No. 14-15624
IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Planned Parenthood Arizona, Inc.; William Richardson, M.D.; and William H. Richardson M.D., P.C., doing business as Tucson Women's Center,
Plaintiffs-Appellants

v.

Will Humble, Director of the Arizona Department of Health Services, in his official capacity,
Defendant-Appellee

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
Civil Action No. 4:14-cv-01910-TUC-DCB
The Honorable David C. Bury, Senior Judge

APPELLANTS' REPLY BRIEF

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTRODUCTION 1

ARGUMENT 2

I. DEFENDANT'S ARGUMENTS CONFIRM THAT THE ARIZONA LAW IS UNCONSTITUTIONALLY VAGUE 2

A. The Arizona Law Does Not Permit the Use of Misoprostol 3

B. Defendant's Confusion Demonstrates That the Arizona Law Is Unconstitutionally Vague 6

C. *Bellotti* Supports Certification 7

II. UNDER BINDING PRECEDENT, THE ARIZONA LAW IMPOSES AN UNDUE BURDEN BECAUSE IT FAILS TO SERVE WOMEN'S HEALTH 8

A. Courts Must Examine, Not Simply Rubber Stamp, Restrictions Claimed to Serve Women's Health 8

B. The Arizona Law Cannot Reasonably Be Understood to Serve Women's Health 11

C. Defendant's New Evidence Is Improper and Irrelevant 13

III. PLAINTIFFS HAVE PRESENTED CONCRETE EVIDENCE THAT THE LAW WILL SUBSTANTIALLY BURDEN WOMEN SEEKING ABORTIONS 16

IV. AT A MINIMUM, PLAINTIFFS ARE ENTITLED TO AS-APPLIED RELIEF BECAUSE THE ARIZONA LAW EXPOSES WOMEN TO SIGNIFICANT HEALTH RISKS 22

V. DEFENDANT'S OTHER ARGUMENTS ARE UNAVAILING 25

A. Plaintiffs' Equal Protection Claim Is Likely to Succeed 25

B. Plaintiffs' Bodily Integrity Claim Is Likely to Succeed 26

CONCLUSION 28

CERTIFICATE OF COMPLIANCE PURSUANT TO CIRCUIT RULE 32-1 29

TABLE OF AUTHORITIES

CASES

Ayotte v. Planned Parenthood of N. New England, 546 U.S. 320 (2006) 17, 23

Bellotti v. Baird, 428 U.S. 132 (1976) 8

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) 14

Citizens United v. Fed. Election Comm'n, 558 U.S. 310 (2010) 24

Cleburne v. Cleburne Living Ctr., 473 U.S. 432 (1985) 26

Cline v. Okla. Coal. for Reprod. Justice, 313 P.3d 253 (Okla. 2013) 5, 15

Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1991) 27

Forbes v. Napolitano, 236 F.3d 1009, 1013 (9th Cir. 2000) 6

Foti v. City of Menlo Park, 146 F.3d 629 (9th Cir. 1998) 7

Gonzales v. Carhart, 550 U.S. 124 (2007) ..... passim

Grayned v. City of Rockford, 408 U.S. 104 (1972) 7

Harris v. McRae, 448 U.S. 297 (1980) 25

In re Mercury Interactive Corp. Secs. Litig., 618 F.3d 988 (9th Cir. 2010) 27

Isaacson v. Horne, 716 F.3d 1213 (2013) 22

Lawrence v. Texas, 539 U.S. 558 (2003) 2

Lowry v. Barnhart, 329 F.3d 1019 (9th Cir. 2003) 13

Mazurek v. Armstrong, 520 U.S. 968 (1997) 9, 10

MKB Mgmt. Corp. v. Burdick, No. 09-2011-CV-02205 (N.D. E. Cent. Jud. Dist. Ct. July 15, 2013) 5

Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502 (6th Cir. 2006) 24

Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976) 25

Planned Parenthood of Idaho, Inc. v. Wasden, 376 F.3d 908 (2004) 22

Planned Parenthood Southeast, Inc. v. Bentley, 951 F. Supp. 2d 1280 (M.D. Ala. 2013) 18

Planned Parenthood Southeast, Inc. v. Strange, __ F.Supp.2d__, 2014 WL 1320158 (M.D. Ala. Mar. 31, 2014) 9

Roe v. Wade, 410 U.S. 113 (1972) 10

Romer v. Evans, 517 U.S. 620 (1996) 26

United States v. Caronia, 703 F.3d 149 (2d Cir. 2012) 14

STATUTES

21 C.F.R. §§ 314.500-560 ..... 4, 14

Ohio Rev. Code Ann. § 2919.123 5

Tex. Health & Safety Code Ann. § 171.061(6) 5

INTRODUCTION

Plaintiffs-Appellants ("Plaintiffs") filed this appeal to enjoin a new Arizona law that would bar hundreds (and possibly thousands) of women each year from accessing the only non-surgical method of ending an early pregnancy. If the law allowed any women to have a non-surgical abortion, it would relegate them to what the American Medical Association ("AMA") and the American College of Obstetricians and Gynecologists ("ACOG") have confirmed is a *less* safe (and *less* effective and *more* burdensome) medication regimen. Plaintiffs' undisputed evidence demonstrates that, by drastically restricting access to medication abortion, the law would prevent some women from obtaining any abortion at all, while exposing many others to needless delay and wholly unnecessary health risks.

