Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
10/15/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2014-006633 10/13/2015

HONORABLE J. RICHARD GAMA

CLERK OF THE COURT
M. Corriveau
Deputy

PLANNED PARENTHOOD ARIZONA INC, et al.

CHRISTOPHER A LAVOY

v.

CARA CHRIST, et al.

ELISSA M GRAVES

MINUTE ENTRY

The Court has had under advisement (i) Plaintiffs' Motion for Summary Judgment (filed May 15, 2014); (ii) Plaintiffs' Supplemental Motion for Summary Judgment (filed Mar. 19, 2015); (iii) Defendant's Cross-Motion for Summary Judgment (filed May 6, 2015); and (iv) Defendant's Motion to Dismiss (filed Sept. 5, 2014). Having read and considered the briefing and having heard oral argument, the Court rules as follows.

In April 2012, the Arizona legislature mandated that the Arizona Department of Health Services ("ADHS") adopt a number of rules regarding abortion, including:

> [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 food and drug administration and that is outlined in the final printing labeling instructions for that medication, drug or substance*.

House Bill ("HB") 2036, codified, in pertinent part, at A.R.S. § 36-449.03(E)(6) (emphasis added) (the "Statute"). In accordance with that mandate, ADHS promulgated A.A.C. R9-10-1508(G) (the "Regulation"), which provides:

> A medical director [of a licensed abortion clinic] shall ensure that any medication, drug, or substance *used to induce an abortion* is administered *in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance*.

(Emphasis added.) The Regulation went into effect in April 2014, but has been stayed by the U.S. Court of Appeals for the Ninth Circuit.[1]

Plaintiffs are Arizona health care providers who offer their patients the option of terminating an early pregnancy using medication alone ("medication abortion"). Defendant is Cory Nelson, Interim Director of ADHS. Plaintiffs challenge the Statute and the Regulation (collectively, the "Arizona Law"), claiming that they drastically restrict access to medication abortion in Arizona. ADHS denies that claim.

I.

Plaintiffs do not dispute that ADHS was exempted from the rulemaking requirements of the Arizona Administrative Procedure Act. *See* HB 2036, § 10.[2] They argue, though, that the Regulation is invalid because ADHS did not promulgate it in accordance with its own policy for exempt rulemaking.[3] Thus, the threshold question is whether ADHS did, in fact, establish a policy for exempt rulemaking.

Plaintiffs point to a webpage maintained by ADHS stating that, after proposing a rule, the agency would take certain steps to provide affected and interested persons with opportunities for input into the exempt rulemaking process.[4] But there is no evidence that the webpage was

[1] *See generally Planned Parenthood Ariz., Inc. v. Humble,* D.C. No. 4:14-cv-01910-DCB (D. Ariz.) (raising claims under the 14th Amendment to the United States Constitution). The federal action has since been stayed pending resolution of this one.

[2] *See generally* A.R.S. title 41, ch. 6.

[3] Compl., Count 2.

[4] The webpage stated that ADHS would post a draft rule for comment, meet with interested and affected persons, revise the draft based on comments received, post a revised draft, revise the draft again based on comments received, file a Notice of Public Information with the Secretary of State, post the revised draft, take further

reflective of any such policy within ADHS. *Cf. Clay v. Ariz. Interscholastic Ass'n, Inc.,* 161 Ariz. 474 (1989) (issue whether student athlete was eligible to participate pursuant to Arizona Interscholastic Association (AIA) rules); *see also Tiffany ex rel. Tiffany v. Ariz. Interscholastic Ass'n, Inc.,* 151 Ariz. 134, 139 (App. 1986) (AIA Executive Board failed to exercise discretion under AIA bylaws); *Tucson Warehouse & Transfer Co. v. Al's Transfer, Inc.,* 77 Ariz. 323, 327-28 (1954) (Corporation Commission failed to follow rule promulgated as a general order). ADHS characterizes the webpage as "a set of informational bullet points," not policy for exempt rulemaking.[5] Although the Court does not necessarily agree with the characterization, it does agree with ADHS that the webpage did not constitute a policy for exempt rulemaking. Accordingly, on this basis,

THE COURT FINDS that ADHS lawfully promulgated the Regulation.

II.

