State of Arkansas *As Engrossed: S3/10/11*
88th General Assembly **A Bill**
Regular Session, 2011 SENATE BILL 840

By: Senator Irvin

For An Act To Be Entitled

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

Subtitle

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:

20-16-1301. Title.

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

20-16-1302. Legislative findings — Purpose.

(a) The General Assembly finds that:

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

(2)(A) As tested and approved by the United States Food and Drug Administration, and as outlined in the drug label, an abortion by mifepristone consists of three (3) two hundred milligram (200 mg) tablets of mifepristone taken orally followed by two (2) two hundred microgram (200 mcg) tablets of misoprostol taken orally, and is effective for forty-nine (49) days after the first day of the woman's last menstrual period.

(B) The patient is to return for a follow-up visit in

order to confirm that a complete termination of pregnancy has occurred;

(3) The treatment described in subdivision (a)(2) of this section 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;

(4) Court testimony by Planned Parenthood and other physicians demonstrates that physicians routinely fail to follow the mifepristone protocol as tested and approved by the United States Food and Drug Administration, and as outlined in the drug label, Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006);

(5) Specifically, Planned Parenthood and other physicians are administering a single oral dose of two hundred milligrams (200 mg) of mifepristone followed by a single vaginal dose of eight-tenths milligrams (8/10 mg) misopristol through sixty-three (63) days after the first day of the woman's last menstrual period without medical supervision and without follow-up care, Planned Parenthood Cincinnati Region, 459 F. Supp. 2 at 630n.7;

(6) The use of mifepristone presents significant medical risks to women, including without limitation:

(A) C. sordellii bacterial infection;

(B) Septic shock;

(C) Toxic shock syndrome;

(D) Adult respiratory distress syndrome from sepsis;

(E) Escheria coli sepsis;

(F) Group B Streptococcus septicemia;

(G) Disseminated intravascular coagulopathy with hepatic and renal failure;

(H) Severe pelvic infection; and

(I) Massive hemorrhage;

(7)(A) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion.

(B) The risk of complications increases with increasing gestational age, and, in the instance of mifepristone, with failure to complete the two-step dosage process;

(8)(A) Off-label use of mifepristone can be deadly.

(B) As of August 2010, a European drug manufacturer

acknowledged at least twenty-nine (29) deaths worldwide related to mifepristone use;

(9)(A) Medical studies have indicated that one (1) to two (2) out of every one thousand (1,000) women who undergo mifepristone abortions will require emergency blood transfusion for massive hemorrhage.

(B) By May 2006, the United States Food and Drug Administration reported that at least one hundred sixteen (116) women required blood transfusions for massive bleeding after mifepristone abortions, with at least fifty-four (54) losing more than one-half (1/2) of their blood volume; and

(10)(A) The absence of proper follow-up care after mifepristone abortions has resulted in at least seventeen (17) women having undetected ectopic pregnancies.

(B) Eleven (11) of the undetected ectopic pregnancies resulted in ectopic rupture.

(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, including without limitation, mifepristone; and

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

20-16-1303. 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 an 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 drug" includes off-label use of drugs known to have abortion-inducing properties that are prescribed specifically with the intent of causing an abortion, including without limitation, misoprostol and methotrexate.

(C) "Abortion-inducing drug" does not include drugs that may be known to cause an abortion, but that are prescribed for other medical indications such as chemotherapeutic agents, diagnostic drugs, and other similar drugs.

(D) Use of drugs under subdivisions (2)(A) and (B) of this section to induce abortion is also known as 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) "Drug label" or "drug's label" means the pamphlet accompanying an abortion-inducing drug that outlines the protocol tested and 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) "Final printing labeling instructions," means the United States Food and Drug Administration document that delineates how a drug is to be used under United States Food and Drug Administration approval;

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

(7) "Mifepristone" means the specific abortion-inducing drug regimen also known as RU-486;

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

(9) "Pregnant" or "pregnancy" means that female reproductive condition of having an unborn child in a woman's uterus; and

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

20-16-1304. Off-label use of mifepristone prohibited.

(a) It is unlawful to knowingly give, sell, dispense, administer, otherwise provide, or prescribe an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in that pregnant woman or enabling another person to induce an abortion in a pregnant woman 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 tested and authorized by the United States Food and Drug Administration and as outlined in the drug label and final printing labeling instructions for the abortion-inducing drug.

(b) A 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 the gestational age and the intrauterine location of the pregnancy before giving, selling,

dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug because:

(1) The failure and complications from *chemical* abortion increase with increasing gestational age;

(2) The physical symptoms of *chemical* abortion can be identical to the symptoms of ectopic pregnancy; and

(3) Abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies.

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

(d)(1) A physician giving, selling, dispensing, administering, otherwise providing or prescribing an 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) Every pregnant woman to whom a physician gives, sells, dispenses, administers otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the physician who will be handling emergencies and the hospital at which emergencies will be handled.

(3) A physician who contracts to handle emergencies under this subsection shall have active admitting privileges and gynecological privileges, surgical privileges, or both, at the hospital designated under this subsection to handle emergencies associated with the use or ingestion of the abortion-inducing drug.

20-16-1305. Reporting.

(a) If a physician provides an abortion-inducing drug to a person for the purpose of inducing an abortion under § 20-16-1304, and if the physician knows that the person who uses the abortion-inducing drug for the purpose of inducing an abortion experiences during or after the use an adverse event, the physician shall provide a written report of the adverse event within three (3) days after the event to:

(1) The United States Food and Drug Administration via the Medwatch Reporting System; and

(2) The Arkansas State Medical Board.

(b)(1) The Arkansas State Medical Board shall compile and retain all reports it receives under this section.

(2) All reports that the board receives under this section are public records open to inspection under the Freedom of Information Act of 1967, § 25-19-101 et seq.

(3) The Arkansas State Medical Board shall not release to any person or entity the name or any other personal identifying information regarding a person who uses an abortion-inducing drug for the purpose of inducing an abortion and who is the subject of a report the Arkansas State Board receives under this section.

20-16-1306. Criminal penalties.

A person who purposely, knowingly, or recklessly violates this *subchapter is guilty of a Class A misdemeanor.*

20-16-1307. Civil penalties.

(a) In addition to whatever remedies are available under the common or statutory law of this state, a violation of this subchapter shall provides a basis for:

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

(2) A professional disciplinary action under the rules of the Arkansas State Medical Board or other appropriate licensing board; and

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

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

(c) If requested, a court shall allow a woman to proceed in an action under this section 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.

20-16-1308. Inspections and investigations.

(a) The Department of Health shall establish policies and procedures

for conducting annual inspections of facilities prescribing, dispensing, administering, or otherwise providing abortion-inducing drugs.

(b) The department shall adopt rules for the conduct of on-site inspections of facilities prescribing, dispensing, administering, or otherwise providing abortion-inducing drugs to ensure compliance with this subchapter.

(c) In promulgating rules under this section, the department shall specifically include rules protecting the confidentiality of all patient records and patient-identifying information reviewed or accessed during the inspections required under this subchapter.

(d) The department shall also establish policies and procedures for conducting inspections and investigations of facilities prescribing, dispensing, administering, or otherwise providing abortion-inducing drugs pursuant to complaints received by the department for alleged violations of the requirements of this subchapter.

(e) The department shall receive, record, and dispose of complaints under the established policies and procedures.

20-16-1309. Construction.

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

(b) This subchapter is not intended to make lawful an abortion that is currently unlawful.

20-16-1310. Right of intervention.

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

/s/Irvin