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

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Exhibit 1:
Declaration of Courtney Schreiber, M.D., M.P.H.
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

followed by misoprostol is endorsed by ACOG. 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). To date, more than two million women have used this method in the United States.

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. Mifepristone binds preferentially to progesterone receptors in the uterus.

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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).
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.\textsuperscript{6}

Mifepristone also triggers the release of endogenous prostaglandins (which can cause uterine contractions),\textsuperscript{7} softens and opens the cervix,\textsuperscript{8} and increases uterine contractility (capacity to contract).\textsuperscript{9} Mifepristone is quickly absorbed, reaching peak concentrations in the blood about one to two hours after it is ingested.\textsuperscript{10} Its initial elimination is slow for the first 72 hours, then increasingly rapid.\textsuperscript{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.\textsuperscript{12} Subsequent research showed that the combination of mifepristone and a prostaglandin (misoprostol) work synergistically to terminate an early pregnancy with high efficacy.\textsuperscript{13}

\textsuperscript{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 Antiprogesterin 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).

\textsuperscript{7} Couzin et al., supra n.5, at 1568; Remi Peyron et al., Early Termination of Pregnancy with Mifepristone (RU486) and the Orally Active Prostaglandin Misoprostol, 328 N. Eng. J. Med. 1509, 1509 (1993).

\textsuperscript{8} Couzin et al., supra n.5, at 1568; Fiala & Gemzel-Danielsson, supra n.6, at 76.

\textsuperscript{9} Couzin 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.

\textsuperscript{10} Heikinheimo et al., supra n.6, at 422; Sarkar, supra n.5, at 114; Fiala & Gemzel-Danielsson, supra n.6, at 68.

\textsuperscript{11} Sarkar, supra n.5, at 115.

\textsuperscript{12} See, e.g., infra n.17.

\textsuperscript{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, \(^\text{14}\) 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;\(^\text{15}\) 3) nearly all of these studies involved higher doses of mifepristone than those currently used by most clinicians;\(^\text{16}\) 4) more recent studies describe the efficacy of mifepristone only when

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\(^\text{14}\) Fiala & Gemzel-Danielsson, supra n.6, at 66; Couzinet et al., supra n.5, at 1568.
\(^\text{15}\) 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).
\(^\text{16}\) 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.\textsuperscript{17} And data from trials of the mifepristone/misoprostol suggest that this proportion increases as gestational age increases.\textsuperscript{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

\textsuperscript{18} Beverly Winikoff et al., \textit{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. 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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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.” 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
g 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. 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

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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. 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. 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

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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.

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. 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.

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

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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. It also states that progesterone injections “counteract[] the effects of the mifepristone and can help you continue to have a healthy, developing pregnancy.” 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

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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


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. 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.\textsuperscript{35}

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.\textsuperscript{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.”\textsuperscript{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.”\textsuperscript{38}

\textsuperscript{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, \textit{available at} http://www.sagepub.com/upm-data/68162_AOP_Author_Guidelines.pdf (stating that the journal requires “[i]ndication if Institutional Review Board or other ethical considerations were needed and/or approved).


\textsuperscript{37} \textit{Id.} at 1591.

\textsuperscript{38} \textit{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

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 physician 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
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 Pregnancy 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)


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"
Courtney Anne Schreiber, MD, MPH

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


Lectures by Invitation:

Mar, 2004 Instructor, Early pregnancy ultrasound course, Planned Parenthood, Philadelphia, PA: "Introduction to Ultrasound"


Jul, 2004 Speaker, Pennslyvania 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"
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"
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
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)
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
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.
Nov, 2014  "Individualized Care of Early Pregnancy Loss" Washington University Department of Obstetrics and Gynecology, St Louis, Mo.
Jan, 2015  "Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Pennsylvania 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:


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):


Research Publications, peer-reviewed reviews:


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


Abstracts:


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.


