

**STATE OF SOUTH DAKOTA
OFFICE OF THE GOVERNOR
EXECUTIVE ORDER 2021-12**

Whereas, Impending federal rulemaking from the Biden Administration this year will put South Dakotan women at risk of serious health complications from abortion-inducing drugs; and,

Whereas, When the FDA approved the use of mifepristone in 2000, it did so under restricted distribution regulations, acknowledging the evident health risks. Then in 2011, the FDA incorporated these restrictions into an official Risk Evaluation and Mitigation Strategy (REMS), limiting how the drug can be dispensed. After years of fighting these safety standards,^[i] the abortion industry took advantage of the pandemic to obtain a court order in July 2020 blocking the requirement that mifepristone be administered in person, a key element of the REMS. The U.S. Supreme Court stayed the court order^[ii] to allow time for the case to be appealed to the Fourth Circuit Court of Appeals, but in April 2021, the FDA officially suspended enforcement of the in-person requirement for the duration of the pandemic. Abortion providers are now permitted to send the abortion pill through the mail via a loosely regulated system of brick-and-mortar clinics, online pharmacies, video calls, and online evaluation forms; and,

Whereas, The FDA is expected to lift additional safety REMS protocols on November 1, 2021, creating unsafe conditions for the dispensing of these dangerous drugs and causing potential harm to women in South Dakota. The result is likely to be an increase in chemical abortions and resulting complications^[iii]; and,

Whereas, A recent study reviewing reported adverse events over a 20-year period found that women can experience severe and life-threatening side-effects after taking the abortion pills, including heavy bleeding, intense pain, and even death^[iv]; and,

Whereas, A woman is 30% more likely to die from an ectopic pregnancy while undergoing an abortion than if she had an ectopic pregnancy but had not sought an abortion. Only an in-person medical exam can confirm an ectopic pregnancy, which the FDA is expected to remove from the regulations; and,

Whereas, The impending change in rule signaled by the FDA is expected to be a dramatic overreach of the executive branch of the Federal government that puts citizens of South Dakota at risk and does not respect the values and interests of a majority of this state.

South Dakota is a state that values life and prioritizes women's health and safety above politics by basing public policy on science and data rather than political talking points. South Dakotans overwhelmingly support life and voted in 2020 to elect a majority of members of the state Legislature who support pro-life issues; and,

Whereas, In conjunction with a case pending before the United States Court of Appeals for the Ninth Circuit, *Chelius v. Beccerra*, the U.S. Food and Drug Administration (FDA) is reviewing the elements of the "Risk Evaluation Mitigation Strategy" (REMS) for mifeprax and its approved generic, mifepristone tablets, 200 mg, in accordance with the REMS assessment provisions of Section 505-1 of the Federal Food, Drug, and Cosmetic Act. From a recent joint motion requesting a stay while the FDA conducts its review:

"The Parties jointly seek a stay of this matter in light of Defendant U.S. Food and Drug Administration's ("FDA") current review of the risk evaluation and mitigation strategy ("REMS") at issue in this case. The Parties agree that the outcome of FDA's review could have a material impact on the course of this litigation. Accordingly, to conserve the resources of the Court and the Parties, the Parties seek a stay of this matter until December 1, 2021, with a joint status report, to include an update on the status of FDA's review, due on November 1, 2021."

Whereas, Permitting the dispensing of mifepristone through the mail or through a mail-order pharmacy is very likely a preview of how the FDA is expected to change the REMS on November 1, 2021; and,

Whereas, The South Dakota Department of Health must act quickly to adopt rules to protect women of South Dakota because we can no longer rely on the US Food & Drug Administration for sound, impartial medical protocols, and include commonsense measures that will assure that the state has effective, medically-indicated protocols in place for the medical community to follow when dispensing the dangerous abortion pills:

NOW, THEREFORE, I, KRISTI NOEM, Governor of the State of South Dakota, by the authority vested in me by the Constitution and the Laws of the State, do hereby Order and Direct the following:

1. Until such a time that the duly elected members of the State Legislature pass legislation to revise our statutes regarding dangerous abortion-inducing drugs and telemedicine, I direct the South Dakota Department of Health to begin emergency rulemaking to be implemented pursuant to the current FDA REMS, which has had a 20-year track record of

helping to protect women's health with sound medical practice, to accomplish the following:


- a) With the proliferation of companies organizing to sell these dangerous drugs online to young women, ensure that medicines, drugs, or any other substances prescribed or dispensed with the intent of terminating the pregnancy of a woman shall only be dispensed by a physician licensed in South Dakota to a patient after examining her in-person to rule out contraindications, including but not limited to, ectopic pregnancy;
- b) Provide that no manufacturer, supplier, physician, or any other person may provide any abortion-inducing drugs directly to women in South Dakota via courier, delivery, telemedicine, or mail service;
- c) Ensure abortion-inducing drugs shall not be dispensed or provided in any school facility or on state grounds, including but not limited to, elementary schools, secondary schools, and institutions of higher education in this state. The abortion industry is targeting young women via social media and school bathrooms are at risk of becoming the new abortion clinics;
- d) Remind licensed physicians dispensing or prescribing abortion-inducing drugs they shall ensure that our state's Informed Consent laws are properly administered;
- e) Develop an abortion clinic license specific to the pharmaceutical nature of medical abortion in keeping with South Dakota's existing surgical abortion clinic licensing requirements (i.e., a license for "pill only" clinics).
- f) Collect empirical data on how often chemical abortions are performed as a percentage of all abortions, how often women experience complications that require medical follow-up (or a second abortion), where the doctor prescribing or dispensing chemical abortion is located, if she was coerced or sex trafficked and forced to take the pills, and more.
- g) As research shows that chemical abortion has a four times greater rate of complications than surgical abortion, the state has an interest in collecting data on the rate of complications seen in our emergency rooms and other medical facilities as a result of chemical abortions. I am therefore directing the Department of Health to enhance reporting requirements for this procedure so that we know how often and how harsh the results are.^[vi]

2. During the 2022 legislative session, it is anticipated that the Legislative Branch and Executive Branch will cooperate on legislation that will make permanent these and other protocols, including requiring the Department of Health make data available to the public


regarding the incidence and types of abortion in our state, as well as the incidences of complications on women and the impact on our traditional health care facilities when they treat complications.

Dated in Pierre, South Dakota this 7th day of September, 2021.




Kristi Noem
Governor of South Dakota

ATTEST:


Steve Barnett
Secretary of State

i. Longbons, T. (2019). The push to expand chemical abortion in the United States. Sebastian's Point.
ii. See https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf.
iii. See Charlotte Lozier Institute (2021). CLJ fact sheet: an abundance of neglect.
iv. Aultman, et al., Issues in Law & Medicine, Volume 36, Number 1, 2021.
v. Atrash H.K., et al. (1990). Ectopic pregnancy concurrent with induced abortion: Incidence and mortality. American Journal of Obstetrics & Gynecology, 162(3), 726-730. doi: 10.1016/0002-9378(90)90995-j.
vi. Niinimaki. OBG. 114(4)2009:795-804. Immediate complications of medical compared with surgical termination of pregnancy.
Credit: Longbons, T. (May 2021), "The Impact of Chemical Abortion by Mail" Charlotte Lozier Institute, available at <https://lozierinstitute.org/the-impact-of-chemical-abortion-by-mail/>; and Longbons, T., Hannah Howard (May 2021), "Chemical Abortion: Coming Soon to a Mailbox Near You," available at <https://www.christianpost.com/voices/chemical-abortion-coming-soon-to-a-mailbox-near-you.html>