Should Plan B be Available Over the Counter?

By:

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"Emergency contraception refers to contraceptive methods that work after unprotected sex but before pregnancy. It is often referred to as the morning after pill".¹ There are several methods of emergency contraception that exist which are safe and effective. Such methods include emergency contraceptive pills and intrauterine devices. Plan B, an emergency contraceptive, has gained much attention during the last couple of years. The issue of whether it should be available over the counter (OTC) in all states in the United States has been challenged. With such a task at hand it is important to examine some of the concerns that the Food and Drug Administration has in allowing pharmacists to dispense Plan B without a prescription and what progress has been made thus far. The role that Canadian pharmacists have in dispensing Plan B can further help to understand this issue as well as some of the thoughts that pharmacists and pharmacy students have on whether Plan B should be available OTC.

It is estimated that there were approximately 3 million unintended pregnancies in 1994 in the United States of America.² According to the Centers for Disease Control and Prevention (CDC) an unintended pregnancy is a one that is either mistimed or unwanted at the time of conception.³ The number of unintended pregnancies varied with age, with the highest being among teenagers younger than eighteen years of age. Out of the women that had unintended pregnancies in 1994, 54% had an abortion while 46% continued the pregnancy to full term.² Furthermore, in 2002 there were about 1.29 million pregnancies that were terminated by means of abortion.⁴ With such statistics available, one wonders if there are any options that patients have in order to avoid diverting to the act of abortion in order to terminate an unwanted pregnancy. Patients have the choice of preventing contraception by use of oral contraceptives as well as condoms, diaphragms and spermicides. When such means of preventing pregnancy fail, women have the option of taking an emergency contraceptive like Plan B.

Plan B is an emergency contraceptive that has shown to reduce the rate of pregnancy. The Food and Drug Administration approved this drug on July 28, 1999. This drug is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Plan B contains 0.75 mg of a single active steroid ingredient, levonorgestrel, which is an entirely synthetic progestogen. It is the first progestin-only emergency contraceptive. The mechanism of action depends on the time of drug administration relative to a
woman’s menstrual cycle. Plan B is believed to primarily work by preventing ovulation or fertilization which is done by altering tubal transport of sperm and/or ova. In addition it may inhibit implantation by changing the endometrium, but is not effective once implantation has occurred. This medication does not work if pregnancy has already occurred. Patients who are prescribed Plan B must take the first tablet within 72 hours of having unprotected intercourse and to take the second tablet 12 hours following the first dose. When Plan B is initiated within 24 hours, the risk of pregnancy is 0.4% then it increases to 2.7% when the first pill is taken 48 to 72 hours after intercourse. The effectiveness of emergency contraception continues to decline after this time frame. In addition, studies have shown that if the pill is taken and pregnancy still occurs, no fetal harm will result as a consequence of taking this medication. This emergency contraceptive, like the oral contraceptive pills does not protect the patient from sexually transmitted diseases. The most common adverse effects that have been reported in clinical trials include nausea, abdominal pain, fatigue, headache, and menstrual changes. Contraindications to the use of Plan B include known or suspected pregnancy because this drug will not terminate pregnancy, hypersensitivity to any component of the product, and undiagnosed abnormal genital bleeding. Although women have the option of Plan B if Plan A (an oral contraceptives or condoms) fails, they must first obtain this medication within the 72 hour window.

Currently in majority of the U.S. states, a woman has only one method of obtaining Plan B and that it through a visit to the physician who can prescribe this medication. This option must assume that there is either a clinic that is open and not completely filled up or that the patients primary physician has an appointment available within 72 hours after engaging in intercourse. Anyone that has ever been to a walk in clinic knows that it fills up quickly and the chances of getting an appointment with a family physician on the same day when the phone call to the office is made, is slim to none. This is of particular concern because if a woman has unprotected intercourse on Friday night, she cannot wait until Monday or Tuesday to see her family physician because by this time the effectiveness of the emergency contraceptive has decreased. If the patient is unable to see a clinic or family doctor, then the patient must go to the emergency room and wait to see a physician there. Once the physician writes a prescription, the patient must then take this paper to the pharmacy in order to get it filled. Once again this requires time that can delay the administration of the drug.

