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7 **SUPERIOR COURT OF ARIZONA**

8 **MARICOPA COUNTY**

9  
10 Planned Parenthood Arizona, Inc.; William  
Richardson, M.D.; and William H.  
11 Richardson, M.D., P.C., doing business as  
Tucson Women's Center,

12 Plaintiffs,

13 vs.

14 Will Humble, Director of the Arizona  
15 Department of Health Services, in his  
official capacity,

16 Defendant.

Case No. CV2014-006633

**COMPLAINT**

17  
18 For their Complaint, Plaintiffs Planned Parenthood Arizona, Inc. ("PPAZ"),  
19 William Richardson, M.D., and William Richardson, M.D., P.C. allege as follows:

20 **Overview of Action**

21 1. Arizona health care providers, on behalf of themselves and their patients,  
22 bring this action to have declared invalid and enjoined a portion of Arizona House Bill  
23 2036 of 2012 ("HB 2036"), Section 2, codified at A.R.S. § 36-449.03(E)(6) ("the Statute")  
24 and the regulation implementing this section, A.A.C. R9-10-1508(G) ("the Regulation"),  
25 because, first, the Statute and Regulation represent an unconstitutional delegation of  
26 legislative authority and, second, the Arizona Department of Health Services ("ADHS")

1 promulgated the Regulation without following the required notice-and-comment  
2 procedures.

3 2. The Statute and Regulation restrict how physicians may perform  
4 medication abortion, a non-surgical alternative that allows women to end an early  
5 pregnancy safely with the use of medication alone, avoiding the need for a surgical  
6 procedure. Nearly half of all women in Arizona who terminate a pregnancy in the first  
7 nine weeks choose medication abortion. Medication abortion involves the use of two  
8 medications: misoprostol and mifepristone, also known by its trade name Mifeprex.

### 9 The Parties and Standing

10 3. Plaintiff PPAZ is a not-for-profit corporation organized under the laws of  
11 Arizona and is the largest provider of reproductive health services in Arizona, operating  
12 health centers throughout the state and providing a broad range of reproductive and  
13 sexual health services, including cervical cancer screening, breast exams, testing and  
14 treatment for sexually transmitted infections, contraception, and surgical and medication  
15 abortion.

16 4. PPAZ has been providing medication abortions since 2001. It currently  
17 provides medication abortion through 63 days or nine weeks of pregnancy, measured  
18 from the first day of a woman's last menstrual period (LMP), using an evidence-based  
19 regimen that has been recommended by the American Medical Association ("AMA") and  
20 the American College of Obstetricians and Gynecologists ("ACOG") and that differs  
21 from the regimen that appears on the Mifeprex label. PPAZ currently provides  
22 medication abortions at four centers: Glendale Health Center, Margaret Sanger Health  
23 Center (in Tucson), Tempe Health Center, and Flagstaff Health Center (which provides  
24 only medication abortion). In 2013, PPAZ provided medication abortions to 2511  
25 patients; 38 percent of eligible patients chose this procedure. PPAZ brings this action on  
26

1 behalf of itself, its patients, and the physicians it employs to provide services to its  
2 patients.

3 5. Plaintiff William Richardson, M.D., is a licensed, board-certified  
4 obstetrician-gynecologist in Tucson. He is the sole owner and director of Tucson  
5 Women's Center. Dr. Richardson provides comprehensive family planning and women's  
6 health services to over a thousand patients each year, from throughout southern Arizona  
7 and beyond, including pregnancy testing, prenatal care, contraception, prenatal  
8 ultrasounds, pregnancy options counseling, gynecological care, and surgical and  
9 medication abortions.

10 6. Dr. Richardson provides abortion services to about 900 women per year,  
11 nearly half of whom choose medication abortion. He opened Tucson Women's Center in  
12 1999 and has been offering his patients medication abortion since 2001. He currently  
13 provides medication abortion using an evidence-based regimen through 63 days LMP  
14 that is recommended by the AMA and ACOG and that differs from the regimen that  
15 appears on the Mifeprex label. Dr. Richardson brings this action on behalf of himself and  
16 his patients.

17 7. Plaintiff William Richardson, M.D., P.C. is a professional corporation  
18 organized under the laws of Arizona and doing business as Tucson Women's Center; this  
19 is the legal entity through which Dr. Richardson engages in the practice of medicine.

20 8. Defendant Will Humble is the Director of the ADHS. ADHS promulgated  
21 HB 2036's implementing regulations, and has the authority to enforce the Regulation.  
22 Defendant Humble is sued in his official capacity.

### 23 Jurisdiction and Venue

24 9. The Superior Court of Arizona has subject matter jurisdiction pursuant to  
25 Article 6, Section 14 of the Arizona Constitution.  
26

1 10. Venue is proper in Maricopa County pursuant to A.R.S. § 12-401(16).

2 **Factual Background**

3 11. On April 10, 2012, the Arizona Legislature passed HB 2036, and on April  
4 12, 2012, Governor Brewer signed it into law. Section 2 of that law, which is the Statute,  
5 mandates that the Director of ADHS adopt rules requiring “[t]hat any medication, drug or  
6 other substance used to induce an abortion is administered in compliance with the  
7 protocol that is authorized by the United States Food and Drug Administration [(“FDA”)]  
8 and that is outlined in the final printing labeling [(“FPL”)] instructions for that  
9 medication, drug or substance.” HB 2036 § 2, codified at A.R.S. § 36-449.03(E)(6).<sup>1</sup>

10 12. Section 10 of HB 2036 states “[f]or the purposes of this act, the department  
11 of health services is exempt from the rule making requirements of title 41, chapter 6,  
12 Arizona Revised Statutes, for two years after the effective date of this act.”

