IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

TULSA WOMEN'S REPRODUCTIVE CLINIC, LLC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D.,

Plaintiffs,

v.

MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, DENNIS CARTER, in his official capacity as President of the Oklahoma State Board of Osteopathic Examiners, and TOM BATES, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors,

Defendants.

CASE NO. CV-2019-2176

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION

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INTRODUCTION

The Oklahoma Constitution contains broad protections for free speech, more extensive even than those emanating from the First Amendment of the Constitution of the United States. The right to free speech protects physicians against laws that compel them to speak against their will, particularly when the government seeks to compel controversial speech that threatens the public's health. In direct contravention of Oklahoma's guarantee of free speech and physicians' legal and ethical duties to their patients, Oklahoma Senate Bill 614 ("S.B. 614") forces physicians to act as the mouthpiece for a government-scripted message. Specifically, S.B. 614 forces physicians to endorse abortion pill "reversal," a controversial, unproven theory that is not based in evidence and has been rejected by major medical organizations. S.B. 614 also forces physicians to inform patients about the Abortion Pill Reversal hotline and website, which connect patients with "healthcare professionals" who provide abortion "reversal" treatments that are, at best, experimental, and at worst, detrimental to patients' health. Knowing or reckless failure to comply with S.B. 614 is punishable as a felony.

Tulsa Women's Reproductive Clinic, LLC and Dr. Alan Braid (collectively "Plaintiffs") represent abortion providers who strongly object to S.B. 614 because it compels them to speak controversial messages with which they disagree, forces them to violate their ethical obligations to their patients, and makes them expose their patients to potential harm.

Earlier this month, the United States District Court for the District of North Dakota enjoined a law similar to S.B. 614, concluding that "[a] law which mandates that physicians become mouthpieces for a false, misleading, and controversial 'abortion reversal' message would not survive any level of constitutional scrutiny." S.B. 614 does exactly this, and likewise fails constitutional review.

Plaintiffs seek a temporary injunction to preserve the status quo and prevent irreparable harm to their constitutional rights. ***Plaintiffs respectfully request the Court to act by S.B. 614's effective date of November 1, 2019.***

STATEMENT OF FACTS

I. Plaintiffs' Provision of Abortion Services in Oklahoma

Tulsa Women's Reproductive Clinic, LLC (the "Clinic") is one of four licensed facilities providing abortion services in Oklahoma. Dr. Alan Braid is the Clinic's principal owner. Affidavit of Alan Braid, M.D. (attached hereto as Ex. 1) ("Braid Aff.") ¶ 1. Dr. Braid, along with the Clinic's three other licensed physicians, provides high quality abortion care to patients primarily from Oklahoma, as well as from Kansas, Arkansas, Missouri, and Texas. Braid Aff. ¶ 4. Approximately 30% of the Clinic's patients receive surgical abortions (*i.e.* abortions that involve the introduction of instruments into the patient's uterus), while 70% receive medication abortions (abortions that are induced through the administration of oral medications). Braid Aff. ¶ 7.

The Clinic uses an evidence-based regimen approved by the Food and Drug Administration ("FDA") for medication abortion up to 10 weeks' pregnancy (measured from the first day of a patient's last menstrual period). Braid Aff. ¶¶ 4, 8. Under this regimen, patients take a combination of two medications: mifepristone at the Clinic, followed 24 to 48 hours later by misoprostol taken at a location of the patient's choosing, usually the patient's home. Braid Aff. ¶ 8. Mifepristone stops the pregnancy from progressing by blocking progesterone receptors, but, if taken alone, it fails to terminate a pregnancy up to 46% of the time. Declaration of Courtney A. Schreiber, M.D., M.P.H. (attached hereto as Ex. 2) ("Schreiber Decl.") ¶¶ 15, 17. Misoprostol works in conjunction with mifepristone to cause uterine contractions to expel the pregnancy from the uterus. Braid Aff. ¶ 8; Schreiber Decl. ¶ 16. When the two drugs are used together, as outlined by the FDA label, the

success rate in the United States for medication abortion is 97.4%. Schreiber Decl.¶ 13; Braid Aff. ¶ 9.

The Clinic typically provides abortion care six days per week. Braid Aff. ¶ 4. At least 72 hours before a patient's abortion, the Clinic's physicians or Clinic staff designated to act as their agents (together, "Physicians") provide the patient with the information currently required under state law—including the risks, benefits, and alternatives to abortion, and information about available resources.[1] Braid Aff. ¶ 11. When patients arrive at the Clinic for their procedure, they undergo an ultrasound and receive counseling on the risks, benefits, and alternative to abortion, available resources, and the types of abortion procedures for which they are eligible. Braid Aff. ¶ 12. No abortion procedure begins until the patient has reviewed all of her options; received relevant, evidence-based information about the procedure she has chosen; provided informed consent to that procedure; and confirmed to the physician that she is confident in her decision to end her pregnancy. Braid Aff. ¶¶ 12, 13. While the vast majority of patients are sure of their decision before receiving counseling, in the rare instance that a patient is unsure, the Clinic's physicians will not provide an abortion (including administering mifepristone) unless and until the patient is firm in her decision to end her pregnancy. Braid Aff. ¶ 13.

[1] *See* 63 O.S. § 1-738.2 (requiring the physician or the physician's agent to discuss certain information with patients at least 72 hours before an abortion, including information unrelated to the process of consenting to the procedure—such as that "medical assistance benefits may be available for prenatal care, childbirth, and neonatal care" and "that the father is liable to assist in the support of her child."); 63 O.S. § 1-738.3 (requiring the physician to offer the patient printed materials about pregnancy, and the "private and public agencies" that assist pregnant individuals); 63 O.S. § 1-745.14 (requiring the physician to inform patients who are eight weeks pregnant or more that it may be possible to hear fetal cardiac activity on a fetal heart rate monitor). A violation of these laws subjects physicians to civil and criminal liability, as well disciplinary action by their state licensing board. 63 O.S. § 1-745.16; 63 O.S. § 1-738.3f; 63 O.S. § 1-738.5.

II. Impact of S.B. 614 on Physicians

S.B. 614 compels Physicians to inform their patients, orally and in writing, on multiple occasions, of an unproven, experimental, and potentially unsafe medical treatment. In addition to the other information Physicians must provide patients before providing abortion care, S.B. 614 requires Physicians, at least 72 hours before providing a medication abortion, to inform the patient that "it may be possible to reverse the intended effects of a medication abortion that uses mifepristone if the woman changes her mind but that time is of the essence," and that "information on reversing the effects of a medication abortion" is available on the State Board of Medical Licensure and Supervision website.[2] S.B. 614 § 1(C)(1)(a)–(b). Physicians must also inform patients, directly or indirectly, of the "Abortion Pill Reversal" ("APR") 24-hour hotline and website, both of which are operated by an anti-abortion organization that refers patients to a network of healthcare providers (the "Abortion Pill Rescue Network" or "APRN") who offer medication abortion "reversal" services.[3] S.B. 614 § 1(C)(1)(b).

Additionally, after providing mifepristone to the patient, S.B. 614 further compels Physicians to give patients government-drafted written "instructions" informing them that "Mifepristone . . . is not always effective in ending a pregnancy. It may be possible to reverse its intended effects" and that the patient may "get immediate help by calling the Abortion Pill

[2] S.B. 614 requires the Oklahoma State Board of Medical Licensure and Supervision to publish materials in print and on their website that inform medication abortion patients about the "possibility" of reversing medication abortion using mifepristone. The website must include the APR hotline number and website address. S.B. 614 §1(E).

[3] Abortion Pill Reversal or Abortion Pill Rescue ("APR") is an organization that connects patients seeking medication abortion "reversal" with the Abortion Pill Rescue Network ("APRN"). APRN includes "more than 800 professional healthcare providers" who will provide abortion pill "reversal" services to patients, including administering progesterone. APR is a program of Heartbeat International, an anti-abortion organization that primarily runs crisis pregnancy centers. *See generally* Abortion Pill Rescue, *About Us*, https://abortionpillreversal.com/about/our-team (last visited Sept. 20, 2019); Heartbeat International, *Our Passion*, https://www.heartbeatinternational.org/about/our-passion (last visited Sept. 20, 2019).

Reversal 24-hour Hotline" or by visiting the APR website. S.B. 614 § 1(C)(2). The same government-drafted script must be "conspicuously" displayed in each waiting room and consultation room used by medication abortion patients, in ¾ inch (*i.e.* 54 point) font. S.B. 614 § 1(B)(1).[4]

Physicians who knowingly or recklessly provide, induce, or attempt to provide an abortion in violation of S.B. 614 are subject to felony charges and civil liability. S.B. 614 § 1(F), (H). A failure to post the government-drafted script results in a $10,000 fine against the facility for each day on which the signage is not posted. S.B. 614 § 1(G).

III. The Scientifically Unsupported Abortion "Reversal" Theory

As explained fully in the attached declaration from Dr. Courtney Schreiber, no credible, scientific evidence supports the theory that mifepristone can be "reversed." Schreiber Decl. ¶¶ 20–30, 38; *see* Braid Aff. ¶ 21. This unfounded theory originates from two physicians, Drs. George Delgado and Mary Davenport, who have posited that administering high doses of progesterone after the patient has taken mifepristone, but before she has taken misoprostol, can counteract mifepristone's effects and stop the medication abortion. Schreiber Decl. ¶ 19. However, there is no credible, scientific evidence that if a patient takes mifepristone alone, subsequent progesterone treatments result in a higher rate of continued pregnancy than simply doing nothing.

Delgado and Davenport's theory of "reversal" is described in two flawed and ethically problematic papers published in 2012 and 2018. Delgado and Davenport's 2012 paper describes seven patients and their 2018 paper discusses 754 patients who ingested mifepristone (but not misoprostol) and were then administered progesterone by a variety of providers. Serious methodological problems abound in both papers. Exs. B and C to Schreiber Decl. Neither was

[4] An example of the script printed in the required font size is attached hereto as Exhibit 4.

published in a respected, peer-reviewed journal, and neither appears to have obtained the proper vetting for ethical research. Schreiber Decl. ¶ 23, 31. Critically, neither paper used a control group comparing progesterone treatment against mifepristone alone—a fatal flaw given that mifepristone (without misoprostol) is known to have a high failure rate. Schreiber Decl. ¶ 33–34. The 2012 paper claims that four of seven patients carried pregnancies to term,[5] while the 2018 paper claims a "reversal" rate of 48%—a figure almost identical to the 46% expected continued pregnancy rate after taking mifepristone alone. Schreiber Decl. ¶ 27; Ex. C to Schreiber Decl. at 8. This alleged "reversal success rate" is likely inflated because (a) as noted, the studies lacked a control group, and (b) most patients were administered progesterone only after an ultrasound already confirmed that mifepristone alone had not terminated the pregnancy, meaning that the pregnancies were already predisposed to continue. Schreiber Decl. ¶ 28. Indeed, the authors admit that these pregnancies "may have survived without progesterone therapy." Schreiber Decl. ¶¶ 28, 35; Exhibit C to Schreiber Decl. at 29. Additionally, the patients in the 2018 paper received progesterone according to ten different regimens, further limiting interpretation of the results. Schreiber Decl. ¶ 36. The authors acknowledge that further research employing randomized controlled trials comparing progesterone doses and routes of administration is needed. Schreiber Decl. ¶ 44.[6]

Major medical organizations reject this supposed evidence that mifepristone can be "reversed." For example, the American Congress of Obstetricians and Gynecologists

[5] Ex. B to Schreiber Decl. This tiny sample size alone precludes physicians from drawing any generally applicable conclusions from its results. The paper was also never reviewed and approved by an institutional review board—a formal group that monitors human research to protect the subjects' rights and welfare. Schreiber Decl. ¶ 11.

[6] The authors were forced to withdraw the 2018 paper after its initial publication. When the article was republished, the authors had rewritten the research methods to describe a fundamentally different research protocol from the original paper yet did nothing to change their methodology. Such a bait and switch is unheard of in reputable scientific publications. Schreiber Decl. ¶¶ 32-33.

("ACOG")[7]—the premier professional organization of women's health providers—has explained that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards" and that papers "with no control groups are among the weakest forms of medical evidence." Schreiber Decl. ¶ 21; Ex. D to Schreiber Decl.; *see also* Braid Aff. ¶21. Moreover, studies and editorials published in the last several years in highly respected journals, including a systematic review of the research on mifepristone "reversal," conclude there is insufficient evidence to determine if treatment with progesterone after mifepristone results in a higher rate of continued pregnancy. Schreiber Decl. ¶ 38.

Drs. Delgado and Davenport are both affiliated with APR, though the organization provides scarce public information identifying the "healthcare professionals" affiliated with APRN, their qualifications or medical backgrounds, or the type of progesterone treatments they seek to administer to patients.

The legislative history of S.B. 614 in the Oklahoma House of Representatives reveals that proponents of S.B. 614 were alerted to the significant flaws in Delgado and Davenport's research, and notified that ACOG and many Oklahoma physicians opposed the bill. The bill's co-sponsors and other proponents dismissed those concerns out of hand.[8]

IV. Ethical Implications of S.B. 614

Physicians' obligations to patients are regulated by applicable state law but are also grounded in the tenets of medical ethics that guide the medical profession. S.B. 614 requires

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[7] ACOG is also referred to as the American College of Obstetricians and Gynecologists.

[8] Indeed, Representative Cyndi Munson noted that physicians and medical associations "who do this work every day, who have spent many, many years becoming doctors, have reached out with concern" about S.B. 614 and questioned why House members were "willing to put women in danger by mandating that physicians lie to their patients." Oklahoma State House of Representatives, *First Regular Session of the 57th Legislature, Day 41 Afternoon Session Debate, SB 614* (Apr. 16, 2019), *available at* http://bit.ly/2mWASj3, 11:34:44AM – 11:35:43AM.

physicians to deliver a state-sponsored message to their patients, in direct contravention of the basic tenets of medical ethics, set forth in the medical profession's cardinal treatise, the *Code of Medical Ethics of the American Medical Association*. Declaration of Matthew Wynia, M.D. (attached hereto as Ex. 3) ("Wynia Decl.") ¶ 29. Among the most fundamental ethical duties physicians owe to their patients are respect for patient autonomy and the duty to do no harm. Wynia Decl. ¶¶ 29, 43. Contrary to these precepts, S.B. 614 forces physicians to tell their patients about an unproven, experimental medical treatment, undermining the basis of the doctor-patient relationship of trust and impeding patients' ability to make informed healthcare decisions. Wynia Decl. ¶ 33.

S.B. 614 also forces physicians to provide information to their patients that is irrelevant and even potentially damaging, undermining patients' ability to provide informed consent to the procedure. Schreiber Decl. ¶¶ 51–58; Wynia Decl. ¶¶ 35-36. Indeed, S.B. 614 may have the perverse effect of encouraging patients who may still be unsure of their decision to have an abortion to nonetheless consent and take mifepristone, under the mistaken belief that they can later change their minds. Schreiber Decl. ¶ 36; Braid Aff. ¶ 25.

Specifically, S.B. 614 forces physicians to repeatedly refer their patients to the APR website and hotline, and thus the APRN healthcare providers willing to prescribe experimental doses of progesterone to "reverse" mifepristone.[9] Ethical principles of experimentation on human subjects, as well as federal law, require physicians to ensure that patients consent to and understand the full extent of a medical experiment. Wynia Decl. ¶ 47; 45 C.F.R. § 46.201-207. Despite this, S.B. 614 forces physicians to implicitly endorse and direct their patients to care that amounts to unethical experimentation by healthcare professionals of unknown qualifications, giving the

[9] ABORTION PILL RESCUE, http://abortionpillreversal.com/ (last visited Sept. 16, 2019).

treatment a false air of legal and medical legitimacy. Wynia Decl. ¶ 38; Schreiber Decl. ¶ 54; Braid Aff. ¶ 30.

Finally, S.B. 614 violates various central provisions of the *Code of Medical Ethics of the American Medical Association*, including physicians' obligations to: uphold fidelity to patients' welfare; build a relationship of trust with patients; maintain truthful and honest communication with patients; honor patients' requests not to receive information; further, rather than undermine, patients' ability to provide informed consent; and prevent political matters from interfering with the delivery of professional care. Wynia Decl. ¶ 51.

ARGUMENT

"The purpose of a temporary injunction is to preserve the status quo and prevent the perpetuation of a wrong or the doing of an act whereby the rights of the moving party may be materially invaded, injured or endangered." *Okla. Pub. Emps. Ass'n v. Okla. Military Dep't*, 2014 OK 48, ¶ 15, 330 P.3d 497, 504 (citation omitted). Oklahoma courts consider the following factors in determining whether to issue a temporary injunction: (1) the applicant's likelihood of success on the merits; (2) irreparable harm to the party seeking relief if injunctive relief is denied; (3) whether applicant's threatened injury outweighs that of the opposing party; and (4) whether the injunction is in the public interest. *Edwards v. Bd. of Cty. Comm'rs of Canadian Cty.*, 2015 OK 58, ¶ 12, 378 P.3d 54, 59. Each factor weighs in favor of granting Plaintiffs temporary injunctive relief.

A. Plaintiffs are Likely to Succeed on the Merits of Their Constitutional Claims

S.B. 614 deprives Physicians of their fundamental right to free speech. The Oklahoma Constitution is highly protective of free speech, providing that "[e]very person may freely speak, write, or publish his sentiments on all subjects, being responsible for the abuse of that right; and no law shall be passed to restrain or abridge the liberty of speech or of the press." Okla. Const. art.

2, § 22. The Supreme Court of Oklahoma has consistently stated that the protections afforded by the Oklahoma Constitution are coextensive with, or greater than, the protections guaranteed by the federal constitution. *See In re Initiative Petition No. 366*, 2002 OK 21, ¶ 7, 46 P.3d 123, 126 ("The Oklahoma Constitution is more protective of speech than is the United States Constitution."); *Gaylord Entm't Co. v. Thompson*, 1998 OK 30 ¶ 13 n.23, 958 P.2d 128, 138 n.23 ("The Oklahoma Constitution's protection of free speech *is far more broadly worded* than the First Amendment's restriction on governmental interference with speech."); *see also Gerhart v. State*, 2015 OK CR 12, ¶ 6, 360 P.3d 1194, 1196 ("A statute which criminalizes speech must be interpreted within the parameters of the First Amendment."). And, as the Supreme Court recently affirmed, federal First Amendment free speech protections are at their zenith where, as here, the government controls the content of speech. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) ("*NIFLA*"). S.B. 614 violates Plaintiffs' free speech rights by forcing them to speak the government's message, with which they disagree, on a controversial topic, in violation of their professional judgment and ethical obligations to their patients. Accordingly, and as described herein, Plaintiffs are highly likely to succeed on the merits.

1. Compelled Speech Regulations Like S.B. 614 are Presumptively Unconstitutional and Subject to Heightened Scrutiny.

The right to free speech "includes both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). In recent years, the U.S. Supreme Court has further emphasized the "damage" done when "individuals are coerced into betraying their convictions." *Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, 138 S. Ct. 2448, 2464 (2018). Compelled speech forces individuals to tailor the content of their speech to the whims of the government. *See NIFLA*, 138 S. Ct. at 2371. Regulations that force speakers to alter

the content of their speech are inherently dangerous and "presumptively unconstitutional." *Reed v. Town of Gilbert, Ariz.*, 135 S. Ct. 2218, 2226 (2015).

In 2018, the Supreme Court held that these free speech principles apply with full force to physician speech. In *NIFLA*, the Court examined a state law requiring, among other things, that licensed pregnancy centers "disseminate a government-drafted notice on site" by posting a notice in the waiting room and on materials provided to clients, informing them that the state offers eligible women free or low-cost access to family-planning services, including abortion. *NIFLA*, 138 S. Ct. at 2369. The Court made clear that "[s]peech is not unprotected merely because it is uttered by professionals," emphasizing the "danger of content-based regulations 'in the fields of medicine and public health, where information can save lives.'" *Id.* at 2371-74 (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011)). *NIFLA* clarified that "because "[d]octors help patients make deeply personal decisions, and their candor is crucial," regulating the content of physicians' speech "pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information." *Id.* at 2374.

As in *NIFLA*, various courts have recognized that regulations constituting government "attempts to compel physicians to deliver its message, especially when that message runs counter to the physician's professional judgment and the patient's autonomous decision about what information she wants," violate the First Amendment. *Stuart v. Camnitz*, 774 F.3d 238, 255 (4th Cir. 2014) (invalidating North Carolina law compelling abortion providers to speak government message about pregnancy); *see also Wollschlaeger v. Governor of Fla.*, 848 F.3d 1293, 1311 (11th Cir. 2017) (en banc) (invalidating Florida law preventing physicians from discussing gun ownership and safety with patients); *Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002) (enjoining federal law prohibiting physicians from communicating with their patients about

medical marijuana). Indeed, just this month, the United States District Court for the District of North Dakota enjoined legislation very similar to S.B. 614, holding that the law at issue violated the First Amendment rights of physicians:

> The Court finds that the mandate of H.B. 1336 violates the First Amendment rights of physicians. Rather than focus on relevant medical information designed to assist a woman in making a free choice, H.B. 1336 expresses ideological beliefs essentially designed to make it more difficult for women to choose an abortion. The North Dakota law requires abortion providers to enunciate the State's viewpoint on an unproven medical and scientific theory, namely whether a chemical abortion can be reversed. ***North Dakota may not violate the First Amendment rights of physicians by compelling them to espouse the State's ideology.*** The law also clearly interferes with the doctor-patient relationship; forces the attending physician to convey to his/her patient a state-mandated message that is devoid of credible scientific evidence; misinforms and misleads the patient; undermines informed consent and the standard of care; and is arguably unethical. ***A law which mandates that physicians become mouthpieces for a false, misleading, and controversial "abortion reversal" message would not survive any level of constitutional scrutiny.***

American Med. Ass'n v. Stenehjem, No. 1:19-cv-00125 at 20 (D.N.D. Sept. 10, 2019) (order granting preliminary injunction) (emphasis added).

S.B. 614 compels Physicians to speak in ways that are far more troubling and intrusive than the speech at issue in *NIFLA*. Here, the law compels speech that is content-based, *and also* speaker- and viewpoint-based. S.B. 614 forces physicians providing abortions, and only those physicians, to adopt and disseminate a controversial government-imposed message that medication abortion may be "reversible," contrary to their views and the consensus of the medical community. Indeed, *NIFLA* cautions against speaker-based laws that leave "unburdened those speakers whose messages are in accord with [the government's] own views." *NIFLA*, 138 S. Ct. at 2378 (internal quotations omitted). Additionally, S.B. 614 forces Physicians to both provide in writing and *orally speak* this controversial, government-scripted message and to repeatedly refer patients to the APR

website and hotline during the patient consultation process, which is otherwise geared towards providing patients with the information they need to provide informed consent.

Whereas the law at issue in *NIFLA* only required clinics to post signage and distribute written material upon check-in, S.B. 614 goes even further, forcing Physicians to direct their patients to the APR website and hotline in three different ways: orally, 72 hours before the procedure; through large, government-scripted notices which must be "conspicuously" posted in every waiting room and consultation room "used by" medication abortion patients; and through state-scripted written "instructions" which must be provided to patients *after* they have taken mifepristone. These mandatory disclosures make Physicians complicit in promoting the scientifically unproven practice of abortion "reversal" through experimental progesterone treatments. Indeed, S.B. 614 forces Physicians to convey the government's specious message and advertise the services of an organization that Physicians believe to be engaged in unprofessional, if not unethical, practices that may be harmful to patients.

2. None of the Exceptions to Heightened Scrutiny Apply to S.B. 614.

The *NIFLA* Court enumerated two circumstances in which it "has afforded less protection for professional speech": (1) for "regulations of professional conduct that incidentally burden speech," and (2) for "factual, noncontroversial information in their commercial speech." 138 S. Ct. at 2372-73 (quotations omitted). Neither exception applies here.

First, S.B. 614 is not a "regulation[] of professional conduct that incidentally burdens speech." *Id.* at 2372. *NIFLA* stated that "[l]ongstanding torts for professional malpractice . . . 'fall within the traditional purview of state regulation of professional conduct.'" *Id.* (quoting *NAACP v. Button*, 371 U.S. 415, 438 (1963)). Requiring a doctor to obtain informed consent is "firmly entrenched in American tort law." *Id.* (citing *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 269 (1990)). In addition, some informed consent laws also fall within the bounds of state

regulated professional conduct. *Id.* (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 884 (1992)). The California state law at issue in *NIFLA* required pregnancy centers to disseminate information on the availability of abortions, and the Court explained that this required disclosure did not fit within this exception because the mandatory "notice provide[d] no information about the risks or benefits of [medical] procedures." *NIFLA*, 138 S. Ct. at 2373. Likewise, S.B. 614 is not a regulation of professional conduct.

The Court in *Casey* found that informing women twenty-four hours before an abortion of the "nature" and "risks" of the abortion procedure, the "probable gestational age" of the pregnancy, and the "medical risks associated with carrying her child to term" furthered the informed consent process. *Casey*, 505 U.S. at 881-82. Unlike the law at issue in *Casey*, S.B. 614 is entirely unrelated to "facilitat[ing] informed consent to a medical procedure," *see NIFLA*, 138 S. Ct. at 2373, and in fact *undermines* informed consent as it (1) forces Physicians to convey a government-scripted message to their patients about a separate, unproven, controversial, and effectively experimental treatment; *and* (2) to repeatedly direct their patients to unknown "healthcare professionals" affiliated with an organization that misrepresents the benefits and risks of this experimental treatment. In *Casey*, the law in question allowed physician judgment not to provide information if it harmed the patient. *Id.* at 967. Here, Physicians are forced to give their patients medically inaccurate messages, and direct their patients to providers who they believe are acting outside the standard of care. Braid Aff. ¶¶ 29-30. A physician's ethical duty to ensure that patients provide "informed consent to a [specific] medical procedure," *NIFLA*, 138 S. Ct. at 2373, cannot be served by government-mandated disclosures that violate both the fundamental tenets of medical ethics (patient autonomy, beneficence, non-malfeasance, and justice) and the *AMA Code of Medical*

Ethics. Wynia Decl. ¶ 33. Compelling Physicians to deliver such a message, and make such referrals, falls far outside *Casey's* narrow definition of informed consent to an abortion procedure.

Second, S.B. 614 falls far outside the exception identified in *NIFLA* for commercial speech related to "purely factual and uncontroversial information about the terms under which [...] services will be available." *See NIFLA*, 138 S. Ct. at 2372 (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985)). First, S.B. 614 does not regulate commercial speech—e.g. speech related to solicitations for business or advertisements, or the terms under which services will be available. Second, the message mandated by S.B. 614 is not "purely factual and uncontroversial." *See id.*; *see also Am. Beverage Ass'n v. City & Cty. of S.F.*, 916 F.3d 749, 755 (9th Cir. 2019). Far from purely factual and uncontroversial information, S.B. 614 compels speech that, at worst, is an outright lie and, at best, is highly controversial. The consensus in the medical community, including from the country's leading medical organizations such as ACOG, is that there is no evidence-based medicine supporting medication abortion "reversal." Schreiber Decl. ¶ 20–21, 38. The controversial nature of the unproven theory of abortion "reversal" alone justifies heightened scrutiny. *See NIFLA*, 136 S. Ct. at 2372; *Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 249-50 (2d Cir. 2014) (striking down requirement to "address abortion, emergency contraception, or prenatal care at the beginning of their contact with potential clients" because it "alters the [speakers'] political speech" and "mandates the discussion of controversial political topics").

3. Even if S.B. 614 Were Understood as a Professional Regulation That Only Incidentally Affects Speech, It Would Still Fail Constitutional Review

Even assuming, arguendo, that S.B. 614 falls within the exception for regulations of professional conduct that incidentally burden speech, that would mean only that something other

than strict scrutiny applies. *See NIFLA*, 138 S. Ct. at 2372-73. Although *NIFLA* did not specify the level of scrutiny, courts after *NIFLA* have held that intermediate scrutiny applies to regulations of professional conduct that incidentally burden speech. *Capital Associated Indus. v. Stein*, 922 F.3d 198, 207-09 (4th Cir. 2019) (explaining, post-*NIFLA*, "[f]or laws with only an incidental impact on speech, intermediate scrutiny strikes the appropriate balance between the states' police powers and individual rights."); *American Med. Ass'n v. Stenehjem*, No. 1:19-cv-00125 at 20 (D.N.D. Sept. 10, 2019) (order granting preliminary injunction) ("assuming H.B. 1336 regulates professional conduct that incidentally burdens speech—intermediate review is the more appropriate standard of review to apply").

Accordingly, even if this Court were to find that S.B. 614 constitutes an informed consent provision that is "part of the practice of medicine, subject to reasonable licensing and regulation by the State," *Casey*, 505 U.S. at 884, the Court should apply at least intermediate scrutiny. Under intermediate scrutiny, the government must prove that the law furthers an important government interest and is substantially tailored to furthering that interest. *See e.g.*, *United States v. O'Brien*, 391 U.S. 367, 377 (1968) (applying intermediate scrutiny to a law with an incidental effect on speech). And, "[a] law which mandates that physicians become mouthpieces for a false, misleading, and controversial 'abortion reversal' message would not survive any level of constitutional scrutiny." *American Med. Ass'n v. Stenehjem*, No. 1:19-cv-00125 at 20 (D.N.D. Sept. 10, 2019) (order granting preliminary injunction). S.B. 614 does exactly this, and thus cannot withstand any level of constitutional review, let alone intermediate scrutiny.

First, the State cannot show an important, let alone compelling, reason why patients seeking medication abortion must be informed by their physicians of an unproven, experimental procedure and repeatedly directed to the APR website and hotline. Rather than furthering a

legitimate public health goal, information about alleged "reversal" is misleading and irrelevant for most, if not all, patients. S.B. 614 is premised on the unproven and, at best, experimental theory that an extended course of high doses of progesterone may reverse the effects of mifepristone—a theory rejected by every leading medical organization.

While the state may have an important interest in ensuring that patients provide informed consent before a medical procedure, no such interest is present here. Far from facilitating informed consent, S.B. 614 instead requires Physicians to mislead women into believing there is a medically sound protocol for reversing a medication abortion when no such protocol exists.[10] *See* Schreiber Decl. ¶ 54. Before taking mifepristone to begin an abortion, patients should understand the truth: that taking mifepristone and misoprostol will end their pregnancy, and that the effects of these drugs cannot be reversed. *See id.* ¶ 16. For this reason, and because mifepristone alone often terminates the pregnancy, physicians, including the Plaintiffs, do not provide patients with mifepristone unless and until their patients are confident in their decision to obtain an abortion. *See id.* ¶¶ 51, 57–58; Braid Aff. 13. There can be no legitimate public health goal in a law that undermines a physician's ability to obtain informed consent and violates physicians' ethical obligations to their patients.

Second, even assuming the State could demonstrate an important interest in informing patients about "reversal," the State cannot show that S.B. 614 is sufficiently tailored to serving that interest. As explained in *NIFLA*, the State could easily inform women about "reversal" "without

[10] The FDA—the national authority on the safety and efficacy of drugs—has not found that large doses of progesterone are either (1) safe to give to women after taking mifepristone or (2) effective at reversing mifepristone's effects to *any* degree. The FDA typically requires a series of clinical trials—usually with a control group to limit research bias—and the trials usually must be supervised and approved by an institutional review board to protect the rights and welfare of the human subjects. *See* Wynia Decl. ¶ 36. Nothing remotely like that type of research has been done with progesterone to "reverse" mifepristone. *See id.* ¶ 24, 36.

burdening a speaker with unwanted speech," as "[most] obviously, it could inform women itself with a public-information campaign" or by "post[ing] the information on public property" near the Clinic. 138 S. Ct. at 2376 (citation omitted). Instead, the State chose to force Physicians to speak the government message themselves, provide it to patients twice in written form, and direct patients to more misleading information via the APR website and hotline. By referring patients to the APR website and hotline, the State forces Physicians to "make a blanket endorsement of information they neither trust nor believe, and over which they have no control." Wynia Decl. ¶ 31. Such lack of tailoring is wholly deficient, particularly since "[p]recision ...must be the touchstone' when it comes to regulations of speech, which 'so closely touc[h] our most precious freedoms.'" *Id.* (quoting *NAACP v. Button*, 371 U.S. at 438).

B. Physicians Will Suffer Irreparable Harm if S.B. 614 is Not Enjoined

Under Oklahoma law, injury is irreparable where "it is incapable of being fully compensated for in damages or where the measure of damages is so speculative that it would be difficult if not impossible to correctly arrive at the amount of the damages." *Edwards*, 378 P.3d at 63. Yet a "threatened deprivation of a constitutional right is itself irreparable harm, and . . . no further showing . . . is required." *Nova Health Sys. v. Pruitt*, No. CV-2015-1838, 2015 Okla. Dist. LEXIS 1045, *10 (Okla. Dist. Ct. Oct. 28, 2015); *see also Kikumura v. Hurley*, 242 F.3d 950, 963 (10th Cir. 2001) ("When an alleged constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.") (internal citation omitted). It is well established that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Planned Parenthood Assoc. of Utah v. Herbert*, 828 F.3d 1245, 123 (10th Cir. 2016), *quoting Elrod v. Burns*, 427 U.S. 347, 373 (1975).

If S.B. 614 is not enjoined, Plaintiffs will suffer irreparable harm to their rights of free speech by being forced to speak a government-mandated message with which they disagree;

misinform their patients; and advertise controversial, scientifically unproven medical services they believe will harm their patients. *See Herbert*, 828 F.3d at 1259 ("The government may not prohibit the dissemination of ideas that it disfavors, nor compel the endorsement of ideas that it approves.") (internal citations and quotation marks omitted). There is no question that these harms cannot be remedied by damages. These infringements on Plaintiffs' constitutional rights alone constitute irreparable harm.

Beyond the constitutional violation, S.B. 614 will also irreparably harm Physicians by forcing them to impose immediate harm on their patients in violation of their ethical obligations. In providing false and misleading information to their patients about the unproven abortion "reversal" theory, physicians who comply with S.B. 614 will impair, rather than further, their patients' ability to provide informed consent to abortion. *See supra* at IV. Physicians acting in compliance with S.B. 614 will also be forced to implicitly endorse APR's messages and network of unidentified "healthcare professionals," even though Plaintiffs believe that APR engages in unprofessional and unethical practices that may be harmful to patients. *Id.* S.B. 614 puts Plaintiffs in the untenable position of either abiding by the law's requirements and harming their patients, or refusing to do so at the risk of their own livelihood and freedom. Either course imposes irreparable harm on both Plaintiffs and their patients.

