Abortive Agents and the Pharmacist’s Right to Refuse

By:

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A legally induced abortion is defined as a procedure performed by a licensed physician or someone acting under the supervision of a licensed physician, which was intended to terminate a suspected or known intrauterine pregnancy and to produce a nonviable fetus at any gestational age. Legally induced abortions include abortions induced by medication as well as surgery. Medication induced abortions are becoming more prominent due to the availability of new abortive drug regimens. The use of abortaficients increases the likelihood that a physician will prescribe a drug that presents a moral dilemma to a pharmacist. Both legal and ethical issues arise and will be addressed regarding the pharmacist's right to refuse to dispense based on personal beliefs.

In 2000, a total of 853,485 legal induced abortions were reported in the United States. The highest percentages of reported abortions were for women who were unmarried (82%), white (55%) and less than 25 years of age (52%). It is estimated that 49% of pregnancies are unintended and for this reason approximately 29% of these pregnancies end in abortion. There were 27 states that reported one or more medical abortion for both 2001 and 2000, the data reflect an increase of 173%, from 6,892 in 2000 to 18,836 in 2001. The common drug regimens currently available for medical abortions include both a Methotrexate/Misoprostol combination and a Mifepristone (RU486)/Misoprostol combination. The morning after pill (Plan B) has ignited a controversial debate regarding the actual labeling of this drug as an abortaficient versus a contraceptive agent.

Before 1973, abortion was illegal in all or most states, and many women died or had serious medical problems as a result. Women often made dangerous attempts to induce their own abortions or resorted to untrained practitioners who performed abortions with unsanitary instruments or conditions. Women were brought into emergency rooms with serious complications -- perforations of the uterus, retained placetas, severe bleeding, cervical wounds, infections, poisoning, shock, and gangrene.

It was not until 1973 when the landmark Supreme Court decision to legalize abortion was put forth after the ruling of the Roe vs. Wade trial. The court ruled that, anywhere in the U.S. a woman and her doctor may freely decide to terminate a pregnancy during the first trimester. The state governments can restrict abortion access after the first trimester with laws intended to protect the
woman’s health; abortions after fetal viability must be available if the woman’s health or life are at risk and state governments can prohibit other abortions.\textsuperscript{6}

The national legal induced abortion ratio increased from 196 per 1,000 live births in 1973 (the first year that 52 areas reported) to 358 per 1,000 in 1979 and remained nearly stable through 1981. The ratio peaked at 364 per 1,000 in 1984 and since then has demonstrated a generally steady decline. In 2001, the abortion ratio was 246 per 1,000 in 49 reporting areas. This represents a 0.4% increase from 2000 (246 per 1,000). The graph below illustrates the abortion patterns within the United States from 1973 to 1998.

Figure

\textsuperscript{1} Number of abortions per 1,000 live births.
\textsuperscript{2} Number of abortions per 1,000 women aged 15–44 years.
\textsuperscript{3} Data are from 48 reporting areas. See Tables 1 and 2.

The steady decline after 1990 may be due to the fact that preventative contraceptive use had been implemented both in the media and in the school systems. Teenage adolescents were more informed and therefore possibly more conscientious in their decision making.

Medication induced abortion has become increasingly more convenient than surgical abortion. When compared to other methods, advantages include: no surgical instruments used, the procedure is less invasive and no anesthetics are required. The procedure can be done in a physician’s office which may offer the woman more privacy, and less exposure to witnesses, when compared to a trip to an abortion clinic. One of the common drug regimens used in medication abortion includes methotrexate and misoprostol in combination. Methotrexate has been available for over fifty years as a treatment for neoplastic diseases, psoriasis as well as rheumatoid arthritis. This drug when used as an abortive agent prevents the cells in the embryo from dividing and is more effective when
used with other agents such as misoprostol. Within a few days or weeks of receiving an injection of Methotrexate (MTX), the pregnancy ends through an experience similar to an early miscarriage. Misoprostol, a synthetic prostaglandin E₁ analog, is a gastric anti-secretory agent with protective effects on the gastroduodenal mucosa. The drug inhibits gastric acid secretion and protects the mucosa from the irritant and/or other (e.g., pharmacologic) effects of certain drugs. When the misoprostol is later inserted into the vagina, the uterus contracts and the pregnancy is usually expelled within 6 to 8 hours.

