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11 **SUPERIOR COURT OF ARIZONA**

12 **MARICOPA COUNTY**

13 Planned Parenthood Arizona, Inc.; William
14 Richardson, M.D.; and William H.
15 Richardson, M.D., P.C., doing business as
16 Tucson Women's Center,

17 Plaintiffs,

18 vs.

17 Will Humble, Director of the Arizona
18 Department of Health Services, in his official
19 capacity,

20 Defendant.

Case No. CV2014-006633

SUPPLEMENTAL COMPLAINT

(Hon. J. Richard Gama)

21 Plaintiffs Planned Parenthood Arizona, Inc., William Richardson, M.D., and William
22 Richardson, M.D., P.C. hereby supplement their Complaint, and in support thereof, allege as
23 follows:

24 **Overview**

25 1. As already alleged in Plaintiffs' Complaint, Plaintiffs are Arizona health care
26 providers, bringing the present action on behalf of themselves and their patients, to have declared

1 invalid and enjoined a portion of Arizona House Bill 2036 of 2012 (“HB 2036”), Section 2,
 2 codified at A.R.S. § 36-449.03(E)(6) (“the Statute”) and the regulation implementing this
 3 section, A.A.C. R9-10-1508(G) (“the Regulation”) (collectively “the Arizona Law”), because,
 4 first, the Arizona Law is an unconstitutional delegation of legislative authority and, second, the
 5 Arizona Department of Health Services (“ADHS”) promulgated the Regulation without
 6 following the required notice-and-comment procedures.

7 2. The need for this Supplemental Complaint has arisen from events occurring since
 8 Plaintiffs filed their initial Complaint. Specifically, in his briefs, Defendant has adopted various,
 9 sometimes contradictory positions on the meaning of the Arizona Law, and thereby on the
 10 medication protocols, if any, that abortion clinics may legally use to administer medication
 11 abortion in Arizona.

12 3. These varied interpretations of the Arizona Law – which, if it takes effect, will be
 13 enforced by Defendant and his agency, ADHS, and with which Plaintiffs will have to comply –
 14 give rise to the need for additional declaratory relief as sought herein.

15 **Supplemental Facts**

16 4. On March 4, 2014, Plaintiffs filed a federal suit challenging the Arizona Law
 17 under the Fourteenth Amendment to the United States Constitution (“the Federal Suit”)—a
 18 challenge not present in this case.

19 5. On April 7, 2014, Plaintiffs filed this case in state court, challenging the Arizona
 20 Law on state law grounds, as more fully described in paragraph 1 *supra* (“the State Suit”) and in
 21 the original Complaint.

22 6. As the Court is aware, the Arizona Law underlying both actions restricts the
 23 administration of medication abortion in Arizona.

24 7. The Statute mandates that Defendant, the director of ADHS, adopt an
 25 administrative rule “requir[ing] . . . [t]hat any medication, drug or other substance used to induce
 26

1 an abortion is administered in compliance with the protocol that is authorized by the united states
2 food and drug administration and that is outlined in the final printing labeling instructions for
3 that medication, drug or substance.” A.R.S. § 36-449.03(E)(6).

4 8. Pursuant thereto, ADHS promulgated the Regulation, which essentially parrots
5 the Statute by stating that the medical director of a licensed abortion clinic “shall ensure” that
6 medications administered to induce abortions are used only as described in the Statute. A.A.C.
7 R9-10-1508(G).

8 9. In the course of defending the two actions, Defendant has adopted various
9 interpretations of the Arizona Law, some contradictory, which affect whether and how, if the
10 Arizona Law takes effect, Plaintiffs will be able to legally provide medication abortion.

11 10. Mifepristone (brand name Mifeprex) is the only medication whose FDA-approved
12 label outlines a protocol for use in inducing abortions. This protocol requires a second drug,
13 misoprostol (brand name Cytotec), to be administered after Mifeprex. Misoprostol is not itself
14 labeled for use in abortions; its FPL describes a protocol only for use in the treatment of certain
15 kinds of ulcers.

16 11. According to ADHS’ annual abortion reports from 2011-2014, Mifeprex and
17 misoprostol used together account for the great majority of non-surgical abortions performed in
18 Arizona.

19 12. Other drugs and protocols may also be used off-label to induce abortions; ADHS’
20 reports state that digoxin, methotrexate used together with misoprostol, misoprostol used by
21 itself, and “other” medications or regimens have all been administered.

22 13. In Defendant’s filings in the Federal Suit and the State Suit, he has alternated
23 between contending the Arizona Law applies to:

24 (a) *all* abortion-inducing drugs (as the law’s plain language indicates);

25 (b) *only* Mifeprex *and* misoprostol when used together; and

26

1 (c) *only* Mifeprex.

2 14. This is significant because it leaves unclear whether and how abortion clinics,
3 including Plaintiffs, may provide abortion-inducing medications other than Mifeprex.

4 15. In the Federal Suit, Defendant has also taken two different positions regarding
5 how the Arizona Law regulates misoprostol when used with Mifeprex. He has argued
6 “alternative[ly]” that:

7 (a) misoprostol *is* an abortion-inducing medication, and thus subject to regulation
8 under the Arizona Law, but even though it is not labeled for use in abortions, it may still
9 be used – but only as outlined on the FPL of another drug, namely Mifeprex; and

10 (b) misoprostol *is not* an abortion-inducing medication, because the Arizona
11 Law’s use of the word “induce” limits its application in a multi-drug protocol only to the
12 first medication in the protocol.

