

December 16, 2003

FDA Advisory Committee on Reproductive Drugs  
Nonprescription Drugs Advisory Committee  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

RE: Docket No. 2001P-0075 Proposal to Switch Status of Emergency Contraceptives from Rx to OTC

Dear Committee Members:

Concerned Women for America (CWA), the nation's largest public policy women's organization, representing over 500,000 members, stands opposed to the proposal to make Plan B, the "morning-after pill," available over-the-counter. CWA has no financial relationship with the sponsor, its product, or its competitors.

It is quite astonishing that the FDA is considering allowing Plan B or any other form of the morning-after pill (MAP) to be sold over-the-counter. 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, exposes women, teenagers and girls to complications such as blood clots and heart attacks.

Ample reasons exist for the FDA Advisory Committees to protect women by advising against over-the-counter access to the morning-after pill, including:

- Absence of scientific studies on: the long-term effects; the effects of repeated usage; the effects on females not counseled or screened for medical contraindications; and on adolescents, as required by the Pediatric Research Equity Act of 2003.
- The promoters' practice of overstating efficacy and understating risks, as cited by the FDA.
- The promoters' refusal to provide women with adequate information to make clear that the MAP can end a pregnancy.

- Increases in sexually transmitted diseases in regions that have allowed easy access to the MAP and, contrary to proponents' claims, the absence in these areas of a decline in surgical abortions.
- The unprecedented and unsubstantiated action by the FDA in 1997 originally to approve the use of the morning-after pill (with a prescription).
- The potential for the morning-after pill to be slipped to women without their knowledge or consent; and the probability of the ready availability of the morning-after pill being used to exploit and coerce women – particularly minors – to engage in risky sexual activity.

The FDA Advisory Committees should advise against allowing a drug that is medically unsafe and untested, which will increase public health problems and will be used against women without their knowledge or consent, to be sold over-the-counter. The FDA should not facilitate attempts by promoters of the morning-after pill to profit at the expense of women's health.

### **Lack of Scientific Studies Eliminates Morning-After Pill as Candidate for OTC**

It would defy logic to make the morning-after pill, a high dose of the birth control pill, available over-the-counter because lower doses of the same drug require a medical exam (to detect contraindications), a prescription, and physician oversight through the duration of use.

Birth control pills are available by prescription only for sound medical reasons: They can cause significant or life-threatening conditions such as blood clots and hearts 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. These and other contraindications would prevent a patient from receiving a prescription.<sup>1</sup> A medical exam supplemented by ongoing physician oversight is necessary to ensure that none of these contraindications exists.<sup>2</sup> 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.

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<sup>1</sup> According to MayoClinic.com, medical problems that may affect the use of progestins include: asthma, epilepsy, heart or circulation problems, kidney disease (severe), migraine headaches, undiagnosed bleeding problems, breast disease, central nervous system disorders such as mental depression, high blood cholesterol, diabetes mellitus, liver disease, other conditions that increase the chances for osteoporosis. (<http://www.mayoclinic.com/invoke.cfm?objectid=5A236570-60AA-447C-BFF244AF15E011AE#g20275701>).

<sup>2</sup> MayoClinic.com states, “It is very important that your health care professional check your progress at regular visits. This will allow your dosage to be adjusted to your changing needs, and will allow any unwanted effects to be detected. ... Progestins may cause some people to become dizzy. Make sure you know how you react to this medicine before your drive, use machines, or do anything else that could be dangerous if you are not alert. ... Check with your doctor as soon as possible if any...side effects occur.” (<http://www.mayoclinic.com/invoke.cfm?objectid=5A236570-60AA-447C-BFF244AF15E011AE#g20275701>).

The process by which the morning-after pill originally gained approval by the FDA is itself a matter of grave concern. In February 1997, a notice appeared in the Federal Register from then-FDA Commissioner David Kessler stating that the FDA was seeking New Drug Applications for “combined oral contraceptives appropriately labeled for use as postcoital emergency contraception.” This active solicitation was based not on evidence acquired from rigorous, unbiased tests that meet FDA standards and prove safety as well as efficacy, but rather from “published literature.”<sup>3</sup> Those familiar with FDA’s practices have called this action “unprecedented.”

The “published literature” (21 references) cited in the FDA notice only address the drug’s effectiveness in reducing birth rates. None concern themselves with the effects of the morning-after pill on women.

