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9  
10 **UNITED STATES DISTRICT COURT**  
11 **DISTRICT OF ARIZONA**

12  
13 Planned Parenthood Arizona, Inc.; Eric Reuss,  
14 M.D.; Paul A. Isaacson, M.D.; Desert Star  
Family Planning, LLC; DeShawn Taylor, M.D.

15 Plaintiffs,

16 v.

17 Mark Brnovich, Arizona Attorney General, in  
18 his official capacity; Cara M. Christ, Director of  
19 the Arizona Department of Health Services, in  
20 her official capacity; Patricia E. McSorley,  
21 Executive Director of the Arizona Medical  
22 Board, in her official capacity; Richard T. Perry,  
23 M.D., Medical Board Chair, in his official  
24 capacity; James Gillard, M.D., Medical Board  
25 Vice Chair, in his official capacity; Jodi A. Bain,  
26 Medical Board Member, in her official capacity;  
27 Marc D. Berg, M.D., Medical Board Member, in  
28 his official capacity; Donna Brister, Medical  
Board Member, in her official capacity; R.  
Screven Farmer, M.D., Medical Board Member,  
in his official capacity; Gary R. Figge, M.D.  
Medical Board Member, in his official capacity;  
Robert E. Fromm, M.D., Medical Board  
Member, in his official capacity; Paul S.  
Gerding, Medical Board Member, in his official  
capacity; Lois Krahn, M.D., Medical Board

Case No. 2:15-cv-01022

**BRIEF FOR AMICI CURIAE  
AMERICAN COLLEGE OF  
OBSTETRICIANS AND  
GYNECOLOGISTS, AMERICAN  
MEDICAL ASSOCIATION, AND  
ARIZONA MEDICAL  
ASSOCIATION IN SUPPORT OF  
PLAINTIFFS' MOTION FOR  
PRELIMINARY INJUNCTION**

1 Member, in her official capacity; Edward G.  
2 Paul, M.D., Medical Board Member, in his  
3 official capacity; Wanda J. Salter, Medical Board  
4 Member, in her official capacity; Jenna Jones,  
5 Executive Director of the Arizona Board of  
6 Osteopathic Examiners in Medicine and Surgery,  
7 in her official capacity; Scott Steingard, D.O.,  
8 Board of Osteopathic Examiners in Medicine  
9 and Surgery President, in his official capacity;  
10 Douglas Cunningham, D.O., Board of  
11 Osteopathic Examiners in Medicine and Surgery  
12 Vice President, in his official capacity; Gary  
13 Erbstoesser, D.O., Board of Osteopathic  
14 Examiners in Medicine and Surgery Member, in  
15 his official capacity; Jerry G. Landau, Board of  
16 Osteopathic Examiners in Medicine and Surgery  
17 Member, in his official capacity; Martin B.  
18 Reiss, D.O., Board of Osteopathic Examiners in  
19 Medicine and Surgery Member, in his official  
20 capacity; Lew Riggs, Board of Osteopathic  
21 Examiners in Medicine and Surgery Member, in  
22 his official capacity; Vas Sabeeh, D.O., Board of  
23 Osteopathic Examiners in Medicine and Surgery  
24 Member, in his official capacity,

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Defendants.

**TABLE OF CONTENTS**

	<b>Page</b>
STATEMENT OF INTEREST OF <i>AMICI CURIAE</i> .....	1
INTRODUCTION .....	2
ARGUMENT .....	4
I.    THE MEDICATION ABORTION “REVERSAL” REQUIREMENT OF ARIZONA SENATE BILL 1318 DEPRIVES PATIENTS OF EVIDENCE-BASED MEDICAL INFORMATION.....	5
II.   S.B. 1318’S REQUIREMENT DAMAGES THE PATIENT- PHYSICIAN RELATIONSHIP BY UNDERMINING INFORMED CONSENT .....	9
III.  FORCING PHYSICIANS TO COMPLY WITH S.B. 1318’S REQUIREMENT INTERFERES WITH PHYSICIANS’ ETHICAL OBLIGATIONS TO PATIENTS .....	13
IV.  S.B. 1318 ENCOURAGES IMPROPER EXPERIMENTATION ON PATIENTS.....	14
CONCLUSION.....	16

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
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22  
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**TABLE OF AUTHORITIES**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
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22  
23  
24  
25  
26  
27  
28

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DRAFT – PRIVILEGED AND CONFIDENTIAL – June 25, 2015 VERSION

**STATEMENT OF INTEREST OF AMICI CURIAE**

1  
2 The American College of Obstetricians and Gynecologists (the “College” or  
3 “ACOG”), the American Medical Association (the “AMA”), and the Arizona Medical  
4 Association (the “ArMA”) submit this brief *amici curiae* in support of Plaintiffs.

5 **ACOG** is a non-profit educational and professional organization founded in 1951.  
6 The College’s objectives are to foster improvements in all aspects of healthcare of women; to  
7 establish and maintain the highest possible standards for education; to publish evidence-  
8 based practice guidelines; to promote high ethical standards; and to encourage contributions  
9 to medical and scientific literature. The College’s companion organization, the American  
10 Congress of Obstetricians and Gynecologists (the “Congress”), is a professional organization  
11 dedicated to the advancement of women’s health and the professional interests of its  
12 members. Sharing more than 56,000 members, including 952 in Arizona, the College and  
13 the Congress are the leading professional associations of physicians who specialize in the  
14 healthcare of women. The College and the Congress recognize that abortion is an essential  
15 health care service and oppose laws regulating medical care that are unsupported by  
16 scientific evidence and that are not necessary to achieve an important public health objective.

