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**Applications for admission pro hac vice forthcoming*
***Admitted pursuant to Ariz. Sup. Ct. R. 38(f)*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc.; Eric Reuss, M.D., M.P.H.; 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

PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION AND MEMORANDUM OF POINTS AND AUTHORITIES

Civil Action No. _____

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 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.

PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Plaintiffs Planned Parenthood Arizona, Inc. ("PPAZ"), Eric Reuss, M.D., M.P.H.; Paul A. Isaacson, M.D.; Desert Star Family Planning, LLC; and DeShawn Taylor, M.D., (collectively hereinafter "Plaintiffs"), by and through their attorneys, hereby move this Court pursuant to Rule 65 of the Federal Rules of Civil Procedure for a temporary restraining order and/or preliminary injunction, restraining Defendants from enforcing portions of S.B. 1318, 52nd Leg., 1st Reg. Sess. (AZ 2015) ("S.B. 1318") (to be codified at Ariz. Rev. Stat. §§ 36-2153(A)(2)(h), (i)) ("the Act"), which without order from this Court will become law on July 3, 2015. This Motion is supported by the following Memorandum of Points and Authorities.[1]

MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

This case concerns a first-of-its kind law that would compel Plaintiffs—against their medical judgment and under threat of losing their licenses to practice medicine—to mislead their patients about the medical treatments available. The Act requires Plaintiffs to tell each patient seeking to have an abortion, orally and in a private meeting, that "it may be possible to reverse the effects of a medication abortion" if she changes her mind later, and that the state is providing information and assistance about doing so. The Act compels Plaintiffs to unwillingly convey this message to *every* patient, including those having a surgical abortion, even though no credible evidence exists that a medication

[1] Because this case involves important factual issues, Plaintiffs request that the Court set an evidentiary hearing on their application for preliminary injunction prior to July 3, 2015. In the (likely) case that a full hearing on the preliminary injunction cannot be set prior to that date, and/or Defendants will not agree to a temporary restraining order to allow the Parties an opportunity to fully prepare for a hearing, Plaintiffs request that the Court issue an order to show cause why a temporary restraining order should not issue, with a preliminary injunction hearing to be scheduled as soon thereafter as is convenient for the Court.

abortion (or any abortion) may be reversed, and even though the message encourages patients to begin a medication abortion before they are certain in their decision whether to have an abortion. The Act also compels Plaintiffs to steer patients toward an unproven, experimental practice that no major medical organization has recognized, and that the American College of Obstetricians and Gynecologists ("ACOG") opposes. Mandating that misleading, unscientific statements be given to and received by every patient seeking an abortion distorts the informed consent process and is harmful to patients.

The Act violates two separate fundamental rights. Because it compels Plaintiffs against their medical judgment and in violation of medical ethics to unwillingly discuss with their patients, "orally and in person," a state-mandated message that is not medically or scientifically supported, and that undermines the purpose of informed consent, the Act violates Arizona physicians' First Amendment right against compelled speech. The Act also violates Plaintiffs' patients' Fourteenth Amendment rights because it requires that they receive untruthful, misleading, and/or irrelevant information about abortion, which impedes rather than assists with their decision-making, and could expose them to unnecessary medical risk.

As is more fully explained below, a preliminary injunction is warranted because: 1) Plaintiffs are likely to succeed on their claims that the Act is unconstitutional; 2) Plaintiffs and their patients will suffer irreparable harm if the Act takes effect; 3) the balance of equities tips strongly in favor of Plaintiffs and their patients; and 4) the public interest will be served by an injunction. *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 911 (9th Cir. 2014) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)), *cert. denied*, 135 S. Ct. 870 (2014).

STATEMENT OF FACTS

A. Current Arizona Abortion Practice

Plaintiffs are Arizona health care providers who provide a full range of reproductive health services to women in Arizona, including abortions; pregnancy

diagnosis and counseling; contraceptive counseling; provision of all methods of contraception; HIV/AIDS testing and counseling; cancer screening; and testing, diagnosis, and treatment of sexually transmitted infections. Decl. of Bryan Howard ¶ 3, attached hereto as Exhibit 3 ("Howard Decl."); Decl. of Dr. Paul Isaacson ¶ 3, attached hereto as Exhibit 4 ("Isaacson Decl."); Decl. of Dr. Eric Reuss ¶ 3, attached hereto as Exhibit 5 ("Reuss Decl."). In providing care to their patients, Plaintiffs follow general principles of medical ethics, among the most fundamental of which is to provide patients with accurate information, in accordance with their medical judgment, training, and experience. Isaacson Decl. ¶¶ 4, 14; *see also* Howard Decl. ¶ 5; Reuss Decl. ¶ 5.

Plaintiffs' patients seek abortions for a variety of medical, psychological, emotional, familial, economic, and personal reasons. Isaacson Decl. ¶ 11; Reuss Decl. ¶¶ 8-10. Approximately one in three women in the United States will have an abortion by age 45, and most who do so either already have children or are planning to raise a family when they are older, financially stable, and/or in a supportive relationship with a partner. Decl. of Dr. Courtney Schreiber ¶ 7, attached hereto as Exhibit 1 ("Schreiber Decl."). Generally, if an Arizona woman seeks an abortion through the first 9-10 weeks of pregnancy as measured from the first day of her last menstrual period ("LMP"), she can choose between a surgical procedure that takes place in a health center (surgical abortion) or a procedure using pills alone (medication abortion). *See* Howard Decl. ¶ 4; Isaacson Decl. ¶ 7; Reuss Decl. ¶ 11; *see also* Schreiber Decl. ¶ 10.

Plaintiffs offer their patients the most common form of medication abortion, an evidenced-based regimen of a combination of two prescription pills: mifepristone and misoprostol (the "mifepristone/misoprostol regimen" or "early medication abortion"). Howard Decl. ¶ 4; Isaacson Decl. ¶ 8; Reuss Decl. ¶ 11. Mifepristone, also known as "RU-486" or by its commercial name Mifeprex, works first by temporarily blocking the hormone progesterone, thereby causing the uterine lining to break down, and by increasing the efficacy of the second medication in the regimen, misoprostol. Schreiber

Decl. ¶¶ 12-13. Misoprostol causes the uterus to contract and expel its contents. *Id.* at ¶ 13. Under current practice, a patient takes mifepristone at her health care facility and up to 72 hours later, usually at home, she takes misoprostol. *Id*. The mifepristone/misoprostol regimen Plaintiffs administer has been endorsed by ACOG, and is supported by vast amounts of clinical data. Schreiber Decl. ¶ 10 & n.3.

Mifepristone is not considered effective enough to use as an abortifacient on its own because it would fail to terminate pregnancy a significant percentage of the time. Schreiber Decl. ¶¶ 13-14 (citing data suggesting failure rate of up to 46 percent in first 49 days, and stating that other data suggest this rate would increase for pregnancies past 49 days). But when mifepristone is combined with misoprostol under the regimen used by Plaintiffs, the process is extremely effective. *Id*. For this reason, to provide an early medication abortion, Plaintiffs administer the two drugs in combination. Howard Decl. ¶ 4; Isaacson Decl. ¶¶ 8-9; Reuss Decl. ¶ 11.

After 9-10 weeks of pregnancy, the only option for most women is to have a surgical abortion; however, for certain medical reasons, medications are sometimes used to induce a non-surgical abortion later in pregnancy. For example, sometimes misoprostol alone is used to induce abortion in a hospital setting; this is called an "induction." Schreiber Decl. ¶ 15; Reuss Decl. ¶ 12(a). Another abortion method sometimes performed later in pregnancy involves using a medication called digoxin to cause fetal demise before the surgical evacuation of the uterus. Schreiber Decl. ¶ 15. Under Arizona law,[2] inductions and abortions via digoxin are both "medication abortions" because medications alone cause the abortion.

As healthcare providers, Plaintiffs have an ethical and legal obligation to obtain informed consent before providing medical treatment, including abortion. As part of the informed consent process, Plaintiffs discuss with each patient relevant information to

[2] *See* Ariz. Rev. Stat. § 36-449.01 ("'Medication abortion' means the use of any medication, drug or other substance that is intended to cause or induce an abortion.").

assist her with her decision of whether to have an abortion. Howard Decl. ¶ 5; Isaacson Decl. ¶¶ 12-13; Reuss Decl. ¶ 13. The information includes a discussion of her options and alternatives (which include carrying the pregnancy to term, adoption, and abortion), the abortion procedures that are available to her, and the risks and benefits associated with each procedure available to her. Howard Decl. ¶ 5; Isaacson Decl. ¶ 12; Reuss Decl. ¶ 13. The goal of the informed consent process is for patients to have the information necessary so that they can make the right decision for themselves. Declaration of Steven Joffe, M.D., M.P.H., at ¶ 18, attached hereto as Exhibit 2 ("Joffe Decl."). *See also* Howard Decl. ¶ 5; Isaacson Decl. ¶ 4; Reuss Decl. ¶¶ 5, 13.

Plaintiffs advise each patient that the decision to have an abortion is hers alone to make, and not to start an abortion, medication or surgical, unless and until she is firm in her decision to terminate the pregnancy. Howard Decl. ¶ 6; Isaacson Decl. ¶ 25; Reuss Decl. ¶ 20. In particular, when providing the mifepristone/misoprostol medication abortion regimen, Plaintiffs counsel each patient to be certain in her decision to terminate her pregnancy before starting the regimen, mainly because although mifepristone is not considered an effective abortifacient on its own (as compared to the combined regimen), mifepristone alone will cause termination in a significant percentage of pregnancies. Howard Decl. ¶ 6; Isaacson Decl. ¶ 26; Reuss Decl. ¶ 20.

B. The Act and Existing Informed Consent Process in Arizona

Existing Arizona law states that an abortion shall not be performed or induced without the voluntary and informed consent of a patient. Ariz. Rev. Stat. § 36-2153(A). Consent is considered voluntary and informed only if a patient seeking an abortion first meets in person with a physician, at least 24 hours before her abortion, to receive certain information, including accurate medical information about a patient's individual pregnancy. *Id.* In addition, a patient must receive from a physician (or a health professional chosen to represent him or her) various statements about Arizona law and policy, including that the Arizona Department of Health Services ("ADHS") maintains a

website regarding abortion and that the patient has a right to review the website, *id.*—similar to the required information approved by the U.S. Supreme Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 882-84 (1992).

The Act challenged here would radically alter existing informed consent requirements by compelling Plaintiffs to tell women seeking an abortion, at least 24 hours beforehand, 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," and that "information on and assistance with reversing the effects of a medication abortion is available on the department of health services' website." S.B. 1318, § 4 (to be codified at Ariz. Rev. Stat. § 36-2153(A)(2)(h), (i)). By statute, physicians and clinics that fail to comply face loss of licensure, other disciplinary action, and liability to private parties. *See* Ariz. Rev. Stat. §§ 36-449.02, 36-449.03; 36-429, 36-430; 32-1857(C); 36-2153(I), (J).

The Act also directs ADHS to 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)). To date, ADHS has not posted on its website the information required by the Act. *A Woman's Right to Know*, Arizona Department of Health Services (last visited June 2, 2015), http://azdhs.gov/phs/owch/informed-consent/right-to-know/index.htm. Indeed, soon after the Act was signed by Governor Ducey, Plaintiff PPAZ's President and CEO wrote to ADHS then-Interim Director Cory Nelson requesting information about what ADHS intends to post on its website in response to the Act's directive, and requested a response by May 22, 2015. Howard Decl. ¶ 10, Exhibit A. After receiving no response to its first letter, on May 22 Plaintiff PPAZ's President and CEO followed up again, this time with current ADHS Director Christ, to request the same information and a response by May 29. Howard Decl. ¶ 11, Exhibit B. On June 1, Plaintiff PPAZ's President and CEO

received a letter from ADHS Director Christ stating that, "[g]iven the impact of [S.B. 1318] the Department is still working through the requirements and vetting potential language," and that the information required under the Act would be posted by July 3, and possibly available sooner, by June 19. *Id.* ¶ 11, Exhibit C.[3]

C. Impact of the Act

The Act violates Plaintiffs' and their patients' rights, forces physicians to violate fundamental principles of medical ethics and thereby negatively impacts the physician-patient relationship, and puts patients at risk.

First, on its face, the Act requires Plaintiffs to tell their patients seeking an abortion, orally and in person, and in a private medical setting, that it "may be possible to reverse the effects of a medication abortion," and that assistance is available to do so. But no evidence exists that a medication abortion can be reversed—whether it is the most common type of medication abortion (the mifepristone/misoprostol regimen) or a medication abortion via induction or digoxin.[4] *See* Schreiber Decl. ¶¶ 16, 42. Indeed, no abortion may ever be reversed; the termination of a pregnancy is always final. Thus, the Act compels Plaintiffs to provide their patients with a state-mandated message that is not medically or scientifically supported, and that is not truthful. Schreiber Decl. ¶ 3; Joffe Decl. ¶¶ 23, 32. In so doing, the Act compels Plaintiffs to violate a fundamental obligation the physician has in the informed consent process, which is to provide patients with honest information. Joffe Decl. ¶¶ 20-23, 32.

Second, the Act forces Plaintiffs to steer their patients toward an experimental medical practice that is unsupported by any credible evidence. Joffe Decl. ¶¶ 32, 45-46.

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[3] This is an additional reason why a temporary restraining order is warranted: to preserve the status quo until Plaintiffs and this Court can consider the specific "information on and assistance with reversing the effects of a medication abortion" the Act would require Plaintiffs to refer their patients.

[4] Nor are Plaintiffs aware of any physicians purporting to reverse a medication abortion after a woman has taken the combined mifepristone/misoprostol regimen, or been given a medication abortion via digoxin or induction.

As the legislature considered and debated the Act, testimony was provided by an Arizona physician, who discussed an experimental practice proposed by a California physician named Dr. George Delgado. *Hearing on S.B. 1318 Before the H. Federalism and State's Rights Comm.*, 2015 Leg., 52nd Sess. (Ariz. 2015) (statement of Dr. Allan Sawyer at 6:15-21:03, *available at* http://azleg.granicus.com/MediaPlayer.php?view_id=13&clip_id=15544). This experimental practice involves giving women numerous injections of large doses of the hormone progesterone to "reverse" the effects of mifepristone, the first drug in the early medication abortion regimen provided by Plaintiffs. *See* Schreiber Decl. ¶¶ 17, 32. Thus, it is notable that even the proponents of this experimental practice do not claim to be able to reverse "the effects of a medication abortion"; the experimental practice relates solely to "reversing" the effects of mifepristone.

Plaintiffs object to being compelled, against their medical judgment, to tell every patient seeking an abortion that a medication abortion may be reversed based on an unproven theory about mifepristone reversal. Howard Decl. ¶¶ 12-13; Isaacson Decl. ¶¶ 17-20; Reuss Decl. ¶¶ 14-16; *see also* Schreiber Decl. ¶¶ 19, 39; Joffe Decl. ¶¶ 30-32. There are no clinical studies demonstrating that the experimental practice is safe or effective, Schreiber Decl. ¶¶ 16, 23-28, 33, nor has any major medical organization recognized it as such. To the contrary, ACOG opposes it because it has not been proven safe or effective. *See* Schreiber Decl. ¶ 20, Exhibit B. Instead of credible evidence, there exists one peer-reviewed article—a case series—of just seven patients who were administered progesterone experimentally years ago; four carried their pregnancies to term, two aborted, and one was lost to follow up. Schreiber Decl. ¶ 17, Exhibit C.

For several reasons, this case series is not evidence that the experimental practice does anything at all, or that it is safe. Case series, because of their anecdotal nature and lack of any scientific design, are especially vulnerable to selection bias and therefore do not support causal inferences. Joffe Decl. ¶ 29, Schreiber Decl. ¶ 22. In other words, case series are not evidence that the treatment they describe actually achieved the outcomes

that were observed. *Id*. Rather, physicians use case series to present observations that, at best, may merit future study. This case series is no different. Joffe Decl. ¶ 30. In fact, its data is questionable even for a case series. Schreiber Decl. ¶¶ 24 (explaining missing details and unrepresentative nature of patients observed). Indeed, Drs. Delgado and Davenport themselves acknowledged the need for clinical studies on their proposed protocol before it could become integrated into standard practice management.[5] Schreiber Decl. ¶ 31; Joffe Decl. ¶ 32. For all the foregoing reasons, even if the Act was meant to refer only to "mifepristone reversal," as opposed to "medication abortion reversal," it still would force Plaintiffs to convey to their patients a state-mandated message that is highly misleading because it is not based on any medical evidence.[6]

The state-mandated message compelled by the Act is also deeply misleading to patients, especially those that are eligible for or considering a medication abortion. It encourages patients to believe that there is evidence, endorsed by their physician and the state, that a medication abortion can be reversed, Joffe Decl. ¶ 28, and that assistance is available to do so, when this is not the case. And Plaintiffs must raise this (medically

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[5] According to public statements by physicians experimenting on women with progesterone, it appears they have now expanded their practice beyond the seven women reported in the case series, but are doing so outside the normal bounds of accepted medical research methods—i.e., without approval by an institutional review board, *see* Joffe Decl. ¶¶ 39-43; Schreiber Decl. ¶¶ 34-36, and with misleading, public statements about the efficacy of their protocol, *see* Schreiber Decl. ¶ 33. The misleading nature of their public statements also calls into question whether any subjects could give true informed consent before participating in the research.

[6] It is puzzling that the Arizona Legislature would now encourage women who choose medication abortion to seek out *unstudied*, off-label progesterone administration, notwithstanding that just a few years ago, it banned women from using an evidence-based, off-label protocol for medication abortion that has been proven safe and effective in peer-review studies involving hundreds of thousands of women. *See Humble*, 753 F.3d 905. Similarly strange is that in the findings to that same law, the Arizona Legislature stated a concern that women might suffer complications from "*failure* to complete the two-step dosage process." H.B. 2036, 50th Leg., 2nd Reg. Sess. (AZ 2012), § 9.A.13 (emphasis added). The Act does not explain the inconsistency inherent in now encouraging women to do just that.

unsupported) possibility of reversing a medication abortion during the informed consent process—the very time at which Plaintiffs are trying to impress on each patient that she must be certain about terminating a pregnancy. Howard Decl. ¶ 16; Isaacson Decl. ¶¶ 22, 24; Reuss Decl. ¶ 19. In this way, the Act undermines a critical message Plaintiffs to seek to convey to their patients during the informed consent process, and creates a risk that a patient may begin an abortion before she is ready. *See* Schreiber Decl. ¶¶ 45-47; Joffe Decl. ¶ 35; Howard Decl. ¶ 16; Reuss Decl. ¶ 20.

The Act also requires Plaintiffs, against their medical judgment, to inform *all* of their patients seeking abortion that it may be possible to reverse the effects of a medication abortion, and that assistance is available to do so. This information, even if it were truthful (which it is not), is wholly irrelevant to many of Plaintiffs' patients who are not eligible for or do not want a medication abortion. This highlights another way in which the Act undermines the purpose of informed consent by distracting patients from the critical information that is necessary to an informed decision. *See* Joffe Decl. ¶ 36.

In all of these ways, the Act forces Plaintiffs, against their own professional, medical judgment, and in their own voice, to convey a message to their patients that is not based on medical evidence, violates the prevailing standard of care, is against their patients' best interests, and is untrue, misleading, and irrelevant. *See* Joffe Decl. ¶¶ 23, 33; Schreiber Decl. ¶¶ 3, 16-33, 39-47. As a result, the Act is harmful to women, to the physician-patient relationship and to the integrity of the medical profession, and it frustrates rather than supports the informed consent process. *See* Joffe Decl. ¶¶ 25, 32-34, 45-46; Schreiber Decl. ¶¶ 39, 41-45, 48.

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO A PRELIMINARY INJUNCTION AND, IF NECESSARY, A TEMPORARY RESTRAINING ORDER

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of

preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Humble*, 753 F.3d at 911 (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). When a court applies this standard, "the elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another." *Pimentel v. Dreyfus*, 670 F.3d 1096, 1105 (9th Cir. 2012) (quoting *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011)). "'[S]erious questions going to the merits' and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Humble*, 753 F.3d at 911 (quoting *Alliance for the Wild Rockies*, 632 F.3d at 1135). "[T]he purpose of a preliminary injunction is to preserve the status quo between the parties pending a resolution of a case on the merits." *McCormack v. Hiedeman*, 694 F.3d 1004, 1019 (9th Cir. 2012). As explained below, Plaintiffs meet this standard.

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

Plaintiffs are highly likely to prevail on their First and Fourteenth Amendment claims. The Act infringes on Plaintiffs' First Amendment rights by compelling them to speak a state-mandated message to every patient about an experimental medical practice that has not been proven safe or effective, that violates the standard of care, and that is antithetical to ensuring informed consent. Accordingly, the Act must be reviewed under heightened scrutiny. The Act clearly fails this demanding test by compelling speech that is not tailored to further even a legitimate government interest. Moreover, the Act is separately unconstitutional under the Fourteenth Amendment, as it requires women seeking to exercise their right to choose abortion to receive information that is untruthful, misleading, and/or irrelevant.

A. The Act Violates Plaintiffs' First Amendment Rights Against Compelled Speech.

1. The Act must be subjected to heightened scrutiny.

The U.S. Supreme Court has long held that the First Amendment protects not only against government restrictions on speech, but also against speech compelled by the government. "Since *all* speech inherently involves choices of what to say and what to leave unsaid, one important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573 (1995) (emphasis added) (internal quotation marks and citations omitted). Thus, "[t]he First Amendment mandates that we presume that speakers, not the government, know best both what they want to say and how to say it." *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 790-91 (1988).

In determining the appropriate level of scrutiny by which to review a challenged measure, the "lodestars . . . must be the nature of the speech taken as a whole and the effect of the compelled statement thereon." *Riley*, 487 U.S. at 796. "[R]ecogniz[ing] the core First Amendment values of the doctor-patient relationship," the Court of Appeals for the Ninth Circuit has reasoned that "professional speech may be entitled to 'the strongest protection our Constitution has to offer.'" *Conant v. Walters*, 309 F.3d 629, 637 (9th Cir. 2002) (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 634 (1995)). Specifically, that court has held "that doctor-patient communications *about* medical treatment receive substantial First Amendment protection." *Pickup v. Brown*, 740 F.3d 1208, 1227-1231 (9th Cir. 2013) (emphasis in original), *cert. denied*, 134 S.Ct 2871 (2014), *and cert. denied sub nom. Welch v. Brown*, 134 S.Ct 2881 (2014). This is because "[a]n integral component of the practice of medicine is the communication between a doctor and a patient," which hinges on "confidence and trust" and a physician's ability "to speak frankly and openly to patients." *Conant*, 309 F.3d at 636 (quoting *Trammel v. United States*, 445 U.S. 40, 51 (1980)); *see also Conant*, 309 F.3d at 636 (noting that the Supreme Court in *Casey* recognized that physician speech is entitled to First Amendment protection because of the significance of the doctor-patient relationship).

In *Conant*, the court applied heightened scrutiny to enjoin a government policy restricting physicians from merely recommending (although not prescribing) medical marijuana to their patients. 309 F.3d at 637-39. The court compared this to a law requiring licensing of psychoanalysts, which it had previously held to be content-neutral as it "did not attempt to 'dictate' the content of what is said in therapy." *Id.* at 637 (discussing *Nat'l Ass'n for the Advancement of Psychoanalysis v. Cal. Bd. of Psychology*, 228 F.3d 1043, 1055-56 (9th Cir. 2000) ["*NAAP*"]). The medical marijuana speech regulation, by contrast, was a content- and viewpoint-based regulation because it applied only to "doctor-patient conversations about the medical use of marijuana," and "condemn[ed] expression of a particular viewpoint, *i.e.* that medical marijuana would likely help a specific patient." *Id*. at 637. The court explained that content-based restrictions on speech are "presumptively invalid," *id.* (quoting *R.A.V. v. City of St. Paul, Minn.*, 505 U.S. 377, 382 (1992)), and "when the government targets . . . particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant," *id.* (quoting *Rosenberger v. Rector*, 515 U.S. 819, 829 (1995)).

Elaborating on *Conant* and *NAAP*, the Ninth Circuit in *Pickup* considered more generally the First Amendment rights of state-regulated health care professionals (including physicians), explaining that:

> At one end of the continuum, where a professional is engaged in a public dialogue, First Amendment protection is at its greatest. . . . At the midpoint of the continuum, within the confines of a professional relationship, First Amendment protection of a professional's speech is somewhat diminished. . . . At the other end of the continuum . . . is the regulation of professional conduct, where the state's power is great, even though such regulation may have an incidental effect on speech.

Pickup, 740 F.3d at 1227-29 (emphasis omitted). The court further explained, "certainly . . . content- or viewpoint based regulation of communication *about* treatment must be closely scrutinized." *Id.* at 1231. Because the law at issue in *Pickup* banned a particular *treatment*, the court held that it was a regulation of conduct, falling at the less speech-

protective end of the spectrum. *Id.* at 1229; *see also Pickup*, 740 F.3d at 1226 (contrasting conduct regulation at issue in *NAAP*, which required psychoanalysts to meet licensing requirements, with the ban on the "mere[] discussion" of marijuana treatment at issue in *Conant*, which restricted speech).

Thus, as both *Pickup* and *Conant* make clear, a content- or viewpoint-based regulation of a physician's speech about medical treatment within the confines of a professional relationship falls in the middle of the continuum, triggering "heightened scrutiny." *Pickup*, 740 F.3d at 1231; *accord Conant*, 309 F.3d at 637-39; *see also Stuart v. Camnitz*, 774 F.3d 238, 248 (4th Cir. 2014) (applying *Pickup* and holding that state-compelled physician speech in the informed consent context "resides somewhere in the middle on that sliding scale" and must satisfy at least intermediate scrutiny to survive).