C. The Balance of Equities and the Public Interest Favor an Injunction

The balance of equities, as well as the public interest, also weigh in favor of an injunction. As set forth above, absent an injunction, Plaintiffs will suffer irreparable harm to their rights to free speech and be forced to impose additional harms on their patients. Conversely, Defendants will not suffer any loss if S.B. 614 is enjoined, as preservation of the status quo is the very purpose of injunctive relief. *RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1208 (10th Cir. 2009). Because

S.B. 614 will deprive Plaintiffs of their rights to free speech, while an injunction will not prejudice the State, the balance of equities favors an injunction.

Finally, granting an injunction would be in the public's best interest because it is always in the public interest to prevent the violation of a party's constitutional rights. *See Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1237 (10th Cir. 2005) ("Vindicating First Amendment freedoms is clearly in the public interest."). Protecting free speech rights is especially important to the public, as they have the right to be informed and not to be misinformed. *See id*; *cf. Allen v. Harrison*, 2016 OK 44, ¶ 9, 374 P.3d 812, 816 ("A physician is charged with the obligation to present the medical facts accurately ....").

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court issue a temporary injunction preventing enforcement by Defendants of S.B. 614 pending final resolution of Plaintiff's claims or further order of the Court, and further request that bond be waived.

Dated: September 25, 2019

Respectfully Submitted,

J. Blake Patton, Oklahoma Bar No. 30673

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 25th day of September, 2019, a true and correct copy of the foregoing was served via U.S. Mail to the following:

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EXHIBIT 1

IN THE DISTRICT COURT FOR THE COUNTY OF OKLAHOMA
STATE OF OKLAHOMA

TULSA WOMEN'S REPRODUCTIVE CLINIC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D.,	)	
Plaintiffs,	)	
v.	)	
	)	CASE NO. _____
MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, DENNIS CARTER, in his official capacity as President of the Oklahoma State Board of Osteopathic Examiners, and TOM BATES, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors,	)	
Defendants.	)	

AFFIDAVIT OF ALAN BRAID, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION

Dr. Alan Braid declares and states the following:

I. Background

1. I am a board-certified obstetrician and gynecologist, licensed to practice medicine in the states of Oklahoma and Texas. I am also the principal owner of Tulsa Women's Reproductive Clinic, LLC ("the Clinic"), an Oklahoma corporation located in Tulsa, Oklahoma. I have read Oklahoma House Bill No. 614 of 2019 ("S.B. 614"), and I submit this declaration in support of Plaintiffs' Motion for Temporary Injunction.

2. I have been providing reproductive health care in Texas, including abortion care, since 1978. I currently practice medicine in Texas and Oklahoma, where I have been providing reproductive healthcare, including abortion care, since August 2018. I provide abortion care at the Clinic, as well as at Alamo Women's Reproductive Services and Alamo City Surgery Center in San Antonio, Texas.

3. I am a Diplomate of the American Board of Obstetrics and Gynecology.[1] My full credentials are listed in my CV, which is attached hereto as Exhibit A.

4. The Clinic is a medical practice in Tulsa, Oklahoma, which provides high-quality abortion care to patients primarily from Oklahoma, as well as to patients from Texas, Missouri, Kansas, and Arkansas. Approximately six days per week, the Clinic provides medication abortion up to 10 weeks of pregnancy measured from the first day of a woman's last menstrual period ("LMP") and surgical abortion up to 17 weeks and 6 days LMP. The Clinic is certified by the National Abortion Federation (NAF) and licensed by the Oklahoma State Board of Health. The Clinic's physicians and staff strive to provide only the best, evidence-based medical care to our patients.

5. I purchased the Clinic in June 2018; it had previously been in operation under a different name for over forty years. The Clinic is one of only four abortion providers in Oklahoma, and the only provider in Tulsa. Two other abortion providers are located in Oklahoma City, and one is in Norman—all approximately a two-hour drive from Tulsa.

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[1] The American Board of Obstetrics and Gynecology (ABOG) board certifies obstetricians and gynecologists (OB GYNS) in the U.S. and Canada. ABOG certifies as Diplomates those who obtain and maintain board certification. ABOG's certification standards are distinct from state licensure requirements and board certification and maintenance are voluntary. *See ABOG*, "Definition of an Obstetrician and Gynecologist," https://www.abog.org/about-abog/policies/definition-of-an-obstetrician-and-gynecologist (last visited Sept. 23, 2019).

6. I have been traveling to Oklahoma to provide abortion care at the Clinic since August 2018. As the Clinic's principal owner, I handle personnel matters and the Clinic's business affairs. I also work with the Clinic's Medical Director to set policies and procedures for all medical care at the Clinic, including but not limited to patient education and counseling for medication abortions, in-clinic medication abortion care, and post-medication abortion follow up appointments and complications management. If any questions arise at the Clinic regarding a medical procedure, the Clinic's Medical Director and I resolve them together.

7. Three other physicians provide abortion care, including medication abortions, at the Clinic on a part-time basis. Approximately 70 percent of the Clinic's abortion patients receive medication abortions and the rest receive surgical abortions.

II. Medication Abortions Provided at the Clinic

8. Medication abortions provided at the Clinic follow the Food and Drug Administration ("FDA") approved regimen of two drugs: mifepristone (a.k.a. Mifeprex) and misoprostol. Put simply, the first drug, mifepristone, stops the pregnancy from progressing. The second drug, misoprostol, works in conjunction with mifepristone to cause uterine contractions to expel the pregnancy from the uterus.

9. I provide medication abortion to patients at the Clinic in accordance with the FDA's current label for mifepristone: I administer mifepristone to patients while they are at the Clinic and then instruct them to take the misoprostol buccally 24 to 48 hours later at home or a location of their choosing. All physicians who provide medication abortion care at the Clinic

follow this regimen, which has been shown to have a 97.4 percent success rate for terminating pregnancies up to 10 weeks LMP in the U.S.[2]

10. In contrast, based on the scientific literature I have reviewed, mifepristone taken on its own (without misoprostol) fails to terminate a pregnancy up to 46% of the time.[3] I would not prescribe mifepristone alone to a patient seeking to end her pregnancy.

III. Existing Informed Consent and Patient Education Processes

11. Under Oklahoma law, I, or my agent, must provide specific state-mandated information to patients seeking abortion care at least seventy-two hours before their abortion procedure.[4] The Clinic's staff members are authorized to act as agents of the Clinic's physicians for this purpose. In other words, when the Clinic's staff members speak these state-mandated messages, they are speaking on my behalf and on behalf of the Clinic's physicians.

12. When patients arrive at the Clinic for an abortion, they undergo an ultrasound to confirm the gestational age of the pregnancy and receive counseling on the risks, benefits, and alternatives to abortion and the types of abortion procedures for which they are eligible. No abortion procedure begins until the patient has reviewed all of her options; received relevant, evidence-based information about the procedure she has chosen; and provided informed consent to the procedure.

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[2] Table 3, *FDA Label for Mifeprex*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[3] *See* Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating without Evidence*, 379(16) New England Journal of Medicine 1401-03 (2018).

[4] 63 O.S. §§ 1-738.2-3.

13. Before I begin any abortion procedure, I ask my patients to confirm that they are firm in their decision to terminate their pregnancy and give them an opportunity to ask me questions about their care. In the very rare event that a patient is not certain in her decision to have an abortion, I will not administer mifepristone or initiate any other abortion procedure unless and until I am certain that the patient has been provided with the relevant information needed for informed consent and is firm in her decision to proceed with the abortion. The other physicians at the Clinic follow the same protocol.

14. As a physician at the Clinic, I am familiar with the reasons women seek our abortion services. I generally do not ask patients why they are terminating their pregnancy, as I feel it is my role to provide safe medical care without judgment, but some patients will volunteer such information. These reasons include, for example, that they have low incomes and/or already have children and feel they cannot adequately parent and support a child or additional children. Other patients seek abortion because continuing a pregnancy poses risks to their physical safety or health. Regardless of the specific circumstances underlying my patients' decision to have an abortion, most patients are sure of their decision by the time they arrive at the Clinic, and all are certain of their decision before I begin any abortion procedure.

IV. Compliance with S.B. 614

15. I understand that S.B. 614 would force me, through my agents, to inform patients orally at least seventy-two hours before their medication abortion "[t]hat it may be possible to reverse the intended effects of a medication abortion that uses mifepristone if the woman changes her mind, but time is of the essence." In addition, I understand that I or my agents must orally inform patients that information and assistance about reversing a medication abortion

using mifepristone—including the Abortion Pill Reversal 24-hour Hotline number and website address—are available on the State Board of Medical Licensure and Supervision's website.

16. I also understand that S.B. 614 mandates that the Clinic, as a facility where medication abortion using mifepristone is provided, must "conspicuously post a sign" in each patient waiting room and consultation room used by medication abortion patients. I understand that this sign must be in ¾ inch font and contain the following specific language about medication abortion reversal:

> "NOTICE TO PATIENTS HAVING MEDICATION ABORTIONS WHICH USE MIFEPRISTONE: Mifepristone, also known as RU-486 or Mifeprex, alone is not always effective in ending a pregnancy. It may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can get immediate help by calling the Abortion Pill Reversal 24-hour Hotline at 877-558-0333 or going to website https://www.abortionpillreversal.com/. Additional information is available on the State Board of Medical Licensure and Supervision's website, www.awomansright.org, which provides informed consent materials under the Woman's Right-to-Know Act, including information about the development of the unborn child and video of ultrasound images of the unborn child at various stages of development."

17. I further understand that after a patient has taken mifepristone, S.B. 614 would require me or my agent to give her written instructions that include the same statement as above in paragraph 15 of this Affidavit.

18. I also understand that under S.B. 614, the Oklahoma State Board of Medical Licensure and Supervision must create materials "designed to inform the female of the possibility of reversing the effects of a medication abortion that uses mifepristone." I understand that I or my agents will be required to offer these materials, which must include the Abortion Pill Reversal website address and hotline phone number, to patients at least seventy-two hours

before they receive a medication abortion using mifepristone. To my current knowledge, these materials have not yet been published.

19. I understand that if I, or another physician at the Clinic, fails to follow these requirements, we can face felony charges, as well as liability for civil damages. Furthermore, if the Clinic fails to display the mandatory signs in all of the waiting rooms and consultation rooms used by medication abortion patients, it is my understanding that the Clinic will be charged $10,000 per day.

20. There is only one room at the Clinic used exclusively by medication abortion patients; all other waiting rooms and consultation rooms are used by both medication and surgical abortion patients. Therefore, the large, government-scripted signage required by S.B. 614 will be visible to patients who are not eligible for medication abortion, or who have decided to have a surgical abortion.

V. Mifepristone "Reversal" Treatment is Not Based in Evidence

21. There is no medically acceptable or reliable evidence that it is possible to "reverse" the intended effects of mifepristone through the use of progesterone or otherwise. I am familiar with the literature on so-called abortion "reversal," including two papers primarily authored by Dr. George Delgado, which claim that administering progesterone to a patient can counteract and thus "reverse" the effects of mifepristone.[5] It is my belief that these papers do not reflect scientific or ethical research methods. The papers' findings are not based in evidence

[5] George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 Annals of Pharmacotherapy e36 (Dec. 2012); George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33(1) Issues in Law & Medicine 1-14 (2018).

and do not provide information relevant to my patients seeking abortion care, as demonstrated by the following flaws:

a. The papers were not properly supervised by an institutional review board or ethical review committee, which are required in research studies to protect human research subjects;

b. There was no control group, meaning that the studied pregnancies could have very well continued on their own without the administration of progesterone;

c. The authors excluded patients whose ultrasounds confirmed embryonic death in their calculations, potentially impacting the final results; and

d. The studies did not separate patients based on gestational age, which affects the success of mifepristone.[6]

22. I only provide my patients information about medical treatments that are backed by evidence-based studies. I am not aware of any evidence-based studies on mifepristone "reversal." I am also not aware of any evidence-based studies about how mifepristone combined with high doses of progesterone impacts patients. And it is my understanding that scientists have not studied how administering progesterone after a patient has taken mifepristone could impact children born to patients who undergo such treatment, and therefore scientists have not ruled out the possibility of birth defects. I accordingly cannot ethically recommend this treatment to my patients.

[6] *See* Grossman & White.

23. Moreover, as far as I am aware, the FDA has not approved any medications, including progesterone, as safe and effective for the purpose of "reversing" Mifepristone.

24. Further, I consistently rely upon the American Congress of Obstetricians and Gynecologists ("ACOG")[7] as the best and most respected source for current, evidence-based best practices in obstetrical and gynecological care. I am aware of ACOG's public statement regarding medication abortion "reversal" and agree with ACOG's conclusions that "so-called abortion 'reversal' procedures are unproven and unethical.[8]"

VI. S.B. 614 is Inconsistent with Physicians' Ethical, Legal, and Professional Obligations to their Patients.

25. As a physician, my ethical duties require me to provide truthful information and evidence-based care to my patients. It is very important to me that patients are able to provide full informed consent before any medical procedure. I am unable to adhere to these ethical duties if I have to provide information to my patients about a treatment that has not been proven by evidence to be safe and effective.

26. S.B. 614's requirement that I or my agent inform patients—both orally and through government-created written notices—that they may "reverse" a medication abortion hinders my ability to inform patients that they must be certain in their decision to end their pregnancy *before* beginning a medication abortion. It is critical that my patients receive this information in clear, understandable terms because for the majority of patients, mifepristone

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[7] ACOG is also known as the American College of Obstetricians and Gynecologists.

[8] Statement of the American Congress of Obstetricians and Gynecologists, *Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science* (Aug. 2017), *available at* https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf?dmc=1&ts=20180206T1955451745.

terminates a pregnancy on its own. I would never administer mifepristone to a patient or want her to take mifepristone unless she was absolutely firm in her decision to terminate her pregnancy. Yet S.B. 614 forces me and the other physicians at the Clinic to tell our patients that they can change their minds *after* the abortion has already begun—a false and misleading statement. S.B. 614 therefore creates a risk that a patient will take mifepristone, and risk terminating her pregnancy, before she has made a final decision.

27. S.B. 614 also interferes with the physician-patient relationship, which is based on the patient's trust in the physician. S.B. 614 damages that trust by forcing the Clinic's staff members, on my behalf, to mislead patients by informing them of a medical treatment that has not been proven by evidence-based studies to be safe and effective. Forcing me to lie to my patients undermines their trust that the medical advice I give them is accurate. The other physicians I employ at the Clinic would similarly be required to mislead their patients—undermining our ability to provide only the best, evidence-based medical care.

28. Further, S.B. 614 forces me, the Clinic staff, and the physicians I employ at the Clinic to refer our patients to the Abortion Pill Reversal website and hotline, essentially endorsing the information provided there. I strongly disagree with the information on the Abortion Pill Reversal website, and unless S.B. 614 is in force, I would never provide the Abortion Pill website address to my patients, or otherwise imply that the information on that website is relevant to their medical care.

29. I only refer patients to physicians and medical providers whom I trust and whom I believe will provide my patients with quality medical services within the appropriate standard of care. I cannot trust healthcare providers who provide a treatment like abortion "reversal" that has not been proven by evidence and is outside the standard of care. S.B. 614 compels me and

my staff to refer our patients to the Abortion Pill Reversal's "healthcare professionals" when we know nothing about the quality of their services and, in fact, believe that they are acting outside the standard of care.

30. I am further concerned that by complying with S.B. 614, I would be exposing my patients to costly, experimental medical treatments with unknown health risks. If a patient is harmed or disappointed by the care that she receives from such treatments, I also worry about how this would affect her trust in me as her physician. I also have concerns about the liability this could inflict upon me and the other physicians at the Clinic.

31. I am also concerned that I or the other physicians at the Clinic might be legally liable to patients for recommending and referring treatment that is not evidence-based. For example, the Clinic treats patients from Texas. If a patient from Texas who had an abortion under my care at the Clinic was harmed as a result of the information I provided her under S.B. 614, and then sued me in my home state of Texas, a Texas court might not be deferential to the Oklahoma statute. I also worry that I or the Clinic's other physicians or staff will be at risk of professional discipline in Oklahoma or another state due to the misleading and untruthful information we must provide patients under S.B. 614.

32. Additionally, I am concerned about S.B. 614's impact on the Clinic's ability to provide all of our patients with relevant, medically accurate information that is supported by reliable evidence. All but one of the Clinic's waiting and consultation rooms are used by both medication and surgical abortion patients. Thus, S.B. 614's signage requirements will necessarily force me, my staff, and the physicians I employ to provide all of our patients seeking abortion care with information about a controversial, experimental, and unreliable procedure that is not supported by sound scientific research and may be completely irrelevant to the

treatment option they have elected. Particularly for patients receiving surgical abortions, information about reversing medication abortion has no relevance at all to their decision-making and may only confuse them.

33. I, along with the Clinic's other physicians and staff, object to S.B. 614 because it compels us to provide patients with government-scripted messages about so-called medication abortion "reversal," information with which we disagree, believe is inaccurate, and believe will harm our patients. I similarly object to authorizing my agents to provide this information to my patients on my behalf. I further object to the physicians I employ being forced to mislead their patients. I also object to being required to direct patients to the Abortion Pill Reversal Hotline and website, which promote inaccurate information, as well as ineffective and potentially harmful services. Finally, I object to posting large signs throughout the Clinic, which contain inaccurate information that is also irrelevant to a number of the Clinic's patients.

34. Because the penalties for not complying with S.B. 614 include felony criminal penalties and civil monetary damages against the physician, S.B. 614 puts me and the physicians I employ in the untenable position of either lying to our patients and potentially subjecting ourselves to malpractice for following the law, or subjecting ourselves to prison time and civil liability for violating the law.

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

Dated this 23 day of September, 2019.

Alan Braid, M.D.

EXHIBIT A

ALAN RICHARD BRAID, M.D.

BOARD CERTIFIED OBSTETRICS AND GYNECOLOGY

DIPLOMATE AMERICAN BOARD OF OBSTETRICS AND GYNECOLOGY

1963 Weequahic High School, Newark, N.J.

1967 Pennsylvania State University B.S.

1972 University of Texas Health Science Center, M.D.

1972-1976 UTHSCSA residency Obstetrics and Gynecology

1976-1978 Dover Air Force Base, Rank of Major, Ob-Gyn Service

1978-2010 Private practice Ob-Gyn, San Antonio, Texas

2010-2012 Owner and Medical Director, Reproductive Services of San Antonio

2012-present Owner and Medical Director, Alamo Women's Reproductive Services

2015-present Owner and Medical Director, Alamo City Surgery Center, San Antonio, Texas

2018-present Owner, Tulsa Women's Reproductive Clinic, Tulsa, Oklahoma

EXHIBIT 2

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

TULSA WOMEN'S REPRODUCTIVE CLINIC, LLC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D.,	)	
Plaintiffs,	)	
v.	)	
MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, TOM BATES, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors,	)	CASE NO. _____
Defendants.		

DECLARATION OF COURTNEY A. SCHREIBER, M.D., M.P.H. IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION

Courtney A. 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 Temporary Injunction preventing enforcement of S.B. 614, which would require physicians or their agents to inform women at least 72 hours prior to having an abortion (a) "[t]hat it may be possible to reverse the intended effects of a medication abortion that uses mifepristone if the woman changes her mind, but time is of the essence," and (b) that "information on reversing the effects of a medication abortion that uses mifepristone," including "the Abortion Pill Reversal 24-hour Hotline number" and website address, is available on the website of the State Board of Medical Licensure and

Supervision." I understand a separate section of S.B. 614 requires that any facility in which medication abortions using mifepristone are provided "conspicuously post a sign" in each patient waiting room and patient consultation room used by medication abortion patients with specific language about medication abortion reversal. The sign must read:

> "NOTICE TO PATIENTS HAVING MEDICATION ABORTIONS WHICH USE MIFEPRISTONE: Mifepristone, also known as RU-486 or Mifeprex, alone is not always effective in ending a pregnancy. It may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can get immediate help by calling the Abortion Pill Reversal 24-hour Hotline at 877-558-0333 or going to website https://www.abortionpillreversal.com/. Additional information is available on the State Board of Medical Licensure and Supervision's website, www.awomansright.org, which provides informed consent materials under the Woman's Right-to-Know Act, including information about the development of the unborn child and video of ultrasound images of the unborn child at various stages of development.."

3. I understand that after a patient has taken mifepristone, S.B. 614 requires the physician or the physician's agent to give the patient written instructions that include the same statement reproduced in paragraph 2 of this Declaration.

4. I understand that the Oklahoma State Board of Medical Licensure and Supervision must prepare materials "designed to inform the female of the possibility of reversing the effects of a medication abortion that uses mifepristone," and that these materials must include the Abortion Pill Reversal website address and hotline phone number. I understand that these materials have not yet been published.

5. Finally, I understand that physicians who provide medication abortion using mifepristone in violation of S.B. 614 would commit a felony criminal offense and be liable for damages in a civil lawsuit filed by the patient, the "father" of the fetus or embryo, or a minor patient's parents or grandparents. I also understand that medical facilities that violate the sign requirement may be fined $10,000 per day.

6. As I explain below, it is my opinion that S.B. 614 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, misleading, and irrelevant to patients; (2) undermines the patient-provider relationship that is the cornerstone to the medical profession by forcing physicians to violate their ethical duty by providing false information to patients; and (3) poses real harm to both physicians and their patients. I base these opinions on my expertise in the fields of obstetrics and gynecology; my experience 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, including the few case series regarding so-called "reversal."

My Credentials as an Expert

7. I am a board-certified obstetrician/gynecologist at the University of Pennsylvania Health System—PennMedicine - 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").[1] At Penn Medicine and the Perelman School of Medicine, University of Pennsylvania, I am Chief of the Division of Family Planning, the Director of the Pregnancy Early Access Center ("PEACE") 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

[1] ACOG is also known as the American Congress of Obstetricians and Gynecologists.

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.

8. I serve on the editorial board of the journal *Contraception*, and I am a reviewer for the *American Journal of Obstetrics and Gynecology*. I have also served as a reviewer for the journal *Pharmacoepidemiology*.

9. At Penn Medicine, I teach medical students as well as residents, including those training in obstetrics/gynecology and family medicine, among others, 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 I have been practicing in this way as an attending physician for 14years at the Perelman School of Medicine.

Abortion and the Science of Medication Abortion

10. Abortion is one of the safest and most common outpatient procedures performed in the United States. Approximately one in four 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.[2]

11. Carrying a pregnancy to term carries much higher risks of both morbidity and mortality than does abortion. The mortality rate associated with pregnancy in the United States is approximately fourteen times higher than the risks associated with abortion, and the complication rates for abortion are similar to, or lower than, complications associated with other outpatient procedures.[3]

12. As indicated above, there are both surgical and non-surgical (i.e., medication) abortion methods available. Medication abortion for early abortions (10 weeks from the first day of the woman's last menstrual period (LMP) or fewer) is a safe method of ending a pregnancy by taking two medications, mifepristone (also known as RU-486 or by its trade name in the U.S., Mifeprex®) and misoprostol, that together cause the woman to undergo a pregnancy termination within a predictable period of time. In order to understand why S.B. 614 is grossly inconsistent with good medical practice and evidence-based care, it is important to understand the nature of medication abortion and how it is provided.

13. I understand that Plaintiffs provide medication abortion using an evidenced-based regimen outlined in the 2016 Food and Drug Administration ("FDA") label for Mifeprex, which involves use of both mifepristone and misoprostol. The dosage, timing, and route of administration of this regimen has been endorsed by ACOG.[4] As set forth in the 2016 label, the protocol for

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[2] *Induced Abortion in the United States* (Guttmacher 2018), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states.

[3] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215, 216-17 (2012).

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

administration of medication abortion is as follows: on day 1, the patient takes 200 mg of mifepristone orally; twenty-four to forty-eight hours later, the patient takes 800 mcg of misoprostol buccally at a location of her choosing. The success rate for medication abortion in the United States under this protocol is 97.4%. As emphasized by the FDA in the updated 2016 label, this protocol has been demonstrated by clinical trials to be safe and extremely effective through seventy days or 10 weeks LMP.[5] To date, more than three million women have used this method in the United States.[6]

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

15. When used in a medication abortion, mifepristone works by binding to 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.[7] Mifepristone binds preferentially to progesterone receptors in the presence of progesterone because it has a higher affinity for the receptors, meaning that mifepristone binds more tightly to the receptors than progesterone does.[8] Mifepristone also triggers the release of endogenous

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[5] FDA Label for Mifeprex, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (detailing studies regarding the safe and effective use of Mifeprex through 70 days LMP).

[6] *Mifeprex Effectiveness and Advantages*, Danco Laboratories (last visited Sept. 11, 2019), https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/.

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

[8] Sitruk-Ware & Spitz, *supra* n.7, at 410; Oskari Heikinheimo et al., *The Pharmacokinetics of Mifepristone in Humans Reveal Insights Into Differential Mechanisms of Antiprogestin Action*, 68 Contraception 421, 425 Table 1 (2003); Christian Fiala & Kristina Gemzell-Danielsson, *Review*

prostaglandins (which can cause uterine contractions),[9] softens and opens the cervix,[10] and increases uterine contractility (capacity to contract).[11] Mifepristone is quickly absorbed, reaching peak concentrations in the blood about one to two hours after it is ingested.[12] Mifepristone is eliminated from the bloodstream slowly for the first 72 hours, then rapidly thereafter.[13]

16. 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 because it failed to work sufficiently well on its own.[14] Subsequent research showed that the combination of mifepristone and a prostaglandin (misoprostol) work synergistically to terminate an early pregnancy with high efficacy.[15] Misoprostol taken buccally between 24 to 48 hours (or up to 72 hours) after taking 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,[16] 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

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of Medical Abortion using Mifepristone in Combination with a Prostaglandin Analogue, 74 Contraception 66, 68 (2006).

[9] Couzinet et al., *supra* n.7, at 1568; Remi Peyron et al., *Early Termination of Pregnancy with Mifepristone (RU 486) and the Orally Active Prostaglandin Misoprostol*, 328 N. Eng. J. Med. 1509, 1509 (1993).

[10] Couzinet et al., *supra* n.7, at 1568; Fiala & Gemzell-Danielsson, *supra* n.8, at 76.

[11] Couzinet et al., *supra* n.7, at 1568; Peyron et al., *supra* n.9, at 1509; Fiala & Gemzell-Danielsson, *supra* n.8, at 68; Sitruk-Ware & Spitz, *supra* n.7, at 411-12.

[12] Heikinheimo et al., *supra* n.8, at 422; Sarkar, *supra* n.7, at 114; Fiala & Gemzell-Danielsson, *supra* n.8, at 68.

[13] Sarkar, *supra* n.7, at 115.

[14] *See, e.g.*, *infra* n.19.

[15] Fiala & Gemzell-Danielsson, *supra* n.8, at 66-67.

[16] Fiala & Gemzell-Danielsson, *supra* n.8, at 66; Couzinet et al., *supra* n.7, at 1568.

to either mifepristone or misoprostol on their own but rather to the combination of the two drugs. Indeed, this is also how the FDA has approved the use of mifepristone for medication abortion.

17. As stated above, early research showed that when mifepristone was used alone to effect abortion, a significant 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;[17] (3) nearly all of these studies involved higher doses of mifepristone than those currently used by most clinicians;[18] (4) more recent studies describe the efficacy of mifepristone only when combined with misoprostol, and researchers do not study or compute success after mifepristone alone; and (5) large, population-based datasets are not available to analyze, since very few women elect to discontinue this medication abortion regimen after ingesting the mifepristone. But there is some evidence to suggest that, even in pregnancies up to 10 weeks LMP, up to 46 percent of women would have continuing pregnancies after taking mifepristone alone.[19] And data

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[17] *See, e.g.*, L. Kovacs 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).

[18] *See, e.g.*, I.T. Cameron et al., *Therapeutic Abortion in Early Pregnancy with Antiprogestogen RU486 Alone or in Combination with Prostaglandin Analogue (Gemeprost)*, 34(5) Contraception 459 (1986) (studying total mifepristone dosage of 600mg, which is three times the current standard dosage).

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

from trials looking at the efficacy of the mifepristone/misoprostol combination suggest that the rate of continued pregnancy increases as gestational age increases.[20]

The Lack of Credible Scientific Research to Support the Possibility of "Reversing" Medication Abortion

18. I understand that S.B. 614 requires physicians (or agents acting on their behalf), at least seventy-two hours before an abortion, to inform every patient who is considering a medication abortion using mifepristone "that it may be possible to reverse the intended effects of a medication abortion that uses mifepristone if the woman changes her mind but that time is of the essence" and that "information on reversing the effects of a medication abortion that uses mifepristone" is available from the state and the Abortion Pill Reversal ("APR") hotline and website. I am aware of a similar law that passed in Arizona several years ago but was later repealed, and another that recently passed in North Dakota and has been enjoined. Until the law in Arizona passed, I had never heard or read of "reversing" mifepristone or any other abortion-inducing drugs, and as an abortion provider and professor, I keep up to date with new research about medication abortion.

19. I am aware of a proposal by two physicians based in California, Dr. George Delgado and Dr. Mary Davenport, that physicians administer progesterone to reverse the effects of mifepristone in women who started the medication abortion regimen but did not take the misoprostol. Delgado and Davenport have published two papers that they claim support their proposal regarding the use of progesterone. These two papers are attached as Exhibits B and C.

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

20. In my medical opinion, the administration of progesterone to reverse the effects of mifepristone is experimental and unsupported by scientific evidence. Thus, requiring physicians or their agents to tell women that "it may be possible to reverse" the "intended effect" of mifepristone and inform them that "information on reversing the effects of a medication abortion that uses mifepristone" can be found on the Abortion Pill Reversal website and hotline could easily mislead patients into wrongly assuming that there are reliable data to support this practice. Doing so on the bases of the published papers, which provide no scientific support for this practice, is unethical, and dangerous to the health and well-being of patients.

21. ACOG has issued a statement to this effect, explaining that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards," and that requiring physicians to inform patients about so-called "reversal" and to make referrals for such treatments "compromise patient care and safety."[21] That statement is attached here as Exhibit D. I agree with ACOG's determinations completely.

22. The two papers written by Dr. Delgado and his colleagues do not come close to providing scientifically valid support for the theory of medication abortion "reversal." The first paper, published in 2012 in the *Annals of Pharmacotherapy*, describes 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.[22] At the end of the case series, Delgado

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[21] Statement of the American Congress of Obstetricians and Gynecologists, *Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science* (Aug. 2017), *available at* https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf?dmc=1&ts=20180206T1955451745.

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

and Davenport propose a protocol of regular intramuscular injections of doses of progesterone (200 mg) administered throughout the first trimester of pregnancy.

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

24. I was also surprised to see that the authors included clinical recommendations at the end of their paper, which the authors describe as containing "case reports."[23] 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 a sample size calculation and a control group are generally required in order to recommend practice change.

25. Not only do appropriately sized data sets not exist on this topic, but the authors of this paper 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.[24] Furthermore, a recent randomized trial published in the New England Journal of Medicine

[23] *Id.*

[24] *Id.*

demonstrated that progesterone does not prevent miscarriage among women who have bleeding in early pregnancy.[25]

26. There are particularly serious problems with drawing any inferences from this paper. 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). The seventh patient was reported as lost to follow-up, and the outcome of her pregnancy is not included.

27. Moreover, as explained above, some women would be expected to 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 paper, the four patients who had a continued pregnancy took mifepristone later in gestation (between seven and ten or eleven weeks),[26] 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 question the validity of the data reported overall). Therefore, it is impossible to draw any conclusion about whether the progesterone injections had any effect at all on the patients' pregnancies.

28. In addition, it appears that all of the patients discussed in the paper as "successes" had confirmed embryonic or fetal cardiac activity before beginning progesterone treatment.[27] This

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[25] Coomarasamy et al., *A Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy*, 380 N. Eng. J. Med. 1815-1824 (2019).

[26] Delgado & Davenport, *supra* n.22.

[27] 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.

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.

29. The paper 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.[28] Some patients even continued taking progesterone into the seventh month of pregnancy. 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 paper. The "success" they report with a variety of regimens raises the likelihood that these women would have had ongoing pregnancies with placebo treatments, as well.

30. In short, no responsible physician would suggest, based on this paper, that "reversal" of mifepristone is possible. As ACOG has explained, Dr. Delgado's claims of "reversing" mifepristone "are unproven and unethical," and his study does not amount to valid "scientific evidence that progesterone" can be used for these purposes.[29]

31. The second Delgado paper, published in 2018 in *Issues in Law and Medicine*, is, if anything, more problematic.[30] First, the journal in which the paper was published is once again noteworthy. *Issues in Law and Medicine* is known primarily as a legal policy journal, not as a publication for peer-reviewed scientific research. The journal's website states that it "is devoted to providing technical and informational assistance to attorneys, health care professionals, educators and administrators on legal, medical, and ethical issues arising from health care

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[28] Delgado & Davenport, *supra* n.22.

[29] Statement of the American Congress of Obstetricians and Gynecologists, *supra* n.21.

[30] George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33(1) Issues in Law & Medicine 1-14 (2018).

decisions." This journal is not one that is utilized by clinicians or scientists for clinically-relevant or actionable data. The journal's website further states that the journal "is co-sponsored by the National Legal Center for the Medically Dependent & Disabled, Inc. and the Watson Bowes Research Institute." The Watson Bowes Research Institute, in turn, is affiliated with the American Association of Pro-Life Obstetricians and Gynecologists (an anti-abortion advocacy organization), according to the latter's tax forms.[31] It is a journal with a political, not scientific, agenda.

32. The paper, entitled "A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone," was published in 2018, but was subsequently withdrawn. Media reports indicate that the University of San Diego's Institutional Review Board ("IRB")[32] requested that the paper be withdrawn "because the wording regarding [Institutional Review Board] approval in the paper was ambiguous, leading many readers to incorrectly conclude that the University of San Diego's IRB had reviewed and approved the entire study," when it had in fact only approved a *retrospective* analysis (meaning, an analysis of data from past events) of pre-existing, patient de-identified data.[33]

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[31] *See* American Association of Pro-Life Obstetricians and Gynecologists, Form 990 (2015), *available at* https://rewire.news/wp-content/uploads/2017/02/AAPLOG-990-2015.pdf.

[32] The professional norm and expectation is that research on human subjects should be approved by an IRB, which is a committee that performs an ethical review of proposed research. The purpose of IRBs is to protect human subjects of research. 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 each one has been through the IRB-approval process. I can attest that this mechanism is not simply administrative but is vital to enabling the delicate balance between medical ethics and scientifically progressive research.

[33] *See* Retraction Watch, *Study Claiming "Abortion Reversal" Is Safe and Effective Temporarily Withdrawn for Ethical Issues*, https://retractionwatch.com/2018/07/17/study-claiming-abortion-reversal-is-safe-and-effective-temporarily-withdrawn-for-ethical-issues/.