In taking this action, the FDA implicitly suggested that the morning-after pill had been tested according to rigorous FDA standards in the intended population — women who had been prescribed and counseled. The FDA is now considering extending the availability of the morning-after pill to a broader audience — females who have not been counseled or screened for contraindications.

No studies have been conducted on the long-term effects or on multiple use. While proponents brush away concern over the effects of repeated use, claiming that women will use it only in “emergencies,” experience shows that, in fact, some customers do rely upon the morning-after pill as a regular form of contraception. Indeed, the Web site for Plan B encourages it to be used “as frequently as needed.”<sup>4</sup>

The World Health Organization warns “repeated use of emergency contraceptive pills in any month can expose women to higher doses of steroids than those recommended during one cycle.” Additionally, morning-after pills “are not recommended for routine use because of the higher possibility of failure compared to regular contraceptives and the increased risk of side effects.”<sup>5</sup> A study conducted at Albert Einstein School of Medicine found that 19 percent of women given Plan B used it, while none of the women given a prescription for Plan B used it.<sup>6</sup> (Promoters of the morning-after pill describe “emergencies” as any act of unprotected sex.)

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<sup>3</sup> “Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception,” Food and Drug Administration, *Federal Register*, Vol. 62, No. 37, February 25, 1997, Notices.

<sup>4</sup> *Plan B (Levonorgestrel) Emergency Contraception: Health Professionals*, as found at [http://www.go2planb.com/section/health\\_professionals/](http://www.go2planb.com/section/health_professionals/)

<sup>5</sup> *Emergency Contraception: A Guide for Service Delivery*; WHO, Geneva, 1998.

<sup>6</sup> “Study Ties ‘Morning-After’ Pill Use to Supply Ease,” Reuters, April 28, 2003.

Those most likely to use the morning-after pill repeatedly include adolescents, whose bodies are still developing and undergoing rapid hormonal changes. Adolescents would be attracted to the MAP by the ability to keep their use of it secret. However they are unlikely to recognize contraindications. They also are not likely to follow directions for administration or to read through or fully understand a medication label.

The Pediatric Research Equity Act of 2003, passed unanimously by the Senate and signed by President Bush on December 3, 2003, gives the FDA the authority to require manufacturers to test the safety and dosing of all new medicines and some already marketed medicines for children. The American Civil Liberties Union of Hawaii notes that teenagers are the prime target for the morning-after pill, saying, "Research shows that [minors are] the very population who may use contraception sporadically or incorrectly and thus may need emergency contraception even more than older women."<sup>7</sup> Yet the MAP has not been adequately tested for use in the pediatric population.

Because the morning-after pill has not been tested for safety, the women who use it will serve as unsuspecting "guinea pigs." There is no system in place for reporting or compiling reports of complications. Further, there is no incentive for those who distribute the pills, or medical personnel who treat women who suffer adverse events, to generate a record of complications.

### **FDA Cites Pill's Marketers for False Advertising**

Ads and marketing campaigns influence consumers more than labels do. In November 2002, the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC) cited Women's Capital Corporation for false advertising of Plan B. The FDA Warning Letter provides evidence of strong concerns for the use and misuse of the drug, concerns that have warranted the prescription status. The FDA's letter also shows the practice of proponents to minimize risks, side effects, proper precautions and indications for use. It reads, in part:

DDMAC has concluded that [Women's Capital Corporation's] ads are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (Act) and applicable implementing regulations. Specifically, the DTC [direct to consumer] radio and print ads overstate efficacy, fail to convey important limitations on use, and minimize important information about risks associated with the use of Plan B Tablets emergency contraception. As a result, the ads raise significant public health and safety concerns.<sup>8</sup>

Additionally, while admitting that one effect of Plan B is to inhibit implantation, promoters of the morning-after pill claim it does not end a pregnancy. What then does

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<sup>7</sup> Stephanie Healea, "Morning-After Pill Bill Passed by State House," *Honolulu Star-Bulletin*, 4 March, 2002, as found at <http://starbulletin.com/2002/03/14/news/story2.html>

<sup>8</sup>Letter to Sharon L. Camp, Ph.D, President and CEO of Women's Capital Corporation, RE: NDA 21-045 Plan B (levonorgestrel) Tablets, 0.75 mg, FDA Warning Letters, released 19 November 2002.

Plan B prevent from implantation? Answer: A newly formed human life, with 46 chromosomes and the DNA to prove its humanity, created at the moment of fertilization. Statements that Plan B does not end a pregnancy are intended to manipulate women who believe that life begins at fertilization. Because 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.