The district court acknowledged these effects but incorrectly held that they were insufficient to meet Plaintiffs' burden. Plaintiffs' Opening Brief, ECF No. 24-1, Apr. 18, 2014 ("OB") explained the district court's legal errors: 1) it failed to construe the law according to its plain language; 2) it failed to consider evidence on whether the law actually serves its purported interest in women's health 3) it failed to follow binding precedent in considering whether the law imposes a "substantial obstacle" on women seeking abortion; and 4) it incorrectly reduced Plaintiffs' bodily integrity and equal protection claims to the same flawed undue burden analysis. The AMA and ACOG have filed an amicus brief in support of

Plaintiffs' appeal, confirming that the Arizona law "jeopardizes women's health" and "serves no legitimate purpose." Brief of Amici Curiae ACOG and AMA, ECF No. 29, Apr. 23, 2014 at 4 ("ACOG/AMA Br.").

Instead of responding to the substance of these arguments or addressing the law of this Circuit, Defendant-Appellee ("Defendant") trivializes what this case is about—cavalierly dismissing as "anecdotal" and "speculative" Plaintiffs' solid, concrete, and undisputed evidence that the law would harm women's health and make abortion needlessly (and sometimes impossibly) difficult to obtain, and arguing that courts should just rubber stamp any regulation the state says advances women's health despite overwhelmingly contrary evidence. As the Supreme Court has consistently recognized, however, a woman's right to have an abortion has "real and substantial protection as an exercise of her liberty under the Due Process Clause," because it is a "fundamental decision[] affecting her destiny," *Lawrence v. Texas*, 539 U.S. 558, 565 (2003). The nature of this right precludes restrictions, such as the Arizona law, that the state claims "protect" women, but that instead gratuitously and substantially burden them.

ARGUMENT

I. DEFENDANT'S ARGUMENTS CONFIRM THAT THE ARIZONA LAW IS UNCONSTITUTIONALLY VAGUE

Plaintiffs showed that the Arizona law is either a de facto ban on medication abortion—because its plain language prevents the use of misoprostol—or is

unconstitutionally vague. OB 8. In response, Defendant concedes he does not know what the Arizona law actually does. Defendant-Appellee's Answering Brief at 20, ECF No. 34-1, Apr. 28, 2014 ("AB"). Instead, he proposes two "alternative" readings, each of which he claims allows misoprostol. AB 19-21. As explained below, these readings are unpersuasive, and only underscore the law's vagueness. They are also contrary to the holdings of both the Oklahoma Supreme Court and a North Dakota district court—the only two courts to have reviewed similarly worded laws.

A. The Arizona Law Does Not Permit the Use of Misoprostol

Defendant first argues that, based on the Arizona law's "regulatory purpose," it restricts both mifepristone and misoprostol in medication abortion, but allows misoprostol to be administered (exclusively) as outlined on the *Mifeprex* (mifepristone) Final Printed Label ("FPL"). AB 19-22, 26-27. As Plaintiffs have already explained, because the plain language of the Arizona law requires that each abortion-inducing drug be administered only as outlined on *its own* label, this reading defies the principle that a court may not usurp the role of the legislature and rewrite a law's text. *See* OB 20-22.[1]

[1] This interpretation is also inconsistent with Defendant's assertion that misoprostol does not cause abortions. *See* AB 20. If that is correct, then misoprostol cannot be subject to any restriction under the Arizona law.

Additionally, Defendant argues that this interpretation complies with the Arizona law's requirement that an abortion-inducing drug be administered under the protocol "authorized" by the Food and Drug Administration ("FDA") because the FDA purportedly "authorized" the Mifeprex FPL regimen as the only permissible medication abortion protocol. AB 22-25. In particular, Defendant claims—for the first time on appeal—that in approving Mifeprex under 21 C.F.R. §§ 314.500-560 ("Subpart H"), the FDA did not just approve the drug, but rather authorized a specific "protocol." AB 23-24. But, as discussed in more detail below, the restrictions applied under Subpart H apply only to Mifeprex's marketing and distribution. They do not authorize (or prohibit) physicians' use of any particular protocol, as that would be beyond the FDA's legal authority. *See infra* at § II.B; *see also* OB 20.[2] Indeed, under Defendant's interpretation, the Arizona law would be redundant: were the FPL protocol the only one "authorized" by the FDA, physicians would already be prohibited from using an evidence-based one.

Defendant's "alternative" interpretation of the Arizona law, also presented for the first time on appeal, is that it "would only apply to mifepristone and would not affect, much less ban, the use of misoprostol for medication abortions." AB 19-22 (citations omitted). He reaches this conclusion by claiming that, when used after

[2] Defendant quotes several instances where the FPL protocol is described as "approved." AB 23. None of these quotations describe the protocol as "authorized."

mifepristone, misoprostol is not a "drug used to induce an abortion." AB 20-21, & n.1. This interpretation is contradicted by the uncontested facts, which show that misoprostol, taken after mifepristone, is intended to induce an abortion. Declaration of William Richardson, M.D. ("Richardson Decl.") ¶ 26. (ER 037-38).[3] For this reason, this interpretation has been rejected by both courts to consider it. *Cline v. Okla. Coal. for Reprod. Justice*, 313 P.3d 253, 259 (Okla. 2013) (misoprostol, used after mifepristone, is "prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman"); *MKB Mgmt. Corp. v. Burdick*, No. 09-2011-CV-02205, slip op at 21 (N.D. E. Cent. Jud. Dist. Ct. July 15, 2013) (same).[4]

[3] Having offered no evidence below, Defendant now relies only on a medical dictionary for his interpretation; however, the dictionary's definition of "induce" does not say whether misoprostol, when taken after mifepristone, fits within that definition, let alone contradict the record.

