Legislative Report on 2016 House Concurrent Resolution 87

Study Related to Whether the Effects of an Abortion Induced with Drugs or Chemicals Can Be Reversed

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LOUISIANA DEPARTMENT OF HEALTH

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Executive Summary

House Concurrent Resolution 87 of the 2016 Regular Legislative Session was authored by representatives Hoffman, Bagley, Cox, Horton, Jackson, and Pope. The resolution requested that the Louisiana Department of Health (LDH) study whether the effects of an abortion induced with drugs or chemicals can be reversed, and report the findings and recommendations concerning this matter to the House and Senate Committees on Health and Welfare. The legislation further required that LDH convene a panel of experts in obstetrics and gynecology and pharmacology to provide guidance on this matter and to aid the department in the study. After posting public notice on the LDH website, the panel of experts was convened by conference call on October 11, 2016 at 8:00 am and was asked to provide written responses to the following questions:

- The resolution cites reports of a method to reverse medication-induced abortions. In your professional opinion, are such procedures scientifically sound and meet established standards of safety and efficacy?

- Is there a position or formal position statement from your professional association(s) regarding procedures intended to reverse medication-induced abortions?

Responses were received by LDH and form the substance of this report. **The panel of experts unanimously agreed that there is insufficient evidence** to suggest that there is a sound method to reverse a medication-induced abortion.

Section 1 – Overview of the Study

House Concurrent Resolution 87 of the 2016 Regular Legislative Session directed the Louisiana Department of Health (LDH) to study whether the effects of an abortion induced with drugs or chemicals can be reversed. The legislation further required that LDH convene a panel of experts in obstetrics and gynecology and pharmacology to provide guidance on this matter and to aid the Department in the study. The panel was convened in accordance with the resolution and was asked to provide written responses to the following questions:

- "The resolution cites reports of a method to reverse medication-induced abortions. In your professional opinion, are such procedures scientifically sound and meet established standards of safety and efficacy?"

- "Is there a position or formal position statement from your professional association(s) regarding procedures intended to reverse medication-induced abortions?"

The following individuals served on the panel for this report and provided valuable content expertise:

- Dr. Bennie Blaylock, Dean of the University of Louisiana at Monroe School of Pharmacy;
- Dr. Kathleen Kennedy, Dean of the Xavier University College of Pharmacy;
- Dr. Lisa Peacock, Chair of the Louisiana State University Health Sciences Center (New Orleans);
- Dr. Gabriella Pridjian, Dean of the Tulane University Department of Obstetrics and Gynecology;
- Dr. Janet S. Rami, Dean of the Southern University School of Nursing; Dr. Kristi Rapp, Clinical Professor at Xavier University College of Pharmacy;
- Dr. Susan Sirmans, Associate Professor at School of Pharmacy, University of Louisiana at Monroe College of Pharmacy; and
- Dr. Valerie Williams, Clinical Professor at the Louisiana State University Health Sciences Center (New Orleans).

Section 2 – Summary of Findings

2.1 – Background on Medication-Induced Abortion

Abortions can be performed by one of two means: using surgical instruments and techniques or using medication. The most common form of medication-induced abortion used in the United States involves the use of two medications: Mifepristone, also known as "RU-486," combined with the drug misoprostol (American Congress of Obstetricians and Gynecologists, 2014).

In 2000 and later in 2016, the U.S. Food and Drug Administration (FDA) approved the use of the drug Mifepristone, together with misoprostol, to end an early pregnancy. According to the FDA, Mifepristone, in conjunction with misoprostol, is taken to end a pregnancy through 70 days gestation (70 days or less since the first day of a woman's last menstrual period). The approved dosing regimen according to the FDA is:

- Day One: 200 milligrams of Mifepristone taken by mouth
- 24 to 48 hours after taking Mifepristone: 800 micrograms of misoprostol is taken orally (in the cheek pouch)
- About 7 to 14 days after taking Mifepristone: Follow-up with a healthcare provider is recommended (Food & Drug Administration, 2016).

Mifepristone blocks the hormone progesterone, which is necessary to maintain a pregnancy. It also works to increase the efficacy of the second medication in the regimen, misoprostol. Misoprostol causes the uterus to contract and expel its contents; thus, terminating the pregnancy (American Congress of Obstetricians and Gynecologists, 2014).