Here, there is no question that the challenged Act regulates speech, not conduct, as it "dictate[s] the content of what is said," *NAAP*, 228 F.3d at 1056, in "doctor-patient communications *about* medical treatment," *Pickup*, 740 F.3d at 1227, and is deserving of heightened scrutiny. *See also Conant*, 309 F.3d at 637-39; *see also Camnitz*, 774 F.3d at 246 (finding regulation to be "quintessential compelled speech" as it "forces physicians to say things they otherwise would not say"). This is undeniably the case considering "the nature of the speech taken as a whole" mandated by the Act, and the "effect of the compelled statement[s]," *Riley*, 487 U.S. at 796. Specifically, the Act mandates speech that directly and negatively alters the content of Plaintiffs' informed consent discussions with their patients in at least three ways:

First, Plaintiffs would never tell their patients, against their best medical judgment, that it "may be possible to reverse . . . a medication abortion," nor would they tell their patients that assistance is available to do so, when no medically accepted evidence exists that it is possible to reverse a medication abortion. Howard Decl. ¶¶ 12-16; Isaacson Decl. ¶¶ 17-19; Reuss Decl. ¶¶ 14-15, 19. Indeed, Plaintiffs would not communicate the mandated information even if the Act were clear that it were only

referring to mifepristone reversal, because no medically accepted evidence exists that it is possible to reverse the effects of mifepristone either.[7] *Id.*; *see additionally* Isaacson Decl. ¶¶ 20-22; Reuss Decl. ¶¶ 16-17.

Second, by forcing Plaintiffs to tell a patient that she may be able to reverse her medication abortion if she later changes her mind, the Act undermines and confuses Plaintiffs' critical message to the patient that she must be certain that she wants to terminate her pregnancy before beginning the medication abortion process. Howard Decl. ¶ 6; Isaacson Decl. ¶ 25; Reuss Decl. ¶ 20; Joffe Decl. ¶ 34; Schreiber Decl. ¶ 47.

Third, but for the Act, Plaintiffs would never tell those patients who are only eligible for or interested in a surgical abortion irrelevant information (even if it were medically supported) about a medication abortion. Howard Decl. ¶ 12; Isaacson Decl. ¶ 27; Reuss Decl. ¶ 18; *see also* Joffe Decl. ¶ 35 ("[I]rrelevant information distracts patients from the critical information that is necessary to an informed decision.").

Put simply, the Act forces Plaintiffs to communicate to their patients in a private medical setting, against their medical judgment, a state-mandated medical message that they otherwise would not give their patients because it is misleading and would violate medical ethics and undermine the goal of the informed consent process.

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[7] To be clear, but for the Act, Plaintiffs would not advise their patients that the state has information and assistance with reversing a medication abortion, because, again, no medically accepted evidence exists that it is possible to reverse a medication abortion. Also, while Plaintiffs do not know what this "assistance" will consist of since ADHS is still vetting the language they intend to post on their website, *see* Howard Decl. ¶¶ 10-11, Exhibits A-C, the only information about which they are aware is the website abortionpillreversal.com. That website not only has numerous false statements about the efficacy of the experimental protocol, Schreiber Decl. ¶ 33, but explains that the "Abortion Pill Reversal" program is part of an organization, Culture of Life Family Services, *About Our Team*, Abortion Pill Reversal (last visited June 1, 2015), www.abortionpillreversal.com/about-us.php, which is categorically opposed to abortion, as well as prescription birth control, *About Culture of Life Family Services*, Culture of Life Family Services (last visited June 1, 2015), www.colfs.org/about-culture-of-family-life-family.php. Plaintiffs, who believe in comprehensive women's health services, object to referring their patients to such an organization.

A law that "mandat[es] speech that a speaker would not otherwise make necessarily alters speech's content," and thus is "a content-based regulation of speech" deserving of particularly searching scrutiny. *Riley*, 487 U.S. at 795; *accord Conant*, 309 F.3d at 637 (content-based regulations of physician speech are "presumptively invalid" (quoting *R.A.V.*, 505 U.S. at 382)); *Camnitz*, 774 F.3d at 245 ("[A] content-based regulation of a medical professional's speech . . . must satisfy at least intermediate scrutiny to survive."); *King v. Governor of N.J.*, 767 F.3d 216, 235 (3d Cir. 2014), *cert. denied sub nom. King v. Christie,* No. 14-672, 2015 WL 1959131 (May 4, 2015) (same); *see also United States v. Alvarez*, 132 S. Ct. 2537, 2544 (2012) ("[C]ontent-based restrictions on speech have been permitted, as a general matter, only when confined to the few 'historic and traditional categories [of expression] long familiar to the bar.'" (quoting *United States v. Stevens*, 559 U.S. 460, 469 (2010)) (reviewing those categories)).

"[T]he violation of the First Amendment is all the more blatant" here because the Act is also impermissibly viewpoint-based. *Conant*, 309 F.3d at 637 (quoting *Rosenberger*, 515 U.S. at 829). The Act singles out informed consent discussions between physicians treating pregnant patients seeking abortions, and compels not only discussion about a particular subject, i.e. purported "medication abortion reversal," but also compels physicians to tell patients the government's viewpoint, i.e. "that it may be possible" to reverse a medication abortion if they change their mind later—even though no evidence exists that this is true, and Plaintiffs as well as the leading medical organization of providers of health care to women, ACOG, disagree with this message. *See id.* (finding a regulation viewpoint-based because it targeted a particular viewpoint, *i.e.*, that medical marijuana would likely help a specific patient); *see also NAAP*, 228 F.3d at 1055-56 (holding that "California's licensing scheme is content and viewpoint neutral; therefore it does not trigger strict scrutiny" because "California does not dictate the content of what is said in therapy"); *Frudden v. Pilling*, 742 F.3d 1199, 1207 (9th Cir. 2014) (policy requiring students to wear uniforms with motto was deserving of strict

scrutiny because it compelled students to disseminate a particular viewpoint); *Ward v. Polite*, 667 F.3d 727, 733 (6th Cir. 2012) ("the most aggressive form of viewpoint discrimination [is] compelling an individual 'to utter what is not in [her] mind'" (quoting *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 634 (1943))).

Finally, the Act compels speech in several uniquely onerous respects that make heightened scrutiny all the more appropriate here, and that clearly distinguish the Act from the requirement upheld in *Planned Parenthood of Southeastern Pennsylvania v. Casey*. There, the Supreme Court upheld a statutory requirement that physicians inform patients about the nature of the procedure, the health risks of abortion and of childbirth, and the probable gestational age of the fetus. It also required that physicians (or health care professionals acting on their behalf) inform women of the availability of state-created materials that described the fetus and contained information about assistance with childbirth and parenting. 505 U.S. at 882-884. Thus, as to the first requirement, the statute only required a physician to inform the woman of standard, general informed consent information that the physician could convey in accordance with his/her medical judgment. And as to the second requirement, the statute only required physicians to *offer* to patients the state's own speech, in state-created pamphlets, and thus there was no question that the views in the pamphlets belonged to the government. *Id.* Moreover, the accuracy of the state's materials was not at issue. *Id.* Finally and importantly, the physician was exempted from complying with this requirement if the physician reasonably believed that the offer of the information would harm the patient. *Id.* at 883.

Here, however, the Act distorts the informed consent process by commanding that Plaintiffs make statements that are not medically or scientifically supported. Schreiber Decl. ¶ 3; Joffe Decl. ¶ 23. Moreover, the state-mandated message directly conflicts with and undermines the critical message Plaintiffs seek to convey to their patients: that they must be certain about whether to terminate their pregnancy before starting an abortion. Howard Decl. ¶ 6; Isaacson Decl. ¶ 25; Reuss Decl. ¶ 20; *see also* Joffe Decl. ¶ 2. And

Plaintiffs must, against their medical judgment and medical ethics, speak the state-mandated message, in their own voice, even though it will negatively interfere with the informed consent process, and is potentially harmful to patients. Schreiber Decl. ¶¶ 47-48; Joffe Decl. ¶¶ 23, 32. The Act thus "'alter[s] the traditional role' of medical professionals," *Conant*, 309 F.3d at 638 (quoting *Legal Servs. Corp. v. Velazquez*, 531 U.S. 544 (2001)), by compelling Plaintiffs to communicate information that is not medically or scientifically supported, and that is misleading to patients. The Act compels Plaintiffs to convey this information under *all* circumstances to *all* patients seeking abortions, no matter how irrelevant or inappropriate it is to an individual woman's circumstances, thereby "'prevent[ing] the physician from exercising his or her medical judgment.'" *Conant*, 309 F.3d at 638 (quoting *Casey*, 505 U.S. at 883-84).[8]

In each of these respects, the speech compelled by the Act is entirely inconsistent with the traditional understanding of informed consent and prevailing norms of medical practice. *See* Joffe Decl. ¶¶ 2, 33; *see also Conant*, 309 F.3d at 638 (heightened scrutiny is applicable to regulation of physician's speech that departs from the "traditional role of medical professionals" and undermines "the proper functioning of [the medical] system[]" (internal quotation and citation omitted); *Camnitz*, 774 F.3d at 247-55 (holding

[8] Two cases from other Circuits, *Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 686 F.3d 889 (8th Cir. 2012) (en banc) and *Texas Medical Providers Performing Abortion Services v. Lakey*, 667 F.3d 570 (5th Cir. 2012), have misapplied *Casey*'s Fourteenth Amendment standard—that information required by law to be given to abortion patients must be "truthful, nonmisleading, and relevant"—to the plaintiffs' First Amendment claims. Those cases were wrongly decided. As the Fourth Circuit Court of Appeals held, *Casey* did not purport to create a new, exceptionally low standard of review of compelled speech merely because the topic of that speech is abortion. *See Camnitz*, 774 F.3d at 249 (holding that *Casey* "does not assert that physicians forfeit their First Amendment rights in the procedures surrounding abortions, nor does it announce the proper level of scrutiny to be applied to abortion regulations that compel speech to [an] extraordinary extent"). And, in any event, this Circuit's authority—most notably *Pickup, Conant,* and *NAAP*—control Plaintiffs' First Amendment claim here. Plaintiffs' Fourteenth Amendment claim, including the application of *Casey*'s "truthful, nomisleading, and relevant" standard, is discussed *infra* at Part II.B.

same where regulation imposed speech "requirements [that] look nothing like traditional informed consent"). Where, as here, a statute regulates a physician's speech about medical treatment in a manner that is incompatible with prevailing norms of medical practice, the law is clear that heightened scrutiny applies. *See, e.g.*, *Conant*, 309 F.3d at 638-39; *Pickup*, 740 P.3d at 1226; *accord Camnitz*, 774 F.3d at 250 (striking down a law mandating speech "beyond the extent permitted for reasonable regulation of the medical profession, . . . threatening harm to the patient's . . . health, interfering with the physician's professional judgment, and compromising the doctor-patient relationship").

Under clear precedent, the Act must be given "heightened" scrutiny, affording Plaintiffs substantial protection against government regulation of communications with their patients about treatment. A law like the Act challenged here, which is plainly antithetical to the purpose of the informed consent process, cannot withstand such review.

2. The Act does not survive heightened scrutiny.

Under heightened scrutiny, the government bears the burden of showing that the challenged law is constitutional. *See, e.g.*, *Alvarez*, 132 S. Ct. at 2544; *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480-81 (1989); *see also Conant*, 309 F.3d at 637-39. Thus, to sustain the burden the Act imposes on Plaintiffs' First Amendment rights, "the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667-68 (2011); *accord Conant*, 309 F.3d at 639 ("To survive First Amendment scrutiny, the government's policy must have the requisite narrow specificity." (internal quotation omitted)). The State cannot satisfy its burden.

As an initial matter, the Act does not satisfy heightened scrutiny because forcing doctors to make medically unsupported statements to patients against the doctor's medical judgment, and in violation of medical ethics, is not a legitimate means of advancing any state interest. As ACOG has determined and as the evidence herein makes plain, there is no credible evidence that a medication abortion—whether the

mifepristone/misoprostol regimen or a medication abortion via induction or digoxin—can be reversed. *See* Schreiber Decl. ¶¶ 16-33, 39, 42, Exhibit C; Joffe Decl. ¶ 26. Compelling physicians to communicate medically unsupported information to patients during the informed consent process—the very process that is meant to enable the patient to make an autonomous decision based on truthful, medically supported information, *see* Joffe Decl. ¶¶ 17-19—simply does not advance any permissible state interest. Indeed, "[a] doctor may not counsel a patient to rely on quack medicine." *Pickup*, 740 F.3d at 1228 (internal quotation marks and citation omitted). And, as the Ninth Circuit held in a comparable context, "the State has no legitimate reason to force retailers to affix false information on their products." *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 958 (9th Cir. 2009). That principle applies with even greater force here: forcing physicians to disregard their medical judgment and medical evidence to make scientifically unsupported statements to their patients during the informed consent process does not permissibly advance any constitutionally sufficient state interest. *Cf. Camnitz,* 774 F.3d at 253-54 ("It subverts the patient's expectations when the physician is compelled to deliver a state message bearing little connection to the search for professional services that led the patient to the doctor's door."); *Duncan v. Scottsdale Med. Imaging, Ltd.*, 205 Ariz. 306, 311 (Ariz. 2003) ("[W]e hold that if a patient's consent is obtained by a health care provider's fraud or misrepresentation, a cause of action for battery is appropriate." (citing 6 Am. Jur. 2d Assault and Battery § 127 (1999)).

For similar reasons, the Act unquestionably fails in its tailoring. Under the heightened scrutiny applicable here, it is the State's burden to prove, at minimum, that the Act's speech mandate is narrowly drawn to achieve a substantial government interest, and that there is a close "fit between the legislature's ends and the means chosen to accomplish those ends." *Sorrell*, 131 S. Ct. at 2668 (quotation marks and citation omitted). Compelling physicians to tell each patient a message that is not medically or

scientifically supported, and that is misleading, is clearly more extensive than necessary to further any state interest, and certainly does not advance an interest in informed medical decision-making. That is especially so when the Act forces physicians to act against their best medical judgment and in violation of the standard of care. *See Conant*, 309 F.3d at 638 (government marijuana policy was similarly unconstitutional as limitation struck down by Supreme Court in that it "'alter[s] the traditional role' of medical professionals by 'prohibit[ing] speech necessary to the proper functioning of those systems'" (quoting *Velazquez*, 531 U.S. 544 (2001))).

Indeed, not only is there an insufficiently close fit between the Act's speech mandate and any proper state interest, but the Act directly undermines women's ability to make an informed choice about abortion. For patients seeking an early medication abortion, the Act compels their trusted medical provider to *mis*inform their decision by making statements lacking scientific or medical support. *See* Schreiber Decl. ¶ 48; Joffe Decl. ¶ 23. And during the same time when the medical provider must communicate to the patient that she should be certain that she wants to terminate her pregnancy before the abortion begins, the Act again undermines the informed consent process by introducing the misleading prospect that reversal is possible, thereby creating the serious risk that a patient may begin an abortion before she is ready—again, contrary to the entire purpose of the informed consent process. *See* Joffe Decl. ¶ 34; Schreiber Decl. ¶¶ 45-47.

The Act also lacks "the requisite narrow specificity" the First Amendment requires, *Conant*, 309 F.3d at 629 (internal citation omitted), because it compels Plaintiffs to convey a state-mandated message that (even if it were medically supported) is wholly irrelevant to many women who are not even eligible for or are not interested in early medication abortion. Compelling physicians to make statements to surgical abortion patients about medication abortion reversal is the very opposite of the tailoring that the First Amendment requires—and indeed, providing irrelevant information distracts a patient from processing the critical information she needs to understand to make an

informed decision. *See* Joffe Decl. ¶ 35; Schreiber Decl. ¶ 41. Similarly, for patients seeking a medication abortion via induction or digoxin, the Act forces physicians to falsely state that such medication abortions can be reversed when no one even claims that is possible. *See* Schreiber Decl. ¶ 42. Once again, mandating speech that misinforms patients is the very opposite of the close means-ends fit that First Amendment requires.

The Act, thus, is a clear violation of Plaintiffs' First Amendment rights. "'If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.'" *Conant*, 309 F.3d at 637 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002)). Therefore, the Act must be enjoined.

B. The Act Violates a Woman's Right to Choose Abortion.

The Act also violates Plaintiffs' patients' Fourteenth Amendment rights. Women have a fundamental liberty interest, protected by the Fourteenth Amendment, in deciding whether to continue a pre-viability pregnancy. *Casey*, 505 U.S. at 845-46. In the specific context of laws mandating the provision of information to women seeking an abortion, the Supreme Court has made clear that such a law is unconstitutional under the Fourteenth Amendment if the information the state compels providers to convey is false, misleading, or irrelevant. *See Casey*, 505 U.S. at 882; *see also Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 540 (9th Cir. 2004) (reasoning that it would be facially irrational to "require[] physicians to provide false or misleading information to women seeking abortions"). This is because "the means chosen by the State to further the interest in potential life *must be calculated to inform* the woman's free choice," *Casey*, 505 U.S. at 877 (emphasis added), and when the state injects false or misleading information into a woman's decision-making process, it does precisely the opposite.

As explained above, the Act requires Plaintiffs to provide untruthful and misleading information to every patient seeking an abortion because there is no evidence that a medication abortion may be reversed. *See supra* pp. 7-10. Specifically, the information mandated by the Act is untruthful and misleading for women seeking early

medication abortion because—as ACOG has emphasized—the notion of "medication abortion reversal" is not supported by the weight of scientific evidence. *See* Schreiber Decl. ¶¶ 16-33, Exhibit C. Moreover, the information mandated by the Act is untruthful and misleading for women seeking medication abortions via induction or digoxin, because there is no evidence—and not even a claim—that such abortions are reversible. *See* Schreiber Decl. ¶ 42. On this basis alone, the Act is unconstitutional under *Casey*.

The Act also violates *Casey* because it compels Plaintiffs to provide information that is wholly irrelevant to the significant share of women who are either ineligible for or uninterested in early medication abortion. Howard Decl. ¶12; Isaacson Decl. ¶ 27; Reuss Decl. ¶ 18, Schreiber Decl. ¶¶ 40-41; Joffe Decl. ¶ 35. *Cf. Planned Parenthood of Ind. v. Comm'r of Ind. Dep't of Health*, 794 F. Supp. 2d 892, 920 (S.D. Ind. 2011) (enjoining compelled physician statement as applied to patients for whom it was not relevant), *rev'd in part on other grounds*, 699 F.3d 962 (7th Cir. 2012). Forcing a physician to tell a woman who is to receive a surgical abortion that "it may be possible to reverse the effects of a medication abortion" plainly does not "inform the woman's free choice," *Casey*, 505 U.S. at 877. Instead, the forced communication of such irrelevant information can only serve to distract from the important—and relevant—informed consent information that medical providers seek to convey to their patients, Joffe Decl. ¶ 35, thereby impermissibly "hinder[ing]" the patient's decision-making, *Casey* at 877.

The Act also fails the *Casey* standard because it does not serve a valid state interest at all, let alone to a degree that justifies the burden it imposes on women seeking an abortion. *See Humble*, 753 F.3d at 913 ("[W]e must . . . ask[] whether and to what extent the challenged regulation actually advances the state's interests. If a burden significantly exceeds what is necessary to advance the state's interests, it is 'undue.'" (citation omitted)). *See also Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 798 (7th Cir. 2013) (same); *Planned Parenthood Southeast, Inc. v. Strange*, 33 F. Supp. 3d 1330, 1340-41 (M.D. Ala. 2014) (same), *supplemented by* 33 F. Supp. 3d 1381,

and amended by 2014 WL 5426891. Critically, the first part of this inquiry requires a real-world look at "whether *and to what extent* the challenged regulation *actually* advances the state's interests." *Humble*, 753 F.3d at 913 (emphasis added). As demonstrated by the evidence here, the Act fails to further any proper state interest because it forces patients to receive information that is false, misleading, and or irrelevant (thus hindering their ability to make a well-informed decision); and, for early medication abortion patients, confuses the physician's critical message that the patient must be certain that she wants to terminate her pregnancy before beginning the medication abortion process. Schreiber Decl. ¶ 47; Joffe Decl. ¶ 34. *See Eden*, 379 F.3d at 540 (laws that require abortion patients to receive false and/or misleading information are irrational on their face, and plainly unconstitutional).

Not only does the Act fail to serve any conceivable state interest, but it also burdens women by misleading them, interfering with their decision-making process, and violating the trust they place in their physician. See *supra* pp. 7-10. *Cf. Humble*, 753 F.3d at 915 (holding that undue burden analysis includes consideration of whether a challenged law would "usurp[] . . . providers' ability to exercise medical judgment" (quoting *Eden*, 379 F.3d at 543)); *Casey*, 505 U.S. at 884 (finding it significant that the informed consent statute "does not prevent the physician from exercising his or her medical judgment"). In these ways, the Act is unlike any informed consent law ever sanctioned and must be enjoined.

III. PLAINTIFFS ARE LIKELY TO SUFFER IRREPARABLE HARM ABSENT PRELIMINARY RELIEF

Absent a temporary injunction, Plaintiffs and their patients will suffer irreparable harm. It is well established that "the deprivation of constitutional rights 'unquestionably constitutes irreparable injury.'" *Humble*, 753 F.3d at 911 (quoting *Melendres v. Arpario*, 695 F.3d 990, 1002 (9th Cir. 2012) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))); *accord Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009); *see also Women's*

Med. Ctr. of Nw. Houston v. Bell, 248 F.3d 411, 422 (5th Cir. 2001) (affirming district court's finding of irreparable harm based on threat to women's constitutional right to abortion). Moreover, "[a] 'colorable First Amendment claim' is 'irreparable injury sufficient to merit the grant of relief.'" *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014) (quoting *Warsoldier v. Woodford*, 418 F.3d 989, 1001 (9th Cir. 2005)).

In addition to the threatened violation of constitutional rights, the Act inhibits informed decision-making, and threatens to harm the physician-patient relationship and the integrity of the medical profession. Joffe Decl. ¶ 46; Howard Decl. ¶¶ 14-18; Isaacson Decl. ¶¶ 22-23. The Act also threatens to steer women toward an experimental medical practice that has not been proven safe or effective, Joffe Decl. ¶¶ 32, 45, and that is opposed by the nation's leading women's medical organization, ACOG, Schreiber Decl. ¶ 20; Joffe Decl. ¶ 26.[9]

IV. THE BALANCE OF HARMS STRONGLY FAVORS PLAINTIFFS AND THE PUBLIC INTEREST IS SERVED BY AN INJUNCTION

The balance of equities also weighs heavily in favor of an injunction. As set forth above, Plaintiffs and their patients will suffer serious harm if the law takes effect, whereas Defendants only stand to lose the ability temporarily to enforce a law that does not serve any state interest, and which is likely to be held unconstitutional. Indeed, where a law threatens the loss of First Amendment rights, "[t]he 'balancing of equities that is undertaken in a conventional equity case is out of place in dealing with rights so important as the . . . rights of expression to be.'" *Galassini v. Town of Fountain Hills, Ariz.*, No. CV-11-02097-PHX-JAT, 2011 WL 5244960, at *6 (D. Ariz. Nov. 3, 2011)

[9] The threat of the Act's onerous penalties, including license revocation, too constitutes irreparable harm. *See, e.g.*, *A Choice for Women v. Butterworth*, 54 F. Supp. 2d 1148, 1158 (S.D. Fla. 1998) (stating that because clinics faced potential prosecution for offering abortions, there was irreparable injury); *Planned Parenthood of Cent. N.J. v. Verniero*, 41 F. Supp. 2d 478, 504 (D.N.J. 1998) (finding irreparable injury, in part, because Planned Parenthood faced heavy fines for noncompliance with abortion regulation), *aff'd sub nom Planned Parenthood of Cent. N.J. v. Farmer*, 220 F.3d 127 (3d Cir. 2000).

(quoting *Shondel v. McDermott*, 775 F.2d 859, 869 (7th Cir. 1985)). *See also Doe v. Harris*, 772 F.3d at 583 (granting preliminary injunction after showing of irreparable injury by threatened loss of First Amendment rights).

Finally, granting an injunction in this case will serve the public interest. "[I]t is always in the public interest to prevent the violation of a party's constitutional rights." *Melandres*, 695 F.3d 990 at 1002 (punctuation and citations omitted) (reviewing cases). *See also Harris*, 772 F.3d at 583 (courts "have consistently recognized the significant public interest in upholding First Amendment principles.") (citation and internal punctuation omitted). It is also in the public interest to protect the integrity of the medical profession and the ability of physicians to act in the best interests of their patients and of those patients to receive truthful, relevant information.

CONCLUSION

For all of the foregoing reasons, Plaintiffs' motion for a preliminary injunction and, if necessary, their request for a temporary restraining order should be granted. Defendants should be enjoined from enforcing the Act pending the final determination of Plaintiffs' claims.[10]

[10] Because Plaintiffs and their patients face a loss of constitutional rights, and Defendants are not faced with any monetary injury if a preliminary injunction is issued, no bond should be required under Fed. R. Civ. P. 65(c). *See, e.g.*, *Galassini*, 2011 WL 5244960, at *7; *United Food & Commercial Workers Local 99 v. Brewer*, 817 F. Supp. 2d 1118, 1128 (D. Ariz. 2011); *see also Diaz v. Brewer*, 656 F.3d 1008, 1015 (9th Cir. 2011) (affirming district court's waiver of bond in constitutional rights case, and noting that under Rule 65(c) "[t]he district court retains discretion as to the amount of security required, *if any*.") (emphasis in original) (internal punctuation and citations omitted)).

