HOUSE BILL NO. 171

INTRODUCED BY S. GREEF

A BILL FOR AN ACT ENTITLED: “AN ACT ADOPTING THE MONTANA ABORTION-INDUCING DRUG RISK PROTOCOL ACT; PROVIDING REQUIREMENTS FOR PROVIDING ABORTION-INDUCING DRUGS TO PREGNANT WOMEN; PROHIBITING PROVIDING ABORTION-INDUCING DRUGS IN SCHOOLS AND ON SCHOOL GROUNDS; REQUIRING INFORMED CONSENT; PROVIDING FOR THE REPORTING OF CHEMICAL ABORTIONS AND ADVERSE EVENTS AND COMPLICATIONS; PROVIDING DEFINITIONS; AND PROVIDING PENALTIES, CIVIL REMEDIES, AND PROFESSIONAL SANCTIONS.”

WHEREAS, in September 2000, the U.S. Food and Drug Administration (FDA) approved the distribution and use of mifepristone (brand name Mifeprex), originally referred to as “RU-486”, an abortion-inducing drug, under the authority of 21 C.F.R. 314.520, also referred to as “Subpart H”, which is the only FDA approval process that allows for postmarketing restrictions. Specifically, the Code of Federal Regulations provides for accelerated approval of certain drugs that are shown to be effective but “can be safely used only if distribution or use is restricted”. The approved FDA protocol for Mifeprex/mifepristone was modified in March 2016; however, the FDA still requires that the distribution and use of Mifeprex/mifepristone be under the supervision of a qualified health care provider who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention or who has made plans to provide surgical intervention through another qualified physician; and

WHEREAS, court testimony by Planned Parenthood and other abortion providers has demonstrated that providers routinely and intentionally failed to follow the September 2000 FDA-approved protocol for Mifeprex/mifepristone. See, e.g., Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006); and

WHEREAS, the use of Mifeprex/mifepristone presents significant medical risks, including but not limited to uterine hemorrhage, viral infections, abdominal pain, cramping, vomiting, headache, fatigue, and pelvic inflammatory disease. Medical evidence demonstrates that women who use abortion-inducing drugs risk four times more complications than those who undergo surgical abortions. At least 3% to 8% of medical abortions

fail to evacuate the pregnancy tissue and require surgical completion. One percent will fail to kill the fetus. If surgical completion is required after a failed medical abortion, the risk of premature delivery in a subsequent pregnancy is more than three times higher. Failure rates increase as gestational age increases. The gestational age range of 63 to 70 days has been inadequately studied. The 2016 FDA gestational age extension was based on only one study worldwide of little more than 300 women; and

WHEREAS, a woman's ability to provide informed consent depends on the extent to which the woman receives information sufficient to make an informed choice. The decision to abort "is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and consequences". Planned Parenthood v. Danforth, 428 U.S. 52, 67 (1976); and

WHEREAS, in recent years, physicians have developed a method to potentially reverse the effects of Mifeprex/mifepristone. This abortion pill reversal or "rescue" process has been discussed in a peer-reviewed study and is based on decades of the safe use of progesterone to stabilize and continue pregnancies. Progesterone has been used safely in pregnancies for decades and is used in in vitro fertilization, infertility treatments, and high-risk pregnancies, including those experiencing preterm labor. Using progesterone to reverse the effects of Mifeprex/mifepristone is a targeted response that is safe for the woman; and

WHEREAS, abortion "record keeping and reporting provisions that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy are permissible". Planned Parenthood v. Danforth, 428 U.S. 80 at 52, 79-81 (1976).

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

NEW SECTION. **Section 1. Short title.** [Sections 1 through 14] may be cited as the "Montana Abortion-Inducing Drug Risk Protocol Act".

