
ABORTION PILL REVERSAL INFORMATION ACT

Model Legislation & Policy Guide
For the 2016 Legislative Year



*Accumulating Victories, Building Momentum,
Advancing a Culture of Life in America*

INTRODUCTION

The incidence of chemical abortions,¹ such those using the Mifeprex regimen (also known as the “RU-486 regimen”), is on the rise. The pro-abortion Guttmacher Institute estimates that chemical abortions account for almost 1 in 4 of all abortions—a substantial increase from 2001, when chemical abortions accounted for just 6 percent of all abortions.²

This increase does not come as a surprise. AUL has long warned of an on-going “chemical abortion revolution”—an uptick in drug-induced abortions which are easier to provide and more profitable for the abortion industry. Guttmacher’s report confirms this dangerous trend. Not only is the incidence of chemical abortions on the rise, but 46 percent of chemical abortions occur at non-specialized clinics.³

Unlike surgical abortions, the drugs used in chemical abortions can be dispensed at any physician’s office as opposed to surgical abortions which are most commonly performed in freestanding abortion clinics. As currently practiced by the abortion industry, abortion providers typically spend very little time (if any) with the woman and provide the drugs farther into pregnancy than is approved by the U.S. Food & Drug Administration (FDA). This willful disregard of women’s health and safety has allowed chemical abortions to become a veritable “cash cow” for Planned Parenthood and other abortion providers.

The Mifeprex regimen is currently the only FDA-approved method for terminating a pregnancy using drugs. In this two-drug process, the first drug—mifepristone—is given to block progesterone receptors (progesterone is necessary for the development of the unborn child). The National Abortion Federation (NAF) states that mifepristone alone results in a complete abortion in 60-80 percent of cases.⁴ For instances when mifepristone does not result in a complete termination, a second drug, misoprostol, is used to induce contractions and to expel the “pregnancy” from the uterus.

Because physicians know exactly how mifepristone works—by blocking progesterone—it is possible to reverse the effects of the drug by flooding the woman’s body with progesterone. The

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 Guttmacher Institute, *Induced Abortion in the United States* (July 2014), available at http://www.guttmacher.org/pubs/fb_induced_abortion.html (last visited June 18, 2015).

³ Guttmacher Institute, *Abortion Incidence and Service Availability in the United States*, 2011 (Mar. 2014), available at <http://www.guttmacher.org/pubs/journals/psrh.46e0414.pdf> (last visited June 18, 2015).

⁴ M.D. Creinin & K.G. Danielsson, *Medical Abortion in Early Pregnancy*, in M. Paul et al., eds., *MANAGEMENT OF UNINTENDED & ABNORMAL PREGNANCY: COMPREHENSIVE ABORTION CARE* (Blackwell Pub. Ltd. 2009).

process, which has been discussed in a peer-reviewed study,⁵ is based upon a well-established medical regimen that is used in other areas of healthcare—specifically, methotrexate and “leucovorin rescue.” Methotrexate, a chemotherapy drug, kills rapidly dividing cells (*i.e.*, cancer cells). Specifically, it blocks the action of folic acid. Typically, physicians allow the methotrexate to work for a day or two, and then give the patient a high dose of folic acid (leucovorin) to compensate for what has been lost. This high dosage of folic acid, in essence, “kicks” the methotrexate off of the cells. This flooding of the patient’s body with folic acid is called a “leucovorin rescue” and is a well-established medical procedure.

Similarly, physicians know exactly how mifepristone works (*i.e.*, by blocking progesterone), and they know that treating a woman with progesterone can “kick off” the mifepristone (*i.e.*, displace mifepristone from the progesterone receptors). This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifepristone-induced blockage.

Progesterone itself has been used safely in pregnancies for decades. It is used in *in vitro* fertilization, infertility treatments, and high-risk pregnancies (such as those experiencing pre-term labor). Using progesterone to reverse the effects of mifepristone is a targeted response that is safe for women.

For a woman who quickly regrets her choice to use mifepristone and wishes to continue her pregnancy, knowledge of this potential reversal option could mean the difference between the life and death of her baby. Abortion Pill Reversal, an organization that assists women in locating physicians trained in the reversal process, reports a 55 to 60 percent success rate for women who attempt to reverse the effects of mifepristone. As of June 22, 2015, 107 babies had been born, with another 80 on the way (*i.e.*, still *in utero*), following the abortion pill reversal process.