Dated: June 4th, 2015

Respectfully submitted,

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**Applications for admission pro hac vice forthcoming*
***Admitted pursuant to Ariz. Sup. Ct. R. 38(f)*

CERTIFICATE OF SERVICE

I hereby certify that on the 4th day of June, 2015, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF system for filing.

s/Lawrence J. Rosenfeld

Planned Parenthood Arizona, Inc., et al. v. Mark Brnovich, Arizona Attorney General, in his official capacity, et al.

PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

INDEX OF EXHIBITS

Exhibit 1:

Declaration of Courtney Schreiber, M.D., M.P.H.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, et al., Plaintiffs, v. Mark Brnovich, Arizona Attorney General, in his official capacity, et al., Defendants.	Civil Action No. _____

Declaration of Courtney Schreiber, M.D., M.P.H.

Courtney Schreiber, M.D., M.P.H., declares and states as follows:

1. I am over 18 years of age and competent to make this declaration.

2. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction and/or Temporary Restraining Order preventing enforcement of SB 1318, which would require physicians to "inform" women at least 24 hours prior to having an abortion 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," and that "information on and assistance with reversing the effects of a medication abortion is available on the department of health services' website." S.B. 1318, § 4 (to be codified at Ariz. Rev. Stat. §§ 36-2153(A)(2)(h), (i)) ("Act"). I understand a separate section of SB 1318 directs the Arizona Department of Health Services to 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." *Id.* (to be codified at Ariz. Rev. Stat. § 36-2153(C)(8)), but that this material has not yet been published.

3. As I explain below, it is my opinion that the Act would force physicians to deviate from the best practice of medicine and the current medical evidence by providing information to patients that: (1) is medically unsupported, and is therefore false or misleading; (2) is irrelevant to most abortion patients; and (3) undermines the informed consent process. It is also my opinion that the Act would force physicians to violate their fiduciary duty to patients. I base these opinions on my expertise as an associate professor of obstetrics and gynecology; my expertise in providing a broad range of reproductive health care to women, including abortions; my expertise as a clinical researcher in the field of reproduction; and my familiarity with the body of scientific literature concerning medication abortion.

My Credentials as an Expert

4. I am a board-certified obstetrician/gynecologist and an Associate Professor in the Department of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania. I am also a Fellow of the American College of Obstetricians and Gynecologists ("ACOG"). At Penn Medicine and the Perelman School of Medicine, University of Pennsylvania, I am the Director of the Penn Family Planning and Pregnancy Loss Center and of the Fellowship in Family Planning, and serve as an attending physician at the Hospital of the University of Pennsylvania. In addition to being an obstetrician/gynecologist, I hold a master's degree in public health with a

concentration in epidemiology (the study of the incidence, distribution, and possible control of diseases and other factors relating to health). I also have expertise in the conduct of human-subjects research in reproduction. A copy of my curriculum vitae is annexed hereto as Exhibit A. As indicated on my CV, I have published over forty peer-reviewed research articles on a wide range of reproductive health issues. In addition, I have been the principal investigator or co-investigator on approximately fifty-five research studies relating to early pregnancy, sexually transmitted infections, abortion, and contraception.

5. I serve on the editorial board of *Contraception*, and serve or have served as a reviewer for the *Fertility and Sterility*, *Pharmacoepidemiology*, and the *American Journal of Obstetrics and Gynecology*.

6. At Penn Medicine, I teach medical students as well as residents, including obstetrics/gynecology and family medicine, among other, both didactically and clinically. Among the subjects I teach is abortion, including medication abortion and surgical abortion. In addition, I direct the Fellowship in Family Planning at Penn, which involves teaching advanced family planning and abortion techniques to doctors who have completed their residencies but want to specialize in this area. I am an expert in the provision of abortion services, having provided this procedure to over 5,000 patients as an integral component of my practice. In so doing, I use various approaches to abortion care, including medication abortion, vacuum aspiration, and dilation and evacuation. I provide general gynecology and expert contraceptive management as well as expert care

in early pregnancy loss (or miscarriage), and have been practicing in this way as an attending physician for ten years at the Perelman School of Medicine.

Abortion and the Science of Medication Abortion

7. Approximately one in three women in the United States will have an abortion by age 45, and most who do so either already have children or are planning to raise a family when they are older, financially stable, and/or in a supportive relationship with a partner.[1]

8. As indicated above, there are both surgical and non-surgical abortion methods available. The Act requires statements concerning non-surgical, or "medication" abortion (though it requires that they be made to all abortion patients regardless of whether or not they are having a medication abortion). In order to understand why the Act is inconsistent with good medical practice and evidence-based care, it is important to understand the nature of medication abortion and how it is provided.

9. Medication abortion is a safe method of ending a pregnancy by taking medications that cause the woman to undergo a pregnancy termination within a predictable period of time.

10. I understand that, for early medication abortions, Plaintiffs use an evidenced-based regimen that involves the most common combination of medications to induce abortion, mifepristone and misoprostol. This combined regimen of mifepristone

[1] Rachel K. Jones et al., *Characteristics of U.S. Abortion Patients 2008* (Guttmacher 2010).

followed by misoprostol is endorsed by ACOG.[2] It has been demonstrated by clinical trials to be safe and extremely effective through sixty-three days of pregnancy, and data additionally support use to seventy days from the first day of the woman's last menstrual period (LMP).[3] To date, more than two million women have used this method in the United States.[4]

11. This is the same combination of medications I use to provide early medication abortion in my own practice and in my teaching.

12. When used in a medication abortion, mifepristone (also known as RU-486 or by its trade name in the U.S., Mifeprex®) works by binding to certain cell receptors in the uterus and elsewhere, temporarily blocking the activity of the hormone progesterone and causing the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall.[5] Mifepristone binds preferentially to progesterone receptors in the

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[2] ACOG, Practice Bulletin Number 143: Medical Management of First-Trimester Abortion 123 Obstet. Gynecol. 676 (Mar. 2014).

[3] A very recent large-scale study on medication abortions through 63 days LMP documented an ongoing intrauterine pregnancy rate of just 0.5% out of 233,805 women. Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 Obstetrics & Gynecology 166, 168 (2013). Although fewer data exist on medication abortions at 64-70 days LMP, available data from a smaller study show an ongoing pregnancy rate of 3.0% during that window out of 304 women. Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120(5) Obstetrics & Gynecology 1070, 1073 (2012).

[4] *More Facts About Mifeprex*, Danco Laboratories (last visited May 29, 2015), http://earlyoptionpill.com/is-mifeprex-right-for-me/more-facts-about-mifeprex/.

[5] N.N. Sarkar, *Mifepristone: Bioavailability, Pharmokinetics, and Use-Effectiveness*, 101 Eur. J. of Obstetrics & Gynecology & Reprod. Biology 113, 115-16 (2002); Regine Sitruk-Ware & Irving Spitz, *Pharmacological Properties of Mifepristone: Toxicology and Safety in Animal and Human Studies*, 68 Contraception 409, 410, 411 (2003); Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU486 (Mifepristone)*, 315(25) N. Eng. J. Med. 1565, 1568 (1986).

presence of progesterone because it has a far higher affinity for the receptors, meaning that mifepristone binds more tightly to the receptors than progesterone does.[6] Mifepristone also triggers the release of endogenous prostaglandins (which can cause uterine contractions),[7] softens and opens the cervix,[8] and increases uterine contractility (capacity to contract).[9] Mifepristone is quickly absorbed, reaching peak concentrations in the blood about one to two hours after it is ingested.[10] Its initial elimination is slow for the first 72 hours, then increasingly rapid.[11]

13. In some percentage of pregnancies, particularly at the earliest stages, mifepristone alone will terminate the pregnancy. However, early research showed that mifepristone could not effectively be used on its own as an abortion-inducing medication (or "abortifacient") because it failed to work sufficiently well on its own.[12] Subsequent research showed that the combination of mifepristone and a prostaglandin (misoprostol) work synergistically to terminate an early pregnancy with high efficacy.[13] Misoprostol,

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[6] Sitruk-Ware & Spitz, *supra* n.5, at 410; Oskari Heikinheimo et al., *The Pharmokinetics of Mifepristone in Humans Reveal Insights Into Differential Mechanisms of Antiprogestin Action*, 68 Contraception 421, 425 Table 1 (2003); Christian Fiala & Kristina Gemzel-Danielsson, *Review of Medical Abortion using Mifepristone in Combination with a Prostaglandin Analogue*, 74 Contraception 66, 68 (2006).
[7] Couzinet et al., *supra* n.5, at 1568; Remi Peyron et al., *Early Termination of Pregnancy with Mifepristone (RU486) and the Orallly Active Prostaglandin Misoprostol*, 328 N. Eng. J. Med. 1509, 1509 (1993).
[8] Couzinet et al., *supra* n.5, at 1568; Fiala & Gemzel-Danielsson, *supra* n.6, at 76.
[9] Couzinet et al., *supra* n.5, at 1568; Peyron et al., *supra* n.7, at 1509; Fiala & Gemzel-Danielsson, *supra* n.6, at 68; Sitruk-Ware & Spitz, *supra* n.5, at 411-12.
[10] Heikinheimo et al., *supra* n.6, at 422; Sarkar, *supra* n.5, at 114; Fiala & Gemzel-Danielsson, *supra* n.6, at 68.
[11] Sarkar, *supra* n.5, at 115.
[12] *See, e.g.*, *infra* n.17.
[13] Fiala & Gemzel-Danielsson, *supra* n.6, at 66-67.

taken usually within 24 hours but up to 72 hours after the mifepristone, induces uterine contractions, and mifepristone is understood to increase the efficacy of misoprostol by weakening the endometrial lining and increasing the strength and efficacy of these contractions,[14] thereby increasing the likelihood that together they will result in pregnancy termination and expulsion. For this reason, "medication abortion" is commonly used to refer not to either mifepristone or misoprostol on their own but rather to the combination of the two drugs. This is also how the Food and Drug Administration approved the use of mifepristone for medication abortion.

14. As stated above, early research showed that when mifepristone was used alone to effect abortion, a not insignificant number of pregnancies continued, making the drug inadequate for pregnancy termination on its own. It is difficult to estimate with accuracy the percentage of medication abortion patients within the full gestational range (through 70 days LMP) who would have ongoing pregnancies after taking mifepristone alone. There are several reasons for this: 1) there are very few studies showing the proportion of pregnancies in which mifepristone alone caused embryonic or fetal demise; 2) almost all of these focused on pregnancies earlier than 49 days LMP;[15] 3) nearly all of these studies involved higher doses of mifepristone than those currently used by most clinicians;[16] 4) more recent studies describe the efficacy of mifepristone only when

[14] Fiala & Gemzel-Danielsson, *supra* n.6, at 66; Couzinet et al., *supra* n.5, at 1568.
[15] *See, e.g.*, L. Kovacks et al., *Termination of Very Early Pregnancy by RU 486 – An Antiprogestational Compound*, 29(5) Contraception 399 (1984) (including only women with pregnancies of 42 days LMP or fewer).
[16] *See, e.g.*, I.T. Cameron et al., *Therapeutic Abortion in Early Pregnancy with Antiprogestogen RU486 Alone or in Combination with Prostaglandin Analogue*

combined with misoprostol and authors do not study or compute success after mifepristone alone; and 5) large, population-based datasets are not available to analyze since few women elect to discontinue this medication abortion regimen after ingesting the mifepristone. But there is some evidence to suggest that, even in early pregnancy, up to 46 percent of women would have continuing pregnancies after taking mifepristone alone.[17] And data from trials of the mifepristone/misoprostol suggest that this proportion increases as gestational age increases.[18]

15. In addition to early medication abortions, physicians administer other medications to induce fetal demise or facilitate abortion. For example, sometimes misoprostol alone is used later in pregnancy to induce an abortion; this can be called an "induction abortion." Another drug, methotrexate, is a folic acid antagonist that interrupts cell division and is used to stop the growth of pregnancy tissue. Though most commonly used to treat ectopic pregnancy, methotrexate can be used to end an intrauterine pregnancy. Other medications, digoxin and KCL, are sometimes used to cause fetal demise before the uterus is surgically (or medically) evacuated.

The Possibility of Reversing Medication Abortion

16. I understand that the Act requires physicians (or other health care professionals acting on their behalf), at least twenty-four hours before an abortion, to

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(Gemeprost), 34(5) Contraception 459 (1986) (studying total mifepristone dosage of 600mg, which is three times the current standard dosage).

[17] Zheng Shu-rong, *RU 486 (Mifepristone): Clinical Trials in China*, 149 Acta Obstet Gynecol Scand Suppl 19, 21 (1989).

[18] Beverly Winikoff et al., *Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Control Trial*, 112(6) Obstetrics & Gynecology 1303, 1306 (2008).

inform every patient, regardless of how far along she is in the pregnancy and whether or not she is considering or is eligible for medication abortion, that "it may be possible to reverse a medication abortion if the woman changes her mind but that time is of the essence." Until the law in Arizona passed, I had never heard or read of "revers[ing] a medication abortion," and I keep up to date with new research about medication abortion.

17. I am aware of a proposal by two physicians based in California, Drs. George Delgado and Mary Davenport, that physicians administer progesterone to reverse the effects of mifepristone in women who started the early medication abortion regimen but did not take the misoprostol. Drs. Delgado and Davenport published a case series in the *Annals of Pharmacotherapy*, describing seven patients who took mifepristone and were then administered progesterone, using various routes of administration (oral, vaginal and intramuscular). Of these patients, four carried their pregnancy to term, two experienced an abortion, and one was lost to follow-up.[19] At the end of the case series, Drs. Delgado and Davenport propose a protocol of regular intramuscular injections of doses of progesterone (200 mg) administered throughout the first trimester of pregnancy.

18. This case series is attached as Exhibit C.

19. In my medical opinion, this proposed protocol is experimental and unsupported by scientific evidence, and requiring physicians to tell women that there is "assistance" available to reverse the effects of mifepristone, could easily mislead patients into wrongly assuming that there are reliable data to support this practice.

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[19] George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 Annals of Pharmacotherapy e36 (Dec. 2012).

20. I understand that ACOG has issued a statement to this effect, explaining that the proposal is "not supported by the body of scientific evidence" or by ACOG's clinical guidelines, and therefore is "not recommended."[20] That statement is attached here as Exhibit B. I agree with it completely.

21. As an initial matter, it is unclear why the authors chose to publish in the *Annals of Pharmacotherapy*, which is not known as one of the journals that obstetrician/gynecologists or women's health clinicians regularly consult and therefore would be unlikely to reach its target audience. By its title, the journal appears to be geared towards authors and readers who are pharmacologists and pharmaceutical scientists, rather than clinicians, and not toward specialists in women's health or reproduction.

22. I was also surprised to see that the authors included clinical recommendations at the end of their case series.[21] Generally, case reports or series are used to identify new possible adverse effects of a drug or to identify a potential novel finding that the author is proposing for future study. Case reports or series are not considered sufficient evidence to support the safety, efficacy, or utility of a new treatment, nor are they considered the basis for providing, or recommending, a new course of treatment. Larger data sets with more rigorous study methodologies that include

[20] Statement of the American Congress of Obstetricians & Gynecologists, Medication Abortion Reversal, *available at* http://www.acog.org/~/media/departments/state%20legislative%20activities/2015AZFactSheetMedicationAbortionReversalfinal.pdf.
[21] *Id.*

a sample size calculation and a control group are generally required in order to recommend practice change.

23. Not only do appropriately sized data sets not exist on this topic, but the authors of this case series disclose that they based their protocol on a different protocol proposed in the separate context of miscarriage prevention, "the protocol of Hilgers," that itself does not appear to have been endorsed by any major medical organization or derived from any peer reviewed studies.[22]

24. There are particularly serious problems with drawing any inferences from this case series. The number of patients reported is so small that no responsible researcher or physician would generalize from the outcomes reported. There is also a scarcity of relevant facts reported for each woman (such as exact gestational age of the pregnancy) and the seventh patient was reported as lost to follow-up and the outcome of her pregnancy is not included.

25. Moreover, as explained above, some women *would* have ongoing pregnancies after taking mifepristone alone, and this percentage would probably be higher the later in pregnancy a patient took the mifepristone. In the case series, the four patients who had a continued pregnancy took mifepristone later in gestation (between seven and ten or eleven weeks),[23] and one of these patients seems to have taken mifepristone beyond the ordinary gestational cut-off for the mifepristone-misoprostol regimen, when mifepristone is known to be less effective (which additionally calls into

[22] *Id.*
[23] *Id.*

question the validity of the data reported overall). Therefore, it is impossible to draw any conclusion about whether the progesterone injections had any effect on the patients' pregnancies.

26. In addition, it appears that all of the patients discussed in the case series as "successes" had confirmed embryonic or fetal cardiac activity before beginning progesterone treatment.[24] This fact—that all of these patients had pregnancies that had already withstood the initial effects of the mifepristone—itself indicates that these pregnancies were predisposed to continue and not demise.

27. The case series also describes a variety of drug regimens provided to the patients, including different routes of administration (intramuscular and oral) of the progesterone, intervals between doses, and durations of doses.[25] The reasons for these variations are not explained, nor is it explained why they used a variety of different formulations and doses, but then recommend one particular regimen at the end of the case series. The "success" they report with a variety of regimens raises the likelihood that these women would have had ongoing pregnancies with placebo, as well.

28. For all these reasons, this single published case series does not provide reliable evidence upon which to base a treatment regimen. At a very practical level, progesterone injections are painful and expensive; it is unethical to recommend a

[24] The authors report that, in one case (of a patient who went on to miscarry), there was no documentation of cardiac activity before treatment, but do not explain why treatment was provided.
[25] *Id.*

treatment that causes pain and potential economic hardship when there is not evident benefit.

29. Moreover, although progesterone is considered a low-risk medication, it does carry risks. Progesterone has been associated with maternal complications such as depression, cholestatic jaundice, and hypertension. And while some data support the general safety of progesterone in pregnancy, there are also some studies that have raised concerns about a possible association with second trimester miscarriage and stillbirth in pregnancies exposed to certain exogenous progesterone preparations.[26] Investigators also have reported associations with hypospadias, a defect in the male infant's genitalia, occurring in the male infants born to women who used progestins (synthetic or pharmacologic progesterones) during pregnancy. [27] While none of these data are conclusive, they are enough to raise concern in the absence of proven benefit.

30. Even absent concerns about high-dose progesterone, which has not been studied at all in this population or for this indication, I am concerned about possible future complications to the pregnancy caused by the mifepristone alone, and a combination of mifepristone and progesterone. While mifepristone is not known to be teratogenic, neither drug has been conclusively shown to be safe for fetal development, and the combined effect of the two has not been studied or even considered at all.

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[26] Paul J. Meiss et al., *Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate*, 348 N. Eng. J. Med. 2379, 2382 (2003).
[27] Suzan L. Carmichael et al., *Maternal Progestin Intake and Risk of Hypospadias*, 159(10) Archives of Pediatric & Adolescent Med. 957 (2005).

31. Indeed, even Drs. Delgado and Davenport in their case series conclude that "*if* further [clinical] trials confirm the success without complications of this or similar protocols, it should become the standard of care" and that currently physicians "may not want" to provide this treatment and only some physicians may be "comfortable" doing so.[28] These statements appear to be an acknowledgement (although insufficient) by the authors that their proposal requires an actual scientific investigation to determine safety and efficacy before it could be considered as a treatment.[29]

32. Further investigation would be especially necessary here because of the pharmacodynamics and pharmacokinetics of the competing medications. I am highly skeptical about the possibility that high doses of progesterone, sometimes beginning several days after the patient ingested the mifepristone and continuing throughout the first trimester of her pregnancy (or beyond), could reverse the effects of mifepristone. As explained above, mifepristone already outcompetes the body's natural progesterone, binds tightly to progesterone receptors within hours of being ingested, and acts quickly and most potently over a time-limited period of about 72 hours. For this reason, I find it unlikely that added progesterone could have any effect once the mifepristone has started

[28] Delgado & Davenport, *supra* n.19 (emphasis added).

[29] I understand that Dr. Delgado and his colleagues now claim to have successfully "reversed" over a hundred medication abortions. AAPLOG APR Statement, Am. Assoc. of ProLife Obstetricians & Gynecologists (Apr. 1, 2015), *available at* http://www.abortionpillreversal.com/uploads/docs/AAPLOG_APR_Statement_4.1.15.docx. For the same reasons explained above, this claim (which has not been published or substantiated in any peer-reviewed publication) cannot be used as evidence of efficacy, because we would expect a significant rate of ongoing pregnancy without *any* intervention (particularly because all of these patients have confirmed embryonic or fetal cardiac activity *before* receiving the progesterone), and an even higher rate for patients who were farther along in their pregnancy when they took the mifepristone.

acting, or that there would be any reason to further elevate a patient's (already high in pregnancy) progesterone levels long after the mifepristone has ceased blocking progesterone receptors. However, further study would be required to definitively answer this question if warranted. To date, sufficient data do not exist to make conclusive statements.

33. In addition to the one published case series, the only other source for information about "mifepristone reversal" about which I am aware is the website that Dr. Delgado seems to maintain, called abortionpillreversal.com. That website states that Abortion Pill Reversal is a program of Culture of Life Family Services headquartered in San Diego, California, of which Dr. Delgado is the Medical Director, and that there is a network of physicians available to assist women who call their hotline. The website represents that there is a treatment that is "effective" in reversing abortion, which is a completely unproven claim.[30] It also states that progesterone injections "counteract[] the effects of the mifepristone and can help you continue to have a healthy, developing pregnancy."[31] This conjecture has not been established, and based on the relative binding affinities and the other information described above, is unlikely to be true. Finally, the website claims that "we have had many successful reversals," and that it "may not be too

[30] Abortion Pill Reversal, http://www.abortionpillreversal.com (last visited May 27, 2015).
[31] *We Can Help Reverse the Abortion Pill*, Abortion Pill Reversal, http://www.abortionpillreversal.com/how-we-can-help.php (last visited May 27, 2015).

late" to reverse an abortion even after 72 hours,[32] which is highly misleading. It also goes against ACOG's recommendations.

34. I also have serious concerns about what Dr. Delgado and his colleagues are doing from the perspective of scientific investigation. In my opinion, their activities amount to research on human subjects as it is commonly understood and as it is defined by the United States Department of Health and Human Services: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 28 C.F.R. § 46.102(d). I base this assessment on their own claims in their one published paper, as well as on media reports and statements, which indicate that these physicians are providing the experimental protocol to hundreds of women (with no indication of proper informed consent ethical review, or data collection/publication), analyzing the results, and discussing these results publicly (and misleadingly) as supporting the efficacy and safety of that experimental protocol.[33]

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[32] *Abortion Pill Reversal Questions*, Abortion Pill Reversal, http://www.abortionpillreversal.com/abortion-pill-questions.php (last visited May 27, 2015).

[33] AAPLOG APR Statement, Am. Assoc. of ProLife Obstetricians & Gynecologists (Apr. 1, 2015), *available at* http://www.abortionpillreversal.com/uploads/docs/AAPLOG_APR_Statement_4.1.15.docx; Shannon Firth, *Reversing Abortion Pill: Can It Be Done?*, MedPage Today (Feb. 24, 2015), http://www.medpagetoday.com/OBGYN/GeneralOBGYN/50164 ("Of the 223 women who have received progesterone, 127 cases succeeded, according to a fact sheet Delgado shared."); Paul Sisson, *Doctor Began Abortion Reversal Movement***,** The San Diego Union-Tribune (April 11, 2015), http://www.utsandiego.com/news/2015/apr/11/george-delgado-abortion-reversal/?#article-copy ("Delgado said since [the 2012 publication of the case series], a growing network of doctors worldwide…have administered progesterone to about 250

35. The professional norm and expectation is that research on human subjects should be approved by an Institutional Review Board ("IRB"), which is a committee that performs an ethical review of proposed research. The purpose of IRBs is to protect subjects. Some IRBs also review the design of a study to assess its potential to generate useful knowledge, and to ensure that the assessed potential benefits of the research outweigh the potential harms from a public health perspective. For these reasons, they are viewed as an important quality control mechanism; the government requires this step as a funding prerequisite, and reputable journals will not publish results obtained without IRB approval or exemption. I have conducted over 50 studies involving human subjects, and every one has been through the IRB-approval process. I can attest that this mechanism is not simply administrative, but actually enables the delicate balance between ethical and scientifically progressive research.

36. It appears from media reports that Dr. Delgado has explicitly stated he does not have or need IRB approval.[34] The fact that Drs. Delgado and Davenport do not have IRB approval for their research additionally raises questions about the reliability of any

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women"); Colette Wilson, *Interview: Reversing the Effects of RU-486*, Lifeline Newsletter (Life Legal Defense Foundation, Napa, CA) Vol. XXIV, NO. 1, Winter 2014, *available at*: http://lldf.org/interview-reversing-effects-ru486/ ("Dr. Delgado: We have established an exciting program called APR (Abortion Pill Reversal)…I have published a case series report in a peer-reviewed medical journal, Annals of Pharmacotherapy, and plan a second article when we have 200 deliveries").

[34] Sisson, *supra* n.33; Firth, *supra* n.33.

data they have collected regarding the efficacy and safety of "abortion reversal" and whether this research is being conducted ethically.[35]

37. Dr. Delgado's and his colleagues' approach also is contrary to ACOG Guidelines on Innovative Practice, which strongly warns against generalizing treatment practices before they have been subjected to rigorous study.[36] As these guidelines explain, there is a risk that, without this control, practices may become widely accepted even though they are ineffective. This proved to be the case, for example, with "[b]ed rest or home uterine activity monitoring for the prevention of prematurity," "[b]one marrow transplant for breast cancer," and "[d]iethylstilbestrol or paternal antigen sensitization for the prevention of recurrent miscarriage."[37] There is also a risk that unstudied treatments may carry "small but potentially important risks" that are not immediately apparent from an initial small sampling of experimental patients; past examples of such treatments include "[l]imb reductions associated with early chorionic villus sampling" and "[s]ex chromosome abnormalities associated with intracytoplasmic sperm injection used in assisted reproductive technology."[38]

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[35] In my opinion, the authors should have obtained IRB approval not just for the unregulated "research" they are currently conducting but also for the case series itself, because of concerns about protecting the anonymity of patients who may or may not have consented to having their outcomes reported. At the very least they should have addressed the issue. Annals of Pharmacotherapy Author Guidelines, *available at* http://www.sagepub.com/upm-data/68162_AOP_Author_Guidelines.pdf (stating that the journal requires "[i]ndicat[ion] if Institutional Review Board or other ethical considerations were needed and/or approved).

