MISSISSIPPI LEGISLATURE REGULAR SESSION 2013

By: Senator(s) Hill, Gandy, Hudson, Smith, McDaniel

To: Public Health and Welfare

COMMITTEE SUBSTITUTE
FOR
SENATE BILL NO. 2795

AN ACT TO CREATE WOMEN'S HEALTH DEFENSE ACT OF 2013; TO DECLARE CERTAIN FINDINGS OF THE LEGISLATURE; TO MAKE IT UNLAWFUL TO KNOWINGLY PROVIDE OR PRESCRIBE ANY ABORTION-INDUCING DRUG TO A PREGNANT WOMAN FOR THE PURPOSE OF INDUCING AN ABORTION IN THAT PREGNANT WOMAN UNLESS THE PERSON WHO 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 FDA AND AS OUTLINED IN THE DRUG LABEL FOR THE ABORTION-INDUCING DRUG; TO REQUIRE THE PHYSICIAN PROVIDING OR PRESCRIBING ANY ABORTION-INDUCING DRUG TO SCHEDULE A 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; TO REQUIRE PHYSICIANS WHO PROVIDE AN ABORTION-INDUCING DRUG TO ANOTHER FOR THE PURPOSE OF INDUCING AN ABORTION TO REPORT THOSE ACTIONS TO THE STATE DEPARTMENT OF HEALTH, AND TO REPORT ADVERSE EVENTS FROM THE USE OF THE ABORTION-INDUCING DRUG TO THE FDA AND TO THE STATE BOARD OF MEDICAL LICENSURE; TO PROVIDE THAT A PERSON WHO INTENTIONALLY, KNOWINGLY OR RECKLESSLY VIOLATES ANY PROVISION OF THIS ACT IS GUILTY OF A MISDEMEANOR; TO PROVIDE THAT FAILURE TO COMPLY WITH THE REQUIREMENTS OF THIS ACT SHALL PROVIDE A BASIS FOR A CIVIL MALPRACTICE ACTION FOR ACTUAL AND PUNITIVE DAMAGES, PROVIDE A BASIS FOR A PROFESSIONAL DISCIPLINARY ACTION AGAINST A PHYSICIAN, AND PROVIDE A BASIS FOR RECOVERY FOR THE WOMAN'S SURVIVORS FOR THE WRONGFUL DEATH OF THE WOMAN; TO AMEND SECTION 73-25-29, MISSISSIPPI CODE OF 1972, TO CONFORM TO THE PRECEDING PROVISIONS; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. This act may be known and cited as the "Women's Health Defense Act of 2013."

SECTION 2. (1) The Legislature finds that:

(a) The Food and Drug Administration (FDA) approved the drug mifepristone, a first-generation [selective] progesterone receptor modulator ([S]PRM), as an abortion-inducing drug with a specific gestation, dosage and administration protocol.

(b) As approved by the FDA, and as outlined in the drug label, an abortion by mifepristone consists of three (3) two hundred (200) milligrams tablets of mifepristone taken orally, followed by two (2) two hundred (200) micrograms tablets of misopristol taken orally, through forty-nine (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. This FDA-approved protocol is referred to as the "Mifeprex regimen."

(c) The aforementioned treatment 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.

(d) The Mifeprex final printed labeling (FPL) outlines the FDA-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol.

(e) Court testimony by Planned Parenthood and other physicians demonstrates that physicians routinely fail to follow

the Mifeprex regimen as approved by the FDA, and as outlined in the Mifeprex Final Printed Labeling.

(f) Specifically, Planned Parenthood and other physicians are administering a single oral dose of two hundred (200) milligrams of mifepristone, followed by a single vaginal or buccal dose of eight-tenths (0.8) milligrams misoprostol, through sixty-three (63) days LMP, without medical supervision, and without follow-up care.

(g) The use of mifepristone presents significant medical risks to women, including, but not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, pelvic inflammatory disease, severe bacterial infection and death.

(h) 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.

(i) In July 2011, the FDA reported two thousand two hundred seven (2,207) adverse events in the United Sates after women used the Mifeprex regimen for the termination of pregnancy. Among those were fourteen (14) deaths, six hundred twelve (612) hospitalizations, three hundred thirty-nine (339) blood transfusions, and two hundred fifty-six (256) infections (including forty-eight (48) "severe infections").