13 16. The first of these two interpretations is at odds with the Arizona Law’s plain text,
14 which states that an abortion-inducing medication must be administered “in compliance with the
15 protocol . . . outlined in the final printing labeling instructions *for that medication.*” A.R.S. § 36-
16 449.03(E)(6) (emphasis added). If the Arizona Law regulates the use of misoprostol when used
17 with Mifeprex, then its only possible effect is to prohibit that use.

18 17. However, if the Arizona Law does not regulate the use of misoprostol when used
19 with Mifeprex, then ADHS has no legal authority to place restrictions on that use, including a
20 restriction that it be used only as outlined on Mifeprex’s FPL.

21 18. This dispute is significant because it determines whether and how the second drug
22 in Arizona’s most commonly-used medication abortion regimen may be used. This includes
23 whether, by banning the regimen’s second step, the Arizona Law is a *de facto* ban on the
24 regimen, and, if the regimen is not banned, then whether abortion clinics’ medical directors must
25 follow the second step of Mifeprex’s FPL protocol (i.e. the administration of misoprostol)

26

1 precisely, or whether they retain discretion to exercise their medical judgment to vary
2 misoprostol's dosage, route of administration, and other aspects of the protocol's second step.

3 19. Finally, in the State Suit, Defendant has taken different positions regarding
4 whether and how the Arizona Law incorporates any future changes to Mifeprex's FPL (as well
5 as the FDA's approval of any FPLs outlining abortion regimens not using Mifeprex).

6 20. Specifically, if Mifeprex's FPL changes in the future, Defendant has said that "the
7 Court could find that" Plaintiffs and other abortion clinics will either be subject to:

8 (a) an "evolving standard" under which they are allowed or even required to
9 follow the new protocol; or

10 (b) an unchanging "exact" standard which requires them to adhere to the old
11 Mifeprex FPL as it read on the date the Arizona Law took effect.

12 21. This is significant because it leaves unclear how Plaintiffs and other abortion
13 clinics can comply with the Arizona Law if Mifeprex's FPL is changed (or if the FDA approves
14 any non-Mifeprex FPLs outlining abortion protocols).

15 22. Resolution of these issues has significant consequences for what abortion
16 regimens, if any, may be lawfully administered by Plaintiffs – and, *a fortiori*, accessed by
17 Plaintiffs' patients.

18 23. None of these issues has yet been resolved in the Federal Suit, State Suit, or
19 otherwise.

20 **COUNT III**
21 **(Declaratory Relief)**
22 **(Whether Arizona Law Applies to All Abortion-Inducing Drugs)**

23 24. Plaintiffs hereby incorporate the preceding allegations, as well as those in their
24 Complaint, as if set forth fully herein.

25 25. A dispute has arisen between the parties regarding whether the Arizona Law
26 applies to all abortion-inducing medications, only to Mifeprex and misoprostol when used
together to induce an abortion, or only to Mifeprex when used to induce an abortion.

1 26. Plaintiffs are entitled to a declaration resolving this issue.

2 **COUNT IV**
3 **(Declaratory Relief)**
4 **(Whether Misoprostol Qualifies as an Abortion-Inducing Drug**
5 **Under the Arizona Law)**

6 27. Plaintiffs hereby incorporate the preceding allegations, as well as those in their
7 Complaint, as if set forth fully herein.

8 28. A dispute has arisen between the parties regarding whether misoprostol is an
9 abortion-inducing medication under the Arizona Law, both when used in medication abortion
10 generally, and more specifically when used in the protocol outlined on Mifeprex's FPL.

11 29. Plaintiffs are entitled to a declaration resolving this issue.

12 **COUNT V**
13 **(Declaratory Relief)**
14 **(Whether the Arizona Law Prohibits the Use of Misoprostol**
15 **in Medication Abortions)**

16 30. Plaintiffs hereby incorporate the preceding allegations, as well as those in their
17 Complaint, as if set forth fully herein.

18 31. A dispute has arisen between the parties regarding whether, if misoprostol is
19 regulated under the Arizona Law, its use in medication abortion is prohibited or whether it may
20 be still be used, but only as outlined in Mifeprex's FPL.

21 32. Plaintiffs are entitled to a declaration resolving this issue.

22 **COUNT VI**
23 **(Declaratory Relief)**
24 **(Whether the Arizona Law Is Limited to Those FDA-Approved Protocols in Place**
25 **When the Arizona Law was Enacted)**

26 33. Plaintiffs hereby incorporate the preceding allegations, as well as those in their
Complaint, as if set forth fully herein.

34. A dispute has arisen between the parties regarding whether, if Mifeprex's FPL is
changed (or if the FDA approves any non-Mifeprex FPLs outlining abortion protocols), Plaintiffs
will be allowed or even required to follow the new protocol(s), or whether they will be forbidden

1 from following the new protocol(s), and required to follow only the protocol appearing on the
2 Mifeprex FPL at the time the Arizona Law was enacted.

3 35. Plaintiffs are entitled to a declaration resolving this issue.

4 WHEREFORE, in addition to the relief sought in their Complaint, Plaintiffs pray for
5 further declaratory relief as described above, as well as such other declaratory relief as the Court
6 may deem appropriate to fully resolve the dispute between the parties.

7 RESPECTFULLY SUBMITTED this 11th day of March, 2015.

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