To ensure that women receive accurate and complete medical information, AUL has drafted informed consent language that requires abortion providers to inform a woman prior to a chemical abortion that she may be able to change her mind and reverse the effects of mifepristone, but that time is of the essence.

⁵ G. Delgado & M.L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, ANNALS OF PHARMACOTHERAPY 46 (Dec. 2012).

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ABORTION PILL REVERSAL INFORMATION ACT

HOUSE/SENATE BILL No. _____

By Representatives/Senators _____

Section 1. Title.

This Act may be known and cited as the “Abortion Pill Reversal Information Act.”

Section 2. Legislative Findings and Purposes.

- (a) The [Legislature] of the State of [Insert name of State] finds that:
- (1) Mifepristone, the first drug in the two-drug chemical abortion procedure commonly referred to as “RU-486,” works by blocking progesterone receptors. Progesterone is necessary for the development of an unborn child.
 - (2) Mifepristone alone results in complete abortion in sixty (60) to eighty (80) percent of cases.
 - (3) However, some women come to regret their decision to abort shortly after ingesting mifepristone.
 - (4) In recent years, physicians have developed a method to potentially reverse the effects of mifepristone.
 - (5) This abortion pill reversal process, which has been discussed in a peer-reviewed study, is based upon a well-established medical regimen that is used in other areas of healthcare—specifically, methotrexate and “leucovorin rescue.”
 - (6) Methotrexate, a chemotherapy drug, kills rapidly dividing cells (cancer cells). It works by blocking the action of folic acid. Typically, physicians allow the methotrexate to work for a day or two, and then give the patient a high dose of folic acid (leucovorin) to compensate for what has been lost. This high dosage of folic acid, in essence, “kicks” the methotrexate off of the cells. This flooding of the patient’s body with folic acid is called a “leucovorin rescue” and is a well-established medical procedure.
 - (7) Understanding the science behind the mechanism of action of mifepristone has allowed physicians to design a specific "rescue" for a woman who has used mifepristone to induce an abortion. Since physicians know exactly how

mifepristone works (*i.e.*, blocking progesterone), physicians know that treating a woman with progesterone can "kick off" the mifepristone (*i.e.*, displace mifepristone from the progesterone receptors). This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifepristone-induced blockage.

- (8) In short, mifepristone floods the progesterone receptors (thus blocking progesterone). To block or "reverse" the effects of the mifepristone, a pregnant woman's body is flooded with progesterone.
- (9) Progesterone itself has been used safely in pregnancies for decades. It is used in *in vitro* fertilization, infertility treatments, and high-risk pregnancies (such as those experiencing pre-term labor). Using progesterone to reverse the effects of mifepristone is a targeted response that is safe for the woman.
- (10) [*As of June 22, 2015, it had been reported that at least one hundred and seven (107) babies had been born following this reversal process, with another eighty (80) on the way (still in utero)*].
- (11) It is essential to the psychological and physical well-being of a woman considering an abortion that she receives comprehensive and accurate information on abortion and its alternatives.
- (12) The knowledgeable exercise of a woman's decision to have an abortion depends on the extent to which she receives sufficient information to make an informed choice between two alternatives: giving birth or having an abortion.
- (13) Adequate and legitimate informed consent includes information which "relat[es] to the consequences to the fetus." *Planned Parenthood v. Casey*, 505 U.S. 833, 882-883 (1992).
- (14) 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).
- (15) "The medical, emotional, and psychological consequences of an abortion are serious and can be lasting. . . ." *H.L. v. Matheson*, 450 U.S. 398, 411 (1981).
- (16) It is "unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained." *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

- (b) Based on the findings in subsection (a) of this Section, the purposes of this Act are to:
- (1) Ensure that every woman considering an abortion receives comprehensive information on abortion, including the potential to reverse the effects of abortion-inducing drugs should she change her mind, and that every woman submitting to an abortion does so only after giving her voluntary and fully informed consent to the procedure;
 - (2) Protect unborn children from a woman's uninformed decision to have an abortion; and
 - (3) Reduce “the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed.” *Planned Parenthood v. Casey*, 505 U.S. 833, 882 (1992).

Section 3. Definitions.

As used in this Act only:

- (a) “**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; or
 - (3) Remove an ectopic pregnancy.
- (b) “**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. 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.).
- (c) “**Department**” means the Department of [*Insert appropriate title*] of the State of [*Insert name of State*].