33. When the paper was subsequently republished, the authors altered the description of their methods but not the results or discussion. Originally, the authors called the paper an "observational case series," which is not actually an accepted or valid study design. The paper is also not a true "case series," because it was *prospective* in design—meaning, all participants provided informed consent before they consented to receive the intervention (here, progesterone)—which is generally not the case with a case-series design. Similarly, the paper is not "observational" because instead of just observing the impact of a treatment on patients, the researchers actively enlisted participants to undergo an *experimental* intervention—here, the administration of progesterone after mifepristone. Worse still, the researchers administered the experimental intervention on patients without a control group, meaning there is no group of similarly situated patients (meaning, patients who took mifepristone but not misoprostol or progesterone) to which the researchers can compare the patients who received progesterone to assess differences in birth outcomes. When the paper was republished, the authors described their methods differently, calling it a "retrospective analysis of clinical data," but did not alter their described results or discussion. It is unheard-of to withdraw a paper, rewrite its methods to describe an entirely different study design, and republish the remainder of the paper unchanged.[34]

34. No valid scientific conclusions can be drawn from the 2018 Delgado paper. It does not include a control group, and so no inference can be made about whether administration of progesterone has any effect (or the size of such effect, if any).[35] It would be inappropriate to draw any conclusions about causation from this paper.

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[34] Delgado et al, *supra* n.30.

[35] The best way to design a study in order to gather any inference about the impact of the exposure (here, progesterone), would be to take women receiving mifepristone, administer progesterone to those women who desire it, and then follow all women, regardless of exposure to progesterone, to their definitive pregnancy outcome. From such a study design, the authors would be able to

35. Moreover, like the 2012 Delgado paper, the 2018 Delgado paper almost certainly overestimates the ongoing pregnancy rate among patients who received progesterone, making its results unreliable. Specifically, women in the paper were administered progesterone only *after* ultrasound was used to confirm ongoing fetal cardiac activity after taking mifepristone (except in an unknown number of instances in which pre-administration ultrasound was not readily available). The fact that the data consisted primarily of women whose pregnancies had already withstood the effects of mifepristone means that the authors were reporting on pregnancies that were already predisposed to continue. The authors generously describe this as a "confounding variable," but the paper does not adequately account for its significance or attempt to statistically control for this as a confounding variable, as any valid scientific research study would do.[36]

36. Additionally, as with Dr. Delgado's 2012 paper, the heterogeneity of the delivery systems described in the 2018 paper further limits any interpretation of the results. The paper lists ten different progesterone regimens, which were not administered by study investigators following a research protocol, but by a dispersed group of clinicians.

37. The paper's ethics are likewise troubling. Because there is no specified regimen being assessed here, women were subjected to doses and routes of progesterone without any clinically actionable outcome gained. There is no sample size calculation provided, so it is entirely possible that more women were exposed than necessary to provide a statistically significant difference with the expected number of live births after mifepristone alone. Were women reimbursed for their time and trouble? Were these women coerced? As a clinician and as an investigator, this paper is deeply troubling on many levels.

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compute the absolute risk, and the relative risk or odds ratios of a continuing pregnancy with and without exposure to progesterone. Dr. Delgado's papers do none of this.

[36] Delgado et al., *supra* n.30.

38. Research and analyses published over the last few years confirm that both publications are inherently flawed and unsupported by the full body of scientific research on mifepristone and progesterone. A systematic review of the research on mifepristone "reversal," published in 2015 in the highly respected journal *Contraception*, demonstrated that evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.[37] This article is attached as Exhibit E. Similarly, an article published in 2018 in the *New England Journal of Medicine*, the most widely read, cited, and influential medical journal in the world, shows that the confidence intervals around the point estimates overlap for women who do and do not use progesterone supplementation after using mifepristone. In essence, there is no evidence at all that progesterone administration after mifepristone use is effective at reversing mifepristone's effects.[38] This article is attached as Exhibit F.

39. Delgado and Davenport published their own purported "systematic review" of the literature on mifepristone "reversal" in *Issues in Law & Medicine* in 2017, but like their other papers, it too is flawed.[39] Delgado and Davenport's review criticizes the review by Grossman et al. published in *Contraception* for including several studies "that did not assess abortion failures with ultrasound to verify if living embryos were present, or had other faulty criteria" despite the fact that Grossman et al. were in fact able to assess the number of continuing pregnancies in these

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[37] Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92(3) Contraception 206-211 (2015).

[38] Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating without Evidence*, 379(16) N. Eng. J. Med. 1401-03 (2018).

[39] Mary Davenport, George Delgado, Matthew Harrison, & Veronica Khauv, *Embryo Survival after Mifepristone: A Systematic Review of the Literature*, 32(1) Issues in Law & Medicine 1-18 (2017).

studies. Meanwhile, Delgado and Davenport provide no rationale for excluding these studies from their review. Delgado and Davenport's review ultimately falls victim to several well-known errors in poorly conducted systematic reviews and meta analyses, including selective reporting, which occurs when the reporting of a subset of outcomes and analyses in the systematic review is based on the results.[40] Finally, it appears that the purpose of this review was to compute the baseline rate of continuing pregnancy without progesterone intervention in the population to inform Delgado's then-upcoming 2018 paper. But their statistical analysis of the papers they reviewed is flawed because the 25% number they cite in the paper as a "control" likely *underestimates* the true rate of continuing pregnancy in the population, with the effect that they *overestimated* the effectiveness of progesterone treatment to "reverse" abortion in their 2018 paper.[41]

40. For all these reasons, the two flawed Delgado papers do not provide 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 treatment that causes pain and potential economic hardship when there is insufficient evidence of benefit to patients.

41. 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

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[40] M.J. Page et al., *Bias Due to Selective Inclusion and Reporting of Outcomes and Analyses in Systematic Reviews of Randomised Trials of Healthcare Interventions*, 1(10) Cochrane Database Syst. Rev. (Oct. 2014).

[41] *See* Delgado et al., *supra* n.30, at 24. To be appropriately conservative in preparation for the planned 2018 paper, the authors instead should have focused on the upper-bound 95% confidence interval around each study's point estimate of the rate of continuing pregnancy. *See* TV Sakpal, *Sample Size Estimation in Clinical Trial*, 1(2) Perspectives in Clinical Research 67-69 (April 2010).

association with second trimester miscarriage and stillbirth in pregnancies exposed to certain exogenous progesterone preparations.[42] 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.[43] While none of these data are conclusive, they are enough to raise concern in the absence of proven benefit.

42. Further, as mentioned above in ¶ 23, recent research on the use of progesterone supplementation during pregnancy by Coomarasamy et al. calls into question its effectiveness in increasing the likelihood that a woman will carry a fetus to term. Specifically, a large, randomized, double-blind, placebo-controlled trial of progesterone use in over four thousand women with threatened miscarriages before twelve weeks of gestation found that the incidence of live births was the same in the group of women who received progesterone and the group that did not.[44] In addition, in an accompanying editorial in the New England Journal, the following statement is made: "In retrospect, it is likely that the initial rationale for hormonal therapy—that is, the observed fall in pregnancy hormone levels before pregnancy loss—was, in fact, a consequence rather than a cause of pregnancy failure. The subsequent enthusiasm for hormonal therapy was driven by overestimation of the incidence of pregnancy loss in the absence of therapy and by reports of seeming success in uncontrolled case series."[45] This statement not only underscores the flaws with the concept of progesterone "rescue therapy" but also highlights the dangers of over-

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[42] Paul J. Meiss et al., *Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate*, 348 N. Eng. J. Med. 2379, 2382 (2003).

[43] Suzan L. Carmichael et al., *Maternal Progestin Intake and Risk of Hypospadias*, 159(10) Archives of Pediatric & Adolescent Med. 957 (2005).

[44] Coomarasamy et al., *supra* n.25.

[45] Michael F. Green, Editorial, *Progesterone for Threatened Abortion*, 380(19) N. Eng. J. Med. 1867 (2019).

interpretation of data derived from case series, the methodology Delgado and associates claim to have used. Clearly, if medical experts cannot draw strong scientific conclusions from a case series, Oklahoma should not be legislating the practice of medicine based on the data they produce.[46]

43. Even absent concerns about high-dose progesterone, which has not been adequately studied in this population or for this indication, I am concerned about possible future complications to the pregnancy caused by the mifepristone alone, as well as a combination of mifepristone and progesterone. While mifepristone is not established to be teratogenic (meaning disruptive of embryonic/fetal development), neither mifepristone nor high doses of progesterone 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. It is entirely possible this regimen could cause harm to the fetus, including birth defects, and almost impossible that it would be acceptable per current federal standards—outlined in the Code of Federal Regulations Part 46, Protection of Human Subjects, Research Involving Pregnant Women or Fetuses[47]—without intensive data safety and monitoring board oversight. There is no mention of such oversight in the Delgado publications.

44. Indeed, even Delgado and Davenport in their 2012 paper 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

[46] While the Coomarasamy et al. study suggested some clinically significant benefit for the small group of patients in the sample that had three or more previous miscarriages (i.e. recurrent miscarriages), the study did not draw any conclusions about the potential benefit to these patients. Patients with recurrent miscarriages are commonly understood to have distinct and even unique medical etiology, as compared to other patients. *See, e.g.*, Mercy Y. Laurino, et al. *Genetic Evaluation and Counseling of Couples with Recurrent Miscarriage: Recommendations of the National Society of Genetic Counselors*, 14(3) Journal of Genetic Counseling (June 2005).

[47] 45 C.F.R. § 46.204.

treatment and only some physicians may be "comfortable" doing so.[48] 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. The 2018 paper similarly acknowledges that only "randomized controlled trials" can "confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient."[49] As described in the *New England Journal of Medicine* editorial regarding the now disproven use of progesterone to help reduce the risk of miscarriage, changes in clinical practice based upon observational studies alone (of which a case series in the least rigorous) have repeatedly been later proven to be misguided, and these findings need to be confirmed (or disproven) with more rigorous study designs.[50]

45. Further investigation would be especially necessary here because of the pharmacodynamics and pharmacokinetics of the competing medications. Given how high natural progesterone levels are in pregnancy already, it seems unlikely that high doses of exogenous 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 (which is at very high levels in pregnancy, naturally), 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 would not expect that exogenous progesterone could have any effect once the mifepristone has started acting or that there would be any reason to further

[48] Delgado & Davenport, *supra* n.22 (emphasis added).

[49] Delgado et al, *supra* n.30, at 29.

[50] *See* Green, *supra* n.45.

elevate a patient's (already high in pregnancy) progesterone levels long after the mifepristone has ceased blocking progesterone receptors, and I would need empiric evidence showing otherwise. Further study would be required. To date, sufficient data do not exist to make conclusive statements.

46. Other than the two published Delgado papers, the only other source for information supporting "mifepristone reversal" about which I am aware is the Abortion Pill Reversal website and hotline that Drs. Delgado and Davenport founded, called abortionpillreversal.com. S.B. 614 requires physicians to refer medication abortion patients to this website and hotline, verbally and in writing, before and after the patient takes mifepristone. The website states that "Abortion Pill Rescue" is a program of Heartbeat International, a "network of pro-life pregnancy resource centers" whose mission "is to make abortion unwanted today and unthinkable for future generations."[51] It appears that Delgado and Davenport are Medical Advisors to this organization and there is a "network" of "professional healthcare providers" available to assist women who call their hotline.[52] The website represents that there is a treatment that is "effective" in reversing abortion, which is a completely unproven claim.[53] It states, "There is an effective process called ABORTION PILL REVERSAL." This statement is false. It also states: "By giving extra progesterone, we hope to outnumber and outcompete the mifepristone in order to reverse the effects of mifepristone."[54] This conjecture has not been established and, based on the relative

[51] *Our Passion*, Heartbeat International, https://www.heartbeatinternational.org/about/our-passion (last visited Sept. 11, 2019).

[52] *About Us,* Abortion Pill Rescue, http://www.abortionpillreversal.com/about/our-team (last visited Sept. 11, 2019).

[53] Abortion Pill Rescue, http://www.abortionpillreversal.com (last visited Sept. 11, 2019).

[54] *FAQ*, Abortion Pill Rescue, https://www.abortionpillreversal.com/faq (last visited Sept. 11, 2019).

binding affinities and the other information described above, is unlikely to be true. The website lists the side-effects of mifepristone as a major section, which is not only irrelevant to their mission, but the side effects listed include additional false claims. Finally, the website claims that "we have had many successful reversals," and that it "may not be too late" to reverse an abortion even after 72 hours,[55] which is highly misleading. It also goes against ACOG's recommendations. All told, this website conveys Abortion Pill Reversal's ideologically based agenda and is dangerous. It is replete with misinformation about mifepristone, and indicates the organization's intention to sow doubt in the patient's mind about the treatment protocol she and her physician have chosen. No physician practicing evidence-based medicine would refer a patient to this website.

47. 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 two published papers, as well as on media reports and statements, which indicate that these physicians are providing various experimental progesterone protocols 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 their proposed experimental progesterone protocols.[56]

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[55] *Id.*

[56] Shannon Firth, *Reversing Abortion Pill: Can It Be Done?*, MedPage Today (Feb. 24, 2015), http://www.medpagetoday.com/OBGYN/GeneralOBGYN/50164 ("Of the 223 women who have received progesterone, 127 cases succeeded, according to a fact sheet Delgado shared."); Colette Wilson, *Interview: Reversing the Effects of RU-486*, Lifeline Newsletter (Life Legal Defense

48. 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.[57] 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."[58] 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."[59]

49. For all the reasons above, in my opinion, the 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 an 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

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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.").

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

[58] *Id.* at 1591.

[59] *Id.* at 1592.

or call the APR hotline to learn more about this treatment. In the unlikely event that 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 S.B. 614 on the Patient-Provider Relationship

50. 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 physicians and patients in a variety of ways.

51. To begin with, the vast majority of women receiving medication abortion are sure of their decision by the time they present for care at an abortion clinic,[60] so information about "reversal" would be irrelevant for those patients. Additionally, part of the value to the clinical encounter is pregnancy options counseling, when the provider reviews the plan of care with the patient *before* initiating any clinical intervention. Falsely claiming that an abortion could be reversible is dangerous to women, and dangerous to the practice of medicine. Women may erroneously believe it is advisable to start the abortion process before they are sure of their decision.

[60] *See, e.g.*, L.J. Ralph et al., *Measuring Decisional Certainty Among Women Seeking Abortion*, 95(3) Contraception 269-278 (2016); D.G. Foster et al., *Attitudes and Decision Making Among Women Seeking Abortions at One U.S. Clinic*, 44(2) Perspectives on Sexual & Reproductive Health 117-124 (2012).

52. S.B. 614 thus disrupts and impedes the patient-provider relationship and contravenes the true purpose of the informed consent process: Namely, to give each patient medical information relevant to their healthcare decision-making in a way that is easy to absorb and understand—i.e., that is clear, concise, and applicable to her circumstances and individual concerns.

53. The mandated information that must be "conspicuously" posted in patient waiting rooms and consultation rooms would also be irrelevant, and even more confusing, for women who are not using mifepristone as a part of the standard medication abortion regimen with misoprostol for abortion up to 10 weeks LMP, but instead are receiving drugs, such as misoprostol alone, 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 information. Moreover, a sign displaying the government's misleading message in 3/4 inch (i.e. 54 point) font, as required by S.B. 614, would be equivalent to the size of a poster. A message of this size and prominence is not typically present in a medical practice and would likely spark concern and confusion among patients. For patients seeking medication abortion with mifepristone, the notice may create confusion about whether the treatment protocol prescribed by their physician is effective, potentially eroding trust and undermining the doctor-patient relationship. Ultimately, the overall effect of the notice is coercive—instilling confusion, doubt, and distrust, all in service of coercing women away from the treatment they have chosen.

54. Furthermore, S.B. 614's requirements are confusing and misleading for medication abortion patients. Under S.B. 614, patients must hear from their physician, or their physician's agent, that reversal "may be possible," and that the state and the APR hotline and website offer assistance with obtaining this treatment. Patients must again receive the same referral to the APR

hotline and website, from their physician or their physician's agent, *after* they receive mifepristone. In this situation, patients are likely to conclude that this treatment is established as safe and effective, which as explained above, is far from true. In effect, S.B. 614 forces physicians and their agents to repeatedly endorse experimental medical treatment and repeatedly refer patients to APR for that treatment, despite the fact that the physicians do not think this treatment is in their patients' best interests. 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. It could even lead a patient to seek a malpractice action against her physician for providing information and advice that deviates from the standard of care.

55. Finally, I am concerned that S.B. 614'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. This concern is compounded by the risk that S.B. 614's required waiting room and consultation room written notices and post-mifepristone "instructions" will expose patients to misinformation about the efficacy of mifepristone "reversal" by referring them to the APR website. 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.

56. If a patient shows signs of ambivalence, I advise her to reflect further, and offer her professional resources if necessary. I do this for medication abortion patients up to 10 weeks LMP 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 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.

57. I believe, therefore, that introducing the misleading prospect that abortion 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 tenets of medicine.

58. For all of these reasons, the disclosures required by S.B. 614 about mifepristone "reversal," and the repeated referrals to the APR hotline and website, compel physicians to distort and damage the relationship of trust that they seek to build with their patients, and forces them to provide information to their patients that they do not agree with and that they think is false, misleading, irrelevant, and/or harmful to women seeking abortions. It violates the tenets of ethical and evidence-based medical care. Rather than promoting physician autonomy in the provision of healthcare and the health of women and families, it damages the physician-patient relationship, undercuts the physician's professional integrity, and harms women.

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

Dated this 24th day of September, 2019.

DocuSigned by:
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Courtney A. Schreiber, M.D., M.P.H.

Exhibit A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 04/25/2019

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)
1995	OTH	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

Military Service:

[none]

Faculty Appointments:

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

2008-2017	Founder and Director, Penn Family Planning and Pregnancy Loss Center
2009-present	Program Director, Fellowship in Family Planning, Hospital of the University of Pennsylvania
2017-present	Director, PEACE (Pregnancy Early Access Center)
2017-present	Chief, Division of Family Planning, Department of Obstetrics and Gynecology, Penn Medicine

Other Appointments:

2018-present	Research Director, Building Interdisciplinary Research Careers in Women's Health K-12 Program, Perelman School of Medicine, University of Pennsylvania
2018-present	Senior Fellow, Leonard Davis Institute of Health Economics

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	James E Constantine Award in Obstetrics and Gynecology, NYU School of Medicine
1999	Dr. Martin Gold Visionary Provider Award, Diana Foundation, NY, NY
2001	Resident Teaching Award, Hospital of the University of Pennsylvania
2004	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
2005	Philip F. Williams Prize Award, American College of OB/GYN
2005	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2010	Women's Way Unsung Heroine Award: Turning Talk into Action
2011	Emily B. Hartshorne Mudd Award for Contributions to the Field of Family Health
2011	The Penn Medicine "Penn Pearls" Award for Excellence in Teaching
2015	Penn Center for Innovation Accelerator Award Phase I
2016	Penn Center for Innovation Accelerator Award Phase II

2019	Clinical Research Forum Top 10 Clinical Research Achievement Award

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2017-present	Fellowship in Family Planning (Advisory Board (Chair, 2018-present))

National:

1995-1999	Medical Students for Choice (Board of Directors)
1997-2002	American Medical Women's Association
1997-present	Physicians for Reproductive Choice and Health (Board of Directors 1997-1999)
1999-Present	American College of Obstetricians and Gynecologists (Physician Member, Committee on Health Care for Underserved Women (2012-2013) Fellow (2002-present) Junior Fellow (1999-2008))
2001-2006	American Society for Reproductive Medicine
2003-present	Association of Reproductive Health Professionals
2003-present	National Abortion Federation
2004-2012	American Public Health Association
2008-Present	Peer Health Exchange (Curriculum Advisory Board)
2012-present	Center for Disease Control Teen Pregnancy Prevention Project, Family Planning Council of Pennsylvania (Consultant)
2014	NIH (Study Section Reviewer: Female Contraceptive Development Program (U01))

Local:

2008-2016	Family Planning Council (Board Member of the Medical Committee)
2008-2016	Women's Medical Fund Medical Advisory Committee
2010-2016	American Civil Liberties Union of Pennsylvania, Clara Bell Duvall Reproductive Freedom Project (Advisory Council Member)
2011-2017	Women's Way (Board Member. Vice Chair of the Board 2014-2016)

Editorial Positions:

2005-Present	Reviewer, *Contraception*
2007-Present	Reviewer, *American Journal Obstetrics and Gynecology*
2008-2010	Reviewer, *Pharmacoepidemiology*
2011-Present	Associate Editor, *Contraception*
2017-present	Section Editor, Contraception, *UpToDate*
2018-present	Deputy Editor, *Contraception*
2018-present	Section Editor, Ectopic Pregnancy, *UpToDate*
2019-present	Editorial Advisory Board, *UpToDate*

Academic and Institutional Committees:

2002-2003	House Officer Committee, Hospital of the University of Pennsylvania
2005-2010	Resident Curriculum Development Committee
2009-Present	Operating Room Committee
2010-2012	Grant Reviewer Penn CFAR Pilot Grants Program
2011-2014	Chair, Management of Early Pregnancy Failure Working Group
2012-2018	Center for AIDS Research Committee on Women and HIV
2013-2018	Core Member, Women's Health Scholar Certificate
2014-2015	Member, Department of Obstetrics and Gynecology Executive Committee
2014-present	Medical School Admissions Interview Committee, Perelman School of Medicine of the University of Pennsylvania.
2018-Present	Member, Review Committee for the Department of Biostatistics, Epidemiology, and Informatics
2018-present	Department of Obstetrics and Gynecology Executive Committee

Major Academic and Clinical Teaching Responsibilities:

2002-2003	Organizer, Ob/Gyn resident journal club, Hospital of the University of Pennsylvania
2002-Present	Lecturer, Ob/Gyn resident didactics and journal club
2005-2015	Lecture on Family Planning, Core Clinical Clerkship in Ob/Gyn (OG200), (8x/yr)
2005-2016	Faculty preceptor, Core Clinical Clerkship in Ob/Gyn (OG200), (1-2x/yr) change end date in FEDS
2006-2017	Lecturer "Contraception", Reproduction module (1 lecture/yr)
2006-2016	"Bridging the Gaps" Academic Mentor for one student each summer
2006-2017	Director, Family Planning Rotation for Ob/Gyn residents
2006-2017	Course Director, Family Planning and Abortion Care Elective (OG300)
2006-2017	Small group discussion leader on abortion and contraception, Reproduction module (2 sessions/yr)
2006-Present	Attending Physician, Family Planning, supervise and teach medical students, residents, and fellows
2006-2016	Attending physician, Resident Gynecology service (4 weeks/yr)
2006-Present	Research mentor for resident research projects
2006-2017	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?"
2006	Hospital of The University of Pennsylvania Department of Obstetrics and Gynecology Grand Rounds: "The Characterization and Treatment of Early Pregnancy Failure"
2007	Division of Cardiology, University of Pennsylvania Medical Center, "Contraception in Women with Congenital Heart Disease",
2008-2010	Mentor, Monika Goyal, MD, Pediatric Emergency Fellow "Prevalence of Trichomonas vaginitis in a symptomatic adolescent ED population
2009-Present	Director, Family Planning Fellowship Program
2010-2012	Fellowship Mentor: Sara Pentlicky, MD
2010-2013	Mentor, Holly Langmuir, MD, Resident in Obstetrics and Gynecology "Immediate postpartum IUD placement: a decision analysis"
2010-2013	Mentor, Peter Vasquez, MD, Resident in Obstetrics and Gynecology "Factors that decrease morbidity among women undergoing second trimester uterine evacuation at an urban academic medical center"
2010-2013	Mentor, Ericka Gibson, MD, Resident in Obstetrics and Gynecology "Risk Factors for pregnancy during contraceptive clinical trials"
2010-2012	Mentor, Sara Pentlicky, MD, Fellow in Family Planning "Weight Loss in the postpartum: impact of different contraceptive methods"
2010-2013	Mentor, Corina Tennant, MD, Resident in Obstetrics and Gynecology "Uptake, acceptability, and continuation of the Implanon contraceptive implant immediately postpartum in an urban medical center"
2011-2013	Mentor, Lily Pemberton, MD, Resident in Obstetrics and Gynecology "establishment of an academic family planning outpatient facility increases uptake of LARC among inner-city women"
2011-2017	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"
2012-2016	Clinician Trainings for the Family Planning Council's CDC Teen Pregnancy Prevention Project
2014-2015	Mentor, Pooja Mehta, MD, ACOG Industry-Funded Research Fellowship in Contraceptive Access within Low-Resource Populations
2014-2016	Mentor, Elizabeth Gurney, MD, Fellow in Family Planning "Six-month Retention Rates of Copper IUDs Placed Immediately Post-placentally"
2014-2016	Mentor, Alyssa Colwill, MD, Resident in Obstetrics and Gynecology "Immediate Post-placental IUD Expulsion - a Retrospective Cohort Study"
2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology, Pennsylvania Hospital, Philadelphia PA
2015-2017	Mentor, Elizabeth Greenstein, MD, Resident in Obstetrics and Gynecology "Doctor-Patient Communication at the Time of Miscarriage Management"
2015-2018	Mentor, Maryl Sackheim, MD, Resident in Obstetrics and Gynecology: "Rapid Repeat Pregnancy at Penn Medicine: Prevalence and Risk Factors"
2015-2017	Mentor, Alhambra Frarey, MD, Fellow in Family Planning "Referral and Delay in Abortion Care: a Cross-sectional Study"
2015	"Contraception for women with rheumatologic disease," Division of Rheumatology of Penn Medicine, Philadelphia Pa.
2016-2018	Mentor, Sarah Horvath, MD, Fellow in Family Planning "Quantifying Feto-Maternal Hemorrhage in the First Trimester of Pregnancy" Winner, Society of Family Planning Young Investigator Award, 2018
2016	"History of Contraception in the US," Master of Public Health Program, University of Pennsylvania, Philadelphia PA
2016	"Academic Medicine as an Instrument of Change," Master of Science of Health Policy, University of Pennsylvania, Philadelphia PA
2017	"The role of public health practice and research in reproductive health" Master of Public Health Program, University of Pennsylvania Perelman School of Medicine. Philadelphia, PA
2017-2019	Mentor, Divyah Nagendra, MD, Fellow in Family Planning "Pain Control for Uterine Evacuation: a Non-Inferiority Trial"
2017	"Academic Medicine as an Instrument of Change," University of Pennsylvania MSHP Program
2018	Pediatric Grand Rounds: Children's Hospital of Philadelphia, "Progress and Opportunities in Adolescent Reproductive Health"

2018-2020	Mentor, Jade Shorter, MD, Fellow in Family Planning "Disparities in Reproductive Health: The Patient Experience with Miscarriage Management"

Lectures by Invitation (Last 5 years):

Mar, 2014	"The management of early pregnancy complications," University of Innsbruck, Innsbruck, Austria
Apr, 2014	Controversies in Family Planning, Fellowship in Family Planning Annual Meeting. Chicago, IL.
May, 2014	Miscarriage Management in the Emergency Department, Grove Foundation Advancing Miscarriage Management Symposium. San Francisco, CA.
Oct, 2014	Demystifying hCG: What hCG is and patterns in normal and abnormal pregnancy. North American Forum on Family Planning, Miami FL.
Nov, 2014	"Individualized Care of Early Pregnancy Loss" Washington University Department of Obstetrics and Gynecology, St Louis, Mo.
Nov, 2014	The Patient's Voice in the Management of Early Pregnancy Loss. V. Chavez, A. Agha, E. Easley, C.A. Schreiber, Association of Early Pregnancy Units (AEPU), Winchester, UK
Apr, 2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Jefferson Hospital, Philadelphia PA
Jul, 2015	"Immediate Postpartum Long Acting Reversible Contraception." Philadelphia Board of Health, Department of Health
Mar, 2016	"Increasing Access to Long-Acting Reversible Contraception for Philadelphia Women." Public Health and Preventive Medicine Section at the College of Physicians of Philadelphia, PA
Apr, 2016	"Immediate Postpartum LARC: Evidence and Implementation." Department of Obstetrics & Gynecology Grand Rounds. WellSpan / York Hospital, York PA
Apr, 2016	Liletta: Challenges and Advantages of a New LNG IUD. Moderated a webinar for the Fellowship in Family Planning and Ryan Program Nationally
Oct, 2016	"Unpacking Complex Contraception," University of British Columbia Interdisciplinary Grand Rounds, Vancouver, BC
Dec, 2016	"LARC for the medically complex patient," ACOG LARC Program, CME accredited webinar
Oct, 2017	"Climbing the career ladder and lifting others as you climb." Society for Family Planning Career Development Seminar, Atlanta, GA.
Nov, 2017	"Personalized Approaches to Early Pregnancy Loss Care" Early Pregnancy Symposium. Philadelphia, PA
Nov, 2017	"Pregnancy of Unknown Location" Early Pregnancy Symposium. Philadelphia, PA
Jan, 2018	"Patient-Centered Early Pregnancy Loss Care," UC San Diego Obstetrics and Gynecology Grand Rounds, San Diego, CA.

Apr, 2018	"Hormonal Contraception and the Risk of Mood Symptoms," North American Society for Psychosocial Obstetrics and Gynecology, Philadelphia, PA.
Oct, 2018	"Advances in the Care of Patients with Early Pregnancy Loss," Magee-Women's Hospital Alumni Day, Pittsburgh, PA
Nov, 2018	"Advances is Early Pregnancy Loss Care" Einstein Healthcare Network, Obstetrics and Gynecology Departmental Grand Rounds
Nov, 2018	"Miscarriage Management: Updates and Innovations" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of ACOG, Santiago, Chile
Nov, 2018	"Healthy Child-Spacing, Healthy Families: Best Practices in Postpartum Contraception" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of ACOG, Santiago, Chile
Jan, 2019	"Advances in the Care of Patients with Early Pregnancy Loss," Obstetrics and Gynecology Grand Rounds, MedStar Washington Hospital Center and MedStar Georgetown University Hospital, Washington, D.C.
Mar, 2019	"Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss" Ob/Gyn Grand rounds, Beth Israel Deaconess Medical Center, Boston MA

Organizing Roles in Scientific Meetings:

Apr, 2010	Chair, National Abortion Federation 2010 Postgraduate course: "Team Work and Patient Safety" Philadelphia, PA
2011	Co-Chair HIV and Women subgroup of the Penn Center For Aids Research, Philadelphia, PA
Apr, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting, Chicago, IL
May, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting, Denver, CO
May, 2013	Co-Chair, Penn CFAR Women and HIV Symposium: "Biobehavioral approaches to HIV prevention and management in adolescent women" Perelman School of Medicine, Philadelphia PA
May, 2014	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting, New Orleans, LA
Apr, 2015	Moderator, second year family planning fellows' research presentations on contraception, San Francisco, California
Apr, 2017	Organizer and Panel Moderator, "Moving Forward: Protecting and Promoting Reproductive Health" University of Pennsylvania

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23. Schreiber CA, Traxler S: State of family planning. Clin Obstet Gynecol 58(2): 392-408, Jun 2015

24. Eisenberg DL, Schreiber CA, Turok DK, Teal SB, Westhoffe CL, Creinin MD: Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. Contraception 92(1): 10-16, July, 2015.

25. Quinley KE, Falk A, Kallan MJ, Datner EM, Carr BG, Schreiber CA: Validation of ICD-9 Codes for Stable Miscarriage in the Emergency Department. West J Emerg Med 16(4): 551-6, July 2015.

26. Schreiber CA, Ratcliffe SJ, Quinley KE, Miller C, Sammel MD: Serum biomarkers to predict successful misoprostol management of early pregnancy failure. Reprod Biol 15(2): 79-85, 2015.

27. Schreiber CA, Ratcliffe SJ, Sammel MD, Whittaker PG.: A self-assessment efficacy tool for spermicide contraceptive users. Am J Obstet Gynecol 214(2): 264.e1-7, Feb 2016.

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30. Roe AH, Traxler SA, Hadjiliadis D, Sammel MD, Schreiber CA: Contraceptive choices and preferences in a cohort of women with cystic fibrosis. Respir Med 121: 1-3, Dec 2016.

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33. Akers AY, Steinway C, Sonalkar S, Perriera LK, Schreiber CA, Harding J, Garcia-Espana JF: Reducing Pain During Intrauterine Device Insertion: A Randomized Controlled Trial in Adolescents and Young Women. Obstet Gynecol 130(4): 795-802, Oct 2017.

34. Sonalkar S, Gurney EP, McAllister A, Schreiber CA: A randomized pilot evaluation of individual-level abortion stigma resulting from Pennsylvania mandated abortion counseling. Contraception 96(4): 227-232, Oct 2017.

35. Colwill AC, Schreiber CA, Sammel MD, Sonalkar S: Six-week retention after postplacental copper intrauterine device placement. Contraception 97(3): 215-218, Mar 2018.

36. Schreiber CA, Teal SB, Blumenthal PD, Keder LM, Olariu AI, Creinin MD: Bleeding patterns for the Liletta levonorgestrel 52 mg intrauterine system. Eur J Contracept Reprod Health Care 23(2): 116-120, Apr 2018.

37. Akers AY, Harding J, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S: Satisfaction with the Intrauterine Device Insertion Procedure Among Adolescent and Young Adult Women. Obstet Gynecol 131(6): 1130-1136, Jun 2018.

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43. Sackeim MG, Gurney EP, Koelper NC, Sammel MD, Schreiber CA: Effect of contraceptive choice on rapid repeat pregnancy. Contraception Nov 2018.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17. Dzuba IG, Grossman D, Schreiber CA: Off-label indications for mifepristone in gynecology and obstetrics. Contraception 92(3): 203-5, Sep 2015.

18. Roe A, Traxler SA, Schreiber CA: Contraception in Women with Cystic Fibrosis: A Systematic Review of the Literature. Contraception 93(1): 3-10, Jan 2016.

19. Horvath S, Schreiber CA: Unintended Pregnancy, Induced Abortion, and Mental Health. Curr Psychiatry Rep 19(11): 77, Sep 2017.

20. Shorter Jm, Atrio JM, Schreiber CA: Management of early pregnancy loss, with a focus on patient-centered care. Semin Perinatol Dec 2018.

Contributions to peer-reviewed research publications, participation cited but not by authorship:

[none]

Research Publications, non-peer reviewed:

[none]

Abstracts (Last 3 years):

1. Gurney E, Sonalkar S, McAllister A, McClusky J, Frarey A, Schreiber CA: Expulsion of Immediate Postplacental Copper IUDs at Six Weeks: A Prospective Cohort Study. Poster presentation, ACOG Annual Clinical and Scientific Meeting, San Diego, CA, May 2017.

2. Sonalkar S, Gurney EP, McAllister A, Schreiber CA: Abortion Stigma Resulting from State Mandated Abortion Consent Language: A Randomized Controlled Trial. ACOG Annual Clinical and Scientific Meeting; San Diego, CA, May 2017.

