The debate over the morning after pill Plan B

By

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Over the counter drugs (OTC) offer easy, convenient, and relatively inexpensive access for treatment of many common acute conditions. The aisles of pharmacies are filled with over the counter drugs that treat conditions ranging from headaches, cold symptoms, and fungal infections to upset stomach and even lice. The pharmacist is often the first line health provider when it comes to questions about which treatments are best for a given patient. There are many varieties of birth control pills (BCP) with varying strengths of hormones that women take on a daily basis to prevent pregnancy. Pharmacists without any hesitation or objections, for the most part, dispense BCPs. However, the recent debate about whether Plan B (levonorgestrel) should also join the multitude of over the counter products has been laced with political, scientific, and ethical concerns. In this paper, I will first discuss the key points of the timeline that followed after Plan B was petitioned to become an over the counter drug. I will then discuss both sides of the debate about whether Plan B should be available OTC. Finally, I will talk about the pharmacist’s right to refuse access to emergency contraception (EC) and what the major arguments are. I will conclude the paper with my personal view on these issues and how this course has helped me reach such beliefs.

The issue of emergency contraception has become a hot topic in the popular media. Recent stories on CNN and other media outlets about Walgreens pharmacists refusing to fill EC scripts have brought the debate to a national scale. EC is a way of preventing a pregnancy from happening after unprotected intercourse has taken place. Emergency contraceptive pills contain the hormones estrogen and progestin, either separately or in combination. Plan B contains only a progestin called levonorgestrel, which is a synthetic hormone that has been used in birth control pills for over 35 years. It is currently available only by prescription.

The mechanism of action of Plan B is not exactly known, and several hypotheses have been proposed. Primarily, it seems that the hormone in Plan B acts by preventing the release of an egg from the ovary (ovulation). A second proposed mechanism is that Plan B may prevent the fertilization of an egg. Furthermore, if a fertilized egg is released, the active ingredient in Plan B may even prevent implantation in the womb. However, once an egg is implanted in the woman’s uterus, Plan B will not have any effect. This is unlike the abortive drug RU-486 (mifepristone), which can end a pregnancy up to 7 weeks after a woman’s last menstrual period. As will be seen later, the belief of which is the
There are many organizations that can petition the FDA to make a drug OTC. For example, an insurance company in California wanted to make several brand name non-sedating antihistamines over the counter, including Zyrtec and Allegra. As such, insurance companies would not cover these medications and patients would be forced to buy them over the counter. In 2001, over 70 organizations, including the American Medical Association (AMA) and the American College of Obstetrics and Gynecology (ACOG) petitioned the FDA to make EC available without a prescription. Two years later, the maker of Plan B, Barr pharmaceuticals, formally asked the FDA to hold hearings on the issue.

In December of 2003, the scientific advisors at the FDA were in favor of allowing for the sale of Plan B over the counter. One of the rationales that led to this decision was that allowing easier access to effective emergency contraception would help to decrease the estimated 3 million unintended pregnancies in the US by almost one half. In May of the following year, in a very uncommon move, the FDA rejected the decision of its own scientific advisors. The FDA cited the fact that there was no data to show that girls under 16 could safely use the product without a physician’s oversight. The makers of Plan B responded to this latest decision by reapplying for OTC status. This time they planned to limit the sale of Plan B to women over the age of 16, much like how cigarettes and alcohol are sold. In August of 2004, however, the FDA postponed their decision, citing a lack of an effective method to enforce such an age limit.

The FDA’s decision to restrict over the counter access to Plan B is laced with controversy. The non-partisan Government Accountability Office (GAO) has made several conclusions regarding the FDA’s decision. First, the GAO found that officials at the FDA had made their decision long before scientists could finish with their research regarding the safety of OTC ECs. Second, it was found that the FDA could have extrapolated data from older teens showing that there was no increase in sexual behavior, something that it does with all other types of contraceptives. Critics believe that the delay to granting OTC status is purely political and that the FDA has caved to pressure from conservative groups and anti-abortion activists. In fact, the Wisconsin Attorney General has asked the governor for permission to sue the FDA for its handling of the application for the request to make Plan B OTC because he believes the FDA has withheld the approval of this drug “over political [and] not scientific or other legitimately accepted grounds” [11].

