THE “MORNING AFTER” PILL RAISES MANY HEALTH RISKS AND OVER-THE-COUNTER USE JEOPARDIZES WOMEN’S HEALTH

The “morning after” pill or “emergency contraception” refers to a high dosage of birth control pills that are taken within 72-120 hours of intercourse. Not-2-Late.com and the 2004 edition of Contraceptive Technology\(^1\) list 17-19 types of emergency contraception (respectively) that are currently available in the United States. Between the two lists, 20 forms of oral contraceptives are included. Two of these are Progestin Only (Plan B\(®\) and Ovrette). The remaining types of oral contraceptives used as emergency contraceptives are a combination of Progestin and Estrogen. (Ogestrel or Ovral; Alesse, Lessina, or Levlite; Levlen or Nordette; Cryssel, Levora, Low-Ogestrel, or Lo/Ovral; Tri-Levlen or Triphasil; Portia, Trivora, or Seasonale; Aviane, and Empresse.

Probably the two most well-known emergency contraceptive pills (ECPs) approved by the FDA are Plan B\(®\) and PREVEN\(®\). Plan B\(®\) contains a synthetic progestin known as levonorgestrel. PREVEN\(®\) contains both progestin (levonorgestrel) and estrogen (ethinyl estradiol). (As of December 30, 2004, PREVEN\(®\) was no longer available in the United States.) Plan B\(®\) is the only dedicated product specifically marketed for emergency contraception.

Approval has been sought to market Plan B\(®\) over-the-counter (OTC), without a prescription. On December 16, 2003, two FDA Advisory Committees recommended (by a vote of 23 to 4) that the FDA approve the request to change the status of Plan B\(®\) from prescription only to OTC. On May 6, 2004, the FDA denied Barr Laboratories’ request to sell Plan B\(®\) without a prescription, due to concerns about the effects of the “morning after” pill on teenagers’ health. However, the FDA left the door open for Barr to submit its petition again after more research is done on the drug’s effects on teenage girls. In the interim, a few states have passed legislation that allows for Plan B\(®\) to be sold over-the-counter without a prescription in those states.

Approval of over-the-counter use of Emergency Contraception (EC) is objectionable for several reasons.\(^2\)

1. **EC can have an abortifacient effect.** An extensive review of the literature lists eleven possible modes of action for emergency contraception, seven of which can be abortifacient, that is, designed to prevent the implantation or survival of the embryo.\(^3\)

2. **Many women are currently unaware of this abortifacient mechanism of ECs.** OTC use will only guarantee continued unawareness by excluding the participation of pharmacists or physicians who might otherwise provide this information.
3. EC carries significant risks and is contraindicated for many women. The package insert itself states that EC should not be used as a routine method of contraception. Eliminating the need for a prescription, and making EC available over-the-counter, will eliminate the oversight needed to ensure that EC is not used routinely. It will also eliminate the clinical monitoring and follow-up needed to address the risk of ectopic pregnancy, a potentially life-threatening condition. In fact, some studies show that the use of EC may also increase the risk of ectopic pregnancy.

4. The potential for misuse of EC is especially of concern in the case of minors. OTC availability will enable a minor to have access to powerful hormonal drugs without physician oversight and without notifying her parents. OTC access may also increase risk-taking behavior and promiscuity: of significant concern given the problem of rising STD rates among teenagers in our country. Finally, if available over-the-counter to anyone who wishes to purchase it, young women may be given an EC without their knowledge or consent.

**The Abortifacient Nature of the Morning After Pill/Emergency Contraception**

There is substantial evidence that EC may act by impeding the development of the embryo or by interfering with the process of implantation. These modes include interference with zygote development, transportation to the uterus, and changes to the endometrial lining. This last mechanism is probably the most commonly recognized abortifacient mechanism within the pro-life community. In this instance, the morning after pill prevents the implantation of an unborn child into the uterus following conception– so it causes an early abortion.

How can we say that this will reduce abortion, when in fact, these pills can cause abortions?

Unfortunately, many women are not aware of this because the medical community now defines “pregnancy” as “implantation,” when in fact, the human life has existed for several days before implantation. If purchased over-the-counter, without a physician or pharmacist to advise them, women are more likely to remain unaware of this mechanism of the morning after pill/emergency contraception.