[4] Defendant attempts to distinguish *MKB* by saying that the North Dakota and United States Constitutions are different, AB 22, but that is irrelevant to *MKB*'s statutory analysis. Similarly, Defendant tries to distinguish *Cline* by pointing out that the Oklahoma statute named misoprostol as an "abortion-inducing drug" in certain circumstances. But the Oklahoma Supreme Court explicitly did not rely on that provision alone; it independently affirmed that the law banned misoprostol because, when giving it after mifepristone, the physician intends for it to cause an abortion. 313 P.3d at 259. By contrast, the laws upheld by Ohio and Texas courts explicitly permit abortions under the Mifeprex FPL protocol, and do not, as here, preclude the evidence-based use of *all* abortion-inducing drugs. *See* Ohio Rev. Code Ann. § 2919.123 (applicable only to "mifepristone"); Tex. Health & Safety Code Ann. § 171.061(6) (defining "Mifeprex Regimen").

This interpretation is also contradicted by Defendant's own arguments. He argues at length that because the legislative findings "clearly describe[] the authorized FDA-approved protocol for medication abortions, including the authorized dosages of both mifepristone *and* misoprostol," it was the legislature's intention to adopt the Mifeprex FPL as Arizona law. *See* AB 26.[5] This is plainly inconsistent with a law that does not require physicians to follow the Mifeprex FPL as to misoprostol. Indeed, Defendant's interpretation is certainly "irrational" under *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 541 (9th Cir. 2004): he is claiming that in order to protect women from the "dangerous" drug Mifeprex and its evidence-based use, the Arizona legislature required triple its necessary dose, followed by misoprostol used in any way a physician deems best. As the only two courts to review similar laws have done, this Court should find that the plain language of the Arizona law bans medication abortion entirely.

B. Defendant's Confusion Demonstrates That the Arizona Law Is Unconstitutionally Vague

The parties agree that a law must afford intelligent physicians a reasonable opportunity to know what is prohibited. *Forbes v. Napolitano*, 236 F.3d 1009, 1013 (9th Cir. 2000) (law that "provides no guidance as to where the state should draw the line between [permitted and prohibited procedures] gives doctors no

[5] Plaintiffs disagree with this characterization of legislative intent. OB 20-21 & n.4.

constructive notice"). Defendant's uncertainty about whether the Arizona law even reaches misoprostol is a powerful demonstration that it fails this test. *Compare* AB 26-27 (the law's meaning is controlled by "clear legislative intent" to regulate the "dosages of both mifepristone *and* misoprostol"), *with* AB 19-20 (under the "plain . . . meaning of the word 'induce'" "misoprostol does not induce an abortion," so it is not a regulated drug).

Plaintiffs have already shown that the law's failure to provide a clearly legal avenue to perform a theoretically legal medical procedure renders it unconstitutionally vague. OB 23-24. Defendant's response only underscores that the law gives insufficient notice to Plaintiffs as to what the Arizona law allows,[6] and leaves Plaintiffs subject to enforcement of the Arizona law on "an *ad hoc* and subjective basis," in violation of their rights. *Foti v. City of Menlo Park*, 146 F.3d 629, 639 (9th Cir. 1998) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972)).

C. *Bellotti* Supports Certification

Defendant contends that certification is inappropriate because no

[6] For example, a doctor cannot know whether she may instruct a patient to take misoprostol at home, or must require her to return to take it at the clinic. Defendant argues both. *Compare* AB 25 ("[t]he FDA thus considered and rejected [the] protocol of allowing at home self administration of misoprostol. . . . Arizona law clearly sets forth the protocol that must be followed . . .") *with* AB 21 ("alternative[ly,] . . . the statute . . . would not affect . . . the use of misoprostol").

interpretation of the Arizona law (Plaintiffs agree) will obviate the need to litigate Plaintiffs' constitutional claims. AB 28. However, the Supreme Court has explained, in a case relied on by Defendant, that certification is nonetheless proper if it could "materially change the nature of the problem." *Bellotti v. Baird*, 428 U.S. 132, 147 (1976) (citation omitted). *Belloti* holds that an authoritative state construction is useful not just to potentially end litigation but also to "define precisely the constitutional question presented." *Id.* at 148; *see also id.* (certification appropriate where it "would avoid *or* substantially modify the federal constitutional challenge to the statute") (emphasis added). Here—especially now that Defendant has advanced two alternative readings of the Arizona law—certification could greatly simplify the federal courts' work by narrowing the issues to be decided.[7]

II. UNDER BINDING PRECEDENT, THE ARIZONA LAW IMPOSES AN UNDUE BURDEN BECAUSE IT FAILS TO SERVE WOMEN'S HEALTH

A. Courts Must Examine, Not Simply Rubber Stamp, Restrictions Claimed to Serve Women's Health

As Plaintiffs established in their opening brief, when the state purports to

[7] Defendant claims there is a presumption against certification after a federal court has issued a decision, AB 29, but that rule—and the cases Defendant cites—applies to a federal court's statutory construction *after a final decision on the merits*. *E.g. Thompson v. Paul*, 547 F.3d 1055 (9th Cir. 2008) (dismissal); *Complaint of McLinn*, 744 F.2d 677 (9th Cir. 1984) (summary judgment).

restrict abortion in the interest of advancing women's health, longstanding precedent requires that courts "[take] care to verify that the law could be reasonably understood to promote, in some legitimate fashion, [this] interest." *Eden*, 379 F.3d at 540 (describing Court's approach in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992)); *see also* OB 25-28. This step is necessary to give "real substance to the woman's liberty to determine whether to carry her pregnancy to full term," *Casey*, 505 U.S. at 869, by protecting women from laws purporting to advance their health that in fact merely restrict their liberty. *See Planned Parenthood Southeast, Inc. v. Strange*, __ F.Supp.2d __, 2014 WL 1320158, at *8 (M.D. Ala. Mar. 31, 2014) (*Casey* plurality rejected Justice Rehnquist's call for "rational basis" review of abortion restrictions).