3. Chen BA, Kimble TD, Ginde SY, Jensen JT, Schreiber CA, Creinin MD: Bleeding patterns do not differ between obese and non-obese women using a levonorgestrel 52-mg intrauterine system. Poster Presentation, North American Forum on Family Planning, Atlanta, GA, Oct 2017.

4. Clement EG, Horvath SK, Koelper N, Sammel MD, Schreiber CA: The language of pregnancy demise: patient-reported clarity and preferences. North American Forum on Family Planning, Atlanta, GA, Oct 2017.

5. Hunter T, Gurney EP, Schreiber C, McAllister A, Sonalkar S: Probability of Pregnancy after Intended Postplacental versus Interval Intrauterine Device Placement. ACOG Annual Clinical and Scientific Meeting; Austin, TX Apr 2018.

6. Eisenberg D, Schreiber C, Carr B, Turok D, Chen B, Creinin M: Change in Bleeding Patterns After Liletta Insertion for Women with Subjective Baseline Heavy Menstrual Bleeding. Poster Presentation, Forum on Family Planning, New Orleans, LA October 2018. Notes: Winner, Translational Poster Award.

7. Flynn A, Sonalkar S, Schreiber CA: Unintended Pregnancy and Contraception among Women with Resolved Pregnancy of Unknown Location. Poster presentation Forum on Family Planning, New Orleans, LA Oct 2018.

8. Horvath S, Luning Prak E, Schreiber C: Flow Cytometric Quantification of Feto-Maternal Maternal Hemorrhage Following Uterine Aspiration. Oral Poster Presentation, Forum on Family Planning, New Orleans, LA Oct, 2018.

9. Lang B, McAllister A, Epperson CN, Schreiber CA: Comparing Mood and Sexual Side Effects among Users of Hormonal and Non-hormonal Contraceptives. Poster Presentation, Forum on Family Planning, New Orleans, LA Oct, 2018.

10. Nagendra D, Harvie H, Koelper N, Sonalkar S, Loza-Avalos S, Schreiber CA: Cost Effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy. Oral presentation, ACOG Annual Clinical and Scientific Meeting, May 2019.

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

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

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

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5. Schreiber CA, Rhoa MF, Holland L: Pelvic Pain. Clinical Handbook of Pediatrics, 3rd Edition. Schwartz MW (eds.). Lippincott Williams and Wilkins, Baltimore, MD, Page: 569-576, 2003.

6. Schreiber CA: The Female Reproductive System. Concepts in Medical Physiology. Seifter J, Sloane D, Ratner A (eds.). Lippincott Williams & Wilkins, Philadelphia, PA, Page: 573-604, October 2005.

7. Barnhart K, Schreiber CA, Shaunik A: Contraception. www.endotext.org 2006.

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12. Sober S, Schreiber CA: Pregnancy Options Counseling. Contraception for Adolescent and Young Adult Women. Whittaker A, Gilliam M (eds.). Springer, May 2013.

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17. Sonalkar S, Schreiber CA, Barnhart KT: Contraception. http://www.ncbi.nlm.nih.gov/books/NBK279148/ De Groot LJ, Beck-Peccoz P, Chrousos G, Dungan K, Grossman A, Hershman JM, Koch C, McLachlan R, New M, Rebar R, Singer F, Vinik A, Weickert MO (eds.). MDTEXT.com South Dartmouth, MA, Nov 2014.

18. Sober S, Schreiber CA: Pregnancy Counseling Options. Contraception for Adolescent and Young Adult Women. Whittaker A, Gilliam M (eds.). Springer Science+Business Media, NY, Chpt 14, 2014.

19. Schreiber CA, Barnhart KT: Contraception. Yen and Jaffe's Reproductive Endocrinology. Jerome F. Strauss II, MD, PhD and Robert L. Barbieri, MD (eds.). Elsevier, 2018.

Books:

[none]

Alternative Media:

[none]

Patents:

Courtney Schreiber: Medical Management of Nonviable Pregnancy. USA Patent Number 62/777,369, 2018.

Exhibit B

Progesterone Use to Reverse the Effects of Mifepristone

George Delgado and Mary L Davenport

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

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

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

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

KEY WORDS: medical abortion, mifepristone, progesterone.

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

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

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

Pharmacology of Mifepristone and Progesterone

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

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

Author information provided at end of text.

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

Current Regimens of Medical Abortion

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

Results of Progesterone Therapy

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

Case Reports

CASE 1

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

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

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

CASE 2

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

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

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

CASE 3

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

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

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

CASE 4

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

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

CASE 5

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

CASE 6

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

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

The abortion was completed 3 days after mifepristone ingestion.

Discussion

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

SUGGESTED PROTOCOL

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

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

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

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

Protocol

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

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

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Exhibit C

A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone

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ABSTRACT:

Background: Some women who take mifepristone, a progesterone receptor antagonist, in order to terminate their pregnancies, change their minds and desire to stop the medical abortion process. There are only two articles in the medical literature documenting the reversal of the effects of mifepristone.

Objective: We present and analyze a series of women who attempted to reverse the effects of mifepristone by taking supplemental progesterone to determine if the reversal of the effects mifepristone with progesterone is possible and safe. Additionally, we compare different progesterone regimens to determine relative efficacies.

Methods: This is a retrospective analysis of clinical data of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone but before taking the second drug in the protocol, misoprostol. We followed the patients, who were given progesterone in an effort to reverse

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the effects of mifepristone, and conducted statistical analyses to determine the efficacies of different protocols compared to a control mifepristone embryo survival rate, derived from the literature.
***Results*: Intramuscular progesterone and high dose oral progesterone were the most effective with reversal rates of 64% ($P < 0.001$) and 68% ($P < 0.001$), respectively. There was no apparent increased risk of birth defects.**
***Conclusions*: The reversal of the effects of mifepristone using progesterone is safe and effective.**

Introduction

Medical induced abortion utilizing mifepristone has been available in the United States since 2000. In 2014, 31% of non-hospital induced abortions were medical induced abortions.[1] Some women decide to attempt to reverse the medical abortion process after taking mifepristone but before taking misoprostol, and inquire about the possibility of reversing the effects of mifepristone.[2]

The new FDA protocol, approved for medical abortion in 2016, involves the administration of mifepristone 200 mg orally as a single dose, which leads to embryonic or fetal demise, followed 24-48 hours later by misoprostol 800 mcg buccally as a single dose, which stimulates myometrial contractions. The protocol is approved up to 70 days after the first day of the last menstrual period.[3] Misoprostol is part of the protocol because mifepristone alone has an incomplete abortion rate of 20-40%, as determined by the end point of complete expulsion.[4]

Pharmacology

Mifepristone is a competitive antagonist of progesterone at the progesterone receptor (PR). It binds to the PR twice as avidly as progesterone.[5] 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.[6]

Demethylation and hydroxylation are catalyzed by CYP3A4; three metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepristone and its metabolites can be measured up to 72 hours after an ingested dose.[5] The half-life of progesterone is longer, approximately 25-55 hours.[6,7]

Effects of Mifepristone

By blocking progesterone receptors, mifepristone leads to the separation of the decidua basalis from the trophoblast. This separation diminishes the oxygen and nutrients that can be delivered to the embryo or fetus by the maternal circulation and is the primary embryocidal and feticidal effect of mifepristone.[4,8,9]

In addition to this primary effect, mifepristone causes softening and dilatation of the cervix.[4] It also leads to myometrial contractions, increased myometrial sensitivity to prostaglandins[4,10] and the disinhibition of prostaglandin synthesis by the myometrium.[11]

Progesterone has been shown to have an autoregulatory effect on progesterone synthesis by the corpus luteum. Blocking progesterone receptors with mifepristone decreases progesterone secretion by the corpus luteum.[12]

Logic of Using Progesterone to Reverse Mifepristone Effects

Mifepristone is a competitive inhibitor of the progesterone receptor. It is well known that receptor agonism and antagonism are parts of a dynamic process that can be influenced by changing concentrations of the agonist or antagonist. Therefore, it makes biologic sense that increasing the progesterone levels in a pregnant woman by giving supplemental progesterone would favor the agonist progesterone effects and blunt the abortifacient effects of mifepristone.

An Animal Model

A Japanese rat study provides basic-science evidence of the ability of progesterone to negate the effects of mifepristone. In this experiment, one group of pregnant rats was given mifepristone while a second was given mifepristone and progesterone. In the group that only received mifepristone, only 33% of the pups survived. In the group that received mifepristone and progesterone, 100% of the pups survived. Furthermore, the first group had characteristic changes in the myometrium and ovaries; the group that received the combination had no such changes.[13]

Early Mifepristone Studies Reporting Continuing Pregnancy

When mifepristone was first studied as an abortifacient, misoprostol was not part of the protocol. During the 1980's, researchers determined that even though mifepristone was effective as an abortifacient, they believed it was necessary to add a prostaglandin analog to achieve a satisfactory complete uterine evacuation rate.[4] We must emphasize that the definition of incomplete abortion is incomplete emptying of the uterus.[14] Embryo or fetus survival is not implied.

The earliest studies also revealed that some embryos survived mifepristone. Baulieu, the principal developer of the drug, stated that at 4-7 weeks the percentages of efficacy of the regimen were approximately 70% for complete abortions, 20% for incomplete abortions and 10% for ongoing pregnancies (i.e., presumed embryo survival). For gestations 8-10 weeks, the comparable rates were 50% for complete abortions, 35% for incomplete abortions and 15% for embryo survival.[15]

In 2015, Grossman et al. published a review of the first case series of progesterone reversal of mifepristone, as well as 13 studies from the 1980's, addressing continuing pregnancies after mifepristone. The authors concluded that there was insufficient evidence to show that progesterone therapy improved survival over expectant management, based on the reported high ongoing pregnancy rates in some of these older studies.[16] However, closer scrutiny of the studies cited for high ongoing pregnancy rates reveals inadequate criteria for the diagnosis of continuing pregnancies. Many early researchers focused on an efficacy end point of complete uterine evacuation, and did not distinguish missed or incomplete abortions from continuing pregnancies (embryo or fetus

survival).[17] Only eight studies cited by Grossman had criteria sufficient to determine embryo survival and showed continuing pregnancy rates of 8-25%.[17]

A recent review found that 18 of the 30 articles investigating mifepristone monotherapy had adequate criteria to determine embryo survival.[17] After eliminating duplicate publications, 12 studies were identified which utilized follow-up ultrasound to distinguish between incomplete or missed abortion and embryo survival at the end of the study period. The mean percentage of embryos surviving mifepristone among all studies was 12.6%.[17] A single dose of 600 mg in five studies of early gestations 42-49 days in 493 subjects showed survivals of 9.4-17.1%.[17,18,19,20,21] Three studies of 58 women with gestations <49 days, using the current predominant 200-300 mg doses, noted embryo survival rates of 10-23.3%.[19,22,23,24] Four studies of 83 women included gestations up to 70 days, daily doses of 100-200 mg, and total doses 400-800 mg.; in three of these four studies, embryo survival was <25%.[25,26,27,28,29,30,31]

Methods

This is a retrospective analysis of clinical data of a group of pregnant women who took progesterone in an effort to reverse the effects of mifepristone. The study was reviewed and approved by an institutional review board. The lead author contributed clinical data from a variety of clinical settings across the United States and several other countries for comparison.

Subjects were pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. Subjects called an informational hotline linked to an informational website and staffed by nurses and a physician assistant. After receiving information about the reversal process, those who decided to proceed with reversal were referred to physicians and mid-level practitioners in their respective geographic areas for treatment. The women gave written informed consent for treatment to their respective treating medical professionals that included permission to track their data. Data were collected from the women themselves and from their treating healtcare professionals.

Data were collected for different variables including gestational age at the time of mifepristone ingestion, mode of delivery of progesterone given, amounts of progesterone received, birth defects and preterm delivery. Progesterone was given in a variety of regimens by the 325 different medical professionals who treated these women. The modes of delivery of progesterone were intramuscular injection of progesterone in oil, oral administration of micronized progesterone, vaginal use of oral micronized progesterone capsules, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel and progesterone vaginal suppositories.

We selected a 25% embryo or fetus survival rate, if mifepristone alone is administered, as a control because it is at the upper range of mifepristone survival rates and close to the 23% survival rate of the one early study that used a single 200 mg dose, the dose currently favored for medical abortions.[17] This study is designed to ascertain which progesterone treatments clinicians have offered to women seeking mifepristone

reversal that demonstrate efficacy beyond the 25% embryo survival rate, and compares the relative efficacies of different treatment protocols to the historic control.

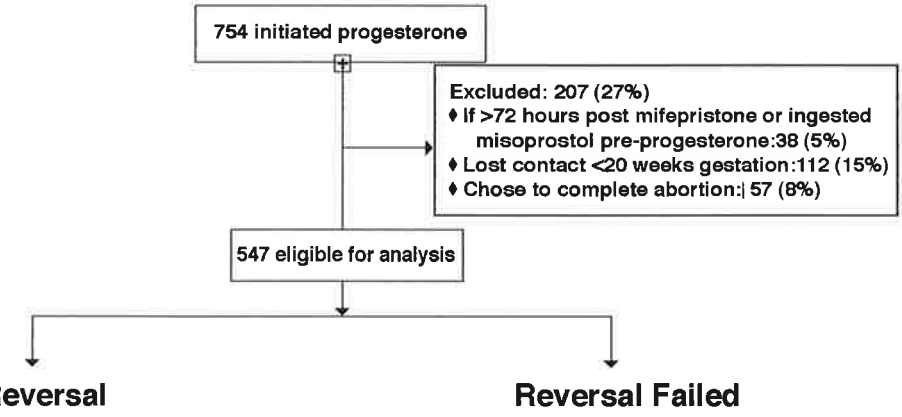
Results

From June 24, 2012 to June 21, 2016, 1,668 calls were received by the hotline from women who had taken mifepristone and were interested in reversal. Seven hundred fifty-four (45%) actually initiated progesterone therapy.

Subjects were included in the study if they were 72 hours or less post-mifepristone and had not taken misoprostol; 38 (5%) did not meet these criteria. Of the women who started progesterone therapy and met inclusion criteria, 116 (15.4%) were lost to follow-up at some point. Of those,112 (14.9%) were lost to follow-up prior to 20 weeks gestation and were excluded from the analysis. Four (0.5%) women remained pregnant with viable fetuses but were lost to follow-up after twenty weeks gestation and were included in the analysis as reversals.

Fifty-seven (7.6%) of the women, after starting progesterone therapy, changed their minds again and either took misoprostol to complete the medical abortion or procured surgical induced abortion. Of those 57, 39 (5.2%) chose to complete abortion medically with misoprostol, seven (0.9%) procured surgical abortions and 11 (1.5%) completed

Figure 1



abortion by unspecified means. These were not included in the analysis as they chose to no longer attempt reversal. See Figure 1.

Women who delivered babies after progesterone therapy or who were lost to follow-up after 20-weeks gestation were considered to have reversed their medical abortions, since any pregnancy loss after 20 weeks would be unlikely to be attributable to the early mifepristone exposure. The data analysis was accomplished using the Statistical Hypothesis Test on a population proportion.

After exclusions, there were 547 patients with analyzable outcomes who underwent progesterone therapy. There were 257 births (47%). Another four were pregnant with viable fetuses but were lost to follow-up after 20 weeks gestation (0.7%). The overall rate of reversal of mifepristone was 48%.

Two subgroups had the highest reversal rates. Those who received progesterone intramuscularly (IM) initially or exclusively had a 64% reversal rate. One subject in this group had an undocumented number of injections. The high-dose oral subgroup received oral progesterone, 400 mg twice a day for three days, followed by 400 mg once a day until the end of the first trimester and had a reversal rate of 68%, similar to the IM group. These survival rates compare favorably with published embryo and fetal survival rate of 25%, if no treatment is attempted,[17] the rate used as a control. See Table 1.

The gestational age at the time of ingestion was directly related to reversal success. See Table 2. This is not surprising since mifepristone embryocidal and feticidal rates fall with advancing gestational age.[33]

There was no correlation between maternal age and rate of reversal. In the subset of records noting time intervals, the time between mifepristone ingestion and the first progesterone dose was not statistically significant in relation to the success rate for reversals attempted within 72 hours of mifepristone injection.

Birth Defects

There were seven reported birth defects in the women who had reversals and follow-up after their deliveries for a rate of 7/257 (2.7%). See Table 3. This is equal to the birth defect rate in the general population of approximately 3%[34] and suggests that there is no increased risk of birth defects in babies born after mifepristone reversal.

Preterm Delivery

There were seven deliveries at <37weeks for a preterm delivery rate of 2.7%. The United States average is 10%.[35]

Multiple Gestations

There were nine sets of twins (4.3% of the pregnancies). There were no higher order multiples.

Discussion

Progesterone Safety

Progesterone is a naturally occurring hormone produced by the corpus luteum and by the placenta, and is essential for maintenance of the maternal fetal interface of pregnancy. It has been used safely in pregnancy for over 50 years.[36] The American Society of Reproductive Medicine states that no long-term risks have been identified when progesterone is used in pregnancy.[37] The FDA has given progesterone a category B rating in pregnancy, in contrast to synthetic progestins.[38]

Table 1: Reversals Compared to Reported Control of 25% Survival if No Treatment Undertaken

Progesterone Group	Number	Reversals	Reversal Failures	Percent Reversals	P Value	95% Confidence Intervals
All Groups	547	261	286	48%	<0.001	0.44-0.52
High Dose Oral	31	21	10	68%	<0.001	0.51-0.84
Intramuscular, All groups	125	80	45	64%	<0.001	0.56-0.72
IM, 1 Injection	50	24	26	48%	<0.001	0.34-0.62
IM, 2-5 Injec.	36	21	15	58%	<0.001	0.42-0.74
IM, 6-8 Injec.	9	9	0	100%	<0.001	0.67-1
IM, 9-10 Injec.	10	9	1	90%	<0.001	0.77-1.0
IM, 11 or More Injec.	19	17	2	89%	<0.001	0.76-1.0
Oral, All Groups	119	64	55	54%	<0.001	0.45-0.63
Oral Caps Vaginally, All Doses	156	61	95	39%	<0.001	0.31-0.47
Vaginal Suppository	34	11	23	32%	0.161	0.17-0.48

A recent retrospective study of a Danish infertility cohort suggested a possible increased risk of acute lymphocytic leukemia and sympathetic neural tumors in children born to mothers who had taken progesterone during pregnancy and before pregnancy. The increased risk was greatest in women who had taken progesterone for three or more cycles.[39] However, the infertility population examined in the Danish study, exposed to

Table 2: Gestational Age Compared to Reversal Rate

Gestational Age	Total	Reversal	Reversal Failure	Reversal %	*P* value	95% Confidence Intervals
5 weeks	76	19	57	25%	0.5	0.15-0.35
6 weeks	113	52	61	46%	<0.001	0.37-0.55
7 weeks	102	50	52	49%	<0.001	0.39-0.59
8 weeks	88	54	34	61%	<0.001	0.51-0.72
9 weeks	30	23	7	77%	<0.001	0.62-0.92

Table 3: Birth Defects

Birth Defect	Instances
Port Wine Stain	1
Bilateral Absent Toe	1
Unilateral Two Absent Fingers	1
Choroid Plexus Cyst	1
Cystic Kidney	1
Unilateral Failed Hearing Test	1
Heart Murmur	1

many cycles of progesterone and other medications, differs significantly from our population of fertile women who had a single exposure to progesterone.

Mifepristone Teratogenicity

While previous human studies are not large in number, the available evidence suggests that mifepristone is not teratogenic.[4,40,41] The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin March 2014 states that there is no evidence that mifepristone is associated with teratogenicity.[42] Our data set, the largest of babies exposed to mifepristone in utero, also indicates that the birth defect risk in women who have reversed mifepristone abortions is no higher than the risk in the general population.

Study Limitations

This study is limited in that it is not a randomized placebo-controlled trial. However, a placebo-controlled trial in the population of women who regret their abortion and

want to save the pregnancy would be unethical. Furthermore, although the number of women lost to follow-up was small, it could have affected the results. In addition, some data collection was incomplete.

One potential confounding variable is the use of ultrasound to select for living embryos prior to the first progesterone dose. It is possible that those embryos who were alive at the time of sonogram may have survived without progesterone therapy. However, our study also included some women who started progesterone therapy prior to sonographic documentation that the embryo was alive. Undoubtably, this group included women who already had an embryonic demise prior to initiation of progesterone therapy. Inclusion of these women would falsely lower the success rate of progesterone therapy. The numbers of women who received or did not receive ultrasound exams prior to initiating therapy were not available to our researchers. If ultrasound is readily available, sound practice would dictate that embryonic or fetal viability should be confirmed, or at least suggested, before treatment is started in order to avoid giving women progesterone unnecessarily and to exclude ectopic pregnancy before starting progesterone therapy.

Conclusions

The use of progesterone to reverse the effects of the competitive progesterone receptor blocker, mifepristone, appears to be both safe and effective. Progesterone therapy makes biologic sense, has been previously published as effective in an animal model and is supported by this case series which demonstrates a statistically significant difference in survival between treatment groups and the historic control. Mifepristone is embryocidal and feticidal but not teratogenic; progesterone is not associated with birth defects.

Based on these new data, two reasonable protocols can be suggested for women who seek to reverse the effects of mifepristone:

1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester; and

2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

Recommendations for Future Research

We propose that further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed to confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient.

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Exhibit D

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

August 2017

Facts Are Important:
Medication Abortion "Reversal" Is Not Supported by Science

Facts are important, especially when discussing the health of women and the American public. Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence,[i] and does not support prescribing progesterone to stop a medical abortion.

Yet, politicians are pushing legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care. Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety.

What is Medication Abortion?

- Medication abortion is the use of medications, rather than surgery, to end a pregnancy. This safe and effective evidence-based regimen includes a combination of two drugs—mifepristone, taken first, and misoprostol, taken at a later point.
- Mifepristone stops the pregnancy growth by blocking the hormone progesterone; misoprostol makes the uterus contract to complete the abortion.
- Medication abortion is more effective when both drugs are used, because mifepristone alone will not always cause abortion. In fact, as many as half of women who take only mifepristone continue their pregnancies.[ii]
- Mifepristone is not known to cause birth defects.

So-called abortion "reversal" procedures are unproven and unethical.

- A 2012 case series reported on six women who took mifepristone and were then administered varying progesterone doses. Four continued their pregnancies.[iii] This is not scientific evidence that progesterone resulted in the continuation of those pregnancies.
- This study was not supervised by an institutional review board (IRB) or an ethical review committee, required to protect human research subjects, raising serious questions regarding the ethics and scientific validity of the results.
- Case series with no control groups are among the weakest forms of medical evidence.[iv]

Legislative mandates based on unproven, unethical research are dangerous to women's health.

Politicians should never mandate treatments or require that physicians tell patients inaccurate information.

Additional ACOG Resources:

- ACOG Practice Bulletin 143 *Medical Management of First-Trimester Abortion* (March 2014)

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Exhibit E

ELSEVIER

Contraception

Contraception 92 (2015) 206–211

Review article

Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review☆

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Abstract

Objective: We conducted a systematic review of the literature on the effectiveness of medical abortion "reversal" treatment. Since the usual care for women seeking to continue pregnancies after ingesting mifepristone is expectant management with fetal surveillance, we also performed a systematic review of continuing pregnancy after mifepristone alone.
Study design: We searched PubMed, CINAHL (*Cumulative Index to Nursing and Allied Health Literature*), Scopus and the Cochrane Library for articles published through March 2015 reporting the proportion of pregnancies continuing after treatment with either mifepristone alone or after an additional treatment following mifepristone aimed at reversing its effect.
Results: From 1115 articles retrieved, 1 study met inclusion criteria for abortion reversal, and 13 studies met criteria for continuing pregnancy after mifepristone alone. The one report of abortion reversal was a case series of 7 patients receiving varying doses of progesterone in oil intramuscularly or micronized progesterone orally or vaginally; 1 patient was lost to follow-up. The study was of poor quality and lacked clear information on patient selection. Four of six women continued the pregnancy to term [67%, 95% confidence interval (CI) 30–90%]. Assuming the lost patient aborted resulted in a continuing pregnancy proportion of 57% (95% CI 25–84%). The proportion of pregnancies continuing 1–2 weeks after mifepristone alone varied from 8% (95% CI 3–22%) to 46% (95% CI 37–56%). Continuing pregnancy was more common with lower mifepristone doses and advanced gestational age.
Conclusions: In the rare case that a woman changes her mind after starting medical abortion, evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.
Implications: Legislation requiring physicians to inform patients about abortion reversal transforms an unproven therapy into law and represents legislative interference in the patient–physician relationship.

Keywords: Medical abortion; Mifepristone; Reversal; Progesterone; Continuing pregnancy

1. Introduction

First-trimester medical abortion involves the use of mifepristone followed by misoprostol, generally up to a gestational age of 63 days from last menstrual period [1,2]. Many women prefer medical abortion to surgical abortion

☆ Conflicts of interest: none.

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0010-7824/

because they perceive it as less invasive and more private [3]. The proportion of all nonhospital abortions in the United States that were early medical abortions increased from 17% in 2008 to 23% in 2011 [4].

In early 2015, legislatures in Arizona and Arkansas passed laws requiring physicians providing abortion to inform women that if they choose to have a medical abortion and then decide not to complete the abortion, the effect of mifepristone may be reversed with specific treatment [5]. Treatment to reverse the effects of mifepristone is not considered an established practice by the American College of Obstetricians and Gynecologists (ACOG) [6] and was not described in a recent practice bulletin on first-trimester medical abortion issued by ACOG and the Society of Family Planning (SFP) [1].

The purpose of this study was to perform a systematic review of the literature on reversal of medical abortion that documented the proportion of pregnancies continuing after treatment. Since the usual care for women seeking to continue pregnancies after ingesting mifepristone is expectant management with fetal surveillance, we also performed a systematic review of continuing pregnancy after treatment with mifepristone alone.

2. Materials and methods

2.1. Systematic review of medical abortion reversal

In this review, we searched for reports of pharmacological methods (e.g., intramuscular injection of progesterone) to reverse the effects of mifepristone prior to administration of misoprostol (or any other prostaglandin) for first-trimester medical abortion. We anticipated few, if any, randomized controlled trials and therefore broadened our search to include cohort studies and case studies or case series; we excluded review articles, editorials and commentaries. The primary outcome was the proportion of women who carried their pregnancies to term after receiving treatment to reverse the effect of mifepristone.

We searched for studies published through March 31, 2015, using databases for PubMed, the CINAHL (*Cumulative Index to Nursing and Allied Health Literature*), Scopus and the Cochrane Library. We combined the following search terms as Medical Subject Headings (MeSH) and text words: induced abortion, steroidal abortifacient agents; mifepristone; Mifeprex; Mifegyne; RU-486; reverse; antidote; progesterone; progestin; first-trimester pregnancy (see Box).

After initial title and abstract screening, two reviewers (DG and KW) independently evaluated full-text articles to determine whether they met the inclusion criteria. For relevant studies, we recorded the number of women enrolled in the study (or included in the case series) and the number of continuing pregnancies. We then calculated the percentage of continuing pregnancies and 95% Wilson Score confidence intervals (CIs) for women receiving reversal therapy.

Box
List of PubMed search terms used in a systematic review of studies on the efficacy of medical abortion reversal

Search	
(1)	"Abortifacient Agents, Steroidal"[mesh] or "Mifepristone" [mesh] or mifepristone or mifegyne or mifeprex or "r 38486" or r38486 or r-38486 or "ru 38486" or "ru 486" or ru486 or ru-486 or ru38486 or "zk 98296" or zk98296 or zk-98296
(2)	"Abortion, Induced"[mesh] or abort* or terminat*
(3)	("Pregnancy"[mesh] or pregnan* and ("first trimester") or (week*)) or "Pregnancy Trimester, First"[mesh] or "early pregnancy"
(4)	revers* or antidote or "Progesterone"[mesh] or progesterone or "progestins"[mesh] or progestin*
	#1 AND #2 AND #3 AND #4 AND (("0001/01/01"[PDAT]: "2015/03/31"[PDAT]) AND "humans"[MeSH Terms])

2.2. Systematic review of continuing pregnancies following the use of mifepristone alone for first-trimester medical abortion

We reviewed cohort studies and randomized controlled trials that used mifepristone alone during the first trimester of pregnancy to induce abortion, which we identified through a search of the same four databases and using the same search strategy, excluding the reversal terms. We also searched the reference lists of relevant publications for additional studies. We excluded studies that only reported medical abortion failure after mifepristone alone and did not specify the number of continuing pregnancies. We calculated the proportion of pregnancies continuing at the time of the follow-up visit after treatment with mifepristone alone and 95% Wilson Score CIs. Because the mifepristone regimens were not uniform, metaanalysis could not be performed.

3. Results

3.1. Systematic review of medical abortion reversal

Of the 319 unduplicated titles identified in our search, one article met our inclusion criteria (Fig. 1). This article was a case series by Delgado and Davenport [7] of seven women who received progesterone treatment after taking mifepristone for medical abortion at 7–11 weeks gestation. The mifepristone dosage was not noted. One patient was lost to follow-up. Of the six patients with follow-up data, four continued the pregnancy and delivered at term with no apparent congenital malformations; two patients aborted the pregnancy within 3 days of taking mifepristone. The progesterone regimen varied from progesterone in oil 200 mg intramuscularly daily to twice per week, sometimes followed by oral micronized progesterone, to micronized

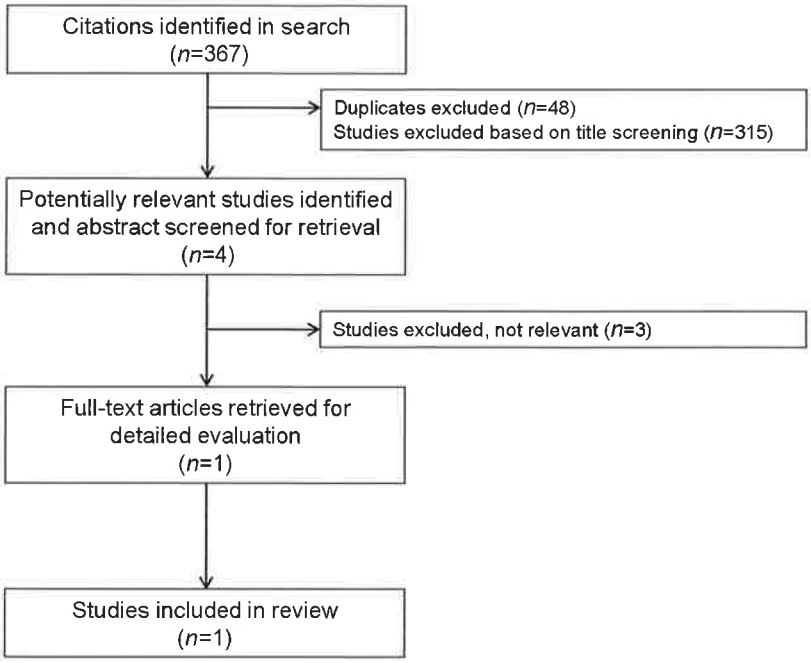

Fig. 1. Summary of study selection process for medical abortion reversal.

progesterone administered vaginally. Therapy was continued for up to 5 months. The publication provides limited details, but it appears that, in at least five cases, a living embryo was documented prior to initiating progesterone treatment. The authors did not report how many women presented seeking medical abortion reversal after taking mifepristone and were found to have already aborted and therefore excluded from treatment. The dates during which cases were collected are not specified, and it is unclear if all women treated were included in the case series. Based on the four continuing pregnancies and excluding the patient lost to follow-up, the proportion of pregnancies continuing after this therapy was 67% (95% CI 30–90%). If we assume that the patient lost to follow-up had an abortion, the continuing pregnancy proportion was 57% (95% CI 25–84%).

3.2. Systematic review of continuing pregnancies following the use of mifepristone alone for first-trimester medical abortion

Our search retrieved 1115 unduplicated articles, and 13 studies in 11 publications met our inclusion criteria (one publication was an English-language article that included two relevant studies performed in China, and one publication provided complete information on two relevant mifepristone dosages) (Fig. 2) [8–18]. Women were generally assessed 1–2 weeks after mifepristone and those with a continuing pregnancy at that time underwent surgical abortion. Table 1 shows for each study the mifepristone regimen used, the gestational age limit, when the follow-up visit occurred, the proportion of pregnancies that had a complete abortion after mifepristone alone and the proportion of pregnancies that were continuing at the follow-up visit. The continuing pregnancy proportions ranged from 8% to 46% with the different regimens.

4. Discussion

We found only one small case series that evaluated a treatment aimed at reversing the effects of mifepristone. The proportion of pregnancies that continued after this treatment was 57–67%, but the 95% CI of this estimate was wide, ranging from 25% to 90% [7]. The study was of poor quality with few details.

Due to the limited information in the article [7], one cannot directly compare the results of this single small series to the continuing pregnancy rate after mifepristone alone, which was as high as 46% in one of the clinical trials [15]. In the report by Delgado and Davenport [7], women presented 7–48 h after mifepristone ingestion, and, except for two cases, the patient had a live embryo at the time of treatment. In order to calculate the proportion of women with a continuing pregnancy seeking this treatment, which would be comparable to the proportion of continuing pregnancies after mifepristone alone, one must know how many women requested treatment and were found to already have an embryonic demise or incomplete abortion. It is reasonable to suppose that women who have an ongoing pregnancy 1–2 days after mifepristone are more likely to have pregnancies that continue to term with no further treatment. It is also possible that some of the continuing pregnancies noted 1–2

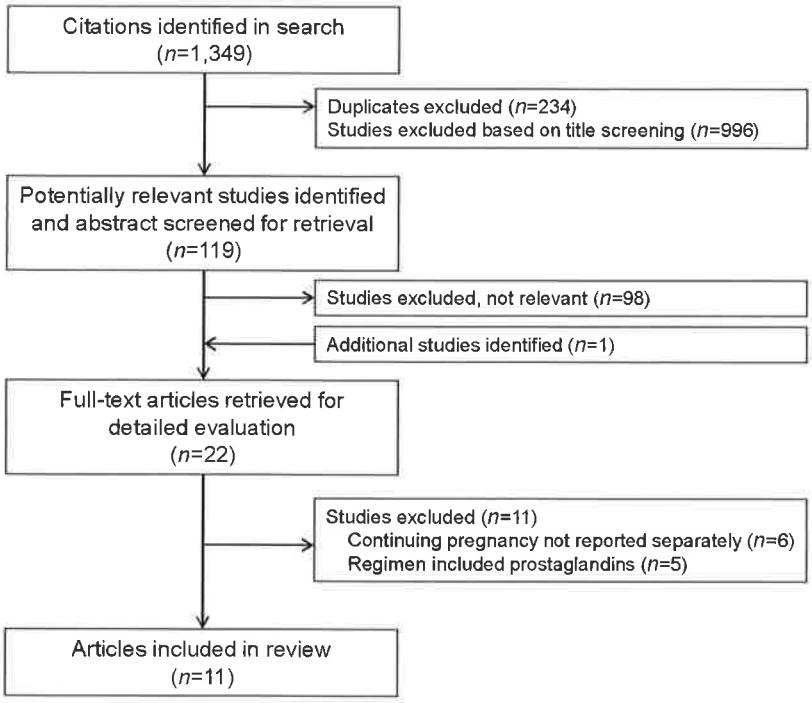

Fig. 2. Summary of study selection process for continuing pregnancy following administration of mifepristone alone for medical abortion.

weeks after treatment in the studies of mifepristone alone may have aborted if the period of follow-up were longer.