2.2 – Literature on Effectiveness of Procedures to Reverse Medication-Induced Abortion

The article, "Continuing Pregnancy after Mifepristone, and 'Reversal' of First Trimester," was published in 2015 in the journal *Contraception.* In the study, Dr. Daniel Grossman conducted a systematic review of literature regarding the effectiveness of medication abortion 'reversal' treatment (Grossman, White, Harris, Reeves, Blumenthal, & Grimes, 2015). Dr. Grossman and a team of researchers searched for reports of pharmacological methods used to reverse the effects of mifepristone prior to the administration of misoprostol for first trimester medical abortions (Grossman, et al, 2015).

After reviewing 1,115 unduplicated articles, and 13 studies in 11 publications using well-established databases of life sciences and biomedicine, such as PubMed, the CINAHL (Cumulative Index to Nursing and Allied Health Literature), Scopus, and the Cochrane Library, the researchers found only one article that matched the criteria (Grossman, et al, 2015). This article, published in the *Annals of Pharmacotherapy*, was based on a very small case series, conducted by Dr. George Delgado, of seven women, who received progesterone treatment after taking mifepristone (the first drug in the medication-induced abortion regimen) 7 to 11 weeks after gestation.

Dr. Grossman and his colleagues noted a number of significant flaws in the case series conducted by Dr. Delgado. These flaws include:

- The sample size was very small, preventing the generalizability or the ability to extrapolate study results and apply them to other populations.[1]
- The dosage of mifepristone was not noted in the case series.
- The study was of poor quality and lacked clear information on patient selection and patient demographics.

[1] One patient was lost to follow-up. Of the 6 patients with follow-up data, four continued the pregnancy and delivered at term with no apparent congenital abnormalities, and two patients aborted the pregnancy within 3 days of taking mifepristone.

- The case series was an experimental treatment on pregnant women, without the usual and customary research safeguards, such as an ethics board or institutional review board (IRB) approval.

Based on their research, Dr. Grossman and his colleagues concluded that there was insufficient evidence to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies than expectant management (closely monitoring the pregnancy) with fetal surveillance after mifepristone (Grossman et al., 2015).

2.3 – Positions of Professional Associations

The only professional association that has expressly stated a position on the procedure is the Arizona Section of the American Congress of Obstetricians and Gynecologists (ACOG). In its position paper, the organization states, "Claims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG's clinical guidance on medication abortion. There are no ACOG guidelines that support this course of action" (ACOG AZ Section, 2015).

The national ACOG further clarifies its position in an amicus brief filed in the case *Planned Parenthood Arizona, Inc., et al v. Mark Brnovich, Arizona Attorney General, et al,* No. CV-15-01022-PHX-SPL (D. Arizona, 2016). In that case, a lawsuit was filed in federal court challenging an Arizona law (SB 1318), which required physicians to inform any woman seeking an abortion in Arizona that "it may be possible to reverse the effects of a medication abortion if the woman changes her mind." *Id*. In the brief, ACOG, joined by the American Medical Association (AMA), and the Arizona Medical Association (ArMA), states:

> "… there is no credible, medical evidence that proves that any treatment 'reverses' the effects of mifepristone. Indeed, SB 1318's requirement appears to be based on a *single* four-page case series [the Delgado study], reporting results for *only six patients*. That series describes a handful of anecdotal experiences for women who received varying doses of progesterone after taking mifepristone, the first drug in the medication abortion protocol, and who did not take the second drug, misoprostol. The case series, which leading medical researchers in the field have described as of 'poor quality,' is unreliable. In developing its clinical guidelines for women's health clinicians, ACOG bases its strongest recommendations only on consistent and strong evidence, such as randomized controlled studies. The case series that is the basis of SB 1318 is not the type of information that ACOG would rely on to form its clinical recommendations." (Parker, Perryman & Payne, 2016)

2.4 – Consideration of Presence or Absence of Sound Scientific Basis for the Procedure

The panel of experts convened by LDH to review this procedure unanimously concluded, based on their professional experience in the areas of obstetrics/gynecology, pharmacology, and nursing and the above-referenced research, that there was insufficient evidence to conclude that the administration of progesterone in an attempt to reverse a medication abortion is scientifically sound. In reaching this conclusion, the panel expressed great concerns about the experimental nature of using progesterone treatment after taking mifepristone, as highlighted in the Delgado study, and the failure of the study to meet the established standards of safety, efficacy, and ethics.

Section 3 – Conclusion

After review of the professional opinions expressed by the panel of experts, the Department finds that there is neither sufficient evidence nor a scientific basis to conclude that the effects of an abortion induced with drugs or chemicals can be reversed.

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