Why the Morning-After Pill should not be available without a prescription

Facts:

The morning-after pill (MAP) lacks testing for safety to women. Access to the drug over-the-counter, or without a prescription, would prompt use among consumers who, unknowingly, have medical conditions that put them at high risk of life-threatening complications. It could be slipped to women without their knowledge, and statutory rapists would rely on it to cover up their abuse of adolescents. In areas that allow easy access, the sexually transmitted disease rates have skyrocketed. The drug owner encourages multiple sex partners (putting women at risk of sexually transmitted diseases, or STDs), and endorses frequent use of the drug, though it has not conducted studies on multiple use. Morning-after pill promoters have been found guilty of overstating the efficacy of the drug and understating the risks to women.

Potential Risks to Women

Over-the-counter access would extend the availability of the MAP to a broader population than any study has included — females who have not been counseled or screened for contraindications.

Easy access allows someone other than the consumer to buy it and then slip it to a woman without her knowledge or consent. Unlike other drugs like aspirin, there is more potential for abuse by someone who, contrary to or unaware of the woman's wishes, does not want her pregnant. Drugs less easy to administer have been used against women:

In one example, Gary Bourgeois' girlfriend refused to have an abortion. During sexual relations, he inserted misoprostol, used in the RU-486 abortion regimen. Later she experienced violent cramps then felt a partly dissolved pill drop from her vagina. Her baby died. He pleaded guilty to aggravated assault and administering a noxious substance in Canada in September, 2003.

In another incident, Dr. Stephen Pack pleaded guilty to injecting Joy Schepis with an abortion-inducing drug in April 2000. The Bronx, New York, doctor jabbed his former lover with a syringe filled with methotrexate, which causes abortions, because she refused to have one.

It will be difficult for doctors to treat complications when the woman's medical history is unknown or hidden.

The morning-after pill is a high dose of the birth control pill, which requires a medical exam, a prescription, and physician oversight. Birth control pills can cause significant or life-threatening conditions such as blood clots, stroke and heart attacks. Birth control pills are contraindicated for women with diabetes, liver problems, heart disease, breast cancer, deep vein thrombosis, and for women who smoke and are over 35. Physician oversight is necessary to ensure that none of these contraindications exists. For example, according to the Centers for Disease Control, approximately 1.85 million women of reproductive age (18 – 44) have diabetes; approximately 500,000 do not know that they have the disease.

The World Health Organization has warned: “There may be a higher percentage of ectopic pregnancies among emergency contraceptive pill failure cases than among a normal pregnant population.”

Nurses at the Royal College of Nursing warned that pharmacists in the United Kingdom (where the drug is available behind the counter) were failing to warn customers of possible complications or carry out routine medical assessments.

Lack or Absence of Scientific Studies

The long-term effects.

The high dosage. A drug’s safety at one dose or range of doses does not mean that the drug is equally safe at a much higher dose. Yet proponents stake their arguments on decades of use of the birth control pill, a lower dose – which is not available over-the-counter.

Repeated usage. In the United Kingdom, one in seven of all women used the morning-after pill repeatedly in the same year.

Females not screened for medical contraindications.

Adolescents.

The Food and Drug Administration’s approval of the morning-after pill with a prescription was not based on controlled scientific studies, but on unscientific, anecdotal evidence. All studies (including those cited in the over-the-counter approval application of Plan B, a brand of the MAP) focus on the drug’s relative reliability in decreasing the expected birth rate, not on the effect on the women who have taken the drug regimen.

Reasons Not to Trust Morning-After Pill Proponents

The FDA found Plan B’s promoters guilty of false advertising, for overstating efficacy (claiming greater effectiveness in prohibiting pregnancies than the evidence shows) and understating the medical risks to women. The FDA stated the “ads raise significant public health and safety concerns.” Yet proponents continue to make similar claims.

Plan B’s promoters make the contradictory claim that the MAP inhibits implantation but does not end a pregnancy. Nearly half of Americans (46 percent) believe life begins at fertilization. Knowledge that the MAP can terminate a pregnancy could affect a woman’s decision to use it; withholding such information violates the principle of informed consent.

Promoters have relied on junk science to claim it does not affect sexual behaviors. At least one study (from the University of Pittsburgh) included only teenagers already engaged in risky sexual activity, and then concluded that easy access to MAP did not change their behavior.

The American College of Obstetricians and Gynecologists (ACOG) recommends that low-dose oral contraceptives be available only with a prescription from a licensed health-care provider. Yet it is recommending that Plan B and other higher-dose hormone regimens be available over-the-counter.

