Plan B®: Pharmacists’ Right to Refusal

By

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Should pharmacists keep their personal beliefs and professional roles separate? Pharmacists as health care providers have professional and ethical responsibilities to their patients. Should a decision to dispense a prescription be based on the personal welfare and health-care needs of the patient, or the morals or beliefs of the health care professionals? As pharmacists, we must abide by not only a set of laws, but by a set of ethics. In pharmacy law it is specified that it is the pharmacist’s obligation to refuse to dispense a prescription when the prescription does not seem to be valid, or if filling the prescription could cause inadvertent harm to the patient. However, the law does not address whether a pharmacist has the right to refuse to dispense based on personal beliefs. Therefore, it is up to each pharmacist, as an autonomous professional, to develop their own code of ethics and abide by these codes.

In recent months, incidents of pharmacists refusing to fill prescriptions for emergency contraception have engaged considerable media attention. According to Planned Parenthood, these incidents have been documented in more than a dozen states. In some of these cases, pharmacists have gone to such extreme lengths as to refuse to fill prescriptions for rape victims; refuse to transfer the prescription to another pharmacy or even return the prescription to the patient; and are also giving their patients religious lectures in which they chastise them for being irresponsible among other things. It is due to these few “bad apple” pharmacists that negative attention has been brought to the profession as a whole, and has put the pharmacists’ right to refuse to dispense a prescription in jeopardy of being taken away. The controversy surrounding this issue is whether pharmacists should be allowed to refuse to fill valid prescriptions on moral or religious grounds, and, if so, what obligation the pharmacy has to the public when its pharmacist refuses. With increased prescribing of the morning after pill, and more legislation to legalize abortaficents, pharmacists are now involved in the abortion issue.¹

One of the main reasons why this issue is so controversial remains surrounding the question, is Plan B® an abortaficient? Plan B® works by restricting ovulation in a woman. Supporters argue it will prevent unplanned pregnancies and abortions. Opponents, however, say the method also can work
after conception, blocking implantation of a tiny embryo in the uterine wall. In such a case, many conservatives believe, an abortion occurs. In order to understand the ethical dilemma one might have in this situation, we must first understand both the mechanism of pregnancy, and the medical definition of pregnancy.

The female reproductive system is quite complicated; however there are several steps which occur prior to conception and pregnancy. In order to reproduce, a female has ovaries, which produce eggs and secrete certain hormones such as estrogen and progestin. The ovaries make follicles, which consist of eggs and at the beginning of each menstrual cycle a group of follicles begin to develop, allowing one to fully develop and mature. This leads to ovulation, the ovary releasing the mature egg, and normally occurs around day 14 of a female’s cycle. After ovulation, the egg is swept into the uterine tube, where a sperm can fertilize it. After intercourse, a sperm can live in the uterine tube for up to 5 days, so if the female ovulates while a sperm is present in the tube, the egg will become fertilized. Following fertilization, the egg undergoes certain meiotic divisions and is able to implant itself in the endometrium on approximately day 7 after ovulation. Physiologically, pregnancy is said to begin not at fertilization but after implantation is complete, approximately one week after fertilization. Accordingly, procedures that work prior to implantation are termed contraceptives. Procedures that cause death of the embryo or fetus after implantation are termed abortifacients. Issues that spark debate about the dispensing of emergency contraceptives are deep rooted in both moral and religious beliefs. W. David Hager, a member of the FDA's Advisory Committee for Reproductive Health Drugs and a member of the CMA, said a package insert under review claims Plan B does not cause abortion. In an article from Christianity Today, Gene Rudd of the Christian Medical Association (CMA), responded to this statement by saying, "If women believe pregnancy begins at fertilization, we are deceiving them, and for the FDA systematically to promote this deception is unbelievable." It clearly appears that the nation is divided on whether a woman becomes pregnant when the egg is fertilized by the sperm, or when the fertilized egg implants itself in the endometrium and becomes an embryo. In order to add to the controversy, the mechanism of action of Plan B is still not exactly understood. Plan B (Levonorgestrel 750 mcg) is a synthetic, progestin-only, emergency oral contraceptive, which was approved by the FDA for prescription only use in July 1999. Emergency contraception prevents pregnancy by stopping or delaying release of an egg (ovulation), blocking fertilization by affecting the egg or sperm, or preventing implantation by making the lining of the uterus inhospitable for pregnancy. The specific mechanism for Plan B is not well known, which is the reason for most of the controversy. There is evidence which points its action to several stages of the reproductive cycle, however most of the scientific evidence suggests that inhibition or delay of ovulation is the primary mechanism of action. Possible secondary mechanisms include disruptions at the
fertilization, embryo transport, or implantation stages of reproduction. Since levonorgestrel is a progestin, a lot of the mechanism of action of Plan B® can be understood by looking at the action of progestins on the human body. The primary contraceptive effect of progestins involves the suppression of the mid-cycle surge of Luteinizing Hormone. At the cellular level, progestins diffuse freely into target cells and bind to the progesterone receptor. These target cells include the female reproductive tract. Once bound to the receptor, progestins are able to slow the frequency of release of gonadotropin releasing hormone (GnRH) which blunts the pre-ovulatory LH surge. This thereby prevents follicular maturation and ovulation. Progestin prevents ovulation in 70-80% of cycles; however the clinical effectiveness of Plan B® is known to be up to 89% effective. This suggests that additional mechanisms may be involved. Progestin also has the ability to alter the endometrium and impair implantation of the egg. It can also increase cervical mucus viscosity, which inhibits sperm migration into the uterus.5