Although the dose of mifepristone was not noted in the report by Delgado and Davenport [7], women likely received 200 mg, which is the dosage recommended by ACOG and SFP and most often used by providers in the US [1,19]. Most of the studies of mifepristone alone used a higher dose, and the one study that compared 600 mg to 200 mg found a higher proportion of continuing pregnancies with 200 mg [18]. In addition, none of the studies of mifepristone alone included women pregnant beyond 56 days, while the report by Delgado and Davenport [7] included women up to 11 weeks gestation. In the first trimester, the risk of continuing pregnancy after medical abortion increases as gestational age advances [15,20].

Progesterone is used for other indications during pregnancy. Injections of 17a-hydroxyprogesterone caproate or administration of vaginal progesterone suppositories or

Table 1
Studies reporting the proportion of women with continuing pregnancies following administration of mifepristone alone for medical abortion

Study	Mifepristone oral dose	N	Gestational age limit	Follow-up visit (number of days after mifepristone)	Complete abortion	Continuing pregnancy at follow-up visit (%, 95% CI)
Birgerson 1988 [9]	10, 25 or 50 mg twice daily for 7 days	153	49 days	8–10 days	67%	27% (20–34%)
Cameron 1986 [8]	150 mg daily for 4 days	20	56 days	14 days	60%	25% (11–47%)
Carol 1989 [17]	600 mg (single dose)	50	39 days	NS	80%	12% (6–24%)
Grimes 1988 [10]	600 mg (single dose)	50	49 days	14 days	88%	10% (4–21%)
Kovacs 1984 [11]	25–100 mg twice daily for 4 days	36[a]	42 days	14 days	61%	8% (3–22%)
Maria 1988a [16]	600 mg (single dose)	149[a]	42 days	7 days	88%	9% (6–15%)
Maria 1988b [18]	600 mg (single dose)	174	49 days	7 days	84%	11% (8–17%)
Maria 1988b [18]	200 mg (single dose)	30	49 days	7 days	63%	23% (12–41%)
Somell 1990 [12]	600 mg (single dose)	70	42 days	7 days	80%	17% (10–28%)
Swahn 1989 [13]	25 mg twice daily for 4 days	14	49 days	14 days	57%	36% (16–61%)
Ylikorkala 1989 [14]	600 mg (single dose)	47[b]	43 days	14 days	70%	11% (5–23%)
Zheng 1989 [15]	600 mg (single dose)	204	42 days	7 days	65%	31% (25–38%)
Zheng 1989 [15]	600 mg (single dose)	95	49 days	7 days	53%	46% (37–56%)

NS, not specified.

[a] One additional participant was later found to have an ectopic and is excluded from the total here.

[b] Three additional participants had a missed abortion at time of treatment and are excluded from the total here.

gel may be used for prevention of preterm birth among women at high risk of early delivery, generally weekly from 16 weeks to 36 weeks gestation [21]. Progesterone supplementation is also used with assisted reproductive technologies that involve treatment with a gonadotropin-releasing hormone (GnRH) analog, agonist or antagonist, which may interrupt the normal functioning of the corpus luteum [22]. Progesterone in oil injections or vaginal suppositories or gel may be used for this purpose, but treatment is generally stopped after 9–12 weeks gestation, by which time the trophoblast is the primary source of progesterone. Progesterone is not associated with an increased risk of congenital anomalies, including genital abnormalities. Adverse events associated with progesterone injections include injection site swelling or irritation [23], as well as the potential of allergies to the yam, soy or peanut used in manufacturing or compounding the medication [21].

However, the evidence supporting the use of progesterone early in pregnancy after GnRH treatment or to prevent preterm birth is not directly applicable to the situation after mifepristone treatment. Mifepristone blocks the progesterone receptor with a higher affinity than progesterone itself [24]. Women treated with mifepristone for abortion have normal pregnancies with high progesterone levels, and it is not clear that adding more progesterone would counteract the effect of the receptor blockade. A recent randomized controlled trial found that insertion of an etonogestrel contraceptive implant, a very potent progestin, immediately after ingestion of mifepristone did not reduce the effectiveness of the medical abortion regimen compared to delayed insertion after abortion completion [25], confirming the findings of a previous pilot study [26]. In addition, the duration of treatment that women received in the report by Delgado and Davenport [7] was more consistent with preterm labor prevention (albeit with an unproven regimen). It also far exceeded the expected duration of action of mifepristone since the drug is undetectable in humans 10 days after ingestion of a 200-mg dose [27].

The evidence to date does not suggest an elevated risk of congenital malformations after mifepristone administration alone. A recent prospective study from France reported on 46 pregnancies exposed to mifepristone only [28]. Two major malformations occurred among 38 continuing pregnancies (5.3%), which, based on these small numbers, does not appear to be significantly elevated above the expected proportion of about 3%. While more prospective data are needed, information about the low risk of congenital malformations after mifepristone exposure should be given to women who decide to continue a pregnancy after taking the drug.

The clinical use and new state laws concerning abortion "reversal" raise serious ethical concerns. The limited data on mifepristone reversal grew out of the anecdotal experiences of physicians who performed experimental treatment on pregnant women, without usual research safeguards. Delgado and Davenport [7] do not report that their study had an ethics board or institutional review board (IRB) approval. Case reports involving retrospective analysis of three or fewer cases do not generally require IRB oversight, although institutions or journals may require IRB review to determine that the report is exempt. While Delgado and Davenport [7] published their findings as a "case report," their study is clearly "research" as defined in federal policy. Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [29]." The report clearly extends into the realm of research, whether measured by its prospective nature, the number of patients on which it reports, its attempt to assess a specific new treatment regimen or the suggestion that the data produced be used to guide treatment of other women. In recognition of the report's limitations, Delgado and Davenport [7] themselves called for further clinical trials before routine use of their protocol. The new laws in Arizona and Arkansas have now bypassed the research process, in effect making all women who undergo this treatment subjects in an uncontrolled, unmonitored experiment.

Providing evidence-based care is part of how physicians meet their beneficence-based obligations to patients, and therefore, it is a *moral* as well as a clinical mandate to base care on accepted scientific fact. The new laws compel physicians to say things that may contradict their clinical knowledge and judgment. Some physicians will not be able to do so in good conscience; they may feel that suggesting unproven treatment or suggesting that a woman can begin an abortion with uncertainty about her decision contradicts their duty to do no harm.

Women rarely change their minds after beginning a medical abortion. According to reports that physicians are required to submit to the drug's manufacturer, between 2000 and 2012, less than 0.004% of women taking mifepristone in the US later chose to continue the pregnancy (personal communication, Danco Laboratories). In such a case, a woman should be counseled that there is a reasonable chance (10–45%) that the pregnancy will continue. We found no credible evidence that using medication after ingestion of mifepristone is better than expectant management in assuring a continuing pregnancy; suggesting otherwise is scientifically untenable. Legislative interference in the patient–physician relationship is unwarranted and dangerous [30]. In the case of recent Arizona and Arkansas laws, this interference transforms an unproven therapy into law, bases law on methodologically flawed research and in effect turns unethical experimentation on pregnant women into legislative mandate. These features of mifepristone reversal represent an affront to responsible research conduct and to the ethical practice of medicine.

Acknowledgments

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Exhibit F

for all disclosures closer to strict scrutiny.

The Court's approach in *NIFLA*, as the dissent noted, "could radically change prior law, perhaps placing much securities law or consumer protection law at constitutional risk." Many health laws could be similarly threatened. Already a lower court has preliminarily enjoined Food and Drug Administration warning labels for cigars on the basis of *NIFLA*.[5] Whether that injunction holds, and whether other health laws will be struck down on First Amendment grounds, remains to be seen. What is clear is that the Court has created new uncertainty, and invited new litigation, regarding numerous health laws that were once assumed to be constitutional.

An audio interview with Prof. Parmet is available at NEJM.org

Disclosure forms provided by the authors are available at NEJM.org.

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Abortion "Reversal" — Legislating without Evidence

Daniel Grossman, M.D., and Kari White, Ph.D., M.P.H.

Women up to 10 weeks pregnant who are having a medication abortion generally take one dose of mifepristone, which blocks the progesterone receptor, followed within 48 hours by a dose of misoprostol, a prostaglandin that causes cervical dilation and uterine contractions, leading to expulsion of the pregnancy tissue. Four states (Arkansas, Idaho, South Dakota, and Utah) require abortion providers to tell their patients about treatment that may reverse the effect of mifepristone if they change their mind after starting a medication abortion. So-called abortion reversal involves administering repeated doses of progesterone. Since 2017, other states have proposed similar bills and the California Board of Registered Nursing approved a course on medication-abortion reversal for continuing-education credit. This trend is troubling because of the lack of medical evidence demonstrating the safety and efficacy of the treatment; laws promoting it essentially encourage women to participate in an unmonitored research experiment.

When states began passing laws on abortion reversal, the only published report on this treatment was a case series involving seven patients. A systematic review we coauthored in 2015 found no evidence that pregnancy continuation was more likely after treatment with progesterone as compared with expectant management among women who had taken mifepristone.[1] Our review found that the proportion of continuing pregnancies after mifepristone alone varied from 8% to 46% in published studies.

Recently, Delgado et al. published a case series involving 754 patients who underwent reversal treatment in the United States and several unnamed countries.[2] After excluding 27% of patients for various reasons, they report that 47% had a live birth. The authors conclude that reversal treatment is effective, citing the higher proportion of continuing pregnancies in their study as compared with a historical control rate of 25% of women who had continuing pregnancies after taking mifepristone alone. This estimate comes from Maria et al., the only published report that examined rates of pregnancy continuation after a single 200-mg dose of mifepristone,[3] which is the dose most commonly used in current medication-abortion regimens. This study, which included 30 women who were up to 7 weeks pregnant, 25 of whom were no more than 6 weeks pregnant, found that 23% had continuing pregnancies 7 days later.

It is difficult to compare the results from Delgado et al. with data on mifepristone alone for several reasons. In the Delgado study, some providers performed ultrasonography in patients presenting for reversal and excluded those found to have embryonic death. These patients were removed from the denominator of the proportion of women with continuing pregnancies, which could have contributed to the higher success rate for reversal treatment — especially at gestational ages of more than 6 weeks, when cardiac activity is more apparent. In addition, the authors excluded patients who were lost to follow-up before 20 weeks, which probably exaggerated the treatment's reported success.

Percentage of Women with Continuing Pregnancies after Taking 200 mg Mifepristone with or without Progesterone.*				
Treatment	Total No. of Pregnancies	Continuing Pregnancies	Percentage of Continuing Pregnancies (95% CI)	P Value
Gestational age ≤6 wk				
Mifepristone followed by progesterone	189	71	38 (31–45)	0.119
Mifepristone alone	25	5	20 (9–39)	
Gestational age ≤7 wk				
Mifepristone followed by progesterone	291	121	42 (36–47)	0.076
Mifepristone alone	30	7	23 (21–41)	

* Data are from Delgado et al.[2] and Maria et al.[3] Maria et al. report a total of seven continuing pregnancies in the sample of 30 women who were 7 weeks pregnant or less. There were two abortion failures among the five women who were between 6 and 7 weeks pregnant, but whether these were continuing pregnancies is unclear. We therefore made the conservative assumption that five of the seven continuing pregnancies occurred among the 25 women who received mifepristone at 6 weeks' gestation or less and that the two failures that occurred among those who were between 6 and 7 weeks pregnant were both continuing pregnancies.

Gestational ages in Delgado et al. (up to 9 weeks) also differed from those in Maria et al. As Delgado et al. note, pregnancy continuation is more common with advanced gestation; therefore, it is important to compare groups of similar gestational age. We analyzed the effectiveness of reversal treatment by comparing rates of continuing pregnancy among women who were up to 6 or 7 weeks pregnant in the two studies.

Among women who were up to 6 weeks pregnant, 38% (95% confidence interval [CI], 31 to 45) of those who received reversal therapy had a continuing pregnancy.[2] This proportion was not significantly different from the 20% (95% CI, 9 to 39) of women who had a continuing pregnancy after taking mifepristone alone ($P=0.119$) (see table).[3] The rates of pregnancy continuation were also not significantly different when we included women who were up to 7 weeks pregnant, despite the fact that the reported success rate for reversal therapy was most likely an overestimate at 7 weeks because some patients were excluded from treatment after ultrasound screening for embryonic viability. Because there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation, we cannot evaluate the effectiveness of reversal treatment beyond this gestational age.

The safety data presented by Delgado et al. are minimal. No adverse events were reported among pregnant women, but it is unclear whether such data were routinely collected. The reported data on birth defects and preterm birth are generally reassuring; given the range of progesterone regimens used and the lack of reporting by regimen, however, it is difficult to draw conclusions about the treatment's safety. Data from a registry in France suggest that exposure to mifepristone alone does not increase the risk of birth defects.[4]

Equally unclear is the demand for reversal treatment. Since participants in the study by Delgado et al. were recruited from several unnamed countries over a period of 4 years, it is impossible to estimate what proportion of patients undergoing medication abortion is represented by this sample. According to data obtained from Danco Laboratories, the U.S. manufacturer of mifepristone, less than 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.[1] Other research indicates that decisional certainty among women having an abortion is high — and higher than it is among patients making other decisions about medical treatment.[5]

Still, efforts should be made at the time of preabortion counseling to identify women who may be conflicted and to provide additional support to help them make an informed decision. Allowing patients to take mifepristone at home, which has been permitted since the drug's label was updated in 2016, may reduce the already small number of women who change their mind by giving patients more control over where and when they take the medication. But for patients who do change their mind after taking mifepristone, what is the best course of action? If a woman changes her mind within an hour after taking the drug, vomiting should be induced. Beyond that time frame, we believe the pregnancy should be carefully followed.

One could argue that the demand for abortion reversal treatment is so low that additional research is not justified. But if

researchers do perform additional studies, it is critical that such studies be rigorously designed and conducted in an ethical manner. Clinical equipoise exists for this question, since there is no evidence that treatment is superior to doing nothing. In such cases, a randomized, placebo-controlled trial is the most appropriate study design. For now, any use of reversal treatment should be considered experimental and offered only in the context of clinical research supervised by an institutional review board (IRB). Delgado et al. obtained IRB approval for their retrospective data analysis, but it is not clear that approval was obtained in advance for their experimental treatment protocol. In fact, the study was retracted temporarily because of concerns raised about what the authors initially described as an IRB "waiver."

We believe that states' mandating that health care providers give patients information about an unproven and experimental therapy is a disturbing intrusion into the relationship between physicians and their patients. Additional states will undoubtedly consider such legislation, despite the lack of evidence for abortion reversal treatment. We should all be concerned when politicians recommend treatment options over the advice of medical professionals.

Disclosure forms provided by the authors are available at NEJM.org.

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Extensively Drug-Resistant Typhoid — Are Conjugate Vaccines Arriving Just in Time?

Jason R. Andrews, M.D., Farah N. Qamar, F.C.P.S., Richelle C. Charles, M.D., and Edward T. Ryan, M.D.

In Hyderabad, Pakistan, an outbreak of extensively drug-resistant (XDR) *Salmonella enterica ssp. enterica* serovar Typhi, resistant to chloramphenicol, ampicillin, trimethoprim–sulfamethoxazole, fluoroquinolones, and third-generation cephalosporins, was recognized in November 2016 and has now spread to Karachi, home to more than 14 million people. More than 1000 cases have been confirmed by blood culture; since most typhoid cases are treated empirically, however, the true number of cases is probably many times greater. The outbreak is being caused by the H58 clade, a multidrug-resistant haplotype of S. Typhi that is common in Asia and areas of Africa. The H58 S. Typhi involved in the outbreak contains a chromosomally integrated antimicrobial-resistance cassette imparting resistance to chloramphenicol, ampicillin, and trimethoprim–sulfamethoxazole, and the XDR variant also contains an IncY plasmid that carries not only the fluoroquinolone-resistance gene *qnrS* but also the CTX-M-15 gene *bla* that mediates resistance to ceftriaxone.[1] S. Typhi already causes invasive disease in 12 million to 22 million people each year, many of whom live in South and Southeast Asia, and the emergence of an XDR variant in this densely populated area is extremely worrisome.[2]

Prior to the advent of antimicrobial therapy, case fatality rates for typhoid fever exceeded 20% in many areas, since untreated disease led to complications such as intestinal perforation. In 1948, the first effective antimicrobial therapy for typhoidal salmonella, chloramphenicol, ushered in a new era in the management of enteric fever (see timeline). Within 2 years, however, the first clinical isolate resistant to chloramphenicol was reported. But resistance was relatively uncommon, and chloramphenicol remained the mainstay of therapy for the next two decades. In the early 1970s, outbreaks of chloramphenicol-resistant typhoid with evidence of horizontal transfer of resistance genes were reported around the world. Ampicillin and trimethoprim–sulfamethoxazole emerged as alternative, albeit possibly inferior, therapies for chloramphenicol-resistant enteric fever. By the late 1980s, resistance to all three antibiotics (multidrug-resistant typhoid) was increasingly

EXHIBIT 3

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

TULSA WOMEN'S REPRODUCTIVE CLINIC, LLC, an Oklahoma limited liability company, on behalf of itself, its physicians, and staff; and ALAN BRAID, M.D., Plaintiffs, v. MICHAEL HUNTER, in his official capacity as Attorney General for the State of Oklahoma, STEVE KUNZWEILER, in his official capacity as District Attorney for Tulsa County, LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, DENNIS CARTER, in his official capacity as President of the Oklahoma State Board of Osteopathic Examiners, and TOM BATES, in his official capacity as Interim Commissioner of Health for the Oklahoma State Board of Health, as well as their employees, agents, and successors, Defendants.	)	CASE NO. _____

DECLARATION OF DR. MATTHEW K. WYNIA IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION

Matthew K. Wynia, M.D., M.P.H, F.A.C.P., declares and states as follows:

Introduction

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

2. As discussed below, I am a board-certified physician licensed to practice medicine and an expert in medical professional ethics. I submit this declaration in support of Plaintiffs' Motion for Temporary Injunction against enforcement of Oklahoma Senate Bill No. 614 of 2019 ("S.B. 614").

3. Based on my personal knowledge, expertise in medical ethics, and nearly three decades of experience as a medical professional, I have been retained to explain the impact that S.B. 614 will have on the ethical obligations of health care professionals (i.e., physicians and their agents) who provide abortion care.

4. As I explain further below, it is my opinion that S.B. 614 will force health care professionals to violate several fundamental principles of medical ethics. S.B. 614 distorts the informed consent process for patients and undermines the trust relationship between patients and doctors; it requires that health care professionals actively hinder their patients' ability to make informed decisions by misleading them; it poses a fundamental challenge to core principles of ethics for performing research on human subjects; and it creates unnecessary and undisclosed risks to patient health and wellbeing.

Professional Credentials and Experience

5. I am currently the Director of the Center for Bioethics and Humanities at the University of Colorado, a position I have held since 2014.

6. I graduated from the University of Oregon Honors College in 1986 with degrees in philosophy and biology.

7. I received an M.D. degree from Oregon Health Sciences University, School of Medicine in 1990.

8. From 1990 to 1994, I was a resident in the Department of Medicine at the Deaconess Hospital in Boston, Massachusetts, serving as Chief Medical Resident from 1993 to 1994.

9. I completed a fellowship in geographic medicine and infectious diseases and a post-doctoral fellowship in health services research at the Tufts' New England Medical Center in

Boston, Massachusetts, and a Master of Public Health degree from Harvard University School of Public Health in Boston, Massachusetts.

10. I am board-certified in internal medicine and infectious diseases. Both certificates are issued by the American Board of Internal Medicine (ABIM) of the American Board of Medical Specialties (ABMS).

11. I have been licensed to practice medicine in Massachusetts and Illinois and currently am licensed in Colorado.

12. I have been practicing in my field for about 29 years and for much of that time I focused on research and teaching about medical professional ethics. For example, from 2000 through 2013, I was the Director of the American Medical Association's Institute for Ethics. While serving in this role, I held many other positions focused on medical ethics. I served on the Board of Directors for the American Society for Bioethics and Humanities from 2001 to 2007 and was President of that organization in 2006 to 2007. I co-chaired the Ethics Committee of the Society of General Internal Medicine in 2000 and again in 2002, and I served as a member from 1997 to 2010. From 2001 to 2002, I was the Chair of the Ethics Forum Program Committee of the American Public Health Association, and from 2002 to 2003 I served as Chair of the Ethics Forum (now the Ethics Section) of the same organization. From 2011 to 2015, I served on the Ethics and Professionalism Committee of the American Board of Medical Specialties, including serving as the senior author on that organization's working definition of medical professionalism (https://www.abms.org/media/84742/abms-definition-of-medical-professionalism.pdf).

13. I am the author or co-author of more than 160 peer-reviewed journal articles, chapters, essays, and books on medical professional ethics, humanities, and related topics. I am the author or co-author of more than twenty peer-reviewed journal articles on medical ethics

specifically concerning patient-doctor communication, the informed consent process, the ethics of medical research on human subjects, addressing the communication needs of patients with lower levels of health literacy and other topics of direct relevance to the current case.

14. My experience and qualifications are set forth in further detail in my curriculum vitae, attached hereto as Exhibit A.

S.B. 614

15. I have reviewed S.B. 614 and the requirements that it imposes on health care professionals performing abortions in Oklahoma.

16. More specifically, I understand that under S.B. 614, physicians are required to inform patients at least seventy-two hours in advance of a planned "medication abortion using mifepristone" that "it may be possible to reverse the intended effects of a medication abortion that uses mifepristone if the women changes her mind but that time is of the essence." I understand that doctors are also to inform the patient that "information on reversing the effects of a medication abortion that uses mifepristone ... is available on the website of the State Board of Medical Licensure and Supervision" and to provide the patient with the Abortion Pill Reversal 24-hour Hotline number and website address.[1]

17. I understand that under S.B. 614, the Oklahoma Board of Medical Licensure and Supervision must produce written materials in print and on its website "designed to inform the female of the possibility of reversing the effects of a medication abortion that uses mifepristone ... and information on resources that may be available to help her reverse its effects." I understand that S.B. 614 requires that the website include the APR hotline number and website address.[2]

[1] S.B. 614, § 1(C)(1).
[2] S.B. 614, § 1(E).

18. I understand that S.B. 614 also requires that any facility in which medication abortions that use mifepristone are provided must "conspicuously post a sign" in each patient waiting room and patient consultation room used by patients to whom such medication abortions that use mifepristone are performed. The sign must read:

> NOTICE TO PATIENTS HAVING MEDICATION ABORTIONS WHICH USE MIFEPRISTONE: Mifepristone, also known as RU-486 or Mifeprex, alone is not always effective in ending a pregnancy. It may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can get immediate help by calling the Abortion Pill Reversal 24-hour Hotline at 877-558-0333 or going to website https://www.abortionpillreversal.com/. Additional information is available on the State Board of Medical Licensure and Supervision's website, www.awomansright.org, which provides informed consent materials under the Woman's Right-to-Know Act, including information about the development of the unborn child and video of ultrasound images of the unborn child at various stages of development.[3]

19. I understand that S.B. 614 further requires physicians to provide written instructions to the patient after she has received the first drug, mifepristone. The written instructions must contain the same statement as that in paragraph 17 of this Declaration.[4]

20. I understand that any physician who performs medication abortions using mifepristone in Oklahoma without complying with S.B. 614 may be found guilty of a felony, and that any clinic or facility that fails to post the required sign "shall be assessed a fine of Ten Thousand Dollars ($10,000) by the State Board of Medical Licensure and Supervision for each day the sign is not posted."[5] I further understand that any physician who fails to comply with S.B. 614 may be liable for damages in a civil suit which may be filed by the person upon whom an

[3] S.B. 614 § 1(B)(2).
[4] S.B. 614 § 1(C)(2).
[5] S.B. 614 § 1(F)–(G).

abortion has been performed or attempted, or her parents or grandparents if she is under 18, as well as "the father of the unborn child who was the subject of the abortion."[6]

21. I understand that according to the Food and Drug Administration ("FDA"), the protocol for administration of medication abortion involves two drugs, mifepristone followed 24 to 48 hours later by misoprostol.[7]

22. I understand that the Abortion Pill Reversal 24-hour Hotline and website are operated by Abortion Pill Rescue (APR), a program of Heartbeat International, Inc. I further understand that APR's "Founding Principles" include that "[p]rogesterone can reverse the effects of mifepristone and has been safely used in pregnancy for over 40 years" and that "[r]eversing a mifepristone chemical abortion is within reasonable medical practice."[8]

23. I also understand that the APR website refers users to a "helpline" that purports to connect them with an "on-call Healthcare Professional" who will "guide [them] towards reversing the effects of the abortion pill."[9] The web site further claims, without citing evidence, that, "There is an effective process called **ABORTION PILL REVERSAL** that can reverse the effects of the Abortion Pill . . . and that this process has a "64-68% success rate."[10] The web site is copyrighted 2019, but it does not provide information on when it was last updated.

24. Finally, I understand that there is no credible scientific research that has been accepted in the broader medical community to support the claim that progesterone may be able to

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[6] S.B. 614, § 1(H).
[7] FDA Label for Mifeprex (March 2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
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[9] Abortion Pill Rescue, "Home," https://abortionpillreversal.com/ (last visited Sept. 23, 2019).
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"reverse" the effects of mifepristone. For example, the American College of Obstetricians and Gynecologists ("ACOG"), a professional association with more than 58,000 members specializing in obstetrics and gynecology,[11] issued a statement that the claims regarding medication abortion "reversal" treatment with progesterone "are not based on science and do not meet clinical standards."[12] ACOG concluded that "abortion reversal" treatments can be dangerous to women's health and that ACOG "does not support prescribing progesterone to stop a medication abortion."

The Requirements of S.B. 614 are Contrary to Fundamental Principles of Medical Ethics, Forcing Physicians to Breach Patients' Trust

25. Medical ethics provide standards of practice—developed by and for members of the profession and that are enforced within the profession—which guide health care professionals in deciding on the best course of action for a given patient. The creation and enforcement of ethical standards is based on the idea that the practice of medicine comprises a public trust, in which it is crucially important that all practitioners adhere to certain core ethical principles in order to retain the trust of patients and the public.[13] In essence, medical ethical principles represent a set of shared promises made by health professionals to our patients and to the larger community.[14]

26. Among the core principles that guide our profession are shared promises related to truth-telling, transparency, showing respect for patients and their families, showing respect for patients' values, promoting beneficence, non-maleficence, and justice, and protecting patients

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[11] ACOG is also known as the American Congress of Obstetricians and Gynecologists.
[12] Statement of the American Congress of Obstetricians and Gynecologists, *Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science* (Aug. 2017), https://www.acog.org/-/media/Departments/Government-Relations-and-Outreach/FactsAreImportantMedicationAbortionReversal.pdf.
[13] Wynia et al., *Medical Professionalism in Society*, N. Engl. J. Med., 342(21):1612-1616 (1999).
[14] Wynia et al., *More Than a List of Values and Desired Behaviors: a Foundational Understanding of Medical Professionalism*, Acad. Med., 89(5), 712d (March 24, 2014).

from unethical practices in medical research.[15] Further, to ethically provide medical care, patients must know that physicians will act as their agents, not as agents of the state. Consistently living up to these fundamental promises is required to sustain the relationship of trust that must exist between patients and doctors. S.B. 614 violates each of these ethical standards.

S.B. 614 Disrupts the Patient-Provider Relationship of Trust

27. By forcing physicians to communicate, both verbally and in writing, confusing and inaccurate information that is not medically supported, and by forcing physicians to refer their patients to the medically inaccurate and misleading APR website and hotline, S.B. 614 requires health professionals performing abortions to violate one of the fundamental tenets of medical ethics—that providers build a relationship of mutual trust with their patients.

28. Patients seeking medical care often must place extraordinary trust in their physician. This trust is necessary, partly due to the vulnerability that can come from being ill, afraid, or in pain, but also because patients must rely on their physician for advice on medical matters because patients, as compared to their physician, generally know less about the risks, benefits and alternatives to various medical options. Physicians, meanwhile, do not know about their patients' unique values, priorities, and preferences regarding medical care options, unless patients are willing to share this often-sensitive information with them. For these reasons, the patient-provider relationship cannot be one governed by the marketplace dictum of "caveat

[15] *See, e.g.*, The American Medical Association (AMA) Code of Medical Ethics, Opinions 2.1.1-2.1.3, *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-2.pdf (last visited Sept. 23, 2019); *see also* Project of the ABIM Foundation, ACP–ASIM Foundation, and European Federation of Internal Medicine, *Medical Professionalism in the New Millennium: A Physician Charter*, Annals Intern. Med., 136(3), 243 (2002), *available at* https://annals.org/aim/fullarticle/474090/medical-professionalism-new-millennium-physician-charter.

emptor" or "buyer beware"; instead it must be based on mutual trust. Medical ethics provides the necessary foundation upon which this trust relationship between patients and doctors is built.

29. To build mutual trust, one core ethical obligation of health care professionals is to provide patients with the relevant information necessary to enable them to make informed decisions about their health or medical treatment consistent with their values, views, and priorities.[16] In other words, health care professionals must ensure that their patients receive medically accurate information to ensure that patients are able to make decisions that are right for them. Widely accepted medical ethics guides and codes emphasize this key responsibility. For example, according to the American Medical Association ("AMA") Code of Medical Ethics, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy."[17] Moreover, "[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."[18]

30. Patients are especially reliant on trust in their medical providers during sensitive periods of medical decision-making, such as when considering or seeking an abortion. Patients must not only be able to trust that the medical information their physicians provide is accurate, but they must be able to expect that this information will be delivered in a way that is sensitive, compassionate, and personalized to best ensure that the patient will be able to understand the

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[16] *See, e.g.*, AMA Code of Medical Ethics, Opinion 2.1.1, *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-2.pdf (last visited Sept. 23, 2019).
[17] *Id.*, Opinion 2.1.3.
[18] *Id.*, Opinion 2.1.1.

information and use it to make the decision that is right for her, based on both medical facts and the patient's own views, goals, and values.

31. While forcing physicians to make government-scripted verbal and written declarations to their patients that are not medically true is extremely corrosive of trust in the patient-physician relationship, the requirement in S.B. 614 that physicians also refer patients to the APR hotline and website multiple times—including *after* the patient receives mifepristone—creates additional layers of concern. When physicians make referrals to other clinicians or resources (including web sites), they are tacitly endorsing the value of the referral. Hence, by repeatedly referring patients to the web site, S.B. 614 would force physicians to implicitly endorse the value and accuracy of the information on the APR website and conveyed by the "Healthcare Professionals" on the APR "Helpline." But the information on the APR website and conveyed through the APR hotline is already medically inaccurate and, even more concerning, it may change at any time. This makes it impossible for physicians to know the extent and types of inaccurate and misleading information they are implicitly endorsing at any given time. S.B. 614, therefore, has the effect of requiring physicians to make a blanket endorsement of information they neither trust nor believe, and over which they have no control.

32. S.B. 614's violations of medical ethics cannot be avoided by the health care professional telling her patient that she should disregard the information that she is about to be told or that she may read on the posted information or APR website about medication abortion "reversal" (assuming that such a warning statement would even be legal under Oklahoma law). First, making such a statement would be an open admission that the physician is willing to say things both aloud and in writing that she doesn't believe to be true (i.e., of the physician's untrustworthiness), and it would force patients to parse which advice their physicians endorse and

which advice they disavow. In addition, such a warning statement would very likely be confusing for patients in many cases, and it would distract from other important and necessary medical information in every case. Therefore, rather than better informing women considering abortions, S.B. 614 will sow confusion while undermining patients' trust in their health care professionals.

S.B. 614 Violates the Ethical Principle of Patient Autonomy

33. S.B. 614 is inconsistent with physicians' ethical responsibility to respect patient autonomy. The ethical principle of autonomy requires that physicians create an open and honest dialogue with patients that facilitates, rather than impedes, their patients' ability to make informed health care decisions.[19] Accordingly, health care professionals should provide patients with truthful, accurate, necessary, and medically relevant information, communicated in a way that best facilitates informed health care decision-making. It would be a gross violation of medical ethics for a health care professional to knowingly provide misleading or inaccurate information to his or her patients because doing so impedes patient autonomy and can be profoundly harmful to trust in the patient-physician relationship.

34. S.B. 614 forces health care professionals to pronounce a standardized government-created message on abortion "reversal," with no opportunity for tailoring this message to the individual patient's needs, values, or goals. As such, S.B. 614 effectively prevents health care professionals from advocating for their patients, and instead mandates them to act as agents of the state in delivering a one-size-fits-all, medically-inaccurate and likely confusing message with which virtually all doctors who provide abortions disagree and that will pose a barrier to their primary ethical responsibility: to ensure that their patients are making informed decisions about treatment options.

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[19] *Id.*, Opinion 2.1.3.

35. A subset of the physician's duty to respect patient autonomy is the moral and legal obligation for physicians to obtain "informed consent" from patients for specific medical procedures. Under the doctrine of informed consent, health care professionals must give their patients accurate and necessary information about the risks and benefits of a specific medical procedure and its alternatives before the patient agrees to undergo that procedure.

36. S.B. 614 undermines a health care professional's ability to obtain fully informed consent to abortion from their patients. Because there is no credible scientific evidence that the effects of medication abortion using mifepristone can be safely and efficiently "reversed," it would be unethical for health care professionals to suggest otherwise. For example, to establish safety and effectiveness of a drug for a specific purpose, the FDA generally requires a series of clinical trials—usually with a control group to limit research bias—and the trials usually must be supervised and approved by an institutional review board to protect the rights and welfare of the human subjects.[20] But no such clinical trials have been performed in this case. Yet, after hearing the disclosures mandated by S.B. 614, patients trustful of their physician's advice would be led to believe, incorrectly, that there is a well-established, safe, and effective procedure to "reverse" the "abortion pill." S.B. 614 would also undermine the physician's ethical obligation to ensure that the patient is making a decision that is truly right for her, including by encouraging some women who aren't sure about having a medication abortion to nonetheless initiate one. The information provided to patients according to S.B. 614 could mislead them into believing that there is a "reversal" option that exists, implying that they can proceed with receiving a medication abortion and delay the "final" abortion decision for later. This can be physically and emotionally harmful

[20] *See generally* FDA webpage, The Drug Development Process, *Step 3: Clinical Research* (January 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research; *see also* 21 C.F.R. § 56.

for the patient, especially if the "reversal" option is later tried and does not work. Thus, S.B. 614 drastically deviates from the fundamental principles of providing accurate, truthful, relevant, and non-misleading information to patients to facilitate informed decision-making.