ACOG did not poll its members. Its recommendation is not representative of its members. MAP proponents had complained that doctors have not been willing to hand out the drug to anyone (apparently a driving reason for them to seek over-the-counter status – to bypass medical intervention intended to protect women).

MAP promoters demonstrate a disturbing lack of concern for women's health:

Plan B's Web site responds to the question, "How often can Plan B be provided," by stating, "Plan B can be provided as frequently as needed."

The Web site acknowledges the need for intervention and oversight. "Providers can help a client determine whether Plan B treatment makes sense given the timing of unprotected intercourse and her level of concern about an unwanted pregnancy." However, over-the-counter access would eliminate "providers," thereby eliminating the opportunity for counsel, caution, and the screening out of women with contraindications.

The Web site encourages unnecessary use of the MAP for women already taking oral contraceptives — even though women are only fertile within days of ovulation: "Women taking oral contraception do not have true menstrual cycles and are at risk of pregnancy. [E]mergency contraception may be indicated."

Advertisements for Plan B include:

One ad portraying 13 young men with the caption, "So many men. So many reasons to have back up contraception."

Another pictures a fraternity, with the words, "Delta Delta Thi. 27 upstanding young men. 34 billion sneaky little sperm."

Another is designed like a poster for adolescents, describing "Damian" as "A Renaissance Guy, a Deep Thinker, an Ancient Soul, a Walking Sperm Factory."

Potential Effect on Public Health

Regions that allow easy access to the MAP experience a significant increase in sexually transmitted diseases. In the United Kingdom, chlamydia cases rose from 7,000 in 1999 to 10,000 cases last year. Gonorrhea cases climbed nearly 50 percent, to nearly 3,000 cases last year, up from 2,000 in 1999. The highest increases were among 16-19 year olds.

Contrary to proponents' claims, the number of surgical abortions has not declined with easy access to MAP. In some areas, the number of abortions increased.

In a UK study of users of MAP, four out of the 12 women interviewed said their choice to have unprotected sexual intercourse was influenced by the knowledge that they could obtain the pill from a pharmacy.

In response to concern that providing the morning-after pill through pharmacists would lead to more unprotected sex, a user of the pill disclosed: "To be honest, in a way, that is what happened to me. I did previously know that X chemist was just over the road and I think, I think if I hadn't have known … if I hadn't have known I could have got it so easily, I would have been more careful, to be honest."

Risk to Adolescents

Many teenagers would be less confident in resisting sexual pressure, particularly if easy access to the pill is in the aggressor's arsenal of coercion. It will increase the likelihood of sexual abuse of girls, and that sexual perpetrators will prolong their rapes undetected.

Adolescents are unlikely to recognize if they have medical contraindications, less likely to follow directions for administration or to fully understand a medication label. They are less prone to seek medical help if they suffer symptoms of complications after secretly taking the MAP, and would not be aware that it lacks adequate testing.

Rather than reducing the core problem of young people engaging in sexual activity (which carries life-long consequences), it encourages sexual activity. An official survey revealed that MAP use among teenage girls in the United Kingdom more than doubled since it became available in pharmacies, increasing from one in 12 teen-agers to one in five. Among them were girls as young as 12. A girl who said she was 10 years old told the pharmacist "she had already used it four times."

Even morning-after pill proponents agree that sexually active girls are likely victims of sexual abuse, and interaction with medical professionals is an important defense.

The Alan Guttmacher Institute reported: "The younger women are when they first have intercourse the more likely they are to have had unwanted or nonvoluntary first sex, seven in 10 of those who had sex before age 13, for example."

"Sexual abuse is a common antecedent of adolescent pregnancy, with up to 66% of pregnant teens reporting histories of abuse…. Pregnancy may also be a sign of ongoing sexual abuse…. Boyer and Fine found that of 535 young women who were pregnant, 44% had been raped, of whom 11% became pregnant as a result of the rape. One half of these young women with rape histories were raped more than once."

Tool for Abusers

The Bangkok Post reported disturbing consequences of easy availability of the morning-after pill for the past 15 years, including:

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).

“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.”

FDA Advisory Committee

The FDA Advisory Committee chairman declared the label comprehension study a “failure” – a full one-third of the women did not understand that the morning-after pill is not to be used as a regular form of birth control.

The committee was presented limited or incomplete information.

Some committee members displayed a disturbing lack of interest in the potential abuse of women, and of practical reality. These members advocated that the morning-after pill should be placed in stores outside the line of vision of pharmacists, so customers would not be embarrassed about obtaining it. The committee members did not say how they expect customers to pay for it without anyone seeing.

The FDA has rejected advisory committee recommendations in the past, most recently regarding silicone breast implants. It is only one of the FDA’s multiple levels for evaluation.