[36] ACOG Committee on Ethics, *Committee Opinion No. 352: Innovative Practice: Ethical Guidelines*, 108 Obstetrics & Gynecology 1589 (2006).

[37] *Id*. at 1591.

[38] *Id*. at 1592.

38. For all the reasons above, in my opinion, the unapproved research that Dr. Delgado and his colleagues are conducting is highly unethical and unprofessional. Likewise, it would be unprofessional for a physician to recommend to a patient that she undergo their experimental protocol (outside of an IRB approved research protocol). As a physician, I would never recommend this treatment to a patient nor would I refer a patient for such care given the current state of the evidence. I also would not suggest to a patient that she visit abortionpillreversal.com to learn more about this treatment. If a patient came to me seeking to interrupt the medication abortion regimen after she had ingested the mifepristone, I would initiate comprehensive pregnancy options counseling and probe as to what had motivated the patient's change of heart; if I confirmed that she carried an ongoing pregnancy and wished to continue to term, I would then refer her for prenatal care.

Effect of the Act on the Informed Consent Process

39. Even apart from the fact that the administration of progesterone to reverse the effects of mifepristone is not supported by medical evidence and that there are concerns that Dr. Delgado's research is not being conducted ethically, it is my opinion that requiring physicians to inform patients about the possibility of medication abortion reversal is in and of itself harmful to patients in a variety of ways.

40. To begin with, for the majority of women having abortions, this information (even if it were accurate, which it is not) will be wholly irrelevant. Many women are ineligible for an early medication abortion because they are past the gestational cut-off or because they have other contraindications to this method. Other

women may be eligible, but are certain that they would prefer a surgical alternative. In 2013, the most recent year for which statistics on abortions have been published by the state, 72 percent of abortions in Arizona were surgical abortions: medication abortion is much less common than surgical abortion, so this information would only even theoretically apply to a small proportion of abortion patients.[39]

41. Requiring that surgical abortion patients receive irrelevant information about medication abortion would be confusing for patients. It also contravenes the purpose of the informed consent process, namely, to give each patient medical information in a way that is easy to absorb and understand—i.e., that is clear, concise, and applicable to her circumstances and individual concerns.

42. The mandated information would also be irrelevant, and even more confusing, for women who are not using mifepristone as a part of the early medication abortion regimen with misoprostol, but instead are receiving abortifacients, such as misoprostol or digoxin, as part of an induction or surgical abortion. No one even claims to have an effective reversal treatment in these circumstances, but that may not be clear to the patient given this confusing and irrelevant legislation.

43. Even for patients having an early medication abortion, the Act's requirement is also highly likely to be misleading. Under the Act, patients must hear from their physician, or another health care professional acting on her behalf, that reversal "may be possible" and that the state offers assistance with obtaining this treatment. In this

[39] Arizona Department of Health Services, *Arizona Health Status and Vital Statistics: Ebook 2013*, 90-91 (Nov. 2014), *available at* http://pub.azdhs.gov/e-books/ahsvs/ahsvs-2013/index.html#90.

situation, patients are likely to conclude that this treatment is established as safe and effective and free, which as explained above, is far from true.

44. In my opinion, these problems cannot be solved by physicians providing further explanation. If a physicians tried to explain that what she had just been required to tell the patient was untrue, misleading, and/or not relevant at all to the patient, that would increase patient confusion and make it harder for the physician to ensure that the patient understood all the relevant facts she needed to make an informed decision about whether or not to proceed with an abortion in the first place. It could also lead a patient not to trust any of the information the physician gave her.

45. Finally, I am concerned that the Act's state-mandated advisory might distort the patient's decision-making and create a risk that she would begin the abortion procedure before she was fully prepared to do so. During the informed consent discussion with my abortion patients, I stress that they should not begin the procedure until they are resolved to terminate their pregnancy.

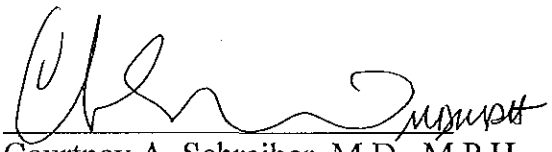
46. If a patient shows signs of ambivalence, I advise her to reflect further, and offer her professional resources if necessary. I do this for early medication abortion patients as well as surgical abortion patients because no patient should undergo a procedure or take a medication she is unsure is indicated or appropriate. In addition, with early medication abortion, patients need to be emotionally prepared for the real possibility that the mifepristone *will* terminate their pregnancy (as it does in a significant percentage of pregnancies). Taking mifepristone is the start of the abortion process.

47. I believe, therefore, that introducing the misleading prospect that post-mifepristone reversal is possible when the patient is in the process of making her abortion decision undermines the physician's efforts to ensure that the patient does not begin pregnancy termination treatment unless she is certain about her decision to end the pregnancy. This is contrary to the most fundamental tenants of medicine.

48. For all of these reasons, I think that the disclosure required by the Act about abortion "reversal" is false, misleading and/or irrelevant to women seeking abortions. It violates the tenants of ethical and evidence-based medical care. Rather than promoting the health of women and families and deferring to women's ability to make sound decisions in consultation with their physician, it harms women, undercuts the physician's professional integrity, and damages the physician-patient relationship.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 3, 2015.



Courtney A. Schreiber, M.D., M.P.H.

Exhibit A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 04/16/2015

Courtney Anne Schreiber, MD, MPH

Address: Department of Obstetrics and Gynecology
3400 Spruce Street, 1000 Courtyard
Philadelphia, PA 19104 United States

If you are not a U.S. citizen or holder of a permanent visa, please indicate the type of visa you have:
none (U.S. citizen)

Education:

1993	B.A.	Columbia College, Columbia University, New York NY (Religion)
1994		University of Pennsylvania, Philadelphia, PA (Postbaccalaurate Premedical Program)
1999	M.D.	New York University School of Medicine, New York, NY
2005	M.P.H.	University of Pittsburgh, Graduate School of Public Health, Epidemiology Track, Pittsburgh, PA (Public Health)

Postgraduate Training and Fellowship Appointments:

1999-2003	Resident, Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Philadelphia, PA
2003-2005	Fellow, Contraceptive Research and Family Planning, University of Pittsburgh, Dept of Obstetrics, Gynecology and Reproductive Sciences, Pittsburgh, PA

Faculty Appointments:

2005-2006	Instructor in Obstetrics and Gynecology, University of Pennsylvania School of Medicine, Philadelphia, PA, University of Pennsylvania
2006-2014	Assistant Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2014-present	Associate Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

2005-Present	Attending in Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Department of Obstetrics and Gynecology, Philadelphia, PA
2008-present	Founder and Director, Penn Family Planning and Pregnancy Loss Center

2009-present	Director, Fellowship in Family Planning, Hospital of the University of Pennsylvania

Other Appointments:

2002-2003	House Officer Committee, Hospital of the University of Pennsylvania
2011-2013	American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women
2012-present	Consultant, Center for Disease Control Teen Pregnacy Prevention Project, Family Planning Council of Pennsylvania
2014-present	Study Section, NICHD: Contraceptive Development

Specialty Certification:

2007	American Board of Obstetrics and Gynecology

Licensure:

2003-Present	Pennsylvania Medical Licensure

Awards, Honors and Membership in Honorary Societies:

1996	Reproductive Health Fellowship, Medical Students for Choice, San Francisco, CA
1998	National Abortion Federation Early Achievement Award
1999	Dr. Martin Gold Visionary Provider Award, Diana Foundation, NY, NY
1999	James E Constantine Award in Obstetrics and Gynecology, NYU School of Medicine
2001	Resident Teaching Award, Hospital of the University of Pennsylvania
2004	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Philip F. Williams Prize Award, American College of OB/GYN
2005	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Donald F. Richardson Memorial Prize Paper Award Nominee, American College of Obstetricians and Gynecologists
2010	Women's Way Unsung Heroine Award: Turning Talk into Action
2011	The Penn Medicine "Penn Pearls" Award for Excellence in Teaching
2011	Emily B. Hartshorne Mudd Award for Contributions to the Field of Family Health

Memberships in Professional and Scientific Societies and Other Professional Activities:

National:

1995-1999	Medical Students for Choice (Board of Directors)

1997-2002	American Medical Women's Association
1997-present	Physicians for Reproductive Choice and Health (Board of Directors 1997-1999)
1999-Present	American College of Obstetricians and Gynecologists (Physician Member, Committee on Health Care for Underserved Women (2012-2013) Fellow (2002-present) Junior Fellow (1999-2008))
2001-2006	American Society for Reproductive Medicine
2003-present	Association of Reproductive Health Professionals
2003-present	National Abortion Federation
2004-present	American Public Health Association
2008-present	Peer Health Exchange (Curriculum Advisory Board)

Local:

2008-Present	Family Planning Council (Board Member of the Medical Committee)
2008-present	Women's Medical Fund Medical Advisory Committee
2010-Present	American Civil Liberties Union of Pennsylvania, Clara Bell Duvall Reproductive Freedom Project (Advisory Council Member)
2011-present	Women's Way (Board Member)
2014-2016	Women's Way (Vice Chair, Board of Directors)

Editorial Positions:

2005-Present	Reviewer, Contraception
2007-Present	Reviewer, American Journal Obstetrics and Gynecology
2008-2010	Reviewer, Pharmacoepidemiology
2010-present	Editor, "Controversies in Family Planning" quarterly series. Contraception
2011-Present	Associate Editor, Contraception
2014	NIH Study Section Reviewer: Female Contraceptive Development Program (U01)
2014	NIH Study Section Reviewer: Female Contraception Review

Academic and Institutional Committees:

2002-2003	House Officer Committee, Hospital of the University of Pennsylvania
2005-Present	Resident Curriculum Development Committee
2009-Present	Operating Room Committee
2010-2012	Grant Reviewer Penn CFAR Pilot Grants Program
2011-Present	Chair, Management of Early Pregnancy Failure Working Group
2012-Present	Center for AIDS Research Committee on Women and HIV
2013-Present	Core Member, Women's Health Scholar Certificate
2014-present	Member, Department of Obstetrics and Gynecology Executive Committee
2014-present	Medical School Admissions Interview Committee, Perelman School of Medicine of the University of Pennsylvania.

Major Academic and Clinical Teaching Responsibilities:

2002-2003	Organizer, Ob/Gyn resident journal club, Hospital of the University of Pennsylvania
2005-Present	Lecture on Family Planning, Core Clinical Clerkship in Ob/Gyn (OG200), (8x/yr)
2005-Present	Faculty preceptor, Core Clinical Clerkship in Ob/Gyn (OG200), (1-2x/yr)
2006-Present	Lecturer "Contraception", Reproduction module (1 lecture/yr)
2006-Present	"Bridging the Gaps" Academic Mentor for one student each summer
2006-Present	Director, Family Planning Rotation for Ob/Gyn residents
2006-Present	Course Director, Family Planning and Abortion Care Elective (OG300)
2006-Present	Small group discussion leader on abortion and contraception, Reproduction module (2 sessions/yr)
2006-Present	Attending physician, Family Planning and Pregnancy Loss Center, supervise and teach medical students. residents, and fellows
2006-Present	Attending physician, Resident Gynecology service (4 weeks/yr)
2006-Present	Research mentor for resident research projects
2006-Present	Lecture "Abortion," Reproduction Module (1 lecture/yr)
2006-2007	Mentor, Sabrina Sukhan, MD, Resident in Obstetrics and Gynecology "Is exposure to prenatal care associated with improved pregnancy outcomes and post partum contraception continuation in a teenage population?"
2008-2010	Mentor, Monika Goyal, MD, Pediatric Emergency Fellow "Prevalence of Trichomonas vaginalis in a symptomatic adolescent ED population
2009-Present	Director, Family Planning Fellowship Program
2010-2012	Fellowship Mentor: Sara Pentlicky, MD
2010-2013	Mentor, Holly Langmuir, MD, Resident in Obstetrics and Gynecology "Immediate postpartum IUD placement: a decision analysis"

2010-2013	Mentor, Peter Vasquez, MD, Resident in Obstetrics and Gynecology "Factors that decrease morbidity among women undergoing second trimester uterine evacuation at an urban academic medical center"
2010-2013	Mentor, Ericka Gibson, MD, Resident in Obstetrics and Gynecology "Risk Factors for pregnancy during contraceptive clinical trials"
2010-2012	Mentor, Sara Pentlicky, MD, Fellow in Family Planning "Weight Loss in the postpartum: impact of different contraceptive methods"
2010-2013	Mentor, Corina Tennant, MD, Resident in Obstetrics and Gynecology "Uptake, acceptability, and continuation of the Implanon contraceptive implant immediately postpartum in an urban medical center"
2011-2013	Mentor, Lily Pemberton, MD, Resident in Obstetrics and Gynecology "establishment of an academic family planning outpatient facility increases uptake of LARC among inner-city women"
2011-present	Public Health Perspectives in Family Planning Instructor and course co-director (offered through the MPH program)
2011-2012	Doris Duke Clinical Research Fellowship Mentor (Mentee - Kelly Quinley - Awarded Society of Academic Emergency Medicine Medical Student Excellence Award)
2011-2013	Fellowship Mentor: Stephanie Sober, MD
2011	Mentor, Valerie Colleselli, medical student, University of Innsbruck, Austria "Medical management of early pregnancy failure (EPF): a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice"
2012-2014	Fellowship Mentor, Susan Wilson, M.D.
2012-2015	Mentor, Andrea Roe, MD, Resident in Obstetrics and Gynecology "Cystic Fibrosis and Fertility"
2012-2015	Mentor, Joni Price, MD, Resident in Obstetrics and Gynecology "Risk of unplanned pregnancy by cycle day among contracepting women"
2012-Present	Clinician Trainings for the Family Planning Council's CDC Teen Pregnancy Prevention Project
2014-2015	Mentor, Pooja Mehta, MD, ACOG Industry-Funded Research Fellowship in Contraceptive Access within Low-Resource Populations

Lectures by Invitation:

Mar, 2004	Instructor, Early pregnancy ultrasound course, Planned Parenthood, Philadelphia, PA: "Introduction to Ultrasound"
Jun, 2004	Invited discussant for the trial development to evaluate the use of ultrasound in medical abortion care. Gynuity, New York, NY: "Medical Abortion Protocol Development"
Jul, 2004	Speaker, Pennsylvania Pharmacist Association, Harrisburg, PA: "Emergency Contraception"

Sep, 2004	Grand Rounds Presenter, University of Buffalo Department of Gynecology-Obstetrics, Buffalo, NY: "Medical Abortion" and "Emergency Contraception"
Feb, 2005	HIV Prevention Trials Network Annual Meeting Plenary Session, Washington DC: "The significance of subclinical pregnancy for clinical trails"
Mar, 2005	Medical Students for Choice Annual Meeting Philadelphia, PA: "Practitioners' Perspectives"
Nov, 2005	Medical Students for Choice Regional Meeting Philadelphia, PA: "Practitioners' Perspectives"
Jan, 2006	Hospital of The University of Pennsylvania Department of Obstetrics and Gynecology Grand Rounds: "The Characterization and Treatment of Early Pregnancy Failure"
Mar, 2006	HIV Prevention Trial Network Microbicides Safety Meeting, Washington DC: "Pregnancy concerns in microbicide trials"
May, 2006	Temple University Hospital Department of Obstetrics and Gynecology Grand Rounds Presenter: "Preventing and Managing the Complications of Second Trimester Abortion"
Jun, 2006	Penn State University School of Medicine Grand Rounds Presentation: "Second Trimester Abortion"
Nov, 2007	Division of Cardiology, University of Pennsylvania Medical Center, "Contraception in Women with Congenital Heart Disease",
Oct, 2008	ASRM Postgraduate Course: Contraceptive Use in Reproductive Endocrinology. Lecture Title: "Contraceptive Use in the Treatment of PMS; Emergency Contraception"
Mar, 2009	"Uterine Evacuation: Medical Management of Early Abortion and Early Pregnancy Failure" Drexel University Department of Obstetrics and Gynecology
Mar, 2010	"Challenges in Family Planning." Duke University School of Medicine Department of Obstetrics and Gynecology, Durham, North Carolina
Mar, 2010	"Uterine Evacuation: Medical Management" Duke University School of Medicine Department of Obstetrics and Gynecology. Durham, North Carolina
May, 2010	"Contraception for Medically Complicated Patients." American College of Obstetricians and Gynecologists Annual Meeting, Ryan Program Annual Meeting, San Francisco, CA
Jun, 2011	"Second Trimester Abortion: Management of Complications," Department of Obstetrics and Gynecology, Jefferson College of Medicine, Philadelphia PA
Jun, 2011	"Medical Management of Uterine Evacuation," Department of Obstetrics and Gynecology Brown University, Providence, RI
Apr, 2012	"Birth Control," Department of Obstetrics and Gynecology, Crozer-Chester Medical Center, Upland, PA
Apr, 2012	"Contraception for Women with Complex Heart Disease," 2012 Heart Disease in Pregnancy Symposium Philadelphia, PA

May, 2012	"Controversies in Family Planning," Fellowship in Family Planning Annual Meeting, San Diego, CA
May, 2012	"Legislative Updates in Pennsylvania," Fellowship in Family Planning Annual Meeting, San Diego, CA
May, 2012	"Establishing and Sustaining Second Trimester Procedure Services," Ryan Program Meeting, San Diego, CA (Moderator)
Sep, 2012	Invited discussant: "A Critical Look at Lowest Dose Oral Contraception: Experts Consensus Roundtable," Medtelligence, Chicago, IL
Nov, 2012	"Lessons Learned from Medical Abortion: Larger Implications for Women's Health," Medical Students for Choice Conference on Family Planning, St. Louis, MO
May, 2013	"Controversies in Family Planning," Fellowship in Family Planning Annual Meeting, New Orleans, LA
Jul, 2013	"Office Based Management of Early Pregnancy Failure," two hour training, Department of Obstetrics and Gynecology Residency Program, Mayo Clinic, Rochester, MN
Oct, 2013	"Immediate Post-Partum LARC: Limited Access to Reliable Contraception," Concurrent Session, North American Forum on Family Planning, Seattle, WA
Oct, 2013	"Contraception after Medical Abortion" North American Forum on Family Planning, Concurrent Session, Seattle, WA
Oct, 2013	"Early Pregnancy Failure: a specialty for the Family Planning Specialist" Plenary Session, North American Forum on Family Planning, Seattle, WA
Mar, 2014	"The management of early pregnancy complications," University of Innsbruck, Innsbruck, Austria
Apr, 2014	Controversies in Family Planning, Fellowship in Family Planning Annual Meeting. Chicago, IL.
May, 2014	Miscarriage Management in the Emergency Department, Grove Foundation Advancing Miscarriage Management Symposium. San Francisco, CA.
Oct, 2014	Demystifying hCG: What hCG is and patterns in normal and abnormal pregnancy. North American Forum on Family Planning, Miami FL.
Nov, 2014	The Patient's Voice in the Management of Early Pregnancy Loss. V. Chavez, A. Agha, E. Easley, C.A. Schreiber, Association of Early Pregnancy Units (AEPU), Winchester, UK
Nov, 2014	"Individulaized Care of Early Pregnacy Loss" Washington University Departmetn of Obstetrics and Gynecology, St Louis, Mo.
Jan, 2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Pennsylvainia Hospital, Philadelphia PA
Jan, 2015	"Contraception for women with rheumatologic disease," Division of Rheumatology of Penn Medicine, Philadelphia Pa.

Apr, 2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Jefferson Hospital, Philadelphia PA

Organizing Roles in Scientific Meetings:

Apr, 2010	Chair, National Abortion Federation 2010 Postgraduate course: "Team Work and Patient Safety" Philadelphia, PA
2011	Co-Chair HIV and Women subgroup of the Penn Center For Aids Research Philadelphia, PA
Apr, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Chicago, IL
May, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Denver, CO
May, 2013	Co-Chair, Penn CFAR Women and HIV Symposium: "Biobehavioral approaches to HIV prevention and management in adolescent women" Perelman School of Medicine, Philadelphia PA
May, 2014	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting New Orleans, LA

Bibliography:

Research Publications, peer reviewed (print or other media):

1. Schreiber CA, Wan L, Sun Y, Krey L, Lee-Huang S: The antiviral agents MAP30 and GAP31 are not toxic to human spermatozoa and may be useful in preventing the sexual transmission of HIV-I. Fertil Steril 72:686-690, 1999.

2. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation. Contraception 71(5):333-336, 2005.

3. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: Same day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation methods. Contraception 72(5):333-36, 2005.

4. Schreiber CA , Creinin MD, Harwood BJ, Murthy AS: A pilot study of mifepristone and misoprostol administered at the same time for abortion from 50-63 days gestation. Contraception 71(6):447-50, 2005.

5. Schreiber CA, Creinin MD, Reeves MF, Harwood BJ: Mifepristone and misoprostol for the treatment of early pregnancy failure: a pilot clinical trial. Contraception 74:458-462, 2006.

6. Schreiber CA, Harwood BJ, Switzer GE, Creinin MD, Reeves MF, Ness RB: Training and attitudes about contraceptive management across primary care specialties: a survey of graduating residents. Contraception 73:618-622, 2006.

7. Schreiber CA, Meyn, L, Creinin MD, Barnhart KT, Hillier SL: The effects of long-term use of nonoxynol-9 on vaginal flora. Obstet Gynecol 107:1-9, 2006.

8. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA: Medical abortion at the same time (MAST) study trial group. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. Obstet Gynecol 109(4):885-894, 2007.

9. Schreiber CA, Sammel M, Barnhart KT, Hillier SL: A little bit pregnant: Modeling how the accurate detection of pregnancy can improve HIV prevention trials. Am J Epidemiol 169(4):515-521, 2009.

10. Schreiber CA, Ratcliffe SJ, Barnhart KT: A randomized controlled trial of the effect of advanced supply of emergency contraception in postpartum teens: a feasibility study. Contraception 81(5):435-40, 2010.

11. Schreiber CA, Sober S, Ratcliffe S, Creinin MD: Ovulation resumption after medical abortion with mifepristone and misoprostol. Contraception 84(3):230-3, 2011.

12. Schreiber CA, Whittington S, Cen L, Maslankowski, L: Good Intentions: Risk factors for unintended pregnancies in the U.S. cohort of a microbicide trial Contraception 83(1):74-81, 2011.

13. Su IH, Schreiber CA, Fay C, Parry S, Elovitz MA, Zhang J, Shaunik A, Barnhart K: Mucosal integrity and inflammatory markers in the female lower genital tract as potential screening tools for vaginal microbicides. Contraception 84(5):525-32, 2011. PMCID: PMC3201765

14. Chen SP, Massaro-Giordano G, Pistilli M, Schreiber CA, Bunya V: Tear osmolarity and dry eye symptoms in women using oral contraception and contact lenses. Cornea 32(4):423-8, 2013.

15. Kinariwala M, Quinley K, Datner E, Schreiber CA: Manual vacuum aspiration in the emergency department for management of early pregnancy failure. Am J Emerg Med 31(1):244-7, 2013.

16. Pentlicky S, Rosen M, Coffey P, Kilbourne-Brook M, Shaunik A, Schreiber CA, Barnhart K: An exploratory, randomized, crossover MRI study of microbicide delivery with the SILCS diaphragm compared to a vaginal applicator. Contraception 87(2):187-92, 2013.

17. Swica Y, Chong E, Middleton T, Prine L, Gold M, Schreiber CA, Winikoff B: Acceptability of home use of mifepristone for medical abortion. Contraception 88(1):122-7, 2013.

18. Warden M, Schreiber C, Steinauer J: Diagnostic criteria for nonviable pregnancy. New Engl J Med 370(1): 86, Jan 2 2014.

19. Colleselli V, Schreiber CA, D'Costa E, Mangesius S, Ludwig W, Seeber BE: Medical management of early pregnancy failure (EPF):a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice. Arch Gynecol Obstet 289(6): 1341-45, Jun 2014.

20. Foster DG, Grossman D. Turok DK, Peipert JF, Prine L, Schreiber CA, Jackson A, Barar R, Schwarz EB: Interest in and experience with IUD self-removal. Contraception 90(1): 54-59, Jul 2014.

21. Wilson S, Tennant C, Sammel MD, Screiber C: Immediate postpartum etonogestrel implant: a contraception option with long-term continuation. Contraception 90(3): 259-64, Sept 2014.

22. Quinley K, Ratcliffe S, Schreiber C: Psychological coping in the immediate post-abortion period. J Women's Health (Larchmt) 23(1):44-50, 2014.

23. Sober S, Schreiber CA: Postpartum contraception. Clin Obstet Gynecol 57(4): 763-76, Dec 2014. PMCID: 25264698

24. Schreiber CA, Ratcliffe SJ, Quinley KE, Miller C, Sammel MD: Serum biomarkers to predict successful misoprostol management of early pregnancy failure. Reproductive Biology 2015.

Research Publications, peer-reviewed reviews:

1. Schreiber CA, Creinin MD: Mifepristone in abortion care. Semin Reprod Med 23(1):82-91, 2005.

2. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (Suppl):19-24, 2005.

3. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (RA suppl):10-12, 2006.

4. Barnhart KT, Schreiber CA: Return to fertility following discontinuation of oral contraceptives. Fertil Steril 91(3):659-63, 2009.

