FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

SUMMARY*

Civil Rights

The panel reversed the district court's denial of plaintiff's motion for a preliminary injunction and remanded with instructions that the district court issue the requested injunction in an action seeking 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 panel assumed without deciding that the Arizona law, which restricts the use of an off-label evidence-based regime of medication abortions, passed rational basis review and moved directly to the application of the undue burden test. The panel held that plaintiffs introduced uncontroverted evidence that the Arizona law substantially burdened women's access to abortion services, and Arizona introduced no evidence that the law advanced in any way Arizona's interest in women's health. The panel concluded that on the record before it, the burden imposed by the Arizona law was undue within the meaning of *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 876 (1992), and *Gonzales v. Carhart*, 550 U.S. 124 (2007). The panel therefore held that the district court abused its discretion when it held that plaintiffs were unlikely to succeed on the merits of their undue burden claim.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

COUNSEL

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Denise Mary Burke, Americans United for Life, Washington, D.C., for Amici Curiae Arizona Legislators.

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.
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> . . . 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.