

House Health Committee
Testimony for HB 2274
Written-Only
February 20, 2019

As a board-certified obstetrician gynecologist, I am compelled to share with the committee the harms that HB 2274 will bring for the women of Kansas. I am a practicing physician and see around 75 patients a week in Wyandotte County. My testimony is submitted on behalf of the American College of Obstetricians and Gynecologists.

HB 2274 would force doctors to provide women with information that is medically inaccurate and could be harmful to a woman's health. My duty as a physician is to provide the best scientific evidence to my patients when caring for them. Medication abortion is safe. Large, well-done studies have demonstrated the safety of medication abortion [1].

The concept that a medication abortion can be reversed is experimental and should not be recommended to women. Much of the conversation of "reversing" medication abortion comes from a physician in California, George Delgado MD, who experimented on women without the oversight of an institutional review board (IRB).

Delgado published a case series [2] of six women who were treated with an experimental progesterone protocol to reverse the effects of mifepristone and prevent abortion. In a systematic literature review published in 2015, Grossman et. al. found no published articles describing this regimen [3], demonstrating Delgado's protocol was in fact experimental. In his paper, Delgado does not report an IRB supervised these interventions, nor does he report the patients gave consent for data to be published. While Delgado presents data on these six women as a "case report," which would not necessarily require oversight by an IRB, the study meets criteria as research. According to the Department of Health and Human Services' Code of Federal Regulations, research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [4]. In the article, birth outcomes are described for four women and one woman is reported as "lost to follow-up," indicating that these women were followed after their described care was completed. Delgado's description of the progesterone protocol and his call for further clinical trials is an attempt at systematic evaluation testing an experimental protocol and thus qualifies as medical research.

In a November 2015 publication, Delgado describes 248 women who received progesterone after taking mifepristone for a medical abortion [5]. Again, he did not cite any oversight from an IRB or state the publication was exempt from IRB review. This paper reported data on the proportion of women with continuing pregnancies after progesterone and the status of those pregnancies. Therefore, he did more than what would be clinically expected – he followed them after treatment as research subjects without their consent. In the paper he indicated he attempted to obtain follow-up information on patient's pregnancies, stating, "getting data from physicians can be difficult" and he had "difficulty tracking patients."

As clinician-researchers, my colleagues and I have a moral obligation to inform patients if they are undergoing experimental therapies or are enrolled a research study. Information about a woman's personal health, such as pregnancy outcomes, should not be tracked without her consent and published without her permission—all without oversight by an IRB. I find Delgado's dishonesty with patients about their involvement in research unethical.

To use dishonest, unethical research to regulate a safe medical procedure would be a disservice to women and physicians. HB 2274's mandate 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.

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1. National Academies of Sciences E, Medicine, Health, Medicine D, Board on Health Care S, Board on Population H, et al. In: *The Safety and Quality of Abortion Care in the United States*. Washington (DC): National Academies Press (US)
2. Delgado G, Davenport ML. Progesterone use to reverse the effects of mifepristone. *Ann Pharmacother* 2012;46:e36.
3. Grossman D, White K, Harris L, et al. Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review. *Contraception*. Sep 2015;92(3):206-211
4. Department of Health and Human Services. Code of Federal Regulations, 45 CFR 46.102 (d); 2009.
5. Delgado G. The reversal of mifepristone with progesterone. *Issues Law Med*. 2015;30(2):169-177.