoever that the law furthers any interest in women's health. The district court found that there was no "supporting evidence for any asserted legislative fact," and that the evidence-based regimen has a "clear advantage" over the on-label regimen. For example, the Arizona legislature cited the dangerousness of mifepristone in support of requiring the on-label regimen, but the on-label regimen requires three times *more* mifepristone than the evidence-based regimen. As the district court found, the FDA not only expects off-label use but encourages it as part of the effective practice of medicine. The Supreme Court itself has noted that off-label use "is an accepted and necessary corollary of the FDA's mission." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *accord id.* at 350–51 & n.5. Arizona argues that the law prohibits not just safe evidence-based regimens for medication abortion but also other, dangerous off-label regimens. But the record contains no evidence that any such dangerous regimen exists or has ever been used by any abortion provider. Therefore, on the current record, the Arizona law appears wholly "unnecessary as a matter of [women's] health." *Eden*, 379 F.3d at 542.

We turn now to the burden imposed by the Arizona law. *Eden* provides a nonexhaustive list of factors relevant to whether a law imposes an undue burden. First, "[a] significant increase in the cost of abortion or the supply of abortion providers and clinics can, at

some point, constitute a substantial obstacle to a significant number of women." 379 F.3d at 541. Under this factor, plaintiffs may rely on such evidence as "testimony that one provider may be forced to stop practicing medicine." *Id.* at 542. Second, we may consider evidence that a law "delays and deters patients obtaining abortions, and that delay in abortion increases health risks." *Id.* Third, we may consider a law's "stigmatizing of abortion practice and usurping of providers' ability to exercise medical judgment." *Id.* at 543. We may also consider the ways in which an abortion regulation interacts with women's lived experience, socioeconomic factors, and other abortion regulations. *See Casey*, 505 U.S. at 887–94 (relying on the effect of domestic abuse on women seeking abortions); *Van Hollen*, 738 F.3d at 796 (citing the cumulative effect of different abortion regulations); *McCormack v. Hiedeman*, 694 F.3d 1004, 1016–18 (9th Cir. 2012) (describing the intersection of socioeconomic factors and abortion regulations).

Plaintiffs introduced evidence that medication abortion is a common procedure strongly favored over surgical abortion by many women. During the eighth and ninth weeks of pregnancy, the Arizona law requires these women to undergo surgical abortions rather than medication abortions. During the first seven weeks of pregnancy, the law requires them to undergo the on-label regimen for medication abortions. For a significant number of women, the law will effectively ban medication abortions outright because many women do not discover they are pregnant before 49 days LMP, the last day the on-label regimen is available under the law. Even for women who discover their pregnancies earlier, practical considerations, such

as the frequency with which clinics can see patients and the difficulties women face in obtaining time off from work or transportation to a clinic, may effectively preclude medication abortion before 49 days LMP. According to the sworn declaration of Beth Otterstein, the main clinician at PPAZ's Flagstaff clinic, some women so strongly prefer medication abortion, and so object to surgical abortion, that they will forego abortion entirely if they cannot obtain a medication abortion.

Taking into consideration the cost of the extra dosage of medicine and of the clinic time imposed by the required additional visit, the on-label regimen costs at least $200 more than the evidence-based regimen. The additional clinic visit also increases costs to the patient for transportation, gas, lodging, and the time she must take off from work. Plaintiffs' evidence shows that these increased costs would reduce the number of women who receive abortions, many of whom, including 40 percent of PPAZ's patients, are poor. Plaintiffs introduced evidence from abortion providers that, for these women, the additional costs are significant and sometimes prohibitive. Plaintiffs introduced a sworn declaration from the medical director of Planned Parenthood of Greater Ohio ("PPGO"), who declared that after Ohio limited medication abortions to the on-label regimen, the number of medication abortions performed by PPGO dropped by almost 65 percent. One of PPGO's clinics was forced to stop providing abortions entirely.

Plaintiffs also introduced evidence that PPAZ's Flagstaff clinic may have to close if it is limited to performing on-label medication abortions. Otterstein

described that as "a likely possibility." Plaintiffs provided specific reasons, tied to the predicted decrease in women who would obtain medication abortions, to explain why the Flagstaff clinic might be compelled to close for economic reasons. Plaintiffs' evidence shows that the closure of the Flagstaff clinic would significantly reduce the number of Arizona women who receive abortions. If the Flagstaff clinic closes, women in northern Arizona who want medication abortions will have to make four visits to the Glendale clinic. Each visit will require, on average, a 321-mile round trip. Some women will have to travel up to 744 miles round-trip for each visit. Otterstein declared that, during the period between 2011 and 2014 when PPAZ's Flagstaff clinic could not provide abortions, many patients said they could not travel to the Glendale clinic and would have to forego abortions entirely. During that period, 48 percent fewer women in northern Arizona received medication abortions from PPAZ, and 35 percent fewer received any abortion from PPAZ, compared with the pre-2011 period. In 2012, 31 percent fewer women in Arizona's three northeastern counties received any abortion from any provider compared with 2010, when the Flagstaff clinic was providing medication abortions.

