State of Arkansas
90th General Assembly
Regular Session, 2015

A Bill

HOUSE BILL 1394

By: Representative C. Fite

For An Act To Be Entitled

AN ACT TO ESTABLISH THE ABORTION-INDUCING DRUGS SAFETY ACT; AND FOR OTHER PURPOSES.

Subtitle

TO ESTABLISH THE ABORTION-INDUCING DRUGS SAFETY ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 16, is amended to add an additional subchapter to read as follows:

Subchapter 15 — Abortion-Inducing Drugs Safety Act

20-16-1501. Title.

This Act may be known and cited as the "Abortion-Inducing Drugs Safety Act."

20-16-1502. Legislative findings and purpose.

(a) The General Assembly finds that:

(1) The United States Food and Drug Administration approved the drug mifepristone, a first-generation progesterone receptor modulator, as an abortion-inducing drug with a specific gestation, dosage, and administration protocol;

(2) The United States Food and Drug Administration approved mifepristone under the rubric of 21 C.F.R. § 314.520, also referred to as "Subpart H," which is the only Food and Drug Administration approval process

that allows for postmarketing restrictions and provides for accelerated approval of certain drugs that are shown to be effective but "can be safely used only if distribution or use is restricted";

(3) The United States Food and Drug Administration does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process;

(4) As approved by the United States Food and Drug Administration and as outlined in the final printed labeling of mifepristone, an abortion by mifepristone consists of three (3) two-hundred (200) mg tablets of mifepristone taken orally, followed by two (2) two-hundred (200) mcg tablets of misoprostol taken orally, through forty-nine (49) days from the first day of the woman's last menstrual period;

(5) The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred;

(6) This United States Food and Drug Administration-approved protocol is referred to as the "Mifeprex regimen";

(7) This treatment requires three (3) office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital and under supervision of a physician;

(8) The final printed labeling of Mifeprex outlines the United States Food and Drug Administration-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

(9) When the United States Food and Drug Administration approved the Mifeprex regimen under Subpart H, it did so with certain restrictions such as the requirement that the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention or has made plans to provide surgical intervention through other qualified physicians;

(10) One (1) of the restrictions imposed by the United States Food and Drug Administration as part of its Subpart H approval is a written agreement that must be signed by both the physician and patient;

(11) In that agreement, the woman, along with the physician, attests to the following, among other statements:

(A) "I believe I am no more than 49 days (7 weeks) pregnant";

(B) "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)"; and

(C) "I will do the following: return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant";

(12) The United States Food and Drug Administration concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex final printed labeling on self-administering misoprostol at home;

(13) Court testimony in Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006), by Planned Parenthood and other abortion providers demonstrates that providers routinely fail to follow the United States Food and Drug Administration-approved protocol for the Mifeprex regimen, as it is outlined in the Mifeprex final printed labeling and that providers are administering a single oral dose of two-hundred (200) mg of mifepristone, followed by a single vaginal or buccal dose of eight-tenths (.8) mg misoprostol, through sixty-three (63) days of the woman's last menstrual period, without medical supervision and without follow-up care;

(14) The use of mifepristone presents significant medical risks to women, including without limitation abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease;

(15) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion and the risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process;

(16)(A) In July 2011, the United States Food and Drug Administration reported two thousand two hundred and seven (2,207) adverse events in the United States of America after women used the Mifeprex regimen for the termination of pregnancy.

(B) Among those were fourteen (14) deaths, six hundred and twelve (612) hospitalizations, three hundred and thirty-nine (339) blood transfusions, and two hundred and fifty-six (256) infections, including forty-eight (48) severe infections;

(17)(A) Off-label or so-called evidence-based use of the

Mifeprex regimen may be deadly.

(B) To date, fourteen (14) women have reportedly died after administration of the Mifeprex regimen, with eight (8) deaths attributed to severe bacterial infection.

(C) All eight (8) of those women administered the regimen in an off-label or evidence-based manner advocated by abortion providers.

(D) The United States Food and Drug Administration has not been able to conclude whether off-label use led to the eight (8) deaths; and

(18) Medical evidence demonstrates that women who use abortion-inducing drugs incur more complications than those who have surgical abortions.

(b) Based on the findings in subsection (a), it is the purpose of this subchapter to:

(1) Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, but not limited to the Mifeprex regimen; and

(2) Ensure that physicians abide by the protocol tested and approved by the United States Food and Drug Administration for such abortion-inducing drugs, as outlined in the drug labels.

20-16-1503. Definitions.

As used in this subchapter:

(1)(A) "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child.

(B) An act under subdivision (1)(A) of this section is not an abortion if the act is performed with the intent to:

(i) Save the life or preserve the health of the unborn child;

(ii) Remove a dead unborn child caused by spontaneous abortion;

(iii) Remove an ectopic pregnancy; or

(iv) Treat a maternal disease or illness for which the prescribed drug is indicated;

(2)(A) “Abortion-inducing drug” means a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child.

(B) "Abortion-inducing drugs" includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol, Cytotec, and methotrexate.