Some medical experts have recommended that a physician that prescribes drugs like Plan B® or Preven® should first inquire as to whether a patient considers conception morally relevant. “If a postfertilization mechanism of hormonal EC use violates the morals of any woman, the failure of the physician or care provider to disclose that information would effectively eliminate the likelihood that the woman’s consent was truly informed.” 4
EC carries significant risks and is contraindicated for many women

The Plan B® package insert indicates that EC is not to be used as a routine method of contraception. However, making Plan B® available over-the-counter will eliminate the oversight that now exists to ensure that EC is not used routinely.

The potential for routine use also raises concerns about safety. Claims about the safety of EC are based on the notion that EC will only be used occasionally or one time. If EC is used on a regular basis, the risks of and contraindications to the use of ordinary contraceptives should be considered. Some of these risks may even be aggravated because EC contains larger amounts of hormones per dose.

Currently, oral contraceptives carry significant risks (some life-threatening) including blood clots, strokes and heart attacks, and liver tumors. In July of 2005, the International Agency for Research on Cancer (a division of the World Health Organization) issued a press release concluding that combined estrogen-progestogen oral contraceptives are carcinogenic to humans (Group 1). IARC stated that oral contraceptives slightly increase the risk of breast, cervix, and liver cancer and decrease the risk of endometrial and ovarian cancer. It is not known if these risks apply to the emergency contraceptive pill regimen, in part, because no data is available concerning the risk of using short-course, high-dose EC among women who have contraindications to routine use of oral contraception.

Oral contraceptives are contraindicated for women with diabetes, breast cancer, liver problems, migraine headaches, heart disease or a history of heart disease, deep vein thrombosis or a history of deep vein thrombosis, and women over 35 who are smokers.

Complications from oral contraceptives (which contain the same ingredients as ECs) increase with women who smoke, are allergic to the medication, have cardiovascular problems or have a history of migraine headaches. Possible side effects include nausea and vomiting, fatigue, irregular bleeding and/or cramping, breast tenderness, headaches, fluid retention, chest pain, yellowing of the skin and eyes, blurred vision, coughing up blood, abdominal pain, dizziness, diarrhea, tiredness/weakness.

Use of oral contraceptives generally “is associated with an increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, liver tumor, gallbladder disease, visual disturbances…and hypertension. Cigarette smoking increases the risk of serious adverse cardiovascular effects during oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes daily) and is markedly greater in women older than 35-40 years of age. Women older than 35 years of age who smoke, and women with ischemic heart disease or a history of this disease, should not take oral contraceptives. Clinicians prescribing oral contraceptives should be aware of the risks associated with oral contraceptive use…”
Diabetic women should also be monitored while taking Plan B® according to the package insert. This is of concern because 1.85 million women of reproductive age (18-44) have diabetes according to the Centers for Disease Control, and approximately 500,000 do not know that they have the disease.

Birth control pills are available by prescription for sound medical reasons. The contraindications mentioned above would prevent a patient from receiving a prescription, and a medical exam supplemented by ongoing physician oversight is necessary to ensure that none of these contraindications exist.

If EC becomes available over-the-counter, this clinical oversight is removed.

Approving over-the-counter access to a high dose of this drug, when a lower-dose cannot be obtained without a medical exam, physician oversight and prescription, will put women at risk. “Women receiving oral contraceptives should be under supervision of a physician who should inform her of the possible risks involved.” Shouldn’t women who receive EC be entitled to the same care, concern and caution?

### Ectopic Pregnancies

Of special concern, is the fact that if EC is available over-the-counter without physician oversight, the diagnosis of an ectopic pregnancy (when the human embryo lodges – or gets stuck - in the fallopian tube rather than in the womb) may be missed. Common side effects of EC, such as nausea and abdominal pain, are also symptoms of an ectopic pregnancy. Women who are not under clinical supervision are unlikely to distinguish between the common side-effects of EC and the symptoms of a potentially life-threatening ectopic pregnancy. The package insert for Plan B® states that health providers should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B®.

But if it’s over-the-counter that oversight by health providers will be removed.

In addition, some studies have shown that the use of Plan B-type EC causes an increase in the incidence of ectopic pregnancies (when the human embryo lodges – or gets stuck - in the fallopian tube rather than in the womb.) In one of these cases, the affected fallopian tube had to be surgically removed. As a result, these women have a greatly reduced possibility of a future pregnancy.