5. Schreiber CA, Barnhart KT: Contraceptive Concerns: Return to Fertility. The Female Patient 34(12), 2009.

6. Gibson E, Schreiber CA: Controversies in Family Planning: When uterine leiomyomas complicate uterine evacuation. Contraception 82(6):486-8, 2010.

7. Vasquez P, Schreiber CA: Controversies in Family Planning: The missing IUD. Contraception 82(2):126-8, 2010.

8. Perron-Burdick M, Schreiber C, Gupta P: Ophthalmic migraines and combined hormonal contraceptives. Contraception 84(5):442-4, 2011.

9. Quinn SM, Schreiber C: Controversies in Family Planning: IUD use in HIV-positive women. Contraception 83(2):99-101, 2011.

10. Sober SP, Schreiber CA: Controversies in family planning: are all oral contraceptive formulations created equal? Contraception 83(5):394-6, 2011.

11. Lathrop E, Schreiber C: Controversies in family planning: management of second-trimester pregnancy terminations complicated by placenta accreta. Contraception 85(1):5-8, 2012.

12. Pentlicky S, Harken T, Schreiber CA: Controversies in family planning: first trimester uterine evacuation for the anticoagulated patient. Contraception 85(5):434-36, 2012.

13. Owen C, Sober S, Schreiber CA: Controversies in family planning: desired pregnancy, IUD in situ and no strings visible. Contraception 88(3):330-3, 2013.

14. Patel PR, Schreiber CA: Controversies in family planning: contraceptive counseling in the solid organ transplant recipient. Contraception 138-142, 2013.

15. Wilson S, Tan G, Baylson M, Schreiber CA: Controversies in family planning: how to manage a fractured IUD. Contraception 599-603, 2013.

Abstracts:

1. Schreiber CA, Barnhart, KT.: C-reactive protein: a marker for ectopic pregnancy? Poster presentation, American College of Obstetrics and Gynecology District III Meeting. Napa, CA. September 2002.

2. Schreiber CA, Barnhart, KT.: Serum markers in ectopic pregnancy. Center for Research on Reproduction and Women's Health; Annual Retreat, University of Pennsylvania School of Medicine. May 2003.

3. Murthy AS, Creinin MD, Harwood B, Schreiber C. : Medical abortion with simultaneous administration of mifepristone and vaginal misoprostol through 49 days gestation. Association of Reproductive Health Professionals Annual Meeting, oral presentation. Contraception 70: 254, September 2004.

4. Murthy AS, Creinin MD, Harwood B, Schreiber C. : Same day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation method. Association of Reproductive Health Professionals Annual Meeting, oral presentation. Contraception 70: 252, September 2004.

5. Schreiber CA, Creinin, MD.: Mifepristone and misoprostol at the same time for abortion from 50 to 63 days' gestation. Association of Reproductive Health Professionals, Annual Meeting, oral presentation. September 2004.

6. Reeves M, Schreiber CA, Harwood B, Creinin MD: Acceptability of medical uterine evacuation among women with normal and abnormal first-trimester pregnancies. Association of Reproductive Health Professionals Annual Meeting. September 2005.

7. Schreiber CA, Creinin MD, Harwood BJ, Reeves MF. : Mifepristone and misoprostol for the treatment of early pregnancy failure: a pilot clinical trial. Association of Reproductive Health Professionals Annual Meeting, poster presentation. Contraception 72: 239, September 2005.

8. Schreiber CA, Harwood BJ, Switzer G, Creinin MD, Reeves MF, Ness R.: Training and attitudes about contraceptive management across primary care specialties: a survey of graduating residents. Association of Reproductive Health Professionals Annual Meeting, poster presentation. Contraception 72: 243, September 2005.

9. Schreiber CA, Meyn, L, Creinin MD, Barnhart KT, Hillier SL.: The effects of long-term use of nonoxynol-9 on vaginal flora. American College of OB/GYN Joint District meeting, oral presentation. October 2005.

10. Schreiber CA, Barnhart KT, Sammel M, Hillier SH : The impact of pregnancy on microbicide clinical trials, Cape Town, South Africa. Poster presentation at the Microbicides Conference, Cape Town, South Africa, March, _ March 2006.

11. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn L: A multicenter, randomized equivalence trial of mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion through 63 days' gestation. Oral prsentation at the American Reproductive Health Professionals Annual Meeting. September 2006.

12. Schreiber CA, Barnhart KB, Sammel M, Hillier, SH: A Little Bit Pregnant: the Challenges of Diagnosing Pregnancy in Microbicide Trials. Poster presentation at the American Reproductive Health Professionals Annual Meeting, La Jolla, CA, _ September, 2006 Notes: American Reproductive Health Professionals Annual Meeting

13. Gracia CR, Lin H, Charlesworth S, Schreiber CA, Barnhart KT, Creinin MD: Sexual function in first-time NuvaRing and OrthoEvra users. Poster presented at the ASRM meeting, Washington, DC, _ October, 2007.

14. Sukhan S, Sammel M, Schreiber CA: Is exposure to prenatal care associated with improved pregnancy outcomes and post partum contraception continuation in a teenage population? Poster Presentation Reproductive Health, Washington, DC, _ September, 2008.

15. Schreiber CA, Su I, Fay C, Barnhart KT: The Inflammatory Effects of Two Vaginal Gels on the Reproductive Tract. poster presentation at Reproductive Health, October 2009; Los Angeles, CA. Contraception supplement, August 2009.

16. Fay C, Su HI, Martino L, Shaunik A, Schreiber CA, Barnhart KT: Inflammatory marker profiles differ between the vagina and endometrium Oral Presentation American Society Reproductive Medicine Atlanta, GA October 2009.

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Exhibit B

CASE REPORTS

Progesterone Use to Reverse the Effects of Mifepristone

George Delgado and Mary L Davenport

OBJECTIVE: To present a series of cases demonstrating successful reversal of mifepristone effects in women who chose to reverse the medical abortion process.

CASE REPORTS: Four of 6 women who took mifepristone were able to carry their pregnancies to term after receiving intramuscular progesterone 200 mg.

DISCUSSION: Mifepristone has been available in the US since 2000. By 2008, approximately 25% of abortions prior to 9 weeks were accomplished with mifepristone. Some women who take mifepristone wish to reverse the medical abortion process. Progesterone competes with mifepristone for the progesterone receptor and may reverse the effects of mifepristone. A PubMed literature search from 1996 to May 2012 did not reveal any trials or case studies evaluating the efficacy of progesterone use to reverse the effects of mifepristone.

CONCLUSIONS: Health care professionals should be aware of the possible use of progesterone to reverse mifepristone in women who have begun the medical abortion process by taking mifepristone and then change their minds.

KEY WORDS: medical abortion, mifepristone, progesterone.

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Mifepristone has been available in the US as an oral tablet since 2000. It is indicated by the Food and Drug Administration (FDA) for termination of pregnancy up to 49 days after the first day of the last menstrual period. Mifepristone is followed 2 days later by misoprostol to complete the abortion.[1]

The drug's development was hailed as a breakthrough in abortion technology and as an advance for women in facilitating control of their bodies and privacy. By 2008, medical abortion replaced surgical abortion in one-fourth of approximately 800,000 abortions performed annually prior to 9 weeks.[2]

We present a series of patients who took mifepristone to terminate their pregnancies and then sought assistance to block the mifepristone effects. The 2-day gap between the ingestion of mifepristone and misoprostol in the typical abortion regimen potentially affords an opportunity to intervene and reverse the effects of the mifepristone. Six physicians in the US trained in NaProTECHNOLOGY protocols at the Pope Paul VI Institute have given progesterone as an antidote to mifepristone, treating 7 patients. The rationale of the proposed treatment was that higher bioavailable levels of progesterone could competitively inhibit the mifepristone to prevent the induced abortion.

Pharmacology of Mifepristone and Progesterone

Mifepristone was first tested to take advantage of its anti-glucocorticoid properties. It binds with high affinity to glucocorticoid receptors, about 4 times as avidly as dexamethasone.[3] When its antiprogesterone properties were discovered it was considered useful for fertility control because of its potential to counteract the actions of progesterone, which is critical for sustaining pregnancy.[4] Additionally, it has been studied for the treatment of endometriosis, uterine fibroids, and Cushing syndrome.[5-7] Mifepristone's most significant application has been in induced abortion because, by binding to the progesterone receptor, placental failure ensues and the developing embryo loses its nutrition and oxygen supply.

Mifepristone is an orally active compound with a nearly 70% absorption rate, but its bioavailability is reduced to approximately 40% because of the first-pass effect.[8] It binds to the progesterone receptor twice as well as progesterone, in addition to binding to the serum transport protein α_1-acid glycoprotein.[9] Demethylation and hydroxylation are catalyzed by CYP3A4; 3 metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepris-

Author information provided at end of text.

tone and its metabolites can be measured up to 72 hours after an ingested dose.[10] The half-life of progesterone is longer, approximately 25-55.13 hours.[11-13]

Current Regimens of Medical Abortion

The original FDA-approved regimen of mifepristone and misoprostol paralleled the European protocol that had been used in the 1990s. It consisted of mifepristone 600 mg followed 2 days later by oral misoprostol 400 µg.[14] Later trials evaluated mifepristone 200 mg.[15-18] The FDA and the drug's distributor recommend the 600-mg dose; however, others state that the 200-mg dose has been used in most of 1 million abortions.[19] The success rate of medical abortion decreases with gestational age. In the FDA clinical trials the rate of incomplete abortion was 5% before 49 days and 7-8% at 50-63 days; the rate of an ongoing living embryo ranged from less than 1% before 49 days to 9% at 57-63 days.[14]

Results of Progesterone Therapy

We report on 6 women who were treated with progesterone in an attempt to reverse pregnancy termination after mifepristone ingestion. Four of these women eventually delivered healthy term newborns. A seventh patient was lost to follow-up. Of the 2 abortions, 1 occurred soon after an intramuscular injection of progesterone was administered (patient 6). Data on this patient are incomplete. The other patient (patient 5) received progesterone micronized 200 mg vaginally 7 hours after ingesting mifepristone and receiving progesterone 200 mg intramuscularly 18 hours after mifepristone. However, a live embryo was not documented at the abortion clinic or in the physician's office for this patient.

Case Reports

CASE 1

A 19-year-old woman, gravida (G) 1 para (P) 0, elected to have the mifepristone effects reversed at gestation age 8 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 30-40 hours following mifepristone ingestion. The progesterone regimen was given 2 consecutive days and then 2 doses every other day, and then twice a week until 9 weeks 5 days.

Progesterone 200 mg in oil intramuscularly was restarted at 11 weeks 2 days and given twice weekly; the dose was then decreased to 100 mg twice a week and stopped at 29 weeks 5 days.

A viable male was delivered at 37 weeks. No untoward effects of progesterone noted and no birth defects were noted. Neonatal complications included neonatal physiologic jaundice and circumcision wound infection.

CASE 2

A 25-year-old woman, G8 P7007, elected to have the mifepristone effects reversed at gestation age 11 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 72 hours following mifepristone ingestion.

Further progesterone treatment included an intramuscular injection of 200 mg in oil for 2 weeks, then progesterone micronized orally for 5 months. No untoward effects of progesterone were noted.

A viable infant was delivered, with no neonatal complications or birth defects noted.

CASE 3

A 19-year-old woman, G3 P1011, elected to have the mifepristone effects reversed at gestation age 7 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 36-48 hours following mifepristone ingestion.

Further progesterone treatment included an intramuscular injection of 200 mg in oil 2 more times the first week, then weekly for 5-6 weeks, then 200 mg in oil twice weekly for 2 weeks, then micronized progesterone orally for 5 months. No untoward effects of progesterone were noted.

A viable infant was delivered at 39 weeks 3 days, with no neonatal complications or birth defects noted.

CASE 4

A 20-year-old woman, G1 P0, elected to have the mifepristone effects reversed at gestational age 7 weeks 4 days. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 46 hours following mifepristone ingestion. Further progesterone treatment included an intramuscular injection of 200 mg in oil twice weekly for 19 weeks. No untoward effects of progesterone were noted.

A viable female infant was delivered at 40 weeks 1 day, with no neonatal complications or birth defects noted.

CASE 5

A 21-year-old woman elected to have the mifepristone effects reversed; gestational age was unknown. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil (time following mifepristone ingestion unknown). The abortion was completed soon after the progesterone injection.

CASE 6

A 19-year-old woman, G1 P0, elected to have the mifepristone effects reversed at gestational age 7 weeks. Misoprostol had not been ingested. The initial micronized

progesterone oral capsule dose was 200 mg administered intravaginally 7 hours following mifepristone ingestion. Further progesterone treatment included an intramuscular injection of 200 mg 18 hours after ingestion, which was repeated 2 days later. No untoward effects of progesterone were noted.

The abortion was completed 3 days after mifepristone ingestion.

Discussion

The experience of these patients suggests that medical abortion can be arrested by progesterone injection after mifepristone ingestion prior to misoprostol due to the competitive action of progesterone versus mifepristone. Possible confounding factors are the lack of embryocidal and feticidal efficacy of mifepristone with increasing gestational age and the absence of documentation of viable pregnancy before ingestion of mifepristone in some patients. We welcome further clinical trials utilizing this protocol or others, in order to have an evidence basis for the best protocol. We believe that if further trials confirm the success without complications of this or similar protocols, it should become the standard of care for obstetrician-gynecologists, family physicians, and emergency department physicians to attempt mifepristone reversal on patient request.

SUGGESTED PROTOCOL

A rational protocol for treating women who have ingested mifepristone and then wish to continue the pregnancy can be considered. We drew on our experience of successfully treating pregnant women with threatened spontaneous abortion or low serum progesterone levels with intramuscular progesterone using the protocol of Hilgers.[19,20] Progesterone has been studied extensively and appears to be safe during all trimesters of pregnancy.

Table 1. Progesterone Dosing and Ultrasound Time Table[a]

Day	Progesterone 200 mg Intramuscularly	Ultrasound to Confirm Viability
1	X	X
2	X	
3	X	
5	X	
7	X	X
9	X	
11	X	
13	X	X
16[a]	X	

[a]Continue twice per week until the end of the first trimester. At end of the first trimester, the dose should be tapered according to the protocol of Hilgers.[19,20]

Protocol

1. Progesterone 200 mg intramuscularly as soon as possible after ingestion of mifepristone.
2. Transvaginal or transabdominal ultrasound as soon as possible to confirm embryonic or fetal viability (Table 1). If less than 6.5 weeks after last menstrual period, monitor serial human chorionic gonadotropin (HCG) levels. However, HCG levels may not increase at the same rate as those of healthy controls.
3. Repeat progesterone 200 mg intramuscularly daily for 2 more days, then every other day until day 13 after the ingestion of mifepristone.
4. Treat with progesterone 200 mg intramuscularly twice weekly until the end of the first trimester and according to the protocol of Hilgers.[19,20] However, do not decrease the dose until the end of the first trimester.

A primary care physician or emergency medicine physician may not want to continue the protocol once it is initiated. Such physicians may want to be ready to refer the patient to a physician comfortable with progesterone supplementation during pregnancy.

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Conflict of interest: Authors reported none

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Exhibit C

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS
Arizona Section

Medication Abortion Reversal

Claims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG's clinical guidance on medication abortion. There are no ACOG guidelines that support this course of action.

Facts are important.

- Mifepristone, previously known as RU486, is part of a combination of drugs used for medication abortion.
- Mifepristone is the first drug in the combination and is not known to cause birth defects.
- Misoprostol is the second drug in the combination, and the evidence-based regimen for medication abortion includes mifepristone taken first and then misoprostol taken at a later point to complete the abortion.
- Because medication abortion requires this combination of medications, many women will not abort just from using the first medication. In 30-50% of women who take mifepristone alone, the pregnancy will continue.

Reliable evidence is not available.

- A 2012 case series describes six women who took mifepristone and then had a series of progesterone injections. This paper describes a handful of experiences, these women received varying regimens of injected progesterone, and this was not a controlled study. Therefore it does not provide evidence that progesterone was responsible for the reported outcomes. In addition, there was no oversight of an institutional review board or an ethical review committee for this intervention.
- Taking mifepristone (without misoprostol) will not always cause abortion by itself, so no intervention may lead to the same result as this case series.
- There are no reliable research studies to prove that any treatment reverses the effects of mifepristone.

What the evidence suggests:

- Available research seems to indicate that in the rare situation where a woman takes mifepristone and then changes her mind, doing nothing and waiting to see what happens is just as effective as intervening with a course of progesterone.
- Progesterone, while generally well tolerated, can cause significant cardiovascular, nervous system and endocrine adverse reactions as well as other side effects.

Exhibit 2:

Declaration of Steven Joffe, M.D., M.P.H.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc., et al.,

Plaintiffs,

v.

Mark Brnovich, Arizona Attorney General, in his official capacity, et al.,

Defendants.

Civil Action No. _____

DECLARATION OF STEVEN JOFFE, M.D., M.P.H, IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Steven Joffe, M.D., M.P.H, declares the following pursuant to 29 U.S.C. § 1746:

1. I submit this declaration in support of Plaintiffs' motion for temporary injunctive relief against enforcement of portions of Arizona Senate Bill 1318 of 2015 ("S.B. 1318" or "the Act").

2. As I explain further below, in my opinion, the Act seriously undermines and distorts the informed consent process for patients considering an abortion, and forces physicians providing abortions to violate fundamental principles of medical ethics. It is also my opinion that rather than facilitating informed decision-making, the Act requires physicians to mislead patients and creates a serious risk of harmful errors in patients' decision-making.

Professional Credentials and Experience

3. I am Associate Professor of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, where I teach various topics

related to medical ethics and conduct research on the subject. I conduct research on ethical issues that arise in medical practice and in clinical research on human subjects, one of which is informed consent.

4. I am also the Vice Chair of Medical Ethics at the Department of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine. In that capacity I lead the activities of the Division of Medical Ethics, with supervisory responsibility for the Division's research and teaching. I also serve as Director of the Penn Fellowship in Advanced Biomedical Ethics.

5. In addition to my work in bioethics, I am a board-certified pediatric hematologist/oncologist, and Associate Professor of Pediatrics at the Perelman School of Medicine. I practice at the Children's Hospital of Philadelphia, where I take care of children undergoing bone marrow transplants for cancer and other serious diseases.

6. I have authored and co-authored numerous peer-reviewed research articles and chapters in medical textbooks, including on issues of medical ethics and informed consent. In addition, I regularly speak on informed consent and other ethical issues that arise in clinical research and practice to a variety of different audiences, including physicians, at national conferences as well as at seminars at medical centers and universities.

7. In my previous role as a member for more than ten years of the Institutional Review Board at Dana-Farber Cancer Institute ("Dana-Farber"), an affiliate of Harvard Medical School, I have formally reviewed, approved, and monitored biomedical and behavioral research involving human subjects in order to protect the rights and welfare of

the research subjects.

8. I have also led and been a member of numerous institutional and national ethics committees. I am currently a member of the Pediatric Ethics Subcommittee of the Food and Drug Administration, Chair of the Bioethics Committee of the Children's Oncology Group, and a member of the Ethics Committee of Children's Hospital of Philadelphia. I was previously a member of the Ethics Advisory Committee at Dana-Farber (which I co-chaired from 2001-09), the Ethics Advisory Committee of Children's Hospital Boston, and the Ethics Committee of the American Society of Clinical Oncology. As part of my role on these committees, I regularly advised and assisted on difficult cases that involved ethical questions and assisted in creating ethics policies for institutions.

9. Prior to joining the University of Pennsylvania, I practiced pediatric hematology/oncology at Boston Children's Hospital and the Dana-Farber Cancer Institute, both affiliated with Harvard Medical School. I also completed four fellowships, including a medical ethics fellowship at Harvard Medical School and a professional ethics faculty fellowship at the Center for Ethics and Professions at Harvard University.

10. In addition to my medical degree, I have a Master's of Public Health degree in epidemiology, which is the study of health-event patterns in a society. Epidemiology focuses on the distribution and causes of disease in human populations, and helps identify risk factors for disease and determine optimal treatment approaches to clinical practice and for preventive medicine.

11. A copy of my curriculum vitae is attached hereto as Exhibit A.

The Act

12. I have reviewed S.B. 1318 and understand that the Act imposes certain requirements on physicians performing abortions in Arizona and women considering having an abortion in Arizona.

13. In particular, I understand that the Act requires that a physician (or a designated health professional acting on behalf of the physician) meet with each patient considering an abortion, at least 24 hours beforehand, to explain in person 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," and that "information on and assistance with reversing the effects of a medication abortion is available on the Department of Health Services' website." S.B. 1318, § 4. I understand that physicians must comply with the Act or face suspension and/or revocation of their medical license.

14. I understand that the Act also directs the Arizona Department of Health Services ("ADHS") to 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. I have been told that ADHS has not posted any information about "reversal" on its website to date.

15. I will begin this Declaration by describing the purpose of informed consent in the medical context. I will then explain why I believe the Act undermines the goal of the informed consent process. Finally, I will discuss other serious ethical concerns that

arise from the Act.

General Principles of Medical Ethics and Informed Consent

16. Medical ethics is a system of moral principles encompassing standards of professional conduct within the practice of medicine and medical research, developed primarily for the benefit of patients and research participants. The central tenets of medical ethics are: (1) respect for patients' autonomy as individuals, including the obligation to act on patients only with their informed consent; (2) acting in patients' best interests, as they define those interests ("beneficence"); (3) avoiding harm to patients ("non-maleficence"); and (4) promoting justice to patients and to society.[1] Ethical physician behavior recognizes that patients' rights and interests are paramount.

17. According to the standard conception of medical ethics, informed consent is fundamental to ethical practice because it is the mechanism by which patients autonomously authorize medical interventions or courses of treatment. Patients have the right to control their own bodies and lives, which means that ultimately the decision about what medical treatment they get is theirs to make.

18. Generally speaking, the goal of the informed consent process is to allow patients to make decisions, consistent with their wishes, values and priorities, about their medical treatment that are based on an understanding of the goals and nature of that treatment, the risks and benefits of the treatment, and the alternatives. Said differently, the goal of the process is to ensure that patients do not undergo any treatment until they

[1] Tom L. Beauchamp & James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS (6th ed. 2009).

have made a fully informed decision that that treatment is right for them, and that its benefits to them outweigh its risks.

19. To make informed consent possible, a patient must be given accurate and necessary information about a particular procedure so that the patient can make the right decision for himself or herself.

20. Under standard medical practice, physicians are expected to exercise appropriate medical judgment regarding what and how much information should be disclosed during the informed consent process. The physician's role and responsibility is to ensure that the information about the course of treatment is given and framed in a way that facilitates rather than impedes informed decision-making. In order to do this, one of the most fundamental obligations the physician has in the informed consent process is to provide patients with truthful information.

21. It would be antithetical to the purpose of informed consent, and a violation of medical ethics, for a physician to give misleading and inaccurate information to a patient during the informed consent process. If a physician were to give a patient misleading or inaccurate information, the physician would be manipulating the patient's decision, thus depriving him or her of the ability to make an authentic decision that is based on his or her own values. Put more simply, providing inaccurate information increases the likelihood that a patient will make a decision that is not the right one for him or her.

22. Thus, given the physician's paramount duty to provide only truthful information to his or her patient, a physician must be able to make reasonable,

professional judgments about validity and materiality in deciding what information to relay in the informed consent process. Patients generally rely on their physicians to identify the relevant information to support informed decision-making. Of particular importance here is that when a physician presents information to a patient about the treatment options that are available and the expected outcomes, the patient expects that information to be grounded in evidence and in the physician's honest beliefs.

Application of These Principles to the Act

23. It is my opinion that the Act forces physicians to violate these elemental principles of informed consent and fundamentally threatens the informed consent process by overriding the physician's medical judgment and compelling physicians to tell patients information that is not supported by credible, scientific evidence, and which I understand is irrelevant to many patients. The Act further distorts the informed consent process, and creates a grave risk of harmful errors in patients' decision-making, by forcing physicians to convey to their patients a message that suggests they do not need to be final in their decision prior to beginning an abortion.

24. It is my understanding that the Plaintiffs in this case offer women different types of abortion, including surgical abortion and medication abortion. I also understand that there are different types of medication abortion, the most common being an early medication abortion regimen that requires the woman to take two drugs, first mifepristone and then misoprostol. It is also my understanding that only women in the first 9-10 weeks of pregnancy are eligible for an early medication abortion using these medications.

25. In my opinion, the Act is detrimental to the informed consent process for patients who seek an early medication abortion because it forces physicians to make statements about "abortion reversal" that do not appear to have an adequate evidentiary basis.

26. I have reviewed a statement from the American College of Obstetricians and Gynecologists ("ACOG") and the Arizona chapter of ACOG, which states that "[c]laims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG's clinical guidance on medication abortion. There are no ACOG guidelines that support this course of action."[2] The ACOG statement also states that a significant percentage of pregnancies do not terminate solely with the first medication in the regimen that I understand Plaintiffs provide to their patients.

27. The ACOG statement I reviewed also discusses a case series about a proposed experimental protocol to "reverse the effects of mifepristone."[3] I have reviewed this case series. The case series discusses seven women who took mifepristone and were given progesterone in an attempt to prevent an abortion. Four of these women carried their pregnancy to term, two of the women aborted, and one of the women inexplicably was lost to follow up. It is my understanding that this case series is the only peer-reviewed publication that reports outcomes after the use of progesterone to "reverse

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[2] ACOG & ACOG Arizona Section, Medication Abortion Reversal, *available at* http://www.acog.org/~/media/departments/state%20legislative%20activities/2015AZFactSheetMedicationAbortionReversalfinal.pdf

[3] George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 ANNALS OF PHARMACOTHERAPY e36 (Dec. 2012).

the effects of mifepristone," and thus is the only apparent basis in the medical literature for the mandated information in the Act.[4]

28. Based on these understandings, in my opinion, there is no credible evidence to support the information mandated by the Act. Moreover, I believe that compelling physicians to present to their patients that abortion reversal may be possible will lead patients to believe that there is an established treatment to achieve that result, when all that exists is a theory that needs further investigation.