(C) This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications such as chemotherapeutic agents or diagnostic drugs.

(D) Use of drugs to induce abortion is also known as a medical, drug-induced, or chemical abortion;

(3) "Adverse event" means an undesirable experience associated with the use of a medical product in a patient, including without limitation an event that causes:

(A) Death;

(B) Threat to life;

(C) Hospitalization;

(D) Disability or permanent damage;

(E) Congenital anomaly or birth defect, or both;

(F) Required intervention to prevent permanent impairment or damage;

(G) Other serious important medical events, including without limitation:

(i) Allergic bronchospasm requiring treatment in an emergency room;

(ii) Serious blood dyscrasias;

(iii) Seizures or convulsions that do not result in hospitalization; and

(iv) The development of drug dependence or drug abuse;

(4) “Final printed labeling” means the United States Food and Drug Administration-approved informational document for an abortion-inducing drug which outlines the protocol authorized by the United States Food and

Drug Administration and agreed upon by the drug company applying for United States Food and Drug Administration authorization of that drug;

(5) "Gestational age" means the time that has elapsed since the first day of the woman's last menstrual period;

(6) "Mifeprex regimen" means the abortion-inducing drug regimen that involves administration of mifepristone or the brand name "Mifeprex" and misoprostol which is the only abortion-inducing drug regimen approved by the United States Food and Drug Administration and is also known as the RU-486 regimen or simply RU-486;

(7) "Mifepristone" means the first drug used in the Mifeprex regimen;

(8) "Misoprostol" means the second drug used in the Mifeprex regimen;

(9) "Physician" means any person licensed to practice medicine in this state including medical doctors and doctors of osteopathy; and

(10) "Unborn child" means the offspring of human beings from conception until birth.

20-16-1504. Unlawful distribution of abortion-inducing drug.

(a)(1) It shall be unlawful to knowingly give, sell, dispense, administer, or otherwise provide or prescribe an abortion-inducing drug to a pregnant woman to induce an abortion or enabling another person to induce an abortion, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician and the provision or prescription of the abortion-inducing drug satisfies the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the drug or drug regimen.

(2) In the case of the Mifeprex regimen, the final printed labeling for Mifeprex includes the United States Food and Drug Administration-approved dosage and administration instructions for both mifepristone and misoprostol.

(b) Because the failure and complication rates from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies, the physician giving, selling,

dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the woman and document in the woman's medical chart prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug the following information without limitation:

(1) Gestational age; and

(2) Intrauterine location of the pregnancy.

(c) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug's label.

(d)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug shall have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department of Health.

(2) The physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

(3) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies.

(e)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug, or an agent of the physician, shall schedule a follow-up visit for the woman for approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding.

(2) The physician or agent of physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment.

(3) A brief description of the efforts made to comply with this subsection, including without limitation the date, time, and identification by name of the person making such efforts, shall be included in the woman's

medical record.

20-16-1505. Reporting.

(a) If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in § 20-16-1504, and if the physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences an adverse event, the physician shall provide a written report of the adverse event within three (3) days of the event to the United States Food and Drug Administration via the Medwatch reporting system and to the Arkansas State Medical Board.

(b)(1) The board shall compile and retain all reports it receives under this section.

(2)(A) All reports received by the board are public records open to inspection under the Arkansas Freedom of Information Act, § 25-19-101 et seq.

(B) The board shall not release to any person or entity the name or any other personal identifying information regarding a person who:

(i) Uses an abortion-inducing drug to induce an abortion; and

(ii) Is the subject of a report received by the board under this section.

20-16-1506. Criminal penalties.

(a) A person who intentionally, knowingly, or recklessly violates a provision of this subchapter is guilty of a Class A misdemeanor.

(b) A criminal penalty may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

20-16-1507. Civil remedies and professional sanctions.

(a) In addition to whatever remedies are available under the common or statutory law of this State, failure to comply with the requirements of this subchapter shall provide a basis for:

(1) A civil malpractice action for actual and punitive damages;

(2) A professional disciplinary action under § 16-114-201 et seq.; and

(3) Recovery for the woman's survivors for the wrongful death of the woman under § 16-62-102.

(b) A civil liability may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

(c) When requested, the court shall allow a woman to proceed using solely her initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman upon whom the drug-induced abortion was performed.

(d) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for a reasonable attorney's fee in favor of the plaintiff against the defendant.

(e) If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court shall also render judgment for reasonable attorney's fee in favor of the defendant against the plaintiff.

20-16-1508. Construction.

(a) This subchapter does not create or recognize a right to abortion.

(b) It is not the intention of this subchapter to make lawful an abortion that is currently unlawful.

20-16-1509. Right of intervention.

The General Assembly, by joint resolution, may appoint one (1) or more of its members, who sponsored or cosponsored this subchapter in his or her official capacity, to intervene as a matter of right in any case in which the constitutionality of this law is challenged.

20-16-1510. Effective date.

This subchapter takes effect on January 1, 2016.