Largely ignoring Plaintiffs' cited precedent, Defendant argues that this step in *Casey*'s analysis is nothing more than a rubber stamp. AB 30-31 (because the legislature made "findings" that it was serving women's health, "the Court cannot consider any evidence" to the contrary).[8] He relies on *Eden*, *Mazurek v. Armstrong*, 520 U.S. 968 (1997), and *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007), but none of those cases supports his extreme position. AB 31, 36.

[8] Defendant also seems confused about Plaintiffs' claim. Plaintiffs do not claim that the legislature acted with an improper purpose. Rather, they claim the law is an undue burden because, *inter alia*, it fails to promote the state's interest in women's health.

Eden's application of *Casey*'s "reasonable relatedness" test, described as an inquiry into whether "a purported health regulation fails to rationally promote an interest in maternal health on its face," *Eden*, 379 F.3d at 540, uncontrovertibly requires a look under the surface of the statute—as does the other precedent summarized in Plaintiffs' opening brief, *see* OB 26-28. Tellingly, *Eden*'s example of a statute that would fail "on its face" is a requirement that physicians provide "false or misleading information" to their patients. *Eden* 379 F.3d at 540. Of course, a court could only ascertain whether state-mandated information was "false"—and even more so, "misleading"—by comparing the information to actual facts outside the text of the statute, and considering its likely effect on patients. Plaintiffs are seeking nothing more than this same look at the evidence.[9]

Mazurek is irrelevant, as it merely reaffirms prior case law, decided under the standard of *Roe v. Wade*, 410 U.S. 113 (1973), that states can require that licensed doctors perform abortion, whether or not the restriction is medically necessary. It does not imply, much less hold, that, in reviewing a law that would eliminate or drastically reduce access to the only non-surgical abortion method,

[9] Moreover, the Arizona law bears no resemblance to the law the *Eden* court found not facially pretextual or irrational. That law was a "typical set of health and safety standards" enacted in response to concerns that a lack of regulation had led to an actual incident involving substandard care. 379 F.3d at 541. Here, the restrictions Arizona is imposing are not typical—indeed, they are contrary—to the provision of high quality medical care, and are opposed by ACOG and the AMA.

courts must ignore evidence that the law contradicts overwhelming medical authority and forces physicians to provide demonstrably inferior care.

Defendant's reliance on the *Gonzales* Court's statement in that states may act "in areas where there is medical and scientific uncertainty," AB 33-34, is similarly misplaced. Even if this standard were applicable in the context of a purported health regulation (not an issue in *Gonzales*, which concerned the government's interest in fetal life), Defendant has failed to demonstrate any uncertainty whatsoever. Order at 7 (finding "no evidence" to support the legislature's rationale and unrebutted evidence that the Arizona law would actually harm women's health). (ER 007). Defendant appears to believe that the legislature's findings in and of themselves establish uncertainty, but *Gonzales* is clear that "[t]he Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake," and may not simply defer to these findings uncritically. 550 U.S. at 165-66.

B. The Arizona Law Cannot Reasonably Be Understood to Serve Women's Health

Defendant's argument that this Court must find that the Arizona law is reasonably related to women's health solely because the legislature said so (in words borrowed from the anti-abortion group Americans United for Life) violates the mandate of *Eden* and *Casey* that courts should "[take] care to verify" whether the law can "be reasonably understood" to promote women's health, *Eden*, 379

F.3d at 540 (citing *Casey*). As Plaintiffs have already fully explained, the Arizona law cannot meet this standard because, at a minimum, it bans a medication regimen that is the current standard of care, that has been extensively studied over more than a decade using data sets exponentially larger than the one submitted to the FDA in 1996, and that has been recognized as safer, less burdensome, and more effective by the AMA and ACOG. OB 6-7; *see also* ACOG/AMA Br.

In the face of this overwhelming evidence, it is absurd that Defendant persists in referring to the current regimen as, *e.g.*, "the procedures Appellants prefer," "non-conforming," and "malleable," AB *passim*, and to the FPL regimen, which has not been widely used in over a decade, as a "uniform" protocol, *id*. at 3. It is even more absurd that Defendant would represent to this Court that Plaintiffs' "only evidence" of the current regimen's superiority is "anecdotal." AB 34. And, as Plaintiffs also explained, the Arizona law is wholly irrational on its face because it requires *more* of the medication it deems dangerous. OB 30-31. Finally, while Defendant criticizes Plaintiffs' regimen (which has been the standard of care for the past eight years) as "ever-evolving," AB 33, most people would prefer that their medical care reflect the latest advances in medicine (and would be unhappy to hear that their only option was a regimen that most physicians had abandoned over a decade ago, and that the AMA and ACOG had labeled "inferior" to, and "less safe" than, the current standard of care).