Generally speaking, there are three major criteria that have to be satisfied before any drug is granted over the counter status. It must be (1) safe, (2) effective, and (3) used to treat a condition that does not require medical supervision. Proponents for OTC Plan B argue that it is safe, with only nausea and vomiting occurring as primary side effects. The second criteria, efficacy, has
also been established as Plan B is considered an efficacious treatment in preventing pregnancy. For example, if it is taken within 12 hours of intercourse, the pregnancy rate is only 0.4%. This number rises to 15% if it is taken within 3 days of sexual intercourse. The final criteria, whether self-management can be handled without proper supervision, also seems to be satisfied. Women inherently know their bodies and are keen as to when to seek medical attention. By satisfying all three criteria, many have argued that Plan B seems to be a suitable candidate for OTC status. Incidentally, in France it is common for school nurses to supply emergency contraception to every senior and junior in high school [3].

The other argument in favor of making EC OTC is one that is promoted by the American College of Obstetrics and Gynecology (ACOG). They argue that if emergency contraception were available, the abortion rate in the US would decrease dramatically, and this will have public health benefits [9]. Furthermore, they argue that there are several situations, which lend themselves to immediate access to effective EC. These include rape, couples who experience a condom break and women who may have been drugged and lured into sex. In a recently completed national survey, more than 700 physicians were surveyed regarding their views on OTC plan B. The survey results showed that 53 percent of the physicians were in favor of OTC distribution, 39 percent favored prescription only, whereas 8 percent felt that it should not be distributed at all [8]. The majority believed that whatever risk the pill caused, it was far less than the risk of an unwanted pregnancy.

The main argument that seeks to oppose the availability of OTC EC is that it promotes reckless sexual activities. Critics argue that women, especially teenagers, will substitute Plan B for other types of birth control measures, such as condoms. They argue that this in turn will increase the rate of sexually transmitted diseases. Dr. Hanna Klaus, an obstetrician-gynecologist who promotes natural family planning, cited the increased Chlamydia and gonorrhea rates in the last four years. She proposed to the FDA that this increase parallels the high profile advertising of the morning after pill. In addition, A Swedish study published in 2002 reported that STDs were on the rise among adolescents who had OTC access to emergency contraception [10]. Those who oppose OTC status for Plan B and other EC also argue that doctors will not be able to monitor for side effects such as nausea, vomiting, headache and bleeding. Even more important, patients might be tempted to avoid any further doctor visits regarding other important health care questions.

Another possible concern arises because some women might use EC not just on an occasional basis, but might depend on it as the preferred method of contraception. Women in the studies with EC did not take emergency contraception very often, and therefore data about the long-term use of Plan B are lacking. The concern is that OTC status for EC will provide easier opportunities for women to repeatedly take Plan B, without knowing any of the
long-term side effects. However, a longitudinal study of teens and young women in the United Kingdom found that only 4% of emergency-contraception users reported taking EC more than twice within 1 year, suggesting that repeated use of emergency contraception within this group was not common [12].

All across the country, there are pharmacists that have refused to dispense emergency contraceptives to women, despite being presented with valid prescriptions. For instance, a pharmacist in Texas refused to dispense an emergency contraceptive to a rape victim, citing moral objections. There are arguments that are both in favor and against the pharmacist’s right to refuse to dispense EC, which will be discussed below.