The Food and Drug Administration ("FDA") is the federal agency charged with approving drugs for sale and marketing in the United States. The FDA establishes the requirements for drug labeling, and it has final approval of all drug labels.

A manufacturer seeking approval to market a drug submits an application to the FDA. The FDA approves a drug based on evidence of clinical trials submitted by the manufacturer. For the most part, after a drug has been approved by the FDA, physicians may prescribe it for purposes and in doses other than those set forth in the final printing label ("FPL"); this is known as off-label (or evidence-based) use. The FDA may condition approval of a drug under "Subpart H," which allows the FDA to impose restrictions on a drug's marketing and distribution;[6] Subpart H does not restrict use of a drug to the on-label regimen.

Mifepristone (brand name Mifeprex) was approved by the FDA in 2000 with Subpart H restrictions; it is the only medication whose FPL outlines a protocol for use in inducing abortions. Mifepristone ends a pregnancy by blocking the hormone progesterone, thereby causing the fertilized egg to detach from the uterine wall. The Mifeprex protocol requires that it

---

comments, re-draft again based on comments received, and then file a Notice of Exempt Rulemaking with the Secretary of State. ADHS admits these steps were "incorrect," *see, e.g.,* Def.'s Resp. to Pls.' Mot. for Summ. J. at 19-20; Def.'s Mot. to Dismiss at 9, and there is no dispute that ADHS did not follow them. In April 2014, after Plaintiffs filed this lawsuit, ADHS reviewed the webpage and concluded it did not reflect the agency's procedure for exempt rulemaking; ADHS "corrected the webpage" in April 2014. (Def.'s SSOF at ¶¶ 18, 22.)

[5] Tr. Aug. 14, 2015 at 22.

[6] *See* Code of Fed. Regulations tit. 21, pt. 314, subpt. H; Def.'s SSOF at ¶ 28.

be taken in conjunction with misoprostol (brand name Cytotec); misoprostol, which causes the uterus to contract and expel its contents, is administered "if the patient is still pregnant" after having taken Mifeprex. Mifeprex and misoprostol used together account for the vast majority of medication abortions performed in Arizona.

Cytotec is not itself labeled for use in abortions. Cytotec's FPL outlines only a protocol for use in the treatment of stomach ulcers; it warns that administration to women who are pregnant can cause an abortion.[7]

A.

Plaintiffs seek a declaration that the Arizona Law incorporates a changeable standard and does not require that medication abortion be performed according to the Mifeprex FPL protocol at the time the Law was enacted.[8]

The best and most reliable indicator of a statute's meaning is its language. *E.g., N. Valley Emergency Specialists, L.L.C. v. Santana,* 208 Ariz. 301, 303 (2004); *Bentley v. Building Our Future*, 217 Ariz. 265, 270 (App. 2007). If the language is clear and unambiguous, the Court will apply it without resorting to other methods of statutory interpretation. *Hoag v. French,* 2015 WL 4911651, at *2 (Ariz. App. Aug. 18, 2015), *citing Stein v. Sonus USA, Inc.*, 214 Ariz. 200, 201 (App. 2007); *N. Valley Emergency Specialists, id., citing Bilke v. State*, 206 Ariz. 462, 464 (2003). The Court is "not at liberty to rewrite [a] statute under the guise of judicial interpretation." *New Sun Bus. Park, LLC v. Yuma Cty.*, 221 Ariz. 43, 47 (App. 2009), *citing State v. Patchin*, 125 Ariz. 501, 502 (App. 1980). "The choice of the appropriate wording rests with the Legislature, and the court may not substitute its judgment for that of the Legislature." *City of Phx. v. Butler*, 110 Ariz. 160, 162 (1973).

At the same time, even where statutory language is clear and unambiguous, the Court will not employ a plain meaning interpretation that would lead to a result at odds with the legislature's intent and purpose of the statute. *E.g., State v. Estrada,* 201 Ariz. 247, 251 (2001); *Bentley, supra*. The Court should avoid "hypertechnical constructions that frustrate legislative intent." *Calik v. Kongable,* 195 Ariz. 496, 501 (1999) (citation omitted). Also, the Court cannot

[7] *See generally Planned Parenthood Ariz., Inc. v. Humble,* 753 F.3d 905 (9th Cir. 2014); *Cline v. Okla. Coalition for Reproductive Justice,* 313 P.3d 253 (Okla. 2013).