17 **AMA** is the largest professional association of physicians, residents, and medical  
18 students in the United States. Additionally, through state and specialty medical societies and  
19 other physician groups seated in the AMA’s House of Delegates, substantially all U.S.  
20 physicians, residents, and medical students are represented in the AMA’s policy-making  
21 process. The objectives of the AMA are to promote the science and art of medicine and the  
22 betterment of public health. AMA members practice in all fields of medical specialization  
23 and in every state, including Arizona.

24 **ArMA** is a voluntary membership organization for Arizona medical and osteopathic  
25 physicians. ArMA’s objectives are to promote the science and art of medicine; to promote  
26 and elevate the standards of medical ethics and medical education; and to promote public  
27 health. ArMA strongly supports the sanctity of the doctor/patient relationship and believes  
28 no physician should ever be compelled to betray the private trust inherent in this relationship.

1 The College and the AMA have previously appeared as *amicus curiae* in various  
2 courts throughout the country, including the U.S. Supreme Court and the Ninth Circuit. In  
3 addition, the College's work has been cited frequently by the Supreme Court and other  
4 federal courts seeking authoritative medical information regarding childbirth and abortion.<sup>1</sup>

### 5 INTRODUCTION

6 Laws that undermine the patient-physician relationship or that subject individuals to  
7 medical care that is not evidence-based threaten public health and compromise a physician's  
8 ability to practice medicine according to the applicable standard of care. In passing Arizona  
9 Senate Bill 1318 (hereinafter referred to as "S.B. 1318" or "the Bill"), the Arizona legislature  
10 has enacted a law that is not based on reliable science and that seeks to substitute the  
11 legislature's views for the medical judgment of physicians to the detriment of women  
12 seeking abortions. S.B. 1318 deprives women of evidence-based medical information,  
13 undermines informed consent, and interferes with physicians' ethical obligations to their  
14 patients. It should be enjoined.

15 S.B. 1318 requires a physician to inform any woman seeking an abortion in Arizona  
16 that "it may be possible to reverse the effects of a medication abortion if the woman changes  
17 her mind but that time is of the essence." *Id.* (to be codified at Ariz. Rev. Stat. 36-  
18 2153(A)(2)(h), (i)). A physician must make this statement even before surgical abortions  
19 and even when, in the physician's judgment such a statement may confuse or harm his or her  
20 patient. Moreover, S.B. 1318 directs the Arizona Department of Health Services ("DHS") to

21  
22 <sup>1</sup> See, e.g., *Stenberg v. Carhart*, 530 U.S. 914, 932-36 (2000) (quoting ACOG's *amicus* brief  
23 extensively and referring to ACOG as among the "significant medical authority" supporting the  
24 comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454  
25 n.38 (1990) (citing ACOG's *amicus* brief in assessing disputed parental notification requirement);  
26 *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted  
27 medical standards" for the provision of obstetric-gynecologic services, including abortions); see also  
28 *Gonzales v. Carhart*, 550 U.S. 124, 170-71, 175-78, 180 (2007) (Ginsburg, J., dissenting) (referring  
to ACOG as "experts" and repeatedly citing ACOG's *amicus* brief and congressional submissions  
regarding abortion procedure); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir.  
2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly  
used and relied upon by obstetricians and gynecologists nationwide to determine the standard and  
the appropriate level of care for their patients"); *Planned Parenthood v. Humble*, 753 F.3d 905, 916-  
17, 930 (9th Cir. 2014) (citing ACOG and the AMA's *amicus* brief as further support for a particular  
medical regimen), *cert. denied*, 134 S. Ct. 870 (2014); *Stuart v. Camnitz*, 774 F.3d 238, 251-52, 254,  
255 (4th Cir. 2014) (citing ACOG's and the AMA's *amicus* brief in assessing how an ultrasound  
requirement exceeded the bounds of traditional informed consent and interfered with physicians'  
medical judgment), *cert. denied*, -- S. Ct. --, 2015 WL 1331672 (2015).



1 post on its website “information on the potential ability of qualified medical professionals to  
2 reverse a medication abortion, including information directing women where to obtain  
3 further information and assistance in locating a medical professional who can aid in the  
4 reversal of a medication abortion.” S.B. 1318 § 4 (to be codified at Ariz. Rev. Stat. 36-  
5 2153(C)(8)).

6 While it is not yet clear what information DHS intends to post on its website, any  
7 information touting that a woman may be able to “reverse” her medication abortion would  
8 not be based on sound science. No reliable medical evidence supports the claim that a  
9 medication abortion can be “reversed” and no major medical associations have endorsed  
10 such a process. S.B. 1318 nevertheless compels physicians to provide such information to  
11 their patients. This message is misleading and potentially harmful to women who are  
12 seeking a medication abortion and is irrelevant and potentially confusing to the vast majority  
13 of women who cannot have, or who do not want, a medication abortion. In these ways, the  
14 law undermines informed consent and the physician-patient relationship.

