

**RE: Docket number 2001P-0075**

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2001P 0075 Joint Meeting of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs. On the safety and efficacy of NDA 21-045 proposing over-the-counter use of Plan B, Women's Capitol Corp. for reducing the chance of pregnancy after unprotected sex.

Comment submitted by:

Name: Ms. Jenny Brown

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Organization type: Other Organization

Organization name:

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Comment:

It seems obvious most people that the current prescription-only status of the Morning-After Pill, which requires women to get (and pay for) a doctor's appointment, is completely ludicrous for a drug most effective to prevent pregnancy when taken within 24 hours—and fairly effective up to 72 hours—after sex.

But some have argued that making the Morning-After Pill an over-the-counter drug, like aspirin and cold medicine, is going too far, and that although the Morning-After Pill is safe, women should be able to obtain it only through a "pharmacist prescription," a status sometimes known as "behind the counter."

We completely disagree. We believe the Morning-After Pill should be immediately made an over-the-counter drug, and that it should be affordable and accessible to women of any age and in all parts of the country. We believe that the U.S. should follow the lead of dozens of other countries which already provide women access to this safe backup birth control method without any restriction. (The Morning-After Pill we are referring to is marketed under the brand names Preven® and Plan B® (levonorgestrel) and is also known as "post-coital contraception" or "emergency contraception.")

We urge the FDA immediately approve the Morning-After Pill for over-the-counter use.

We have identified six arguments for pharmacist prescription status, and we respond to them below, based on our experience talking to hundreds of women about their experiences with the Morning-After Pill and with contraceptives in general, and based on our conclusions from over 3-decades of campaigning for women's equality.

1 Pharmacists have more information, and can be trusted to dispense the pill, when necessary, to women who request it.

We say this sounds good in theory, but fails in practice.

First, in our experience, many pharmacists will not fill prescriptions for the Morning-After Pill because of personal religious beliefs.

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In 1991, a pharmacist at the infirmary at the University of Florida in Gainesville was discovered to be refusing to fill women's prescriptions for the Morning-After Pill. Feminists protested and the university was eventually forced to ask for his resignation. But there was evidently still a problem as the University of Florida then had to institute a system to call another pharmacist if the pharmacist on duty refused to fill these prescriptions.

How widespread is this problem? A phone survey of 315 Pennsylvania pharmacists reported in the October 2003 issue of the journal *Contraception* noted that of the 65% of "pharmacists surveyed who could not fill a same-day prescription, 7 percent cited personal beliefs as the reason, while 6 percent said it was against store policy." ("Study: Pharmacists not informed on morning-after pill," *Mavis McCullough Philadelphia Inquirer*, Oct. 21, 2003.)

There is even an organization, *Pharmacists for Life International*, founded by pharmacists who refused to fill women's prescriptions for oral contraceptives "because they believed they cause abortion," according to a 2002 article by Patti Miller. Miller writes: "The organization... has been effective in expanding the right of health professionals to refuse to provide reproductive health services such as contraception and emergency contraception. The president of PFLI is Karen Rixner, a pharmacist who was fired by Kmart in 1996 after she lied to a patient that an oral contraceptive was out of stock to avoid filling a prescription." (Patti Miller, "Do No Harm: Far-Right Medical Groups and Religion Don't Mix," full article available at: [http://www.rtrc.org/news/commentary/do\\_no\\_harm.htm](http://www.rtrc.org/news/commentary/do_no_harm.htm))

Second, while some pharmacists refuse prescriptions on religious grounds, some will counsel women that they don't need it based on where they are in their menstrual cycle, a guess a best, and it's the woman, not the pharmacist, who will pay the price for errors. We know pharmacists will do this because this is the experience we have now, with doctors and physicians assistants who tell us we do not need the Morning-After Pill. Some women report being left alone in a room with a calendar by their medical practitioner, and told to try to figure out the date of their last menstrual period. If they can't remember it, they're told, they can't have the Morning After Pill. Women have even been told by medical professionals that they shouldn't put "all those chemicals" (meaning the Morning-After Pill) in their bodies, and are then told they should get on daily birth control pills! Daily oral contraceptives can have serious long-term side-effects not associated with the extremely short duration dose of hormones in the Morning-After Pill.

