Defending Life 2012

Deadly Convenience

RU-486, Plan B, ella, and the Danger of “Contraceptive Equity”

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Chemical abortion (also referred to as “medical abortion”) is the new frontier for abortion advocates. More and more abortion clinics are turning from surgical abortions in the first trimester to focus exclusively on chemical abortion, such as the RU-486 regimen. Examining recent abortion trends, the pro-abortion Guttmacher Institute reported that by 2008 chemical abortion had “become an integral part” of the abortion industry, and the number and proportion of all abortions accounted for by this method “grew substantially.” Because some state laws do not define “abortion” in such a way as to include chemical abortions, the RU-486 regimen may fly under the radar, so to speak, and allow clinics to dispense it without regard to abortion regulations in the state.

Another recent development—a repackaging of the “safe, legal, and rare” mantra of the 1990s—is President Barack Obama’s claim that he wants to reduce the number of abortions in the United States. This rings of the abortion advocates’ claims that reduction of abortion is dependent upon prevention of pregnancy. Prevention of pregnancy, they claim, is in turn dependent upon access to “emergency contraception” and regular contraception. Further, access to contraception is not enough; pro-abortion advocates want employers to pay for it.

These arguments come at the detriment to women. Abortion-inducing drugs and “emergency contraception” are dangerous and potentially deadly, and contraceptive equity laws serve only to burden a healthcare system already in crisis.

ISSUES

RU-486

On September 28, 2000, the U.S. Food and Drug Administration (FDA) approved the drug regimen RU-486 under Subpart H, its accelerated approval regulations specifically enacted to quickly approve drugs for HIV patients.

Under the regimen approved by the FDA, a woman takes the first dose at a doctor’s office or abortion clinic. This initial ingestion blocks progesterone from getting to the baby, and the baby starves to death. The woman is to return 36 to 48 hours later to take a second drug, misoprostol (a prostaglandin), which causes the woman to expel the baby. The woman returns for a third visit approximately 14 days later for an exam to confirm that the baby has been
completely expelled and to monitor bleeding. If the procedure fails, a woman must undergo a surgical abortion.²

Since its approval, thousands of women have faced complications following use of RU-486. A 2011 FDA report accounts for at least 2,207 cases of severe adverse events, including hemorrhaging, blood loss requiring transfusions, serious infection, and 14 deaths.³

A concern for women’s health and safety is heightened when considering the fact that the reports to the FDA about complications are inadequate. A 2006 review of Adverse Event Reports (AERs) related to the use of the RU-486 drug regimen, conducted by Dr. Margaret M. Gary, M.D. and Dr. Donna J. Harrison, M.D. found that the reports “relied upon by the FDA to monitor mifepristone’s postmarketing safety are grossly deficient due to extremely poor quality.”⁴

What is not being reported to the FDA about the dangerous drug regimen is also disturbing. The limitation of the AER system was detailed by Michael F. Mangano, Principal Deputy Inspector General of the Department of Health and Human Services, in his testimony before the U.S. Senate committee, when he stated, “Adverse Event Reporting systems typically detect only a small proportion of events that actually occur. They are passive systems that depend on someone linking an adverse event with the use of a product, then reporting the event…. Adverse Event Reports in and of themselves typically cannot generate conclusive evidence about the safety of a product or ingredient. Rather the system generates signals that FDA must assess to confirm if, in fact, a public health problem exists…. With limited information to draw upon to generate signals, it is not surprising that FDA rarely reaches the point of knowing whether a safety action is warranted to protect consumers.”⁵

Adding to this dangerous scenario is that abortion-providers open flout the FDA protocol and state restrictions on abortion. In 2010, Planned Parenthood clinics in Iowa began the use of telemedicine, or “telemed,” to distribute of RU-486. Typically, patients are put in a room where an off-site abortion provider appears on a computer monitor (via an Internet connection) and explains the medical abortion procedure (i.e., the RU-486 regime). The abortion provider never actually examines the woman or performs needed tests such as an ultrasound. After the brief teleconference, the drugs comprising the RU-486 regime, namely Mifeprex/Mifepristone and Misoprostol, are prescribed. A button is then pushed and a box opens containing the drugs, which are then administered to the patient by a nurse or “clinician” (who may or may not be licensed). The woman is sent home with the second dose of the regimen, and no provision is made for follow-up evaluations or visits.