15 In 2012, the Arizona legislature passed H.B. 2036, which required physicians to  
16 administer abortion-inducing medications in accordance only with final, printed labeling  
17 instructions for those medications. That bill—which ACOG and AMA also opposed—  
18 forced doctors to follow an outdated procedure that was less effective, more expensive, and  
19 more likely to result in complications than a different evidence-based regimen followed by  
20 nearly all providers in the U.S. (including in Arizona) performing terminations. *See Planned*  
21 *Parenthood of Arizona, Inc. v. Humble*, 753 F.3d 905, 908 (9th Cir. 2014). The Ninth  
22 Circuit reversed this Court’s denial of Planned Parenthood’s motion to enjoin enforcement of  
23 the law. Citing a brief filed by *amici curiae* (ACOG and AMA), the Ninth Circuit in *Humble*  
24 determined that H.B. 2036 did not clearly advance the state’s purported interest in women’s  
25 health and “usurp[ed] providers’ ability to exercise medical judgment.” *Id.* at 916-17  
26 (internal alteration and citation omitted).

27 S.B. 1318 fosters the same inappropriate, non-scientific, medical intervention. The  
28 implementation of S.B. 1318 would deprive women of the best, evidence-based medical

1 information and would substitute unqualified legislative views for the medical judgment of  
2 trained physicians. For these and the reasons discussed more fully below, *amici curiae*,  
3 leading medical societies whose policies represent the considered judgments of the many  
4 physicians in this country, urge the court to enjoin the Bill.

### 5 ARGUMENT

6 S.B. 1318 compels physicians to deliver information to their patients that is untested,  
7 unproven, and misleading.<sup>2</sup> The law thus interferes with the patient-physician relationship,  
8 undermines bedrock principles of informed consent, and deprives women seeking abortions  
9 in Arizona of the best, evidence-based medical information. As leading medical societies,  
10 *amici curiae* are uniquely positioned to evaluate both the medical propriety of the law and its  
11 impact on patients.

12 *First*, there is no reliable evidence that medication abortions can, in fact, be  
13 “reversed” through a course of treatment. Requiring physicians to make statements to the  
14 contrary or to steer patients towards resources for such purported abortion “reversal”  
15 treatments deprives women of access to the best, evidence-based medical information.

16 *Second*, the law is antithetical to the purpose of the informed consent process because  
17 it forces practitioners to provide information that is not supported by credible medical  
18 evidence, that is misleading, and that is not individually tailored to their patients’ needs.

19 *Third*, S.B. 1318 substitutes the Arizona legislature’s judgment for that of Arizona  
20 physicians and dictates that a physician must inform his or her patient of a particular course  
21 of treatment, even if the physician believes the claim to be untrue or harmful to the patient.

22 *Finally*, if not enjoined, the law will encourage improper experimentation on women,  
23 as it may result in use of procedures unsupported by evidence developed in a proper  
24 research-based setting and with appropriate consent procedures and oversight.

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28 <sup>2</sup> Unless expressly discussed herein, *amici curiae* do not express an opinion on all or other  
aspects of S.B. 1318.

1 **I. THE MEDICATION ABORTION “REVERSAL” REQUIREMENT OF**  
2 **ARIZONA SENATE BILL 1318 DEPRIVES PATIENTS OF EVIDENCE-**  
3 **BASED MEDICAL INFORMATION**

4 Women should be afforded medical care that is based on the best available evidence-  
5 based medical information. S.B. 1318 deprives women of such evidence-based information  
6 by requiring that physicians discuss claims of medication abortion “reversal” with their  
7 patients and even steer patients toward such untested techniques. *First*, there is no medically  
8 accepted evidence that a medication abortion can be “reversed.” *Amici curiae* have not  
9 endorsed this approach. Indeed, the approach is not recommended in ACOG’s clinical  
10 guidance on medication abortion<sup>3</sup>—nor are there ACOG guidelines that support this course  
11 of action. *Second*, the untested treatment underlying purported medication abortion  
12 “reversal” may be harmful to some patients. Mandating that a physician discuss medication  
13 abortion “reversal” under this backdrop will only cause confusion and lead to potentially  
14 harmful outcomes.

15 Abortions can be performed by one of two means: using surgical instruments and  
16 techniques or using medication. The most common form of a medication abortion is a  
17 regimen that uses a combination of two prescription drugs: mifepristone and misoprostol.<sup>4</sup>  
18 Mifepristone, also known as “RU-486” or by its commercial name Mifeprex, temporarily  
19 blocks the hormone progesterone, which is necessary to maintain pregnancy. It also works  
20 to increase the efficacy of the second medication in the regimen, misoprostol. Misoprostol  
21 causes the uterus to contract and expel its contents. Because medication abortion requires a  
22 combination of medications, many pregnancies are not aborted after using only the first  
23 medication. Indeed, studies suggest that even in the earliest days of pregnancy, 8% to 46%  
24 of women who take mifepristone alone, at higher doses than are currently administered, (and  
25 do not continue the regimen by taking the second medication, misoprostol) continue their  
26

27 <sup>3</sup> *Medical Management of First-Trimester Abortion*, ACOG Practice Bulletin No. 143 (Mar.  
28 2014).

<sup>4</sup> *Id.*

1 pregnancies.<sup>5</sup> It is understood that this rate would be higher later in pregnancy, and could  
2 well be higher still at the lower doses currently used.<sup>6</sup>

3 Ignoring these medical facts, S.B. 1318 requires that physicians discuss with each  
4 patient the possibility of “reversing” a medication abortion and that physicians refer patients  
5 to a website where they can obtain information about how to do so. S.B. 1318 even requires  
6 that physicians discuss the possibility of a medication abortion “reversal” with patients who  
7 are obtaining an indisputably *irreversible* surgical abortion—the predominant form of  
8 abortion in Arizona. For those patients obtaining a medication abortion, the requirement  
9 fares no better: there is no credible, medical evidence that proves that any treatment  
10 “reverses” the effects of mifepristone.<sup>7</sup> Indeed, S.B. 1318’s requirement appears to be based  
11 on a *single* four-page case series, reporting results for *only six patients*.<sup>8</sup> That series  
12 describes a handful of anecdotal experiences for women who received varying doses of  
13 progesterone after taking mifepristone, the first drug in the medication abortion protocol, and  
14 who did not take the second drug, misoprostol.