One-quarter of early medical abortions in non-hospital facilities were performed using methotrexate, which was available before the Food and Drug Administration (FDA) approved mifepristone in September 2000. However, 82% of medical abortion providers were using mifepristone. Although not approved as an abortive agent, this regimen is commonly used as an off-label drug regimen. A number of side-effects are possible, including nausea, vomiting, diarrhea, abdominal pain, dizziness, and/or fever and chills and vaginal bleeding. The combination of methotrexate and misoprostol represents a safe and effective alternative to invasive methods for the termination of early pregnancy. This regimen when given within 49 days of last menstrual cycle has shown efficacy in 95% of the patient population. This current regimen is expected to be replaced with the newer regimen including both mifepristone and misoprostol due to the possibility of a better safety history and a faster onset of effect.

The medication mifepristone was developed in France, by Dr. Etienne-Emile Baulieu, in 1980. It is widely known as "RU-486" throughout North America. The letters are taken from the initials of the pharmaceutical company Roussel-Uclaf. The "486" is an arbitrary lab serial number. It was first introduced in France, where it was called Mifegyne®. It has been used, in combination with prostaglandin medication, to induce abortions in about 500,000 women over two decades.

In September 2000, the U.S. Food and Drug Administration approved the abortion drug mifepristone (Mifiprex®) to be marketed in the United States as an alternative to surgical abortion. Since then, mifepristone has become available in 45 US states and the District of Columbia, and major health insurers have added coverage for mifepristone for eligible women. This drug has been approved for induced abortions of gestations of 49 days or less since the last menstrual period, but is not yet approved for any other uses. Mifepristone blocks the action of progesterone, a hormone necessary to sustain a pregnancy. It binds itself to progesterone receptors on the wall of the uterus thus blocking the effect of the woman's natural progesterone. This triggers the shedding of the uterine wall. Under the currently approved regimen, treatment with oral mifepristone and oral misoprostol requires three office visits for most women. After counseling and a physical exam, an eligible woman takes one oral dose of three 200-mg tablets of mifepristone (600 mg total). Two days later, the woman returns to the clinic for misoprostol. If the woman's pregnancy has not ended with use of mifepristone
alone (mifepristone is successful by itself in 2% to 5% of cases), she takes two 200-μg tablets of misoprostol orally (400 μg total). She then receives instructions about possible side effects and about whom to contact for questions and emergencies. Approximately 12 days later, she returns to the clinic to confirm that the abortion is complete. At the follow-up visit or sooner, a complete abortion can be confirmed clinically or through ultrasonography. If an ongoing pregnancy with cardiac activity is confirmed through ultrasonographic examination, a vacuum abortion should be performed.11 Data from three large French and American trials showed complete abortion rates at less than 49 days of gestation ranging from 92% to 97% percent.12 Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous Mifeprex® use. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. The FDA recently became aware (July 19, 2005) of four women in the United States who died from sepsis (severe illness caused by infection of the bloodstream) after taking Mifeprex® and misoprostol. Sepsis is a known risk related to any type of abortion. The symptoms in these cases were not the usual symptoms of sepsis. It is not known whether using Mifeprex or misoprostol caused these deaths. Patients may experience stomach pain or discomfort, or have weakness, nausea, vomiting, or diarrhea with or without fever, more than 24 hours after taking misoprostol. These symptoms, even without a fever, may indicate sepsis.13 Both medication regimens were found to have high levels of success at ≤49 days of gestation but may have lower efficacy at longer gestation.6 Even though both were relatively safe, complications can occur and is a major safety concern that pharmacists must consider and inform patients when dispensing these medications.

Plan B (levonorgestrel product) is another regimen that may be looked at as an abortive agent. The FDA refers to this agent as an emergency contraceptive that is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Emergency contraceptives are not effective if the woman is already pregnant. The method of action of Plan B acts by preventing ovulation or fertilization by altering tubal transport of sperm and/or ova. It may also inhibit implantation by altering the endometrium. It is not effective once the process of implantation has begun.14 The first tablet should be taken within 72 hours of intercourse. The next tablet should be taken 12 hours later. Depending on an individuals definition of human life will determine if a person views this agent as an abortaficient. This concept will be discussed further when demonstrating the general view of the population in regards to this agent.

At present there are 33 states that currently enforce parental consent or notification laws for minors seeking an abortion: AL, AR, AZ, CO, DE, GA, IA, ID, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, ND, NE, OH, PA, RI, SC, SD, TN, TX, UT, VA,WI, WV, and WY. The Supreme Court ruled that minors must have the alternative of seeking a court order authorizing the procedure.15
Now that medications are made so easily available, the pharmacist is faced with the decision of dispensing the medication to patients or not. The pharmacist must decide if he is going to refuse to fill the medication.