37. Furthermore, in complying with S.B. 614's requirement to provide patients who have already elected to take mifepristone and who have taken it with a repeat "instruction" that their decision can still be reversed, the physician would effectively be asking the patient to reconsider her decision to proceed with an abortion after she has already given informed consent and started the procedure, implying that the physician believes that the patient made the wrong decision. By asking that patients second guess their decision in this way, the physician is likely to alienate patients and generate feelings of guilt, stigma and shame. It is contrary to the ethical principles of informed consent to introduce self-doubt and shame into a patient's decision-making process and medical care in this manner.

38. The problems created by S.B. 614 in obtaining informed consent are compounded by multiple statements on the APR website, which assure patients that medication abortion "reversal" is not only effective but has been shown to be safe. None of these statements are supported by reliable data; rather, the web site provides only one-sided anecdotes, testimonials and other promotional marketing materials. Requiring physicians to endorse statements and services that are at best questionable, and at worst misleading and harmful, would degrade the medical profession, the doctor-patient relationship, and the process for obtaining a patient's informed consent.

39. Further, the APR website indicates that the hotline is staffed with "Healthcare Professionals" who can "guide [the patient] towards reversing the effects of the abortion pill." The specific qualifications and training of the "medical professionals" staffing the hotline are not

disclosed. Requiring physicians to refer patients to unverified individuals offering unspecified information and services would be contrary to foundational principles of medical ethics even if the underlying service had some medical validity, and it is especially egregious in this case.

40. The scripted information S.B. 614 requires doctors convey to their patients is medically inaccurate, but even if it were accurate, compelling health care professionals to give the same strictly scripted information to all patients also undermines the medical ethics principle of patient autonomy because it prevents health care professionals from tailoring information for each patient based on medical appropriateness. For example, for some patients the scripted information would be inappropriate, even if it were medically accurate, because information about "reversing" a medication abortion is not relevant to their individual circumstances. Communicating irrelevant information can distract patients from hearing and understanding the critical medical information they actually need to make an informed decision, thereby further obstructing the ethically and legally-obligatory process of obtaining informed consent.

41. Further compounding the potential harms of a physician delivering or endorsing inaccurate, unreliable and uncertain information is that the information physicians must provide to patients under S.B. 614 will be confusing for many patients. There is wide agreement that information delivered to patients should be presented in a way that patients are most likely to understand, using plain language and, for written information, keeping the reading level of information within a reasonable range (e.g., 4th-6th grade).[21] The written statement that must be

[21] *See Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals*, THE JOINT COMMISSION, 20 (2010) https://www.jointcomission.org/assets/1/6/ARoadmapforHospitalsfinalversion727.pdf (stating that informed consent materials should be written at a 5th grade or lower reading level).

posted in clinic areas under S.B. 614 is written at a Fleisch-Kincaid grade level of 20.1, which is considerably higher than most Americans can generally comprehend.

S.B. 614 Violates Additional Ethical Principles, Including Beneficence, Non-Maleficence, and Justice

42. S.B. 614 would also force health care professionals to violate the ethical principles of beneficence and non-maleficence, as it forces physicians to inflict harm on patients without any countervailing benefit. Furthermore, it forces health professionals to disproportionately harm already-disadvantaged patients, which is an affront to the ethical principle of justice.

43. Beneficence and non-maleficence are complementary terms, with ancient roots in medical ethics, dating from the Hippocratic dictum that physicians must "make a habit of two things—to help, or at least, to do no harm."[22] Beneficence requires physicians to act in ways that best benefit their patients, while non-maleficence requires physicians to minimize potential harms to patients.

44. S.B. 614 requires physicians to breach both of these dictates because medication abortion "reversal" treatment has not been proven safe or effective. Because there are no long-term studies on the effects of attempted abortion "reversal" on women's health or on the health of the fetus (if it survives), telling patients that it is a standard medical option is fundamentally deceptive and is both unhelpful and potentially harmful. Several possible harms of this deception seem likely, including that patients might experience additional distress or anxiety as a result of being told "reversal" is a legitimate medical option, especially in cases where a subsequently attempted abortion "reversal" treatment is unsuccessful. S.B. 614 might also cause patients to experience prolonged guilt, shame, and/or stigma associated with their abortion because of S.B.

[22] Hippocrates, *Epidemics*, Bk. I, Sect. XI (circa 400 BCE) (tr. W.H.S. Jones, 1, 165 (1923)), *available at* https://www.bartleby.com/73/847.html.

614's implication that their decision is not yet final. In addition, S.B. 614 would force physicians to refer patients to the APR website, which includes a set of selected anecdotes of women who underwent a medical abortion and went on to experience severe pain, shame and regret. It is apparent that these stories are not intended to inform women about the various possible consequences of medication abortion, since there are no stories representing the experiences of women who underwent the procedure with any different outcomes. Rather, the stories are carefully curated to generate feelings of fear and shame among women considering or undergoing medication abortion. For a physician to intentionally inflict needless fear and feelings of shame on a patient is a profound breach of professional ethics.

45. Compounding these ethical problems is the fact that S.B. 614 will have a disproportionate impact on the most vulnerable patients seeking abortion services, which means that physicians will be forced to participate in exacerbating an injustice.[23] A number of studies have shown that patients who, as a group, tend to experience health care disparities and worse health outcomes are also less likely to be well-informed about birth control and abortion.[24] As a result, these already-disadvantaged patients will be most likely to be harmed by receiving inaccurate and misleading information about abortion services from their physicians.

S.B. 614 Violates Ethical Guidelines for Scientific Research

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[23] AMA Code of Ethics, Opinion 8.5, *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-8.pdf (last visited June 17, 2019).

[24] *See, e.g.*, Branch et., *Prevention of Unintended Pregnancy and HIV/STIs Among Latinos in Rural Communities: Perspectives of Health Care Providers*, Health Care Women Int., 31(8), 718 (August 2010), *available at* ; Dehlendorf et al., *Race, Ethnicity and Differences in Contraception Among Low-Income Women: Methods Received by Family PACT Clients, California, 2001-2007*, Perspect. Sex Reprod. Health, 43(3), 181 (September 2011), *available at* https://www.ncbi.nlm.nih.gov/pubmed/21884386/; Whitaker et al., *Effect of a Brief Educational Intervention on the Attitudes of Young Women Toward the Intrauterine Device*, J. Pediatr. Adolesc. Gynecol., 23(2), 116 (April 2010), *available at* https://www.ncbi.nlm.nih.gov/pubmed/19896397.

46. S.B. 614 forces physicians to violate medical ethics regarding the protection of human subjects of scientific research.

47. The ethical rules governing research on human beings stemmed in part from human experimentation that took place during the Second World War, and were articulated in the 1970s in a publication by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled the Belmont Report. These rules were subsequently incorporated into federal regulations at 45 C.F.R. § 46 (i.e., the so-called "Common Rule").[25] The Common Rule applies to all physicians and others working in institutions that receive virtually any federal funds for any type of biomedical research. The Common Rule is built around three of the core medical ethical principles noted above, namely: respect for persons, beneficence, and justice.[26]

48. Because there is no accepted scientific evidence that administration of progesterone safely and effectively "reverses" medication abortion, ingesting this drug in an attempt to do so is unproven and therefore effectively experimental.

49. For use of an experimental treatment to meet the ethical foundations of the Belmont Report and regulations of the Common Rule, health professionals must ensure, for example, that the protocol for using the experimental treatment has been approved by an institutional review board (IRB). Health professionals engaged in research on human beings must also obtain informed consent from each patient specific to participation in the experiment, ensuring that participating patients understand the full extent of the experiment, their rights to withdraw from the experiment

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[25] *See also* The Nuremberg Code, *available at* https://history.nih.gov/research/downloads/nuremberg.pdf (last visited June 17, 2019).

[26] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979); 45 C.F.R. § 46.201-207.

without penalty, and so on. Progesterone treatment to "reverse" abortion does not meet these minimal requirements to protect human subjects of medical experimentation.

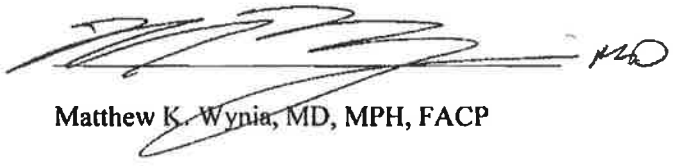
50. S.B. 614 specifically hides the fact that this treatment is poorly studied and understood, as it forces physicians to direct patients to progesterone treatment without any of the benefits or protections of an ethically-conducted medical experiment and under the misrepresentation (from the APR website) that this procedure is "effective" and has a "64-68% success rate." Fundamentally, this misrepresentation will serve to mislead or coerce patients who want to "undo" a medication abortion to participate in an unethical experiment without their knowledge. For physicians who are forced to deliver a misleading and inaccurate message that might cause their patients to enroll in an experiment without their full knowledge, doing so is highly unethical. In sum, S.B. 614 compels health care professionals, contrary to the principles of medical ethics, to be complicit in unethical experimentation on their patients.

Conclusion

51. For all of the foregoing reasons, it is my opinion that the requirements of S.B. 614 are contrary to the core principles of medical ethics. S.B. 614 damages the patient-physician relationship, undermines patient autonomy generally as well as the informed consent process, forces physicians to do harm to their patients without countervailing benefit, and violates principles of medical research ethics.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated this 23day of Sept 2019



Matthew K. Wynia, MD, MPH, FACP

EXHIBIT A

Matthew K. Wynia, MD, MPH, FACP

Director, Center for Bioethics and Humanities
University of Colorado, Anschutz Medical Campus

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PROFESSIONAL EXPERIENCE

CURRENT POSITIONS

PROFESSOR OF MEDICINE
DIRECTOR, THE CENTER FOR BIOETHICS AND HUMANITIES, University of Colorado, Anschutz Medical Campus (2014-current)

♦ Leads strategic planning and programs in bioethics and humanities across medical, nursing, pharmacy, dental, public health and graduate degree programs as well as teaching and outreach across all 4 CU campuses.

♦ The Center for Bioethics and Humanities serves as a resource for clinical and organizational ethics, a forum for public learning and deliberation, and a catalyst for improving health and health care in Colorado and the US.

PREVIOUS PROFESSIONAL POSITIONS AND APPOINTMENTS

DIRECTOR, PHYSICIAN AND PATIENT ENGAGEMENT FOR IMPROVING HEALTH OUTCOMES, American Medical Association (2013-2015)

♦ Lead for engaging AMA members, non-member physicians, and other members of health care teams in AMA initiatives to improve health outcomes, including by working with AMA Communications and Marketing teams to develop messages and delivery vehicles and by recruiting and managing relationships with clinical practice sites for prototyping, piloting, and spreading improvement models.

♦ Studied and developed plans for sustainability and national spread of improvement strategies, including by examining factors that support the effective engagement of physicians, other health professionals, and patients in improvement efforts.

CLINICAL ASSISTANT PROFESSOR IN MEDICINE, University of Chicago (2003-2015)

♦ Cared for a panel of outpatients at the University of Chicago Hospital, Division of Infectious Diseases and served annually as inpatient ward attending on the General Internal Medicine service. Regularly taught in several courses on topics including health policy and health system reform, health disparities, HIV/AIDS, and patient-doctor communication.

DIRECTOR, THE CENTER FOR PATIENT SAFETY, American Medical Association (2011-2013)
AND
DIRECTOR, THE INSTITUTE FOR ETHICS, American Medical Association (2000-2013)

♦ Led AMA research programs in patient safety and bioethics. Used health services research methods to explore issues in medical ethics and professionalism, public health ethics, health disparities, and related topics. Authored more than 100 peer-reviewed publications and numerous additional book chapters, books, published letters and reports.

♦ Increased the reach and profile of the AMA among both academic researchers and clinical practitioners working in bioethics, patient safety, and health policy. Evidence of success includes invited service on advisory boards for the Institute of Medicine (including co-chairing Working Groups on team-based care and on transdisciplinary professionalism), The Joint Commission, the US Department of Health and Human Services Office of Minority Health, the ABMS and ABIM, and others. Recent academic research collaborators at the Mayo Clinic, Johns Hopkins, Harvard, the University of Michigan, Northwestern University, the University of Chicago and others.

♦ Developed and grew the Ethical Force® program, including rolling out a line of tools to reliably measure and track the ethical and practice climate in health care organizations. Includes managing grants that support new product research and development and working closely with a multi-stakeholder Oversight Body comprising diverse health care leaders to create new products and innovative plans for dissemination.

♦ Delivered more than 150 presentations to community organizations and professional groups, both nationally and internationally, promoting the work and products of the Institute for Ethics and Center for Patient Safety.

♦ Led the Project on the History of African Americans in Organized Medicine (www.ama-assn.org/go/afamhistory), with a publication in JAMA that prompted the AMA to apologize for its history of segregation and discrimination and led to significant ongoing AMA investment in the Commission to End Health Care Disparities in collaboration with the NMA and NHMA.

♦ Conducted more than a dozen national physician surveys and other research projects exploring how physicians handle ethical issues in practice, with survey findings published in *JAMA*, *Health Affairs*, *American Journal of Bioethics*, *American Journal of Public Health* and others.

♦ Developed and ran the joint AMA-MCW Online Fellowship in Physician Professionalism with the Medical College of Wisconsin.

♦ Worked in close collaboration with the United States Holocaust Memorial Museum Center for Advanced Holocaust Studies on a nationwide lecture series based on the Museum's Special Exhibition, *Deadly Medicine: Creating a Master Race*.

PREVIOUS APPOINTMENTS AND POSITIONS

1999-2000	Assistant Vice-President, Institute Affairs Ethics Standards Group American Medical Association
1997-2000	Section Director, Managed Care Ethics The Institute for Ethics American Medical Association
1997 - 2003	Clinical Associate in Medicine Infectious Diseases and General Internal Medicine University of Chicago
1995-1997	AHCPR Post-Doctoral Fellow in Health Services Research Tufts University School of Medicine, New England Medical Center Division of Clinical Care Research, Boston, MA
1994-1997	Clinical Fellow in Geographic Medicine and Infectious Diseases Tufts University School of Medicine, New England Medical Center Division of Geographic Medicine and Infectious Diseases, Boston, MA
1993-1997	Assistant Physician in the University Health Services Harvard University Health Service, Cambridge, MA
1993-1994	Instructor in Medicine, Harvard Medical School, Boston MA
1991-1993	Associate Clinical Fellow in Adolescent Medicine, Harvard Medical School, The Children's Hospital, Boston, MA

1990-1993 Clinical Fellow in Medicine, Harvard Medical School, The Deaconess Hospital, Boston, MA

TRAINING, LICENSURE, AND PROFESSIONAL SOCIETY ACTIVITIES

EDUCATION/POST GRADUATE TRAINING

B.A. University of Oregon, Honors College
Eugene, Oregon
Majors: Philosophy and Biology
September 1982-June 1986
Honors Thesis: Paternalism in Medicine

Université de Poitiers
Poitiers, France
Courses in Physics, Philosophy, Economics and German
September 1983-July 1984

M.D. Oregon Health Sciences University, School of Medicine
Portland, Oregon
September 1986-June 1990

Residency 1990-1993 Resident in Medicine, Department of Medicine, The Deaconess Hospital, Boston MA
1993-1994 Chief Medical Resident, Department of Medicine, The Deaconess Hospital, Boston MA

Fellowships 1994-1997 Fellowship in Geographic Medicine and Infectious Diseases, Tufts' New England Medical Center, Boston MA.
1995-1997 AHCPR Post-Doctoral Fellowship in Health Services Research, Division of Clinical Care Research, New England Medical Center, Boston MA

M.P.H. Harvard University School of Public Health,
Department of Health Policy and Management
Boston, MA
September 1995-May 1997

MEDICAL LICENSURE

Massachusetts license # 75401 (since January 1992)
Illinois License #036-095846 (since July 1997)
Colorado license # DR.0055463 (Since June 2015)

BOARD CERTIFICATIONS

American Board of Internal Medicine (ABIM) certification September, 1993 (#152716), recertification in 2003 and 2013

Infectious Diseases (ABMS) Board Certification October, 1996 (#152716), recertification in 2003 and 2014

SELECTED PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

NATIONAL ACADEMY OF SCIENCES, ENGINEERING AND MEDICINE

- Committee on Evidence-Based Practices for Public Health Emergency Preparedness and Response
  - Member, 2018-
- Forum on Medical and Public Health Preparedness for Catastrophic Events

- Member, 2015-
- Chair, Workshop on Exploring the Use of Health Approaches in Community-Level Strategies to Countering Violent Extremism and Radicalization. Washington DC. September 7-8, 2017.

- Best Practice Innovations Collaborative (an initiative of the IOM Roundtable on Sciencce and Value Driven Health Care),
  - Co-Chair, Team-Based Care Working Group, 2012-2013
  - Authored Working Group Products: Discussion Paper, *Core Principles & Values of Effective Team-Based Health Care* (2012) and JAMA Viewpoint, *Challenges at the Intersection of Team-Based and Patient-Centered Health Care: Insights From an IOM Working Group* (2012)
- Global Forum on Innovations in Health Professions Education
  - Co-Chair, Transdisciplinary Professionalism Workshop, May 2013
  - Authored Workshop Products: Workshop Summary, *Establishing Transdisciplinary Professionalism for Improving Health Outcomes* (2013), and JAMA Viewpoint, *A Unified Code of Ethics for Health Professionals: Insights From an IOM Workshop* (2014)
- Reviewer for *Essential Health Benefits: Balancing Coverage and Cost (2011)* and *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response (2012).*

AMERICAN BOARD OF MEDICAL SPECIALTIES

- Ethics and Professionalism Committee, 2011- 2015
  - Authored work products: *ABMS Definition of Professionalism*, Adopted by the Board January 18, 2012. (http://www.abms.org/media/84742/abms-definition-of-medical-professionalism.pdf); *More than a list of values and desired behaviors: a foundational understanding of medicine professionalism*, Academic Medicine May 2014.

AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES

- Board of Directors, 2001-2007
- Treasurer, 2003-2004
- President, 2005-2006

AMERICAN PSYCHOLOGICAL ASSOCIATION

- Commission on Ethics Processes (to address issues related to the participation of psychologists in coercive national security interrogations),
  - Member, 2016-2017
  - Chair, Subcommittee on Ethical Culture and Organizational Integrity Assessment (SECOIA)

AMERICAN PUBLIC HEALTH ASSOCIATION

- Member, Medical Care Section and Ethics Section, 1998-
- Invited participant in the Leadership Forum meeting to develop a Code of Ethics for Public Health Practice. Kansas City, MO, 2001.
- Chair, Ethics Forum Program Committee, 2001-2002
- Chair, Ethics Forum (now the Ethics Section), 2002-2003

COLORADO MEDICAL SOCIETY

- Member, Special Advisory Committee on ColoradoCare (single payer ballot measure), 2016
- Special Advisor, Council on Ethical and Judicial Affairs

SOCIETY OF GENERAL INTERNAL MEDICINE

- Society of General Internal Medicine (SGIM), Member, 1995-present

- *SGIM Forum,* Associate Editor, 1995-97
- Ethics Committee member, 1997~2010 (Co-Chair 2000, 2002)
- Health Policy Committee member, 1997-2000
- Task Force on Health Disparities, 2003~2010

AMERICAN COLLEGE OF PHYSICIANS

- American College of Physicians (ACP), Member, 1990- present. Fellow, 2006-present.
- ACP Massachusetts Chapter Health and Public Policy Committee, 1993-97
- Northern Illinois chapter Health and Public Policy Committee, 2008-present; co-chair 2012-13

AMERICAN MEDICAL ASSOCIATION

- American Medical Association (AMA), Member, 1992-present
- American Medical Association-Resident Physicians' Section Delegate, 1993-97
- AMA Resident Representative to the Graduate Medical Education Advisory Committee, 1994.

MASSACHUSETTS MEDICAL SOCIETY

- Massachusetts Medical Society Resident Physician Section (MMS-RPS), Governing Councilor, 1993-97
- MMS-RPS, Chairperson, 1996-97
- MMS, Trustee, 1995-96
- MMS, Alternate Trustee, 1994-95
- MMS, Task Force on a Managed Care Core Curriculum, 1996
- MMS, Committee on Tax Supported Medical Care, 1993-1995
- MMS Committee on Public Health, 1995-97. Vice-Chair, 1996-97

OTHER PROFESSIONAL MEMBERSHIPS

- Infectious Diseases Society of America
- Physicians for Human Rights
- Physicians for a National Health Plan
- Physicians for Social Responsibility
- American Academy on Communication in Healthcare
- American College of Physician Executives
- National Medical Association

EDITORIAL ACTIVITIES

EDITORIAL BOARD AND CONTRIBUTING EDITOR: Am J Bioethics (2005-present)

REVIEWER FOR: N Engl J Med, JAMA, Ann Intern Med, J Law Med Ethics, Health Affairs, J Gen Intern Med, Health Serv Res and others.

TEACHING RESPONSIBILITIES (Selected)

AMA/MCW Fellowship in Physician Ethics and Professionalism, program director, 2000-2010

"The history and meaning of ethics and professionalism in health care," 3-credit graduate course, offered annually, Medical College of Wisconsin, course director 2000-2010

Interprofessional Education Council, University of Colorado Anschutz Medical Campus, member, 2014-current

HSMP6617 | Interpreting Health Policy and Management Research, Colorado School of Public Health, 2-credit graduate course, course co-director, 2019-current

PUBLICATIONS

PEER-REVIEWED JOURNAL ARTICLES

1. Wynia, MK, Shapiro B, Kuvin JT, Skolnick PR. Fatal Castleman's disease and pulmonary Kaposi's sarcoma in an HIV sero-positive woman. *J Acquir Imm Defic Syndr* 1995; 9(7):814-816.
2. Wynia, MK. Culinary metaphors in medicine. *Inf. Dis. Clin. Pract* 1995; 4(6):437-440.
3. Wynia, MK. The Oregon Capitation Initiative: lessons and warnings, from the forefront of the backlash. *JAMA* 1996; 276(17):1441-1444.
4. Wynia, MK. Economic analyses, the medical commons and patients' dilemmas: what is the physician's role? *J Invest Med* 1997; 45(2):35-43.
5. Wynia MK, Picken HA, Selker HP. Physicians' views on capitated payment for medical care: Does familiarity foster acceptance? *Am J Man Care* 1997; 3:1497-1502.
6. Wynia MK, Ioannidis JPA, Lau J. Comparing lifelong strategies to prevent Pneumocystis carinii pneumonia in patients with variable rates of HIV disease progression: a decision and cost analysis. *AIDS* 1998; 12:1317-1325.
7. Wynia MK, Eisenberg DM, Wilson IB. Physician-patient communication about complementary and alternative medical therapies: a survey of physicians caring for patients with human immunodeficiency virus infection. *J Alt Complement Med* 1999; 5(5):447-456.
8. Wynia MK, Latham SR, Kao AC, Berg JW, Emanuel LL. Medical professionalism in society. *N Engl J Med* 1999; 342(21):1612-1616.
9. Wynia MK. Ethics matters: performance measures for ethics quality. *Effective Clin Pract.* 1999; 2(6):294-299.
10. Wynia MK, Cummins DS, VanGeest JB, Wilson IB. Physician manipulation of reimbursement rules for patients: between a rock and a hard place. *JAMA*. 2000; 283(14):1858-1865.
11. Geraghty KE, Wynia MK. Advocacy and Community: The Social Role of Physicians over the last 1000 Years. Part I of III. *Medscape General Medicine* October 30, 2000. Available online at: http://www.medscape.com/Medscape/GeneralMedicine/journal/2000/v02.n05/mgm1030.gera/mgm1030.gera-01.html
12. Geraghty KE, Wynia MK. Advocacy and Community: The Social Role of Physicians over the last 1000 Years. Part II of III. *Medscape General Medicine* November 6, 2000. Available online at: http://www.medscape.com/Medscape/GeneralMedicine/journal/2000/v02.n06/mgm1106.gera/mgm1106.gera-01.html
13. Geraghty KE, Wynia MK. Advocacy and Community: The Social Role of Physicians over the last 1000 Years. Part III of III. *Medscape General Medicine* November 13, 2000. Available online at: http://www.medscape.com/Medscape/GeneralMedicine/journal/2000/v02.n06/mgm1113.gera/mgm1113.gera-01.html
14. Schlesinger M, Wynia M, Cummins D. Some distinctive features of the impact of managed care on psychiatry. *Harvard Rev Psych.* 2000; 8:216-230.
15. Wynia MK, Coughlin SS, Alpert S, Cummins DS, Emanuel, LL. Shared expectations for protection of identifiable health care information: report of a national consensus process. *J Gen Intern Med.* 2001;16:100-111.
16. Wynia MK. "If one more doctor tells me I'm crazy, I'm going to go postal!" Through the Doctor's Eyes. *The Virtual Mentor.* Sept. 7, 2001. Available at www.VirtualMentor.org
17. VanGeest JB, Wynia MK, Cummins DS, Wilson IB. Effects of different monetary incentives on the return rate of a national mail survey of physicians. *Med Care* 2001;39(2):197-201.
18. Wynia MK, Zucker D, Supran S, Selker, H. Patient Protection and Risk Selection: Do primary care physicians encourage their patients to join or avoid capitated health plans according to the patients' health status? *J Gen Intern Med.* 2002;17:40-47.
19. VanGeest JB, Wynia MK, Cummins DS, Wilson IB. Measuring deception: test-retest reliability of physicians' self-reported manipulation of reimbursement rules for patients. *Med Care Res Rev.* 2002;59(2):184-196.
20. Wynia MK, Gostin L. The bioterrorist threat and access to health care. *Science.* 2002;296:1613.

21. Wynia MK, VanGeest JB, Cummings DS, Wilson IB. Do physicians not offer useful services because of coverage restrictions? *Health Affairs* 2003;22(4):190-197.
22. Alexander GC, Wynia MK. Ready and willing? Physician readiness and willingness to treat potential victims of bioterror. *Health Affairs* 2003; 22(5): 189-197.
23. Huber S, Wynia MK. When pestilence prevails: physician responsibilities in epidemics. *Am J Bioethics* 4:1W5-W11 (available at http://bioethics.net/journal/infocus/pdf/4_1_IF_w05_Huber.pdf)
24. Wynia MK. Civic obligations in medicine. Does "professional" civil disobedience tear, or repair, the basic fabric of society? *The Virtual Mentor*. January 2004. Available at: http://www.ama-assn.org/ama/pub/category/11780.html.
25. Wynia MK, Gostin LO. Ethical challenges in preparing for bioterrorism: the role of the health care system. *Am J Public Health* 2004; 94 (7):1096-1102.
26. Berkman ND, Wynia MK, Churchill LR. Gaps, Conflicts, and Consensus in the Ethics Statements of Professional Associations, Medical Groups, and Health Plans. *J Med Ethics* 2004 Aug;30(4):395-401
27. Wynia MK, Cummins D, Fleming D, Karsjens K, Orr A, Sabin J, Saphire-Bernstein I, Witlen R, writing for the Oversight Body of the Ethical Force Program. Improving fairness in coverage decisions: performance expectations for quality improvement. *Am J Bioethics* 2004;4(3):87-100.
28. Weiner SJ, VanGeest JB, Wynia MK, Cummins DS, Wilson IB. Falling into Line: The Impact of Utilization Review Hassles on Physician Adherence to Insurance Contracts. *J Clin Ethics* 2004 Summer;15(2):139-48.
29. Slutsman J., Kass N., McGready J, Wynia M. Health Information, The HIPAA Privacy Rule, And Health Care: What Do Physicians Think? *Health Affairs*.2005; 24(3):832-42.
30. Wynia MK. Consequentialism and harsh interrogations. *Am J Bioethics* 2005 5(1):4-6.
31. Wynia MK. Science, faith and AIDS: the battle over harm reduction. *Am J Bioethics* 2005 5(2):3-4
32. Wynia MK. Public health principlism: the precautionary principle and beyond. *Am J Bioethics* 2005 5(3):3-4
33. McKoy JM, Karsjens KL, Wynia M, MacDonald-Glenn L. Is ethics for sale?...Juggling law and ethics in managed care. *DePaul J Health Care Law*. 2005 Spring;8(3):559-613
34. Wynia MK. Oversimplifications I: Doctors don't do public health. *Am J Bioethics* 2005 5(4):4-5
35. Wynia MK. Oversimplifications II: Public health ethics ignores individual rights. *Am J Bioethics*. 2005 Sep-Oct;5(5):6-8.
36. GC Alexander, J Kurlander, MK Wynia. Physicians in retainer ("concierge") practice: A national survey of physician, patient and practice characteristics. *J Gen Intern Med.* 2005; 20(12):1079-83.
37. Wynia MK. Judging public health research: Epistemology, public health and the law. *Am J Bioethics* 2005 5(6):4-7.
38. Alexander GC, Larkin GL, Wynia MK. Physicians' Preparedness for Bioterrorism and Other Public Health Priorities. *Acad Emerg Med.* 2006 Nov;13(11):1238-41. Epub 2006 Apr 13.
39. Wynia MK. Risk and trust in public health: a cautionary tale. *Am J Bioethics*. 2006 Mar-Apr;6(2):3-6.
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43. Wynia MK. Routine screening: informed consent, stigma and the waning of HIV exceptionalism. *Am J Bioethics*. 2006 Jul-Aug;6(4):5-8.
44. Wynia MK. Ethics and Public Health Emergencies: Rationing Vaccines. *Am J Bioethics.* 2006 Nov-Dec;6(6):4-7.

45. Wynia MK. Ethics and Public Health Emergencies: Restrictions on Liberty. *Am J Bioethics.* 2007; 7(2):1-5.
46. Wynia MK. Ethics and public health emergencies: Encouraging responsibility. *Am J Bioethics.* 2007; 7(4):1-4.
47. Wynia MK, Wells AL. Light from the flames of hell: Remembrance and lessons of the Holocaust for today's medical profession. *Isr Med Assoc J.* 2007; 9(3):186-88.
48. Levine MA, Wynia MK, Schyve PM et al. Improving access to health care: A consensus ethical framework to guide proposals for reform. *Hastings Center Report* 2007; 37(5):14-19.
49. Smith WR, Betancourt JJR, Wynia MK, et al. Recommendations for teaching about racial and ethnic disparities in health and health care. *Ann Intern Med* 2007; 147:654-65.
50. Wynia MK. Public health, public trust and lobbying. *Am J Bioethics.* 2007; 7(6):4-7.
51. Wynia MK. Mandating vaccination: What counts as a "mandate" in public health and when should they be used? *Am J Bioethics* 2007; 7(12):2-6.
52. Alexander GC, Lin S, Sayla MA, Wynia MK. Development of a Measure of Physician Engagement in Addressing Racial and Ethnic Health Care Disparities. *Health Services Research* (OnlineEarly Article, published online: 10-Sep-2007) 2008; 43(2):773-84.
53. Phongsak SK, Wynia MK, Gadon M, Alexander GC. A Qualitative Study of Physicians' Engagement in Reducing Health Care Disparities *J Nat Med Assoc* 2007; 99(12):1315-22.
54. Wynia MK. Laying the groundwork for a defense against participation in torture? *Hastings Cent Rep.* 2008 38(1):11-13.
55. Klein JW, Schubiner LO, Gadon M, Wynia MK. Physicians' experiences and opinions regarding strategies to improve care for minority patients. *J Health Disp Res Pract* 2008; 2(2):75-90.
56. Matiasek J, Wynia MK. Reconceptualizing the informed consent process at eight innovative hospitals. *Jt Comm J Qual and Pat Safety.* 2008; 34(3):127-37.
57. Baker RB, Washington HA, Olakanmi O, Savitt TL, Jacobs EA, Hoover E, Wynia MK. African American physicians and organized medicine, 1846-1968: origins of a racial divide. *JAMA* 2008; 300(3):306-313.
58. Wynia MK. The short history and tenuous future of medical professionalism: The erosion of medicine's social contract. *Perspect Biol Med.* 2008 Autumn; 51(4):565-78.
59. Wynia MK. Abusive interrogations of detainees in the war on terror: Whether it 'works' isn't really the issue. Newsletter on Philosophy and Medicine. American Philosophical Association. Fall 2008; 8(1): 21-6.
60. Wynia MK. Personal responsibility, public policy, and the economic stimulus plan. *Hastings Cent Rep.* 2009; 39(2):13-15
61. Baker RB, Washington HA, Olakanmi O, Savitt TL, Jacobs EA, Hoover E, Wynia MK. Creating a segregated medical profession: African American physicians and organized medicine, 1846-1910. *J Natl Med Assoc.* 2009; 101(6):501-12.
62. Washington HA, Baker RB, Olakanmi O, Savitt TL, Jacobs EA, Hoover E, Wynia MK. Segregation, civil rights, and health disparities: the legacy of African American physicians and organized medicine, 1910-1968. *J Natl Med Assoc.* 2009; 101(6):513-27.
63. Wynia MK. The risks of rewards in health care; How pay-for-performance could threaten, or bolster, medical professionalism. *J Gen Intern Med.* 2009; 24(7):884-7.
64. Chen DT, Wynia MK, Moloney RM, Alexander GC. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: results of a national survey. *Pharmacoepidemiol Drug Saf.* 2009; 18(11):1094-100.
65. Wynia M, Boren D. Better regulation of industry-sponsored clinical trials is long overdue. *J Law Med Ethics.* 2009; 37(3):410-19.
66. Wynia MK. Osborn CY. Health literacy and communication quality in health care organizations. *J Health Commun.* 2010; 15 (suppl 2):102-15.

