ABORTION-INDUCING DRUGS SAFETY ACT (RU-486 & RESPONSE TO "TELEMED" ABORTIONS)

Model Legislation & Policy Guide

For the 2014 Legislative Year

AMERICANS UNITED FOR LIFE

Changing Law to Protect Human Life, State by State

INTRODUCTION

Chemical abortion,[1] such as that caused by the Mifeprex regimen (also known as the RU-486 regimen), has become a veritable "pot of gold" for Planned Parenthood and other abortion providers. Because the Mifeprex regimen is virtually unregulated in the majority of states, abortion providers have been misusing it for years in order to boost their profit margins.

For example, the Food and Drug Administration (FDA) approved the Mifeprex regimen to be used only in the first 49 days following a woman's last menstrual period (LMP), at a clinic or medical facility and under the supervision of a physician, and in the following manner:

- Day One: Mifeprex Administration: Three 200 mg tablets of Mifeprex are taken in a single oral dose
- Day Three: Misoprostol Administration: Two 200 mcg tablets of misoprostol are taken orally
- Day 14: Post-Treatment Examination: The patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medical abortion treatment failures.[2]

However, abortion providers including Planned Parenthood readily admit[3] that they provide the Mifeprex regimen to women up to 63 days LMP and provide women with just a single oral dose of mifepristone, followed by a single dose of misoprostol, which they direct women to administer vaginally or buccally instead of orally. Abortion providers even direct women to take the drugs at home and in the absence of physician oversight. No follow-up care is ensured.

Why the blatant misuse? Certainly not because it is safer for women. Abortion providers misuse the Mifeprex regimen because it is more convenient—and more profitable. By providing it to women through 63 days LMP and sending them home to ingest misoprostol (the second drug) alone, abortion providers can charge more women for abortions, increasing their profits exponentially.

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[1] Chemical abortion involves the ingestion of drugs in order to terminate pregnancy. It is contrasted with surgical abortion procedures, such as dilation & curettage, where the abortion provider physically removes the unborn child.

[2] *See* Mifeprex Final Printed Labeling (FPL), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited July 10, 2013) (hereinafter "Mifeprex FPL"); FDA, *Mifeprex (mifepristone) Information* (July 19, 2011), available at http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111323.htm (last visited July 10, 2013).

[3] Planned Parenthood has documented this misuse in court records in both the Sixth Circuit Court of Appeals and a state court in Arizona. Other abortion providers have documented this misuse in court records in an Oklahoma state court.

That abortion providers' agenda is dominated by financial priorities rather than concern for women's health has been seen in the state of Iowa, where abortion providers began using "telemed" services to provide the Mifeprex regimen (*i.e.*, a "telemed" abortion). Rather than meet with the woman personally, abortion provider Susan Haskell and Planned Parenthood of the Heartland began consulting with patients over Skype or other teleconferencing systems. Under this scheme, Haskell briefly addresses abortion patients from a teleconferencing hook-up from her office in Des Moines. After explaining the medical abortion process, a button is pushed and an electronic drawer opens that contains the drugs. There is no examination, no physician-patient relationship, and no patient follow-up with a physician, but it does allow Haskell the opportunity to provide abortions to more women without ever having to meet with the women in person.

In other words, chemical abortion is the new profit-boosting frontier for abortion providers.

Yet abortion providers misleadingly label this misuse as "evidence-based." However,what the "evidence" really demonstrates is that even the FDA-approved protocol carries significant risks, and misusing the drugs places women at greater risk. The drug manufacturer admits that *"[n]early all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."*[4] These adverse reactions include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.[5]

In fact, in July of 2011, the FDA reported 2,207 adverse events in the U.S. after women used the Mifeprex regimen for the termination of pregnancy. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[6] Of the reported deaths, eight were from severe bacterial infection. All eight women administered misoprostol either vaginally or buccally—*i.e.*, in an off-label, unapproved manner.[7] The FDA has received no reports of women dying from bacterial infection after administering the regimen according to the FDA-approved protocol.[8]

Further, the Mifeprex regimen is particularly dangerous because its side effects are confusingly similar to the symptoms of an ectopic pregnancy. Failing to properly diagnose an ectopic

[4] *See* Mifeprex FPL, *supra* (emphasis added).
[5] *Id*. at 12 (Table 3).
[6] FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011), available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited July 11, 2013).
[7] *Id*.

pregnancy can lead to a rupture of the fallopian tube, causing bleeding, severe pain, and even death.

By failing to follow the FDA protocol, abortion providers are clearly placing women's health and lives even more at risk.

In order to protect women against the risks and misuse of the Mifeprex regimen, AUL has drafted the "Abortion-Inducing Drugs Safety Act," along with detailed talking points. Importantly, this model has been updated to include a requirement that a physician actually examine a woman before providing the Mifeprex regimen (*see* Section 4(b)), effectively precluding the use of so-called "telemed" abortions).

For more information and drafting assistance, please contact AUL's Legislative Coordinator at (202) 289-1478 or Legislation@AUL.org.

DENISE M. BURKE, ESQ.
Vice President of Legal Affairs
Americans United for Life

[8] *Id*.

