

1 SB96
2 127457-1
3 By Senator Allen
4 RFD: Health
5 First Read: 07-FEB-12
6 PFD: 01/25/2012

2
3
4
5
6
7
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

1 governmental entity without enactment by a 2/3 vote
2 unless: it comes within one of a number of
3 specified exceptions; it is approved by the
4 affected entity; or the Legislature appropriates
5 funds, or provides a local source of revenue, to
6 the entity for the purpose.

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

14
15 A BILL
16 TO BE ENTITLED
17 AN ACT
18

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

1 appearing as Section 111.05 of the Official Recompilation of
2 the Constitution of Alabama of 1901, as amended.

3 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

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

6 Section 2. The Legislature hereby finds and
7 declares:

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

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

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

25 (4) Court testimony by Planned Parenthood and other
26 physicians demonstrates that physicians routinely fail to

1 follow the mifepristone protocol as tested and approved by the
2 FDA.

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

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

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

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

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

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

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

21 (1) ABORTION. The act of using or prescribing any
22 instrument, medicine, drug, or any other substance, device, or
23 means with the intent to terminate the clinically diagnosable
24 pregnancy of a woman, with knowledge that the termination by
25 those means will with reasonable likelihood cause the death of

1 the unborn child. Such use, prescription, or means is not an
2 abortion if done with the intent to:

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

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

7 c. Remove an ectopic pregnancy.

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

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

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

23 (4) DRUG LABEL or DRUG'S LABEL. The pamphlet
24 accompanying an abortion-inducing drug which outlines the
25 protocol tested and authorized by the U.S. Food and Drug

1 Administration (FDA) and agreed upon by the drug company
2 applying for FDA authorization of that drug.

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

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

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

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

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

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

17 (b) It shall be unlawful to knowingly give, sell,
18 dispense, administer, otherwise provide, or prescribe any
19 abortion-inducing drug to a pregnant woman for the purpose of
20 inducing an abortion in that pregnant woman, or enabling
21 another person to induce an abortion in a pregnant woman,
22 unless the person who gives, sells, dispenses, administers, or
23 otherwise provides or prescribes the abortion-inducing drug is
24 a physician, and the provision or prescription of the
25 abortion-inducing drug satisfies the protocol tested is

1 authorized by the FDA as outlined in the drug label for the
2 abortion-inducing drug.

3 (c) Because the failure and complications from
4 medical abortion increase with increasing gestational age,
5 because the physical symptoms of medical abortion can be
6 identical to the symptoms of ectopic pregnancy, and because
7 abortion-inducing drugs do not treat ectopic pregnancies but
8 rather are contraindicated in ectopic pregnancies, the
9 physician giving, selling, dispensing, administering, or
10 otherwise providing or prescribing the abortion-inducing drug
11 must first examine in person the woman and document, in the
12 woman's medical chart, gestational age and intrauterine
13 location of the pregnancy prior to giving, selling,
14 dispensing, administering, or otherwise providing or
15 prescribing the abortion-inducing drug.

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

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

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

24 (3) Provide every pregnant woman write the name and
25 phone number of the physician who will be handling

1 emergencies, and the hospital at which any emergencies will be
2 handled.

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

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

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

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

18 Section 6. If a physician provides an
19 abortion-inducing drug to another for the purpose of inducing
20 an abortion as authorized in this act, and if the physician
21 knows that the person who uses the abortion-inducing drug for
22 the purpose of inducing an abortion experiences during or
23 after the use an adverse event, as defined by the FDA, the
24 physician shall provide a written report of the event within
25 three days to the FDA via the Medwatch Reporting System and to
26 the department.

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

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

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

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

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

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

16 (b) No civil liability may be assessed against the
17 pregnant woman upon whom the drug-induced abortion is
18 performed.

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

24 (d) If judgment is rendered in favor of the
25 plaintiff, the court shall also render judgment for a

1 reasonable attorney's fee in favor of the plaintiff against
2 the defendant.

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

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

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

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

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

1 provision to other persons not similarly situated or to other,
2 dissimilar circumstances.

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