Plan B® has been approved for use as a postcoital contraception within 72 hours of unprotected intercourse, and before prescribing the physician is supposed to confirm a negative pregnancy test. Plan B® is classified in the FDA pregnancy category X and is contraindicated for use during pregnancy or suspected pregnancy. Absolute contraindications to use of Plan B® include; breast cancer, cervical cancer, ectopic pregnancy, hepatic disease, incomplete abortion, jaundice, pregnancy, uterine cancer, vaginal bleeding, and vaginal cancer. Plan B® is not intended to be used as a routine contraceptive. It is not effective for the termination of pregnancy. The first dose of Plan B® is to be given preferably within 12-24 hours and no later than 72 hours after the event. A second dose must be given 12 hours after the initial dose. This specific requirement is a major reason why the refusal to dispense the medication has caused such controversy. For every hour that the medication is not taken, the effectiveness of the medication decreases.5

Plan B®, like any other medication, has certain drug interactions and adverse drug reactions and patients need to be monitored of such events by their physician. Adverse reactions associated with Plan B® are usually minimal. Nausea/vomiting occur in roughly 23% and 5%, respectively, of patients. Other common side effects include abdominal pain, fatigue, headache, menstrual changes, and dizziness. Serious side effects are not common, and therefore the use of this medication would not bring harm to the patient and can be dispensed.5

We as pharmacists have been taught to look at the scientific facts of a situation, and then use professional judgment to interpret those facts into how we choose to practice pharmacy. In order to understand differences in opinion while looking at the facts pertaining to emergency contraception and dispensing Plan B®, I decided to survey my fellow peers. By completing a survey, I was able to demonstrate any trends in beliefs among those in, or pursuing, a practice in pharmacy on how pharmacists are divided on this issue, and how this may affect
our future practice. The following is a table of questions in the survey, and the corresponding results of both pharmacy students and practicing pharmacists:

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<thead>
<tr>
<th>Survey Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Should state law require pharmacists to fill certain prescriptions for their patients?</td>
<td>17%</td>
<td>83%</td>
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<tr>
<td>Should the patient’s rights overcome the beliefs of a pharmacist if a legal drug is prescribed by a physician?</td>
<td>67%</td>
<td>33%</td>
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<tr>
<td>Should pharmacists have the authority to refuse filling prescriptions for emergency contraceptives such as Plan B®?</td>
<td>60%</td>
<td>40%</td>
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<tr>
<td>Should pharmacists have the authority to refuse filling prescriptions for emergency contraceptives such as Plan B® in cases of sexual assault?</td>
<td>43%</td>
<td>57%</td>
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<tr>
<td>If they refuse to dispense a prescription, should pharmacists be required to refer patients to another pharmacy which will and can fill the prescription in a timely manner?</td>
<td>87%</td>
<td>13%</td>
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By looking at the results one can see that there is a significant trend in interest towards pharmacists keeping their right to refuse to dispense. Only 17% of the 30 surveyed thought that there should be state law requiring the filling of certain prescriptions. Also 60% felt that pharmacists should have the right to refuse filling Plan B® prescriptions, however 87% still thought that the patient should be referred to someone who could fill their prescription. Therefore it is obvious that while having the desire to hold on to their professional autonomy, pharmacists still place the best interest of the patient highly.