15 The case series, which leading medical researchers in the field have described as of  
16 “poor quality,”<sup>9</sup> is unreliable. In developing its clinical guidelines for use by women’s health  
17 clinicians, ACOG bases its strongest recommendations only on consistent and strong  
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22 <sup>5</sup> See, e.g., Daniel Grossman, et al., *Continuing Pregnancy After Mifepristone and “Reversal”*  
23 *of First-Trimester Medical Abortion: A Systematic Review*, *Contraception* at 6 (article accepted June  
2, 2015), doi: 10.1016/j.contraception.2015.06.001 [hereinafter “Grossman”].

24 <sup>6</sup> Grossman, *supra* note 5, at 8.

25 <sup>7</sup> *Id.* Even a supporter who testified in favor of the Bill acknowledged that medication  
26 abortion reversal research is ongoing and “has not been widely published and is not widely known.”  
*Arizona House Federalism and States’ Rights Part 1* (Mar. 11, 2015, 17:20-17:40), available at  
[http://azleg.granicus.com/MediaPlayer.php?view\\_id=13&clip\\_id=15544](http://azleg.granicus.com/MediaPlayer.php?view_id=13&clip_id=15544) (testimony of Dr. Allen  
Sawyer).

27 <sup>8</sup> George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of*  
28 *Mifepristone*, *THE ANNALS OF PHARMACOTHERAPY* (Dec. 2012), available at  
<http://www.ncbi.nlm.nih.gov/pubmed/23191936> [hereinafter “Delgado & Davenport”].

<sup>9</sup> Grossman, *supra* note 5, at 7.

1 evidence, such as, when possible, randomized controlled studies.<sup>10</sup> The case series that is the  
2 basis of S.B. 1318 is not the type of information that ACOG would rely on to form its  
3 clinical recommendations. Likewise the case series is clearly an insufficient foundation for a  
4 legislative mandate.

5 *First*, the case series was not controlled, meaning there was no control group that was  
6 studied that did not receive the progesterone treatment. While four of the six patients in the  
7 study who received progesterone went on to carry their pregnancies to term, the study did not  
8 isolate the progesterone as the cause of the continued pregnancies, as opposed to the fact that  
9 these patients did not take the second drug in the medication abortion regimen. Given that  
10 mifepristone alone will not cause an abortion in many cases, the failure to take the second  
11 medication, misoprostol, may well have been responsible for the outcomes observed. In  
12 short, the paper does not provide evidence of causation establishing that treatment with  
13 progesterone was responsible for the reported outcomes.<sup>11</sup>

14 *Second*, the paper's reliability is further undermined by its tiny sample size and the  
15 limited information provided on the handful of women who were involved. The case series  
16 followed a total of seven women who underwent the progesterone regimen, but it provides  
17 no information about the outcome of the seventh patient and claims the authors were unable  
18 to follow up with her. Excluding the seventh patient, the paper reports that four of six  
19 treated women (67%) continued their pregnancies. Confidence intervals are used by

20  
21 <sup>10</sup> Hal C. Lawrence, M.D., *The American College of Obstetricians and Gynecologists Supports*  
22 *Access to Women's Health Care*, 125 *OBSTETRICS & GYNECOLOGY* 1282, 1283 (June 2015)  
23 (“Recommendations are ranked according to the strength of the supporting evidence.”). In addition,  
24 the Council of Medical Specialty Societies (of which ACOG is a member), makes clear in their  
25 *Principles for the Development of Specialty Society Clinical Guidelines* that the strength of a clinical  
26 guideline recommendation should be based on the strength of the supporting evidence and an  
27 assessment of the benefits and harms. See Council of Medical Specialty Societies, *Principles for the*  
28 *Development of Specialty Society Clinical Guidelines*, at 5, available at  
[http://www.cmss.org/uploadedFiles/Site/CMSS\\_Policies/CMSS%20Principles%20for%20the%20Development%20of%20Specialty%20Society%20Guidelines%20-%20September%202012.pdf](http://www.cmss.org/uploadedFiles/Site/CMSS_Policies/CMSS%20Principles%20for%20the%20Development%20of%20Specialty%20Society%20Guidelines%20-%20September%202012.pdf).

25 <sup>11</sup> ACOG, *Reading the Medical Literature*, available at <http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature> (stating, regarding case reports, that “[t]hese studies provide limited information about the relationship between exposure and the outcome of interest.”); Trygve Nissen and Rolf Wynn, *The Clinical Case Report: a Review of Its Merits and Limitations*, *BMC Research Notes* (2014), available at <http://www.biomedcentral.com/1756-0500/7/264> (“Causality cannot be inferred from an uncontrolled observation. An association does not imply a cause-effect relationship. The observation or event in question could be a mere coincidence. This is a limitation shared by all the descriptive studies.”).