29. Case series are not considered reliable evidence that a new treatment is safe or effective. A case series is a report, usually retrospective, on the treatment or outcomes of a group of individual patients. Essentially, they are observational/anecdotal reports, generally published by physicians, which lack any scientific design. Because case series have no control group (one to compare outcomes), it is very difficult to know what would have happened to the patients had they not received the treatment described in the case series. Moreover, case series are especially vulnerable to selection bias, which means the results reported may not appropriately represent the wider population.

30. At best, case series may generate hypotheses for future study. They are not the type of evidence on which to base a practice standard. The only exception to this is when the historical outcome of a particular disease is known with absolute certainty, such as when all patients are known, virtually without exception, to die of a particular disease. If a case series shows that a new treatment leads to a starkly different outcome from what

[4] Because I am not an obstetrician-gynecologist, I am not providing an opinion regarding the biological plausibility of the regimen described in this case series.

has been seen historically, that case series may have some evidentiary value. That is not the case with the Delgado and Davenport case series.

31. For these reasons, the Delgado and Davenport case series cannot be described as evidence that the protocol proposed in the case series actually increases the likelihood that a woman would successfully continue her pregnancy after receiving mifepristone. In fact, the authors seem to concede this point, and acknowledge that the proposed protocol requires further study before it could become an established treatment. Specifically, they conclude in the case series only that "[t]he experience of the[] patients *suggests* that medical abortion can be arrested," and "that *if* further [clinical] trials confirm the success without complications of this or similar protocols, it should become the standard of care . . . ." (emphasis added).[5]

32. Given that there is no credible evidence that the effects of a medication abortion, or mifepristone, can be "reversed," it would be improper and unethical for a physician to suggest otherwise to his or her patients. Doing so would constitute the delivery of inaccurate and misleading information to the patient, which indisputably is detrimental to the patient's ability to make an informed decision, and contrary to medical ethics.

33. Moreover, in my opinion, the Act dangerously bypasses a critical step in the development of evidence-based medicine, putting patients at risk of harm. I can think of no other area in medicine, including my area of practice which involves treating children with serious and fatal diseases, where physicians are forced to tell their patients

[5] Delgado & Davenport, *supra* note 3.

about the availability of an experimental treatment discussed in a case series—especially when the authors of the case series acknowledge that further clinical trials are needed to prove that the experimental treatment is effective and safe. It is even harder to imagine being required to do this as part of the informed consent process for a treatment that your patient is requesting, when the experimental treatment proposes to undo that very same treatment. In this additional way, the Act deviates drastically from traditional norms of informed consent.

34. Additionally, in my opinion, the Act is also harmful to patients because it forces physicians to communicate a message to their patients that suggests to them that they need not be committed in their decision to terminate the pregnancy before beginning the abortion. This is directly contrary to physicians' ethical obligations as part of the informed consent process. Because the goal of the informed consent process is to ensure that a patient does not undergo any course of treatment that the patient does not truly want, it would undermine the purpose of the informed consent for a physician to say things (or be forced to say things) that encourage a patient to delay making a final decision about whether to undergo a course of treatment until after the treatment has begun. This is particularly so when patients are seeking a treatment with a desired outcome that has significant implications for their life, as abortion does, and when there is no question that, once women start the procedure, in many cases (contrary to what the Act seems to imply) their pregnancy will end. Thus, in my opinion, the Act's required message could mislead women who are uncertain about terminating their pregnancies into proceeding based on the *inaccurate* assumption that an option for reversal exists

should they change their mind. This highlights another way in which the Act distorts the purpose of the informed consent process.

35. Finally, I understand that the Act requires physicians to discuss with all of their patients, even those who are not eligible for an early medication abortion and those who have chosen to have a surgical abortion, a message that is strictly about a specific regimen for medication abortion. Requiring that physicians provide their patients with irrelevant information as part of the informed consent process serves no medical purpose and undermines the goal of the informed consent process. Providing irrelevant information distracts patients from the critical information that is necessary to an informed decision.

36. In my opinion, the problems presented by the Act cannot be avoided merely by the physician telling the patient that the government thinks the reversal option exists even though the physician personally disagrees. Merely bringing up the possibility wrongly encourages the patient to consider a possibility for which there is no evidence. It also fails to restore respect for the patient's autonomy because it stills requires her to hear, from a health care professional in whom she needs to trust, a medical message that is not based on adequate research. In addition, such a message is certain to confuse patients and to distract them from the essential information needed to make this very important decision.

Unethical Conduct of Ethical Research

37. In my opinion, the Act is also problematic because it forces physicians to effectively steer their patients to physicians who appear to be conducting research on

humans without any oversight or approval by an independent ethics committee. This is not only troubling for women seeking medication abortions, but it also highlights another way in which the Act forces physicians to act against their patients' best interests.

38. In addition to reviewing the Delgado and Davenport 2012 case series, I have also reviewed media reports and statements that have described these authors' activities, intentions and goals regarding their proposed protocol. It appears, in my opinion, that the authors' activities fall squarely within the realm of medical research, and that this research is not being conducted ethically.

39. Based on media reports and statements, the authors of the 2012 case series and other physicians appear to be providing the experimental protocol discussed in their case series to hundreds of women.[6] But more than just providing the protocol, physicians appear to be tracking and reporting outcomes to a project led by Dr. Delgado. These outcomes are then being analyzed systematically by physicians and statisticians, with the express goal of publishing the results.[7] In addition, as the authors of the case series

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[6] Am. Assoc. of Pro-Life Obstetricians & Gynecologists, AAPLOG APR Statement, (Apr. 1, 2015), *available at* http://www.abortionpillreversal.com/uploads/docs/AAPLOG_APR_Statement_4.1.15.docx; Shannon Firth, *Reversing Abortion Pill: Can It Be Done?*, MEDPAGE TODAY (Feb. 24, 2015), http://www.medpagetoday.com/OBGYN/GeneralOBGYN/50164 ("As of Dec. 31 2014…[o]f the 223 women who have received progesterone, 127 cases succeeded, according to a fact sheet Delgado shared."); Paul Sisson, *Doctor began abortion reversal movement*, THE SAN DIEGO UNION-TRIBUNE (Apr. 11, 2015), http://www.utsandiego.com/news/2015/apr/11/george-delgado-abortion-reversal/?#article-copy ("Delgado said since [the 2012 publication of the case series], a growing network of doctors worldwide…have administered progesterone to about 250 women").

[7] AAPLOG APR Statement, *supra* note 6 ("Outcomes of treatment are reported to the APR project of Culture of Life Family Services, and analyzed by physicians, RNs and a

noted, they have a clear intent to alter the standard of care.[8]

40. In my opinion, these activities constitute research on human subjects as it is commonly understood and as it is defined by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its *Belmont Report*: "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."[9]

41. However, media reports suggest that no independent ethics committee or board has approved of this research.[10]

42. The professional norm and expectation in the biomedical research

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statistician associated with the project. As more women receive this therapy, the results will continue to be reported in the medical literature."); Colette Wilson, *Interview: Reversing the Effects of RU-486*, LIFELINE (Life Legal Defense Foundation, Napa, CA) VOL. XXIV, NO. 1, Winter 2015, *available at*: http://lldf.org/interview-reversing-effects-ru486/ ("Dr. Delgado: We have established an exciting program called APR (Abortion Pill Reversal)...I have published a case series report in a peer-reviewed medical journal, Annals of Pharmacotherapy, and plan a second article when we have 200 deliveries").

[8] Delgado & Davenport, *supra* note 3 ("We believe that if further trials confirm the success without complications of this or similar protocols, it should become the standard of care . . . .")

[9] The Nat'l Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by the National Research Act, and was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. The Belmont Report summarizes the basic ethical principles identified by the Commission.

[10] Firth, *supra* note 6 ("In an email, Delgado said that...institutional review board is not required to follow cases"); Sisson, *supra* note 6 ("Delgado said his nonprofit organization —Culture of Life Family Services, which runs the Abortion Pill Reversal program —has not begun working with a review board or designing a more comprehensive study").

community is that research on human subjects should be approved by an Institutional Review Board ("IRB"), which is a committee that performs an ethical review of proposed research. Generally, before approving research proposals, IRBs are necessary to determine that (1) risks to subjects will be minimized through sound research design and, whenever appropriate, the use of procedures already being performed on subjects for clinical purposes; (2) risks will be "reasonable in relation to" the anticipated benefits for the subjects and to the importance of any discoveries that are expected to result; (3) selection of subjects will be equitable, taking special consideration of research involving vulnerable populations, including pregnant women; (4) informed consent will be sought; (5) consent will be appropriately documented; (6) the research proposal provides for monitoring the collected data to ensure subject safety; and (7) the study will follow appropriate efforts to protect subjects' privacy and maintain the confidentiality of data.[11] Specifically, IRBs must review and approve research protocols (plans), informed consent documents, recruitment materials and other core study documents before participants are enrolled in the research.

43. Without IRB approval, there are serious questions about the reliability of any data a physician purports to have collected regarding the efficacy and safety of a proposed treatment, as well as about whether the research was conducted ethically.

44. I have participated as a researcher in clinical trials and human subjects research studies and every trial/study has been through the IRB approval process prior to the initiation of the research. This is done not only because it is the professional norm

[11] *See* 45 C.F.R. § 46.111.

(and for this reason every institution I have worked for has required this) and because it is ethical, but also because if the research demonstrates that a new course of treatment is safe and effective, we want the medical community to know that the research was done rigorously and that the results are valid—in other words, that the treatment is evidenced-based—so that other physicians can offer or recommend the treatment to their patients with confidence. IRB approval is also important to assuring other physicians that the research results were obtained ethically. Without this assurance, it would be unethical under most circumstances for physicians to use such research results in their practices.

45. In my opinion, the Act requires physicians to essentially refer their patients to doctors offering an unproven, experimental treatment and conducting apparently unethical research. This is contrary to medical ethics and potentially harmful to women seeking abortions. Physicians should always make referral decisions based on the best interests of their patients and should not refer a patient unless the physician is confident that the services provided on referral will be performed competently and in accordance with accepted scientific standards, ethical norms, and legal requirements.[12]

46. For all of these reasons, it is my opinion that the requirements of the Act are contrary to the principles of medical ethics and informed consent. The Act is detrimental to the informed consent process, and thus, rather than help women considering abortions, the Act threatens their rights and welfare. The Act also harms the physician-patient relationship and is a serious affront to the integrity of the medical

[12] *See* Am. Med. Assoc., *Opinion 8.132 - Referral of Patients: Disclosure of Limitations*; *Opinion 3.04 - Referral of Patients*.

profession.

I declare under penalty of perjury that the forgoing is true and correct.

Dated: June 3, 2015

Steven Joffe, M.D., M.P.H.

Exhibit A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 05/14/2015

Steven Joffe

Address: 3401 Market Street, Suite 320
Philadelphia, PA 19104 USA

If you are not a U.S. citizen or holder of a permanent visa, please indicate the type of visa you have:
none (U.S. citizen)

Education:

1984		University High School, Tucson, AZ
1988	A.B.	Harvard College (Fine Art)
1992	M.D.	University of California, San Francisco School of Medicine (Medicine)
1996	M.P.H.	University of California, Berkeley (Epidemiology)

Postgraduate Training and Fellowship Appointments:

1992-1993	Intern, Pediatrics, University of California, San Francisco
1993-1995	Resident, Pediatrics, University of California, San Francisco
1996-1997	Research Fellow, Department of Research, Kaiser Permanente Northern California
1997-2000	Clinical Fellow, Pediatric Hematology/Oncology, Children's Hospital Boston and Dana-Farber Cancer Institute
1998-2000	Research Fellow, Clinical Effectiveness, Children's Hospital Boston
1998-2000	Fellow, Medical Ethics, Harvard Medical School
2000-2001	Faculty Fellow, Professional Ethics, Center for Ethics and the Professions, Harvard University

Military Service:

[none]

Faculty Appointments:

2000-2004	Instructor of Pediatrics, Harvard Medical School
2004-2010	Assistant Professor of Pediatrics, Harvard Medical School
2010-present	Associate Professor of Pediatrics, Harvard Medical School
2012-present	Associate Professor of Global Health and Social Medicine (Secondary), Harvard Medical School
2013-present	Associate Professor of Medical Ethics and Health Policy in Pediatrics, University of Pennsylvania School of Medicine (Secondary)
2013-present	Associate Professor of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

1995-1997	Medical Staff, Department of Pediatrics, St. Luke's Hospital, San Francisco, CA
1998-2010	Medical Staff, Department of Pediatrics, Newton-Wellesley Hospital, Newtown, MA
2000-present	Attending Physician, Department of Medicine Division of Hematology and Oncology, Children's Hospital Boston
2000-present	Medical Staff, Department of Pediatrics, Winchester Hospital, Winchester, MA
2001-present	Hospital Ethicist, Dana-Farber Cancer Institute
2007-present	Faculty Director, Survey and Data Management Core, Dana-Farber Cancer Institute
2011-present	Director, Ethics Program in Clinical and Translational Research (EPiCTR), Harvard Catalyst (Associate Director, 2008-2011), Harvard Medical School

Other Appointments:

1995-1997	Assistant Physician, Department of Pediatrics, University of California, San Francisco
1995-1997	Pool Physician, Department of Pediatrics, Kaiser Permanente, Walnut Creek, CA
1998-2002	Medical Staff, Department of Pediatrics, Saints Memorial Medical Center, Boston, MA
2000-present	Attending Physician, Department of Pediatric Oncology, Dana-Farber Cancer Institute
2008-2012	Data Monitoring Committee Member, Genzyme Corporation

Specialty Certification:

[none]

Licensure:

1993-1997	California License Registration
1995	American Board of Pediatrics Certificate
1997	Massachusetts License Registration
2000	American Board of Pediatrics, Sub-board in Hematology/Oncology Certificate
2013	Pennsylvania License Registration

Awards, Honors and Membership in Honorary Societies:

1983	National Merit Scholarship
1985-1988	John Harvard Scholar, Harvard College
1987	Phi Beta Kappa, Harvard College
1988	Regents Scholar, University of California, San Francisco
1992	Academic Excellence Award (Co-Valedictorian), University of California, San Francisco
1992	Alpha Omega Alpha, University of California, San Francisco

1995	Housestaff Teaching Award, Department of Pediatrics, University of California, San Francisco
2002	Award for Excellence in Human Research Protection, Health Improvement Institute
2011	Excellence in Tutoring Award, Harvard Medical School
2013	Fellow, The Hastings Center

Memberships in Professional and Scientific Societies and Other Professional Activities:

National:

1992-2000	American Academy of Pediatrics
1999-Present	American Society of Clinical Oncology (Member, Subcommittee on Genetic Testing 2001-2003 Member, Ethics Committee 2002-2006 Member, Data Governance Oversight Committee, CancerLinQ, 2014-2015)
2001-Present	American Society of Bioethics and Humanities
2003-Present	Children's Oncology Group, Bioethics Committee (Vice-Chair 2003-2008 Chair 2008-Present)
2003-Present	Public Responsibility in Medicine and Research (PRIM&R) (Member, Annual Conference Planning Committee 2006-2009 Member, Education Committee 2007-2010)
2005-2011	Cancer and Leukemia Group B, Ethics Committee
2006-2007	National Institutes of Health, National Cancer Institute Central IRB Evaluation Review Panel
2007-Present	Society for Pediatric Research
2007-Present	U.S. Food and Drug Administration, Pediatric Ethics Subcommittee, Advisory Committee
2008-Present	American Society for Blood and Marrow Transplantation
2008-2012	Genzyme Corporation, Data Monitoring Committee Member
2008	National Institutes of Health, Center for Scientific Review, Ad hoc member, Special Emphasis Panel (ZRG1 HOP-J(90)S)
2009-Present	Center for International Blood and Marrow Transplantation Research, Health Policy Working Committee (Co-chair 2009-2014)

2009	National Cancer Institute/American Society of Clinical Oncology, Planning Committee, Science of Clinical Trial Accrual Symposium
2009	National Institutes of Health, Biobehavioral and Behavioral Processes IRG, Division of AIDS, Behavioral and Population Sciences, Center for Scientific Review, Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2009	National Institutes of Health, National Human Genome Research Institute (Ethical, Legal and Social Implications Program), Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2009	Pfizer, Inc., Multi-Regional Clinical Trials Committee
2010-2013	U.S. Department of Health and Human Services, Secretary's Advisory Committee for Human Research Protections (SACHRP)
2011-Present	NHGRI Clinical Sequencing Exploratory Research (CSER) Consortium ELSI Group (Chair 2013-present)
2011	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics
2012-Present	American Pediatric Society
2013-Present	National Institute of Allergy and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID) HIV Prevention Data and Safety Monitoring Board - Africa
2014-Present	Advisory and Executive Committees, Center for International Blood and Marrow Transplant Research (CIBMTR) (Member 2014-present)
2014-Present	African HIV Data Safety and Monitoring Board, National Institute of Allergies and Infectious Diseases (NIAID), Division of AIDS (DAIDS) (Member 2014-present)
2014-Present	American Society of Human Genetics (Member 2014-Present)
2015-Present	Board of Scientific Counselors, National Institutes of Health Clinical Center (Member 2015-present)
2015-Present	Committee on Federal Research Regulations and Reporting Requirements, National Academy of Sciences (Member, 2015-Present)
2015	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics

Local:

2008-2011	Department of Public Health, Commonwealth of Massachusetts, Altered Standards of Care Advisory Committee
2012-2013	Massachusetts General Hospital, Advisory Committee, Program in Cancer Outcomes Research Training (PCORT), Institute for Technology Assessment
2014-Present	Children's Hospital of Philadelphia Ethics Committee (Member 2014-Present)

Editorial Positions:

2005-2013	Editorial Board Member, Journal of Clinical Oncology
2005-2009	Editorial Board Member, Critical Reviews of Oncology and Hematology

Academic and Institutional Committees:

1998-2012	Member, Institutional Review Board, Dana-Farber Cancer Institute
2000-2013	Member, Ethics Advisory Committee, Children's Hospital Boston
2000-2013	Member, Ethics Advisory Committee, Dana-Farber Cancer Institute (Co-chair 2001-2009)
2000-2009	Member, Board of Trustees Quality Assurance and Risk Management Committee, Dana-Farber Cancer Institute
2001-2004	Member, Research Integrity and Compliance Committee, Dana-Farber Cancer Institute
2001-2012	Member, Clinical Research Leadership Committee (formerly Clinical Research Policy and Operations Committee), Dana-Farber/Harvard Cancer Center
2002-2013	Member, Steering Committee, Division of Medical Ethics, Harvard Medical School
2003	Member, Organizational Ethics Task Force on the Refusal of Blood Products, Children's Hospital Boston
2003-2009	Partners HealthCare, Ethics Leaders Committee
2004-2013	Partners HealthCare, Embryonic Stem Cell Research Oversight (ESCRO) Committee
2005-2009	Member, Ethics Leaders, Harvard Medical School
2005-2006	Partners HealthCare, Tissue Banking Task Force
2008-2010	Member, Admissions Committee, Harvard Medical School
2009-2013	Member, Informed Cohort Oversight Board, Children's Hospital
2011-2013	Expert Reader and Examiner, Committee on Awards and Honors, Harvard Medical School
2012-2013	Member, Research Conflict of Interest Management Committee, Dana-Farber Cancer Institute

Major Academic and Clinical Teaching Responsibilities:

2000-2003	Attending Physician, Pediatric Oncology, Jimmy Fund Clinic, Dana-Farber Cancer Institute (4 Fellows for 100 hours every year)

2000-2002	Attending Physician for Inpatient Oncology Service, Children's Hospital Boston (6 Fellows and 4 Residents for 200 hours every year)
2002-2013	Attending Physician for Hematopoietic Stem Cell Transplant Service, Children's Hospital Boston (6 Fellows and 2 Residents for 150 hours every year)
2003-2012	Attending Physician, Pediatric Stem Cell Transplant Outpatient Service, Dana-Farber Cancer Institute (3-4 Fellows for 200 hours every year)
2003	Informed Consent Presentation, Breast Cancer: Current Controversies and New Horizons, Harvard Medical School (CME)
2003-2011	Case-Based Ethical Dilemmas, Practical Aspects of Palliative Care, Harvard Medical School (CME Single Presentation every year)
2008-2012	Medical Ethics and Professionalism Course for first-year medical students (one 2 hour session per week for 14 weeks)
2008	"Therapeutic Innovation or Research" - Seminar, June 2008, Harvard School of Public Health
2008	"Ethics of research with human subjects" - Seminar, June 2008, Harvard Medical School
2008	"Informed consent to treatment and research" - Seminar, October 2008, Division of Medical Ethics, Harvard Medical School
2009	"The ethical conundrum of incidental findings in clinical & translational research" - Lecture, June 2009, Harvard Catalyst Colloquium Series
2009	"Informed consent to treatment and research" - Seminar, September 2009, Division of Medical Ethics, Harvard Medical School
2009	"Conflict of Interest in Biomedical Research" - Seminar, October 2009, Longitudinal Clinical Research Seminar/Bioethics Module, ME 731.0a, Scholars in Clinical Science Program, Harvard Medical School
2009	"Ethics and professional integrity in clinical and translational research" - Seminar, October 2009, Clinical Investigator Training Program, Harvard Medical School
2009	"At the point of the spear: ethical and scientific challenges in translational trials" - Lecturer, November 2009, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"Cancer patients' attitudes towards stored tissue research: outcomes and value of a factorial survey" - Lecture, January 2010, Harvard Pediatric Health Services Research Fellowship Program
2010	"Ethics in clinical research" - March 2010, Department of Medicine Residency Program, Children's Hospital Boston
2010	"What makes clinical research ethical?" - March 2010, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"The scientist as a responsible member of society" - June 2010, Responsible Conduct of Research Course, Dana-Farber Cancer Institute

2010	"Innovative treatment - research" - June 2010, Harvard Medical School Bioethics Course
2010	"Ethical issues in medical research" - Lecture, July 2010, CURE Summer Program, Dana-Farber Cancer Institute
2010	"Ethics in medical research" - Lecture, July 2010, Harvard Catalyst Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Medical School
2010	"Informed consent, subject selection and recruitment" - Lecture, September 2010, Scholars in Clinical Science Program, Harvard Medical School
2010	"Ethics and integrity in clinical research" - Lecture, September 2010, Introduction to Clinical Research Course, Children's Hospital Boston
2010	"Conflicts of interest" - Lecture, October 2010, Scholars in Clinical Science, Harvard Medical School
2010	"Case-based ethical dilemmas" - Lecture, October 2010, Practical Aspects of Palliative Care Course, Harvard Medical School
2010	"Informed consent to treatment and research" - Lecture, October 2010, Harvard Medical School Ethics Fellowship, Harvard Medical School
2010	"Attitudes of cancer patients and parents toward biobanking for future research" - Lecture, November 2010, Brigham and Women's Center for Bioethics, Research in Progress Seminar
2011	"Ethical conduct of research: Issues in consent" - Lecture, January 2011, Harvard Medical School Fellowship Programs in General Medicine and Primary Care, Pediatric Health Services Research, and Complementary and Alternative Medicine, Serving the Underserved: The Responsible Conduct of Research for the Underserved
2011	"Evaluating the ethics of clinical research" - Lecture, March 2011, Introduction to Clinical Investigation Course, Harvard Catalyst
2011	"Informed consent to research" - Lecture, April 2011, Training Session for Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
2011	"Ethics in medical research" - Lecture, August 2011, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst
2011	"Human subjects protection in survey research" - Seminar, September 2011, UMass Boston/Dana-Farber Harvard Cancer Center Survey and Statistical Methods Core Seminar Series
2011	"Ethics in integrity in clinical research" - Lecture, September 2011, Introduction to Clinical Research Course, Children's Hospital Boston
2011	"Case-based dilemmas: Ethical challenges in end-of-life care" - Lecture, September 2011, Practical Aspects of Palliative Care Course, Harvard Medical School

2011	"Informed consent, subject selection and recruitment" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Conflicts of interest" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Informed consent to treatment and research" - Lecture, October 2011, Ethics Fellowship, Harvard Medical School
2011	"Ethics in clinic research" - Lecture, October 2011, Clinical Investigator Seminar, Dana-Farber Cancer Institute
2012	"Children's capacity to participate in research decisions" - Lecture, January 2012, Department of Medicine Grand Rounds, Children's Hospital Boston
2012	"Ethics & professional integrity in clinical and translational research" - Lecture, January 2012, Clinical Investigator Training Program, Harvard Medical School
2012	"The scientist as a responsible member of society" - Lecture, March 2012, Responsible Conduct of Research Course, Dana-Farber Cancer Institute
2012	"Responsible conduct of research" - Lecture, May 2012, Pediatric Health Services Research Fellowship, Children's Hospital Boston
2012	"Ethics in medical research" - Lecture, July 2012, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst/HMS
2012	"Informed consent, subject selection and recruitment" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Ethics and integrity in clinical research" - Lecture, September 2012, Introduction to Clinical Research Course, Children's Hospital Boston
2012	"Conflict of interest" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Informed consent to treatment and research" - Lecture, October 2012, Ethics Fellowship, Harvard Medical School
2013	"Evaluating the Ethics of Clinical & Translational Research" - Lecture, October 2013, Pediatric Translational Research Workshop for Basic Scientists, Children's Hospital of Philadelphia
2013	"Ethics in Biomedical Research," Guest Lecture, Health Policy and Research Methods I
2013	Course Director, BIOE701, "Bioethics Proseminar"
2014	"Evaluating Informed Consent for Clinical Research" - Lecture, EPI690, University of Pennsylvania
2014	"Mandate or Millstone? The Ethical Challenge of Genomic Incidental Findings," Ellen Hyman-Browne Memorial Lecture, October 2014, Children's Hospital of Philadelphia

