State of Arkansas *As Engrossed: H3/8/21*
93rd General Assembly **A Bill**
Regular Session, 2021 HOUSE BILL 1402

By: Representative Barker
By: Senator B. Johnson

For An Act To Be Entitled

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

Subtitle

TO AMEND THE ABORTION-INDUCING DRUGS SAFETY ACT.

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

SECTION 1. Arkansas Code §§ 20-16-1502 — 20-16-1504 are amended to read as follows:

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 United States 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 that 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-milligram tablets of mifepristone taken orally, followed by two (2) two-hundred-microgram 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 milligrams (200 mg) of mifepristone, followed by a single vaginal or buccal dose of eight-tenths of one milligram (.8 mg) of 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 seven (2,207) adverse events in the United States after women used the Mifeprex regimen for the termination of pregnancy.~~

~~(B) Among those were fourteen (14) deaths, six hundred twelve (612) hospitalizations, three hundred thirty-nine (339) blood transfusions, and two hundred 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.~~

(1) The use of abortion-inducing drugs, including the Mifeprex regimen, also known as "RU-486" or "mifepristone", presents significant medical risks, including without limitation incomplete abortion, sepsis or other infections, uterine hemorrhage, blood clots, abdominal pain, fever, vomiting, headache, fatigue, pelvic inflammatory disease, and death;

(2) Medical evidence demonstrates that women who use abortion-inducing drugs risk significantly more complications than those who undergo surgical abortions;

(3) The risk of complications, as well as the failure rate for drug-induced abortions, increases with advancing gestational age;

(4) A woman's ability to provide informed consent depends on the extent to which the woman receives information sufficient to make an informed choice;

(5) The decision to abort "is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and *consequences", as stated in Planned Parenthood v. Danforth, 428 U.S. 52, 67 (1976);*

(6) To facilitate reliable scientific studies and research on the safety and efficacy of abortion-inducing drugs, it is essential that the medical and public health communities have access to accurate information on the efficacy of abortion-inducing drugs and resulting complications;

(7) Abortion "recordkeeping and reporting *requirements* that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy are *permissible", as stated in Planned Parenthood v. Danforth, 428 U.S. 52, 80 (1976);* and

(8) "The collection of information with respect to actual patients is a vital element of medical research, and so it cannot be said that the [abortion reporting] requirements serve no purpose other than to make abortions more *difficult", as stated in Planned Parenthood v. Casey, 505 U.S. 833, 900-901 (1992).*

(b) Based on the findings in subsection (a) of this section, 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.~~

(1) Protect the health and welfare of every woman considering a drug-induced abortion;

(2) Ensure that:

(A) A physician examines a woman before prescribing, administering, or dispensing an abortion-inducing drug; and

(B) A woman considering a drug-induced abortion receives comprehensive information on abortion-inducing drugs;

(3) Reduce "the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully *informed", as stated in Planned Parenthood v. Casey, 505 U.S. 833, 882 (1992); and*

(4) Add to the sum of medical and public health knowledge through the compilation of relevant data on drug-induced abortions performed in the state, as well as on all medical complications and maternal deaths resulting from these abortions.

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; or

(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 that 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)~~(4) "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)~~(5) "Physician" means any person licensed to practice medicine in this state, including medical doctors and doctors of osteopathy; and

~~(10)~~(6) "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 enable 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 the 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.~~

(a) Abortion-inducing drugs shall only be prescribed, administered, dispensed, or otherwise provided by a physician following procedures set out in this subchapter.

(b) It is unlawful for any manufacturer, supplier, physician, or any other person to provide any abortion-inducing drug via courier, delivery, or mail service.

(c) Before providing an abortion-inducing drug, the physician prescribing, administering, dispensing, or otherwise providing the abortion-inducing drug shall:

(1) Examine the pregnant woman in person;

(2) Independently verify that an intrauterine pregnancy exists;

(3)(A) Determine the woman's blood type.

(B) If the pregnant woman is Rh negative, the physician shall be able to and offer to administer RhoGAM at the time of the abortion; and

(4) Document in the pregnant woman's medical chart or record the gestational age and intrauterine location of the pregnancy and whether the pregnant woman received treatment for Rh negativity.

(d) A physician prescribing, administering, dispensing, or otherwise providing an abortion-inducing drug shall be credentialed and competent to handle abortion complication management, including emergency transfer, or have a signed agreement with an associated physician who is credentialed to handle abortion complications.

(e) When a signed agreement exists between an associated physician, every pregnant woman to whom a physician prescribes, administers, dispenses, or otherwise provides an abortion-inducing drug shall be given the name and telephone number of the associated physician.

(f) The physician prescribing, administering, dispensing, or otherwise providing an abortion-inducing drug or an agent of the physician shall schedule a follow-up visit for the woman at approximately seven (7) to

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.

(g) The physician or an agent of the physician shall make all reasonable efforts to ensure that the woman returns for the scheduled follow-up appointment.

(h) A brief description of all efforts made to comply with subsections (f) and (g) of this section, including the date, time, and identification by name of the person making such efforts, shall be included in the woman's medical chart or record.

SECTION 2. DO NOT CODIFY. SAVINGS CLAUSE. If any section or part of a section of this act is determined by a court to be unconstitutional, the Abortion-Inducing Drugs Safety Act, § 20-16-1501 et seq., shall be revived, and to prevent a hiatus in the law, the relevant section or part of a section of the Abortion-Inducing Drugs Safety Act shall remain in full force and effect from and after the effective date of this act notwithstanding its repeal by this act.

/s/Barker