Statement to the Health and Welfare Committee of the Vermont Senate – 2/21/25
Addressing questions related to the safety of mifepristone and to its use via telehealth

Thank you for having me today. My name is Clara Keegan and I am a family physician in Chittenden County providing comprehensive family medicine, including abortion care.

I understand that there were some questions on the safety of abortion medication without an in person visit. I would like to take this time to talk a little bit about the drugs used in medication abortion and why the evidence supports its safe use through both telemedicine and questionnaire or messaging.

Abortion using misoprostol with or without mifepristone has been shown to be both safe and effective. This can be done with the guidance of a health care professional (telemedicine) or without professional assistance (self-managed abortion).

Mifepristone is a steroid that blocks progesterone and glucocorticoid activity. Animal studies of daily use for up to 6 months showed no toxicity. Mifepristone was first studied for abortion in France in the 1980s. With a 600 mg dose, 8.7% of pregnancies continued, while with a 200 mg dose, 26.7% of pregnancies continued. Because these failure rates were so high, misoprostol was added to the treatment protocol. Misoprostol is a prostaglandin hormone that causes the uterus to contract and empty. The combination of mifepristone followed by misoprostol is more effective than either medication alone, though if access to mifepristone is limited, misoprostol will work by itself.

Mifepristone and misoprostol for abortion was originally approved based on 5743 patients. The most common effects of this treatment are uterine bleeding and painful uterine cramps, which are the expected effect as the medicines essentially cause a miscarriage. The most common symptoms reported are abdominal pain (56%), nausea (54%), tiredness (50%), and breast pain (28%). Often these symptoms are present prior to the administration of the medicine and then are a bit worse with the treatment. Additional studies of 94,165 people treated over 3 years of clinical use in the United States showed that serious complications occur in only about 2.2 out of 1000 cases. The most frequent complication is heavy bleeding.

There are a few reasons not to use mifepristone or to be cautious with its use, such as in people with adrenal or kidney failure, those to take corticosteroids every day or in those who have previously had allergic reactions to it. We can ask basic questions of patients to screen for these conditions.

Mifepristone is not effective for ectopic pregnancy so patients must be assessed for their risk. The rate of ectopic is 20.7 per 1000 pregnancies (about 2%). Risk is higher in people with a previous ectopic, an IUD in place, a history of tubal surgery, and a history of treatment for pelvic inflammatory disease. Symptoms that suggest the possibility of ectopic pregnancy are bleeding since the last period and pain or a mass in the lower pelvis. We can ask questions about these symptoms without seeing a patient in-person. Then if patients have these risk factors or symptoms they need an ultrasound before they are treated with mifepristone. An ectopic pregnancy will not resolve with mifepristone and misoprostol and would need to be diagnosed to help prevent complications.

Clinical assessment is used to determine gestational age, contraindications, or risk of ectopic pregnancy. Guidance is provided by the drug labeling from the manufacturers. Direct physical contact is not required to elicit this history.

Investigation of telehealth abortion has demonstrated that mifepristone and misoprostol can be provided safely and effectively through synchronous and asynchronous telemedicine. Among 6034 patients, 97.7% abortions were complete without further intervention. This is comparable to efficacy of in-person administration reported by the manufacturer. No serious adverse events occurred in 99.8% of patients. There were no cases that indicated that the pregnancy was further than 70 days gestation at the time of medication administration.

Mifepristone falls under the FDA's Risk Evaluation and Mitigation Strategy (REMS) program. The purpose of the mifepristone REMS program is to require prescribers to be able to assess if patients are candidates for this treatment and to be able to help patients access further treatment if complications were to develop. Mifepristone can only be dispensed by (or under the supervision of) certified prescribers or certified pharmacies, and patients must be informed of the potential risks of treatment. A Patient Agreement Form must be reviewed with and signed by the patient and the health care provider. The patient must receive the mifepristone Medication Guide, which provides FDA-approved information about the medication.

I hope that this clinical information has demonstrated how safe and well-studied these medications are. The modality of the visit does not change the safety of this drug and only increases the accessibility of a medication that in many states have been completely banned or severely limited.

I am happy to take any questions.

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