NEW SECTION. **Section 2. Legislative findings and purpose.** The purpose of [sections 1 through 14] is to further the important and compelling state interests of:

(1) protecting the health and welfare of a woman considering a chemical abortion;

(2) ensuring that a medical practitioner examines a woman prior to dispensing an abortion-inducing

drug in order to confirm the gestational age of the unborn child, the intrauterine location of the unborn child, and that the unborn child is alive because the routine administration of an abortion-inducing drug following spontaneous miscarriage is unnecessary and exposes the woman to unnecessary risks associated with the abortion-inducing drug;

(3) ensuring that a medical practitioner does not prescribe or dispense an abortion-inducing drug after 70 days have elapsed since the first day of a woman's last menstrual period;

(4) reducing the risk that a woman may elect an abortion only to discover later, with devastating psychological consequences, that the woman's decision was not fully informed;

(5) ensuring that a woman considering a chemical abortion receives comprehensive information on abortion-inducing drugs, including the potential to reverse the effects of the drugs if the woman changes the woman's mind, and that a woman submitting to an abortion does so only after giving voluntary and fully informed consent to the procedure; and

(6) promoting the health and safety of women by adding to the sum of medical and public health knowledge through the compilation of relevant data on chemical abortions performed in the state as well as data on all medical complications and maternal deaths resulting from these abortions.

NEW SECTION. **Section 3. Definitions.** As used in [sections 1 through 14], the following definitions apply:

(1) "Abortion" means the act of using or prescribing an 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 termination by those means will with reasonable likelihood cause the death of the unborn child. The term does not include an act to terminate a pregnancy with the intent to:

(a) save the life or preserve the health of the unborn child;

(b) remove a dead unborn child caused by spontaneous abortion;

(c) remove an ectopic pregnancy; or

(d) treat a maternal disease or illness for which the prescribed drug is indicated.

(2) "Abortion-inducing drug" or "chemical abortion" means a medicine, drug, or any other substance provided 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 the off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as mifepristone, misoprostol, and methotrexate. The term does not include drugs that may be known to cause an abortion that are prescribed for other medical indications.

(3) "Adverse event" means an untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. The term does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

(4) "Associated medical practitioner" means a person authorized under 50-20-109 to perform an abortion who has entered into an associated medical practitioner agreement.

(5) "Complication" means an adverse physical or psychological condition arising from the performance of an abortion, including but not limited to uterine perforation, cervical perforation, infection, heavy or uncontrolled bleeding, hemorrhage, blood clots resulting in pulmonary embolism or deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion, pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, metabolic disorder, shock, embolism, coma, placenta previa in subsequent pregnancies, preterm delivery in subsequent pregnancies, free fluid in the abdomen, hemolytic reaction due to the administration of ABO-incompatible blood or blood products, adverse reactions to anesthesia and other drugs, subsequent development of breast cancer, death, psychological complications such as depression, suicidal ideation, anxiety, and sleeping disorders, and any other adverse event.

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

(7) "Medical practitioner" means a person authorized under 50-20-109 to perform an abortion in this state.

(8) "Pregnant" or "pregnancy" means the female reproductive condition of having an unborn child in the uterus.

(9) "Provide" mean any act of giving, selling, dispensing, administering, transferring possession to, or otherwise providing or prescribing an abortion-inducing drug.

(10) "Qualified medical practitioner" means a medical practitioner who has the ability to:

(a) identify and document a viable intrauterine pregnancy;

(b) assess the gestational age of pregnancy and inform the woman of gestational age-specific risks;

(c) diagnose ectopic pregnancy;

(d) determine blood type and administer RhoGAM if a woman is Rh negative;

(e) assess for signs of domestic abuse, reproductive control, human trafficking, and other signals of coerced abortion;

(f) provide surgical intervention or who has entered into a contract with another qualified medical practitioner to provide surgical intervention; and

(g) supervise and bear legal responsibility for any agent, employee, or contractor who is participating in any part of a procedure, including but not limited to preprocedure evaluation and care.

(11) "Unborn child" means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born alive as defined in 1 U.S.C. 8(b).

NEW SECTION. **Section 4. In-person requirement.** An abortion-inducing drug may be provided only by a qualified medical practitioner following the procedures set forth in [sections 1 through 14]. A manufacturer, supplier, medical practitioner, qualified medical practitioner, or any other person may not provide an abortion-inducing drug via courier, delivery, or mail service.

NEW SECTION. **Section 5. Distribution of abortion-inducing drugs.** (1) Because the failure and complication rates from a chemical abortion increase with advancing gestational age and because the physical symptoms of chemical abortion can be identical to the symptoms of ectopic pregnancy and abortion-inducing drugs do not treat ectopic pregnancies and are contraindicated in ectopic pregnancies, the qualified medical practitioner providing an abortion-inducing drug shall examine the woman in person and, prior to providing an abortion-inducing drug, shall:

(a) independently verify that a pregnancy exists;

(b) determine the woman’s blood type, and if the woman is Rh negative, be able to and offer to administer RhoGAM at the time of the abortion;

(c) inform the woman that the woman may see the remains of the unborn child in the process of

completing the abortion; and

(d) document in the woman's medical chart the gestational age and intrauterine location of the pregnancy and whether the woman received treatment for Rh negativity, as diagnosed by the most accurate standard of medical care.

