109TH CONGRESS
2D SESSION

S. 3939

To require the Food and Drug Administration to establish restrictions regarding the qualifications of physicians to prescribe the abortion drug commonly known as RU–486.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 26, 2006

Mr. VITTER (for himself, Mr. INHOFE, Mr. BROWNBACK, and Mr. SANTORUM) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To require the Food and Drug Administration to establish restrictions regarding the qualifications of physicians to prescribe the abortion drug commonly known as RU–486.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''RU–486 Patient Health and Safety Protection Act''.

SEC. 2. ESTABLISHMENT OF RESTRICTIONS REGARDING PRESCRIBING OF CERTAIN ABORTION DRUG.

(a) IN GENERAL.—With respect to the application that was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the drug mifepristone (commonly referred to as RU–486, marketed as MIFEPREX), and that was approved on September 28, 2000, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall within 90 days of the date of enactment of this Act, modify the conditions of the approval of such drug to establish the additional restriction that the drug may not be prescribed or administered by any person other than a licensed physician who meets the following requirements:

(1) The physician is qualified to personally handle complications resulting from an incomplete abortion or ectopic pregnancy.

(2) The physician has been trained to perform surgical abortions and has met all current applicable legal requirements to perform such abortions.

(3) The physician is qualified for ultrasound dating of pregnancy and detecting of ectopic pregnancy.

(4) The physician has completed a program regarding the prescribing of such drug that uses a

curriculum approved by the Secretary in accordance with subsection (c)(1).

(5) The physician has admitting privileges at a hospital to which the physician can travel in one hour or less, determined on the basis of starting at the principal medical office of the physician and traveling to the hospital, using the transportation means normally used by the physician to travel to the hospital, and under the average conditions of travel for the physician.

(6) The physician has been trained to recognize and treat afebrile infections, in accordance with guidelines established under subsection (c)(2).

(b) INFORMATIONAL REQUIREMENTS.—With respect to information provided to patients in connection with the prescription of the drug referred to in subsection (a), the Secretary of Health and Human Services shall require that such patient information include—

(1) an additional strongly worded warning (as determined by the Secretary of Health and Human Services) regarding the nature of life-threatening afebrile infections and instructions on how to recognize afebrile infections, including the fact that women taking RU–486 and an accompanying prostaglandin for abortion have died from afebrile

infections, hemmorage, heart attack, and rupture of undetected ectopic pregnancies; and

(2) an additional strongly worded warning (as determined by the Secretary) against all possible deviations from the FDA-approved methods of administration, such as reduced dosage, increased dosage, failure to return for supervised administration on day 3, and vaginal self-administration of misoprostol.

(c) GUIDELINES.—

(1) CURRICULUM.—The Secretary of Health and Human Services shall establish guidelines for the review and approval of curriculum to be used for purposes of subsection (a)(4).

(2) TRAINING.—The Secretary of Health and Human Services shall establish guidelines for the training of physicians for purposes of subsection (a)(6).

(d) LIMITATION.—With respect to the administration of a drug referred to in subsection (a), a physician shall not deviate from the Food and Drug Administration approved methods of administration of such a drug.

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