Pharmacists are professionals that practice behind a standard code of ethics. Society relies on pharmacists to exercise their judgment and expertise when dispensing a medication. Pharmacists are not simply dispensing robots that must fill every prescription that they are presented with. There are many instances in which two drugs adversely interact with one another, and society expects that pharmacists will use their powers not to dispense in such a situation. The same can be argued when pharmacists are presented with a Plan B prescription. Pharmacists have morals that are not checked at the front door of the pharmacy. The decision to dispense a certain medication will be reflected in that pharmacist’s moral views.Neither doctors nor nurses are expected to disregard their ethical values when making health care decisions. For instance, doctors are not forced to engage in an abortive procedure against their will. As part of the health care team, pharmacists, like doctors, should also be given the right to refuse to participate in an activity that they believe violates a subset of their moral values. Some may argue that performing an abortion is not the same as dispensing an emergency contraceptive. However, the meaning of when life actually starts and Plan B’s possible effects on ovulation and fertilization blur any distinction between abortion and dispensing Plan B.

To further illustrate this argument, one can consider a draftee in a time of war. The young male has a right to refuse to go to war because of conscientious objections. This is an essential part of living in a democratic society—the protection from being forced to perform a task against one’s will. Pharmacists can be said to be exercising their own version of conscientious objection when they refuse to fill an order for an emergency contraceptive. For the pro-life pharmacist, the act of dispensing such a medication is murder in disguise, and as for the draftee who refuses to go to war, pharmacists should not be forced to engage in an act that they believe is akin to murder.

In light of the aforementioned arguments, there are those who vehemently oppose the right of the pharmacist to refuse. Such critics have used the pharmacist’s own code of ethics to support their view. The code of ethics clearly states, “A pharmacist places concern for the well-being of the patient at the center of professional practice.” It is argued that there may not be a better place
for a pharmacist to be concerned towards a patient than when he or she is presented with a prescription for emergency contraception. Women in such situations are often confused, scared, and sometimes angry depending on their situation. If pharmacists are to follow their own written code of ethics, they have a duty to “respect the autonomy and dignity of each patient” and to “serve individual needs of the patient.”

The mechanism of action of Plan B plays an important role in this debate. Even though Plan B may prevent pregnancy after sexual intercourse, many agree that it is not similar to abortion and pharmacists have no ground comparing it to such a procedure. Critics argue that Plan B does not inhibit an unwanted pregnancy, but it acts to either prevent ovulation or create a hostile uterine environment. In 2002, Washington State governor Gary Locke signed a law that required hospitals in the state of offer emergency contraception to rape survivors. Catholic hospitals in the state took into consideration the dual mechanism of action of Plan B when they took a stand with the new law. They stated that because it would be impossible to determine whether fertilization has already occurred in the 72 hours after the rape, hospitals couldn’t be sure whether the use of EC will prevent fertilization or implantation. Therefore, the use of EC would depend on the woman’s intent, and the Catholic Health Association would support the use of EC if the intent were to prevent fertilization, but not implantation. As such, pharmacists should not stand in the way of the use of EC for rape survivors if the intent is to prevent fertilization.

When pharmacists refuse to fill prescriptions for EC, does that give them the right to refuse other types of prescriptions? This is yet another argument that pharmacists simply do not have at their disposal the patient’s circumstances and past history when making a decision regarding whether to fill a prescription. Should pharmacists refuse to fill HIV medication to someone because they assume the patient is a homosexual and thus has engaged in sinful behavior? The pharmacist’s refusal to fill one kind of medication may lead to a snowball effect whereby other kinds of potentially life saving drugs are denied because of personal moral objections.

The right to refuse to fill an EC request may have more dire long-term consequences. Consider for example a young, unemployed woman living in a rural area who has experienced a condom break. Unlike her urban counterpart, she does not have access to a multitude of pharmacies that she can drive to should one refuse to fill an EC prescription. As the hours pass by and the young woman is denied access to EC, the chances of pregnancy increase. After the 72-hour limit, pregnancy will most likely ensue, and therefore the only option available is to abort the pregnancy. The pharmacist, by denying timely access to EC, has in essence participated in assisted abortion.