1 researchers to describe the precision of an estimated percentage, with narrow confidence  
2 intervals indicating good precision and wider confidence intervals indicating less precision.  
3 Medical researchers Daniel Grossman, Kari White, Lisa Harris, Matthew Reeves, Paul D.  
4 Blumenthal, Beverly Winikoff, and David A. Grimes calculated the 95% confidence interval  
5 for the 67% of continued pregnancies in the case series. They note that the confidence  
6 interval is wide—ranging from 25% to 90%.<sup>12</sup> This means that if the study was repeated 100  
7 times, then the true result would—95 out 100 times—fall into the range of 25% and 90%.  
8 The range is so large and imprecise that the case series provides no reliable information.<sup>13</sup>  
9 Indeed, the broad range underscores that such a small sample size can hardly provide  
10 evidence sufficient to support a state law that could affect thousands of women per year.<sup>14</sup> In  
11 addition, even if the small sample size were not problematic by itself, the case series fails to  
12 report relevant facts for each of the six treated women (such as the exact gestational age of  
13 the pregnancy and the dose of mifepristone).

14 *Third*, the case series was not conducted with the oversight of an institutional review  
15 board (“IRB”) or an ethical review committee, as federal regulations governing federal  
16 funding of human research and most research institutions require for research on human  
17 subjects.<sup>15</sup> IRBs are recognized by the research community as a safeguard to protect the  
18 rights and welfare of human research subjects. When the federal government provides  
19 funding for research on human subjects, it requires that IRBs approve research protocols to

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20  
21 <sup>12</sup> See, e.g., Grossman, *supra* note 5. Other sources have found a similarly wide range in the  
22 confidence interval. See Dr. David Grimes, *The ‘Science’ Behind Arizona’s Mandatory ‘Abortion  
23 Reversal’ Advice*, Apr. 15, 2015, available at [http://rhrealitycheck.org/article/2015/04/08/science-  
24 behind-arizonas-mandatory-abortion-reversal-advice/](http://rhrealitycheck.org/article/2015/04/08/science-behind-arizonas-mandatory-abortion-reversal-advice/).

25 <sup>13</sup> Even if the study had a narrower confidence interval, there are other substantial problems  
26 with drawing any conclusions from the study, including, as noted *supra*, that the study did not  
27 include a control group.

28 <sup>14</sup> *Abortions in Arizona: 2013 Abortion Report*, Arizona Department of Health Services, 4-5  
(Sept. 9, 2014), available at [www.azdhs.gov/diro/reports/pdf/2013-arizona-abortion-report.pdf](http://www.azdhs.gov/diro/reports/pdf/2013-arizona-abortion-report.pdf)  
(noting that in calendar year 2013, between 13,000 and 16,000 abortions were performed in  
Arizona).

<sup>15</sup> ACOG Comm. on Ethics, Comm. Op. No. 352, *Innovative Practice: Ethical Guidelines*, at 3  
(Dec. 2006) [hereinafter “Comm. Op. No. 352”]; see also 45 C.F.R. § 46.109 (“An IRB shall review  
and have authority to approve, require modifications in (to secure approval), or disapprove of all  
research activities covered by this policy.”).

1 ensure the following: adequate disclosures to potential participants, informed consent from  
 2 participants, appropriate risk-to-benefit ratio, protection of participants' privacy, and  
 3 participants' freedom to withdraw from the study at any time. Research conducted on  
 4 human subjects without IRB approval—such as the case series that forms the basis of S.B.  
 5 1318 here—raises series questions regarding the ethics and scientific validity of the  
 6 information reported therein.

7 Finally, apart from the lack of reliable evidence described above, the experimental  
 8 protocol involving the administration of progesterone for so-called “reversal” of medication  
 9 abortion relied on in the only article that the law appears to be based on may be harmful to  
 10 some patients. While progesterone is generally well tolerated, it can cause significant  
 11 cardiovascular, nervous system, and endocrine adverse reactions as well as other side  
 12 effects.<sup>16</sup> Yet, S.B. 1318 requires that physicians inform every patient about the possibility  
 13 of abortion “reversal” and direct every patient to the DHS website for assistance on how to  
 14 do so, even in cases where that protocol or any other so-called “reversal” treatment could, in  
 15 the individual physician's judgment, be harmful to a particular patient.

## 16 **II. S.B. 1318'S REQUIREMENT DAMAGES THE PATIENT-PHYSICIAN** 17 **RELATIONSHIP BY UNDERMINING INFORMED CONSENT**

18 The requirement set forth in S.B. 1318 is also antithetical to the long-standing  
 19 principle of informed consent, an ethical concept that is integral to contemporary medical  
 20 ethics and practice.<sup>17</sup> “[I]nformed consent’ contains two major elements: 1) comprehension  
 21 (or understanding) and 2) free consent.”<sup>18</sup> “Comprehension (as an element in informed  
 22 consent) includes the patient's awareness and understanding of her situation and possibilities.  
 23 It implies that she has been given adequate information about her diagnosis, prognosis, and  
 24

25 <sup>16</sup> ACOG Fact Sheet, Medication Abortion Reversal, *available at*  
 26 <http://www.acog.org/~media/departments/state%20legislative%20activities/2015AZFactSheetMedicationAbortionReversalfinal.pdf>; *Progesterone Drug Label Information*, U.S. NATIONAL LIBRARY OF  
 27 MEDICINE, [http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b79abe4a-0242-41da-b91b-](http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b79abe4a-0242-41da-b91b-df723b85f0cc)  
 28 [df723b85f0cc](http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b79abe4a-0242-41da-b91b-df723b85f0cc) (last accessed June 25, 2015, 3:30 PM).