ABORTION-INDUCING DRUGS SAFETY ACT

[**Drafter's Note:** *AUL has drafted detailed talking points to assist those interested in introducing this model in preparing for and countering arguments typically raised by abortion providers. Those talking points are available upon request by contacting AUL's Legislative Coordinator at (202) 289-1478 or Legislation@AUL.org.*]

HOUSE/SENATE BILL No. _____
By Representatives/Senators _____

Section 1. Title.

This Act may be known and cited as the "Abortion-Inducing Drugs Safety Act."

Section 2. Legislative Findings and Purposes.

[**Drafter's Note:** *Challenges to Mifeprex regulations have demonstrated the necessity of including certain facts related to the Mifeprex regimen in order to make clear the State's intent. It is imperative to include the following findings, as well as the definitions, in the bill or as part of the legislative record.*]

(a) The [*Legislature*] of the State of [*Insert name of State*] finds that:

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

(2) As approved by the FDA, and as outlined in the Mifeprex drug label, an abortion by mifepristone consists of three (3) two-hundred (200) mg tablets of mifepristone taken orally, followed by two (2) two-hundred (200) mcg tablets of misoprostol 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."

(3) 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.

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

(5) Court testimony by Planned Parenthood and other abortion providers demonstrates that providers routinely fail to follow the FDA-approved protocol for the Mifeprex regimen, as it is outlined in the Mifeprex FPL. *See*, *e.g.*, *Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626 (S.D. Oh. 2006).

(6) Specifically, Planned Parenthood and other abortion providers are administering a single oral dose of two-hundred (200) mg of mifepristone, followed by a single *vaginal* or *buccal* dose of eight-tenths (.8) mg misoprostol, through sixty-three (63) days LMP, without medical supervision, and without follow-up care. *See*, *e.g.*, *Planned Parenthood Cincinnati Region*, 459 F. Supp. 2d at 630n.7.

(7) 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, and pelvic inflammatory disease.

(8) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process.

(9) In July 2011, the FDA reported 2,207 adverse events in the U.S. after women used the Mifeprex regimen for the termination of pregnancy. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").

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

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

(b) Based on the findings in Subsection (a) of this Section, it is the purpose of this Act to:

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

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

Section 3. Definitions.

(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 which are prescribed for other medical indications (*e.g.*, chemotherapeutic agents, diagnostic drugs, etc.).

Use of such drugs to induce abortion is also known as **"medical [*and/or chemical*] 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. Such use, prescription, or means is not an abortion if done with the intent to:

(1) Save the life or preserve the health of the unborn child;

(2) Remove a dead unborn child caused by spontaneous abortion;

(3) Remove an ectopic pregnancy; or

(4) Treat a maternal disease or illness for which the prescribed drug is indicated.

(c) "**Department**" means the Department of [*Insert appropriate title*] of the State of [*Insert name of State*].

(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 regimen.

(h) "**Misoprostol**" 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 mother's [*woman's*] uterus.

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

Section 4. Unlawful Distribution of Abortion-Inducing Drug.

(a) It shall be unlawful to knowingly give, sell, dispense, administer, 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 as outlined in the final printed labeling (FPL) for the drug or drug regimen. In the case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (Mifeprex) and misoprostol.

(b) Because the failure and complication rates from medical abortion increase with advancing 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 prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug.

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

(d) The physician giving, selling, dispensing, administering, 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, 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.

(e) The physician giving, selling, dispensing, administering, otherwise providing, or prescribing any abortion-inducing drug, or an agent of said 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. Said physician or agent of 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 such efforts, shall be included in the woman's medical record.

Section 5. Reporting.

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, and 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 adverse event within three (3) days of the event to the FDA via the Medwatch Reporting System [*and to the State Medical Board*].

[*The State Medical Board shall compile and retain all reports it receives under this Section. All reports the Board receives are public records open to inspection under [Insert citation(s) to or appropriate reference(s) to applicable State code section(s) regarding public records]. In no case shall the State Medical Board release to any person or entity the name or any other personal identifying information regarding a person who uses an abortion-inducing drug for the purpose of inducing an abortion and who is the subject of a report the State Medical Board receives under this provision.*]

An "**adverse event**" shall be defined for purposes of this Act according to the FDA criteria given in the Medwatch Reporting System.

[**Drafter's Note:** *Inclusion of the reporting requirements is optional and may be removed without diminishing the effect of the regulation itself.*]

Section 6. Criminal Penalties.

A person who intentionally, knowingly, or recklessly violates any provision of this Act is guilty of a [*Insert appropriate penalty/offense classification*]. In this Section, "**intentionally**" is defined by Section [*Insert section number*] of the [*State Penal Code*].

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

Section 7. Civil Penalties.

(a) In addition to whatever remedies are available under the common or statutory law of this State, failure to comply with the requirements of this Act shall:

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

(2) Provide a basis for a professional disciplinary action under [*Medical Malpractice Act*].

(3) Provide a basis for recovery for the woman's survivors for the wrongful death of the woman under the [*Wrongful Death Act*].

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

(c) 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.

(d) 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. Construction.