67. Hasnain-Wynia R, Van Dyke K, Youdelman M, Krautkramer C, Ivey SL, Kaleba E, Wynia MK. Barriers to collecting patient race, ethnicity and primary language data in physician practices: an exploratory study. *J Nat Med Assoc.* 2010; 102(9):769-75.
68. Wynia MK, Ivey SL, Hasnain-Wynia R. Collection of data on patients' race and ethnic group by physician practices. *N Engl J Med.* 2010 Mar 4;362(9):846-50
69. Wynia MK. The role of professionalism and self-regulation in detecting impaired and incompetent physicians. *JAMA* 2010; 304(2):210-2.
70. Wynia M, Dunn K. Dreams and nightmares: Practical and ethical issues for patients and physicians using personal health records. *J Law Med Ethics.* 2010; 38(1):64-73.
71. Subbarao I, Wynia MK, Burkle FM Jr. The elephant in the room: Competition and collaboration among relief organizations during high-profile disasters. *J Clin Ethics.* 2010; 21(4):328-34.
72. Hotze TD, Shah K, Anderson E, Wynia MK. "Doctor, Would You Prescribe a Pill to Help Me ...?" A National Survey of Physicians on Using Medicine for Human Enhancement. *Am J Bioeth* 2011. 11(1):3-13.
73. Wynia MK, Torres GW, Lemieux J. Many physicians are willing to use patients' electronic personal health records, but doctors differ by location, gender, and practice. *Health Affairs.* 2011; 30(2):266-73.
74. Kirschner KL, Brashler R, Crigger BJ, Wynia MK, Halvorsen A. Should health care professionals Google patients or family members? *Phys Med Rehab.* 2011 Apr;3(4):372-6.
75. Wynia MK, Classen DC. Ambulatory patient safety: Learning from the last decade, moving ahead in the next. *JAMA.* 2011; 306(22):2504-5.
76. Jean-Jacques M, Wynia MK. Practicing the fundamentals of patient-centered care. *J Gen Intern Med.* 2012; 27(4):398-400.
77. Crigger BJ, Wynia MK. The honesty effect. *Hastings Cent Rep.* 2012; 42(3):3.
78. Wynia MK. Making it easier to do the right thing: a modern communication QI agenda. *Patient Educ Counsel.* 2012; 88(3):364-6.
79. Maul LR, Regenstein M, Andres A, Wright R, Wynia MK. Using a risk assessment approach to determine which factors influence whether partially-bilingual physicians rely on their non-English language skills or call an interpreter. *Jt Comm J Qual Patient Saf.* 2012; 38(7):328-36.
80. Wynia MK, VonKohorn I, Mitchell PH. Challenges at the intersection of team-based and patient-centered health care. Insights from an IOM working group. *JAMA* 2012; 308(13):1327-8.
81. Wynia MK, Sabin JE. Ethical challenges come home. *J Gen Intern Med* 2013; 28(1):9-11.Online First 2012: http://dx.doi.org/10.1007/s11606-012-2232-0 (Erratum: Nov. 21, 2012)
82. Jager AJ, Wynia MK. Who gets a teach back? Patient-reported incidence of experiencing a teach back. *J Health Commun.* 2012; 17 suppl 3:294-302.
83. Regenstein M, Andres E, Wynia MK. Appropriate use of non-English language skills in clinical care. *JAMA* 2013; 309(2):145-6.
84. Wynia MK. The intractable and the novel: looking ahead in bioethics. *Am J Bioeth* 2013; 13(1):11-2.
85. Andres E, Wynia MK, Regenstein M, Maul L. Should I call an interpreter? How do physicians with second language skills decide? *J Health Care Poor Underserved* 2013; 24(2):525-39.
86. Crigger BJ, Wynia MK. Evaluating ethics quality. *AJOB Primary Research.* 2013; 4(1):2-6
87. Tilburt JC, Wynia MK, Sheeler RD, Thorsteindottir B, Jame KM, Eggington JS, Liebow M, Hurst S, Danis M, Goold SD. Views of US physicians about controlling health care costs. *JAMA* 2013; 310(4):380-8.
88. Jager AJ, Wynia MK. Variance in patient access to support persons by race/ethnicity and language preference: an analysis of patient survey data. *J Health Disparities Res Pract.* 2013; 6(2):article 5. Available at: http://digitalscholarship.unlv.edu/jhdrp/vol6/iss2/5

89. Gallagher TH, Mello MM, Levinson W, Wynia MK, Sachdiva AK, Snyder-Sulmasy L, Truog RD, Conway J, Mazor K, Lembitz A, Bell SK, Sokol-Hessner L, Shapiro J, Puopolo AL, Arnold R. Talking with patients about other clinicians' errors. *N Eng J Med* 2013; 369(18):1752-7.
90. Tilburt JC, Wynia MK, Montori VM, et al. Shared decision-making as a cost-containment strategy:US physician reactions from a cross-sectional survey. *BMJ Open* 2014; 4(1):e004027
91. Wynia MK, Kishore SP, Belar CD. A unified code of ethics for health professionals: insights from an IOM workshop. *JAMA* 2014; 311(8):799-800.
92. Wynia MK, Papadakis MA, Sullivan WM, Hafferty FW. More than a list of values and desired behaviors: a foundational understanding of medical professionalism. *Acad Med.* 2014; Mar 24 (ePub ahead of print) 89(5):712-4. doi: 10.1097/ACM.0000000000000212.
93. Wynia M. Doctor as advocate or doctor as citizen. *Virtual Mentor*. 2014; Sep 1;16(9):694-8. doi: 10.1001/virtualmentor.2014.16.09.ecas1-1409
94. Nora LM, Wynia MK, Granatir T. Of the profession, by the profession and for patients, families and communities. ABMS Board certification and medicine's professional self-regulation. *JAMA*. 2015 May 12;313(18):1805-6. doi: 10.1001/jama.2015.4025
95. Nurok M, Lee YY, Ma Y, KirwanA, Wynia M, Segal S. Are surgeons and anaesthesiologists lying to each other or gaming the system? A national random sample survey about "truth-telling practices" in the perioperative setting in the United States. *Patient Saf Surg*. 2015 Nov 10;9:34. doi: 10.1186/s13037-015-0080-7
96. Wozniak G, Khan T, Gillespie C, Sifuentes L, Hasan O, Ritchey M, Kmetik K, Wynia M. Hypertension control cascade: a framework to improve hypertension awareness, treatment and control. *J Clin Hypertens* (Greenwich). 2016 Mar;18(3):232-9. doi: 10.1111/jch.12654.
97. Leslie L, Cherry RF, Mulla A, Abbott J, Furfari K, Glover JJ, Harnke B, Wynia MK. Domains of quality for clinical ethics case consultation: a mixed methods systematic review. *Syst Rev*. 2016; 5(95). doi: 10.1186/s13643-016-0273-x. Review. PMID:2726776
98. Jager AJ, Choudhry SA, Marsteller JA, Telford RP, Wynia MK. Development and initial validation of a new practice context assessment tool for ambulatory practices engaged in quality improvement. *Am J Med Qual*. 2016; pii: 1062860616659132. [Epub ahead of print] PMID: 27469005
99. Boonyasai RT, Rakotz MK, Lubomski LH, Daniel DM, Marsteller JA, Taylor KS, Cooper LA, Hasan O, Wynia MK. Measure accurately, Act rapidly, Partner with patients: an intuitive and practical three part framework to guide efforts to improve hypertension control. *J Clin Hypertens*. 2017; Mar 23 doi: 10.1111/jch.12995. [Epub ahead of print] PMID:28332303
100. Rakotz MK, Townsend RR, Yang J, Alpert BS, Heneghan KA, Wynia M, Wozniak GD. Medical students and measuring blood pressure: results from the American Medical Association blood pressure check challenge. *J Clin Hypertens*. 2017; 19(6):614-9. doi: 10.1111/jch.13018. Epub 2017 Apr 28. PMID: 28452119
101. Wynia MK, Eisenman D, Hanfling D. Ideologically-motivated violence: a public health approach to prevention. *Am J Public Health*. 2017; 107(8):1244-6. doi: 10.2105/AJPH.2017.303907.
102. Wynia MK, Macpherson CC. Should health professionals speak up to reduce the health risks of climate change? *AMA J Ethics*. 2017; 19(12):1202-10.
103. Cervantes L, Richardson S, Raghavan R, Hou N, Hasnain-Wynia R, Wynia MK, Kleiner C, Chonchol M, Tong A. Clinicians' perspectives on providing emergency-only hemodialysis to undocumented immigrants: a qualitative study. *Ann Intern Med*. 2018; 169(2):78-86
104. Goldberg DS, Lederer DJ, MacKenzie EJ, Moss M, Samet JM, Schumacker PT, Wedzicha JA, Wynia MK. The Phillip Morris Foundation for a Smoke Free World. A cause for concern. *Ann Am Thorac Soc*. 2018; 15(11):1269-72.
105. Leep Hunderfund AN, Dyrbye LN, Starr SR, Mandrekar J, Tilburt JC, George P, Baxley EG, Gonzalo JD, Moriates C, Goold SD, Carney PA, Miller BM, Grethlein SJ, Fancher TL, Wynia MK, Reed DA. Attitudes toward cost conscious care among US physicians and medical students; ananlysis

of national cross-sectional survey data by age and state of training. *BMC Med Educ.* 2018; 18(1):275 doi: 10.1186/s12909-018-1388-7.

106. Stephenson CR, Wittich CM, Pacyna JE, Wynia MK, Hasan O, Tilburt JC. Primary care physicians' perceptions of practice improvement as a professional responsibility: a cross-sectional study. *Med Educ Online.* 23(1):1474700. doi: 10.1080/10872981.2018.1474700.
107. Wynia, M., Ethical issues during outbreaks of infectious disease. *Audio Digest Emergency Medicine* 35:21(November7), 2018.

BOOKS, BOOK CHAPTERS AND REPORTS

108. Wynia MK, Emanuel LL. Credentialing Standards and Quality Care. In: Ethical Challenges in Managed Care: A Casebook. KG Gervais, R Priester, DE Vawter, KK Otte, and MM Solberg, editors. Georgetown Univeristy Press, Baltimore, MD, 1999.
109. Wynia MK (primary author) for the Ethical Force Program Oversight Body. Protecting Identifiable Health Care Informational Privacy – a Consensus Report on Eight Content Areas for Performance Measure Development. (report) The Ethical Force Program, Chicago, IL, 2001.
110. Wynia MK. When the Quantity of Mercy is Strained: Physician Deception of Insurers for Patients. In, Malingering and Illness Deception, Oxford University Press, New York, NY, 2003.
111. Wynia MK, R Witlen, D Cummins, K Karsjens, A Orr, for the Ethical Force Program Oversight Body. Ensuring Fairness in Health Care Coverage Decisions: A Consensus Report on the Ethical Design and Administration of Health Care Benefits Packages.(report) The Ethical Force Program. Chicago, IL, 2004.
112. Mills AE, Chen DT, Werhane PH, Wynia MK. Introduction and Summary and Conclusions. In, Professionalism in Tomorrow's Healthcare System. Mills AE, Chen DT, Werhane PH, Wynia MK, editors. University Publishing Group, Hagerstown MD, 2005.
113. Wynia MK. The Birth of Medical Professionalism. Professionalism and Professional Associations. In, Parsi KP, Sheehan MN, editors. Healing as vocation: A primer on medical professionalism. Rowman and Littlefield, Lanham MD, 2006.
114. Wynia MK, Matiasek JM. Promising Practices for Patient-Centered Communication with Vulnerable Populations: Examples from Eight Hospitals. (report) The Commonwealth Fund, August 2006. (Available at: http://www.cmwf.org/publications/publications_show.htm?doc_id=397067)
115. Wynia MK, Kurlander JE, Green SK. Physician professionalism and preparing for epidemics: challenges and opportunities. In: Ethics and Epidemics. J Balint, S Philpott, R Baker, and M Strosberg eds. Advances in Bioethics series, Vol 9. Elsevier, Amsterdam. 2006. Pp:135-161.
116. Wynia MK, Schwab AP. Ensuring Fairness in Health Care Coverage Decisions: An Employer's Guide to Making Good Decisions on Tough Issues. 2006. AMACOM Press, New York, NY.
117. Improving Communication – Improving Care. How health care organizations can ensure effective, patient-centered communication with people from diverse populations. An Ethical Force program consensus report. American Medical Association. Chicago, IL. 2006. Available at: www.ama-assn.org/ama1/pub/upload/mm/369/ef_imp_comm.pdf
118. Wynia MK, Kurlander JE. Physician ethics and participation in quality improvement: renewing a professional obligation. In: Health Care Quality Improvement: Ethical and Regulatory Issues. Bruce Jennings, Mary Ann Baily, Melissa Bottrell, and Joanne Lynn, eds. The Hastings Center: Garrison, NY, January 2007.
119. Alexander GC, Wynia MK. Survey research in bioethics. In: Empirical Methods for Bioethics: A Primer. Ed Jaboby L and Siminoff LA. JAI Press (Elsevier). Oxford UK. 2008.
120. Lorincz CY, Drazen E, Sokol PE, Neerukonda KV, Metzger J, Toepp MC, Maul L, Classen DC, Wynia MK. Research in Ambulatory Patient Safety 2000–2010: A 10-Year Review. American Medical Association, Chicago IL 2011. Available at: https://c.ymcdn.com/sites/npsf.site-ym.com/resource/resmgr/PDF/Research-in-Amb-Pat-Saf_AMAr.pdf.

121. Wynia MK. Legal and Ethical Issues in Disasters. In: Advanced Disaster Life Support Course Mannual 3.0. JA Armstrong and RB Schwartz, eds. American Medical Association, Chicago IL. 2012.
122. Mitchell P, Wynia MK, Golden R, McNellis R, Okun S, Webb CE, rohrbach V, VonKohorn I. Core Principles and Values of Team-Based Care. Institute of Medicine. National Academy of Sciences. October 2012.
123. Sokol PE, Wynia MK. Writing for the AMA Expert Panel on Care Transitions. There and Home Again, Safely: Five Responsibilities of Ambulatory Practices in High Quality Care Transitions. American Medical Association, Chicago IL 2013. Available at:http://selfmanagementalliance.org/wp-content/uploads/2013/11/There-and-Home-Safely_ambulatory-practices.pdf

ESSAYS, LETTERS AND OTHER NON-PEER REVIEWED PUBLICATIONS

124. Wynia M. "Do Everything" (letter) *Ann Int Med* 121(1):77. July 1994, and comments, *Ann Int Med* 121(11):900-901, Dec. 1994
125. Wynia MK. Drive-through deliveries: legislating standards of care. (editorial) *SGIM Forum*, September 1995;18(9):5,7.
126. Wynia MK. The "right-sizing" of post-graduate medical education. (editorial) *SGIM Forum*, November 1995;18(10):2,5.
127. Wynia M. Member of AMA not happy with Medicare deal. (letter) *The Boston Globe*, Oct. 17, 1995.
128. Wynia, MK The oversupply of specialists and graduates of foreign medical schools. (letter) *N Engl J Med* 1995; 333(26):1781.
129. Wynia, MK. Growth reduction vs. budget cuts for Medicare: what's in a name? (letter) *JAMA* 1996;276(1):30.
130. Wynia MK. The AMA's support for GOP Medicare proposals and the future of the AMA. (editorial) *SGIM Forum*, February 1996; 19(2):1,4.
131. Wynia MK. Risk is money. (editorial) *SGIM Forum,* April 1996; 19(4):2,4,6-7.
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135. Wynia MK. When the quantity of mercy is strain'd. (editorial) *SGIM Forum*. April, 1997
136. Wynia MK. Of empowerment, allocation rules, and ethical alternatives. (editorial) *SGIM Forum*. August, 1997
137. Wynia MK. Professionalism and professional associations in modern medicine. *Audio-Digest Family Practice* 1999; 47(32): August 28.
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143. Wynia MK, Crigger B. The administrator's dilemma. (newsletter item) *News@VHA Ethics*: Policy Perspectives. 2003; 2. Available at www.ethics.va.gov/vhaethics/2003-2/briefs8.html
144. Wynia MK, Clark CC. Physicians as citizens. (letter) *JAMA* 2004; 291(17):2075-76
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146. Wynia M, Witlen R. Medicare coverage for technological innovations. (letter) *N Engl J Med* 2004 351:719-720.
147. Wynia MK. Mercy coming under strain. (peer commentary) *Am J Bioethics*. 2004;4(4):74-76.
148. Wynia MK. Civil disobedience: the devil is in the details. (letter) *Hastings Cent Rep*. 2005 Jul-Aug;35(4):4-5
149. Schwab AP, Carroll KA, Wynia MK. What is managed care anyway? (peer commentary) *Am J Bioeth*. 2006 Jan-Feb;6(1):36-7.
150. Wynia MK, Gamble VN. Mistrust among minorities and the trustworthiness of medicine. (letter) *PLoS Med*. 2006 May;3(5):e244
151. Wynia MK. Cost-effectiveness analysis in the United States. (letter) *JAMA*. 2006 Jun 21;295(23):2722
152. Wynia MK. Balancing evidence-based medicine and cultural competence in the quest to end healthcare disparities. (web video editorial) *MedGenMed*. 2006 Apr 24;8(2):22.
153. Wynia MK. Who is measuring the ethical quality of care in American medicine? No one, yet. *MedGenMed*. (web video editorial) 2006 May 19;8(2):49.
154. Wynia MK. What can doctors do about health literacy? (web video editorial) *MedGenMed* 2006; 8(4):1. Available at: http://www.medscape.com/viewarticle/545030?src=mp
155. Wynia MK, Johnson M. Practicing Evidence-Based *and* Culturally Competent Medicine: Is it Possible? Response 2. (commentary) *Virtual Mentor*. 2007; 9:572-578. (available at: http://www.ama-assn.org/ama/pub/category/17813.html)
156. Wynia MK. Should doctors force feed prisoners? (web video editorial) *MedGenMed* 2007 October 5; 9(4):5. (Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=18311355) and a reader and the author respond at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=18311400
157. Wynia MK. Electronic personal health records: Should doctors worry? *Medscape J Med*. 2008;10(8):204. Epub 2008 Aug 29.
158. Wynia MK. Answering the "So what?" question for empirical research in bioethics. (peer commentary) *Am J Bioeth*. 2009;9(6-7):68-9.
159. Hotze TD, Shah K, Anderson EE, Wynia MK. Response to open peer commentaries on "'Doctor, would you prescribe a pill to help me … ?' A national survey of physicians on using medicine for human enhancement". *Am J Bioeth*.2011;11(1):W1-3.
160. Wynia MK, Goold SD. Fairness and the public's role in defining decent benefits. (peer commentary) *Am J Bioeth*. 2011;11(7):1-2
161. Wynia MK. Commentary. Wiley-Blackwell Exchange. The Changing Face of War. Available at: http://wileyblackwellwar.files.wordpress.com/2011/11/calkins_commentary1_matthew_k-_wynia.pdf
162. Wynia MK. Knowledge, Wisdom, and Service: The Meaning and Teaching of Professionalism in Medicine. Center for the Study of Ethics in Society at Western Michigan University; Kalamazoo, MI. Papers published by the Center. Vol. XIX, No. 2; 2012.
163. Hafferty FW, Wynia MK, Papadakis MA, Sullivan WM. In reply to Barnhoorn and Youngson and to Jones and Thaxton. *Acad Med*. 2014 Dec;89(12):1579-80. doi: 10.1097/ACM.0000000000000538
164. Wynia MK, Silvers WS, Lazarus JA. How do US and Canadian medical schools teach about the role of physicians in the Holocaust? *Acad Med*. 2015 Jun;90(6):699-700.
165. Wynia MK. Thwarting shared decision making is an egregious medical error: let's treat it like one. *Am J Bioeth*. 2017; 17(11):54-6.

166. Wynia MK. Why it is important to promote clinical independence among health professionals working in prisons, jails, and other detention settings. *Am J Public Health.* 2018; 108(4):440-1.
167. Kwan BM, Millward SR, Himber M, Ressalam J, Wald H, Wynia M, Coors ME. Inspired translation: synthesizing qualitative research and Boot Camp Translation to achieve meaningful community engagement. *Am J Bioeth.* 2018; 18(4):29-31.
168. Humbyrd CJ, Wynia M. Profit motives require a proscriptive approach. *Am J Bioeth.* 2019; 19(6):30-1.

TEACHING AND SELECTED LECTURES AND PRESENTATIONS

TEACHING

University of Chicago Hospital
General medical inpatient attending
0.5-1 month/year, 1997-2015.
Frequent guest lecturer for HIV, Health Disparities, and Patient and Doctor courses on topics including ethics and new payment models, race and trust, ethics in HIV care, and the history of African Americans in organized medicine.

Infectious Diseases Clinic attending
University of Chicago
½ day/week, 1997-2015

University of Colorado Hospital
General medical inpatient attending
2 blocks (1 month)/year, 2015-current

Interprofessional Education and Development Program
Member of the IPE Council, 2014-current
IPE faculty member

COURSE DIRECTOR

The History and Meaning of Ethics and Professionalism in Medicine
Medical College of Wisconsin, Graduate Program in Bioethics
3 credit course, offered once yearly, 2000-2010.

HSMP 6617: Interpreting Health Policy and Management Research
Colorado School of Public Health (co-led with Dr. Eric Campbell)
2 credit required course, offered annual, 2019-

FELLOWSHIP DIRECTOR

AMA-MCW Online Fellowship in Medical Ethics and Professionalism, 2000-2010

FELLOWSHIP DIRECTOR

Institute for Ethics Fellowship at the American Medical Association, 1999-2007

SELECTED LECTURES AND PRESENTATIONS

1. *A prospective trial to improve residents' teaching behaviors.* SGIM Annual Meeting. San Diego, CA. April 1995. (CME)

2. *Practical issues in establishing a teaching improvement program for residents.* Workshop presentation, SGIM Annual Meeting. Washington, DC. May 1996. (CME)
3. *Ethical issues in medical practice systems.* American Medical Association National Leadership Conference. Philadelphia, PA. March 1997.
4. *Assessing lifelong strategies for prophylaxis of Pneumocystis carinii pneumonia in patients with AIDS: a decision analysis.* American Federation for Medical Research Annual Meeting (Biomedicine '97). Washington, DC. April 1997. (CME)
5. *Financial and patient advocacy issues in the patient/physician relationship in managed care: principles and practice.* SGIM Annual Meeting. Washington, DC. May 1997. (CME)
6. *Resources, Rationing and Responsibility: Ethical issues in managed care.* Keynote address: Heartland Bioethics Center. Des Moines, IA. October 1997
7. *Patient Advocacy in the Modern Era: When the Quality of Mercy is Strained.* American College of Medical Quality Annual Meeting. Orlando, FL. November 1997. (CME)
8. *Calling All Parties to Account: An Introduction to the Ethical FORCE Program.* American Public Health Association Annual Meeting. Indianapolis, IN. November 1997.
9. *Ethics and Managed Care.* AMA-MSS Section VII Conference. New York, NY. November 1997.
10. *Accountability and Organizational Ethics: Should organizations of physicians be held to the same ethical standards as individual physicians?* Suffolk District Medical Society. Boston, MA. December 1997.
11. *Ethical Issues in Managed Care.* Broadlawns Medical Center Annual Medical Staff Meeting. Des Moines, IA. January 1998. (CME)
12. *Economic Analyses: When they work, when you should worry.* Cardiovascular Health in the 21st Century Conference. San Francisco, CA. February 1998. (CME)
13. *Ethical Issues in Managed Care: The physician's perspective.* 21st Century Founders Club at the Park Ridge Center. Chicago, IL. February 1998.
14. *Ethical Issues in Managed Care: Patient Advocacy in the Modern Era.* The Healthcare Assembly. Boston, MA. March 1998.
15. *Managed Care in Missouri: Physicians Grade Their Hospitals.* Missouri State Medical Association Annual Meeting. St. Louis, MO. April 1998. (CME)
16. *Ethics and Organizations: Advocating Professional Integrity for the AMA.* Tenth Annual Bioethics Summer Retreat. Brewster, MA. June 1998.
17. *Ethical and Legal Conflicts in Managed Care: What is the Medical Society's Role?* Annual Meeting of the American Association of Medical Society Executives. San Diego, CA. August 1998.
18. *Accountability for Ethics Standards in Managed Care: What is the Professional Association's Role?* Harvard/NIH National Conference on Ethics and Managed Care. Washington DC, October 1998.
19. *Ethical Issues in the Managed Care Environment.* Northwest Mental Health Associates, Annual Meeting. Salishan Lodge, OR. November 1998.
20. *Determining Benefits in Managed Care: Developing Legitimacy in Resource Allocation.* American Public Health Association, Annual Meeting. Washington, DC. November 1998.
21. *Professionalism in Medicine: The Role of Medical Societies.* Dean's Hour, University of North Dakota School of Medicine and Health Sciences. Grand Forks, ND. November 1998. (CME)
22. *Benefits Determinations: Issues in Legitimate Resource Allocation.* International Society for the Advancement of Humanism in Medicine. Crested Butte, CO. February 1999.
23. *Accountability: Professional Ethics in the Evolving Health Care Delivery System.* International Society for the Advancement of Humanism in Medicine. Crested Butte, CO. February 1999.
24. *Professionalism in the Health Care Delivery System: Report of a Survey of Public Relations Practitioners.* Health Academy of the Public relations Society of America, Annual Meeting. Washington DC. April 1999.
25. *Accountability for Ethics Quality.* United Nurses of America-AFSCME Annual Meeting. Washington DC. May 1999.

26. *Physician Income at Risk for the Costs of Patient Care: Results of a National Physician Survey.* Society of General Internal Medicine, Annual Meeting. San Francisco, CA. May 1999. (CME)
27. *Physician Responses to Utilization Review Pressures: Results of a National Physician Survey.* Association for Health Services Research Annual Meeting. Chicago IL. June 1999. (CME)
28. *The Role of Professionals in Society: A Model of Physician Professionalism.* Association for Politics in the Life Sciences Annual Meeting. Atlanta GA. September 1999.
29. *Ethics Quality: Toward a New Set of Performance Measures.* Association for Politics in the Life Sciences Annual Meeting. Atlanta GA. September 1999.
30. *Organizational Ethics. The AMA Experience.* VA Bioethics National Conference. Minneapolis MN. September 1999. (CME)
31. *Ethical Implications of Managed Care.* Iowa Managed Care Association: Annual Policy Conference. Des Moines IA. October 1999.
32. *Corporatization and Public Health: Is Anything Sacred?* American Public Health Association Annual Meeting. Chicago IL. November 1999.
33. *Listening to Employee Benefits Decision-Makers Discuss Health Plan Quality: Focus Groups with Potential Users of Performance Measures.* SGIM Annual Meeting. Boston MA. May 2000 (CME)
34. *Do Physician Decide Not to Offer Their Patients Useful Services That Are Not Covered by Health Plans?* A National Survey. SGIM Annual Meeting. Boston MA. May 2000. (CME)
35. *Errors in Medicine – Practical and Ethical Issues.* 2000 Bioethics Retreat, Asilomar CA. June 2000.
36. *Can You Keep a Secret? Privacy and HSR. AHSR Annual Meeting.* Los Angeles CA. June 2000.
37. *Ethical Standards in the Delivery of Healthcare Services: A Comparative Analysis of Ethics Policies and Codes of Professional/Medical Ethics.* AHSR Annual Meeting. Los Angeles CA. June 2000.
38. *Physician Professionalism: Ethics for the 21st Century.* American Health Quality Association Annual Meeting, Keynote Address. New Orleans, LA. September 2000. (CME)
39. *Professionalism and the Role of Professionals in Society.* Colorado Medical Society Annual Meeting, Keynote Address. Aspen, CO. September 2000. (CME)
40. *Standing Straight and Tall against the Wind: Medical Ethics and Professionalism in Today's Practice Environment.* Medical Assurance Company of Mississippi Annual Meeting. Jackson, MS. October 2000. (CME)
41. *Patient Protection and Risk Selection: Do Primary Care Physicians Encourage Patients to Join or Avoid Capitated Health Plans According to the Patients' Health Status?* American Society for Bioethics and Humanities Annual Meeting. Salt Lake City, UT. October 2000.
42. *Advocacy and Community: An Historical Perspective on the Social Roles of Physicians.* American Society for Bioethics and Humanities Annual Meeting. Salt Lake City, UT. October 2000.
43. *Tissue Banking and Relations with Commercial Organizations: Conceptualizing the Ethical Considerations.* Harvard Brain Tissue Resource Center External Scientific Advisory Board Meeting. New Orleans, LA. November 2000.
44. *Protecting Privacy and Confidentiality in Health Care.* American Public Health Association Annual Meeting, Boston, MA. November 2000.
45. *Commercialization and Public Health: Is Anything Sacred?* American Public Health Association Annual Meeting, Boston, MA. November 2000.
46. *Professionalism in Medicine.* Alabama Quality Assurance Foundation 17th Annual Robert G. Sherrill Conference. Birmingham, AL. February 2001. (CME)
47. *Beyond Pandora's Box: Privacy and the Human Genome.* United Healthcare *In Focus* Presentation. New York, NY. March 2001.
48. *Professionalism and Professional Obligations.* Medical College of Wisconsin. The Chan Bioethics Lecture. May 2001.
49. *Professionalism in Health Care.* South Dakota State Medical Association Annual Meeting. Sioux Falls, SD. June 2001. (CME)

50. *Professionalism in Law and Medicine.* American Society of Medical Association Counsels Annual Meeting. Orcas Island, WA. September 2001.
51. *Privacy and Health Care: What Ethical Standards Apply?* American Public Health Association Annual Meeting. Atlanta, GA. October 2001.
52. *Sleep deprivation, ethics and work hours rules: 6 problems, no easy solutions.* Sleep, Fatigue and Medical Training Conference. American Academy of Sleep Medicine. Alexandria, VA. October 2001. (CME)
53. *When the Quantity of Mercy is Strained: Physician Deception of Insurers for Patients.* Malingering and Illness Deception Conference of Cardiff University. Oxford, England. November 2001.
54. *Accountability for Ethics Quality: Privacy and Confidentiality.* American Law Firm Association. Chicago, IL. June 2002.
55. *Race, Trust and Tuskegee: The Effects of Broken Trust on Health Disparities.* Address to the Minority Affairs Consortium of the AMA and the AMA Medical Student Section. Chicago, IL. June 2002.
56. *Shame, Fear and Malpractice: Barriers to Quality Improvement.* American Society of Medical Association Counsels. Chicago IL. June 2002.
57. *Conscientious Practice: Physicians' Historical Obligation to Treat Patients in Epidemics.* Bioethics Retreat, 2002. Lake Placid, NY, June 2002.
58. *Building the Business Case for Patient Safety: The View from Ethics.* JCAHO and ARHR Symposium for CEOs. Arlington, VA. September 2002.
59. *The Future of Palliative and End of Life Care Initiatives.* Michigan State Medical Society Annual Ethics Meeting: Caring Beyond Cure. Traverse City, MI. October 2002. (CME)
60. *Understanding the History and Writing of Codes of Ethics.* American Society for Bioethics and Humanities Annual Meeting. Baltimore, MD. October 2002.
61. *Should Public Health Practitioners Swear an Oath?* American Public Health Association Annual Meeting. Philadelphia, PA. November 2002.
62. *Medical Privacy in the Information Age.* Invited Testimony to the National Academy of Sciences, Computer Science and Telecommunications Board Committee on Privacy in the Information Age. Washington, DC. November 2002.
63. *Professional Ethics and Preparing for Bioterror.* Johns Hopkins University Greenwall Fellows Seminar and Bioethics Interest Group presentations. December 2002.
64. *Race, Trust and Tuskegee: Professional Ethics, Broken Trust and Health Disparities.* Oregon Health Sciences University Invited Ethics Lecture. Portland, OR. March 2003. (CME)
65. *Race, Trust and Tuskegee: Professional Ethics, Broken Trust and Health Disparities.* Wayne State University Surgical and Medical Grand Rounds presentations. Detroit, MI. April 2003. (CME)
66. *Improving Fairness in Coverage Decisions: A Role of Performance Measurement?* Wayne State University Family Practice Group Invited Lecture. Detroit, MI. April 2003.
67. *Truth and Lies: Are the Rules Different for Lawyers?* Panel Discussion. American Bar Association 29th Annual National Conference on Professional Responsibility. Chicago, IL. May 2003.
68. *Promoting Ethical Expectations in Health Care.* Nephrology Carrier Advisory Panel. New York, NY. June 2003. (CME)
69. *Physician Obligations in Epidemics: The Case of SARS.* Bioethics Retreat 2003. Bellaire, MI. June 2003.
70. *Race, Trust, and Tuskegee: Professional Ethics, Broken Trust, and Health Disparities.* National Institutes of Health Director's Council of Public Representatives. Bethesda, MD. October 2003.
71. *The Physician's Obligation to Participate in Quality Improvement Activities.* The Ethics of Improving Health Care Quality and Safety: Meeting II. The Hastings Center. Garrison, NY. November 2003.
72. *Shame, Fear and Malpractice: Disclosing Medical Errors to Patients.* Northeast Iowa Ethics Conference. Iowa Medical Society. Waterloo, IA. December 2003. (CME)

73. *Professionalism and Preparedness for Bioterrorism: Challenges and Opportunities.* Ethics and Epidemics: An International Conference on the Ethical Dimensions of Epidemic Control. Union College, Schenectady, NY. March 2004. (CME)
74. *"If One More Doctor Tells Me I'm Crazy... I'll Go Postal!" Psychogenic Parasitosis and Paternalism in Clinical Practice.* Grand Rounds, University of Chicago. Chicago, IL.. March 2004. (CME)
75. *Professionalism and Preparing for Epidemics: Challenges and Opportunities.* Ethics and Infectious Disease. The 14th Annual Intermountain Medical Ethics Conference. Salt Lake City, UT. May 2004. (CME)
76. *The Hours.* American Bar Association 30th National Conference on Professional Responsibility. Naples, FLA. June 2004.
77. *Race, Trust, and Tuskegee...* American Medical Association Medical Student Section. Chicago, IL. June 2004.
78. *Physician Ethics and the Quality Improvement Movement.* Grand Rounds, Washoe Medical Center. Reno, NV. June 2004. (CME)
79. *Professionalism and the Role of Health Professionals in Society.* Special Interest Ethics CME Program. Saint Mary's Regional Medical Center. Reno, NV. June 2004. (CME)
80. *Promoting Trustworthiness through Performance Measurement: The Ethical Force Program.* Strengthening the Informed Consent Process to Address Racial and Ethnic Health Disparities. US Dept of Health and Human Services, Office of Minority Health conference. Tuskegee University, AL. June 2004.
81. *Race, Trust, and Tuskegee: Professional Ethics, Broken Trust, and Health Disparities.* Disparities in Health in America: Working Toward Social Justice. 2nd Annual Summer Workshop. Keynote Grand Rounds Speaker. MD Anderson Cancer Center, Houston, TX. July 2004. (CME)
82. *Ethics and Epidemics: Challenges and Opportunities.* Department of Pediatrics Grand Rounds. Cook County Hospital. Chicago IL. September 2004. (CME)
83. *National Perspectives on Addressing Racial and Ethnic Health Disparities.* Connecticut Health Foundation Conference. New Haven, CT. October 2004.
84. *Organized Medicine and Caregivers in Partnership to Eliminate Health Disparities.* American Psychiatric Association Institute on Psychiatric Services. Atlanta GA. October 2004. (CME)
85. *The AMA Ethical Force Program Consensus Report on Fair Coverage Decisions: Implications for Managed Care Pharmacy.* Academy of Managed Care Pharmacy 2004 Educational Conference. Baltimore MD. October 2004.
86. *Health Care Ethics and the Quality Improvement Movement.* Oregon Psychological Association Workshop. Portland OR. November 2004. (CEU).
87. *Nazis and Medical Ethics: Context and Lessons.* University of Chicago Hospital. Chicago IL. January 2005. (CME)
88. *Nazis and Medical Ethics: Context and Lessons.* Loyola University, Stritch School of Medicine. Chicago IL. January 2005. (CME)
89. *Nazis and Medical Ethics: Context and Lessons.* Northwestern University School of Medicine. Chicago IL. January 2005. (CME)
90. *The Challenges of Professional Self-Regulation.* The Ethics of Bioethics. Union College, ASBH Spring Meeting. Schenectady NY. April 2005. (CME)
91. *Ethical Challenges in Preparing for Bioterrorism: The Role of the Health Care System.* Cleveland Clinic Foundation, Departments of Infectious Diseases and Bioethics. Cleveland OH. April 2005. (CME)
92. *Health Care Ethics and the Quality Improvement Movement.* Cleveland State University (The Cole Center). Cleveland OH. April 2005. (CME)
93. *Workshop: Education to Eliminate Health Disparities.* Society for General Internal Medicine Annual Meeting. New Orleans LA. May 2005. *(CME)*

94. *Tsunami Aid: Lessons Learned from America's First Military-Civilian Disaster Response Mission.* Milwaukee Academy of Medicine. Milwaukee WI. May 2005.
95. *Telling the Truth to Patients: Disclosure of Medical Errors.* American Bar Association Annual Conference on Professionalism. Chicago IL. June 2005.
96. *Health Care Ethics and the Quality Improvement Movement.* Catholic Health Services Annual Ethics Conference. Cincinnati OH. October 2005. (CME)
97. *Tsunami Aid: Lessons Learned from America's First Military-Civilian Disaster Response Mission.* Leadership Call. AMEDD (US Army Medical Department Center and School). San Antonio, TX. October 2005. (CME)
98. *Ethics and Epidemics: Challenges and Opportunities.* Brooke Army Medical Center Grand Rounds. San Antonio, TX. October 2005. (CME)
99. *Whom do we serve?* Presidential Address to the American Society for Bioethics and Humanities. Washington DC. October 2005.
100. *The History and Ethics of Quality Improvement in Health Care.* The Boyden Lecture. St. Vincent's Hospital/providence Health System. Portland OR. November 2005. (CME)
101. *Race, Trust, and Research: Study does not 'debunk' that minorities are less likely to participate in research due to mistrust.* Office of Minority Health Leadership Summit on Racial and Ethnic Health Disparities. Washington DC. January 2006.
102. *Improving Communication with Vulnerable Populations: Promising Practices from 8 Site Visits.* (Session on Improving Language Access and Cultural Competence: Where do we go from here?) Families USA Health Action Conference. Washington DC. January 2006.
103. *Tsunami Aid: Altruism and Self-Interest, Lessons from America's First Combined Civilian-Military Medical Mission.* The Stambaugh Lecture. University of Louisville. Louisville, KY. March 2006. (CME)
104. *Ethics and Communicating with Vulnerable Populations.* The 16th Annual Kinsman Conference Keynote Address. Bend, OR. April 2006. (CME)
105. *Privacy and Confidentiality in Health Care: Where do we go from here?* Spring Medical-Surgical Behavioral Science Conference, US Army European Regional Medical Command. Willingen, Germany. April 2006. (CME)
106. *Shame, Fear and Medical Errors: Why does "sorry" seem to be the hardest word?* Spring Medical-Surgical Behavioral Science Conference, US Army European Regional Medical Command. Willingen, Germany. April 2006. (CME)
107. *Ethics and Epidemics: The duty to treat.* American Society of Medical Association Counsels Annual Meeting. Chicago, IL. June 2006.
108. *Concierge Medicine.* Bioethics Summer Retreat. Lake Tahoe, CA. June 2006.
109. *Opening the Door to Improved Patient-Centered Communication: Consensus and Controversies.* Joint Commission on Accreditation of Health Care Organizations Conference on Health Literacy. Chicago, IL. June 2006.
110. *Obligations at the Bedside and Beyond.* Humanism 2006: Setting the Professional Compass. Gold Humanism Honor Society Second Biennial Conference. Chicago, IL. September 2006.
111. *Ethical Issues in Making Coverage Decisions.* Keynote Session. 52nd Annual Employee Benefits Conference. International Foundation of Employee Benefit Plans. Las Vegas, NV. October, 2006.
112. *Ensuring Fairness in Coverage Decisions.* Case Western Reserve University School of Medicine, Ethics Grand Rounds. Cleveland, OH. November, 2006.
113. *Successful Consumer-Clinician Health IT Interactions.* Connecting Americans to Health Care conference. Washington DC. December 2006.
114. *Pride, Prestige and Power: The challenges of enforcing a code of ethics.* Intelligence and Ethics 2007. Springfield, VA. January 2007.
115. *Ethics and Health Plan Benefit Design.* Michigan Educational Association (MESSA) annual conference. Bay City, MI. March 2007.