<sup>17</sup> ACOG Comm. on Ethics, Comm. Op. No. 439, at 2 (2009, reaffirmed 2012) [hereinafter  
 “Comm. Op. No. 439”].

<sup>18</sup> *Id.*

1 alternative treatment choices, including the option of no treatment,” such that she would be  
2 able to meaningfully consent to medical procedures.<sup>19</sup> Indeed, “the most commonly accepted  
3 foundation for informed consent is the principle of respect for persons. This principle  
4 expresses an ethical requirement to treat persons as ‘ends in themselves’ (that is, not to use  
5 them solely as means or instruments for someone else’s purposes and goals.)”<sup>20</sup>

6 Far from furthering informed consent, the Bill in fact *undermines* patients’ ability to  
7 provide informed consent by potentially confusing patients with false and misleading—and  
8 in many cases irrelevant—information and by interfering with the patient-physician  
9 relationship. As noted above, although S.B. 1318 requires that a physician say that  
10 medication abortion “reversal” “may be possible,” there is no evidence to support this claim.  
11 Moreover, when a patient is considering any medical procedure or treatment, it is important  
12 that her physician counsel her on her options to ensure that she is certain about her decision  
13 to consent to a particular procedure or treatment. Such counseling to ensure the patient is  
14 ultimately sure about her decision is especially important where a woman is considering  
15 whether to have an abortion.<sup>21</sup> If a woman is uncertain, then the decision about an abortion  
16 technique is delayed until she has reached a firm decision.

17 S.B. 1318, however, requires practitioners to suggest to a patient they do not have to  
18 be certain about their decision before they begin the abortion. Thus, S.B. 1318 could lead a  
19 patient to begin a medication abortion procedure with a false perception that she can change  
20 her mind later and continue her pregnancy. The data is clear that, in some cases, the  
21 mifepristone alone will terminate her pregnancy even if she does not take the misoprostol,  
22 and there is no evidence that this effect can be “reversed.” *Amici* are concerned that raising  
23 the prospect of “reversal” in this highly misleading way could undermine physician’s efforts  
24 to ensure that patients do not undertake a procedure or treatment they are unsure they want.  
25

26 \_\_\_\_\_  
27 <sup>19</sup> *Id.* at 3.

28 <sup>20</sup> *Id.*

<sup>21</sup> ACOG, Practice Bulletin No. 143, *Medical Management of First-Trimester Abortion* (Mar. 2014).



1 S.B. 1318 poses a different harm to the majority of abortion patients who have an  
2 abortion through a surgical procedure or another medical regimen not involving  
3 mifepristone. For such patients—*i.e.* those who do not want or cannot have a medication  
4 abortion and are considering a different abortion procedure—S.B. 1318’s abortion “reversal”  
5 speech requirement would be entirely irrelevant and thus contrary to the principle that  
6 informed consent should be tailored to the individual patient.<sup>22</sup> As a consequence, the state  
7 mandated language could distract women from the information that is actually needed to  
8 make an informed decision on whether to have an abortion.

9 Moreover, S.B. 1318 may further confuse patients by forcing practitioners to direct  
10 them to a third party information source, the DHS website, for “information on and  
11 assistance with reversing the effects of a medication abortion.”<sup>23</sup> Assuming *arguendo* that  
12 such information will be publicly available at a later date—even though it currently is not—  
13 this requirement results in practitioners providing the appearance of approval for the third  
14 party information to their patients, even where practitioners may well disagree with and  
15 conclude it to be false and/or misleading, and not supported by credible, medical evidence.

16 S.B. 1318 further undermines the informed consent process by eroding the patient-  
17 physician relationship. The patient-physician relationship is grounded in confidentiality,  
18 trust, and honesty.<sup>24</sup> Patients rely on their physicians for advice about the most intimate and  
19 important medical decisions. Thus, “[b]y encouraging an ongoing and open communication  
20 of *relevant* information . . . the physician enables the patient to exercise personal choice” in  
21 the medical treatment she receives.<sup>25</sup> S.B. 1318 damages the patient-physician relationship  
22 by requiring physicians to recite specific language to their patients about the unsupported  
23

24 <sup>22</sup> Comm. Op. No. 439, *supra* note 17; *see also* AMA Code of Medical Ethics, *Op. 8.08 -*  
25 *Informed Consent* (“Physicians should sensitively and respectfully disclose all relevant medical  
information to patients. The quantity and specificity of this information should be tailored to meet  
the preferences and needs of individual patients.”).

26 <sup>23</sup> S.B. 1318 § 4 (to be codified at Ariz. Rev. Stat. 36-2153(A)(2)(h),(i)).

27 <sup>24</sup> American College of Obstetricians and Gynecologists, Code of Professional Ethics (July  
2011) at 2; AMA Code of Medical Ethics, *Opinion 10.01 - Fundamental Elements of the Patient-*  
*Physician Relationship*.

28 <sup>25</sup> ACOG Comm. On Ethics, Comm. Op. No. 390, *Ethical Decision Making in Obstetrics and*  
*Gynecology*, at 6 (2007, reaffirmed 2013) [hereinafter “Comm. Op. No. 390”].

1 possibility of medication abortion “reversal” even where the physician believes the  
2 information would be harmful or is wholly irrelevant to the patient.