Medical authorities in the United Kingdom have warned physicians about the danger of ectopic pregnancy following use of EC. In the United Kingdom, the Committee on Safety of Medicines found 12 ectopic pregnancies out of 201 unintended pregnancies following the use of levonorgestrel – the active ingredient in Plan B®. The Committee urged follow-up for women who have taken the drugs and did not experience a normal period afterwards.
As noted by the American Hospital Formulary Service: “An increased incidence of ectopic pregnancies in women receiving continuous low-dose norethindrone therapy has been reported. Diagnosis of ectopic pregnancy in patients receiving oral progestins may be complicated by the fact that pregnancies are unexpected and relatively infrequent. In addition, the symptoms of ectopic pregnancy and the adverse effects of low-dose progestin administration (i.e. breakthrough bleeding, spotting, menstrual irregularity, and amenorrhea) are similar. The possibility of an ectopic pregnancy should be considered whenever a patient receiving a low-dose progestin contraceptive experiences pelvic discomfort.”

Potential for Misuse and Minors

Over-the-counter access to EC raises several concerns with respect to America’s youth.

1. FDA approval of over-the-counter access to EC will expose America’s youth to serious health risks.

2. If approved, we may also expect that rates of STDs among teens will skyrocket.

3. Over-the-counter EC will generate an increase in rates of sexual violence committed against adolescent girls.

4. Over-the-counter EC will lead to an increase in the pregnancy rate among teenagers.13

5. Over-the-counter EC will not reduce the abortion rate.

More Health Risks

The risks that we know about have been previously discussed. Unfortunately, “the risks of EC to adolescents have never been adequately studied. To gauge the level of risk that EC poses to teens, one need only to consider the damage caused by Norplant. This progestin-only hormonal contraceptive – the same active ingredient as Plan B®—is no longer available for use in America because it is so dangerous. Known risks include significant weight gain, depression, ovarian cyst enlargement, gallbladder disease, high blood pressure and respiratory disorders.14 Among teenagers, some of these common side effects could result in increased rates of bulimia, anorexia, or clinical depression. Also, an increased risk of ectopic pregnancy has been associated with use of Plan B-type EC.15 Abdominal pain is also a common side effect of Plan B®.16

Since OTC/EC precludes parental involvement, it is likely that teenage girls who buy Plan B® at the drugstore and experience abdominal pain may not confide in parents
so that a physician could diagnose if a life-threatening ectopic pregnancy had occurred. OTC/EC approval would mean that young people would be free to purchase and use (abuse) this powerful hormone without supervision or follow up.”

RU-486 was approved by the FDA in a swift and politically-motivated manner: and we’ve seen the result with the death of Holly Patterson. Her parents did not know that she had taken RU-486, until it was too late. Heartbeat is thankful that the FDA is appearing to be more cautious this time. If a young teenager can buy this over the counter, time and time again, without a parents’ knowledge and without medical supervision, who knows what the consequences will be?

Physician involvement and parental notification should be encouraged: particularly with such high dosage hormones and the attendant risks.

**STDs**

Easy access to EC may increase risk-taking behaviors and promiscuity. EC has been widely promoted as a “back-up” if a woman does not use contraception or has so-called “unprotected” intercourse. Plan B® has been specifically advertised as a back-up on their website: “if Plan A fails, go to Plan B” (http://www.go2planb.com.)

Most women using contraceptives are concerned with avoiding pregnancy. They may not be as concerned about preventing sexually transmitted diseases. Should Plan B® become available over-the-counter, younger women taught to rely on this “back-up” may well choose it as their primary method of avoiding pregnancy.

“Extensive EC publicity campaigns have already promoted risk-taking sexual behaviors, especially among young women. Ads developed by the Women’s Capital Corporation to market Plan B target younger audiences. One ad shows a group of young men standing outside a dormitory, with the message: ‘So many men. So many reasons to have back-up contraception.’ Another shows fraternity members on a soccer field, with the message: ‘Delta Delta Thi. 27 Upstanding Young Men. 34 Billion Sneaky Little Sperm.’ The clear message here is that casual sexual involvement, particularly for college-age women, is without adverse consequences if one has ready access to this ‘back-up.’”