This use of telemedicine is a direct violation of FDA requirements for dispensing RU-486, and puts a woman at grave risk. Dispensing the abortion drug regimen after videoconferencing in place of a face-to-face visit between doctor and patient, places women in greater jeopardy. At a minimum, a “virtual visit” cannot accurately assess the gestational age of the unborn child or rule out ectopic pregnancy.

In order to protect women against the risks of RU-486, AUL has drafted a model bill entitled the “Abortion-Inducing Drugs (RU-486) Safe-
ty Act.” AUL has also specifically prepared a “telemed response” packet for use in conjunction with our “Abortion-Inducing Drugs Safety Act,” allowing legislators to launch a multi-pronged response to the threat of “telemed abortions” in their states.

**Emergency Contraception**

In 1999, the FDA first approved the distribution of “emergency contraception” (EC), specifically “Plan B,” by prescription. EC is allegedly prescribed after a woman has had sex without contraception. Within 72 hours after intercourse, the woman takes the first dose; 12 hours later, she takes a second dose. When taken according to this regimen, EC is only 79 to 89 percent effective in preventing pregnancy or implantation.6

On August 24, 2006, the FDA approved over-the-counter sales of Plan B to women 18 years of age and over. But this was not enough for pro-abortion groups, who continued litigation and pushed for the availability of EC to minors. On March 23, 2009, a federal district court in New York ruled that Plan B must be made available to 17-year-old minors and directed the FDA to reconsider its policies regarding minors’ access. The Obama Administration did not appeal and the FDA has indicated intent to comply with the ruling.

In 2010, the FDA approved the controversial drug *ella* as another “emergency contraceptive” option. Importantly, *ella* is not an “improved” version of Plan B; instead, the chemical make-up of *ella* is similar to the abortion drug RU-486. Both are selective progesterone receptor modulators (SPRMs). This means that though labeled as “contraception,” *ella* works the same way as RU-486.7 By blocking progesterone—a hormone necessary to build and maintain the uterine wall during pregnancy—an SPRM can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by starving it to death. Put another way, *ella* can abort a pregnancy, no matter whose definition of “pregnancy” is used.

When the FDA approved *ella*, it did not make any assurance that it would not disrupt a pregnancy. In fact, the FDA said that *ella* may “affect” implantation.8 The FDA chose different language when it approved Plan B, saying it may “prevent” implantation but explicitly stating that once an embryo implanted, Plan B would not terminate the pregnancy.9

Furthermore, the FDA specifically advises that *ella* should not be taken if there is a “known or suspected” pregnancy. Moreover, scientific studies demonstrate that *ella* not only prevents implantation, but can harm an “established” pregnancy. The FDA’s prescribing instructions for *ella* cite animal studies demonstrating high embryo-fetal loss.10 In addition, the European Medicines Agency (EMEA), the EU equivalent of the FDA, indicated that *ella* “is embryotoxic at low doses, when given to rats and rabbits.”11
Finally, *ella* raises serious health and safety concerns. For example, the FDA’s prescribing instructions specifically note that the following have not been researched: the safety and efficacy of repeated use of *ella*; how *ella* may interact with hormonal contraceptives; the effects of *ella* on minors; the risks to a fetus when *ella* is administered to a pregnant woman; and the risks to an infant when *ella* is taken by a nursing mother.