3 Contrary to the approach S.B. 1318 mandates, informed consent should be a fluid  
4 discussion in which the practitioner can account for the unique needs of an individual patient  
5 faced with a given choice.<sup>26</sup> Accordingly, “within the broad requirement for informed  
6 consent, the individual practitioner traditionally has been permitted, and indeed expected, to  
7 exercise independent judgment in determining what the potential treatments, risks, benefits,  
8 and alternatives are in any particular case, and, thus, what information should be  
9 communicated to the patient.”<sup>27</sup> Because there is no scientific evidence underlying  
10 medication abortion “reversal,” practitioners will be unable to adequately describe the  
11 progesterone treatment to their patients or answer any follow-up questions.<sup>28</sup> In addition, by  
12 requiring additional—and in many cases irrelevant—language for the informed consent  
13 process, S.B. 1318 makes it unnecessarily challenging for practitioners to provide their  
14 patients with concise, easy to understand, and individually tailored information for their  
15 patients to provide informed consent.<sup>29</sup> As a consequence, S.B. 1318 makes it much harder  
16 for practitioners to discern whether a patient has understood all *relevant* facts such that she is  
17 in fact providing informed consent based on her own free choice.<sup>30</sup>

18 Moreover, the confusion a patient will experience when her practitioner delivers the  
19 state mandated information on possible abortion “reversal” may cause her to lose confidence

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21 <sup>26</sup> Comm. Op. No. 439, *supra* note 17, at 5; *see also* AMA Code of Medical Ethics, *Op. 8.08 - Informed Consent*.

22 <sup>27</sup> Marshall B. Kapp, *Abortion and Informed Consent Requirements*, 144 AM. J. OBSTET. &  
23 GYNECOL. 1, 3 (1982); *see* Scott Woodcock, *Abortion Counselling and The Informed Consent*  
24 *Dilemma*, 25 BIOETHICS, 495, 502 (2011) (“[B]eyond the basic requirements (and constraints) that  
are minimally necessary for a medically responsible discharge of informed consent, there is no way  
for fixed policy standards to substitute for the practical skills that allow healthcare workers to  
ascertain what further information will enable patients to reach fully autonomous decisions.”).

25 <sup>28</sup> Comm. Op. No. 439, *supra* note 17.

26 <sup>29</sup> Comm. Op. No. 390, *supra* note 25, at 6 (“Critical to the process of informing the patient is  
the physician’s integrity in *choosing* the information that is given to the patient . . . . The point is not  
merely to disclose information but to ensure patient comprehension of *relevant* information.”)  
(emphasis added).

27 <sup>30</sup> Comm. Op. No. 439, *supra* note 17; *see also* Howard Minkoff & Mary Faith Marshall,  
28 *Government-Scripted Consent: When Medical Ethics and Law Collide*, Hastings Center Report 39,  
No. 5, 1 (2009) (“Informed consent requires voluntariness – freedom from coercion, undue  
influence, or bias . . .”).

1 in her practitioner and to distrust any of the information she received, further damaging the  
2 patient-physician relationship and the informed consent process.

3  
4 **III. FORCING PHYSICIANS TO COMPLY WITH S.B. 1318'S REQUIREMENT**  
5 **INTERFERES WITH PHYSICIANS' ETHICAL OBLIGATIONS TO**  
6 **PATIENTS**

7 S.B. 1318 is antithetical to the basic precept that the patient-physician relationship is  
8 the central focus of all ethical concerns, and the welfare of the patient must therefore form  
9 the basis of all medical judgments.<sup>31</sup> ACOG's Code of Professional Ethics states that "the  
10 welfare of the patient must form the basis for all medical judgments. . . . The obstetrician-  
11 gynecologist should . . . exercise all reasonable means to ensure that the most appropriate  
12 care is provided to the patient."<sup>32</sup> Similarly, AMA policy provides that "[w]ithin the patient-  
13 physician relationship, a physician is ethically required to use sound medical judgment,  
14 holding the best interests of the patient as paramount."<sup>33</sup>

15 For these reasons, it is essential that the patient-physician relationship be protected  
16 from unnecessary and inappropriate government intrusion.<sup>34</sup> "Laws that require physicians  
17 to give, or withhold, specific information when counseling patients, or that mandate which  
18 tests, procedures, treatment alternatives, or medicines physicians can perform, prescribe, or

19  
20 <sup>31</sup> ACOG Code of Professional Ethics, at 2; AMA Code of Medical Ethics, *Op. 10.01 - Fundamental Elements of the Patient-Physician Relationship*.

21 <sup>32</sup> ACOG, Code of Professional Ethics of the American College of Obstetricians and  
22 Gynecologists, available at <http://www.acog.org/~media/Departments/National%20Officer%20Nominations%20Process/ACOGcode.pdf>.

23 <sup>33</sup> See, e.g., AMA, Policy H-120.988, *Patient Access to Treatments Prescribed by Their Physicians*, available at <https://www.ama-assn.org/ssl3/ecom/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fhtml%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-120.988.HTM> (confirming the AMA's strong support for the proposition that "a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence and sound medical opinion").

24  
25  
26 <sup>34</sup> See Minkoff & Ecker, *When Legislators Play Doctor: The Ethics of Mandatory Preabortion Ultrasound Examinations*, 120 OBSTETRICS & GYNECOLOGY 647, 649 (2012) ("Prescriptions for counseling and caring can lead a therapeutic relationship to deteriorate into an adversarial one. Given the precedence that should be afforded to their fiduciary obligation to their patients, physicians' participation in legislated care, care coerced under threat of penalty, and transmittal of unwanted and potentially irrelevant information could be considered an abdication of professional obligations.").