(2) A qualified medical practitioner providing an abortion-inducing drug must be credentialed and competent to handle complications management, including emergency transfer, or must have a signed contract with an associated medical practitioner who is credentialed to handle complications and must be able to produce the signed contract on demand by the woman or by the department. Each woman to whom a qualified medical practitioner provides an abortion-inducing drug must be given the name and phone number of the associated medical practitioner.

(3) The qualified medical practitioner providing an abortion-inducing drug, or an agent of the qualified medical practitioner, shall schedule a follow-up visit for the woman at approximately 7 to 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 qualified medical practitioner 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 the efforts, must be included in the woman's medical record.

NEW SECTION. **Section 6. Prohibition on providing abortion-inducing drugs at elementary, secondary, and postsecondary schools.** An abortion-inducing drug may not be provided in an elementary, secondary, or postsecondary school facility or on school grounds.

NEW SECTION. **Section 7. Informed consent requirements for abortion-inducing drugs.** (1) An abortion-inducing drug may not be provided without the informed consent of the pregnant woman to whom the abortion-inducing drug is being provided.

(2) Informed consent to a chemical abortion must be obtained at least 24 hours before the abortion-inducing drug is provided to the pregnant woman, except when, in reasonable medical judgment, compliance with this subsection would pose a greater risk of:

(a) the death of the pregnant woman; or

(b) the substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions, of the pregnant woman.

(3) A form created by the department must be used by a qualified medical practitioner to obtain the consent required prior to providing an abortion-inducing drug.

(4) A consent form is not valid and consent is not sufficient unless:

(a) the woman initials each entry, list, description, or declaration required to be included in the consent form as provided in subsection (5);

(b) the woman signs the consent statement described in subsection (5)(j); and

(c) the qualified medical practitioner signs the qualified medical practitioner declaration described in subsection (5)(k).

(5) The consent form must include, but is not limited to the following:

(a) the probable gestational age of the unborn child as determined by both patient history and ultrasound results used to confirm gestational age;

(b) a detailed description of the steps to complete the chemical abortion;

(c) a detailed list of the risks related to the specific abortion-inducing drug or drugs to be used, including but not limited to hemorrhage, failure to remove all tissue of the unborn child, which may require an additional procedure, sepsis, sterility, and possible continuation of pregnancy;

(d) information about Rh incompatibility, including that if the pregnant woman has an Rh negative blood type, the woman should receive an injection of Rh immunoglobulin at the time of the abortion to prevent Rh incompatibility in future pregnancies, which can lead to complications and miscarriage in future pregnancies;

(e) a description of the risks of complications from a chemical abortion, including incomplete abortion, which increase with advancing gestational age;

(f) information about the possibility of reversing the effects of the chemical abortion if the pregnant woman changes the woman's mind and that time is of the essence;

(g) information that the pregnant woman could see the remains of the unborn child in the process of completing the abortion;

(h) information that initial studies suggest that children born after reversing the effects of an abortion-

inducing drug have no greater risk of birth defects than the general population and that initial studies suggest that there is no increased risk of maternal mortality after reversing the effects of an abortion-inducing drug;

(i) notice that information on and assistance with reversing the effects of abortion-inducing drugs are available in the state-prepared materials; and

(j) an acknowledgment of risks and consent statement, which must be signed by the woman. The statement must include but is not limited to the following declarations, which must be individually initialed by the woman, that:

(i) the woman understands that the abortion-inducing drug regimen or procedure is intended to end the woman's pregnancy and will result in the death of the unborn child;

(ii) the woman is not being forced to have an abortion, the woman has the choice not to have the abortion, and the woman may withdraw the woman's consent to the abortion-inducing drug regimen even after beginning the abortion-inducing drug regimen;

(iii) the woman understands that the chemical abortion regimen or procedure to be used has specific risks and may result in specific complications;

(iv) the woman has been given the opportunity to ask questions about the woman's pregnancy, the development of the unborn child, alternatives to abortion, the abortion-inducing drug or drugs to be used, and the risks and complications inherent to the abortion-inducing drug or drugs to be used;