In addition, since *ella*’s chemical make-up and mode of action are very similar to RU-486, serious concerns exist about *ella*’s risk to women’s health. RU-486 is known to cause serious adverse health risks such as severe bleeding, ruptured tubal pregnancies, serious infections, and even death. Further study is necessary to ensure *ella* is safe for women, particularly if it is used off-label.

**Contraceptive Equity**

In recent years, abortion advocates began clamouring for contraceptive equity laws, which require that employers and insurers who offer prescription drug coverage also include coverage for contraception. These laws mandate that employers and insurers with convictions against contraceptive use must violate their consciences or beliefs. While most contraceptive equity laws offer an exemption for organizations dedicated to inculcating religious values or beliefs (e.g., churches), many of these laws do not provide the same protection for religiously-affiliated organizations that serve the general public. For example, religiously-affiliated groups or para-church organizations—such as adoption agencies and charitable organizations—are not exempt and must provide prescription coverage for contraceptives.

In addition to this obvious infringement on freedom of conscience, contraceptive equity laws also worsen a healthcare system that is already in crisis. If religiously-affiliated organizations are forced to choose between following their beliefs and providing prescription coverage, it is likely many if not most will choose simply to stop providing prescription coverage to their employees. Contrary to abortion advocates’ claims that contraceptive equity laws will improve women’s health, this would leave a greater number of women—and men—without prescription coverage.

Under a recent federal mandate, nearly all private insurance plans will be required to provide full-coverage for the “full range of FDA approved contraceptives,” which includes abortion-inducing drugs such as *ella*, and other drugs and devices with known life-ending mechanisms of action, such as Plan B and Intrauterine Devices (IUDs). The mandate came through guidelines issued by the Health Resources Services Administration (HRSA), a federal agency that was tasked with determining what constitutes “preventive services” under the Patient Protection and Affordable Care Act (PPACA). The Department of Health and Human Services (HHS) issued a regulation permitting HRSA to adopt a narrow “religious employer” conscience exemption to its mandate; however, the definition offered by HHS is so narrow, that most religious schools, hospitals, and charitable organizations will not be protected. Moreover, non-religiously affiliated employers—whose pro-life consciences are nonetheless violated—are unquestionably subject to the mandate.
Further, contraceptive equity laws open the door for laws requiring employers and insurers to provide coverage for abortion. The abortion lobby will likely use the same rationalization—that it is allegedly key to vital healthcare service—to justify mandated insurance coverage of abortion.

**KEY TERMS**

- An [abortifacient](#) (sometimes referred to as an abortifacient) is a drug that causes an abortion.

- **Emergency contraception (EC)** is allegedly used to prevent pregnancy after unprotected sexual intercourse. It is also referred to as the morning-after pill or postcoital contraception. Particular products approved by the FDA are known as Plan B and Preven, and ella.

- RU-486 is a chemical abortifacient which is also known as mifepristone, or by its brand name, Mifeprex. It is taken to end pregnancy, not to prevent it.

**MYTHS & FACTS**

**Myth:** Proper clinical trials demonstrate that RU-486 is “safe and effective.”

**Fact:** One of the FDA’s rules is that “uncontrolled studies or partially-controlled studies are not acceptable as the sole basis for the approval claims of effectiveness.” Yet neither the French trials nor the U.S. trial solely relied upon in approving RU-486 were blinded or controlled, and they did not yield “safe and effective” results. Almost 86 percent of patients in the first French trial and 93 percent in the second French trial experienced at least one adverse effect as a result of using RU-486. Ninety-nine percent of patients in the U.S. trial experienced adverse effects—23 percent of which were severe.

Furthermore, RU-486 has not been tested on females under the age of 18, yet it is given to females in this age group.