Since EC is marketed to those who engage in ‘unprotected sex,’ and since an over-the-counter manner of dispensing the drug precludes proper counseling for teens, OTC/EC will cause a dramatic increase in rates of sexually transmitted diseases. In Washington State, and in Sweden, where EC has been made widely available, rates of STD infection have been increasing significantly since EC was introduced. In fact, in the five years that EC has been made available over-the-counter, cases of Chlamydia have increased 56%. 

According to the Population Research Institute, adolescents age 15-19 currently represent 46% of all cases of Chlamydia in the United States. Moreover, 1 in 4
sexually active teenagers contract an STD at some point. HIV/AIDS is of particular concern. Currently, girls and young women acquire HIV an average of 10 years earlier than young men. In the United States, women now account for 30% of new HIV infections each year. Half of the new HIV cases are in those younger than 25 years, and half of those are in women.21

The Plan B® package insert acknowledges that this “back-up” does not protect against STDs: “Plan B®, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.”22

Using EC won’t protect adolescents and women from contracting STDs. Only 100% abstinence will.

**Violence against women**

Some have promoted EC as a response to sexual violence committed against teens. While some may believe that sexually assaulted teenage girls should have access to EC at a drugstore, most parents of a daughter that has been raped or sexually assaulted believe their daughter deserves much more: counseling, testing for STDs, a police report, and preservation of forensic evidence to incarcerate the rapist/abuser.

*Making EC available over-the-counter, also increases the potential for EC to be slipped to women without their knowledge or consent.*

In Thailand, men are the most frequent buyers of the “morning-after” pill. In June of 2002, the Bangkok Post reported several disturbing consequences of having the morning-after pill over-the-counter for the past 15 years.23 The following synopsis of this report is taken from the December 16, 2003 letter regarding the *Proposal to Switch Status of Emergency Contraceptives from Rx to OTC*, submitted to the FDA by Wendy Wright, Senior Policy Director, Concerned Women for America, at page five. The full text of these comments may be found at [http://www.cwfa.org/images/content/ww-maptest.pdf](http://www.cwfa.org/images/content/ww-maptest.pdf):

- Random studies showed that men are the most frequent buyers. “They buy the pills for their girlfriends or wives so that they don’t have to wear condoms and feel they’re at no risk of becoming a father afterwards. Some women I’ve spoken to said that they didn’t even know what they were taking; that the guy just said it was a health supplement,” said Nattaya Boonpakdee, program assistant at the Population Council (an agency dedicated to promoting and developing contraception and abortion methods).

- “Many women take three pills in a single week. Obviously, those can’t all be emergencies,” said Nattaya Boonpakdee.
• It was not uncommon for women to take more than 10 pills a month, although the maximum recommended monthly dose is four tablets (two occasions of unprotected sex), according to clinic worker Waranya Pitaktepsombat.

• “A woman taking the emergency pill is probably not insisting on the use of a condom and this practice is likely to be more common now among youngsters and married couples. This inevitably puts them at high risk of contracting sexually transmitted diseases. And, as statistics show, a high percentage of AIDS victims contracted the virus from their [long-term] partners,” stated Dr. Niyada Kiatying-Angsulee of the Faculty of Pharmaceutical Sciences at Chulalongkorn University.

The article notes, “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.”

“Forcing women to use oral contraceptives on a regular basis, especially these highly concentrated morning-after pills, is likely to put women’s health at risk,” said Dr. Niyada Kiatying-Angsulee of the Faculty of Pharmaceutical Sciences at Chulalongkorn University.

“The MAP, unlike an injection or vaginal inserts, can easily be administered without a woman’s knowledge. Providing over-the-counter access to the morning-after pill, which needs only to be swallowed, will ensure that it will be slipped to women without their consent or knowledge. When complications occur, victims and their doctors will not know the cause.”

The easy availability of over-the-counter EC will also be used to exploit and coerce women – particularly minors – to engage in risky sexual activity. It will make it more difficult for teenage girls to resist the pressure to have sex, and will trivialize the act of rape. Today, we hear of reports of adult men relying on family planning clinics to obtain contraception for the minor girls they are sexually abusing. We shouldn’t provide them with one more over-the-counter “tool” to allow their abuse and sexual exploitation to go unmonitored and undetected.