Because Defendant has presented only unsupported legislative findings that the Arizona law actually furthers women's health, while *all* the evidence demonstrates precisely the opposite, the district court's denial of the preliminary injunction was in error.

C. Defendant's New Evidence Is Improper and Irrelevant

While continuing to argue that "the Court does [sic] cannot consider any evidence" as to whether the law serves women's health, AB 31, Defendant also has submitted a slew of new documents related to the FDA's approval of mifepristone over a decade ago. AB 5-12; *see also* Supplemental Excerpts of Record at 001-86, ECF No. 34-2, Apr. 28, 2014 ("SER"). This supplementation is inappropriate at this appellate stage, where this Court reviews the record that was before the district court. *See Lowry v. Barnhart*, 329 F.3d 1019, 1024-26 (9th Cir. 2003). Moreover, Defendant's submission is merely a smokescreen to give the impression of ambiguity where none exists.

Defendant argues that the documents he now submits show that the FDA somehow restricted providers from using their own professional judgment as to how to provide medication abortions. As Plaintiffs have explained, that is not the case. The FDA regulates how medications are marketed. It does not regulate the practice of medicine, nor does it draft the FPL or select the regimen described therein—the manufacturer does. And once a medication is on the market, it is

common and accepted medical practice (indeed, physicians are professionally *obligated*) to alter the dosages and uses of medications in response to substantial medical research, as providers have done for medication abortion. *See* OB 14, 20; *see also* Declaration of Lisa Rarick, M.D. ("Rarick Decl.") ¶¶ 8-18 (ER 081-85); ACOG/AMA Br. at 16-17; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("Off-label" use is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"); *United States v. Caronia*, 703 F.3d 149, 152-53 (2d Cir. 2012) (reviewing case law and the FDA's recognition of the importance of evidence-based use and affirming "the FDA generally does not regulate how physicians use approved drugs").

The new documents Defendant submits have no bearing on these facts. These documents relate to the fact that mifepristone was approved under Subpart H, which allows the FDA to place certain restrictions on the post-approval distribution or use of a drug. For example, the FDA may restrict distribution of a drug to "physicians with special training or experience." 21 C.F.R. § 314.520(a)(1). Using this authority, the FDA, in its Approval Letter, required the manufacturer to limit distribution to physicians who meet eight qualifications, *see* Letter from Center for Drug Evaluation and Research to Population Council, Sept. 28, 2000, such as that they have the ability to diagnose ectopic pregnancies, and

that they review the Medication Guide with patients and have them sign an agreement confirming they understand the procedure. (SER 002.)

But neither the FDA Approval Letter nor anything else requires prescribers of mifepristone to provide any particular regimen to their patients, or to limit care to the first seven weeks of pregnancy. *Id.; see also Cline*, 313 P.3d at 261 n.17 ("Although the FDA required mifepristone's sponsor to distribute the drug only under conditions where it would be provided by or under the supervision of a physician who was able to meet certain criteria, the FDA did not go so far as to require that administering physicians utilize mifepristone according only to the protocol described in the FDA-approved label").[10]

Indeed, the FDA has recognized that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment." Rarick Decl. ¶ 18 (quoting FDA Information Sheet). (ER 084-85.) Moreover, in specifically discussing *mifepristone*, the FDA has made clear that "physicians exercise their

[10] While the FDA, in 2000, rejected a proposal to outline home administration of misoprostol on the Mifeprex FPL because it found *insufficient* evidence at that time that this method was safe and effective, home administration has since been demonstrated over large-scale studies to be safe and effective, and to provide numerous benefits to patients (including making it *easier* to comply with the two-step regimen). For this reason, ACOG gives this method its highest level of recommendation. *See* Declaration of Daniel Grossman, M.D. ("Grossman Decl.") ¶¶ 32-35. (ER 054-57.)

judgment in prescribing what they feel is best for the patient, [and] they may decide to use an 'off-label' regimen, rather than the approved regimen." Mifepristone Questions and Answers 4/17/2002, U.S. Food and Drug Administration (last updated Aug. 26, 2013), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111354.htm. And the Medication Guide for mifepristone (part of the FPL) informs patients that "[m]edicines are sometimes prescribed for purposes other than those listed in a Medication Guide." (SER 029.)

Given that the FDA itself has recognized the appropriateness of evidence-based medicine, it cannot be *per se* reasonable, as Defendant argues, AB 31-34, for a state to mandate indefinite adherence to an FPL—much less an FPL such as this, which is demonstrably inferior to the current standard of care. Thus Defendant's new evidence, in addition to being improperly presented here, does nothing to rebut the evidence presented below that the Arizona law cannot "be reasonably understood to promote" women's health. *Eden*, 379 F.3d at 540.

III. PLAINTIFFS HAVE PRESENTED CONCRETE EVIDENCE THAT THE LAW WILL SUBSTANTIALLY BURDEN WOMEN SEEKING ABORTIONS

As Plaintiffs have established, the "substantial obstacle" test is "record-dependent," *Eden*, 379 F.3d at 541, and requires that a challenged law be considered in the context of all the other significant obstacles women face, whether

imposed by the state, by "happenstance," AB 41, or by personal circumstances such as poverty. OB 32-34; *see also Casey*, 505 U.S. at 892-94 (considering real-world effect of a spousal notice requirement, including wide-spread spousal abuse).[11] Contrary to this binding authority, Defendant argues that other Arizona restrictions have no bearing on the effect of the Arizona law, and that it cannot impose a substantial obstacle unless Plaintiffs demonstrate that it would prevent women from obtaining an abortion altogether. AB 29, 44.