On the other hand, there are 34 countries that dispense Plan B without a prescription. Furthermore there are seven US states that allow pharmacists to dispense this medication without a prescription. These states include Alaska, California, Hawaii, Maine, New Hampshire, New Mexico, and Washington. Canada also offers Plan B over-the-counter. Although some states and countries dispense Plan B without a prescription, Sweden and Norway are the only countries that allow unrestricted over-the-counter sales. These countries allow for the dispensing of Plan B without a prescription and as a result they are helping to decrease the number of unwanted pregnancies. In order to have Plan B available
OTC in all states in the US, this drug must be reclassified in accordance with the Food and Drug Administration (FDA) regulations.

The Food, Drug, and Cosmetic Act of 1938 was the primary piece of legislation that mandated that drugs be cleared by the FDA before they could be marketed for humans to utilize. This law required that medications be proven to be safe before they were marketed and also banned the sale of misbranded or contaminated drugs and also set forth the rules for labeling. From the time that the Food, Drug, and Cosmetic Act has been passed, a company must file a new drug application (NDA), and once the FDA approves it, the sponsor may market the product. For generic medications to become approved an abbreviated NDA may be utilized. In 1951, the Durham-Humphrey amendments were established which differentiated between prescription and OTC drugs. Prior to this time, different manufacturers made different decisions about whether to market a drug as prescription or OTC. This caused confusion among patients and pharmacists and more importantly the FDA was unable to make sure that the OTC products were safe for patients to used without the supervision of the physician. Finally in 1962, the Kefauver-Harris amendments were established which demanded that drugs not only be proven to be safe but that they also had to be shown to be effective for the intended use. In 1972, the OTC Drug Review was established which reviewed the safety, efficacy and labeling of OTC products. The review process was made up of three phases: an advisory panel review, creation of a tentative monograph and publication of a final monograph. The OTC Drug Review has resulted in the reclassification of 40 primary product ingredients from prescription only to OTC status.

Although the drug review process is one way to reclassify products from prescription to OTC status, this can be done by other means. The first way is when new clinical research provides information that allow for the approval of the drug for an OTC indication and therefore the manufacturer can file a new NDA. A second way is for the FDA to file an appeal for reclassification if it is found that the drug does not require a prescription in order to be used safely. A third method is to file a supplemental NDA to the original NDA if there are favorable post marketing safety experience for a product that suggest that the drug may be safely used without supervision by the physician.

Before any of the methods can be undertaken to reclassify the drug from prescription to OTC status, there are criteria that must be met. First, the indication for the OTC drug should be similar to the prescription indication and must allow for easy diagnosis and monitoring by the patient. Second, the drug should have favorable adverse event and drug interaction profiles, relatively low toxicity and a low potential for abuse. This information can be obtained from clinical trial results and post marketing safety surveillance data, which is submitted to the FDA by the manufacturer of the product. The last criteria that must be met is that the drug should not have any special monitoring requirements or have a narrow therapeutic index that would make it impractical for use without a prescription. During a
meeting on December 16, 2003, Dr. Dickerson, President-elect of the American College of Obstetricians and Gynecologists, addressed some of these criteria. He stated that “Plan B is safe, and it is effective. It is not teratogenic. It has no potential for overdose or addiction. It does not require special medical screening. It is easy to use, and the labeling instructions are clear and understandable.”10 Having looked at some of the issues that must be overcome in order to make a drug like Plan B available OTC, one can analyze the steps that were taken by Barr Laboratories in the attempt to allow for the dispensing of Plan B without a prescription and the current status of the situation.

Plan B was approved by the FDA in 1999 as a safe and effective prescription only emergency contraceptive for women. On April 21, 2003, Women’s Capital Corporation submitted an application to the FDA for OTC status. Later that year, on December 8, 2003, representative Joseph Pitts, along with 43 Republican Members of Congress, including Majority Leader Tom Delay, sent a letter to the FDA advising it to reject Plan B for OTC status. On December 16, 2003, the FDA’s Reproductive Health Drugs Advisory Committee voted 23–4 in favor of Plan B becoming available OTC.1 At this point it seemed that based on the results of the vote; Plan B would be available without a prescription in no time. However, on May 6, 2004 the FDA rejected the application, because it claimed there was insufficient information about how younger adolescents would use this emergency contraceptive without a prescription. Barr Laboratories submitted another application to the FDA on July 22, 2004, for a unique and unprecedented dual prescribing status for Plan B, suggesting that Plan B be OTC for women ages 16 and older but remain a prescription-only product for girls 15 and younger. In late January of 2005, the FDA failed to issue a decision on the Plan B application by the deadline, which they themselves had set. The most recent development on the issue of FDA’s decision of Plan B OTC status is that on November 3, 2005 representatives Maloney, Shays, Inslee, and Crowley introduced “Plan B for Plan B Act of 2005.” This bill requires the FDA to make a decision on the OTC status of Plan B and either approve it or deny it.11, 12