13 13. ADHS maintains a website entitled “Office of Administrative Counsel &  
14 Rules: Rulemaking Process” that establishes an “Exempt Rulemaking Process” for  
15 “[r]ules [that] are exempt from the rulemaking requirements in A.R.S § Title 41, Chapter  
16 6 . . . if authorized by a specific statute.”

17 14. This “Exempt Rulemaking Process” process requires ADHS, after initially  
18 proposing the rules, to receive comments and make revisions three times, including  
19 (during the first iteration) by meeting with affected and interested persons.

20 15. On November 21, 2013, pursuant to the legislative mandate in Section 2 of  
21 the Act, ADHS posted “Draft Rules Issued for Abortion Clinics” online, and on  
22 November 29, 2013, the Secretary of State published a Notice of Public Information in  
23  
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25 <sup>1</sup> HB 2036 requires ADHS to make numerous other rule changes as well – these are rule changes  
26 not directly “relating to the abortion procedure.” HB 2036 § 2, codified at A.R.S. § 36-  
449.03(E).

1 the Arizona Administrative Register. The Online Survey was open for comments until  
2 December 19, 2013.

3 16. On January 27, 2014, without providing the additional opportunities for  
4 comment that its own policy requires, and without any public meetings, ADHS  
5 promulgated HB 2036's implementing regulations.

6 17. Among the implementing regulations is the Regulation, which requires the  
7 medical director of a facility licensed as an abortion clinic to "ensure that any medication,  
8 drug or other substance used to induce an abortion is administered in compliance with the  
9 protocol that is authorized by the United States Food and Drug Administration and that is  
10 outlined in the final printing labeling instructions for that medication, drug or substance."  
11 The implementing regulation's effective date was April 1, 2014.

12 18. Any clinic that fails to comply with these requirements is subject to a civil  
13 penalty, license suspension or revocation, or other enforcement actions by ADHS. A.A.C.  
14 § R9-10-1515.

15 19. The content of a drug's FPL is written by a drug's manufacturer and subject  
16 to approval by the FDA. At no point is its content subject to review or approval by the  
17 Arizona legislature or ADHS.

## 18 COUNT I

### 19 **Non-Delegation**

20 20. Plaintiffs hereby reaffirm and re-allege each and every allegation made in  
21 paragraphs 1-19 above as if set forth fully herein.

22 21. This claim is brought pursuant to the Uniform Declaratory Judgment Act,  
23 codified at A.R.S. §§ 12-1831 through 12-1846.

24 22. The Statute and Regulation define a *state* standard of conduct by reference  
25 to an external *federal/private-sector* standard, specifically the "protocol" for a drug (*i.e.*,  
26

1 the instructions for use) written by a drug company, approved by the FDA, and appearing  
2 on a drug's FPL. That federal standard is not fixed, *but* could change if the manufacturer  
3 asks the FDA for, and it approves, changes to the "protocol."

4 23. The Court should declare that the Statute and Regulation unconstitutionally  
5 delegate legislative authority for the regulation of medication abortions in Arizona to the  
6 FDA and to drug companies, and permanently enjoin Defendant, and his employees,  
7 agents, and successors in office from enforcing them.

## 8 COUNT II

### 9 **Administrative Law**

10 24. Plaintiffs hereby reaffirm and re-allege each and every allegation made in  
11 paragraphs 1-23 above as if set forth fully herein.

12 25. This claim is brought pursuant to the Uniform Declaratory Judgment Act,  
13 codified at A.R.S. §§ 12-1831 through 12-1846.

14 26. While HB 2036's implementing regulations were exempt from the  
15 rulemaking requirements in Title 41, Chapter 6, Arizona Revised Statutes, they were still  
16 subject to ADHS's internal procedures for exempt rulemaking. These procedures are  
17 published on the ADHS website and require multiple postings of the draft rules for  
18 comment, that ADHS meet with interested persons, and that it take their comments into  
19 consideration.

20 27. ADHS did not follow these procedures when promulgating HB 2036's  
21 implementing regulations.

22 28. The Court should therefore declare the Statute and Regulation unlawful and  
23 permanently enjoin Defendant, and his employees, agents, and successors in office from  
24 enforcing them.

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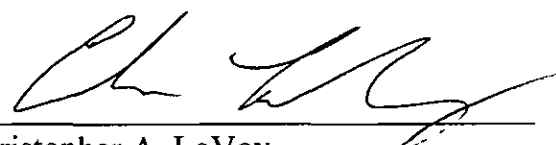
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WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

- A. For a declaratory judgment that that the Statute and Regulation are unlawful and/or unconstitutional and unenforceable;
- B. For a temporary restraining order, preliminary injunction, and/or permanent injunction restraining Defendant, and his employees, agents, and successors in office from enforcing each and every statute and/or regulation declared unlawful and/or unconstitutional.
- C. For an award of Plaintiffs' reasonable attorneys' fees pursuant to the private attorney general doctrine;
- D. For an award of Plaintiffs' costs pursuant to A.R.S. § 12-341.01; and
- E. For such other relief as the Court deems just and equitable.

RESPECTFULLY SUBMITTED this 7th day of April, 2014.

TIFFANY & BOSCO, P.A.

By: 

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