Casey used the phrase "substantial obstacle," not "absolute" or "insurmountable" obstacle, to describe a burden that would be "undue." Moreover, the Court has consistently held that abortion restrictions pose an undue burden if they expose women to "significant health risks"—regardless of whether they also prevent women from obtaining an abortion. *See, e.g.*, *Gonzales*, 550 U.S. at 161 ("The prohibition in the Act would be unconstitutional, under precedents we here assume to be controlling, if it 'subject[ed] [women] to significant health risks.'") (quoting *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 327-28 (2006) (citing *Casey*, 505 U.S. at 880)).

Following this guidance, this Court has repeatedly found obstacles to be

[11] Defendant dismisses as dicta *Eden*'s statement that "a significant increase in the cost of an abortion . . . can, at some point, constitute a substantial obstacle." AB 39. But this statement was central to this Court's decision to reverse the district court and instruct it to consider cost, among other factors, on remand.

"substantial" because they were onerous and unnecessary—not because they were demonstrably insurmountable. *See McCormack v. Hiedeman*, 694 F.3d 1004, 1015 (9th Cir. 2012) (Idaho law "puts an undue burden on women seeking abortions by requiring them to police their provider's compliance with Idaho's regulations"); *Eden*, 379 F.3d at 542 (considering delay as a burden because it would impose unnecessary health risks); *see also Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 798 (2013); *Planned Parenthood Se., Inc. v. Bentley*, 951 F. Supp. 2d 1280, 1287 (M.D. Ala. 2013).[12]

Plaintiffs have presented undisputed evidence, recognized by the district court, that the Arizona law will impose heavy burdens on *most if not all* women seeking a medication abortion: at a minimum, it will deny all or most of them the only safe, non-surgical abortion method, and (assuming it does not ban medication abortion altogether) force the rest to follow an inferior regimen. It is certain to force many, and likely all, northern Arizona women to travel hundreds of additional miles to obtain an abortion. OB 8-12. Under the law of this Circuit and others, the Arizona law likely imposes substantial obstacles. And—importantly—it

[12] That *McCormack* concerned a criminal statute is irrelevant to its holding—applicable here—that the "undue burden" test requires a real-world examination of a woman's obstacles to obtaining abortion (including those imposed by other laws), and that an obstacle need not be absolute to be "substantial." *See* OB 32-34. Also, contrary to Defendant's characterization, *Van Hollen* focused principally on the very problems present here: the lack of evidence "that the medical grounds [for the law] are legitimate" and the burdens it would impose. 738 F.3d at 796-98.

will impose these obstacles *for no valid reason*.[13]

In an effort to minimize the effects of the law, Defendant misrepresents important facts. Using data from a four-year-old, 31-state survey, he suggests medication abortion is not that common. AB 14, 39. But that is irrelevant to the uncontested fact that 43 percent of eligible *Arizona* women chose medication abortion in 2012, the most recent year for which data is available. Grossman Decl. ¶ 27. (ER 049.)

Defendant also misrepresents the burdens of an FPL mandate. He persists in denying, as "demonstrably false," AB 38, the fact that an FPL mandate would ban medication abortion for women in their eighth and ninth weeks.[14] And he describes the FPL regimen as requiring only an extra trip. AB 1. That burden is significant enough, but Defendant has omitted that the mandate would also force women to

[13] Even if Plaintiffs had to show that the Arizona law would prevent women from having an abortion altogether, they are likely to succeed. In *Casey*, the Court held a spousal consent requirement unconstitutional because it was "likely to prevent a significant number of women from obtaining an abortion," 505 U.S. at 893, even though that number was only a small percentage of the total number of women seeking an abortion. Here, too, Plaintiffs' evidence shows that a significant number of women are likely to be prevented by the Arizona law from obtaining an abortion. OB 11-12, 35; Declaration of Beth Otterstein ("Otterstein Decl.") ¶¶ 4, 21. (ER 019, 024.)

[14] This ban will affect many women because seven weeks is early in a pregnancy and many women do not realize they are pregnant, or cannot arrange the necessary clinic appointments, by that date. Otterstein Decl. ¶¶ 13-15. (ER 022-23.) *See also* Order at 7. (ER 007.)

ingest three times the necessary mifepristone, exposing them to unnecessary side effects and a wholly unnecessary cost increase of at least $200,[15] and would also force them to experience the effects of the misoprostol while on the road rather than in a safe, private space of their choosing. Defendant also ignores that an FPL mandate would make medication abortion less effective, significantly raising the risk that these women would need surgical follow-up.

Plaintiffs submitted evidence explaining how these burdens would harm their patients, who are disproportionately low-income and, in most cases, are trying to squeeze medical care in between childcare responsibilities and inflexible work schedules. Otterstein Decl. ¶¶ 9-11. (ER 020-21.) And these are women already burdened by other medically unnecessary state restrictions on abortion. OB 9-10, 34-35.