Throughout this year there were a couple of people that resigned from their positions as a result of the issues with Plan B. The first person was Dr. Susan F. Wood, Ph.D., Assistant Commissioner for Women’s Health and Director of the FDA’s Office of Women’s Health, who resigned in protest over the FDA’s handling of the Plan B application. She resigned on August 31, 2005. Dr Wood’s announcement read in part, "I have spent the last 15 years working to ensure that science informs good health policy decisions. I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled. I therefore have submitted my resignation effective today.” 13 The second person to resign was FDA Commissioner Lester Crawford who resigned on September 23, 2005 after only two months as FDA commissioner. The reason why Crawford resigned so abruptly is unknown. The third person was a consultant and former member of FDA’s Nonprescription Drug Advisory Committee, Frank Davidoff, who resigned on
October 7, 2005 and said that “the agency is ignoring science in favor of politics in delaying approval of the drug for over-the-counter sales.”

The current issue that has resulted in the stalling of the FDA approval of the drug for OTC sale is controversy over whether Plan B should be sold without a prescription to those that are 16 years and younger. To address this issue there was a study published in the Journal of Obstetrics and Gynecology in September 2005. In the abstract it was concluded that young adolescents that had better access to emergency contraceptives used it more often, however this did not decrease the use of usual contraception nor increase sexual risk behavior. In addition, in a recent interview on 60 minutes on CBS News, Dr. Wood said that “the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Medical Association have all endorsed making this product available over the counter. That includes pediatrics, meaning younger girls.” Having the study as well as the support form the different organizations about the use of Plan B in adolescents and younger women, it brings to question whether the reason that FDA will not approve the drug is due to scientific data or whether it is merely a political issue.

FDA will make the final decision on the availability of Plan B, but there are many advantages and reason why Plan B should become available without a prescription. Primarily, if Plan B was available without a prescription, this would decrease the amount of unintended pregnancies. Unintended pregnancies can be ascribed to three main factors: when contraception in not practiced, when contraception is used incorrectly or inconsistently, and when the contraception fails to work. A second benefit would be a reduction in the number of abortions. In 2000, approximately one quarter of all pregnancies ended in abortion and only 1.3% of these women said that they took an emergency contraceptive to prevent the pregnancy. Trussel et al. estimated that a wider use of emergency contraceptives could possibly reduce the number of unintended pregnancies by 49% and also reduce the overall number of abortions by 50%. A third advantage is that having Plan OTC would result in a reduction in healthcare costs. It was shown through a modeling of the cost and outcomes that obtaining the emergency contraceptive directly form a pharmacist resulted in a $48 to $158 saving for public and private payer settings, respectively. Moreover, the availability of Plan B without a prescription would allow women to have access to the drug without feeling embarrassed to see the doctor. The embarrassment that is associated with requesting this medication from the physician can cause women to refrain from getting the medication and therefore result in unwanted pregnancies. Since the drug must be administered within a 72 hour window, having it accessible without a prescription would allow women to receive this medication even within 24 hours after having unprotected sex and therefore decreasing the rate of pregnancy to 0.4% if given in this earlier time frame. Finally, one can say that a woman has the best knowledge of when the unprotected event took place and can therefore administer the medication in the appropriate time interval. As stated in an article by Shi CW et al. “the recognition of women’s rights and autonomy in making health...
care decisions is an additional supporting argument."18 Pharmacists are in the perfect environment to provide the information necessary to dispense the medication to the appropriate patient and at the appropriate time. Many pharmacists work in an environment that is accessible to patients 24 hours a day, and 7 days a week.