1 administer are detrimental to the patient-physician relationship and are ill-advised.”<sup>35</sup>

2 Consistent with the requirements of a medical license, physicians must use their judgment  
3 and provide individualized care based on each patient’s needs.

4 By requiring that physicians discuss the “possibility” of abortion “reversal” with  
5 patients even in cases where a physician does not believe that protocol is based on reliable  
6 science, S.B. 1318 interferes with a physician’s obligation to utilize his or her best medical  
7 judgment. Worse, as noted above, S.B. 1318 leaves no room for a physician to exercise *any*  
8 discretion, even in instances when the information is irrelevant to the patient’s treatment, or  
9 when the physician genuinely believes that providing the required information would harm  
10 the patient.

11 S.B. 1318’s interference with a physician’s medical judgment is not merely  
12 theoretical. S.B. 1318 imposes a variety of consequences on physicians if their own medical  
13 judgment does not comport with the disclosure requirement. Physicians could face license  
14 suspension or revocation if they fail to abide by S.B. 1318’s disclosure requirement.<sup>36</sup> They  
15 could also be exposed to private litigation by patients, patients’ spouses, or the parents of  
16 patients under the age of 18 for failure to comply. The Bill, thus, presents a physician with a  
17 dilemma between violating the law or disregarding his or her own medical judgment.

#### 18 **IV. S.B. 1318 ENCOURAGES IMPROPER EXPERIMENTATION ON PATIENTS**

19  
20 If not enjoined, S.B. 1318 will encourage improper experimentation on patients  
21 outside of a research setting and thus without the protections afforded to human subjects in  
22 such a setting. As noted above, the universe of underlying documentation for “reversing”  
23 medication abortions is a four-page case series documenting a handful of independent and  
24

25 <sup>35</sup> ACOG Statement of Policy: *Legislative Interference with Patient Care, Medical Decisions,*  
26 *and the Patient-Physician Relationship*, available at  
<http://www.acog.org/~media/Statements%20of%20Policy/Public/2013LegislativeInterference.pdf>;  
27 *see also* AMA Code of Medical Ethics, *Op. 8.082 - Withholding Information from Patients*  
28 (“[P]hysicians should honor patient requests not to be informed of certain medical information . . .”).

<sup>36</sup> Ariz. Rev. Stat. § 36-2153(I) (stating that failure to comply with the Act is considered an “act of unprofessional conduct and is subject to license suspension or revocation” by the Arizona Medical Board).

1 uncontrolled anecdotal reports, in which four of six documented pregnancies proceeded to  
2 term following varying progesterone dosages (some administered intramuscularly and others  
3 orally) at various points after mifepristone ingestion. S.B. 1318 nevertheless prematurely  
4 endorses, on a statewide scale, the use of progesterone in an effort to “reverse” medication  
5 abortions—apparently on that basis alone—and despite the fact that, to date, no formal  
6 research-based clinical trials validating or invalidating a progesterone protocol as a safe and  
7 effective means to “reverse” medication abortions have occurred. Indeed, the case series  
8 itself provides a *suggested* progesterone protocol *only*—and notably, a different regimen  
9 from those received by the women described in the paper—and concedes that further trials  
10 are necessary before the suggested progesterone protocol or similar protocols can become a  
11 “standard of care.”<sup>37</sup> Thus, at present, abortion “reversal” treatment is experimental at best.

12 While innovation in medicine is valued and strongly supported by *amici curiae*, it is  
13 important that “‘radically new procedures’ be tested by formal research at an early stage” to  
14 ensure that such procedures—like the use of progesterone to “reverse” a medication  
15 abortion—are safe and effective.<sup>38</sup> This preference for formal research over random  
16 experimentation is of particular emphasis where an “innovation is expected to result in  
17 generalizable knowledge.”<sup>39</sup> Here, by memorializing possible medication abortion  
18 “reversal” in a law that will apply to any and all women seeking an abortion in the state of  
19 Arizona, the State is endorsing experimentation on a potentially large scale, and with no  
20 guaranteed oversight by an ethics committee, board, or IRB.

21 *Amici curiae* support innovations in medicine, but such innovations should be based  
22 on a sound foundation of medical research with appropriate controls. S.B. 1318 promotes  
23 and generalizes a medical experiment on a potentially massive scale, with the women of  
24 Arizona as unknowing guinea pigs.

25  
26 <sup>37</sup> Delgado & Davenport, *supra* note 7, at 3.

27 <sup>38</sup> Comm. Op. No. 352, *supra* note 15, at 3.

28 <sup>39</sup> *Id.* at 6; Department of Health, Education, and Welfare; Protection of Human Subjects; Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,193 (Apr. 18, 1979).

**CONCLUSION**

1  
2 As the foregoing demonstrates, S.B. 1318 substantially infringes the freedom of  
3 speech of physicians, and it impermissibly undermines the patient-physician relationship and  
4 the purposes of informed consent, and exposes patients to medical risk—all without a  
5 countervailing medical justification. The law therefore violates the First and Fourteenth  
6 Amendments of the U.S. Constitution. For these reasons and on account of the legal  
7 authorities set forth in Plaintiffs’ brief, *amici* believe the law should be held invalid and  
8 Plaintiffs’ motion for preliminary injunction should be granted.

9  
10 Dated: June 25, 2015

Respectfully submitted,

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