- (d) “**Medical emergency**” means that condition which, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function.
- (e) “**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.**”
- (f) “**Mifepristone**” means the first drug used in the Mifeprex regimen.
- (g) “**Misoprostol**” means the second drug used in the Mifeprex regimen.
- (h) “**Physician**” means any person licensed to practice medicine in this State. The term includes medical doctors and doctors of osteopathy.
- (i) “**Pregnant**” or “**pregnancy**” means that female reproductive condition of having an unborn child in the mother’s [*woman’s*] uterus.
- (j) “**Qualified person**” means an agent of the physician who is a psychologist, licensed social worker, licensed professional counselor, registered nurse, or physician.
- (k) “**Unborn child**” means the offspring of human beings from conception until birth.

Section 4. Information Required on Abortion Pill Reversal

Except in the case of a medical emergency, at least twenty-four (24) hours prior to an abortion being performed or induced utilizing abortion-inducing drugs, the physician performing the abortion on the pregnant woman, the referring physician, or a qualified person assisting the physician shall, orally and in person, inform the woman of the following:

- (a) That it may be possible to reverse the effects of the abortion should she change her mind, but that time is of the essence; and
- (b) That information on and assistance with reversing the effects of abortion-inducing drugs is available in the state-prepared materials.

Section 5. Information Required in State-Prepared Materials

(a) The Department shall cause to be published in the printed materials, state-prepared website, and informational DVD required under [*Insert reference(s) to state statutes, administrative rules, or other authority related to informed consent for abortion*] the following statement:

“Information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs, such as mifepristone (brand name Mifeprex), commonly referred to as “RU-486,” including information directing women to obtain further information at <http://www.abortionpillreversal.com/> and by contacting (877) 558-0333 for assistance in locating a medical professional that can aide in the reversal of an abortion.”

(b) On an annual basis, the Department shall review and update, if necessary, the statement required in subsection 5(a).

Section 6. Criminal Penalties.

Any person who intentionally, knowingly, or recklessly violates this Act is guilty of a [*Insert appropriate penalty/offense classification*].

Section 7. Civil Penalties.

(a) In addition to any and all remedies 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*].

(b) No civil liability may be assessed against the female upon whom the 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.

(e) 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 shall also render judgment for reasonable attorney's fee in favor of the defendant against the plaintiff.

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. 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 10. 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 11. Effective Date.

This Act shall take effect on [*Insert date*].

TALKING POINTS

The incidence of chemical abortion is on the rise.

- Today, nearly 25 percent of abortions involve the use of abortion-inducing drugs, compared to only 6 percent in 2001.⁶
- As such, it represents a “growth industry” for abortion providers.

In general, mifepristone (the first drug in the Mifeprex regimen) alone results in a complete abortion in 60-80 percent of cases.⁷

- **Mifepristone works by blocking progesterone receptors** (progesterone is necessary for the development of the unborn child).
- “Complete abortion” refers to a complete expulsion of the pregnancy (*i.e.*, baby); we do not know the condition of the baby when he or she is expelled (*i.e.*, whether the baby is still alive).
- Because mifepristone does not result in a complete abortion in some cases, **misoprostol is used (in the United States) to induce contractions** to expel the pregnancy (*i.e.*, baby) from the uterus.
- The FDA-approved mifepristone (Mifeprex) label⁸ recognizes that mifepristone alone may terminate the pregnancy:
 - Under the dosage and administration instructions, the label states that misoprostol (the second drug) is to be given “**unless** abortion has occurred” (*i.e.*, the pregnancy has already been completely terminated by mifepristone).
 - In the Patient Agreement signed by the woman and the physician, the woman agrees that she will “return to my provider’s office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol **if** I am still pregnant.”
 - In other words, the use of misoprostol (the second drug) is unnecessary in some cases because termination of pregnancy has already occurred.

⁶ See, e.g., Guttmacher Institute, *Induced Abortion in the United States* (July 2014), available at http://www.guttmacher.org/pubs/fb_induced_abortion.html (last visited June 18, 2015).

⁷ M.D. Creinin & K.G. Danielsson, *Medical Abortion in Early Pregnancy*, in M. Paul et al., eds., *MANAGEMENT OF UNINTENDED & ABNORMAL PREGNANCY: COMPREHENSIVE ABORTION CARE* (Blackwell Pub. Ltd. 2009). One of the editors of this abortion manual is Dr. David A. Grimes, one of the abortion lobby’s most prominent expert witnesses. His studies are frequently cited in court documents.

