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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

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

Plaintiffs,

v.

Mark Brnovich, Arizona Attorney General, in his official capacity; Cara M. Christ, Director of the Arizona Department of Health Services, in her official capacity; Patricia E. McSorley, Executive Director of the Arizona Medical Board, in her official capacity; Richard T. Perry, M.D., Medical Board Chair, in his official capacity; James Gillard, M.D., Medical Board Vice Chair, in his official capacity; Jodi A. Bain, Medical Board Member, in her official capacity; Marc D. Berg, M.D., Medical Board Member, in 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

Member, in her official capacity; Edward G. Paul, M.D., Medical Board Member, in his official capacity; Wanda J. Salter, Medical Board Member, in her official capacity; Jenna Jones, Executive Director of the Arizona Board of Osteopathic Examiners in Medicine and Surgery, in her official capacity; Scott Steingard, D.O., Board of Osteopathic Examiners in Medicine and Surgery President, in his official capacity; Douglas Cunningham, D.O., Board of Osteopathic Examiners in Medicine and Surgery Vice President, in his official capacity; Gary Erbstoesser, D.O., Board of Osteopathic Examiners in Medicine and Surgery Member, in his official capacity; Jerry G. Landau, Board of Osteopathic Examiners in Medicine and Surgery Member, in his official capacity; Martin B. Reiss, D.O., Board of Osteopathic Examiners in Medicine and Surgery Member, in his official capacity; Lew Riggs, Board of Osteopathic Examiners in Medicine and Surgery Member, in his official capacity; Vas Sabeeh, D.O., Board of Osteopathic Examiners in Medicine and Surgery Member, in his official capacity,

Defendants.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

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

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

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

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

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

INTRODUCTION

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

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

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[1] *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 932-36 (2000) (quoting ACOG's *amicus* brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's *amicus* brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *see also 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).

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

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

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

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

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

ARGUMENT

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

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

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

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

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

[2] Unless expressly discussed herein, *amici curiae* do not express an opinion on all or other aspects of S.B. 1318.

I. THE MEDICATION ABORTION "REVERSAL" REQUIREMENT OF ARIZONA SENATE BILL 1318 DEPRIVES PATIENTS OF EVIDENCE-BASED MEDICAL INFORMATION

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

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

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[3] *Medical Management of First-Trimester Abortion*, ACOG Practice Bulletin No. 143 (Mar. 2014).

[4] *Id.*

pregnancies.[5] It is understood that this rate would be higher later in pregnancy, and could well be higher still at the lower doses currently used.[6]

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

The case series, which leading medical researchers in the field have described as of "poor quality,"[9] is unreliable. In developing its clinical guidelines for use by women's health clinicians, ACOG bases its strongest recommendations only on consistent and strong

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[5] *See, e.g.*, Daniel Grossman, et al., *Continuing Pregnancy After Mifepristone and "Reversal" 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"].

[6] Grossman, *supra* note 5, at 8.

[7] *Id*. Even a supporter who testified in favor of the Bill acknowledged that medication 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 (testimony of Dr. Allen Sawyer).

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

[9] Grossman, *supra* note 5, at 7.

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

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

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

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[10] Hal C. Lawrence, M.D., *The American College of Obstetricians and Gynecologists Supports Access to Women's Health Care*, 125 OBSTETRICS & GYNECOLOGY 1282, 1283 (June 2015) ("Recommendations are ranked according to the strength of the supporting evidence."). In addition, the Council of Medical Specialty Societies (of which ACOG is a member), makes clear in their Principles for the Development of Specialty Society Clinical Guidelines that the strength of a clinical guideline recommendation should be based on the strength of the supporting evidence and an assessment of the benefits and harms. *See* Council of Medical Specialty Societies, *Principles for the 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.

[11] 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.").

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

Third, the case series was not conducted with the oversight of an institutional review board ("IRB") or an ethical review committee, as federal regulations governing federal funding of human research and most research institutions require for research on human subjects.[15] IRBs are recognized by the research community as a safeguard to protect the rights and welfare of human research subjects. When the federal government provides funding for research on human subjects, it requires that IRBs approve research protocols to

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

[13] Even if the study had a narrower confidence interval, there are other substantial problems with drawing any conclusions from the study, including, as noted *supra*, that the study did not include a control group.

[14] *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 (noting that in calendar year 2013, between 13,000 and 16,000 abortions were performed in Arizona).

[15] 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.").

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

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

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

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

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

[17] ACOG Comm. on Ethics, Comm. Op. No. 439, at 2 (2009, reaffirmed 2012) [hereinafter "Comm. Op. No. 439"].

[18] *Id.*

alternative treatment choices, including the option of no treatment," such that she would be able to meaningfully consent to medical procedures.[19] Indeed, "the most commonly accepted foundation for informed consent is the principle of respect for persons. This principle expresses an ethical requirement to treat persons as 'ends in themselves' (that is, not to use them solely as means or instruments for someone else's purposes and goals.)"[20]

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

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

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[19] *Id.* at 3.

[20] *Id.*

[21] ACOG, Practice Bulletin No. 143, *Medical Management of First-Trimester Abortion* (Mar. 2014).

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

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

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

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[22] Comm. Op. No. 439, *supra* note 17; *see also* AMA Code of Medical Ethics, *Op. 8.08 - 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.").

[23] S.B. 1318 § 4 (to be codified at Ariz. Rev. Stat. 36-2153(A)(2)(h),(i)).

[24] 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*.

[25] 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"].

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

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

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

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[26] Comm. Op. No. 439, *supra* note 17, at 5; *see also* AMA Code of Medical Ethics, *Op. 8.08 - Informed Consent*.

[27] Marshall B. Kapp, *Abortion and Informed Consent Requirements*, 144 AM. J. OBSTET. & GYNECOL. 1, 3 (1982); *see* Scott Woodcock, *Abortion Counselling and The Informed Consent 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.").

[28] Comm. Op. No. 439, *supra* note 17.

[29] 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).

[30] Comm. Op. No. 439, *supra* note 17; *see also* Howard Minkoff & Mary Faith Marshall, *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 . . . .").

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

III. FORCING PHYSICIANS TO COMPLY WITH S.B. 1318'S REQUIREMENT INTERFERES WITH PHYSICIANS' ETHICAL OBLIGATIONS TO PATIENTS

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

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

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[31] ACOG Code of Professional Ethics, at 2; AMA Code of Medical Ethics, *Op. 10.01 - Fundamental Elements of the Patient-Physician Relationship.*

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

[33] *See, e.g.*, AMA, Policy H-120.988, *Patient Access to Treatments Prescribed by Their Physicians*, *available at* https://www.ama-assn.org/ssl3/ecomm/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").

[34] *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 and abdication of professional obligations.").

administer are detrimental to the patient-physician relationship and are ill-advised."[35] Consistent with the requirements of a medical license, physicians must use their judgment and provide individualized care based on each patient's needs.

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

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

IV. S.B. 1318 ENCOURAGES IMPROPER EXPERIMENTATION ON PATIENTS

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

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

[36] 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).

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

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

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

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[37] Delgado & Davenport, *supra* note 7, at 3.

[38] Comm. Op. No. 352, *supra* note 15, at 3.

[39] *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

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

Dated: June 25, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 25, 2015, I electronically filed the foregoing Motion for Leave to File Brief of *Amici Curiae* with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to the following parties:

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