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


Editorials, Reviews, Chapters, including participation in committee reports (print or other media):


Exhibit B
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 α₄-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-
tone and its metabolites can be measured up to 72 hours after an ingested dose.\textsuperscript{9} The half-life of progesterone is longer, approximately 25-55.13 hours.\textsuperscript{10-13}

**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.\textsuperscript{14} Later trials evaluated mifepristone 200 mg.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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\textsuperscript{a}

<table>
<thead>
<tr>
<th>Day</th>
<th>Progesterone 200 mg Intramuscularly</th>
<th>Ultrasound to Confirm Viability</th>
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<tbody>
<tr>
<td>1</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>2</td>
<td>X</td>
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<tr>
<td>3</td>
<td>X</td>
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<td>5</td>
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<td>X</td>
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<td>9</td>
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<tr>
<td>11</td>
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<td></td>
</tr>
<tr>
<td>13</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>16*</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

*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.\textsuperscript{19,20}

We thank the physicians who provided patient data for this case series: Jean Tevald Golden DO, Jonnalyn Belocura MD, Matthew Harrison MD, and Dara Welborn MD.

References

Exhibit C
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.                                               Civil Action No. 1

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

Defendants.

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. 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

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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 "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."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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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 if they had 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).

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

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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. 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. In addition, as the authors of the case series

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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 \textit{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 statistician associated with the project. As more women receive this therapy, the results will continue to be reported in the medical literature.

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\(^{8}\) Delgado & Davenport, \textit{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, \textit{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, \textit{supra} note 6 ("In an email, Delgado said that...institutional review board is not required to follow cases"); Sisson, \textit{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.\textsuperscript{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.

\textsuperscript{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 evidence-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

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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
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
1997-2010 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
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:
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:

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<th>Year Range</th>
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<tr>
<td>2005-2013</td>
<td>Editorial Board Member, Journal of Clinical Oncology</td>
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<tr>
<td>2005-2009</td>
<td>Editorial Board Member, Critical Reviews of Oncology and Hematology</td>
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Academic and Institutional Committees:

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

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<tr>
<td>2000-2003</td>
<td>Attending Physician, Pediatric Oncology, Jimmy Fund Clinic, Dana-Farber Cancer Institute (4 Fellows for 100 hours every year)</td>
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<tr>
<td>2000-2002</td>
<td>Attending Physician for Inpatient Oncology Service, Children's Hospital Boston (6 Fellows and 4 Residents for 200 hours every year)</td>
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<td>2002-2013</td>
<td>Attending Physician for Hematopoietic Stem Cell Transplant Service, Children's Hospital Boston (6 Fellows and 2 Residents for 150 hours every year)</td>
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<tr>
<td>2003-2012</td>
<td>Attending Physician, Pediatric Stem Cell Transplant Outpatient Service, Dana-Farber Cancer Institute (3-4 Fellows for 200 hours every year)</td>
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<td>2003-2011</td>
<td>Case-Based Ethical Dilemmas, Practical Aspects of Palliative Care, Harvard Medical School (CME Single Presentation every year)</td>
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<td>2008-2012</td>
<td>Medical Ethics and Professionalism Course for first-year medical students (one 2 hour session per week for 14 weeks)</td>
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<td>2008</td>
<td>&quot;Therapeutic Innovation or Research&quot; - Seminar, June 2008, Harvard School of Public Health</td>
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<td>2008</td>
<td>&quot;Ethics of research with human subjects&quot; - Seminar, June 2008, Harvard Medical School</td>
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<td>2008</td>
<td>&quot;Informed consent to treatment and research&quot; - Seminar, October 2008, Division of Medical Ethics, Harvard Medical School</td>
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<td>2009</td>
<td>&quot;The ethical conundrum of incidental findings in clinical &amp; translational research&quot; - Lecture, June 2009, Harvard Catalyst Colloquium Series</td>
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<td>2009</td>
<td>&quot;Informed consent to treatment and research&quot; - Seminar, September 2009, Division of Medical Ethics, Harvard Medical School</td>
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<td>2009</td>
<td>&quot;Conflict of Interest in Biomedical Research&quot; - Seminar, October 2009, Longitudinal Clinical Research Seminar/Bioethics Module, ME 731.0a, Scholars in Clinical Science Program, Harvard Medical School</td>
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<td>2009</td>
<td>&quot;Ethics and professional integrity in clinical and translational research&quot; - Seminar, October 2009, Clinical Investigator Training Program, Harvard Medical School</td>
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<td>2009</td>
<td>&quot;At the point of the spear: ethical and scientific challenges in translational trials&quot; - Lecturer, November 2009, Introduction to Clinical Investigation Course, Harvard Catalyst</td>
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<td>&quot;Cancer patients' attitudes towards stored tissue research: outcomes and value of a factorial survey&quot; - Lecture, January 2010, Harvard Pediatric Health Services Research Fellowship Program</td>
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<td>2010</td>
<td>&quot;Ethics in clinical research&quot; - March 2010, Department of Medicine Residency Program, Children's Hospital Boston</td>
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<td>2010</td>
<td>&quot;The scientist as a responsible member of society&quot; - June 2010, Responsible Conduct of Research Course, Dana-Farber Cancer Institute</td>
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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  "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  "Informed consent to research" - Lecture, April 2011, Training Session for Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute


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
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<th>Year</th>
<th>Title</th>
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<tr>
<td>2011</td>
<td>&quot;Informed consent, subject selection and recruitment&quot; - Lecture,</td>
<td>September 2011, Scholars in Clinical Science Program, Harvard Medical School</td>
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<td>&quot;Conflicts of interest&quot; - Lecture, September 2011, Scholars in</td>
<td>Clinical Science Program, Harvard Medical School</td>
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<td>&quot;Informed consent to treatment and research&quot; - Lecture, October</td>
<td>2011, Ethics Fellowship, Harvard Medical School</td>
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<td>October 2011, Clinical Investigator Seminar, Dana-Farber Cancer</td>
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<td>&quot;Ethics in clinic research&quot; - Lecture, October 2011, Clinical</td>
<td>Investigator Seminar, Dana-Farber Cancer Institute</td>
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<td>&quot;Children's capacity to participate in research decisions&quot; - Lecture,</td>
<td>January 2012, Department of Medicine Grand Rounds, Children's Hospital Boston</td>
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<td></td>
<td>&quot;Ethics &amp; professional integrity in clinical and translational</td>
<td>research&quot; - Lecture, January 2012, Clinical Investigator Training Program, Harvard Medical School</td>
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<td>&quot;The scientist as a responsible member of society&quot; - Lecture, March</td>
<td>2012, Responsible Conduct of Research Course, Dana-Farber Cancer Institute</td>
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<td>&quot;Responsible conduct of research&quot; - Lecture, May 2012, Pediatric</td>
<td>Health Services Research Fellowship, Children's Hospital Boston</td>
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<td>&quot;Informed consent, subject selection and recruitment&quot; - Lecture,</td>
<td>September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS</td>
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<td>&quot;Ethics and integrity in clinical research&quot; - Lecture, September</td>
<td>2012, Introduction to Clinical Research Course, Children's Hospital Boston</td>
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<td>2012</td>
<td>&quot;Conflict of interest&quot; - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS</td>
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<td>&quot;Informed consent to treatment and research&quot; - Lecture, October</td>
<td>2012, Ethics Fellowship, Harvard Medical School</td>
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<td>October 2012, Ethics Fellowship, Harvard Medical School</td>
<td>&quot;Evaluating the Ethics of Clinical &amp; Translational Research&quot; - Lecture, October 2013, Pediatric Translational Research Workshop for Basic Scientists, Children's Hospital of Philadelphia</td>
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<td>&quot;Ethics in Biomedical Research,&quot; Guest Lecture, Health Policy and</td>
<td>Research Methods I</td>
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<td>Research Methods I</td>
<td>Course Director, BIOE701, &quot;Bioethics Proseminar&quot;</td>
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<td></td>
<td>&quot;Evaluating Informed Consent for Clinical Research&quot; - Lecture,</td>
<td>EPI690, University of Pennsylvania</td>
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<td></td>
<td>&quot;Mandate or Millstone? The Ethical Challenge of Genomic Incidental</td>
<td>Findings,&quot; Ellen Hyman-Browne Memorial Lecture, October 2014, Children's Hospital of Philadelphia</td>
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</table>
2014 "Evaluating the Ethics of Clinical Research" - How to Be An Academic Radiologist, Department of Radiology, University of Pennsylvania Perelman School of Medicine
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
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, Washington
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
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<th>Date</th>
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<tr>
<td>Dec, 2011</td>
<td>&quot;A Great Debate: Be it resolved that clinical equipoise should determine whether it is ethical to randomize subjects between two treatments&quot; Annual Meeting, Public Responsibility in Medicine and Research, National Harbor, Maryland</td>
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<td>Dec, 2011</td>
<td>&quot;Children's Capacity to Participate in Research Decisions&quot; Annual Meeting, Public Responsibility in Medicine and Research, National Harbor, Maryland</td>
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<tr>
<td>Jan, 2012</td>
<td>&quot;Children's Capacity to Participate in Research Decisions&quot; Dr. Jennifer Ann Kierson Memorial Pediatric Grand Rounds, Herman and Walter Samuelson Children's Hospital at Sinai, Baltimore, Maryland</td>
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<tr>
<td>Feb, 2012</td>