A study published recently in the Journal of the American Medical Association sought to evaluate the effect of direct access to emergency
contraception through pharmacies on reproductive health outcomes [2]. This is one of the few randomized, single blind, controlled studies that incorporated a large number of women (2117). The women were assigned to one of three groups: the first group had pharmacy access to EC. The pharmacists participating in the study were instructed to counsel the women on the proper use of the EC as well as side effects and monitoring parameters. The second group received 3 packets of Plan B in advance (advanced provision) and was given directions on the proper use. The final group of women were asked to return to the clinic should they require access to EC. The primary outcome measures of this study were the use of EC, the number of pregnancies, and the sexually transmitted diseases at 6 months. When the results were in, it was found that the women in the pharmacy access group were not more likely to use emergency contraception as compared to women who were asked to return to the clinic. However, women who were given the Plan B in advance were twice as likely to use it as the control group. Compared to the control, the pharmacy access group and the advanced provision group did not have a lower pregnancy rate. The authors concluded that even though giving women Plan B in advance will increase its use, the “public health impact may be negligible because of high rates of unprotected intercourse and relative underutilization of the method”. They further stated, “it seems unreasonable to restrict access to EC to clinics” [2].

The Roman Catholic Church teaches that life begins at fertilization. This comes from the belief that “the program of what this living being will be” is established from “the first instant” [5]. The church distinguishes between the beginning of life and “ensoulment”, which is when the body and soul fuse. Some believe that ensoulment may take up to forty to eighty days following fertilization. However, abortion, even before ensoulment, is still unacceptable in the church’s teachings.

The idea of abortion is a very controversial issue that inflames people on both sides. Those who support abortions might value the woman’s life over that of the unborn fetus. They believe it could be justified when the consideration is based on what is best for the woman. Opponents of abortion always value the sanctity of the unborn child at all stages of development. ECs do not clearly fit the definition of abortion as easily as other drugs such as RU-486. Nonetheless, depending on when someone believes life begins, ECs can be regarded as abortaficents. For instance, a pharmacist who believes that life begins at fertilization may not dispense Plan B because he or she knows that it may interfere with the implantation of a fertilized egg. The pharmacist who believes that life begins at implantation may not have any objections in dispensing Plan B and other ECs.

The code of ethics for pharmacists clearly states the pharmacist must respect that patient autonomy and “personal and cultural differences among patients”. Pharmacists who are presented with valid prescriptions for emergency
contraception might find comfort in referring the women to pharmacists with no such objections. However, some believe that referring women is not an acceptable option because the pharmacist was ultimately involved in helping facilitate access to EC. By referring patients to pharmacies that will fill EC prescriptions, liability suits maybe avoided because the pharmacist would be seen as having exercised reasonable care in assuring the patient has access to proper pharmaceutical care. Women may argue that the denial to fill EC prescriptions is the same as filling the wrong drug. The argument is as follows: when a pharmacist fills a prescription incorrectly, the patient does not receive the intended medication he or she was prescribed. Similarly, when a pharmacist refuses access to EC, the patient does not receive the intended drug prescribed, which can be considered a breach of duty should civil action be taken. Furthermore, a woman who is denied EC and subsequently undergoes an unsuccessful abortion may file for civil action against the pharmacist. The woman can claim that the injuries suffered could have been averted had the pharmacist fulfilled his or her professional duty.

Many jurisdictions have statues or laws that respect the ideologies of health care workers. The only state that has statues pertaining specifically to pharmacists is South Dakota. Other states have enacted general clauses that are more relevant to abortion and the protection of doctors and nurses from subsequent legal action should they refuse participation in such procedures. As mentioned previously, ECPs may or may not be seen as abortafacient agents, and as such, the applicability of such statutes is not clear for pharmacists. Even if pharmacists are successful in arguing that EC is a form of abortion, the mere action of dispensing it may not be seen as direct participation in an abortive procedure.