116. *Ethics and Patient-Centered Communication with Diverse Populations.* Cedars-Sinai Medical Center, Ethics Grand Rounds. Los Angeles, CA. March 2007. (CME)
117. *The Nazis and Medical Ethics: Context and lessons.* 18th Israeli Medical Association World Fellowship Conference. Jerusalem, Israel. April 2007.
118. *The Nazis and Medical Ethics: Context and lessons.* Technion Institute School of Medicine, Holocaust Martyr's and Hero's Remembrance Day. Haifa, Israel. April 2007.
119. *Ethics and P4P: What is known about the effects of P4P on physician ethics and the patient-physician relationship?* Internal Medicine 2007 (ACP Annual Meeting). San Diego, CA. April 2007.
120. *Military Medical Ethics: Where do we go from here?* NEAGO Annual Conference. Kennebunkport, ME. June 2007
121. *Patient Centered Communication with Vulnerable Populations: Promising Practices for Addressing Low Health Literacy.* American Society of Health System Pharmacists Annual Meeting. San Francisco, CA. June 2007.
122. *Better Regulation of Industry-Sponsored Research: Long Overdue.* Pitts Memorial Lectures. Charleston, SC. September 2007.
123. *The End of HIV Exceptionalism? Ethical issues and barriers to routine screening for HIV.* Infectious Disease Society of American Annual Meeting (Poster presentation). San Diego CA. October 2007.
124. *Ethics and Access to Care: An Ethical Framework to Guide Health System Reform.* Keynote Presentation. 3rd Annual Community Conference on Health Care Ethics. Denver CO. October 2007.
125. *The AMA-United States Holocaust Memorial Museum (USHMM) Educational Collaborative.* American Society for Bioethics and Humanities Annual Meeting. Washington DC. October 2007.
126. *African American Physicians and the American Medical Association. American Society for Bioethics and Humanities Annual Meeting,* (History Affinity Group). Washington DC. October 2007.
127. *Ethics and Communication with Vulnerable Populations.* Ethics Rounds. Texas Tech Medical Center. Lubbock TX. November 2007.
128. *Pay for Performance: What is known of the effects of P4P on the patient-physician relationship and physician professionalism?* Fall medical/surgical symposium. Lubbock-Crosby-Garza County Medical Society. Lubbock TX. November 2007.
129. *Mandating Vaccines:* What counts as a "mandate" in public health, and when should they be used? Pediatric Grand Rounds. Cook County Hospital. Chicago IL. December 4, 2007
130. *Professional Ethics, Broken Trust and Health Disparities.* University of Chicago Research Grand Rounds. Chicago IL. December 2007.
131. *Ethics and Epidemics.* Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research. St Louis, MO. December 2007.
132. *Ethics and Access to Care.* National Congress on the Un and Under Insured. Washington DC. December 2007.
133. *Ethics and Pay for Performance.* The Nigel Roberts Lecture. American College of Medical Quality. Austin, TX. February 2008.
134. *Regulating Industry-Supported Research: What do we know?* UIMCC Clinical Ethics Conference. Chicago, IL. March 2008.
135. *Ethics and Quality Improvement: Measuring the ethical climate in health care organizations.* Association of Health Care Consultants. Chicago, IL. March 2008.
136. *Ethics and Pay-for-Performance.* Bander Center on Medical Business Ethics, Inaugural Lecture. St. Louis, MO. April 2008.
137. *Abusive interrogation of detainees in the war on terror: Whether it "works" isn't really the issue.* American Philosophical Association Midwest regional meeting. Chicago, IL. April 2008.
138. *Ethics and Communication with Vulnerable Populations.* Marshall University, Joan C. Edwards Medical School Grand Rounds. Huntington, WV. May 2008.

139. *African American Physicians and Organized Medicine.* University of Chicago, Bowman Society Lecture. Chicago, IL. August 2008.
140. *Organizational commitment: strategies to build leadership support for assessing and improving communication quality.* Diversity Rx. Minneapolis, MN. September 2008.
141. *Incentives for Performance Improvement and their Effects on Professionalism.* NIQIE Conference. Washington DC. October 2008.
142. *Routine screening for HIV and the waning of HIV exceptionalism.* American Society for Bioethics and Humanities Annual Meeting. Cleveland OH. October 2008.
143. *Improving Health Literacy among Latinos: Language Precedes Patient-Centered Communication. (Poster)* American Public Health Association Annual Meeting. San Diego CA. October 2008.
144. *Pay for Performance and physician professionalism* and *Industry support of medical research.* Mulach Lecture Series. St. Clair Hospital. Pittsburgh PA. February 2009.
145. *Measuring patient-centered communication in health care organizations.* Vanderbilt University visiting professor in health care communication. Nashville TN. February 2009.
146. *Understanding our legacy: African American physicians and organized medicine.* Florida State University Ethics Grand Rounds. Tallahassee FL. March 2009.
147. *Pay for performance and physician professionalism.* Provena Health Ethics Day, Keynote. Tinley Park IL. March 2009.
148. *Restrictions and rationing: Ethical challenges for medical professionals after the duty to treat is accepted.* Bethesda National Naval Medical Center Ethics Conference. Bethesda MD. March 2009.
149. *Practical and ethical issues in using personal health records: Results of a national physician survey.* HiMSS PHR committee WebEx presentation. April 2009.
150. *National health care reform: a moral and economic imperative.* Oregon Health and Sciences University Madeline Brill Nelson Speaker. Portland OR. May 2009.
151. *Physicians' views on using PHRs.* Testimony to NCVHS Subcommittee on Privacy, Confidentiality and Security. Washington DC. May 2009.
152. *Personalized medicine and PHRs.* Harvard University and the Nuffield Bioethics Council invitational conference. Boston MA. May 2009.
153. *Pay for performance and physician professionalism.* Loyola University School of Medicine Grand Rounds. Chicago IL. August 2009.
154. *Ethical and legal issues in disaster response.* University of Washington, IDSA and AMA meeting on pandemic planning. Seattle WA. September 2009.
155. *Taking steps to ensure universal access.* Annual Missouri Ethics Conference. Columbia MO. October 2009.
156. *From norms to numbers: Using survey research in bioethics.* American Society for Bioethics and Humanities Annual Meeting Precourse. Washington DC. October 2009.
157. *Improving ethics quality in health care.* American Society for Bioethics and Humanities Annual Meeting. Washington DC. October 2009.
158. *The role of organizational factors in addressing health literacy.* Institute of Medicine 1st Annual Health Literacy Research Conference. Washington DC. October 2009.
159. *Teaching ethics and professionalism in the basic science years.* St. George's University School of Medicine Visiting Professor. Grenada. October 2009.
160. *Physician professionalism and pay-for-performance.* Northwestern University Institute for Healthcare Studies Seminar. Chicago IL. December 2009.
161. *Health System Reform.* Loyola University Stritch School of Medicine. Chicago IL. January 2010.
162. *Health System Reform.* Chicago Rosalind Franklin Medical School. Chicago IL. January 2010.
163. *Physician and Patient Views on Using PHRs: National Survey Results.* HIMSS Annual Conference. Atlanta GA. March 2010.

164. *Physician accountability based on clinical performance measurement is risky and could harm professionalism. Assigned position taken for a debate for the ACP Board of Regents.* Toronto ON. April 2010.
165. *Dilemmas in the science and technology landscape of the future.* Plenary at the Institute for the Future Annual Health Horizons Conference. San Francisco, CA. June 2010.
166. *Ethical Challenges in Health System Reform.* Plenary at the Annual Bioethics Retreat Conference. Key West, FL. June 2010.
167. *The Nazis and Medical Ethics: Context and Lessons.* Illinois Holocaust Museum and Education Center. August 2010.
168. *"Cito, Longe, Tarde!" Are physicians reliable first-line responders.* Centers for Disease Control Ethics Conference. Atlanta GA. September 2010.
169. *Professionalism and vaccination mandates: When should professional obligation trump individual liberty?* DeVos Medical Ethics Colloquy. Grand Rapids, MI. September 2010.
170. *Epidemics, Communities, and Research Ethics in Historical Perspective.* Panel Discussion Chair, with Susan Lederer, PhD, Bob Baker, PhD and Sean Philpott, PhD. ASBH Annual Meeting. San Diego CA. October 2010
171. *Professionalism and Public Trust: The Importance of Addressing COI in Medicine.* Korean Society for Medical Ethics. Seoul South Korea. October 2010.
172. *Dancing with a Porcupine: Physician Interactions with the Pharmaceutical Industry.* Korean Society for Medical Ethics. Seoul South Korea. October 2010.
173. *Ethics and Public Health Emergencies.* Joint CME Conference of IDSA/AMA/UW. Portland OR. November 2010
174. *The Nazis and Medical Ethics: Context and Lessons.* Presented at: John Marshall Law School; Chicago Medical School; Alexian Brothers Medical Center; Illinois Holocaust Museum and Education Center. November 2010.
175. *Physicians Views on Personal Health Records.* Roundtable discussion hosted by the Federal Trace Commission and the Office of the National Coordinator of Health Information Technology. Washington DC. December 2010.
176. *Health Reform and Health Disparities.* Loyola University School of Medicine. Invited lecture to the first year class. Maywood, IL. January 2011.
177. *Podcast interview on using medicine for enhancement.* The Bioethics Channel. Available at: http://itunes.apple.com/us/podcast/the-bioethics-channel/id301896826. January 2011.
178. *African American Physicians and the AMA.* Invited lecture to Northwestern University School of Medicine. Chicago IL. January 2011.
179. *Medicine and the Holocaust.* Boston Public Library. February 2010.
180. *African American Physicians and the AMA.* Regional Student National Medical Association Meeting. Chicago IL. February 2011.
181. *Ethics in HIV Care.* Lecture for course at University of Chicago Pritzker School of Medicine. Chicago IL. March 2011.
182. *From Research to Action: Practical Tools for Addressing Racial and Ethnic Disparities in Health Care.* Society for General Internal Medicine Workshop session. Phoenix AZ. May 2011.
183. *How do Physicians Think about Stewardship in Health Care? A Qualitative National Study.* Society for General Internal Medicine Annual Meeting. Oral abstract. Phoenix AZ. May 2011.
184. *Deadly Medicine: Medicine and the Holocaust.* Northwestern University School of Medicine, Department of Internal Medicine Grand Rounds. Chicago IL. May 2011. (CME)
185. *Deadly Medicine: Medicine and the Holocaust.* Newton-Wellesley Hospital, Department of Surgery Grand Rounds. Boston MA. April 2011. (CME)
186. *Deadly Medicine: Medicine and the Holocaust.* Massachusetts General Hospital, Department of Obstetrics and Gynecology Grand Rounds. Boston MA. May 2011. (CME)

187. *Deadly Medicine: Medicine and the Holocaust.* Boston Medical Library/Countway Library Special Lecture. Boston MA. May 2011.
188. *Deadly Medicine: Medicine and the Holocaust.* Northwestern University Department of Medicine Grand Rounds. Chicago IL. May 2011.
189. *African Americans in the Medical Profession: Confronting a Painful Legacy.* Duke University Conference on Social Determinants of Health Disparities. Durham NC. August 2011.
190. *Health Disparities and Mistrust in Health Care.* Lecture to University of Chicago MSI class. Chicago IL. August 2011.
191. *Quality Improvement:An Ethical Foundation of Practice?* Kaiser Conference on Ethics and Quality Improvement. Orange CA. September 2011.
192. *Physicians and the Care of LGBT Patients: Results of a national survey.* GLMA Annual Meeting. Oral presentation. Atlanta GA. September 2011.
193. *Knowledge, Wisdom and Purpose: The Meaning and Teaching of Professionalism in Medicine.* Western Michigan University Medical Humanities Conference. Keynote address. September 2011.
194. *Making it Easier to Do the Right Thing: Professionalism, Communication and Organizations.* International Conference on Communication in Health Care. Keynote address. October 2011.
195. *Restrictions, Rationing and Responsibilities: The 3 R's of ethics in disaster response.* Meeting to develop a code for emergency health ethics for the state of Arizona. Arizona State University. Tempe AZ. November 2011.
196. *Ethical Issues in Health System Reform.* Rehabilitation Institute of Chicago Grand Rounds. Chicago IL. December 2011.
197. *The Three R's of Ethics and Disaster Response.* Visiting Professorship, Health Law Institute, University of Alberta School of Law, Edmunton Alberta. January 2012.
198. *American Values: Health System Reform and the Ethics of American Medicine.* Public Lecture, Visting Professor, University of California, Davis. February 2012.
199. *Medicine and the Holocaust.* AMSA Annual Conference. Atlanta GA. March 2012.
200. *Deadly Medicine: Creating the Master Race.* The Richmon Lecture. Mt. Sinai School of Medicine. March 2012.
201. *Ambulatory Patient Safety.* AHRQ Annual Meeting of PSOs. Bethesda MD. April 2012.
202. *Medicine and the Holocaust.* Internal Medicine Grand Rounds, Tufts University School of Medicine. Boston MA. April 2012.
203. *Medicine and the Holocaust.* Bicknell Lecture, American Urological Society Annual Meeting. Atlanta GA. May 2012.
204. *Medicine and the Holocaust.* Museum of Jewish Heritage, New York NY. July 2012.
205. *Improving Ambulatory Patient Care: Lessons from the last (lost) decade..* 11th National Quality Colloquium, Cambridge MA. August 2012.
206. *Making the case for integration of practice redesign and education reform.* Institute of Medicine. Global Forum on Innovation in Health Professional Education. Washington DC. August 2012.
207. *Professionalism and Quality Improvement: Promises and Pitfalls.* ABMS Board Congress. Chicago IL. September 2012.
208. *Professionalism in an evolving American Medical Association.* ABIM Foundation/Mayo Clinic Roundtable on Advancing Professionalism in Practice. Philadelphia PA. September 2012.
209. *The meaning and teaching of professionalism in medicine.* Educating Tomorrow's Lawyers conference. Denver CO. September 2012.
210. *The short history and tenuous future of medical professionalism.* ACGME Baldwin Lecture Series. Chicago IL. September 2012.
211. *Doctors of the Dark Side:* Screening and Panel Discussion. Northwestern University Feinberg School of Medicine. Chicago IL. November 2012.
212. *Assessing health disparities and cultural competence.* 2012 Summit on the Science of Eliminating Health Disparities. National Harbor MD. December 2012.

213. *Professionalism and the roles of professionals in society.* Museum of Jewish Heritage. New York NY. January 2013.
214. *Gifts, Trips, Rebates and Sunshine: US Physicians' Relations with Pharmaceutical Companies.* Korean Society for Medical Ethics Annual Meeting, Opening Plenary. Seoul South Korea. September 2013.
215. *Let's Do It Together! Collaborative Leadership, Shared Professionalism, and Improving Outcomes through High-Functioning Health Care Teams.* American College of Clinical Pharmacists Annual Conference, Opening Plenary. Albuquerque NM. October 2013.

Visiting Expert for the Ministry of Health and the Academy of Medicine of Singapore. November 2013, Lecture series included the following:

216. *Knowledge, wisdom, and service: The meaning and teaching of professionalism in medicine*
217. *Why MOC?*
218. *Teaching ethics and professional values in medical school and residency: The top 10 methods*
219. *What if our medical associations keep shrinking until they are gone?*
220. *How to assess professionalism*
221. *The short history and tenuous future of medical professionalism.*
222. *Organization ethics in health care: What can we learn from QI and safety science?*
223. *How to pay doctors: Ethical challenges and practical considerations in the US.*

224. *Medicine and the Holocaust.* Nott Memorial Hall, Union College, Albany NY. February 27, 2014.
225. *A Sneak Peek at the AMA Improving Health Outcomes Initiative: A M.A.P. to Achieving Optimal Blood Pressure Control.* Illinois State Medical Society Conference. Keeping Pace: Strategies for Medical Practice 2014 and Beyond. Hamburger University, Oakbrook IL. February 28, 2014.
226. *Leadership in a changing health care system.*(Keynote) Oregon Academy of Family Physicians. Portland Oregon. April 25, 2014.
227. *Professional Responsibility or Personal Autonomy: Mandatory Vaccination of Health Professionals.* (Keynote) Symposium: Influenza immunization in the health care workplace. University of Calgary, Calgary Canada. June 11, 2014.
228. *Engaging patients in quality improvement.* World Congress Patient Engagement Summit. Boston MA. August 9, 2014.
229. *Ethical implications of allocating scarce and untested medication.* IOM Forum on Medical and Public Health Preparedness for Catastrophic Events. Washington DC. October 30, 2014.
230. *Healthcare Quality, Ethics and the Community: The Links to Professionalism and Leadership.* AAMC Annual Meeting. November 7, 2014.
231. *Ethics and Ebola Control.* SUNY Downstate Medical Center Grand Rounds. Brooklyn, NY. December 5, 2014.
232. *White Coat Ceremony Keynote Lecture.* St. George's Medical School. Grenada. January 30, 2015.
233. *Ethics and decision making at the end of life.* OLLI Lecture. Denver CO. February 11, 2105.
234. *Transdisciplinary professionalism.* Arizona State University, Tempe AZ. March 21, 2015.
235. *Improving Health Outcomes: Opportunities for Collaboration.* AMA Accelerating Change in Medical Education (ACE) consortium meeting. Portland OR. April 13, 2015.
236. *African Americans and American Medicine: confronting a painful legacy.* University of Chicago School of Medicine lecture to first year students. Chicago IL. September 8, 2015.
237. *Jeckyll and Hyde: the musical.* A conversation with the audience about medical ethics and the story of Jeckyll and Hyde. The Aurora Fox Arts Theater. Aurora CO. September 27, 2015.
238. *Hard Call: The Electronic Heart.* Fulginiti Pavilion, Aurora CO. October 15, 2105.

239. *Fear knot: the implications of using scare tactics in clinical care.* International Conference on Communication in Health Care. New Orleans, LA. October 27, 2015.
240. *Ethical Guidance on Quality of Care During Global Health Disasters* | Global Health and Disasters Course. University of Colorado Center for Global Health. Aurora CO. November 9, 2015.
241. *Evaluation challenges for the Enhanced CLAS Standards.* American Evaluation Association annual meeting. Chicago IL. November 14, 2015.
242. *The history and meaning of ethics and professionalism in health care.* Loyola University Stritch School of Medicine. Lecture to first year class. Chicago IL. November 167, 2015.
243. *How healers became killers: Nazi doctors on modern medical ethics.* St George's University School of Medicine. Lecture to first year class. St. Georges, Grenada. January 12, 2016
244. *On dancing with porcupines: professionalism, public trust and physician interactions with industry.* St George's University School of Medicine. Lecture to first year class. St. Georges, Grenada. January 15, 2016
245. *Ethical issues at the end of life.* Oschner Lifelong Learning Institute lecture. Highline Community Church, Denver CO. February 3, 2016
246. *Arts in Medicine lecture.* Fulginiti Pavilion, Aurora CO. February 29, 2016
247. *Bioethx Twitter Chat*: Medicine and the Holocaust in Medical Education: Ethical Imperative? With Ashley Fernandez, MD. April 11, 2016.
248. *Non-standard care or unregulated research: what is "innovative" care?* CHEF Conference plenary presentation. Thornton CO. April 15, 2016
249. *Pharmaceuticals – exorbitant costs and shortages: what is the role of ethics?* CHEF Conference. Thornton CO. April 15, 2016
250. *Race and trust in health care.* Racial Reconciliation Summit. Christ's Church Apostolic. Aurora CO. May 14, 2016.
251. *The ethics of sample size determinations.* University of Florida, Short Course on selecting a valid sample size. Msay 19, 2016
252. *Why debates over physician assisted dying won't die.* Aspen Center for Social Values public lecture. Aspen CO. May 25, 2016.
253. *Non-standard care or unregulated research: what is "innovative" care?* University of Cinicinnati Charles L Heaton Endowed Lecture. Cincinnati OH. June 9, 2016. [CME]
254. *Physician assistance in dying: historical and contemporary issues.* Lecture to palliative care fellows. University of Colorado Hospital. June 20, 2016.
255. *Non-standard care or unregulated research: what is "innovative" care?* Bioethics Summer Retreat. Lake Geneva WI. June 24, 2016.
256. *Non-standard care or unregulated research: what is "innovative" care?* Ethics liaisons meeting, Children's Hospital Colorado. Aurora CO. July 13, 2016.
257. *Academic integrity.* Lecture to incoming science graduate students at CU Denver. Denver CO. August 17, 2016.
258. *African Americans and American Medicine: confronting a painful legacy.* University of Chicago School of Medicine lecture to first year students. Chicago IL. September 1, 2016.
259. *Exploring the Use of Health Approaches in Community-Level Strategies to Countering Violent Extremism and Radicalization.* National Academies of Sciences, Engineering and Medicine. Workshop Chair. Washington DC. September 7-8, 2016.
260. *Health professional ethics and the work of countering ideologically-motivated violence.* National Academies of Sciences, Engineering and Medicine. Workshop Chair. Washington DC. September 8, 2016.
261. *How healers became killers: Nazi doctors and modern medical ethics.* Samuel and Pauline Bleicher endowed lecture. University of Miami, Miami FL.September 14, 2016. [CME]
262. *Medicine and profession, medicine as business.* Opening keynote, Aspen Program for Ethical Health Care Leadership. Aspen CO. September 18, 2016. [CME]

263. *Transdisciplinary professionalism:* what is it and why do we need it in health care? Bernie Karshmer memorial lecture. University of Colorado Anschutz Medical Campus, Aurora CO. September 28, 2016.
264. *Ethical guidance for global health.* Annual Global Health Course. University of Colorado Center for Global Health. Aurora CO. October 17, 2016. [CME]
265. *Physician assisted dying: historical and ethical issues.* 14th Annual Rocky Mountain Hospital Medicine Symposium. Denver CO. October 17, 2016. [CME]
266. *How healers became killers: Nazi doctors and modern medical ethics.* Montview Presbyterian Church. Denver CO. December 6, 2016.
267. *Hard Call:* Derailed. Fulginiti Pavilion, Aurora CO. December 12, 2016.
268. *The Ethics of Innovation: Therapeutic Innovative and Unregulated Research.* 2nd Annual Colorado Fetology Conference. Keynote address. Beaver Creek CO. January 8, 2017.
269. *The 3 R's of ethics in disaster response.* Global health lecture series. University of Colorado Center for Global Health. Aurora CO. January 11, 2017.
270. *The AMA and the USHMM Deadly Medicine Special Exhibition: reflections on the past, lessons for the future*. Bioethics after the Holocaust meeting. Houston TX. January 23, 2017.
271. *How Healers Became Killers: Nazi Doctors and Modern Medical Ethics*. Misericordia University Holocaust Remembrance Day event keynote, with Dr. Patricia Heberer-Rice of the USHMM. Dallas PA. January 26, 2017.
272. *Transdisciplinary Professionalism*: What is it and why do we need it in health care? Children's Hospital Colorado Ethics Committee. Aurora CO. Feb 1, 2017.
273. *OLLI discussion panel: because we can, should we?* With Drs. Marilyn Coors, Daniel Goldberg, Larry Hunter and Kathleen Barnes. Harvest Bible Chapel. Denver CO. February 1, 2017.
274. *Physician-assisted dying: historical and contemporary issues*. American College of Physicians Regional Meeting. Colorado Springs CO. February 3, 2017.
275. *Physician assisted dying in Colorado – an update and discussion.* University of Colorado Hospital Annual Ethics Retreat. Aurora CO. February 9, 2017.
276. *Ethics and effective communication with diverse populations.* Maryland Patient Safety Summit. Baltimore MD. March 17, 2017.
277. *How Healers Became Killers: Nazi Doctors and Modern Medical Ethics.* Florida American College of Surgeons Annual Meeting. Orlando FL. April 29, 2017.
278. *How to sustain (and grow) your clinical ethics service in a time of tight budgets.* International Conference on Clinical Ethics Case Consultation (ICCEC) Keynote presentation. Singapore. May 26, 2017.
279. *Quelling Violent Extremism with Public Health Tools.* Aspen Ideas Festival, Spotlight Health 2017. Aspen CO. June 23, 2017. (Video available at: https://www.aspenideas.org/session/quelling-violent-extremism-public-health-tools)
280. *Colorado Matters (NPR affiliate interview show) on Hard Call podcast series.* August 7, 2017. Denver CO
281. *Ethical issues in sample size determinations.* Georgetown/Howard University Short Course. August 28, 2017. Washington DC.
282. *Health disparities and the history of African American physician in American medical organizations.* University of Chicago, Pritzker School of Medicine, Agust 29, 2017.
283. *Medical aid in dying: ethical and historical issues.* Medical Grand Rounds. University of Colorado Hospital. September 6, 2017. Aurora CO.
284. *Health care as profession/health care as business.* Opening keynote, Aspen Ethical Leadership Program. September 11, 2017. Aspen, CO.
285. *End of life options, panel discussion.* 2040 Partners for Health Summit. September 14, 2017. Aurora CO.

286. *Medical Assistance in Dying – still a live issue.* CLEAR Annual Conference. September 15, 2017. Denver CO
287. *Ethics and innovative care.* Colorado Nursing Leadership Conference plenary presentation. September 22, 2017. Vail CO.
288. *Ethics in medicine: making hard calls.* Mini Med School lecture. University of Colorado School of Medicine. September 27, 2017. Aurora CO.
289. *Engaging the public in medical ethics: making hard calls.* Public Lecture. Colorado School of Mines. October 10, 2017. Golden CO.
290. *Lessons on the 70th Anniversary of the Nuremberg Doctors' Trial.* ASBH Annual Meeting. October 19, 2017. Kansas City, KS.
291. *Derailed: a Hard Call story exploring mental illness stigma.* Let's Talk: Conversations about Women's Health. (public lecture). October 26, 2017. Aurora CO
292. *Making hard calls in health and medicine – engaging the public in ethical deliberation.* Colorado State University (public lecture). October 27, 2017. Fort Collins, CO.
293. *Making hard calls in health and medicine – engaging the public in ethical deliberation.* Cristus St. Vincent Regional Healthcare System annual ethics meeting. November 4, 2017. Santa Fe NM.
294. *Ethical issues in sample size determinations.* Harvard short course. November 29, 2017. Boston MA
295. *Health care ethics: making the hard calls.* Department of Anesthesiology Grand Rounds. University of Colorado Hospital. December 11, 2017. Aurora CO.
296. *The compassionate utilitarian: reconciling competing ethical values in efforts to regulate cannabis use.* Ben Gurion University. January 11, 2018. Be'er Sheva, Israel.
297. *What should we know? Data variation around medical aid in dying in the US.* National Academy of Medicine workshop. February 13, 2018. Washington DC.
298. *Ethical issues in selecting sample sizes.* UNC-Chapel Hill. March 14, 2018. Chapel Hill, NC.
299. *Using virtual platforms to engage stakeholders and inform big data research.* University of Colorado Data Science to Patient Value Symposium. March 19, 2018. Aurora, CO.
300. *Medical privacy and telling patients' stories.* University of Colorado Denver. Visiting lecture for class on podcasting. March 29, 2018. Denver CO.
301. *Holocaust Genocide and Contemporary Bioethics programming:* April 6-13, 2018. Multiple lectures across the state of Colorado.
302. *Ethics, Professionalism and Taking Control of the Burnout Crisis in Health Care.* Physician Burnout: Integrated Strategies for Diverse Stakeholders. May 10, 2018. Beaver Creek, CO.
303. *Nihil sub sole novum:* there's nothing new under the sun. SomaLogic Guest Speaker Research Ethics Series, session II. May 29, 2018. Boulder, CO.
304. *Caring for Diverse and Communication-Vulnerable Populations.* ECRI Institute National Speaker Series Webinar. July 31, 2018.
305. *African American physicians and organized medicine: a painful legacy.* University of Chicago Pritzker School of Medicine, lecture to incoming students. August 23, 2018. Chicago, IL.
306. *Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond - A Workshop.* A Hard Call® interactive presentation. National Academy of Medicine. September 5, 2018. Washington DC.
307. *Ethical standards for research on humans: universal or local?* SomaLogic. October 3, 2018. Boulder, CO.
308. *Northern Colorado Legislative Night.* Colorado Medical Society event with state legislators. October 10, 2018. Fort Collins, CO.
309. *Professionalism in Medicine.* Loyola University Guest webinar. November 20, 2018.
310. *Communication Quality Improvement: Measuring and Improving the Communication Climate in Multi-disciplinary Care Environments.* Visiting Lecture. Ben Gurion University, Be'er Sheva, Israel. November 26, 2018.

311. *Challenges of Teaching about the Holocaust and Health Professional Ethics.* UNESCO Bioethics and Health Law Conference. November 27, 2018. Jerusalem, Israel.
312. *M.A.I.D. in Colorado: more questions than answers.* Harvard Bioethics Conference. April 11, 2019. Boston, MA.
313. *Benefits of sensitive, standardized data collection around end of life options.* Harvard Bioethics Conference. April 12, 2019. Boston, MA.
314. *Uniting to Prevent School Violence. What have we learned 20 years after Columbine?* University of Colorado Symposium. April 16, 2019. Aurora, CO.
315. *Human rights in health care: dilemmas of doctors in detention settings.* University of Colorado, Colorado Springs, and presented again at University of Colorado, Denver. May 2 and 3, 2019.
316. *Nazi doctors and modern medical ethics.* Presented twice, at University of Indiana Purdue University of health sciences campus and Shaarey Tefilla Synagogue. May 17, 2019.

EXHIBIT 4

"NOTICE TO PATIENTS HAVING MEDICATION ABORTIONS WHICH USE MIFEPRISTONE: Mifepristone, also known as RU-486 or Mifeprex, alone is not always effective in ending a pregnancy. It may be possible to

reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can get immediate help by calling the Abortion Pill Reversal 24-hour Hotline at 877-

558-0333 or going to Abortion Pill Reversal website, https://www.abortionpillreversal.com/. Additional information is available on the State Board of Medical Licensure and Supervision's website, www.awomansright.org,

which provides informed consent materials under the Woman's Right-to-Know Act, including information about the development of the unborn child and video of ultrasound images of the unborn child at

various stages of development."