<td>&quot;Are Investigators Obligated to Ensure Understanding?&quot; &quot;Rethinking the Ethics of Clinical Research,&quot; Symposium in Honor of Alan Wertheimer, Trent Center for Bioethics, Duke University</td>
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<td>Mar, 2012</td>
<td>&quot;Children's Capacity to Participate in Research Decisions&quot; Pediatric Oncology Grand Rounds, MD Anderson Cancer Center, Houston, Texas</td>
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<tr>
<td>May, 2012</td>
<td>&quot;Benefit-risk Assessment and Informed Consent in Clinical Research&quot; Institute for History and Ethics of Medicine and National Center for Tumor Diseases, Faculty of Medicine, University of Heidelberg, Germany</td>
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<td>May, 2012</td>
<td>&quot;Frequency and Effects of Conflicts of Interest in Clinical Trials&quot; Institute for History and Ethics of Medicine and National Center for Tumor Diseases, Faculty of Medicine, University of Heidelberg, Germany</td>
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<td>Jun, 2012</td>
<td>&quot;Children's Capacity to Participate in Research Decisions&quot; Child Health Evaluative Services Rounds, Hospital for Sick Children, Toronto, Canada</td>
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<td>Jul, 2012</td>
<td>&quot;Whither the Children? The classic dilemma of pediatric clinical research&quot; Donovan Memorial Research Ethics Lecture, St. Agnes Hospital, Baltimore, Maryland</td>
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<td>Oct, 2012</td>
<td>&quot;Integrating Genomic Sequencing Into Cancer Care: Clinical &amp; Ethical Challenges&quot; Medical Oncology Grand Rounds, IWK Health Centre, Dalhousie University, Halifax, Nova Scotia, Canada</td>
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<td>Oct, 2012</td>
<td>&quot;Children's Capacity to Participate in Research Decisions&quot; Department of Pediatrics Grand Rounds, IWK Health Centre, Dalhousie University, Halifax, Nova Scotia, Canada</td>
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<td>Dec, 2012</td>
<td>&quot;Framing the Protections for Children in Research&quot; Public Responsibility in Medicine &amp; Research Annual Conference, San Diego, CA</td>
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<td>Dec, 2012</td>
<td>&quot;Regulatory Requirements and Ethical Considerations Regarding Pediatric Assent in Research&quot;</td>
<td>Public Responsibility in Medicine &amp; Research Annual Conference, San Diego, CA</td>
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<td>Feb, 2013</td>
<td>&quot;The Patient-Doctor Relationship&quot;</td>
<td>Department of Bioethics Fellows Seminar, National Institutes of Health</td>
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<tr>
<td>Apr, 2013</td>
<td>&quot;Children's capacity to participate in research decisions&quot;</td>
<td>Department of Pediatrics Grand Rounds, Connecticut Children's Medical Center, Hartford, CT</td>
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<td>Sep, 2013</td>
<td>&quot;Involving Children in Decisions about Research&quot;</td>
<td>Achieving Excellence in Clinical Research, Advocate Health Care, Oak Brook, IL</td>
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<td>Oct, 2013</td>
<td>&quot;Clarifying risks and benefits in transplant clinical trials&quot;</td>
<td>National Marrow Donor Program Council Meeting Plenary, Minneapolis, MN</td>
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<td>Oct, 2013</td>
<td>&quot;Conflicts of Interest&quot;</td>
<td>Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, MD</td>
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<td>Nov, 2013</td>
<td>&quot;Returning Genetic Results from Biobank Research: A Reality-Based Perspective&quot;</td>
<td>Returning Genetic Results in Biobanks: Opening an International Dialogue, Brocher Institute, Hermance, Switzerland</td>
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<tr>
<td>Nov, 2013</td>
<td>&quot;Framing the protections for children in research&quot;</td>
<td>Public Responsibility in Medicine &amp; Research (PRIM&amp;R) Annual Meeting, Boston, MA</td>
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<td>Nov, 2013</td>
<td>&quot;Children's capacity to make research decisions&quot;</td>
<td>Public Responsibility in Medicine &amp; Research (PRIM&amp;R), Boston, MA</td>
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<td>Nov, 2013</td>
<td>&quot;A pediatric perspective on biobank research&quot;</td>
<td>Public Responsibility in Medicine &amp; Research (PRIM&amp;R), Boston, MA</td>
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<td>Feb, 2014</td>
<td>&quot;The Patient-Doctor Relationship&quot;</td>
<td>Committee on National Statistics, National Academies of Sciences, Washington, DC</td>
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<td>Apr, 2014</td>
<td>&quot;Attitudes Towards Return of Incidental Genetic Findings Among Participants in the Jackson and Framingham Heart Studies&quot;</td>
<td>Genetics Research Seminar, Dana-Farber Cancer Institute, Boston MA</td>
</tr>
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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:
Orlanda, Florida