In 1998 it was revealed that the same infirmary at the University of Florida was requiring women to fill out forms if they wanted to receive a prescription for the Morning-After Pill. They were asked if they had been sexually assaulted and asked to pledge to use reliable birth control from now on. Women said they thought the form meant they could not get the Morning-After Pill again if they needed it. After protests from feminists, who pointed out that the form was misleading, discriminatory and unnecessary, the infirmary agreed they had been in error and stopped using the form.

2. A panicked or uninformed woman may take the pill incorrectly or use it inappropriately if they don't get professional advice.

This builds on the stereotype of women as ditzzy and incompetent. No one asks if men are really competent to use minoxidil, an over-the-counter baldness medication, which warns you to stop using it if you have chest pain, rapid heartbeat, faintness or dizziness. Yet men aren't required to have a pharmacist's counseling to alert them to the serious nature of these symptoms. The Morning-After Pill has only minor side-effects, and most women experience no side-effects.

Plan B, the progestosterone-only Morning-After Pill, consists of two pills to be taken within 72 hours of unprotected intercourse. The first pill is taken immediately and the second 12 hours later. Even at our

most panicked, these are not difficult instructions to follow. Most of our panic stems from not being able to obtain the pill when we need it.

Pharmacists are not necessarily knowledgeable about the Morning-After Pill. In studies conducted in New York and Pennsylvania, pharmacists had alarmingly little knowledge of the Morning-After Pill, and many disseminated misinformation about it.

In the 2003 Pennsylvania survey of 315 pharmacists:

- "13 percent of the pharmacists incorrectly stated the time parameters for using emergency contraception.
- 5 percent said it was not available in the United States
- 28 percent did not know a brand name.
- 13 percent confused emergency contraception with the abortion pill or thought it caused an abortion "

Among 100 New York City pharmacists surveyed by Planned Parenthood in August and September of 1998, shortly after the pill's approval by the FDA:

"Thirty-seven pharmacists received poor ratings for their knowledge of emergency contraception. A poor rating means the pharmacist either knew nothing about emergency contraception or only provided incorrect information about the treatment. Two-thirds, or sixty pharmacists, provided some type of incorrect information about emergency contraception. Only 3 received an excellent rating, correctly providing all the key facts about emergency contraception."

Planned Parenthood found that four thought the Morning-After Pill caused abortion, eleven said it was not available in the United States, and "Of the 34 pharmacists who discussed the time frame in which to take emergency contraception, only 12 correctly identified the time frame as within 72 hours."

(The Planned Parenthood report is available at:  
<http://www.ppnyc.org/new/publications/exccutive.html>)

Other access issues:

Pharmacist prescriptions will force a women to stand in the middle of a drug store, in front of other customers, and discuss the last time she had sex, when her last period was, and other private information. This will discourage a lot of women from getting it.

Although many drugstores are open 24 hours a day, most do not have pharmacists on duty more than 10 or 12 hours a day. And when a pharmacist is there, there is frequently a long line for service. This creates another obstacle for women if the Morning-After Pill is pharmacist-prescribed.

In consciousness-raising women talk about the difficulty of getting off time during work or school hours and dealing with other life responsibilities while trying to obtain the Morning-After Pill in the quickest possible time period. The terrible squeeze for time can be explained by the fact that in U.S., we already work the longest hours in the industrialized world, and women are still burdened with extra unfair responsibilities at home.

We should be able to send a man to pick up the Morning-After Pill for us. This is only feasible if the drug is over-the-counter.

In addition, NARAL/NY has cited\* a 2002 study that simulated over-the-counter availability of emergency contraception, nearly all the subjects used the product (Plan B®) appropriately and safely. The incidence of contraindicated use was extremely low (1.3%). (Raymond EG, Chen P, Dalcbout SM. "Actual Use" Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner. *Obstet Gynecol* 2003, 102: 17-23.)

**3. Over-the-counter access to the Morning-After Pill will allow women to be irresponsible about birth control.**

Women, by seeking the Morning-After Pill, are taking responsibility, as we do again and again when it comes to birth control. Women do this not because we are morally superior to men but simply because we pay a higher price for failures, and because in many cases men won't take responsibility by wearing a condom, or even by telling their partners if one breaks or slips off during intercourse.

