SB298

127457-2

By Senators Allen, Beason, Waggoner, Brewbaker, Dial, Reed, McGill and Whatley

RFD: Health

First Read: 29-MAR-11

SB298

ENGROSSED

A BILL

TO BE ENTITLED

AN ACT

To establish the Abortion-Inducing Drug Safety Act; to provide findings and define terms; to provide guidelines for abortion-inducing drugs; to provide criminal penalties and civil remedies for violations; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the Constitution of Alabama of 1901, now appearing as Section 111.05 of the Official Recompilation of the Constitution of Alabama of 1901, as amended.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. This act may be known and cited as the Abortion-Inducing Drug Safety Act.

Section 2. The Legislature hereby finds and declares:

(1) The Food and Drug Administration (FDA) approved the drug mifepristone, a first-generation (selective) progesterone receptor modulator (SPRM), as an

abortion-inducing drug with a specific gestation, dosage, and administration protocol.

(2) As tested and approved by the FDA, and as outlined in the drug label, an abortion by mifepristone consists of three 200 mg tablets of mifepristone taken orally followed by two 200 mcg tablets of misopristol taken orally, through 49 days LMP, a gestational measurement using the first day of the woman's last menstrual period as a marker. The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred.

(3) The aforementioned treatment requires three in-person 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 FDA.

(5) The use of mifepristone presents significant medical risks to women.

(6) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with increasing gestational age, and, in the instance of mifepristone, with failure to complete the two-step dosage process.

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

Section 3. This act is enacted for the following purposes:

(1) To protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, but not limited to, mifepristone.

(2) To ensure that physicians abide by the protocol tested and approved by the FDA for such abortion-inducing drugs, as outlined in the drug labels.

Section 4. For purpose of this act, the following words and phrases shall have the following meanings:

(1) ABORTION. 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. Such use, prescription, or means is not an abortion if done with the intent to:

a. Save the life or preserve the health of an unborn child.

b. Remove a dead unborn child caused by spontaneous abortion.

c. Remove an ectopic pregnancy.

d. Treat a maternal disease or illness for which the prescribed drug is indicated.

(2) ABORTION-INDUCING DRUG. 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. This 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. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications (e.g., chemotherapeutic agents, diagnostic drugs, etc.).

(3) DEPARTMENT. The Department of Public Health.

(4) DRUG LABEL or DRUG'S LABEL. The pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the U.S. Food and Drug Administration (FDA) and agreed upon by the drug company applying for FDA authorization of that drug.

(5) MEDICAL ABORTION. The causing of an abortion by the use of an abortion-inducing drug.

(6) MIFEPRISTONE. The specific abortion-inducing drug regimen also known as RU-486.

(7) PHYSICIAN. Any person licensed to practice medicine in this state. The term includes medical doctors and doctors of osteopathy.

(8) PREGNANT or PREGNANCY. A female reproductive condition of having an unborn child in the woman's uterus.

(9) UNBORN CHILD. The offspring of human beings from conception until birth.

Section 5. (a) It shall be unlawful to provide a medical abortion to a woman without her being examined in person by a physician and as further required by this act.

(b) It shall be unlawful to knowingly give, sell, dispense, administer, otherwise provide, or prescribe any 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 is authorized by the FDA as outlined in the drug label for the abortion-inducing drug.

(c) Because the failure and complications from medical abortion increase with increasing 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 must first examine in person the woman and document, in the woman's medical chart, gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug.

(d) A physician who gives, sells, dispenses, administers, otherwise provides, or prescribes any abortion-inducing drug shall:

(1) Provide every pregnant woman with a copy of the drug's label.

(2) 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.

(3) Provide every pregnant woman write the name and phone number of the physician who will be handling emergencies, and the hospital at which any emergencies will be handled.

(4) Schedule an in-person follow-up visit for the woman at approximately 14 days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding.

(5) Make all reasonable efforts to ensure that the woman returns for the scheduled appointment.

(6) Provide a brief description of the efforts made to comply with this subdivision, including the date, time, and identification by name of the person making the efforts, shall be included in the woman's medical record.

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

Section 6. If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in this act, 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, as defined by the FDA, the physician shall provide a written report of the event within three days to the FDA via the Medwatch Reporting System and to the department.

Section 7. (a) A person who intentionally, knowingly, or recklessly violates any provision of this act is guilty of a Class C felony.

(b) No criminal penalty may be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

Section 8. (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 act shall:

(1) Provide a basis for a civil malpractice action for actual and punitive damages.

(2) Provide a basis for a professional disciplinary action under the State Board of Medical Examiners.

(3) Provide a basis for recovery for the woman's survivors for the wrongful death of the woman.

(b) No civil liability may 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.

Section 9. (a) Nothing in this act shall be construed as creating or recognizing a right to abortion.

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

Section 10. The Legislature, by joint resolution, may appoint one or more of its members, who sponsored or cosponsored this act 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.

Section 11. Although this bill would have as its purpose or effect the requirement of a new or increased expenditure of local funds, the bill is excluded from further requirements and application under Amendment 621, now appearing as Section 111.05 of the Official Recompilation of the Constitution of Alabama of 1901, as amended, because the bill defines a new crime or amends the definition of an existing crime.

Section 12. Any provision of this act held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable herefrom and shall not affect the remainder hereof or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

Section 13. This act shall become effective 90 days from Governor signing.

Senate

Read for the first time and referred to the Senate committee on Health	29-MAR-11
Read for the second time and placed on the calendar	06-APR-11
Read for the third time and passed as amended	24-MAY-11

Yeas 26
Nays 6

Patrick Harris
Secretary