(a) Nothing in this Act shall be construed as creating or recognizing a right to abortion.

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

Section 9. Right of Intervention.

The [*Legislature*], by joint resolution, may appoint one or more of its members, who sponsored or cosponsored this Act in his or her official capacity, to intervene as a matter of right in any case in which the constitutionality of this law is challenged.

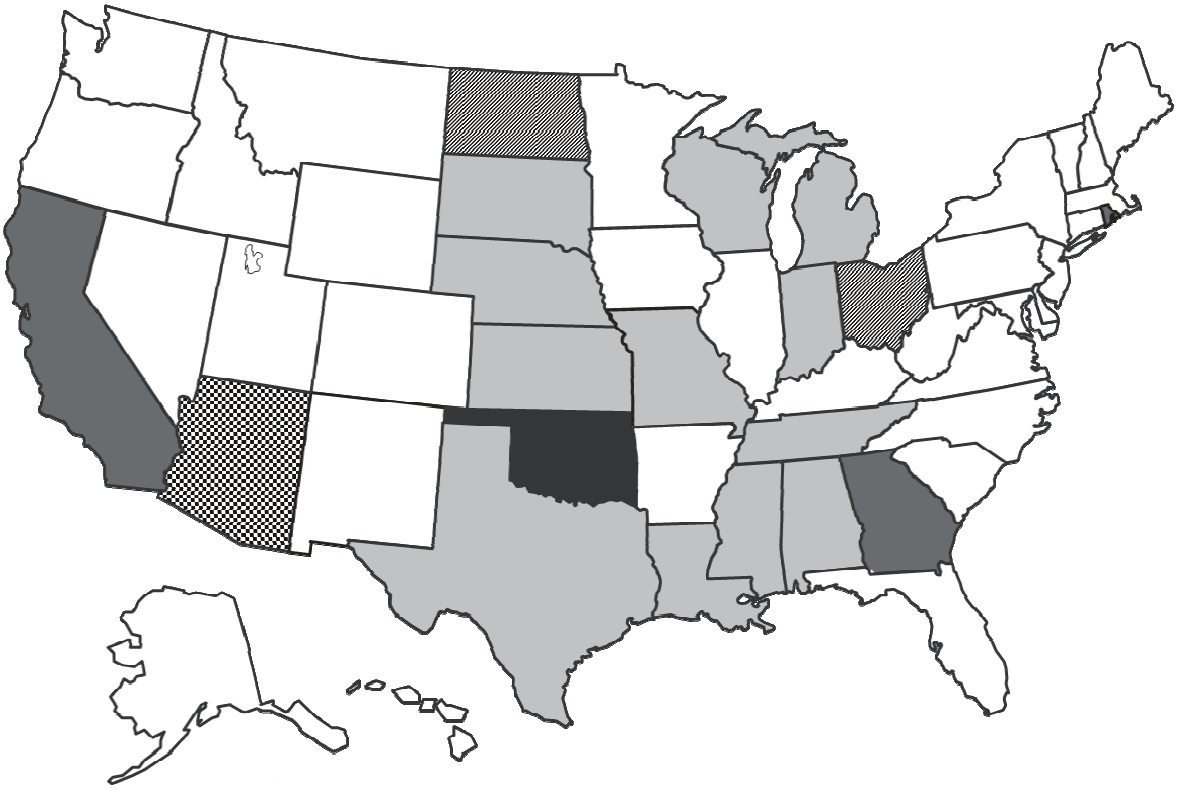
Section 10. Severability.

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 such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable herefrom and shall not affect the remainder hereof or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

Section 11. Effective Date.

This Act takes effect on [*Insert date*].

STATE OF THE STATES: WHERE ARE WE NOW?
RU-486 REGULATIONS



One state maintains comprehensive regulations of abortion-inducing drugs that limit administration to the protocol allowed by the FDA and effectively prohibits "telemed abortions:" AZ.

Two states maintain comprehensive regulations of abortion-inducing drugs that limit administration to the protocol allowed by the FDA and effectively prohibit "telemed abortions," but are currently in litigation: ND and OH (in effect during litigation).

One state maintains comprehensive regulations of abortion-inducing drugs that limit administration to the protocol allowed by the FDA and effectively prohibits "telemed abortions," but only the provisions regulating administration of the drug regimen are in litigation: OK.

Twelve states maintain regulations that effectively prohibit "telemed abortions": AL, IN, KS, LA, MI, MS, MO (awaiting signature as of July 2013), NE, SD, TN, TX, and WI.

Three states specifically impose minimal administrative regulations on the dispensing of abortion-inducing drugs: CA, GA, and RI.

More detailed information about the need and justification for laws regulating abortion-inducing drugs including RU-486 can be found in AUL's annual publication *Defending Life.*

Defending Life 2013, Deconstructing Roe: Abortion's Negative Impact on Women is available online at AUL.org or for purchase at Amazon.com.

For further information regarding this or other AUL policy guides, please contact:

AMERICANS UNITED FOR LIFE
655 15th Street NW, Suite 410
Washington DC 20005
202.289.1478 | Fax 202.289.1473 | Legislation@AUL.org

www.AUL.org