Court of Appeals No. 14-15624

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' SURREPLY IN RESPONSE TO *AMICUS CURIAE* BRIEF OF 32 ARIZONA LEGISLATORS

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Plaintiffs-Appellants Planned Parenthood Arizona, Inc., William Richardson, M.D., and William H. Richardson M.D., P.C. (collectively, "Plaintiffs") respectfully submit this Surreply in Response to *Amicus Curiae* Brief of 32 Arizona Legislators in Support of Defendant-Appellee and Affirmance of the District Court, ECF No. 43-1, May 5, 2014 (respectively, "*Amici*" and "*Amicus* Br.").

A. Amici's facts are unreliable and misleading.

The "facts" *Amici* cite are unreliable and misleading. They do not counter Plaintiffs' showing of, at a minimum, important questions going to the merits of their claims under *Tucson Woman's Clinic v. Eden*, 379 F.3d 531 (9th Cir. 2004).

Amici misleadingly state that Defendant relied on "experts," *Amicus* Br. at 28-29; in fact, Defendant relied completely on legislative findings. *Amici* try to bolster the record with their own lay analysis of the facts, but that analysis is deeply flawed. Most notably, *Amici* repeatedly quote a Food and Drug Administration ("FDA") adverse event report ("AER") comparing the number of women who have died following various medication abortion regimens. *Amicus* Br. *passim*. These figures lack denominators, and they do not distinguish among regimens used, so they have no bearing on the relative risks of different regimens. *See* Grossman Decl. ¶ 32. (approximately two million American women have used Plaintiffs' method or other evidence-based regimens; few have used the FPL

method). (ER 054-55) *Amici* also neglect to mention that the FDA has found "[n]o causal relationship between the use of Mifeprex and misoprostol and [fatal infections]" and that there have been zero deaths from infection following Plaintiffs' regimen, in over 700,000 cases studied. *Id.* ¶¶ 38, 46; U.S. Gov't Accountability Office, GAO-08-751, FDA: Approval and Oversight of Mifeprex (2008) ("GAO Report"). (ER 057, 061; SER 75.) Moreover, federal courts generally recognize that AER data is so unreliable as to be generally inadmissible under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See In re Baycol Products Litig.*, 532 F. Supp. 2d 1029, 1040-42 (D. Minn. 2007) (reviewing cases).

Amici advance a theory regarding Mifeprex's supposed interference with the body's immune system. *Amicus* Br. at 21. This *undermines* support for *Amici*'s preferred regimen, which requires *triple* the necessary Mifeprex dosage. It also ignores the FDA's own observation that the CDC's findings and the medical literature reflect that *pregnancy*, not Mifeprex, elevates infection risk. (SER 75-76); Grossman Decl. ¶ 38. (ER 057-58.)

Amici also misleadingly represent that complication rates for medication abortion are substantially higher than for surgical abortion. *Amicus* Br. at 26. The uncontradicted record shows the two are comparable. Grossman Decl. ¶¶ 22-24,

39. (ER 050-52, 058).[1] Similarly, *Amici* impugn Plaintiffs' "ethics" in having patients sign an agreement concerning a regimen they do not follow, *Amicus* Br. at 30-31—again an argument not raised below—but ignore that the law they support mandates deviation from ethical standards. *See* Brief of Amici Curiae American College of Obstetricians and Gynecologists the American Medical Association at 4, 16, ECF No. 29, Apr. 23, 2014 (the law "requires that physicians depart from their ethical obligation to provide the best possible care for their patients using their sound medical judgment—insisting, rather, that physicians substitute the judgment of the Arizona legislature for their own").

B. Amici's statements about the FDA approval process are unfounded.

Plaintiffs have conclusively established that the FDA does not authorize drug regimens, has never authorized any Mifeprex regimen, and never intended to preclude physicians from using their best medical judgment when performing medication abortion. Plaintiffs' Opening Brief, ECF No. 24-1, Apr. 18, 2014 at 19-20; Rarick Decl. ¶ 8; Grossman Decl. ¶ 26. (ER 081; ER 052.) *Amici* incorrectly state that the FPL regimen was "deemed safest by the FDA," *Amicus* Br. at 6; the

[1] At any rate, "[j]ust as for other medical procedures that carry risks of morbidity or mortality, the requirement upheld in *Casey* left women to decide, in consultation with their medical providers, whether they wish to undertake known risks" associated with abortion. *Isaacson v. Horne*, 716 F.3d 1213, 1229 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 905 (2014).

FDA has never compared the FPL regimen to any evidence-based regimen. Rarick Decl. ¶ 8 (ER 081).

Amici attempt to show that the FDA has restricted physicians' discretion to use Mifeprex by misleadingly citing an FDA "approvable letter" issued *prior* to the FDA's approval of the RU-486 regimen. *Amicus* Br. at 15. This interim letter, which is not in the record, in no way reflects the FDA's final determination of Mifeprex's approval. *See* Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications, 69 Fed. Reg. 43351-01 at *43351-*43353. The FDA's *real* approval letter refers solely to restrictions on the "distribution," not the "use" of mifepristone. (SER 2, 9.) Rarick Decl. ¶ 9. (ER 081.) *Amici* also neglect to disclose that the GAO report, which they cite elsewehre, clearly reflects that the FDA is aware of evidence-based use and does not object to it. (SER 75-76.)

Finally, *Amici* inexplicably assume that, "the Patient Agreement would be useful as a 'reference' only if a women were using the protocol outlined, [thus] commonsense indicates that the FDA intended patients to follow the protocol outlined." *Amicus* Br. at 20. It is uncontested that the Patient Agreement contains numerous components other than the FPL, such as information on patients' potential symptoms and on the need for follow-up to confirm termination, none of which reflect the FDA's intention for the FPL regimen to be used. *See* GAO

Report (by signing the agreement, "patients attest to fully understanding the treatment and its potential complications"). (SER 041.) As stated *supra*, the FDA does not authorize drug regimens and has never required physicians to use Mifeprex following a specific regimen; *Amici*'s misstatements do not change that.

Dated: May 8, 2014

Respectfully submitted,

/s/Alice Clapman

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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2014, 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.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ *Alice Clapman*