If the FDA switches Plan B to over-the-counter, it will no longer have direct oversight of advertisements for the drug, and therefore cannot protect the public from the sponsor's misleading advertisements.

### **Easy Access to the Morning-after Pill Has Led to an Increase in Sexually Transmitted Diseases, No Reduction in Abortion Rates, and Repeat Use**

Sexually transmitted diseases (STDs) are at epidemic proportions in the United States, and even abortion supporters admit that abortions should be "rare." Yet places that expanded access of the morning-after pill by dropping the requirement for a prescription have experienced higher STD rates, and no decrease in abortions.

- **Scotland** – Scotland has made the morning-after pill accessible for years, yet abortions increased between 1990 and 1999. In Glasgow, MAP prescriptions increased 300 percent from 1992 to 1999. Yet, this did not result in a decrease in abortions.<sup>9</sup> In Lothian, where schools handed out condoms and sent pupils to clinics for the MAP, teenage pregnancies among 13-15 year-olds soared 10 percent in one year.<sup>10</sup>
- **Washington State** – A pilot program to provide the morning-after pill through pharmacists since February 1998 focused on increasing access and use. However, the program did not review STD or abortion rates, nor did it record complications suffered by MAP users.<sup>11</sup> Washington Center for Health Statistics reports abortion rates that only reflect the same small decrease in abortions reported nationwide where the MAP was not as easily accessible.
- **United Kingdom** – Making the morning-after pill available through pharmacists (without a prescription) coincides with surges in STD rates. In areas where a limited program began in 1999 (which was then expanded nationwide in January 2001), chlamydia cases rose from 7,000 in 1999 to 10,000 cases last year. Gonorrhea cases

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<sup>9</sup> "Briefing Paper on the Morning-After Pill," Scottish Council on Human Bio-ethics, as quoted by Susan E. Wills, "Deconstructing Rosie," *National Review Online*, 21 March 2002, as found at <http://www.nationalreview.com/comment/comment-willsprint032102.html>.

<sup>10</sup> Graham Grant, "Birth Control For Teens So Pregnancies Go Up By 10pc," *Daily Mail* (London), 1 December 2003, ED\_Sci, p.10.

<sup>11</sup> "Expanding Access to Emergency Contraceptive Pills in Washington State: Promoting Pharmacist/Prescriber Collaborative Agreements," Project Summary, Washington State Department of Health, Board of Pharmacy, author's copy.

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.<sup>12</sup>

An official survey of chemist shops, family planning clinics and schools revealed that 25,200 girls under 16 (the age of consent in England) were given the morning-after pill in 2001. Among them were girls as young as 12.<sup>13</sup>

MAP use among teenage girls in the UK has more than doubled since it became available in pharmacies, increasing from one in 12 teen-agers to one in five.<sup>14</sup>

“Women aged under 20 were twice as likely as those aged 20 and over to have used the morning-after pill at least once in the past year.”<sup>15</sup> Of the more than 20 percent of 18-19 year olds who used the morning-after pill, nearly a quarter had taken it more than once in the same year. One in seven of all women used the morning-after pill repeatedly in the same year.<sup>16</sup>

Nurses at the Royal College of Nursing’s annual conference in 2003 called for tighter regulations, warning that suppliers (pharmacists) were failing to warn customers of possible complications or carry out routine medical assessments.<sup>17</sup>

In a study published in *Social Science & Medicine*, pharmacists and users of the MAP expressed major concerns about the easy access. These included the potential for misuse, changes in contraceptive use, and the impact on sexually transmitted diseases.<sup>18</sup>

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<sup>12</sup> Beezy Marsh, Suzanne Finney, “Morning-after pill fuels the epidemic of sexual diseases,” *Daily Mail* (London), 18 October 2003, Second edition, p.7.

<sup>13</sup> Alfred Lee, “Alarming rise in use of ‘morning-after’ pills by under-16s,” *Straits Times*, Europe Bureau, 29 January 2002

<sup>14</sup> Doughty, S., “Morning-after pill lures teens,” *Herald Sun*, 28 March 2003, as cited in a letter to the Secretary of Australia’s National Drugs and Poisons Schedule Committee, Therapeutic Goods Administration, from Mary Joseph of the Australian Federation of Right to Life Associations, 18 August 2003.

<sup>15</sup> *Contraception and Sexual Health*, Office for National Statistics (UK) (2003), 2001, as cited in letter the Secretary of Australia’s National Drugs and Poisons Schedule Committee, Therapeutic Goods Administration, 18 August 2003.