⁸ Mifeprex Final Printed Labeling (FPL), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited June 18, 2015).

It is possible to reverse the effects of abortion-inducing drugs, but time is of the essence.

- **In recent years, doctors have started utilizing a process that enables women who have already ingested mifepristone to stop the abortion process.**
- This particular process, first initiated by Dr. George Delgado, **is similar to a well-established medical principle used in other areas of healthcare (e.g., methotrexate and leucovorin rescue).**
 - Methotrexate is used as a chemotherapy drug.
 - Methotrexate kills rapidly dividing cells (e.g., cancer cells). Methotrexate works by blocking the action of folic acid.
 - Typically, physicians allow the methotrexate to work for a day or two, then give the patient a high dose of folic acid (leucovorin) to compensate for what has been lost.
 - This high dosage of folic acid in essence “kicks” the methotrexate off of the cells.
 - This flooding of the patient’s body with folic acid is called a “leucovorin rescue” and is a well-established medical procedure.
- **The “abortion reversal” process is based on the same scientific principle.**

Understanding the science behind the mechanism of action of mifepristone allows physicians to design a specific "rescue" for a woman who has been exposed to mifepristone. **Since physicians know exactly how mifepristone works, physicians know that progesterone can "kick off" the mifepristone (i.e., displace mifepristone from the progesterone receptors).** This allows the woman's body to respond naturally to progesterone and to effectively fight the effects of the mifepristone blockage.

 - Mifepristone floods the progesterone receptors (thus blocking progesterone).
 - To block or “reverse” the effects of the mifepristone, a pregnant woman’s body is flooded with progesterone.
 - Progesterone should be started within 24-72 hours of mifepristone ingestion.
- **Progesterone has been used safely in pregnancies for 40 years.**
 - It is used in *in vitro* fertilization, infertility treatments, and high risk pregnancies (including those involving preterm labor).
 - It is very targeted.
 - We know it is safe in pregnancy.

- **Dr. Delgado has a published *peer-reviewed* study on the process.**⁹
 - The study presented seven patients who took mifepristone to terminate pregnancies and then sought assistance to block the effects of mifepristone.
 - Of the seven patients, four went on to deliver healthy full-term babies. One patient was lost to follow up, while the abortion was completed in the other two patients.
 - “The experience of these patients suggests that [chemical] abortion can be arrested by progesterone injection after mifepristone ingestion [and] prior to misoprostol due to the competitive action of progesterone versus mifepristone.”

- **Dr. Alan Sawyer, a well-known obstetrician/gynecologist, has successfully performed the process and testified in favor of an Arizona abortion pill reversal information bill in 2015 (enacted).**¹⁰
 - “The abortion pill RU-486 (mifepristone) is a potent antagonist of progesterone and cortisol. The antiprogestational effects of RU-486 (mifepristone) will result in fetal death, as progesterone is essential for fetal growth and survival. Natural micronized progesterone supplementation, either by intramuscular injections or by oral administration, can be used to overcome the antiprogestational properties of RU-486 (mifepristone).”
 - “I started [a patient] on a protocol of high dose progesterone to undo the lethal effects of the antiprogestosterone medication RU-486 (mifepristone)... She is now past her first trimester, and her baby is now out of danger and doing well, and has a due date in September.”
 - “Natural micronized progesterone supplementation has been used for years in obstetrics, gynecology, and infertility care. The safety of progesterone supplementation during pregnancy has been well established, and this is used routinely for high risk pregnancies such as those conceived through *in vitro* fertilization and also for pregnancies at risk of preterm labor.”
 - “Administration of supplemental progesterone to women who have taken RU-486 (mifepristone) can overcome the antiprogestational effects of the RU-486 (mifepristone), support the early pregnancy, and effectively stop the medical abortion from occurring.”

⁹ G. Delgado & M.L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, ANNALS OF PHARMACOTHERAPY 46 (Dec. 2012).