2014	"Evaluating the Ethics _of Clinical Research" - How to Be An Academic Radiologist, Department of Radiology, University of Pennsylvania Perelman School of Medicine
2014	"Ebola virus disease" - GlobalMed, November 2014, University of Pennsylvania
2014	"Ethics in Biomedical Research" - Guest lecture, Health Services and Policy Research Methods I, December 2014, University of Pennsylvania
2015	"Pediatric Ethics" - Lecture, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"History of Research Ethics" and "Pediatric Ethics" - Leader, Small group discussions, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"Ethics in pediatric hematopoietic stem cell transplant," Pediatric HSCT Education Series
2015	"Involving Children in _Decisions about Research"- Pediatric Grand Rounds, Children's Hospital of Philadelphia, April 2015

Lectures by Invitation (Last 5 years):

Feb, 2010	"Improving the Trial Experience from the Patient's Perspective: informed consent and related issues" - American Society of Blood and Marrow Transplantation (ASBMT) Annual Meeting, Orlando, Florida
May, 2010	"Conflicts of Interest in Clinical Studies" - Clinical Trials Training Course, American Society of Gene and Cell Therapy Annual Meeting, Washington, D.C.
Jun, 2010	"Decision-making Capacity: Lessons from Pediatrics" - American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, Illinois
Jun, 2010	"Ethics in Cancer Clinical Research" - American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, Illinois
Aug, 2010	"Assessing Quality in IRB Review: Theoretical and Empirical Issues" - Treuman Katz Center for Pediatric Bioethics, Seattle Children's Hospital, Seattle, Washington
Aug, 2010	"Financial Relationships with Industry: Even more challenging than we thought" - Biomedical Research Integrity Series, University of Washington/Fred Hutchinson Cancer Research Center, Seattle, Washinton
Aug, 2010	"Attitudes Towards Biobanking Among Cancer Patients and Parents" - Seattle Children's Hospital, Seattle, Washington
Sep, 2010	"Conflicts of Interest" - Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, Maryland

Sep, 2010	"Ethical Challenges in Clinical Trials" - Plenary Presentation, Society of Clinical Research Associates (SOCRA) Annual Meeting, Dallas, Texas
Dec, 2010	"Great Debate: The obligation to participate in research" - Plenary Presentation, Advancing Ethical Research Annual Conference, Public Responsibility in Medicine and Research (PRIM&R), San Diego, California
Dec, 2010	"Ethical Analysis of Phase I Trials in Pediatric Oncology" - Advancing Ethical Research Annual Conference, Public Responsibility in Medicine and Research (PRIM&R), San Diego, California
Dec, 2010	"Ethics of Pediatric Clinical Research" - Advancing Ethical Research Annual Conference, Public Responsibility in Medicine and Research (PRIM&R), San Diego, California
Apr, 2011	"Equipoise: An irrelevant concept in clinical trial design" - American Association for Cancer Research Annual Meeting (AACR), Orlando, Florida
Jun, 2011	"Defining and Measuring Therapeutic Misconception in Informed Consent for Research" - Institute for Human Values in Health Care, Medical University of South Carolina, Charleston, South Carolina
Jun, 2011	"Introduction to the Ethics of Early-Phase Clinical Trials" - 2011 ASCO Annual Meeting Education Session, Chicago, Illinois
Jun, 2011	"Designing & Conducting Ethical Research Involving Children with Serious Medical Illness" - Principal Investigator Lecture Series, New York University School of Medicine, New York, New York
Sep, 2011	"Conflicts of Interest" - Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, Maryland
Oct, 2011	"Emerging Areas of Debate" - Conflicts of Interest in Medical Practice: A National Symposium, American Society of Law, Medicine and Ethics, Pittsburgh, Pennsylvania
Oct, 2011	"The Limits of Permissible Risk in Clinical Research" - American Society of Bioethics and Humanities Annual Meeting, Minneapolis, MN
Nov, 2011	"Children's Capacity to Participate in Research Decisions" - Grand Rounds, Alberta Children's Hospital, Calgary, Canada
Nov, 2011	"Justifying Research Oversight" - Research Ethics: Re-examining Key Concerns, Center for Bioethics, Health and Society, Wake Forest University, Winston-Salem, North Carolina
Nov, 2011	"Decision making and ethics in a transplant context" - Pediatric Oncology Group of Ontario Annual Symposium, Toronto, Canada
Dec, 2011	"Children's Capacity to Participate in Research Decisions" - Camille Sarrouf Endowed Lecture on Bioethics and Medical Humanities, St. Jude Children's Research Hospital, Memphis, Tennessee

Dec, 2011	"A Great Debate: Be it resolved that clinical equipoise should determine whether it is ethical to randomize subjects between two treatments" Annual Meeting, Public Responsibility in Medicine and Research, National Harbor, Maryland
Dec, 2011	"The Clinical Laboratory Improvements Act and Research: Practical & Ethical Challenges" - Annual Meeting, Public Responsibility in Medicine and Research, National Harbor, Maryland
Dec, 2011	"Children's Capacity to Participate in Research Decisions" - Annual Meeting, Public Responsibility in Medicine and Research, National Harbor, Maryland
Jan, 2012	"Children's Capacity to Participate in Research Decisions" - Dr. Jennifer Ann Kierson Memorial Pediatric Grand Rounds, Herman and Walter Samuelson Children's Hospital at Sinai, Baltimore, Maryland
Feb, 2012	"Are Investigators Obligated to Ensure Understanding?" - "Rethinking the Ethics of Clinical Research," Symposium in Honor of Alan Wertheimer, Trent Center for Bioethics, Duke University
Mar, 2012	"Children's Capacity to Participate in Research Decisions" - Pediatric Oncology Grand Rounds, MD Anderson Cancer Center, Houston, Texas
Apr, 2012	"Paradigms Under Strain: informed consent in the genomic research context" - American Association for Cancer Research Annual Meeting, Chicago, Illinois
May, 2012	"Benefit-risk Assessment and Informed Consent in Clinical Research" - Institute for History and Ethics of Medicine and National Center for Tumor Diseases, Faculty of Medicine, University of Heidelberg, Germany
May, 2012	"Frequency and Effects of Conflicts of Interest in Clinical Trials" - Institute for History and Ethics of Medicine and National Center for Tumor Diseases, Faculty of Medicine, University of Heidelberg, Germany
Jun, 2012	"Children's Capacity to Participate in Research Decisions" - Child Health Evaluative Services Rounds, Hospital for Sick Children, Toronto, Canada
Jul, 2012	"Whither the Children? The classic dilemma of pediatric clinical research" - Donovan Memorial Research Ethics Lecture, St. Agnes Hospital, Baltimore, Maryland
Oct, 2012	"Integrating Genomic Sequencing Into Cancer Care: Clinical & Ethical Challenges" - Medical Oncology Grand Rounds, IWK Health Centre, Dalhousie University, Halifax, Nova Scotia, Canada
Oct, 2012	"Children's Capacity to Participate in Research Decisions" - Department of Pediatrics Grand Rounds, IWK Health Centre, Dalhousie University, Halifax, Novia Scotia, Canada
Dec, 2012	"Framing the Protections for Children in Research" - Public Responsibility in Medicine & Research Annual Conference, San Diego, CA

Dec, 2012	"Regulatory Requirements and Ethical Considerations Regarding Pediatric Assent in Research" - Public Responsibility in Medicine & Research Annual Conference, San Diego, CA
Feb, 2013	"The Patient-Doctor Relationship" - Department of Bioethics Fellows Seminar, National Institutes of Health
Apr, 2013	"Children's capacity to participate in research decisions" - Department of Pediatrics Grand Rounds, Connecticut Children's Medical Center, Hartford, CT
Apr, 2013	"An integrated germline analysis platform for comprehensive clinical cancer genomics" - American Association for Cancer Research 2013 Annual Meeting, Washington, DC
Sep, 2013	"Involving Children in _Decisions about Research" - Achieving Excellence in Clinical Research, Advocate Health Care, Oak Brook, IL
Sep, 2013	"Is Equipoise Necessary for Ethical Clinical Trials?" - Achieving Excellence in Clinical Research, Advocate Health Care, Oak Brook, IL
Oct, 2013	"Who Decides? Parent and Child Perspectives about Children Participating in Research" - American Society for Bioethics & Humanities (ASBH) 2013 Annual Meeting, Atlanta, GA
Oct, 2013	"Clarifying risks and benefits in_transplant clinical trials" - National Marrow Donor Program Council Meeting Plenary, Minneapolis, MN
Oct, 2013	"Conflicts of Interest" - Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, MD
Nov, 2013	"Returning Genetic Results from Biobank Research: A Reality-Based Perspective" - Returning Genetic Results in Biobanks: Opening an International Dialogue, Brocher Institute, Hermance, Switzerland
Nov, 2013	"Framing the protections for children in research" - Public Responsibility in Medicine & Research (PRIM&R) Annual Meeting, Boston, MA
Nov, 2013	"Children's capacity to make research decisions" - Public Responsibility in Medicine & Research (PRIM&R), Boston, MA
Nov, 2013	"A pediatric perspective on biobank research" - Public Responsibility in Medicine & Research (PRIM&R), Boston, MA
Feb, 2014	"The Patient-Doctor Relationship" - Department of Bioethics, National Institutes of Health, Washington DC
Feb, 2014	"The Case for a Stringent Approach to Returning Results" - Committee on National Statistics, National Academies of Sciences, Washington, DC
Apr, 2014	"Attitudes Towards Return of Incidental Genetic Findings Among Participants in the Jackson and Framingham Heart Studies" - Genetics Research Seminar, Dana-Farber Cancer Institute, Boston MA

Apr, 2014	"The Clinical Use of Genetics in Pediatrics" - Pediatrics Pharmacogenomics & Personalized Medicine, Children's Mercy Hospital, Kansas City MO
May, 2014	"Informed Consent and Privacy in Genomic Research" - Allen Institute, Seattle WA
Jun, 2014	"Ethics of Early-Phase Trials in Children with Cancer" - Australian and New Zealand Children's Haematology/Oncology Group Annual Scientific Meeting, Sydney, Australia
Jun, 2014	"Ethical Challenges in Genomic Medicine" - Australian and New Zealand Children's Haematology/Oncology Group Annual Scientific Meeting, Sydney, Australia
Jul, 2014	"Learning Healthcare Systems: Ethically Integrating Research into Pediatric Care" - Tenth Annual Pediatric Bioethics Conference, Seattle Children's Hospital, Seattle WA
Oct, 2014	"Ethics of children as stem cell donors" - American Association of Blood Banks Annual Meeting, Philadelphia PA
Oct, 2014	"Conflicts of Interest" - Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda MD
Oct, 2014	"The ethics of early-phase trials in children with cancer" - Treuman Katz Lectureship, Treuman Katz Center for Pediatric Bioethics, Seattle Children's Hospital, Seattle WA
Oct, 2014	"Informed Consent to Treatment and Research" - Ethics Fellowship, Harvard Medical School, Cambridge MA
Nov, 2014	"Returning Hemoglobinopathy Results to Blood Donors: Ethical Considerations" - Testimony given to Advisory Committee on Blood & Tissue Safety & Availability, Department of Health and Human Services, Arlington VA
Nov, 2014	"Informed Consent for Cluster Trials: Necessary or Not?" - American Society of Nephrology Annual Meeting, Philadelphia PA
Dec, 2014	"Views of Patients and Physicians about Protocolized Dialysis Treatment in RCTs and Clinical Care" - PRIM&R Annual Meeting, Baltimore MD
Jan, 2015	"Nonfinancial Incentives to Research Participants" - Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, presented at Brocher Institute, Hermance, Switzerland
Feb, 2015	"Involving Children in Important Medical Decisions" - Pediatric Ethics Grand Rounds, Visiting Scholar, Department of Pediatrics and Center for Bioethics, UNC Chapel Hill School of Medicine
Mar, 2015	"Children as Stem Cell Donors in Research," Workshop Leader, National Institutes of Health
Mar, 2015	"The Patient-Doctor Relationship," Department of Bioethics, National Institutes of Health Clinical Center

Organizing Roles in Scientific Meetings:

Nov, 2008	Plenary Panel Moderator, "What is Exploitation in Research?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Orlanda, Florida
Nov, 2009	Plenary Panel Moderator, "Ethics in Research: Who's minding the store?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Nashville, Tennessee
Oct, 2014	Moderator, "Compensation for Research Related Injuries: Interdisciplinary Perspectives", American Society of Bioethics & Humanities San Diego, CA
Nov, 2014	Organizer, "Write Winning Grant Proposals," Perelman School of Medicine at the University of Pennsylvania and Grant Writers' Seminars and Workshops University of Pennsylvania, Philadelphia PA
Dec, 2014	Session moderator/organizer, "Inside the Black Box: Empirical Research on IRBs," Public Responsibility in Medicine & Research (PRIM&R) Annual Meeting Baltimore, MD

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Research Publications, peer reviewed (print or other media):

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2. Joffe S, Escobar GJ, Black SB, Armstrong MA, Lieu TA. : Rehospitalization for Respiratory Syncytial Virus Among Premature Infants. Pediatrics 104(4 Pt 1): 894-9, 1999.

3. Joffe S, Ray GT, Escobar GJ, Black SB, Lieu TA.: Cost-Effectiveness of Respiratory Syncytial Virus Prophylaxis Among Preterm Infants. Pediatrics. 104(3 Pt 1): 419-27, 1999.

4. Higuchi LM, Joffe S, Neufeld EJ, Weisdorf S, Rosh J, Murch S, Devenyi A, Thompson JF, Lewis JD, Bousvaros A.: Inflammatory Bowel Disease Associated with Immune Thrombocytopenic Purpura in Children. J Pediatr Gastroenterol Nutr 33(5): 582-7, 2001.

5. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC.: Quality of Informed Consent: A New Measure of Understanding Among Research Subjects. J Natl Cancer Inst. 93(2): 139-47, 2001.

6. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC.: Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey. Lancet. 358(9295): 1772-7, 2001.

7. Joffe S, Weeks JC. : Views of American Oncologists About the Purposes of Clinical Trials. J Natl Cancer Inst. 94(24): 1847-53, 2002.

8. Joffe S, Manocchia M, Weeks JC, Cleary PD.: What Do Patients Value in Their Hospital Care? An Empirical Perspective on Autonomy Centered Bioethics. J Med Ethics. 29(2): 103-8, 2003.

9. Joffe S. : Public Dialogue and the Boundaries of Moral Community. J Clin Ethics. 14(1-2): 101-8, 2003.

10. Joffe S, Harrington DP, George SL, Emanuel EJ, Budzinski LA, Weeks JC.: Satisfaction of the uncertainty principle in cancer clinical trials: retrospective cohort analysis. BMJ. 328(7454): 1463, 2004.

11. Lee SJ, Joffe S, Kim HT, Socie G, Gilman AL, Wingard JR, Horowitz MM, Cella D, Syrjala KL. : Physicians' Attitudes About Quality-of-Life Issues in Hematopoietic Stem Cell Transplantation. Blood. 104(7): 2194-200, 2004.

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13. Peppercorn JM, Weeks JC, Cook EF, Joffe S.: Comparison of Outcomes in Cancer Patients Treated Within and Outside Clinical Trials: Conceptual Framework and Structured Review. Lancet. 363(9405): 263-70, 2004.

14. Little MO, Moczynski WV, Richardson PG, Joffe S.: Dana-Farber Cancer Institute Ethics Rounds: Life-Threatening Illness and the Desire to Adopt. Kennedy Inst Ethics J. 15(4): 385-93, 2005.

15. Hampson LA, Agrawal M, Joffe S, Gross CP, Verter J, Emanuel EJ. : Patients' Views on Financial Conflicts of Interest in Cancer Research Trials. N Engl J Med. 355(22): 2330-7, 2006.

16. Joffe S, Fernandez CV, Pentz RD, Ungar DR, Mathew NA, Turner CW, Alessandri AJ, Woodman CL, Singer DA, Kodish E.: Involving Children in Decision-Making About Research Participation. J Pediatr. 149(6): 862-8, 2006.

17. Joffe S, Miller FG. : Rethinking Risk-Benefit Assessment for Phase I Cancer Trials. J Clin Oncol. 24(19): 2987-90, 2006.

18. Miller FG, Joffe S. : Evaluating the Therapeutic Misconception. Kennedy Inst Ethics J. 16(4): 353-66, 2006.

19. Hampson LA, Joffe S, Fowler R, Verter J, and Emanuel EJ. : The Frequency, Type, and Monetary Value of Financial Conflicts of Interest in Cancer Clinical Research. J Clin Oncol. 25(24): 3609-14, 2007.

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21. Joffe S, Mello MM, Cook EF, Lee SJ. : Advance Care Planning in Patients Undergoing Hematopoietic Cell Transplantation. Biol Blood Marrow Transplant. 13(1): 65-73, 2007.

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24. Kesselheim JC, Johnson J, Joffe S. : Pediatricians' Reports of Their Education in Ethics. Arch Pediatr Adol Med 162(4): 368-73, 2008.

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Exhibit 3:

Declaration of Bryan Howard

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc., et al.,

Plaintiffs,

v.

Mark Brnovich, Arizona Attorney General, in his official capacity, et al.,

Defendants.

Civil Action No. _____

DECLARATION OF BRYAN HOWARD IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Bryan Howard declares the following pursuant to 29 U.S.C. § 1746:

1. I am President and CEO of Plaintiff Planned Parenthood Arizona, Inc. ("PPAZ"). I am responsible for the management of all of PPAZ's health centers, and therefore am familiar with our practices and the services we provide. I also am familiar with the select provisions of Arizona S.B. 1318 that are being challenged in this case. S.B. 1318, § 4 (to be codified at Ariz. Rev. Stat. 36-2153(A)(2)(h), (i)) ("the Act"). I submit this declaration in support of Plaintiffs' Motion for temporary injunctive relief.

2. I have been President of PPAZ since 2007, which is the affiliate of Planned Parenthood Federation of America that serves the state of Arizona. For 10 years before that, I was President of Planned Parenthood of Central and Northern Arizona, which was one of two Planned Parenthood affiliates in Arizona that merged in 2007 to form PPAZ.

3. PPAZ is a not-for-profit corporation organized under the laws of Arizona. It is the largest provider of reproductive health services in Arizona, operating 11 health

centers throughout the state and providing a wide range of reproductive health services, including pregnancy diagnosis and counseling; contraceptive counseling; provision of all methods of contraception; HIV/AIDS testing and counseling; cancer screening; and testing, diagnosis, and treatment of sexually transmitted infections.

4. PPAZ also provides abortion services at four of its health centers: in Glendale, Flagstaff, Tempe and Tucson. PPAZ provides medication abortion at all four health centers, and surgical abortion at all but the Flagstaff health center. In 2014, PPAZ provided approximately 2000 medication abortions and 4500 surgical abortions. Medication abortions provided at PPAZ use a regimen of a combination of two prescription drugs: mifepristone and misoprostol. We offer this regimen to our patients through the first nine weeks of pregnancy measured from the first day of a woman's last menstrual period (lmp).

5. As part of our ethical and legal duties to our patients, just like all medical providers, before we provide any medical services or treatment to a patient we must obtain informed consent. In order to do that, we provide every patient with information about the risks, benefits, and alternatives of the treatment under consideration, and an opportunity to ask any questions the patient has. Specifically, for women seeking to have an abortion, we give them information about their alternatives to abortion: *i.e.*, carrying the pregnancy to term and either parenthood or adoption, and offer informational resources related to those alternatives if they want them. Our purpose throughout this process is to provide patients with accurate and relevant information so that the woman can make the right decision for herself about what she wants to do with her pregnancy.

6. Before providing an abortion to any patient who chooses one, as part of the informed consent process, we stress to the patient that she should be firm in her decision; if she is not, we tell her to take more time to make a decision and that we will not provide her with an abortion until and only if she is ready. This is the case whether the woman is having an early medication abortion or a surgical abortion. For women having an early medication abortion, I understand that mifepristone is only one part of the two-drug regimen we provide, and that the mifepristone may not end a patient's pregnancy without that second step. Nonetheless, we counsel each patient not to take the mifepristone until she is certain she wants to terminate her pregnancy because we want her to be prepared for the very real possibility that the mifepristone will cause an abortion.

7. In 2009, the Arizona legislature passed a law requiring that women seeking an abortion meet with a physician in person at least 24 hours before an abortion is provided to be given certain state-mandated information. The law requires that physicians discuss with patients certain medical information, including the nature of the procedure, the gestational age of the pregnancy, the risks of abortion, and alternatives to abortion (all of which we would do otherwise in order to fulfill common law and ethical obligations). In addition, the woman must receive information about the "probable anatomical and physiological characteristics" of the embryo or fetus, and other statements of Arizona law and policy.

8. I understand that the Act would require that in addition to this other state-mandated information, our physicians now "inform" every woman seeking an abortion, at least 24 hours beforehand, 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," and that "information on and assistance with reversing the effects of a medication abortion is available on the department of health services' website." S.B. 1318, § 4 (to be codified at Ariz. Rev. Stat. 36-2153(A)(2)(h), (i)).

9. I understand that the Act also directs the Arizona Department of Health Services ("ADHS") to 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." *Id.* (to be codified at Ariz. Rev. Stat. 36-2153(C)(8)).

10. Because the Act requires our physicians to tell women about the availability of this information from ADHS, soon after the Act was signed into law, on April 21, 2015, I wrote to then-Interim Director of ADHS, Cory Nelson, requesting information about what ADHS intends to post on its website and in its materials about the Act. *See* Exhibit 1. I requested a response by May 22, 2015, but I did not receive a response by that date.

11. On May 22, I followed up again, this time with current ADHS Director Christ, requesting this information, and asked for a response by May 29, *see* Exhibit 2, but did not receive a response by that date. On June 1, I received via email a letter from ADHS Director Christ stating that "[g]iven the impact of [S.B. 1318] the Department is still working through the requirements and vetting potential language." *See* Exhibit 3. The letter also stated that the Department will have the language posted by the effective

date of the law, and will possibly have the language finalized sooner, by June 19. *Id.*

12. PPAZ and its physicians are troubled by the Act's requirements and are concerned about the effect the Act will have on our patients. As an initial matter, the information mandated by the Act, which is about medication abortion, is wholly irrelevant to many of our patients who can only have a surgical abortion because their pregnancy is too far along to have the medication abortion regimen we offer, and thus can only have a surgical abortion. We also object to providing this information because at the most basic level, the language of the Act makes no sense because an abortion can never be reversed. To suggest that to our patients would be completely confusing to them.

13. It is also my understanding that there is no medically acceptable or reliable evidence that a medication abortion can be reversed, and that the only physicians who believe in "reversal" are providing women with an experimental protocol to reverse mifepristone (and not the entire mifepristone/misoprostol medication abortion regimen we provide), which the American College of Obstetricians and Gynecologists ("ACOG") does *not* recommend because it is "not supported by the body of scientific evidence." Statement of the American Congress of Obstetricians & Gynecologists Arizona Section, Medication Abortion Reversal, *available at* http://www.acog.org/~/media/departments/state%20legislative%20activities/2015AZFactSheetMedicationAbortionReversalfinal.pdf

14. A fundamental part of PPAZ's approach to providing medical care is that we give our patients medically accurate information, meaning information that is supported by medical evidence and consistent with the general standard of care. Our patients trust us to provide them with straightforward, accurate, and relevant information.

The Act forces us to violate that trust by giving them misleading information.

15. In addition, we object that the Act forces us to direct patients to providers for whom we know nothing about the quality of their services and, in fact, believe that they are acting outside the standard of care. We would never do this willingly, and this too hurts our relationship with our patients.

16. Apart from these concerns, as I testified to in the legislature when it was considering the Act, forcing us to tell women as part of the informed consent process essentially that their abortion can be reversed if they change their mind later directly contradicts the important message we convey to our patients, which is that they must be entirely resolved and certain in their decision to terminate their pregnancy before the abortion begins. The Act thus creates a risk that a patient will take mifepristone, and risk terminating her pregnancy, before she is fully decided. The Act simply does not help women make informed decisions.

17. The physicians that work at PPAZ are licensed by both the Arizona Board of Medicine and the Arizona Board of Osteopathic Examiners. Because the penalties for not complying with the law include loss of individual or clinic licensure, the Act puts us and our physicians in the untenable position of either violating our duties to act in the best interest of our patients or losing the ability to continue providing important medical services.

18. While for decades abortion providers have faced targeted harassment and intimidation for doing their jobs, they are also no longer able to provide care to their patients compatible with evidence-based best practices, like physicians in neighboring

states can. This new law, like earlier ones, would only make it harder for us to recruit and retain providers because they would be required to provide their patients with information that they know is not truthful and that is misleading. Requiring this of our providers stigmatizes these professionals and erodes relationships with medical community peers simply for providing a constitutionally protected, legal and safe medical service.

I declare under penalty of perjury that the forgoing is true and correct.

Dated: June 3, 2015

Bryan Howard

Exhibit A

From: **Jodi Liggett** <jliggett@ppaz.org>
Date: Tue, Apr 21, 2015 at 6:19 PM
Subject: correspondence from Planned Parenthood AZ
To: "cory.nelson@azdhs.gov" <cory.nelson@azdhs.gov>
Cc: Bryan Howard <bhoward@ppaz.org>, "Clapman, Alice" <alice.clapman@ppfa.org>, "Rosenfeld, Lawrence J." <lawrence.rosenfeld@squirepb.com>, "Diana.Salgado@ppfa.org" <Diana.Salgado@ppfa.org>

Director Nelson,
Please see attached correspondence from our CEO Bryan Howard.
Let me know if you have any questions; a hard copy will follow via regular mail.
Jodi Liggett

Jodi R. Liggett J.D.
Director of Public Policy
Planned Parenthood Arizona
5651 North 7th Street
Phoenix, AZ 85014
602-263-4226 office
1126 extension
602-481-0403 cell
jliggett@ppaz.org

Planned Parenthood
Care. No matter what.
Planned Parenthood Arizona, Inc.