Finally, plaintiffs introduced evidence that the Arizona law may delay abortions, thereby increasing health risks. *See Eden*, 379 F.3d at 542. Dr. Daniel Grossman, a board-certified obstetrician-gynecologist, provided a sworn declaration in which he cited a Washington study that found "that rural women who had to travel more than 75 miles to obtain an abortion were two to three times more likely than women travelling less than 75 miles to terminate after 12

weeks." Dr. Grossman declared that "delaying abortions until later in pregnancy drives up the risks of complications." If the Flagstaff clinic closes, most women in northern Arizona will have to travel more than 75 additional miles to obtain an abortion. Although there may be cases in which additional travel time does not in itself rise to the level of an undue burden, this factor must be evaluated on a case-by-case basis and balanced against the strength of the state's interest. *Casey*, 505 U.S. at 885–86.

Plaintiffs have introduced uncontroverted evidence that the Arizona law substantially burdens women's access to abortion services, and Arizona has introduced no evidence that the law advances in any way its interest in women's health. Plaintiffs' evidence shows that the Arizona law "usurp[s] . . . providers' ability to exercise medical judgment," *Eden*, 379 F.3d at 543, by requiring them to administer a less safe, less effective treatment regimen. *See* Brief for American College of Obstetricians & Gynecologists and the American Medical Ass'n as Amici Curiae at 13–17. The district court found that "medication abortion is extremely safe and safer than the alternative surgical procedure." It also found that the evidence-based regimen is safer and more effective than the on-label regimen. On the record before us, we conclude that the burden imposed by the Arizona law is undue within the meaning of *Casey* and *Gonzales*. *See Casey*, 505 U.S. at 877; *Gonzales*, 550 U.S. at 146, 158. We therefore hold that the district court abused its discretion when it held that plaintiffs were unlikely to succeed on the merits of their undue burden claim.

On the current record, the burden imposed by the Arizona law is undue even if some women who are denied a medication abortion under the evidence-based regimen will nonetheless obtain an abortion. Neither the Supreme Court nor this court has ever held that a burden must be absolute to be undue. *See Eden*, 379 F.3d at 540–43 (not requiring evidence that women would be totally prevented from obtaining abortions). Evidence in the record shows that women in Arizona will be burdened with a significant increase in the cost of medication, and that many women will be delayed in, or deterred from, seeking an abortion if the evidence-based regimen is foreclosed to them. The availability of on-label medication abortions during the first seven weeks of pregnancy, and of surgical abortions thereafter, therefore does not preclude a finding of undue burden.

The Court in *Gonzales* upheld the federal ban on late-term dilation and extraction abortion ("D&X"), citing the availability of a safe alternative late-term procedure, dilation and evacuation abortion ("D&E"). 550 U.S. at 166–67. But *Gonzales* did not hold that the existence of a safe alternative procedure is, in itself, determinative. The undue burden claim in *Gonzales* was based only on the law's failure to allow D&X when required to protect a woman's health. *Id.* at 161–67. *Gonzales* did not address the relevance of safe alternative procedures in challenges based on other kinds of burden. And in *Gonzales*, the challenged law left in place "a commonly used and generally accepted method" that was very similar to the one it banned. *Id.* at 165. Therefore, the burden in *Gonzales* was slight, while the government's interest in fetal life was sufficient to justify the burden. Here, the Arizona law

imposes a greater burden and is not justified by any interest. Moreover, for women between 49 and 63 days LMP, the Arizona law prohibits medication abortion entirely, leaving surgical abortion as the only legal alternative. In contrast to D&E and D&X, medication abortion and surgical abortion are very dissimilar procedures.

The court in *Van Hollen* granted a preliminary injunction against the enforcement of the Wisconsin law on the ground that "the medical grounds thus far presented . . . are feeble, yet the burden great." 738 F.3d at 798. Here, the "medical grounds thus far presented" are not merely "feeble." They are non-existent. On the current record, the Arizona law imposes an undue—and therefore unconstitutional—burden on women's access to abortion. We therefore conclude, at this stage of the proceedings, that plaintiffs have shown that they are likely ultimately to succeed on the merits of their undue burden claim.

In its brief to us, Arizona does not argue that plaintiffs have not shown a likelihood of irreparable harm or that the balance of hardships and the public interest do not favor a preliminary injunction. *See Alliance for the Wild Rockies*, 632 F.3d at 1135. Therefore, any argument based on these factors is waived. *See Thompson v. Runnels*, 705 F.3d 1089, 1103 (9th Cir. 2013). Because we hold that plaintiffs have shown a likelihood of success on their undue burden claim, we do not reach their other claims. We express no view on the merits of those claims.

Conclusion

We hold that plaintiffs have shown a likelihood of success on their claim that the Arizona law imposes an undue burden on a woman's right to abortion. We therefore reverse the district court's denial of plaintiffs' motion for a preliminary injunction and remand with instructions to issue the requested preliminary injunction.

REVERSED and REMANDED.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

CV 14-1910 TUC DCB

[Filed March 31, 2014]

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.	)

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. 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

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

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 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

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[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)).

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* 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

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[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 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).

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 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

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

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 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.

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[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.)

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 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.

/s/ David C. Bury
David C. Bury
United States District Judge