Along with the advantages discussed above, there are many concerns that arise from allowing the distribution of Plan B without a prescription. One possibility is that the OTC status could result in frequent use of the drug although literature indicated that repeated use in uncommon. This is of greatest concern with the adolescents but data that is available does not suggest any tendency on the part of adolescents to use the method frequently.17 A second concern is that women may substitute emergency contraception for regular contraception or that they may use their method of contraception inconsistently. Studies do not show this relationship; rather studies indicate that women use emergency contraceptives following the occasional episode of unprotected sex. Another disadvantage might be that the use of condoms might decrease due to the accessibility of emergency contraceptive. This is especially of concern due to the risk of acquiring sexually transmitted disease from not using a condom. In actuality, easier access to emergency contraceptives does not appear to decrease the use of condoms.17 Furthermore, a recent study showed that “condom use was higher among those with the pills, too; they used condoms 77% of the time, compared with 62% among the education-only group.” 19 Finally of great concern is the potential to increase sexual activity among adolescents once Plan B can be acquired without a prescription. There is no evidence to suggest such that OTC availability would actually encourage sexual promiscuity among adolescents. Overall there is no evidence to suggest that the switch of Plan B from prescription status to OTC status would result in the abuse of this medication.17

As mentioned previously, Plan B is available without a prescription in several countries and in some on the US states. Canada is one of the countries that approved Plan B for OTC use. In December 2000 British Columbia became the first province to give specially trained pharmacists independent prescriptive authority, therefore allowing them to provide emergency contraception without a physician’s prescription. A study was conducted to determine whether granting this authority to pharmacists would result in women getting their emergency contraceptive from the pharmacist rather than the physician. In addition, this study analyzed whether the availability of emergency contraceptive from pharmacist would cause an overall increase in the number of prescriptions for emergency contraceptives. There were other emergency contraceptives that were included in addition to Plan B, and the results indicated that number of prescriptions for emergency contraceptives increased from a pre-policy mean of 8805 in the years 1996 to 2000 to a post-policy total in 2002 of 17 794. In addition, pharmacists dispensed Plan B more frequently than physicians. Women aged 20–24 had the highest frequency of use during all the study years, and all age groups displayed an overall increase in use. On average, 2.1% of the women received an
emergency contraceptive 3 or more times a year over the period of the study and more women received this medication in urban regions when compared to the rural areas of the province. An analysis showed that 56.2% of women these drugs because their method of birth control failed, 55.7% of the women received the emergency contraceptive within 24 hours after having unprotected intercourse, and 1.1% of the women received this medication for future use. On April 19, 2005, Health Canada approved emergency contraception for use without a doctor’s prescription, allowing the medication to be sold at pharmacies nationwide.

Since the time that Plan B has been available without a prescription in Canada, many pharmacists feel that they have an important role in dispensing this medication. The profession of pharmacy has been taken to a higher level, were pharmacists can play a great role in women’s health. Before Plan B can be dispensed, the pharmacist must counsel the patient in a private area or a room if one is available. This is important because pharmacists need to educate the patient about the proper time to take the drug as well as any side effects that the patient may expect. More importantly, the pharmacist has the duty to make sure that the patient does not have any contraindications to using the medication. Prior to December 8, 2005 pharmacists practicing in Ontario were required to fill out a form which included the patients name, date of the last menstrual period, when the unprotected event occurred and the usual method of birth control. In addition, the pharmacist was required to document whether the drug was dispensed and retain this form for pharmacy records. Some patients felt that the form was violating their privacy and on December 8, 2005, the Ontario College of Pharmacists sent out a letter stating that pharmacists were no longer required to use the form. Without the form, pharmacists still have the responsibility to provide patients with information about the drug as well as effective counseling. In addition to providing counseling about the medication itself, pharmacists also take this opportunity to counsel patients on proper methods of birth control and the need to protect oneself from sexually transmitted diseases by using adequate protection.