Having presented no evidence himself, Defendant dismisses Plaintiffs' evidence as "grossly overbroad" and "nothing more than speculation." AB 39-41. Far from it, Plaintiffs' evidence includes data showing that an FPL restriction enacted in Ohio reduced the number of women able to obtain a medication abortion by nearly *two-thirds*. OB 9. It also includes data showing that when

[15] While Defendant acknowledges this cost later in passing, he dismisses it as "incremental." AB 41. But a price increase of about 40 percent, or $200, would be overwhelming for many of Plaintiffs' patients, who struggle with basic expenses. Otterstein Decl. ¶ 11. (ER 021-22.)

Planned Parenthood Arizona ("PPAZ") was temporarily unable to offer medication abortion in Flagstaff, the number of Northern Arizona women able to obtain *any* kind of abortion from PPAZ fell by more than *one-third*, and the number receiving a *medication* abortion fell by nearly *half*. OB 11-12. Indeed, it is hard to imagine how any evidence, in a pre-enforcement challenge, could satisfy Defendant's proposed standard.

Finally, Defendant asserts that the state can, for no reason, ban any common procedure, even the only non-surgical one (chosen by nearly half of eligible women), as long as it is not the *most* common. AB 39. But neither the Supreme Court nor this Court has ever allowed such a ban. Indeed, if states could enact such bans, they could prohibit any new, safer, and better method of abortion *before* it became the most common, thereby permanently freezing the progress of medicine with respect to abortion. This cannot possibly be consistent with the Supreme Court's recognition that women have a fundamental right to terminate their pregnancies.[16]

[16] Nor can it be consistent with that right for the state to claim it is not an undue burden if abortions are available out of state. *See* AB 42 n.5. Under that logic, a state could ban abortion entirely by pointing to the fact that it available elsewhere. No court has ever sanctioned such an argument. To the contrary, in *Casey*, the Court struck down Pennsylvania's spousal notice requirement without considering that neighboring states such as New Jersey did not have one. *Cf. Missouri ex rel. Gaines v. Canada*, 305 U.S. 337, 350 (1938) (the Fourteenth Amendment "is an obligation the burden of which cannot be cast by one State upon another, and no

IV. AT A MINIMUM, PLAINTIFFS ARE ENTITLED TO AS-APPLIED RELIEF BECAUSE THE ARIZONA LAW EXPOSES WOMEN TO SIGNIFICANT HEALTH RISKS

Defendant seems to agree (as he must) that an abortion restriction may not expose women to significant health risks. *See Casey*, 505 U.S. at 880 (upholding Pennsylvania law only because it had been interpreted such that it "would not *in any way* pose a significant threat to the life or health of a woman") (emphasis added); *see also Gonzales*, 550 U.S. at 161; *Isaacson v. Horne*, 716 F.3d 1213, 1227 (2013) ("To preclude a woman from receiving a medically necessary abortion is to impose an unconstitutional burden." (quoting *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 922-23 (2004)).

Yet Defendant claims that the Arizona law must be upheld because Plaintiffs have not "suggested, much less produced evidence to show" that the law will pose a significant health risk to some women. AB 46. This is false. Plaintiffs presented detailed evidence that the Arizona law, which at a minimum will leave only a surgical abortion method available after seven weeks, will expose some women to significant health risks. For example, Plaintiffs presented evidence that some women have physiological conditions—such as abnormal uterine structures, large uterine fibroids, cervical stenosis, vaginismus, venous scaring, severe obesity, or

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State can be excused from performance by what another State may do or fail to do.").

an extremely flexed uterus—that make surgical abortion extremely difficult and put them at much higher risk of complications. Richardson Decl. ¶ 13; Grossman Decl. ¶ 21 (explaining that, for these women, medication abortion is "significantly safer" than surgical abortion). (ER 033-34; ER 050.) Plaintiffs also presented evidence that, for some women (such as survivors of sexual assault or ritual female circumcisions), surgical abortion would pose significant mental health risks. Richardson Decl. ¶ 14; Grossman Decl. ¶ 20. (ER 033, ER 049-50.) Indeed, Dr. Richardson explained that he has performed medication abortions for these very reasons in his practice. Richardson Decl. ¶ 13. (ER 033.) Defendant presented no evidence in response.

There can, therefore, be no question that Plaintiffs are likely to succeed on their claim that the Arizona law is unconstitutional because it exposes these women to significant health risks. The only remaining question is: "what is the proper relief?" *Ayotte*, 546 U.S. at 967 ("[w]hen a statute restricting access to abortion may be applied in a manner that harms women's health," the question is not whether a remedy is available, but the scope of that remedy). Here, because the number of women who face significant health risks from surgical abortion is relatively small (although far from insignificant), Plaintiffs sought limited relief as applied to these women. *See* Complaint ¶ 95 (asking that the law be enjoined "as applied to women for whom a banned medication abortion is necessary, in

appropriate medical judgment, to protect the life or health of the woman").[17] (ER 115.)

Contrary to Defendant's suggestion that *Gonzales* forecloses this limited remedy, AB 48, Plaintiffs did exactly what *Gonzales* instructs: they brought a pre-enforcement, as-applied challenge and showed "that in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used." 550 U.S. at 167. Indeed, the Sixth Circuit affirmed identical as-applied relief in Ohio. *See Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 514 (6th Cir. 2006) (affirming in part preliminary injunction because "the abortion regulation at issue could pose a significant health risk to women with particular medical conditions" including "a bicornuate (i.e. divided) uterus, extreme flexion of the uterus, large uterine fibroids, cervical stenosis, female genital mutilation, and other abnormalities of the female genital tract"). Plaintiffs here are, at a minimum, entitled to the same.