5651 North 7th Street
Phoenix, AZ 85014-2500

April 21, 2015

Cory Nelson, Interim Director
Arizona Department of Health Services
150 N. 18th Avenue
Phoenix, AZ 85007

Dear Mr. Nelson:

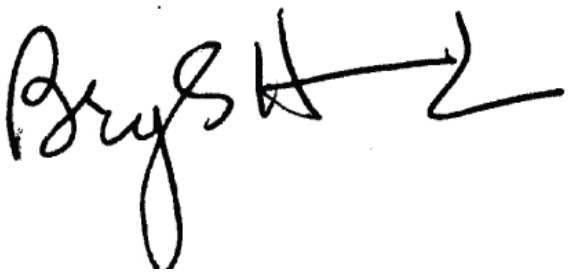
I am writing regarding recently-enacted Arizona S.B. 1318, 52nd Leg., 1st Reg. Sess. (2015), which I understand has an effective date of July 3, 2015.

As I presume you are aware, S.B. 1318 requires abortion providers to inform women prior to having an abortion 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," and that "information on and assistance with reversing the effects of a medication abortion is available on the department of health services' website." S.B. 1318, § 4 (to be codified at Ariz. Rev. Stat. 36-2153(A)(2)(h), (i)). The law also directs the Arizona Department of Health Services to 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." *Id.* (to be codified at Ariz. Rev. Stat. 36-2153(C)(8)).

As an abortion provider impacted by these requirements, Planned Parenthood Arizona is very interested in learning what "information on and assistance with reversing the effects of a medication abortion" the Department will place on its website, and when the content will be available. Given that the law is scheduled to take effect on July 3, I request that you provide Planned Parenthood Arizona with this information no later than Friday, May 22.

If you wish to discuss this, please do not hesitate to contact me at 602-568-3487

Sincerely,



Bryan Howard
President and CEO, Planned Parenthood Arizona

Exhibit B

From: Bryan Howard
Sent: Friday, May 22, 2015 4:28 PM
To: 'wendy.snyder@azdhs.gov'
Subject: FW: correspondence from Planned Parenthood AZ

Dear Ms. Snyder:

Thank you for taking my call to Dr. Christ this afternoon. Below you will find the message that conveyed an electronic copy of my letter back on April 21, 2015. We sent a hard copy as well. I would be grateful if you would bring my call and correspondence to Dr. Christ's attention. I am sure these are busy days for ADHS but, given the short window between now and the implementation date of the statute, I would appreciate it if Dr.Christ would call me next week, i.e., by May 29.

To confirm, I can be reached at (602) 568-3487.

Thank you very much.

Bryan S. Howard
President
Planned Parenthood Arizona, Inc. / Planned Parenthood Advocates of Arizona

---------- Forwarded message ----------
From: **Jodi Liggett** <jliggett@ppaz.org>
Date: Tue, Apr 21, 2015 at 6:19 PM
Subject: correspondence from Planned Parenthood AZ
To: "cory.nelson@azdhs.gov" <cory.nelson@azdhs.gov>
Cc: Bryan Howard <bhoward@ppaz.org>, "Clapman, Alice" <alice.clapman@ppfa.org>, "Rosenfeld, Lawrence J." <lawrence.rosenfeld@squirepb.com>, "Diana.Salgado@ppfa.org" <Diana.Salgado@ppfa.org>

Director Nelson,
Please see attached correspondence from our CEO Bryan Howard.
Let me know if you have any questions; a hard copy will follow via regular mail.
Jodi Liggett

Jodi R. Liggett J.D.
Director of Public Policy
Planned Parenthood Arizona
5651 North 7th Street
Phoenix, AZ 85014
602-263-4226 office
1126 extension
602-481-0403 cell
jliggett@ppaz.org
For more information or to make a donation, visit online at ppaz.org. Care. No Matter What.

Exhibit C

From: "Wendy Snyder" <Wendy.Snyder@azdhs.gov>
To: "Jodi Liggett" <jliggett@ppaz.org>
Cc: "Bryan Howard" <bhoward@ppaz.org>, "Cara Christ" <Cara.Christ@azdhs.gov>
Subject: FW: correspondence from Planned Parenthood AZ

Dear Ms. Liggett: In regards to the attached correspondence, please see the attached response letter from Dr. Cara Christ, Director of the Arizona Department of Health Services. Please let us know if you have any questions.

Wendy Snyder
Executive Assistant to the Director
Arizona Department of Health Services
150 N. 18th Avenue, Suite 500
Phoenix, Arizona 85007
Phone: (602) 542-1140 Fax: (602) 542-1062
wendy.snyder@azdhs.gov<mailto:wendy.snyder@azdhs.gov>
www.azdhs.gov<http://www.azdhs.gov/>

[Description: Description: adhslogo]

~Health and Wellness for all Arizonans ~

From: Bryan Howard [mailto:bhoward@ppaz.org]
Sent: Friday, May 22, 2015 4:28 PM
To: Wendy Snyder
Subject: FW: correspondence from Planned Parenthood AZ

Dear Ms. Snyder:

Thank you for taking my call to Dr. Christ this afternoon. Below you will find the message that conveyed an electronic copy of my letter back on April 21, 2015. We sent a hard copy as well. I would be grateful if you would bring my call and correspondence to Dr. Christ's attention. I am sure these are busy days for ADHS but, given the short window between now and the implementation date of the statute, I would appreciate it if Dr. Christ would call me next week, i.e., by May 29.

To confirm, I can be reached at (602) 568-3487.

Thank you very much.

Bryan S. Howard
President
Planned Parenthood Arizona, Inc. / Planned Parenthood Advocates of Arizona

---------- Forwarded message ----------
From: Jodi Liggett <jliggett@ppaz.org<mailto:jliggett@ppaz.org>>
Date: Tue, Apr 21, 2015 at 6:19 PM
Subject: correspondence from Planned Parenthood AZ
To: "cory.nelson@azdhs.gov<mailto:cory.nelson@azdhs.gov>" <cory.nelson@azdhs.gov<mailto:cory.nelson@azdhs.gov>>
Cc: Bryan Howard <bhoward@ppaz.org<mailto:bhoward@ppaz.org>>, "Clapman, Alice"

<alice.clapman@ppfa.org<mailto:alice.clapman@ppfa.org>>, "Rosenfeld, Lawrence J." <lawrence.rosenfeld@squirepb.com<mailto:lawrence.rosenfeld@squirepb.com>>, "Diana.Salgado@ppfa.org<mailto:Diana.Salgado@ppfa.org>" <Diana.Salgado@ppfa.org<mailto:Diana.Salgado@ppfa.org>>
Director Nelson,
Please see attached correspondence from our CEO Bryan Howard.
Let me know if you have any questions; a hard copy will follow via regular mail.
Jodi Liggett

Jodi R. Liggett J.D.
Director of Public Policy
Planned Parenthood Arizona
5651 North 7th Street
Phoenix, AZ 85014
602-263-4226 office
1126 extension
602-481-0403 cell
jliggett@ppaz.org<mailto:jliggett@ppaz.org>
For more information or to make a donation, visit online atppaz.org<https://urldefense.proofpoint.com/v2/url?u=http-3A__www.ppaz.org_&d=AwMGaQ&c=7xsdzXc1VkZyGw_71SwgiP92fiZryvVSehvDkp0td30&r=y5gT52psTPRDRGIbF8GrUQ-iQtkLoieQBc-eNm1e7FE&m=B5ox1hVW1t3Eg9Ai68zLeO8-zUg0x1WA5J8RcmxEgFY&s=DV7stbfJ5KRllaTsWSup50AbydPhALShcxmRJ2mLDWM&e=>. Care. No Matter What.

Arizona Department of Health Services

Office of the Director

150 N. 18th Avenue, Suite 500
Phoenix, Arizona 85007-3247
(602) 542-1025
(602) 542-0883 FAX
Internet: www.azdhs.gov

DOUGLAS A. DUCEY, GOVERNOR
CARA M. CHIRST, MD, DIRECTOR

June 1, 2015

Mr. Brian Howard, CEO and President
Planned Parenthood Arizona
5651 North 7th Street
Phoenix, Arizona 85014-2500

Dear Mr. Howard:

I am writing in response to your inquiry regarding the recently-enacted Arizona S.B. 1318, 52nd Leg., 1st Reg. Sess. (2015), with an effective date of July 3, 2015.

As you are aware, the bill directs the Arizona Department of Health Services (Department) to post on our 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."

Given the impact of this bill, the Department is still working through the requirements and vetting potential language. The Department will meet the required timeframe of posting by July 3, 2015. We are hoping to have finalized language by June 19, 2015. If the language is completed, we will send it to you so that you have advanced notification of what we are posting.

Please let me know if you have any additional questions.

Sincerely,

C M. Christ MD

Cara Christ, MD
Director

CC:CC:wms

Exhibit 4:

Declaration of Paul A. Isaacson, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc., et al., Plaintiffs, v. Mark Brnovich, Arizona Attorney General, in his official capacity, et al., Defendants.	Civil Action No. _____

DECLARATION OF PAUL A. ISAACSON, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND/OR TEMPORARY RESTRAINING ORDER

PAUL A. ISAACSON, M.D., declares and states the following:

1. I am a Plaintiff in this lawsuit. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction and/or Temporary Restraining Order against enforcement of provisions of Arizona Senate Bill 1318 of 2015, to be codified at Ariz. Rev. Stat. § 36-2153(A)(2)(h), (i) ("the Act").

2. I am a physician licensed to practice medicine in Arizona. I am a board-certified obstetrician and gynecologist. I have provided reproductive health care, including performing abortions and delivering babies, to thousands of women in Arizona over more than twenty years.

3. I am currently a physician at Reproductive Choice Arizona, PLC, doing business as Family Planning Associates Medical Group ("FPA"). FPA is a private medical practice in Phoenix, which I own along with another physician. It is licensed as

an abortion clinic by the Arizona Department of Health Services. At FPA, we provide a variety of services, including gynecological services, family planning, well-woman exams, STD testing, and abortions.

4. Before every medical intervention I provide, my staff and I have a conversation with the patient to obtain the patient's informed consent. I am ethically bound to provide each patient only medical information that is true, is based on my good medical judgment, and is relevant and not misleading in her particular situation. If I tell patients things that are false or misleading, I cannot know if their consent to the intervention is truly informed and voluntary.

5. I am participating in this lawsuit because I do not wish to lie to or mislead my patients, nor do I wish to have my staff lie to or mislead them, as the Act will require us to do. The Act interferes with my ability to ethically care for my patients, who entrust me with their well-being. It is outrageous, it is dangerous, and it is wrong.

My Abortion Patients and Practice

6. Medication abortion is the termination of a pregnancy using only medication. Surgical abortion is the use of instruments to terminate a pregnancy.

7. FPA provides early medication abortion to patients up to 9 weeks since their last menstrual period ("lmp") and surgical abortion prior to viability.

8. For medication abortion procedures, I use an evidence-based regimen involving two medications. A patient takes the first medication, mifepristone, at FPA, and the second medication, misoprostol, 12 to 24 hours later, at home.

9. In simple terms, mifepristone blocks the effect of progesterone, weakening the uterus' ability to sustain a pregnancy. By itself, it terminates a pregnancy in many but not all cases. Misoprostol causes uterine contractions to expel the contents of the uterus. Together, the two medications are effective at terminating an early pregnancy in nearly all cases. A woman's experience with early medication abortion is similar to a miscarriage.

10. Last year, FPA provided approximately 1900 abortions. About 17 percent of our abortion patients chose medication abortion. The rest of our abortion patients had a surgical abortion.

11. Eligible patients choose medication abortion for a variety of reasons. For instance, some patients may choose it because it is a less invasive procedure than surgical abortion, or it feels more natural to them. Other patients may choose it because they can keep the abortion secret from an abusive partner – unlike with surgical abortion, medication abortion patients do not need someone to drive them to and from the clinic. Each woman's choice is personal to her.

12. At least 24 hours before I begin any abortion with a patient, I begin an informed consent process with that patient. Among other things, I discuss with each patient the alternatives available to her, the risks and benefits of various abortion procedures and carrying to term, and what she should expect during and after an abortion. A counselor who works for FPA also meets with the patient as part of the informed consent process.

13. In no part of the informed consent process is it my job to steer patients in

favor of or against having an abortion, or toward having any particular method of abortion. It is my job to make sure that each patient receives all the information necessary so that she can make the right choice for herself.

14. All medical information I discuss with patients is based on medical evidence, my training and experience as a physician, and my best medical judgment. I consider giving patients medical information that is not based on any of these sources to be a form of lying.

15. I do not lie to or mislead my patients because it is unethical.

16. I also do not lie to or mislead my patients because I need them to trust me and to have confidence in me, so that I know their consent is based on a correct understanding of the risks, benefits, and expected outcome of the procedure, and that it is truly voluntary.

The Act and My Practice

17. I have read the Act and am distressed by it. It requires us to inform every woman who comes to FPA for abortion care that "[i]t may be possible to reverse the effects of a medication abortion if [she] changes her mind but that time is of the essence" and that "[i]nformation about and assistance with reversing the effects of a medication abortion is available on the department of health services' website."

18. This is ridiculous. Termination of a pregnancy is never reversible.

19. I am aware of no medical evidence supporting the notion that the effects of mediation abortion are reversible.

20. I am aware of a single case series published in the medical literature in which a handful of physicians claim to have "reversed" the effects of mifepristone in some proportion of a very small number of women through administering high doses of progesterone. Without a control group and a much larger sample size, and knowing more about the women in the study, it is not possible to say that the claimed "reversal" in some women was caused by the progesterone, or whether this data is simply consistent with the fact that mifepristone alone does not terminate a pregnancy a significant percentage of the time. Thus, this case series is not evidence that it is possible to "reverse" mifepristone, and it does not provide information that is relevant for my patients.

21. A case series of this kind is, at most, an idea for potential future research. It does not contain medical information pertinent to my practice as a physician, caring for patients who rely on my medical knowledge and judgment. In no other area of my practice am I required to tell my patients about the purported results of a case series.

22. The Act nevertheless requires me or my counselor to provide information about "reversing" a medication abortion to all our abortion patients. This is very upsetting. It requires us to provide patients information that is not based on medical evidence and is against my medical judgment. It will encourage patients to believe that medication abortion may be reversible, when there is no evidence that this is true.

23. The relationship I have with my patients at FPA is built on trust, which must include patients' understanding that what we tell them is based on facts and on medical judgment and knowledge. Discussing the State's view that medication abortion may be reversible disrupts that trust – it pollutes what must be a frank and honest

conversation with lies and false, misleading information. If we are required to lie to and mislead our patients as the Act demands, I will lose my patients' trust, and the medical information I am trying to convey as their physician will be distorted.

24. Also, I cannot be sure that my patients' consent is informed if we are required to discuss misleading and irrelevant information with them. Some patients may instead feel encouraged to make choices based on the misinformation that the Act says we have to convey, rather than an accurate understanding of the facts.

25. An important aspect of obtaining informed consent from each of my abortion patients is to ensure that each one wants to have an abortion. If a patient says she has doubts, or if she appears uncertain, I tell her she should not go ahead with the abortion – either by starting a surgical or a medical procedure. I tell her she can always come back if and when she is certain of her decision.

26. The Act requires that this important message – to wait to begin the process only when she is sure – be muddied. It requires us to suggest to a woman, before an abortion, that she can change her mind after she starts the process of a medication abortion. But that is wrong: the time to decide is before the beginning of the process. This is particularly important because mifepristone alone may terminate a pregnancy. But it is also important because a patient should never take medication unnecessarily.

27. Even if it were true, the State's message would also be irrelevant for most of my patients. For my patients undergoing abortion procedures after 9 weeks, who are not eligible for medication abortion, the message simply has nothing to do with their choice.

28. In all my years as a physician, I have never seen a law like the Act. It would force us to lie to our patients and endanger their well-being, both of which are completely contrary to my ethics and to my duties as a physician, or face the loss of medical license and my livelihood.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 2nd, 2015

Paul A. Isaacson, M.D.

Exhibit 5:

Declaration of Eric Reuss, M.D., M.P.H.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc., et al., Plaintiffs, v. Mark Brnovich, Arizona Attorney General, in his official capacity, et al., Defendants.	Civil Action No. _____

DECLARATION OF ERIC REUSS, M.D., M.P.H.

ERIC REUSS, M.D., M.P.H., declares and states the following:

1. I am a Plaintiff in this lawsuit. I submit this declaration in support of Plaintiffs' Motion for a Temporary Restraining Order and a Preliminary Injunction against enforcement of portions of Arizona Senate Bill 1318 of 2015 ("SB 1318"), to be codified at A.R.S. § 36-2153(A)(2)(h), (i) ("the Act").

2. I am a physician licensed to practice medicine in Arizona, which I have done for 15 years. I am actively engaged in the practice of obstetrics and gynecology, in which I am board-certified. I have a private, solo, general obstetrics and gynecology practice, Scottsdale Obstetrics & Gynecology, P.C., in Scottsdale, Arizona. I am a

Fellow of the American College of Obstetricians and Gynecologists, Treasurer of that organization's Arizona Section, and immediate past Chair of Obstetrics and Gynecology at Scottsdale Healthcare Osborn. I am participating in this lawsuit in my individual capacity, and not as the representative of any organization.

3. I treat approximately 1100 patients each year. I provide them with the full range of general obstetrics and gynecology care. This includes well-woman care such as screening for gynecological cancer, heart disease and cholesterol; gynecological surgery; basic fertility services; family planning services (contraception); and general health advice.

4. For my pregnant patients wanting to carry to term, I provide prenatal and labor and delivery care. I deliver approximately 150 babies each year. For my patients who wish to terminate pregnancy – because they do not want to have a child, because medical problems arise in the pregnancy, or because they are in the process of losing the pregnancy – I provide abortion care or refer to another provider who does so.

5. For every single medical treatment I provide, I obtain the patient's informed consent. In obtaining that consent, I am ethically bound to impart only information that is truthful, medically sound, and not misleading. Along with providing excellent quality care, that is my highest duty to my patients. Without truthful and non-misleading information in the informed consent dialogue, the patient cannot know the risks, benefits, and expected outcomes of the proposed intervention, and I cannot be confident that she has given informed consent.

6. I am participating in this lawsuit because the Act interferes with and

perverts my duty to my patients. It requires me to mislead my patients, who entrust me with their wellbeing. This is appalling, and it is dangerous.

My Abortion Patients and Practice

7. I provide abortion care for approximately 20 patients each year, making abortion a tiny part of my practice. Nonetheless, it is an important aspect of my practice for those patients desiring it, for whom it is a major medical decision with profound implications.

8. At least half my patients who terminate pregnancy decide to do so after receiving a diagnosis of fetal anomaly, or after suffering medical events that reveal a very poor obstetrical prognosis, including a likelihood or a certainty that the patient will lose the pregnancy, which laypeople sometimes call "miscarriage."

9. My patients who have decided to terminate pregnancy after receiving a diagnosis of fetal anomaly include women who have learned that the fetus has little to no chance of survival because of cystic hygroma with hydrops (too much fluid stored in the lymph sacs); thalassemia major (a severe disorder of the red blood cells); and renal agenesis (the lack of kidneys).

10. My patients who wanted to be pregnant but then decide to terminate include both women who could try to remain pregnant even in the face of a very poor obstetrical prognosis, and women who are sure to lose the pregnancy. For example, I have had patients whose membranes ruptured and who lost all the amniotic fluid at 18-19 weeks. Under the care of a perinatologist (a high-risk obstetrician-gynecologist), such women

sometimes try to maintain the pregnancy, knowing that they are likely to lose it and/or that the effect on the fetus is likely severe or even fatal. Other women in these circumstances, including some of my patients, decide to end the pregnancy through induced abortion. Yet other of my abortion patients have had ruptured membranes and/or infection at 17 weeks, and no hope of maintaining the pregnancy.

11. For approximately half my abortion patients, I provide early medication abortion through 9 weeks LMP (9 weeks as measured from the first day of the woman's last menstrual period). For these procedures, I use the most common, evidence-based mifepristone-misoprostol regimen, which has been endorsed by the American College of Obstetricians and Gynecologists. The first medication, mifepristone, often causes embryonic demise, and is more likely to do so earlier in pregnancy. The second medication, misoprostol, causes uterine contractions, so that the woman undergoes an experience much like an early spontaneous abortion, or "miscarriage," in lay terms. At this early point in pregnancy, either mifepristone or misoprostol alone may terminate a pregnancy, but the most effective regimen combines the two medications in this way.

12. The remainder of my abortion patients choose one of the following procedures:

a) Second trimester induction abortion, which induces labor using misoprostol to cause uterine contractions. Like the early mifepristone-misoprostol regimen I use earlier in pregnancy, this method relies entirely on medications.

b) A surgical procedure, in which the physician empties the uterus. In my

practice, I use the vacuum aspiration method through 12 weeks. This method relies on suction to empty the uterus. From 13 to 15 weeks, I use the dilation and evacuation (D&E) method, in which the physician dilates (opens) the cervix and then empties the uterus using suction and instruments.

13. It is important for my patients to have truthful and relevant information on which to base the decision of which of these procedures to undergo because each option provides a different set of risks and benefits that may or may not affect the decision of the patient. It is part of my job as a physician to give unbiased information so that my patient can decide which procedure is best for her – whether the care she seeks is abortion or any other aspect of obstetrical and gynecological care.

The Act and My Practice

14. I have read the Act, and I am troubled. It requires me to inform each woman who comes to me for abortion care – including those getting surgical abortions – that "[i]t may be possible to reverse the effects of a medication abortion if" the patient changes "her mind but that time is of the essence" and that "[i]nformation on and assistance with reversing the effects of a medication abortion is available on the department of health services' website."

15. I am not aware of any claims, let alone any scientific evidence, that the effects of any "medication abortion" are reversible, whether the most common form (the mifepristone-misoprostol regimen) or the form I use in the second trimester (induction

using misoprostol).

16. Rather, I am aware that a handful of physicians claim to have reversed the effects not of the mifepristone-misoprostol medication abortion regimen, but of the first drug in that regimen, mifepristone. Mifepristone works by blocking the pregnancy hormone progesterone. These physicians claim to have reversed this action by administering high-dose injections of progesterone to women who have not yet taken the second drug in the regimen (misoprostol). But there is no evidence that the women who had ongoing pregnancies after such injections did so because of the injections, rather than because they were among the women for whom the mifepristone alone was simply not effective. (Indeed, mifepristone is prescribed in combination with misoprostol precisely because it is not highly effective on its own.)

17. Thus, as to my patients getting the mifepristone-misoprostol regimen, the Act's required disclosures about reversing "medication abortion" are inaccurate and misleading. No one even claims that the mifepristone-misoprostol medication abortion regimen itself is reversible, and the claims about progesterone injections after mifepristone are not supported by scientific evidence.

18. Moreover, the Act requires every one of my patients seeking abortion care to receive this information, including patients who cannot have or do not wish to have a mifepristone-misoprostol medication abortion. Informing a patient getting a surgical abortion that a medication abortion is reversible can only confuse the informed consent discussion. It is similarly harmful to mandate giving this information to women getting induction abortions, which no one – not even the physicians experimenting with

progesterone after mifepristone – claims may be reversible.

19. Thus, to tell a patient that a physician may be able "to reverse the effects of a medication abortion" is to mislead or even to lie within the context of obtaining informed consent, which I would never do to any patient, whether she seeks well-woman care, abortion care, prenatal and delivery care, or any other care I provide. I cannot think of a greater disservice to my patients.

20. In addition, making these false statements could recklessly encourage patients to initiate abortion procedures without making a truly final decision. As with all my patients, my duty with an abortion patient is to make sure she understands that she must be certain in her decision *before* I begin the procedure. In the context of medication abortion, that means she must be sure before I take the first step – of administering mifepristone in an early mifepristone-misoprostol procedure, or of administering misoprostol in an induction abortion – because that first step alone can end the pregnancy. It would therefore be unethical to suggest to a woman before she starts an abortion that her time to change her mind lasts after the procedure has begun. By requiring me to give inaccurate information, the Act forces me to violate my duty to act in the best interests of my patients.

21. The Act forces me either to violate my duty by misleading my patients, or to face license suspension, license revocation, and civil suits – in other words, loss of my livelihood and of the profession to which I have devoted my life. This is morally objectionable. The Act, which lacks medical foundation, threatens my ethical provision of medical care and my patients' wellbeing.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 21, 2015

Eric Reuss, M.D., M.P.H.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Planned Parenthood Arizona, Inc., et al.,

Plaintiffs,

v.

Mark Brnovich, Arizona Attorney General, in his official capacity, et al.,

Defendants.

Civil Action No. _____

[PROPOSED] ORDER TO SHOW CAUSE

This matter having come before the Court, and the Court having received papers from Plaintiffs to obtain a temporary restraining order and/or preliminary injunction issued pursuant to Rule 65(b) of the Federal Rules of Civil Procedure, and the Court having considered the pleadings and supporting papers herein,

IT IS HEREBY ORDERED that the Defendants shall appear on the ___ day of _____, 2015 at __:___ a.m./p.m. to show cause, if any exists, as to why a temporary restraining order and/or preliminary injunction should not be issued in this matter as set forth in Plaintiffs' Motion for Temporary Restraining Order and/or Preliminary Injunction.