

1 SB6
2 127457-2
3 By Senator Allen
4 RFD: Health
5 First Read: 07-FEB-12
6 PFD: 06/13/2011

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8 SYNOPSIS: This bill would establish the
9 Abortion-Inducing Drug Safety Act.

10 This bill would provide legislative findings
11 and purposes.

12 This bill would make it unlawful to
13 administer any abortion-inducing drug to a woman
14 without her receiving an exam by a physician.

15 This bill would provide a physician with
16 guidelines to follow in administering an
17 abortion-inducing drug.

18 This bill provides for criminal and civil
19 penalties.

20 Amendment 621 of the Constitution of Alabama
21 of 1901, now appearing as Section 111.05 of the
22 Official Recompilation of the Constitution of
23 Alabama of 1901, as amended, prohibits a general
24 law whose purpose or effect would be to require a
25 new or increased expenditure of local funds from
26 becoming effective with regard to a local
27 governmental entity without enactment by a 2/3 vote

1 unless: it comes within one of a number of
2 specified exceptions; it is approved by the
3 affected entity; or the Legislature appropriates
4 funds, or provides a local source of revenue, to
5 the entity for the purpose.

6 The purpose or effect of this bill would be
7 to require a new or increased expenditure of local
8 funds within the meaning of the amendment. However,
9 the bill does not require approval of a local
10 governmental entity or enactment by a 2/3 vote to
11 become effective because it comes within one of the
12 specified exceptions contained in the amendment.

13
14 A BILL
15 TO BE ENTITLED
16 AN ACT

17
18 To establish the Abortion-Inducing Drug Safety Act;
19 to provide findings and define terms; to provide guidelines
20 for abortion-inducing drugs; to provide criminal penalties and
21 civil remedies for violations; and in connection therewith
22 would have as its purpose or effect the requirement of a new
23 or increased expenditure of local funds within the meaning of
24 Amendment 621 of the Constitution of Alabama of 1901, now
25 appearing as Section 111.05 of the Official Recompilation of
26 the Constitution of Alabama of 1901, as amended.

27 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

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

3 Section 2. The Legislature hereby finds and
4 declares:

5 (1) The Food and Drug Administration (FDA) approved
6 the drug mifepristone, a first-generation (selective)
7 progesterone receptor modulator (SPRM), as an
8 abortion-inducing drug with a specific gestation, dosage, and
9 administration protocol.

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

18 (3) The aforementioned treatment requires three
19 in-person office visits by the patient, and the dosages may
20 only be administered in a clinic, medical office, or hospital
21 and under supervision of a physician.

22 (4) Court testimony by Planned Parenthood and other
23 physicians demonstrates that physicians routinely fail to
24 follow the mifepristone protocol as tested and approved by the
25 FDA.

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

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

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

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

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

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

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

17 (1) ABORTION. The act of using or prescribing any
18 instrument, medicine, drug, or any other substance, device, or
19 means with the intent to terminate the clinically diagnosable
20 pregnancy of a woman, with knowledge that the termination by
21 those means will with reasonable likelihood cause the death of
22 the unborn child. Such use, prescription, or means is not an
23 abortion if done with the intent to:

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

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

1 c. Remove an ectopic pregnancy.

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

4 (2) ABORTION-INDUCING DRUG. A medicine, drug, or any
5 other substance prescribed or dispensed with the intent of
6 terminating the clinically diagnosable pregnancy of a woman,
7 with knowledge that the termination will with reasonable
8 likelihood cause the death of the unborn child. This includes
9 off-label use of drugs known to have abortion-inducing
10 properties, which are prescribed specifically with the intent
11 of causing an abortion, such as misoprostol (Cytotec), and
12 methotrexate. This definition does not apply to drugs that may
13 be known to cause an abortion, but which are prescribed for
14 other medical indications (e.g., chemotherapeutic agents,
15 diagnostic drugs, etc.).

16 (3) DEPARTMENT. The Department of Public Health.

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

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

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

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

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

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

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

11 (b) It shall be unlawful to knowingly give, sell,
12 dispense, administer, otherwise provide, or prescribe any
13 abortion-inducing drug to a pregnant woman for the purpose of
14 inducing an abortion in that pregnant woman, or enabling
15 another person to induce an abortion in a pregnant woman,
16 unless the person who gives, sells, dispenses, administers, or
17 otherwise provides or prescribes the abortion-inducing drug is
18 a physician, and the provision or prescription of the
19 abortion-inducing drug satisfies the protocol tested is
20 authorized by the FDA as outlined in the drug label for the
21 abortion-inducing drug.

22 (c) Because the failure and complications from
23 medical abortion increase with increasing gestational age,
24 because the physical symptoms of medical abortion can be
25 identical to the symptoms of ectopic pregnancy, and because
26 abortion-inducing drugs do not treat ectopic pregnancies but
27 rather are contraindicated in ectopic pregnancies, the

1 physician giving, selling, dispensing, administering, or
2 otherwise providing or prescribing the abortion-inducing drug
3 must first examine in person the woman and document, in the
4 woman's medical chart, gestational age and intrauterine
5 location of the pregnancy prior to giving, selling,
6 dispensing, administering, or otherwise providing or
7 prescribing the abortion-inducing drug.

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

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

13 (2) Have a signed contract with a physician who
14 agrees to handle complications and be able to produce that
15 signed contract on demand by the patient or by the department.

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

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

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

26 (6) Provide a brief description of the efforts made
27 to comply with this subdivision, including the date, time, and

1 identification by name of the person making the efforts, shall
2 be included in the woman's medical record.

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

8 Section 6. If a physician provides an
9 abortion-inducing drug to another for the purpose of inducing
10 an abortion as authorized in this act, and if the physician
11 knows that the person who uses the abortion-inducing drug for
12 the purpose of inducing an abortion experiences during or
13 after the use an adverse event, as defined by the FDA, the
14 physician shall provide a written report of the event within
15 three days to the FDA via the Medwatch Reporting System and to
16 the department.

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

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

23 Section 8. (a) In addition to whatever remedies are
24 available under the common or statutory law of this state,
25 failure to comply with the requirements of this act shall:

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

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

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

5 (b) No civil liability may be assessed against the
6 pregnant woman upon whom the drug-induced abortion is
7 performed.

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

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

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

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

21 Section 10. The Legislature, by joint resolution,
22 may appoint one or more of its members, who sponsored or
23 cosponsored this act in his or her official capacity, to
24 intervene as a matter of right in any case in which the
25 constitutionality of this law is challenged.

26 Section 11. Although this bill would have as its
27 purpose or effect the requirement of a new or increased

1 expenditure of local funds, the bill is excluded from further
2 requirements and application under Amendment 621, now
3 appearing as Section 111.05 of the Official Recompilation of
4 the Constitution of Alabama of 1901, as amended, because the
5 bill defines a new crime or amends the definition of an
6 existing crime.

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

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