(j) "Off-label" or so-called "evidence-based" use of the Mifeprex regimen can be deadly. To date, fourteen (14) women have reportedly died after administration of the Mifeprex regimen, with eight (8) deaths attributed to severe bacterial infection. All eight (8) of those women administered the regimen in an "off-label" or "evidence-based" manner advocated by abortion providers.

(k) Medical evidence demonstrates that women who utilize abortion-inducing drugs incur more complications than those who have surgical abortions.

(2) Based on the findings in subsection (1) of this section, it is the purpose of this act to:

(a) Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, but not limited to, the Mifeprex regimen.

(b) Ensure that physicians abide by the protocol approved by the FDA for such abortion-inducing drugs, as outlined in the drug labels.

SECTION 3. As used in this act, the following terms shall have the meanings ascribed herein unless the context indicates otherwise:

(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. 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 that are prescribed for other medical indications (e.g., chemotherapeutic agents and diagnostic drugs). Use of those drugs to induce abortion is also known as "medical abortion."

(b) "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. That use, prescription or means is not an abortion if done with the intent to:

(i) Save the life or preserve the health of the 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.

(c) "Department" means the State Department of Health.

(d) "Final printed labeling (FPL)" means the FDA-approved informational document for an abortion-inducing drug

which outlines the protocol authorized by the FDA and agreed upon by the drug company applying for FDA authorization of that drug.

(e) "LMP" or "gestational age" means the time that has elapsed since the first day of the woman's last menstrual period.

(f) "Mifeprex regimen" means the abortion-inducing drug regimen that involves administration of mifepristone (brand name "Mifeprex") and misoprostol. It is the only abortion-inducing drug regimen approved by the FDA. It is also known as the "RU-486 regimen" or simply "RU-486."

(g) "Mifepristone" means the first drug used in the Mifeprex regime.

(h) "Misopristol" means the second drug used in the Mifeprex regimen.

(i) "Physician" means any person licensed to practice medicine in this state. The term includes medical doctors and doctors of osteopathy.

(j) "Pregnant" or "pregnancy" means that female reproductive condition of having an unborn child in the woman's uterus.

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

SECTION 4. (1) It shall be unlawful to knowingly give, sell, dispense, administer or 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 authorized by the FDA and as outlined in the Final Printed Labeling (FPL) for the abortion-inducing drug. In the case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (Mifeprex) and misoprostol.

(2) 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 the woman and document, in the woman's medical chart, gestational age and intrauterine location of the pregnancy before giving, selling, dispensing, administering or otherwise providing or prescribing the abortion-inducing drug.

(3) Every pregnant woman to whom a physician gives, sells, dispenses, administers or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug's label.

(4) The physician giving, selling, dispensing, administering or otherwise providing or prescribing the abortion-inducing drug must 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. Every pregnant woman to whom a physician gives, sells, dispenses, administers or 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 any emergencies will be handled. 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.

(5) The physician giving, selling, dispensing, administering or otherwise providing or prescribing any abortion-inducing drug, or an agent of the physician, must schedule a follow-up visit for the woman at approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding. The physician or agent of the physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment. A brief description of the efforts made to comply with this subsection, including the date, time and identification

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

SECTION 5. (1) If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in Section 4 of this act:

(a) The physician shall report that action to the department; and

(b) If the physician knows that the woman 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 serious event within three (3) days of the event to the FDA via the Medwatch Reporting System and to the State Board of Medical Licensure, which shall compile and retain all reports it receives under this section. No identifying information of the woman shall be reported to the State Board of Medical Licensure.

(2) For the purposes of this section, "adverse event" shall be defined according to the FDA criteria given in the Medwatch Reporting System.

SECTION 6. (1) A person who intentionally, knowingly or recklessly violates any provision of this act is guilty of a misdemeanor.

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

SECTION 7. (1) In addition to any remedies that are available under the statutory laws of this state, failure to comply with the requirements of this act shall:

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

(b) Provide a basis for a professional disciplinary action under Section 73-25-29; and

(c) Provide a basis for recovery for the woman's survivors for the wrongful death of the woman under Section 11-7-13.

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

(3) 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.

(4) 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 8. (1) Nothing in this act shall be construed as creating or recognizing a right to abortion.

