INTRODUCTION

Brenda Vise, a 38-year old pharmaceutical representative, died on September 12, 2001. Holly Patterson, an 18-year old student, died on September 17, 2003. Chanelle Bryant, 22-years old, died on January 14, 2004. Vivian Tran, also 22 years old, died on December 29, 2003. Orianne Shevin, a 34-year old attorney and mother of two, died on June 14, 2005.

What do these women have in common? They all took RU-486, the so-called “abortion pill,” and died—most from a C. Sordelli infection and one from a ruptured ectopic pregnancy. RU-486—a drug that its proponents claim is a “safe” and “easy” method of abortion—has killed at least 29 women worldwide including at least 8 American women.

In 1988, the French government first approved RU-486. However, the U.S. Food and Drug Administration (FDA) initially considered RU-486 dangerous and banned the importation of the drug. Later in 1993, following the wishes of then-President Bill Clinton, the FDA lifted the import ban and the Department of Health and Human Services (HHS) brokered a deal for the drug manufacturer, Roussel-Uclaf, to gratuitously donate the rights to distribute RU-486 in the U.S. to the Population Council, an organization whose mission is to research, develop and introduce birth control methods (including abortion) to control populations—“especially [for] disadvantage populations.”

Since the Population Council is a research and policy organization, not a drug company, it founded Danco Laboratories for the sole purpose of marketing and distributing RU-486 in the U.S. Unable to find a U.S. company willing to manufacture the drug, Danco Laboratories turned to China—a nation known for coerced abortions—and a manufacturer formerly cited by the FDA for tainted drugs.

In September 2000—during the final days of the Clinton Administration—the FDA approved RU-486, or “Mifeprex” (generic name: mifepristone), under its accelerated approval regulations designed to expedite drug approvals for HIV patients. Suddenly, the FDA deemed that the benefits of RU-486 outweighed the risks and required that it receive expedited approval. In other words, the FDA succumbed to intense political pressure from the Population Council and abortion advocates to approve the drug.

On its website and in its literature, Danco Laboratories advertises RU-486 as a “safe” and “easy” abortion option. However, the U.S. trials and subsequent market use are to the contrary. It is neither safe nor easy.
A RU-486 or chemical abortion is, in reality, a long, messy, and dangerous process. RU-486 is a synthetic steroid that requires two drugs and three doctor visits to abort an unborn child at 7 weeks of gestation or less. During the first visit, the woman takes three pills (Mifeprex) to chemically destroy the unborn child’s environment, deprive him/her of nourishment, and subsequently starve the child to death. During the second visit, if the woman is still pregnant she is given a prostaglandin (misoprostol), which causes cramping to expel the child in something similar to a very heavy and painful (and, at times, deadly) menstruation cycle. The third office visit (14 days later) confirms the woman is well and the abortion complete. If the RU-486 abortion is unsuccessful, the women must consider the possibility of birth defects and typically then undergoes a surgical abortion.

During highly-controlled trials conducted from September 1994 to September 1995 and reported in the *New England Journal of Medicine*, RU-486 was shown to involve significant risks of life-threatening complications for even the healthiest of women.

The study cited excessive bleeding as the most serious risk. Excessive bleeding left 4 women needing blood transfusions, 25 women requiring hospitalization (including emergency-room visits), 56 women with “surgical interventions,” and 22 women needing intravenous fluids. To the logical observer, these “adverse events” would equate to “medical emergencies,” but the Population Council dismissed these life-threatening complications as normal and expected with a chemical abortion.

The studies also indicated that women suffered from abdominal pain, nausea, vomiting and diarrhea. Abdominal pain, referred to as “cramps,” was so significant that 68% of women received at least one pain medication and 29% received opiates. One woman was hospitalized for the intense pain and actually needed two “surgical interventions.”

Further, the study results also confirmed that a chemical abortion “procedure” must begin within 49 days of conception, otherwise the baby’s size and development are too advanced and complications are admittedly too severe and dangerous.

Inexplicably, the report paid little attention to the other adverse events women reported including headache (32%); dizziness (12%); back pain (9%); fatigue (9%); fever (4%); vaginitis (4%); viral infections (4%); rigors (3%); dyspepsia (3%); and asthenia, leg pain, anxiety, insomnia, anemia, syncope, leukorrhea, and sinusitis (2% each). And if that is not enough, endometritis occurred in 19 women. These are not just percentages and not simply insignificant statistics, but real women experiencing real complications (some requiring timely, life-saving measures) after taking RU-486.
The Population Council acknowledged that the study showed that RU-486 had a low success rate and attempted to rationalize the discrepancy as merely “a lack of experience with [chemical] abortion in the United States as well as the design of [the] study.” If this is true, then how much lower would the success rate and higher the complication rate be once approved by the FDA and introduced to the uncontrolled and unmonitored marketplace? Unfortunately, U.S. women are finding out first-hand.