The debate over OTC Plan B has been playing out locally in Michigan as well. Representative John Stahl has introduced a bill to ban the sale of OTC Plan B should it ever become available. He cites the lack of scientific evidence as his main reason for proposing the bill. Groups that oppose this bill include the American Civil Liberties Union and Planned Parenthood Affiliates of Michigan, who argue that women should have a right to choose which form of contraception they desire [6].

I recently completed a survey among pharmacy students to examine their views on the issue of OTC Plan B. The survey was as follows:

Thank you for taking the time to fill out this survey. Please rest assured that all answers will be kept confidential and that participation is voluntary. The responses will be used to help examine the views of pharmacy students regarding the emergency contraceptive “Plan B” for a research paper.
Male ________
Female ______
Age:  18-29 _____ 29-39 _____ > 40 ______
Religion: __________
Race: __________
Do you believe that taking Plan B is the same as having an abortion?
Yes _____
No _____
Do you believe Plan B should be granted over the counter status?
Yes _____
No _____
Why or Why not? __________________________________________
_________________________________________________________
Should pharmacists have a role in dispensing Plan B to women?
Yes _____
No _____
Should pharmacists have the right to refuse to dispense Plan B if they believe it violates their ethical, moral, or religious beliefs? Yes _____ No _____
If you refuse to dispense Plan B as a pharmacist, would you refer women to pharmacists who have no such objections?
Yes ___
No ___
Depends on the situation (rape for instance) ____
Do you believe that Plan B and RU-486 belong to the same class of medication?

Yes ___

No ___

What's RU-486? _____

If Plan B is granted OTC status and pharmacists are allowed to dispense it to women, will this help or hurt the image of pharmacy?

Help it ____   Hurt it _____

After tabulating the results, I found that many (62%) of those surveyed believed that taking Plan B is akin to having an abortion. This was also reflected in the fact that not many favored emergency contraception be available over the counter (34%). The majority (75%) felt that the pharmacist should have a role in dispensing EC. This particular question, however, may have been answered differently if the group surveyed were not pharmacy students. Not surprisingly, most of the pharmacy students (80%) did not believe that Plan B was similar to RU-486 in its mechanism of action. When asked whether pharmacists should have the right to refuse to dispense EC, the results were split down the middle, with 54% believing that pharmacists should have the right to refuse to dispense EC if it violated their ethical or religious beliefs. Many students (68%) who did not want to dispense Plan B were in favor of referring women to other pharmacies that would grant them access. Finally, most students (83%) believed that the availability of OTC Plan B would help the image of pharmacy. This statistic correlated well with the question that asked whether the pharmacist should have a role in dispensing EC.

In deciding how I felt about the issue, I had to think about what I have learned in this course in addition to what my personal values and morals are. My religious teachings prohibit abortion, and as such dispensing a drug such as RU-486 is clearly not permitted. However, as I explained above, EC does not fit the abortion criteria with certainty, and therefore it becomes difficult to reject EC prescriptions based on their abortive mechanism. However, as a pharmacist the value that is most important to me is patient autonomy. As such, I believe the pharmacist should not deny patients access to any kind of emergency contraceptive, unless there are contraindications for its use in a particular patient. When patients present with requests for Plan B, they are often confused, worried, and even frightened. Pharmacists are in an ideal position to help explain to patients how to use emergency contraception properly, and as such I believe Plan B should be placed behind the counter, much like pseudoephedrine-containing products are. Patients will feel more comfortable approaching the
pharmacist for not only EC, but for other health related concerns, which will only improve the image of pharmacy. When patients present with valid prescriptions for EC, pharmacists should seek to help facilitate their proper use to those women. Pharmacists should respect the right of patients to use such treatments, much like they respect the right to use HIV medications and regular birth control.

Pharmacy has become a profession where science and morals have clashed, and this will only increase in the future as advances in genetic technology become more prevalent. Pharmacists should stay current on debates and concerns that pertain to such ethical dilemmas in order to decide how their own beliefs will fit in and which activities they will or will not participate in.
References