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

SECTION 9. 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 to give it the maximum effect permitted by law, unless the holding is one of utter invalidity or unenforceability, in which event the provision shall be deemed severable from this act and shall not affect the remainder of the act or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

SECTION 10. Section 73-25-29, Mississippi Code of 1972, is amended as follows:

73-25-29. The grounds for the nonissuance, suspension, revocation or restriction of a license or the denial of reinstatement or renewal of a license are:

(1) Habitual personal use of narcotic drugs, or any other drug having addiction-forming or addiction-sustaining liability.

(2) Habitual use of intoxicating liquors, or any beverage, to an extent which affects professional competency.

(3) Administering, dispensing or prescribing any narcotic drug, or any other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice.

(4) Conviction of violation of any federal or state law regulating the possession, distribution or use of any narcotic

drug or any drug considered a controlled substance under state or federal law, a certified copy of the conviction order or judgment rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(5) Procuring, or attempting to procure, or aiding in, an abortion that is not medically indicated.

(6) Conviction of a felony or misdemeanor involving moral turpitude, a certified copy of the conviction order or judgment rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(7) Obtaining or attempting to obtain a license by fraud or deception.

(8) Unprofessional conduct, which includes, but is not limited to:

(a) Practicing medicine under a false or assumed name or impersonating another practitioner, living or dead.

(b) Knowingly performing any act which in any way assists an unlicensed person to practice medicine.

(c) Making or willfully causing to be made any flamboyant claims concerning the licensee's professional excellence.

(d) Being guilty of any dishonorable or unethical conduct likely to deceive, defraud or harm the public.

(e) Obtaining a fee as personal compensation or gain from a person on fraudulent representation of a disease or

injury condition generally considered incurable by competent medical authority in the light of current scientific knowledge and practice can be cured or offering, undertaking, attempting or agreeing to cure or treat the same by a secret method, which he refuses to divulge to the board upon request.

(f) Use of any false, fraudulent or forged statement or document, or the use of any fraudulent, deceitful, dishonest or immoral practice in connection with any of the licensing requirements, including the signing in his professional capacity any certificate that is known to be false at the time he makes or signs such certificate.

(g) Failing to identify a physician's school of practice in all professional uses of his name by use of his earned degree or a description of his school of practice.

(9) The refusal of a licensing authority of another state or jurisdiction to issue or renew a license, permit or certificate to practice medicine in that jurisdiction or the revocation, suspension or other restriction imposed on a license, permit or certificate issued by such licensing authority which prevents or restricts practice in that jurisdiction, a certified copy of the disciplinary order or action taken by the other state or jurisdiction being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(10) Surrender of a license or authorization to practice medicine in another state or jurisdiction or surrender of

membership on any medical staff or in any medical or professional association or society while under disciplinary investigation by any of those authorities or bodies for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this section.

(11) Final sanctions imposed by the United States Department of Health and Human Services, Office of Inspector General or any successor federal agency or office, based upon a finding of incompetency, gross misconduct or failure to meet professionally recognized standards of health care; a certified copy of the notice of final sanction being prima facie evidence thereof. As used in this paragraph, the term "final sanction" means the written notice to a physician from the United States Department of Health and Human Services, Officer of Inspector General or any successor federal agency or office, which implements the exclusion.

(12) Failure to furnish the board, its investigators or representatives information legally requested by the board.

(13) Violation of any provision(s) of the Medical Practice Act or the rules and regulations of the board or of any order, stipulation or agreement with the board.

(14) Violation(s) of the provisions of Sections 41-121-1 through 41-121-9 relating to deceptive advertisement by health care practitioners. This paragraph shall stand repealed on July 1, 2016.

(15) Failure to comply with the requirements of Sections 1 through 9 of this act.

In addition to the grounds specified above, the board shall be authorized to suspend the license of any licensee for being out of compliance with an order for support, as defined in Section 93-11-153. The procedure for suspension of a license for being out of compliance with an order for support, and the procedure for the reissuance or reinstatement of a license suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license suspended for that purpose, shall be governed by Section 93-11-157 or 93-11-163, as the case may be. If there is any conflict between any provision of Section 93-11-157 or 93-11-163 and any provision of this chapter, the provisions of Section 93-11-157 or 93-11-163, as the case may be, shall control.

SECTION 11. This act shall take effect and be in force from and after July 1, 2013.