[17] Defendant complains about the placement of the words "as applied" in Plaintiffs' Complaint, AB 48, but those words properly appear "on the last page" in the prayer for relief because the issue is one of remedy. As the Supreme Court has explained, "[t]he distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case involving a constitutional challenge." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 331 (2010). Rather, "it goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint." *Id*.

V. DEFENDANT'S OTHER ARGUMENTS ARE UNAVAILING

A. Plaintiffs' Equal Protection Claim Is Likely to Succeed

As Plaintiffs explained in their opening brief, the Arizona law violates their equal protection rights for two independent reasons: First, it singles out abortion clinics from other abortion providers, such as individual physicians' offices and hospitals. Its restrictions apply only to the former, while the rest can continue to offer women the superior, evidence-based regimen that Defendant—against all the evidence—claims is "dangerous and potentially deadly," AB 13 (quoting legislative finding). Second, the law irrationally singles out medications used for abortion, as opposed to other, more risky drugs that are prescribed differently from their original labels.[18]

In response, Defendant argues that courts are free to single out abortion providers for no reason. AB 56-57. But the Supreme Court has never held this,[19]

[18] Defendant claims Plaintiffs waived this argument because they did not make it in their opening district court brief. AB 53. That is false. *See* Pls.' Br. Supp. Mot. Prelim. Inj. at 16-17, Mar. 6, 2014. (Further Excerpts of Record 171-72.)

[19] Defendant relies on *Harris v. McRae*, 448 U.S. 297 (1980) and *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52 (1976), but neither case supports his position. *Harris* holds only that states may, to advance an interest in *fetal life*, refuse to *pay* for non-medically necessary abortion services. 448 U.S. at 314-17. *Danforth* was not an equal protection challenge at all, and its ruling with respect to a woman's right to choose supports Plaintiffs here. In particular, the Court expressed concern that the record-keeping requirement singled abortion providers out for differential treatment, but upheld it only because it found it was both "reasonably directed to the preservation of maternal health" and had "no

and this Court made clear in *Eden* that states do *not* have any such special latitude. The test is the same as in any other context, and such a classification is invalid if irrational or motivated by improper purpose. *Eden*, 379 F.3d at 544-47 (citing *Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440, 446 (1985) and *Romer v. Evans*, 517 U.S. 620, 631-32 (1996)).

Defendant also misrepresents *Eden* as holding that states may draw arbitrary lines based on the number of abortions provided. AB 57. To the contrary, *Eden* held that "numerical" classifications are *not* "insulate[d]" from scrutiny, 379 F.3d at 547, but that it was rational for the legislature to have a numerical threshold for *licensing* requirements because "smaller practices would be unduly burdened by the comprehensive [licensing scheme]." *Id*. Here, by contrast, the burdens of the Arizona law fall almost exclusively on the patient, and Defendant has provided no rationale whatsoever for "protecting" some patients but not others. Even if there were some rationale for a numerical distinction, that would not explain why the Arizona law allows hospitals to continue prescribing an evidence-based regimen for medication abortion regardless of how many abortions they provide.

B. Plaintiffs' Bodily Integrity Claim Is Likely to Succeed

As Plaintiffs explained in their opening brief, women have a right to bodily

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legally significant impact or consequence on the abortion decision or on the physician-patient relationship." *Danforth*, 428 U.S. at 80-81.

integrity—independent of their right to reproductive autonomy—and the Arizona law violates this right by depriving them of their only non-surgical treatment option (or, for any women still able to obtain a medication abortion, by forcing them into a burdensome regimen involving unnecessary medication and side effects). *See* OB 37-39.

After arguing below that Plaintiffs' bodily integrity claim fails because in his view the Arizona law is an FPL mandate, and because the right to bodily integrity is subsumed under *Casey*, Defendant now argues for the first time that Plaintiffs' claim fails because abortion itself is a voluntary decision. This argument should be considered waived. *In re Mercury Interactive Corp. Secs. Litig.*, 618 F.3d 988, 992 (9th Cir. 2010) ("We apply a general rule against entertaining arguments on appeal that were not presented or developed before the district court." (citation and internal punctuation omitted)). Regardless, Defendant's argument fails as a matter of law. In *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1991), the Court considered a state standard that prohibited withdrawing life-sustaining treatment from an individual in a persistent vegetative state. The Arizona law also removes certain medical treatment options by operation of state law. It places women in the untenable position of either having to forego a fundamental constitutional right (to choose abortion) or having to "consent" to surgery (or unnecessary medication) when a safe, non-surgical option is available

(but barred by the state for no reason).

If Defendant were right that this has no implications for the right to bodily integrity, the state could—with no justification whatsoever—bar individuals from obtaining any manner of medical care, thereby subjecting them to pain, incapacitation, and even risk of death. In the abortion context, the state could ban all abortion methods except complete removal of the uterus, simply because most women could "decide" under these circumstances to continue their pregnancy. That cannot be the law. Once the inquiry is properly focused on women who have chosen to exercise their fundamental right to an abortion, and on whether the state can, for no reason, bar them from accessing the only safe alternative to surgery, Plaintiffs are likely to succeed on this claim.

CONCLUSION

For the foregoing reasons and those presented in their opening brief, this Court should reverse the district court's decision denying Plaintiffs' Motion for a Preliminary Injunction, and remand this case for trial.

CERTIFICATE OF COMPLIANCE PURSUANT TO CIRCUIT RULE 32-1

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,894 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 Times New Roman size 14.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on May 2, 2014.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/Alice Clapman