One way for women to take responsibility is by having the Morning-After Pill around before a problem arises. But we don't know whether pharmacists will be willing to give women the Morning-After Pill to have "just in case." Based on our experience with other medical professionals on this issue, we suspect that some will and some won't, and again our ability to determine what we want to do with our bodies will be in the hands of someone else.

If the Morning-After Pill is over-the-counter, more and more women will make sure they have a current dose in their medicine cabinets at home, for themselves and friends who need it.

**4. Some women can't read, or can't read English, and therefore may take the pill inappropriately, so having a pharmacist explain it to them will avoid problems.**

The solution to illiteracy is free publicly-funded adult reading programs and adequate public school funding. Women who have been cheated out of learning to read should not be insulted and injured further by having their right to control their bodies blocked by unfair rules masquerading as concern for their well being.

A woman who needs more instruction may ask a pharmacist for advice on taking the pill, but she should not be coerced into doing so.

Package instructions and information should be multilingual—at least as multilingual as instructions for computer equipment packaged for the European and Latin American markets—and pictorial representations should also be included, as advocated by the National Women's Health Network.

If pharmacists are not multilingual, they will be of less help in explaining the use of the Morning-After Pill to non-English speakers than a multilingual package insert.

**5. If the Morning After Pill is over the counter, women won't use other birth control methods, and this may increase the prevalence of sexually transmitted diseases.**

The Morning-After Pill is clearly a backup method of contraception. In fact, women testifying in favor of making the Morning-After Pill over the counter state that they are currently using daily birth control pills as a backup to the condoms they use to protect themselves from pregnancy and sexually transmitted diseases. If the Morning-After Pill were more easily and cheaply available, they could rely on it rather than daily contraceptive use.

In fact, in our experience, the Morning After Pill is most needed as a backup to condom use, and makes condom use a better option for us.

Although we think the Morning-After Pill—and all contraceptives—should be available free of charge, in the immediate term it won't be; it is expected to cost around \$25 a dose. Therefore it is ridiculous to suggest that women will use the Morning-After Pill as a routine birth control method.

**6. Women who are raped should be encouraged to seek counseling and medical help. If the Morning-After Pill is available at the corner drug store, women will be less likely to seek this counseling.**

No woman should have her right to control her body held hostage until she reveals a sexual assault. We must be allowed to assess all our options in these difficult situations, and women know that we are often blamed and punished when we come forward. On this issue, the National Women's Health Network writes:

"The Network ... opposes policies which require or otherwise pressure survivors to obtain such services against the woman's own desire or will. Therefore, the Network does not believe that the prescription requirement for [the Morning-After Pill] should be maintained in order to make it necessary for sexual assault survivors to go to a health care provider." (December 1999 statement by the National Women's Health Network, supporting over-the-counter status for the Morning-After Pill.)

### Conclusion

Women know that any woman who reveals that she has had sex is stigmatized as a "slut." This is especially prevalent against young women and unmarried women. Men face no such stigma, although they often perpetuate it against women. Requiring women to reveal the details of sexual activity to a pharmacist—who may be a stranger, or worse, an acquaintance—is humiliating and unnecessary unless there is an overwhelming safety reason.

There isn't, according to the 60 organizations, including the American Medical Association, that support over-the-counter status.

There's a double standard when it comes to birth control which women confront again and again: birth control is too weighty a decision for women to have in their hands, we're told, it must be mediated by professionals and experts. Yet we are the ones who pay the price and bear the burdens.

We learned from the Boston Women's Health Collective (authors of *Our Bodies, Ourselves*) that those who are set up as experts often serve to keep information from us. Women are the experts on our situation, and we can quickly become experts on medical issues that affect our lives.

We learned from Redstockings, the radical feminists who first spoke out about their then-illegal abortions in 1969, that women are the experts on our lives. Not men, not the church, not legislators, not doctors or hospital boards or pharmacists or counselors, no matter how well-meaning or well-educated.

Jenny Brown  
December 5, 2003  
Gainesville (Florida) Women's Liberation

Founded in 1968: oldest women's liberation organization in the South.