<sup>16</sup> Ibid.

<sup>17</sup> Isabel Oakeshott, “Nurses warn on morning-after pill,” *Evening Standard*, 30 April 2003, as found at <http://www.thisislondon.co.uk/news/articles/4589702?source=Evening%20Standard>.

<sup>18</sup> Paul Bissell and Claire Anderson, “Supplying emergency contraception via community pharmacists in the UK: reflections on the experiences of users and providers,” *Social Science & Medicine*, Volume 57, Issue 12, December 2003, Pages 2367-2378.

It must be noted that the system in the UK provides training to pharmacists. They counsel patients, determine whether use of the MAP is appropriate, can consult with local doctors, and have the authority to deny requests for the morning-after pill. Intervention also allows pharmacists to refer clients to other agencies. In contrast, the FDA has been asked to make the morning-after pill over-the-counter. Its sale would occur without even the UK's meager intervention by pharmacists to reduce the medical and criminal risks to women.

The study revealed these comments from pharmacists:

“I think we have to hammer home the message with some of them. I've felt that those who come in giggling about it, it's important to underline that this isn't a joke. One girl had been in three times, and then you start to get the thumbscrews out with them. If they're not getting the message that it's only for occasional use, then we have to tell them.”

A girl who said she was 10 years old told the pharmacist “she had already used it [EHC] four times.” The pharmacist declined her request and referred her to a sexual health clinic.

“I think the pharmacy service offers anonymity for those who don't want their doctors to know they have taken EHC [Emergency Hormonal Contraception].”

“We have a say over whether we supply it or not. They can't just come in and demand it and all that. We have to make sure there's, that we're sure there's a clinical need for the MAP.”

Female pharmacists expressed concern that easy access to the morning-after pill would result in men coercing women, particularly young or less assertive women, into having sexual intercourse against their will.

In response to concern that providing the morning-after pill in the pharmacy 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.”

The researchers found limited evidence of women repeatedly using the morning-after pill. However, they concede that pharmacists would not know how often customers have obtained the drug from other stores and clinics.

In a different study among users of the pill, 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.<sup>19</sup>

- **Australia** – “Teenagers are the most frequent users of emergency contraception at Australian Family Planning clinics.”<sup>20</sup> Teenagers are not likely to know or diagnose their medical conditions, 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. Many teenagers would also be less confident in resisting sexual pressure, particularly if easy access to the pill is in the aggressor’s arsenal of coercion.

### **“Men Are The Most Frequent Buyers” of the Morning-After Pill in Thailand.**

The *Bangkok Post* reported several disturbing consequences of having the morning-after pill over-the-counter for the past 15 years.<sup>21</sup> These included:

- 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

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<sup>19</sup> P. Bissell, R. Harness and A. Anderson, “The sale of emergency hormonal contraception in community pharmacies in the UK: The views of users.” *International Journal of Pharmacy Practice*, Suppl. (2002), p. R47, as cited in “Supplying emergency contraception via community pharmacists in the UK: reflections on the experiences of users and providers,” *Social Science & Medicine*, Volume 57, Issue 12, December 2003, Pages 2367-2378.

<sup>20</sup> Skinner, S. and Hickey, M. “Current priorities for adolescent sexual and reproductive health in Australia,” *Medical Journal of Australia*, vol. 179(3), 2003, pp. 158-161, as cited in letter to the Secretary of Australia’s National Drugs and Poisons Schedule Committee, Therapeutic Goods Administration, 18 August 2003.

<sup>21</sup> Karnjariya Sukrung, “Morning-after blues,” *Bangkok Post*, 10 June 2002, as found at <http://www.morningafterpill.org/bangkok.htm>.



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

### **Tool for Abusers and Statutory Rapists**

Congress is currently debating measures to reduce the risk of statutory rapists using federally funded contraception to conceal sexual abuse of their young victims. This national effort is fueled by reports of adult men relying on family planning clinics to obtain contraception for the minor girls they are sexually abusing. Converting the morning-after pill to over-the-counter would thwart congressional attempts to protect minors from sexual abuse.

Although adult women may be less susceptible to being coerced into sexual activity, they may become victims of those who do not want the woman to be pregnant. In one illustrative example, Gary Bourgeois tried to convince his pregnant girlfriend to have an abortion, which she refused. 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.<sup>22</sup>

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 because she refused to have an abortion.<sup>23</sup>

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

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<sup>22</sup> Tu Thanh Ha, “Man admits inducing woman’s miscarriage; Montrealer pleads guilty in case where anti-ulcer drug was slipped to girlfriend who had refused to have an abortion,” *The Globe and Mail* [Montreal, Canada], September 17, 2003.