**Myth:** A chemical abortion is safer than surgical abortion and carries fewer and less severe side effects.

**Fact:** The common side effects of RU-486 are painful contractions, nausea, vomiting, diarrhea, pelvic pain and spasms, dizziness, and headaches. Most women experience excessive bleeding, which can last for weeks. RU-486 patients report “significantly longer bleeding” and “significantly higher levels” of pain, nausea, vomiting, and diarrhea than women who have surgical abortions. In one study, RU-486 failed in 18.3 percent of patients, while surgical abortions failed in only 4.7 percent of patients. In addition, the potential long-term effects of chemical abortion, such as effects on fertility and future pregnancies, are not known.

A recent Australian study confirmed that RU-486 abortions are more dangerous than surgical abortions; 5.7 percent of women using RU-486 required re-admittance to hospitals, with only 0.4 percent of patients requiring such intervention after surgical abortion.

**Myth:** RU-486 was properly approved through the FDA’s channels, so it must be safe.

**Fact:** RU-486 was actually approved through the FDA’s “Accelerated Approval Regulations.” These regulations were designed for
drugs “that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments.” Yet, as demonstrated above, RU-486 was not adequately tested for its safety and effectiveness and it does not provide meaningful therapeutic benefit over the surgical abortion options already available. In addition, pregnancy is not a “serious or life-threatening illness.” RU-486 should not have been approved under this accelerated procedure.

Further, the approved RU-486 regimen is dangerous and does not adequately protect women. It does not require an ultrasound, which is necessary to determine the gestational age of the pregnancy and whether the pregnancy is ectopic. RU-486 is particularly dangerous because its side effects are confusingly similar to the symptoms of an ectopic pregnancy.

In addition, anyone with a medical license—including untrained psychiatrists, podiatrists, and other non-related specialists—can prescribe RU-486.

Moreover, doctors and clinics are not using RU-486 as approved by the FDA, which is “for the medical termination of intrauterine pregnancies through 49 days’ pregnancy” and requires at least three office visits. RU-486 is openly administered to women with pregnancies beyond seven weeks, and the second office visit is often eliminated. Failing to follow the approved regimen of an already dangerous drug puts women’s health and lives even more at risk.

**Myth:** Studies prove that “telemed” abortions are safe.

**Fact:** In addition to the inherent dangers of chemical abortions (and specifically RU-486), there are glaring flaws in so-called “studies” relied on for the claim that telemed abortions are safe.

For example, a “study” by Ibis Reproductive Health (Ibis) has been promoted as demonstrating telemed abortion safety. However, Ibis admits on its website that its “projects focus on improving access to abortion.” In other words, Ibis was conducting “research” with the specific purpose of supporting “reproductive rights.” The Ibis “study,” which leverages “research” to accomplish its abortion-driven mission, was not reported by an independent researcher publishing results from a scientific study in a peer-reviewed journal.

**Myth:** Over-the-counter access to “emergency contraception” will reduce the number of unplanned pregnancies and abortions.

**Fact:** There are at least 23 studies from 10 countries revealing that “emergency contraception” (EC) does not reduce pregnancy and abortion rates. With the increased rate of sexual activity and the substantial failure rate of EC, the over-the-counter availability of “emergency contraception” cannot be expected to reduce the number of pregnancies or abortions. Furthermore, in those areas with easy access to EC, the number of sexually transmitted diseases has skyrocketed.

**Myth:** Over-the-counter access to “emergency contraceptives” is safe.

**Fact:** Over-the-counter access to “emergency contraceptives” is inherently unsafe. First, over-the-counter access makes “emergency contraceptives” available to a larger popula-
tion of women than any trial has tested. Second, “emergency contraceptives” are used to exploit women. “Although many feminists believe that the morning-after pill gives them more control over their own bodies, it would seem, judging from the few studies conducted so far, that it is actually being used by men to exploit women.”

Easy access to an easily-administered drug encourages the continued exploitation of women by sexual predators.

**Myth:** “Emergency contraception” is safe for females under the age of 18.

**Fact:** Researchers have not specifically investigated the impact and side-effects of “emergency contraceptive” use on minors.