Since its September 2000 FDA approval, RU-486 has caused at least 8 deaths, 9 life-threatening incidents, 116 blood transfusions, and 232 hospitalizations for more than 1,100 women in the U.S. who experienced significant medical complications. These numbers are only the incidents reported to and by the FDA and are likely an inadequate reflection of actual incidences.

These results are further complicated by the common practice of abortion providers – including Planned Parenthood clinics – to ignore the FDA-approved protocol for dispensing the drug, taking “shortcuts” that further imperil women’s lives.

In order to protect women against the risks of RU-486, AUL has drafted the “Abortion-Inducing Drugs Safety Act.” For more information and drafting assistance, please contact AUL’s Legislative Coordinator (312) 568-4717 or Legislation@AUL.org.

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ABORTION-INDUCING DRUGS SAFETY ACT

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.

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

(1) The Food and Drug Administration (FDA) approved the drug mifepristone as an abortion-inducing drug with a specific gestation, dosage, and administration protocol.

(2) As tested and approved by the FDA, and as outlined in the drug label, an abortion by mifepristone consists of three oral doses of 200 mg of mifepristone, followed by a single oral dose of .4 mg misoprostol, (more commonly known as the RU-486 regime) through 49 days LMP (a gestational measurement using the first day of the woman’s “last menstrual period” as a marker).

(3) As tested and approved by the FDA, and as outlined in the drug label, the aforementioned treatment requires three office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital under supervision of a physician.

(4) Specifically, on Day One, three 200 mg tablets are taken in a single oral dose; on Day Three, the patient returns and, unless an abortion has occurred and is confirmed, the patient takes two 200 Ag (400 Ag) tablets of misoprostol orally. On Day 14, the patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred.

(5) Court testimony by Planned Parenthood and other physicians demonstrates that physicians routinely fail to follow the mifepristone protocol as tested and approved by the FDA, and as outlined in the drug label. See Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006).
Specifically, Planned Parenthood and other physicians are administering a single oral dose of 200 mg of mifepristone, followed by a single vaginal dose of .8 mg misopristol, through 63 days LMP, without medical supervision, and without follow-up care. *See Planned Parenthood Cincinnati Region*, 459 F. Supp. 2d at 630n.7.

The use of mifepristone presents significant medical risks to women, including but not limited to *C. sordellii* bacterial infection, septic shock, toxic shock syndrome, adult respiratory distress syndrome from sepsis, *Escheria coli* sepsis, group B Streptococcus septicemia, disseminated intravascular coagulopathy (DIC) with hepatic and renal failure, severe pelvic infection, and massive hemorrhage.

“Off-label” use of mifepristone can be deadly. As of September 2007, at least eight American women had died from mifepristone abortions.

Medical studies have indicated that 1 to 2 out of every 1,000 women who undergo drug-induced abortions will require emergency blood transfusion for massive hemorrhage. The FDA has reported that at least 116 women have required blood transfusions for massive bleeding after drug-induced abortions, with at least 54 losing more than half of their blood volume.

The absence of proper follow-up care after drug-induced abortions has resulted in at least 17 women having undetected ectopic pregnancies, eleven of which resulted in ectopic rupture.

These dangerous risks demand strict adherence to the FDA-approved protocol outlined above.

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 mifepristone.

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.

(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 an unborn child;
2. remove a dead unborn child caused by spontaneous abortion; or
3. remove an ectopic pregnancy.

(c) “Department” means the Department of [Insert appropriate title] of the State of [Insert State].

(d) “Drug label” means the pamphlet accompanying an abortion-inducing drug which outlines the protocol tested and authorized by the FDA and agreed upon by the drug company applying for FDA authorization of that drug. Also known as “final printing labeling instructions,” it is the FDA document which delineates how a drug is to be used according to the FDA approval.

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

(f) “Mifepristone” means the specific abortion-inducing drug regimen also known as RU-486.

(g) “Physician” means any person licensed to practice medicine in this State. The term includes medical doctors and doctors of osteopathy.

(h) “Pregnant” or “pregnancy” means that female reproductive condition of having an unborn child in the mother’s [woman’s] uterus.
(i) “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 tested and authorized by the FDA and as outlined in the label for the abortion-inducing drug.

(b) 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.

(c) 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.

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 person 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 24 hours 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 [citation to or

Abortion-Inducing Drugs Safety Act 8 Americans United for Life
appropriate reference 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.

Section 6. Criminal Penalties.

A person who intentionally, knowingly, or recklessly violates any provision of this Act is guilty of a [Insert class of felony or misdemeanor]. 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 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 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 here from 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

- Two states require that RU-486 be administered in compliance with the approved FDA protocol and the drug label (but both laws are in litigation): OH and OK
- Four states specifically impose minimal administrative regulations on the dispensation of RU-486: CA, GA, NC, and RI.
More detailed information about the need and justification for laws regulating abortifacients including RU-486 can be found in AUL’s annual publication *Defending Life 2009: A State by State Legal Guide to Abortion, Bioethics, and the End of Life.*

*Defending Life 2009* is available online at AUL.org or for purchase at Amazon.com.

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

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