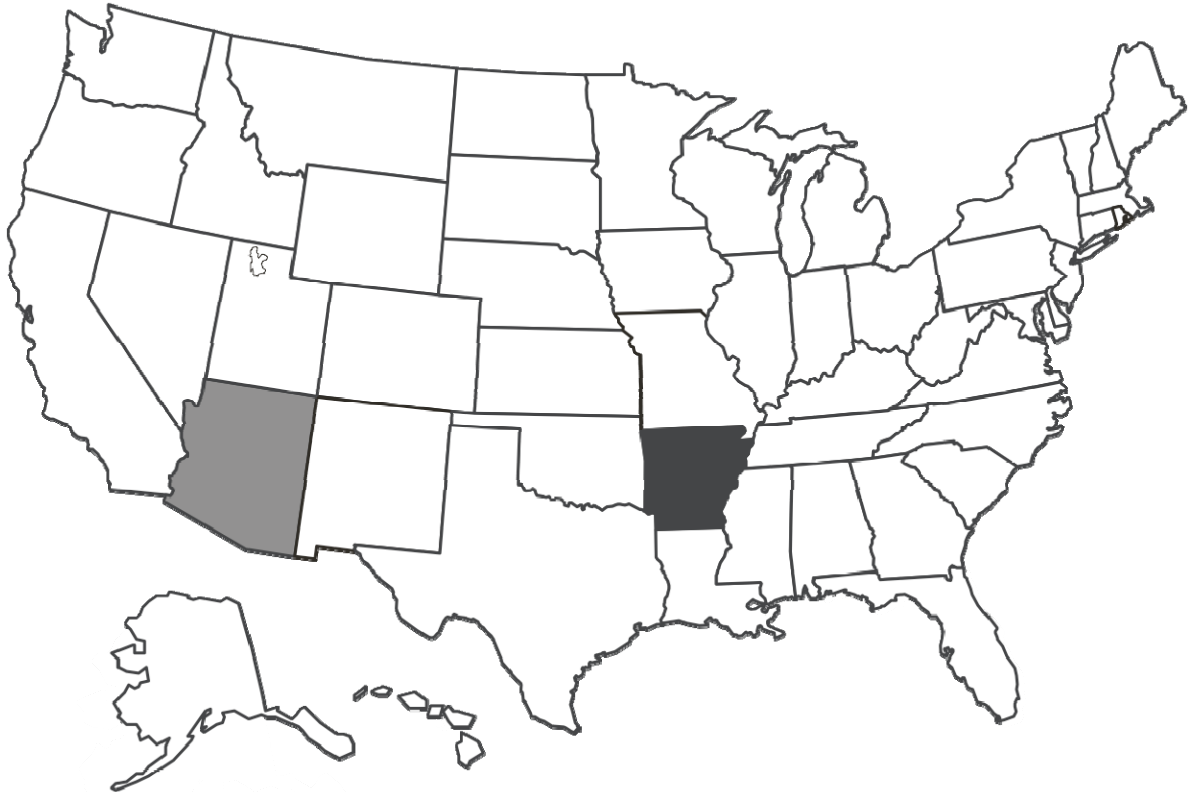
¹⁰ Dr. Alan Sawyer, Testimony in favor of Arizona Senate House Bill 1318 (2015), available at http://www.azpolicy.org/_blog/5_Minutes_for_Families/post/a-second-chance/ (last visited June 18, 2015).

- As of June 22, 2015, it had been reported that **107 babies have been born following this process, with another 80 on the way (still *in utero*)**. At least **275 physicians in the United States, along with another 20 physicians internationally, are trained and ready to assist women requesting assistance through Abortion Pill Reversal which reports a 55-60 percent success rate.**

The Supreme Court has repeatedly reaffirmed the importance of informed consent in its abortion cases.

- Informed consent is a “bedrock” of proper medical care.
- Adequate and legitimate informed consent includes information which “relat[es] to the consequences to the fetus.” *Planned Parenthood v. Casey*, 505 U.S. 833, 882-883 (1992).
- 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).
- “The medical, emotional, and psychological consequences of an abortion are serious and can be lasting. . . .” *H.L. v. Matheson*, 450 U.S. 398, 411 (1981).
- It is “unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained.” *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007). This is particularly true when the woman learns that the abortion industry hid information that could have led her to reverse the chemical abortion process and go on to have a healthy child.

STATE OF THE STATES: WHERE ARE WE NOW? ABORTION PILL REVERSAL INFORMATION REQUIREMENTS



One state requires that informed consent before an abortion includes information on the possibility of reversing the effects of abortion-inducing drugs: AR.



One state law requiring that informed consent before an abortion includes information on the possibility of reversing the effects of abortion-inducing drugs is in litigation: AZ.

More detailed information on abortion-inducing drugs and legislation to protect women from the negative consequences of chemical abortions can be found in AUL's annual publication *Defending Life*.

Defending Life 2015 is available online at AUL.org.

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

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