**EC use will increase pregnancy rate and will not reduce the abortion rate**

According to the Population Research Institute, studies have shown that increased rates of pregnancy occur among teens with increased use of EC.

Another study showed that teenagers whose pregnancies ended in induced abortion were more likely to have used EC before conception, and that teens who use EC were more willing to engage in “risk-taking” behavior.
Although some argue that access to EC will reduce the abortion rate, such arguments fail for two reasons. First, as noted above, the drugs themselves can have an abortifacient action. Second, regions that have made the drugs widely available have not seen such reductions. In Scotland, where EC (or the “morning-after” pill) has been accessible for years, the abortion rate increased between 1990 and 1999. In Glasgow, MAP prescriptions increased by approximately 300% from 1992 to 1999. Yet, this did not result in a decrease in abortions. In Washington State, the “morning-after” pill was made available through pharmacists via a pilot program. Unfortunately, the program only focused on increasing access and use and did not review STD or abortion rates. However, the Washington Center for Health Statistics reports abortion rates that only reflect the same small decrease in abortions reported nationwide where EC is not as easily accessible.

**Conclusion**

Clearly, making EC or the “morning after” pill available over-the-counter will result in more abortions and will jeopardize women’s health. It will encourage frequent use by making it easily accessible to anyone. Eliminating the need for a prescription, and making EC available over-the-counter, will eliminate the oversight needed to ensure that EC is not used routinely and that it is not used by women for whom use is contraindicated and/or by women who have not consented to taking EC but have had it “slipped” to them without their knowledge or consent. It will also eliminate the clinical monitoring and follow-up needed to address the risk of ectopic pregnancy, a potentially life-threatening condition. It will cause an increase in the already too high STD rates by encouraging risky sexual activity, and be given by statutory rapists to adolescents to cover up the continuing abuse.

2 Some of the material used in this Fact Sheet was obtained from the December 5, 2003 Comments on FDA Proposal to Change EC from Prescription to Over-the-Counter, submitted to the FDA by the USCCB. The full text of these comments contains an excellent analysis and may be found at http://www.nccbuscc.org/ogc/ec-fda.htm. Additional information was obtained from the Population Research Institute, PRI Weekly Briefing, March 5, 2004, Volume 6/No. 9.


6 © 2002, ASHP, American Hospital Formulary Service, Contraceptives 68:12, Estrogen-Progesterin Combinations. It should be noted that the text from the American Hospital Formulary Service titled “Contraceptives 68:12 Progesterins” refers the reader to the report on Estrogen-Progesterin Combinations for Cautions and Drug Interactions. While PREVEN® contains both Estrogen and Progestin, Plan B® contains only Progestin.


9 Id.


15 See footnote 10.

16 Plan B® Package Insert, “Adverse Reactions.” Available at www.go2planb.com/section/about/package_insert. 18% of adverse events involved abdominal pain.


18 December 5, 2003 Comments on FDA Proposal to Change EC from Prescription to Over-the-Counter, submitted to the FDA by the USCCB. http://www.nccbuscc.org/ogc/ec-fda.htm (accessed on 3/29/04.)

20 In the year before EC was made available in pharmacies, annual cases of Chlamydia numbered 9,523; by 2002 the number had risen to 14,936. See footnote 18, supra.


24 December 16, 2003 letter regarding the Proposal to Switch Status of Emergency Contraceptives from Rx to OTC, submitted to the FDA by Wendy Wright, Senior Policy Director, Concerned Women for America, at pages 9-10.

25 “Birth control for teens so pregnancies go up by 10 percent,” Daily Mail (London), December 1, 2003. (“A controversial sex education programme that hands out condoms in school was branded a failure last night after figures showed a [10%] rise in teenage pregnancy rates.” Under the initiative, schools hand out condoms and pupils are sent to clinics for the morning-after-pill. While teenage pregnancy rates have fallen across Scotland, they have risen sharply in the Lothian area to 59.1 pregnancies for every 1,000 females.) Cited in Population Research Institute, PRI Weekly Briefing, March 5, 2004, Volume 6/No. 9, footnote 12.


For some FDA testimonies pertaining to the Morning After Pill from Concerned Women for America, go to http://www.cwfa.org/articles/5000/CWA/life/index.htm