(v) the woman was specifically told that “information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional who can aid in the reversal of an abortion”;

(vi) the woman has been provided access to state-prepared, printed materials on informed consent for abortion;

(vii) if applicable, the woman has been given the name and phone number of the associated medical practitioner who has agreed to provide medical care and treatment in the event of complications associated with the abortion-inducing drug regimen or procedure;

(viii) the qualified medical practitioner will schedule an in-person follow-up visit for the woman approximately 7 to 14 days after providing the abortion-inducing drug or drugs to confirm that the pregnancy is

completely terminated and to assess the degree of bleeding and other complications;

(ix) the woman has received or been given sufficient information to give the woman's informed consent to the abortion-inducing drug regimen or procedure; and

(x) the woman has a private right of action to sue the qualified medical practitioner under the laws of the state if the woman feels coerced or misled prior to obtaining an abortion and how to access state resources regarding the woman's legal right to obtain relief; and

(k) a qualified medical practitioner declaration that must be signed by the qualified medical practitioner, stating that the qualified medical practitioner has explained the abortion-inducing drug or drugs to be used, has provided all of the information required in this subsection (5) and has answered all of the woman’s questions.

NEW SECTION. **Section 8. Information required in state-prepared materials.** (1) The department shall publish state-prepared, printed materials on informed consent for abortion and shall include the following statement:

“Information on the potential ability of qualified medical practitioners to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional who can aid in the reversal of an abortion.”

(2) The department shall annually review and update, if necessary, the statement requirement under subsection (1).

(3) As part of the informed consent counseling services required in [section 7], the qualified medical practitioner shall inform the pregnant woman about abortion pill reversal and provide the woman with the state-prepared materials described in subsection (1).

NEW SECTION. **Section 9. Reporting on chemical abortions.** (1) For the purpose of promoting maternal health and adding to the sum of medical and public health knowledge through the compilation of relevant data, a report of each chemical abortion performed must be made to the department on forms prescribed by the department. The reports must be completed by the facility in which the abortion-inducing drug

was provided, signed by the qualified medical practitioner who provided the abortion-inducing drug, and transmitted to the department within 15 days after each reporting month.

(2) A report must include, at a minimum, the following information:

(a) identification of the qualified medical practitioner who provided the abortion-inducing drug;

(b) whether the chemical abortion was completed at the facility in which the abortion-inducing drug was provided or at an alternative location;

(c) the referring medical practitioner, agency, or service, if any;

(d) the pregnant woman's county, state, and country of residence;

(e) the pregnant woman's age and race;

(f) the number of previous pregnancies, number of live births, and number of previous abortions of the pregnant woman;

(g) the probable gestational age of the unborn child as determined by both patient history and ultrasound results used to confirm the gestational age. The report must include the date of the ultrasound and gestational age determined on that date.

(h) the abortion-inducing drug or drugs used, the date each was provided to the pregnant woman, and the reason for the abortion, if known;

(i) preexisting medical conditions of the pregnant woman that would complicate the pregnancy, if any;

(j) whether the woman returned for a follow-up examination to determine completion of the abortion procedure and to assess bleeding, the date and results of the follow-up examination, and what reasonable efforts were made by the qualified medical practitioner to encourage the woman to return for a follow-up examination if the woman did not;

(k) whether the woman suffered any complications and, if so, what specific complications arose and what follow-up treatment was needed; and

(l) the amount billed to cover the treatment for specific complications, including whether the treatment was billed to medicaid, private insurance, private pay, or another method, including charges for any physician, hospital, emergency room, prescription or other drugs, laboratory tests, and other costs for treatment rendered.

(3) Reports required under this section may not contain:

(a) the name of the pregnant woman;

(b) common identifiers, such as a social security number or driver's license number; or

(c) other information or identifiers that would make it possible to identify, in any manner or under any circumstances, a pregnant woman who has obtained or seeks to obtain a chemical abortion.

(4) A qualified medical practitioner who provides an abortion-inducing drug to a pregnant woman who knows that the woman experiences, during or after the use of the abortion-inducing drug, an adverse event shall provide a written report of the adverse event within 3 days of the event to the United States food and drug administration via the medwatch reporting system, to the department, and to the state board of medical examiners.