[8] Suppl. Compl., Count 6. ADHS urges that this issue is not ripe. The Court agrees with Plaintiffs that this misapprehends their claim, which seeks a declaration regarding what the Arizona Law means *now*. *Cf. Lake Havasu Resort, Inc. v. Commercial Loan Ins. Corp.,* 139 Ariz. 369, 377 (App. 1983) (declaratory relief will not be based on facts that may arise in the future).

apply a statute's clear and unambiguous language if to do so "would lead to impossible or absurd results." *Ponderosa Fire Dist. v. Coconino Cty.*, 235 Ariz. 597, 602 (App. 2014); *see also id.* at 604.

The Arizona Law is clear and unambiguous. It does not mention a particular FPL protocol. ADHS urges an interpretation that incorporates by reference the Mifeprex FPL protocol at the time the Arizona Law was enacted (i.e., 2012).[9] But if that is what the legislature intended, it could have said just that.[10] ADHS infers such intent from reference to a Mifeprex FPL protocol in the Findings of HB 2036 (at § 9(A)(9)). But the Findings are not part of the Statute, and the reference is to the 2005 Mifeprex FPL protocol.[11] In the end, the question is whether incorporating by reference a Mifeprex FPL protocol as of 2012 would lead to an absurd result. If that protocol changes, did the legislature intend for physicians to follow an outdated one? If Mifeprex's approval is revoked, did the legislature intend for physicians to continue to administer it by following a formerly-approved protocol? If the FDA approves another abortion-inducing drug, did the legislature intend that physicians could not prescribe it at all? Clearly those results would be absurd. Accordingly, on this basis,

THE COURT FINDS that the Arizona Law incorporates a changeable standard and does not require that medication abortion be performed according to the Mifeprex FPL protocol at the time the Law was enacted.

B.

Plaintiffs argue that the Arizona Law is an unconstitutional delegation of legislative authority because it impermissibly (1) gives the power to make Arizona law to drug companies and the FDA and (2) adopts a changeable standard.[12]

Our supreme court has spoken on this precise issue:

---

[9] ADHS relies on *Arizona Citizens Clean Elections Comm'n v. Brain,* 233 Ariz. 280, 287 (App. 2013) for the proposition that, when a statute adopts or refers to another statute by specific reference, the adoption takes the adopted statute as it exists at the time of the adoption. (Def.'s Resp. to Pls.' Suppl. Mot. for Summ. J. at 13.) As Plaintiffs note, however, the Mifeprex FPL protocol is not a statute, and the Arizona Law does not specifically reference it. Further, the Court of Appeals' opinion was subsequently vacated on the precise issue of statutory construction on which ADHS relies. *See generally Arizona Citizens Clean Elections Comm'n v. Brain,* 234 Ariz. 322 (2014).

[10] *See, e.g.*, A.R.S. §§ 49-1003(C); 3-601.01(A); 11-875(A)(2); 41-2124(A)(2), (B); and 15-151(E).

[11] The Mifeprex FPL on the FDA's website was updated in 2009. (*See* Pls.' Reply in Supp. of Suppl. Mot. at 3 n.2.)
[12] Compl., Count 1; *see* Ariz. Const. art. IV, pt. 1, § 1.

> *It is perfectly legitimate for the Legislature to adopt existing federal rules, regulations or statutes as the law of this state.* The rationale of course, is that, assuming the Legislature has the power to act in a certain area, it should not be required to set out in full that which can be incorporated by a single citation. *However, it is universally held that an incorporation by state statute of rules, regulations, and statutes of federal bodies to be promulgated subsequent to the enactment of the state statute constitutes an unlawful delegation of legislative power.* Since the Legislature exercises absolutely no control over Congress or its agencies, the adoption as state law of those bodies' *prospective enactments* is viewed as a complete abdication of legislative power.

State v. Williams, 119 Ariz. 595, 598-99 (1978) (emphasis added; citations omitted). "An improper delegation of legislative authority may occur when a statute (and, by implication, a rule) incorporates later-developed standards not promulgated by the Legislature or an Arizona agency." *Gutierrez v. Indus. Comm'n,* 226 Ariz. 395, 398 (2011).