Pharmacists, who have conflicting view points of whether or not pregnancy occurs after implantation, as they were taught in school, or at fertilization, as they may personally believe, ultimately face an ethical dilemma when a patient brings in a prescription for Plan B®. By looking at a short case study, maybe you can put yourself in that pharmacist’s shoes, and can weight the options that they might have. Patient AR is a 21-year-old college student at Wayne State University. She presents at your pharmacy with a prescription for Plan B®. The instructions are to take one tablet immediately and the second in 12 hours. Plan B® contains levonorgestrel and is used as an emergency contraceptive when taken in this manner. As a pharmacist you know the mechanism of this medication is to inhibit or delay ovulation, or fertilizations, or to prohibit implantation of a fertilized egg within 72 hours of intercourse. You are the only pharmacist on duty, and have strong pro-life beliefs. Firm in your beliefs, you immediately refuse to dispense the prescription believing that the prescription is being used as an abortaficient. AR explains that she needs to have the prescription filled soon, because it is very close to 72 hours since intercourse. She begins crying and pleading with you to fill the prescription and explains that she can not have the prescription filled at another pharmacy because this is the
only one that allows her to charge, and her financial aid has not come in yet. You advise AR that she should seek counseling and share your religious belief with her. AR explains that she was walking home from her volunteer job at the children's hospital when she was attacked and raped. AR leaves the pharmacy very upset, without the prescription. Later she calls the pharmacy, explains the situation to the pharmacy manager, and demands that you be fired. Did you have a right to refuse to dispense the drug? What duty did you have to AR? What are the implications to your patient AR, your employer, co-workers, the profession, and society? What can be done to minimize the effects of this volatile issue? 

It is clear that as the pharmacist, you are faced with an ethical decision. You try to remember what your ethics teacher in pharmacy school taught you – nonmaleficence, beneficence, autonomy, justice, and fidelity – the key principles of ethics. You slowly remember that you must consider each value, and weigh it in the specific situation you are in. Is self-determination (autonomy) in this case more important than providing benefit to your patient (beneficence). Trying to get your priorities straight, you start to think of what choices you have in this matter. You first gather all of the information that you can, about not only the situation your patient is in, but about the drug in question, and how it works. With this information you can now begin to think about what options you have, and what will evidently be the best for your patient, while still allowing you to sleep at night. Your first choice is to do nothing. Simply put your foot down and turn the patient away, why should you have to even question your moral beliefs. Your profession allows you to have autonomy and to do whatever you see is just. However, if you choose to go down that path, you must consider the harm you could potentially cause the patient and the potential unborn child. The use of emergency contraceptives could prevent an estimated 1.7 million unintended pregnancies and 800,000 abortions each year. If you do not fill this prescription, and AR becomes pregnant, she will most likely be one of the 800,000 unnecessary abortions this year. Think to yourself what is in the best interest of this patient, potentially preventing implantation of the egg, or actually going through the process of an abortion. Another choice you have is to place nonmaleficence as your priority, and not help your patient yourself, but find someone who can help her. You can devote the time and energy it might take to at least try to find another pharmacist who will fill her prescription and maybe wave the fee until she is able to pay for it. The third choice you may have is to swallow your ethical beliefs, and fill the prescription. By doing so, you may have put beneficence and justice for your patient about your own personal beliefs. However, this decision may haunt you for the rest of your life due to those beliefs, and you may never be able to forgive yourself. As with any ethical dilemma, no choice is easy. You must consider the impact of all your decisions not only on yourself, and your patient, but to the profession of pharmacy as a whole. Doing nothing is one of the worst things that can be done. The pharmacist must at least ensure that their patient get the treatment that they deserve.
Cases just like the one discussed are happening all around the country. At an Eckerd's pharmacy in Texas, a pharmacist refused to dispense emergency contraception to a sexual assault victim on the grounds that it "violated his morals." The other pharmacists on duty also refused to fill the prescription. This woman was able to fill her prescription at a Walgreen's pharmacy later that evening. All three Eckerd's pharmacists were eventually fired for violating the patient's rights.7 After a sexual assault one recent weekend, a young Tucson woman spent three frantic days trying to obtain the drug to prevent a pregnancy, knowing that each passing day lowered the chance the drug would work. While calling dozens of Tucson pharmacies trying to fill a prescription for emergency contraception, she found that most did not stock the drug. When she finally did find a pharmacy with it, she said she was told the pharmacist on duty would not dispense it because of religious and moral objections. "I was so shocked," said the 20-year-old woman, who, as a victim of sexual assault, is not being named by the Star. "I just did not understand how they could legally refuse to do this."8 A CVS pharmacist in Texas refused to dispense a prescription for birth control pills. The pharmacist told the patient and her husband that she did not "personally believe in birth control," birth control was not right, and "[birth control] pills cause cancer." The prescription was eventually filled the next evening and delivered to the patient's home. A woman in New Hampshire was denied emergency contraception by a Brooks pharmacist. The pharmacist claimed moral objections to both dispensing and transferring the prescription. By the time the managers at this Brooks Pharmacy resolved the situation, it was too late.7 A federal jury awarded 28-year-old Michelle Diaz $19,000 in back pay and more than $28,000 in damages in her religious discrimination and free speech suit against a California health clinic. Diaz was fired after she refused to dispense the "morning-after" pill, which inhibits the implantation of fertilized eggs. "When that sperm and that egg meet, that was my child's life, and my life and your life," Diaz said after the verdict was announced. "And that is how every other life is going to begin. When that life starts, I cannot infringe on that. I won't be a part of ending that." County officials say they'll ask a district judge to set the verdict aside.2