**Myth:** *ella* is just another form of the “emergency contraceptive,” Plan B.

**Fact:** *ella* is actually an abortion drug like RU-486. RU-486 is the parent compound of *ella*, and *ella* possesses the same mechanisms of action as RU-486. Thus, it blocks progesterone, prevents implantation, and interferes with the development of a human embryo.

**Myth:** *ella* is a safe alternative to Plan B.

**Fact:** Unfortunately, very little is known about the safety of *ella*. What we do know, however, is that RU-486 is the parent compound of *ella*, and therefore women who use *ella* may be subject to the same substantial health risks.

**Myth:** Women need contraceptive equity laws to combat their employers’ gender discrimination because women spend as much as 68 percent more than men in out-of-pocket healthcare costs, due in large part to the cost of prescription contraceptives and the various costs of unintended pregnancies.

**Fact:** The abortion lobby has neither established that a significant connection exists between lack of coverage for contraceptives and unintended pregnancies, nor has it proven that the higher healthcare costs are not a result of factors other than differences in plan coverage, such as differing illness or medical service usage levels.

**Myth:** Contraceptive equity laws are cost-effective because they save employers the costs resulting from their employees’ unintended pregnancies.

**Fact:** The abortion lobby relies on an assumption that employees not using contraceptives because of the costs will begin using contraceptives if their states enact contraceptive equity laws. No studies validate this assumption. Instead, rising healthcare costs have reduced the number of employers offering their employees any health benefits and increased the number of employees turning down their employers’ offer of health coverage. Insurance mandates such as contraceptive equity laws will further compromise the ability of employers to offer affordable health plans to their employees.

**Myth:** Contraceptive equity laws are an issue of fairness because insurance plans cover drugs specifically for men, like Viagra.

**Fact:** Providing coverage for contraception is not analogous to providing coverage for Viagra. Most health plans pay for Viagra only when a man seeks it to address impotence rather than to enhance sexual performance. When a man utilizes Viagra in this context, he is using it to treat infertility, a medical disorder. On the other hand, a woman uses contraceptives solely to prevent a pregnancy, a completely natural condition.

**Myth:** Contraceptive equity laws have nothing
to do with abortion.

**Fact:** Contraceptive equity laws that require coverage for “all FDA approved contraception” include abortion-inducing drugs, such as ella, and other drugs and devices that have been labelled by the FDA as “contraception” despite known life-ending mechanisms of action.

Additionally, as contraceptive equity laws without comprehensive freedom of conscience protections are increasingly adopted in the states (and now the federal government), it will become easier for abortion advocates to justify mandated insurance coverage of abortion using the same rationalizations used to support mandatory contraception coverage.

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**Endnotes**


6. The Plan B One-Step label states, “Among women receiving Plan B One-Step, 84% of expected pregnancies were prevented and among those women taking Plan B, 79% of expected pregnancies were prevented.” See Plan B One-Step label, at 6, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf (last visited January 31, 2011).


10. See ella Labeling Information, supra.


13. See id. at nn.313 & 317 & accompanying text.


16. Id.


18. 21 C.F.R. § 314.500.


20. See AAPLOG et al., supra, at nn.313 & 317 & accompanying text. Instead, the patients administer misoprostol vaginally—not orally, as approved—at home. Id.


Pregnancy and STIs, 293. Amer. Med. Ass’n 54 (2005); X. Hu et al., Advanced provision of emergency contraception to postnatal women in China makes no difference in abortion rates: a randomized controlled trial, 72 Contraception 72 (2005).


24 See, e.g., D.L. Blithe et al., Development of the selective progesterone receptor modulator CDB-2914 for clinical indications, 68 Steroids 1013 (Nov. 2003); R.M. Brenner et al., Intrauterine administration of CDB-2914 (Ulipristal) suppresses the endometrium of rhesus macaques, 81 Contraception 336 (Apr. 2010); EllaOne Product Report, Annex 1; D.J. Harrison & J.G. Mitroka, supra.