In order to examine how current pharmacists and pharmacy students feel about the issue of plan B either being available OTC or potentially becoming available OTC, a survey was conducted. A total of 60 participants were included, and a set of 12 questions were prepared on the topic of Plan B. People that were surveyed included pharmacy students and pharmacists who either practiced or interned in Windsor, Ontario or Detroit, Michigan. The survey began with a couple general questions about the person’s gender, age, professional status, place of practice or internship, and religious background. There was a relatively equal amount of females and males, as well as Americans and Canadians and that majority of people were Roman Catholic. The general questions were followed by a set of 12 questions pertaining to the dispensing of Plan B without a prescription. The first 6 questions pertained to American pharmacy students and pharmacists while the last 6 questions were answered by Canadian pharmacy students and pharmacists. Furthermore the survey concluded with statements regarding factors that affected their answers to the questions. These choices included religious
background, patient’s right to the medication, pharmacist’s right to refuse to dispense the medication, the age of the patient, and the situation that led to the possible pregnancy. Once that data was collected, the following graph was constructed to illustrate the results.

Graph 1- Comparison of People that Answered YES or NO

Graph-1 illustrates the results of the answers to the questions when pharmacists and students were combined into one group. The answer to question 1 revealed that the majority of people thought that if Plan B becomes available OTC, then more young women will abuse the use of this medication and use it as an easy way out of carelessness. This is contrary to what was stated in one article where there was no increase in the frequency of use if the medication became available OTC. The second question as well as question 11 addressed the issue of whether one would dispense the medication more without a prescription. The Americans surveyed felt that they would dispense a larger amount of Plan B without a prescription and the Canadians said that they too dispense Plan B more now that it is available OTC. This result in of no surprise because having the option of obtaining the medication directly from a pharmacist eliminates the need for a visit to the doctor’s office. The next issue addressed in number 3 and 7 was a pharmacist’s willingness or level of comfort when dispensing the medication once it gained OTC status. 62% of Americans stated that they would not feel uncomfortable. Similarly, 79% of Canadians said that they were not less willing to dispense the medication without a prescription. Another issue that the FDA seems to be concerned about is the age of the patient. Questions 4, 8, 9 and 12
addressed this concept by asking participants whether Plan B should only be dispensed to women that are 16 years or older and whether they would feel uncomfortable dispensing the medication to a 15 year old versus a 40 year old women. Most of the Americans felt that this medication should be dispensed to women that are 16 years or older as illustrated in the results to question 4. On the other hand the Canadians responded that they would feel equally comfortable dispensing Plan B to a 15 year old and a 40 year old female as illustrated in the answers to question 8 and 9, respectively. Furthermore, 79% of Canadians felt that an age restriction is not necessary. There are some instances that women require Plan B following an assault, and this was examined in questions 5 and 10. Both Americans and Canadians felt that they would be more willing to dispense Plan B if they knew that the possible pregnancy was a result of an assault. Finally question number 6 was directed at participants that practiced or interned in the United States. This question asked whether Plan B should be available without a prescription and results show that 62% of participants answered yes.

A second graph was formulated to examine if there was a difference to how pharmacists and pharmacy students replied to the questions. Graph 2 shows that only the answers to question number 1 and 6 differed among pharmacy students and pharmacists. While students felt that women would abuse this medication more if it became available OTC, pharmacists thought the opposite and replied “No” to this question. The second question that had a disagreement between the pharmacist and students was question 6 which asked the question of
whether one thinks that Plan B should be available without a prescription. 63% of students answered “Yes” to this question, and 67% of the pharmacists answered “No”. As stated earlier, participants were also required to choose any statements that affected their answers to the questions. Majority of participants felt that the patient’s right to the medication affected the answers the most while their religious background was of least importance.

The question of whether the prescription requirement for Plan B will be removed still needs to be answered. Plan B meets all the criteria that are necessary to reclassify it as an OTC product. Primarily, the OTC indication is the same as the prescription indication Secondly, Plan B has few side effects and a relatively low potential for abuse. Finally this drug does not have any special monitoring requirements that would make it impractical for use without a prescription. FDA scientists have also said that this medication is safe for use. Furthermore, a study published in the Journal of Obstetrics and Gynecology in September 2005 showed that an increased access to emergency contraceptives among adolescents did not lessen the use of regular contraception and did not lead to an increase in risky behavior.15 All this data and information supports the switch of Plan B from prescription to OTC but it is up to the FDA to determine the final status of the drug. Some people will continue to think that Plan B should never be dispensed without a prescription while others feel that the OTC status will provide women with more effective methods of preventing unwanted pregnancies and therefore decrease the amount of abortions.
References