In 1998 the APHA attempted to appeal to both the rights of the patient, and to the rights of the pharmacist by developing a refusal clause. Refusal clauses that allow an expression of religious beliefs can be considered acceptable if they provide an adequate plan for referral (APHA, 2003). Health care must not be disrupted or obstructed by either untold delay or barrier. Under the view of these organizations professionals who object to providing a service need to do so consistently and provide forewarning to their employers and clientele. All prescription referrals must be directed to a local pharmacist or pharmacy that is within a reasonable distance. "Should the alternate means provided by the employer fail to operate...in a timely fashion...then the pharmacist has a duty to the patient to dispense the medication" (APhA, 1998).9

Although we as pharmacists have professional autonomy we must look to organizations like the APhA in order to help us have a solid middle ground
between our personal beliefs and the duty and obligations we have to our patients. A pharmacist has a duty to refuse to fill a prescription if, in the pharmacist's professional judgment, filling it as written will cause unnecessary harm to the patient. This includes if the physician made an error in the strength or dosage, if a drug interaction is possible, or if it seems, in the pharmacist's judgment, that the prescription was obtained illegally. Society expects pharmacists to use sound professional judgment to make objective decisions based on facts that affect the healthcare outcome of their patients. Patients put a lot of trust in their pharmacists, and preserving this trusting and covenantal relationship is key to our profession. It is clear that ethical problems will arise and it is up to the pharmacist to remember to try to resolve the issue while at the same time not compromising ethical issues such as nonmaleficence and beneficence. In the APHA code of ethics it states that, “a pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients”. The pharmacist must understand that the patient is also capable of making decisions regarding their health care and moral choices. Even though you may not agree with those choices you must have respect for the patient and do what is in their best interest. There are ways to maintain your own personal beliefs as a pharmacist without destroying the relationship between you and your patient, or destroying how society views our profession as a whole.

Based on my own research and the literature searches about the controversial subject of Plan B® and the pharmacists' right to refusal, I am able to conclude that pharmacists cannot completely separate their personal beliefs and professional roles. There will always be a pharmacist who does not feel he/she can compromise their personal beliefs for the best interest of their patient. What pharmacists can do is take a proactive role in ensuring that all pharmacists handle such a situation in a manner that keeps a good light on our profession as a whole. The APhA has already taken this step by guiding pharmacists with a refusal clause, which guarantees the right of the pharmacist to refuse as long as they are willing to provide the patient with another way to get the treatment they deserve. However, if pharmacists cannot take this matter into their own hands, it might become necessary for the state to get involved and create laws which specify when a pharmacist has the right to refuse to dispense, and what they must do for the patient if they use this right. The issue seems to be based on the fact of whether the pharmacist views pregnancy as when the egg is fertilized or after it is implanted in the uterus. The medical world views pregnancy as after the fertilized egg is implanted, therefore making Plan B® a contraceptive, not an abortaficient. One thing pharmacists need to remember is when they take a job, they need to comply with that employer's company policy, or they may lose their job as in the few cases that have happened across the nation. Pharmacists need to decide whether the company they work for has positions on issues that may conflict with their own personal beliefs. Most importantly, we as health care
professionals need to realize what effect just a few pharmacists could have on the profession as a whole. As pharmacists, we should all remember the oath we took; at this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy. I will consider the welfare of humanity and relief of human suffering my primary concerns. I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patient I serve. I will keep abreast of developments and maintain professional competency in my profession of pharmacy. I will maintain the highest principles of moral, ethical, and legal conduct. I will embrace and advocate change in the profession of pharmacy that improves patient care. I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public. Society expects that pharmacists, among other health care providers, put their best interests ahead of anything else. It is justifiable that pharmacists do not and should not want their professional judgment about whether or not they choose to fill a prescription to be mandated to them by law. With Plan B®, pharmacists need to decide whether even though they may have the authority to refuse such prescriptions, it is worth exercising this authority without regard for their patients’ well being and own autonomy when it comes to their health. In order to not lose the trust and loyalty of their patients’, pharmacists need to be able to have sound reasons for each of their actions. Sometimes telling a patient that it goes against your personal beliefs is just not a good enough reason and they will always expect you to continue to service them by making sure they get the care that they are searching for.
References


9. www.apha.org