Plaintiffs dispute that a drug's FPL has the legal force of a "federal rule, regulation or statute." But Plaintiffs both marginalize the FDA's control of a drug's FPL and ignore that the Arizona Law adopts a drug *protocol* that is authorized by the FDA *and* that is outlined on the FPL. That said, as the Court has found, the Arizona Law incorporates a changeable standard and does not require that medication abortion be performed according to the Mifeprex FPL protocol at the time the Law was enacted.[13] Accordingly, on this basis,

THE COURT FINDS that the Arizona Law is an unconstitutional delegation of legislative authority.

III.

Plaintiffs allege three additional claims for declaratory judgment. The Court addresses each in turn.

[13] *See supra* § II(A).

A.

Does the Arizona Law regulate *all* abortion-inducing "medications, drugs, or substances"?[14] ADHS does not dispute that it does, "presuming 'induce' is properly understood according to its intent."[15] Accordingly, on this basis,

THE COURT FINDS that the Arizona Law regulates all abortion-inducing medications, drugs, or substances.

B.

Is misoprostol an abortion-inducing drug?[16] Clearly it can be. Misoprostol can induce an abortion by "caus[ing] the uterus to contract and expel its contents.[17] Cytotec's FPL warns as much. But is misoprostol an abortion-inducing drug when used in the protocol outlined on the Mifeprex FPL?[18] Plaintiffs urge that it must be because it is administered to women who are still pregnant after taking Mifeprex, with the intent to terminate their pregnancies. The Court agrees with Plaintiffs. For its part, ADHS does not answer the question so much as it obliquely rephrases it, urging that Mifeprex, not misoprostol, is *the* abortion-inducing drug when adhering to the Mifeprex protocol.[19] Put another way, ADHS posits, Mifeprex induces the abortion and misoprostol completes it.[20] The Arizona Law is clear and unambiguous, though, and the Court cannot rewrite it; it applies to "*any* medication, drug or other substance *used to induce an abortion*," not "the first of two in a series…." Accordingly, on this basis,

THE COURT FINDS that misoprostol is an abortion-inducing drug under the Arizona Law, including when used in the protocol outlined on Mifeprex's FPL.

---

[14] Suppl. Compl., Count 3 (distinguishing "all" from application of the Law to only Mifeprex or Mifeprex and misoprostol together).

[15] Def.'s Resp. to Pls.' Suppl. Mot for Summ. J.. at 5 n.1.

[16] Suppl. Compl., Count 4.

[17] *Planned Parenthood,* 753 F.3d at 907. ADHS' counsel admits that misoprostol "has been used standing alone to induce abortion for a long time." Tr. Aug. 14, 2015 at 35.

[18] *See supra* n.16.

[19] *E.g.,* Def.'s Cross-Mot. for Summ. J. at 8.

[20] Tr. Aug. 14, 2015 at 35.

C.

Is use of misoprostol in medication abortion an off-label use prohibited by the Arizona Law?[21] Plaintiffs urge that it is, arguing: (1) the Arizona Law requires that an abortion-inducing drug be administered according to the FDA-approved protocol outlined in the FPL "*for that* medication, drug or substance"; (2) misoprostol is an abortion-inducing drug, including when used in the protocol outlined on the Mifeprex FPL; and (3) Cytotec's FPL does not outline a protocol for use in inducing abortions. But surely this is a hypertechnical construction of the Arizona Law that would frustrate the legislature's intent and the Law's purpose, *i.e.,* that an abortion-inducing drug be administered according to the FDA-approved protocol outlined on its FPL. *Mifeprex's FPL outlines a protocol that requires the use of misoprostol.* Accordingly, on this basis,

THE COURT FINDS that the Arizona Law does not prohibit use of misoprostol according to the protocol outlined on Mifeprex's FPL.

IV.

Based on and to the extent consistent with the foregoing,

IT IS ORDERED granting in part and denying in part (i) Plaintiffs' Motion for Summary Judgment (filed May 15, 2014); (ii) Plaintiffs' Supplemental Motion for Summary Judgment (filed Mar. 19, 2015); and (iii) Defendant's Cross-Motion for Summary Judgment (filed May 6, 2015).

IT IS FURTHER ORDERED granting in part and denying in part Defendant's Motion to Dismiss (filed Sept. 5, 2014).

[21] Suppl. Compl., Count 5.