<sup>23</sup> Dan Kadison, “Doc gets 2 yrs. for needle attack on pregnant gal pal,” *New York Post*, April 21, 2001.

consent or knowledge. When complications occur, victims and their doctors will not know the cause.

### **Morning-after Pill Linked to Ectopic Pregnancy**

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.”<sup>24</sup> Scientists believe that the pill may slow the journey of the egg to the womb in some women by affecting tiny hairs inside the fallopian tubes.

Britain’s Chief Medical Officer, Sir Liam Donaldson, sent a letter to doctors in January 2003 stating that 12 cases of ectopic pregnancy out of 201 pregnancies followed failure of Levonelle (levonorgestrel 0.75 mg). The letter noted that ectopic pregnancies are more likely to occur in women taking progestogen-only pills.<sup>25</sup> Schering Health Care, the maker of Levonelle, was ordered to change the wording of patient information leaflets to clarify the potential risk of ectopic pregnancy.

Dr. Terri Foran, medical director of FPA Health (Family Planning Australia) in Sydney, said, “Of those pregnancies that are not prevented by the [contraceptive] method, it would appear likely that an increased proportion of these might be ectopic.”<sup>26</sup>

Similarly, the Lis Maternity Hospital in Tel-Aviv reported three cases of ectopic pregnancies occurring in women who ingested levonorgestrel. The women, aged 19, 20 and 34, were “without apparent risk for ectopic pregnancy.”<sup>27</sup>

### **Goal: Sell More Product, Not Ensure Women’s Health**

Promoters of the MAP demonstrate a disturbing inclination to encourage liberal use of the drug, in contrast to claims it will only be used for “emergencies.” For example, a Q & A section of the Plan B Web site:

- Responds to the question, “How often can Plan B be provided,” by stating, “Plan B can be provided as frequently as needed.”

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<sup>24</sup> “Emergency Contraception: A Guide for Service Delivery,” (World Health Organization: Geneva, Switzerland), 1998, as cited in to the Secretary of Australia’s National Drugs and Poisons Schedule Committee, Therapeutic Goods Administration, from Mary Joseph of the Australian Federation of Right to Life Associations, 20 May 2003.

<sup>25</sup> Richard Woodman, “UK warns of ectopic risk with ‘morning-after’ pill,” Reuters Health, 30 January 2003.

<sup>26</sup> Beezy Marsh, Anna Patty, “Ectopic pregnancy link to morning-after pill,” *The Daily Telegraph* (Sydney, Australia), 31 January 2003.

<sup>27</sup> Sheffer-Mimouni G., Pauzer D. Maslovitch S., et al, “Ectopic pregnancies following levonorgestrel contraception,” *Contraception*, 2003:67:267-269.

- 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, Women’s Capital Corporation is asking the FDA to eliminate “providers,” which would eliminate the opportunity for counsel, caution, and the screening out of women with contraindications.<sup>28</sup>
- Dismisses the lack of pediatric testing by stating, “Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 as for users 16 years and older.”<sup>29</sup>
- Encourages use of the MAP throughout the cycle by planting doubt in 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.”<sup>30</sup>

## Conclusion

The evidence is clear. Sale of the morning-after pill over the counter will encourage frequent use by making it easily accessible to anyone, causing medical threats to women with undetected contraindications, including women who have not consented to taking the morning-after pill. It would 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.

On behalf of women throughout the United States, Concerned Women for America requests the FDA Advisory Committees to protect women and girls from serious medical risk by declining the request to make the morning-after pill Plan B available over-the-counter. Additionally, we ask the Committee to recommend that the original FDA approval for the morning-after pill with prescription be reviewed and rescinded.

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<sup>28</sup> “Should Plan B be provided if intercourse did not occur mid-cycle? ” Plan B (Levonorgestrel) Emergency Contraception: Health Professionals, found at [http://www.go2planb.com/section/health\\_professionals/](http://www.go2planb.com/section/health_professionals/)

<sup>29</sup> “Are there age limitations on the use of Plan B? ” Ibid.

<sup>30</sup> “Is emergency contraception appropriate for women using highly effective methods, such as oral or injectable contraceptives? ” Ibid.