(5) (a) A medical practitioner, qualified medical practitioner, associated medical practitioner, or other health care provider who treats a woman, either contemporaneously to or at any time after a chemical abortion, for an adverse event or complication related to a chemical abortion shall make a report of the adverse event to the department on forms prescribed by the department. The reports must be completed by the facility in which the adverse event or complication treatment was provided, signed by the medical practitioner, qualified medical practitioner, associated medical practitioner, or other health care provider who treated the adverse event or complication, and transmitted to the department within 15 days after each reporting month.

(b) The report must include, at a minimum:

(i) the information required under subsections (2)(a) through (2)(j) and (2)(l); and

(ii) information about the specific complications that arose, whether an emergency transfer was required, and whether any follow-up treatment was needed, including whether additional drugs or medications were provided in order to complete the abortion.

(6) The department shall prepare a comprehensive annual statistical report for the legislature based on the data gathered from reports under this section. The aggregated data must also be made available to the public by the department in a downloadable format.

(7) The department shall summarize aggregate data from the reports required under [sections 1 through 14] and submit the data to the U.S. centers for disease control and prevention for the purpose of inclusion in the annual vital statistics report.

(8) Reports filed pursuant to this section must be deemed public records and must be available to the public in accordance with the confidentiality and public records reporting laws of this state. Original copies of all

reports filed under this section must be available to the state board of medical examiners, state board of pharmacy, state law enforcement officials, and child protective services for use in the performance of their official duties.

(9) Absent a valid court order or judicial subpoena, the department or any other state department, agency, office, or employee may not compare data concerning chemical abortions or abortion complications maintained in an electronic or other information system file with data in any other electronic or other information system, the comparison of which could result in identifying, in any manner or under any circumstances, a woman obtaining or seeking to obtain a chemical abortion.

(10) Statistical information that may reveal the identity of a woman obtaining or seeking to obtain a chemical abortion may not be maintained by the department or any other state department, agency, office, employee, or contractor.

(11) The department shall communicate the reporting requirements of this section to all medical professional organizations, medical practitioners, and facilities operating in the state.

NEW SECTION. **Section 10. Production of reporting forms.** The department shall create and distribute the forms required by [sections 1 through 14] within 60 days after [the effective date of this act].

NEW SECTION. **Section 11. Criminal penalties.** (1) A person who purposely or knowingly or negligently violates any provision of [sections 1 through 14] is guilty of a felony and upon conviction shall be fined an amount not to exceed $50,000, be imprisoned in a state prison for a term not to exceed 20 years, or both. As used in this section, “purposely", "knowingly", and "negligently" have the meanings provided in 45-2-101.

(2) A criminal penalty may not be assessed against the pregnant woman on whom the chemical abortion is attempted or performed.

NEW SECTION. **Section 12. Civil remedies and professional sanctions.** (1) In addition to all other remedies available under the laws of this state, failure to comply with the requirements of [sections 1 through 14]:

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

(b) provides a basis for professional disciplinary action under Title 37 for the suspension or revocation of the license of a health care provider; and

(c) provides a basis for recovery for the woman's survivors for the wrongful death of the woman under 27-1-513.

(2) Civil liability may not be imposed against the pregnant woman on whom the chemical abortion is attempted or performed.

(3) When requested, the court shall allow a woman to proceed using solely the woman's initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman on whom the chemical abortion was attempted or performed.

(4) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for reasonable attorney fees in favor of the plaintiff against the defendant.

(5) If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court may render judgment for reasonable attorney fees in favor of the defendant against the plaintiff.

NEW SECTION. **Section 13. Construction.** [Sections 1 through 14] may not be construed to:

(1) create or recognize a right to abortion;

(2) make lawful an abortion that is otherwise unlawful; or

(3) repeal, replace, or otherwise invalidate existing federal laws, regulations, or policies.

NEW SECTION. **Section 14. Right of intervention.** The legislature, by joint resolution, may appoint one or more of its members, who sponsored or cosponsored [sections 1 through 14] in the member's official capacity, to intervene as a matter of right in any case in which the constitutionality of [sections 1 through 14] is challenged.

NEW SECTION. **Section 15. Codification instruction.** [Sections 1 through 14] are intended to be codified as a new part in Title 50, chapter 20, and the provisions of Title 50, chapter 20, apply to [sections 1

through 14].

NEW SECTION. **Section 16. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

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