Nashville, Tennessee

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

Baltimore, MD

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


Research Publications, peer-reviewed reviews:
[none]

Contributions to peer-reviewed research publications, participation cited but not by authorship:
[none]

Research Publications, non-peer reviewed:
[none]

Abstracts (Last 3 years):

Editorials, Reviews, Chapters, including participation in committee reports (print or other media):


7. Abel GA, Penson RT, Joffe S, Schapira L, Chabner BA, Lynch TJ. : Direct-to-


9. Joffe S, Truog RD, Shurin S, Emanuel EJ. : Ethical Considerations in Pediatric
Oncology. Principles and Practice of Pediatric Oncology. Philadelphia, PA:

10. Joffe S. : Altruistic Discourse and Therapeutic Misconception in Research Informed


12. Schneider KA, Chittenden AB, Branda KJ, Branda KJ, Keenan MA, Joffe S,
Patenaude AF, Reynolds H, Dent K, Eubanks S, Goldman J, Leroy B, Warren NS,
Taylor K, Vockley CW, Garber JE. : Ethical Issues in Cancer Genetics: 1) Whose

13. Ungar D, Joffe S, Kodish E. : Children are Not Small Adults: Documentation of

Ethics. Emanuel EJ, Grady C, Crouch RA, Lie RK, Miller FG, Wendler D. (eds.).


16. Lipton J, Joffe S, Ullrich NJ. : CNS Relapse of Myelogenous Leukemia

Principles and Practice of Pediatric Oncology. Pizzo, PA and Poplack, DG (eds.).

The Ethics of Consent: Theory and Practice, Miller FG, Wertheimer A. (eds.).


Books:
[none]

Alternative Media:
[none]

Patents:
[none]
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 PLAINITIFFS’
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
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.

This e-mail is for the sole use of the intended recipients and contains information belonging to Planned Parenthood Arizona, which is confidential and/or legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance on the contents of this e-mail information is strictly prohibited. If you have received this e-mail in error, please immediately notify the sender by reply e-mail and destroy all copies of the original message.
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
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
Exhibit C
Dear Ms. Snyder:

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

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

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---------- 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"
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
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For more information or to make a donation, visit online at ppaz.org

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June 1, 2015

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

Dear Mr. Howard:


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,

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  
is 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  

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
diversity 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
corneration 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 medication 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.

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.