“Refusal Clauses” were first enacted in response to the nationwide legislation on abortion in the Roe Vs. Wade decision as mentioned above. These policies were designed to allow doctors and other direct providers of health care to refuse to perform or assist in an abortion, and hospitals to refuse to allow abortion on their premises. This is an ongoing debate as pharmacists are refusing to fill emergency contraception and abortive agents. This movement resulted in the term “conscience clause” which gives pharmacists the right to refuse to perform certain services based on a violation of personal beliefs or values.16

In some states, legislators are introducing bills that would explicitly grant pharmacists the right to refuse to dispense drugs related to contraception on moral grounds. Other states are introducing legislation that would require pharmacies to fill any legal prescription for birth control.

There are four States (Arkansas, Georgia, Mississippi, and South Dakota) that have passed laws allowing a pharmacist to refuse to dispense emergency contraception drugs. Illinois passed an emergency rule that requires a pharmacist to dispense FDA approved contraception. California has also introduced legislation that would require a pharmacist to dispense a prescription except in specified circumstances. Three States (Missouri, New Jersey, and West Virginia) have introduced legislation that would require pharmacists to fill prescriptions.16

On May 5 2005, Michigan passed Bill 4741, which has been referred to as the conscientious objector accommodation act. This bill provides standards to protect and accommodate the right of conscience of health care providers who conscientiously object to providing or participating in certain health care services under certain circumstances. It also provides protection from certain liability; and to provide for penalties and remedies.17 This Bill allows the pharmacist or any other health care provider to object as a matter of conscience to providing or participating in a health care service on ethical, moral, or religious grounds. The pharmacist may object to dispensing medications under certain circumstances. These circumstances include: notifying his or her employer in writing of a conscientious objection, the notice must be given directly to his or her supervisor and must include a statement explaining his or her conscientious objection and the health care service or services to which he or she specifically objects to providing or participating in under this act. Within 7 days after receiving a written objection, an employer must develop an accommodation plan with the health care provider to ensure that the health care provider will not be scheduled or requested to participate in a health care service. An employer must not refuse employment or staff privileges to a pharmacist who has exercised his or her rights.
to assert an objection to providing or participating in a health care service. This act does not excuse a health care provider from a duty that exists under any other law pertaining to current standards of acceptable health care practice. It does not relieve a pharmacist from the procedure to inform a patient of the patient’s condition, prognosis, risk of receiving or forgoing relevant health care services for the condition, including the availability of a health care service to which the health care provider conscientiously objects.17

Due to the growing debate on the pharmacists’ right to refuse, a survey was conducted to obtain an opinion within the general public. There were 55 people who participated in this survey. Participants included those in pharmacy school, the general public and adolescents. The survey was multi-center including participants from both Canada and the United States. The ages ranged anywhere from 15 to 50 years old and included all areas of ethnicity and religious background. The study subjects were 67% female and 33% male, 57% were 22-29 years old, 24% were between the ages of 15-21 and 17% were over the age of 30. The religious background of most participants was Catholic and less than 5% were either Hindu, Protestant, Islam or other.

The survey concentrated on three prime areas. In the first section of the survey, participants were given a case where they had to be the pharmacist. A young girl (17 years of age) came into the pharmacy and presented the pharmacist with a prescription. The prescription was for Mifeprex® and they had to decide if they were going to dispense the medication. The results showed that 67% of the participants would dispense the abortive agent, 12% said they would not dispense the medication and 21% were undecided and not sure what they would do. The basic finding showed that of the 12% of those who said they would not dispense, the majority were either of Hindu or Islam descent, where only one other person was Protestant. More than half the participants said that if the girl would have been over the age of 25 they would have been more inclined to dispense the medication.

The participants of the survey then had to decide if they felt that it was the pharmacist’s responsibility to direct the teenager to another pharmacy where she could get the prescription filled. A total of 64% of the participants felt that it was the pharmacist’s duty to direct the patient to another store.

The next question posed determined how participants felt about the issue of the pharmacist’s obligation to fill all prescriptions that physicians write for. Approximately 64% of the participants felt that pharmacists do not have the obligation to dispense all medications that physicians prescribe where 26% felt that pharmacists should dispense all medications that physicians write for and 10% were undecided. When conducting this survey, many people from the general public assumed that pharmacist’s had to dispense every single medication that physicians write for. Many elderly individuals were surprised that
pharmacist’s had the right to not fill a prescription if they thought it was unsafe for the patient.

The next few questions on the survey dealt with the issue of Plan B, the so-called emergency contraceptive. Before this survey was conducted, there were many opposing debates on the correct labeling of this medication. Some people made it quite apparent that they felt that this drug was a form of birth control whereas others strongly believed that it was an abortive agent. There has been much publicity concerning this issue where pharmacists refuse to dispense this medication. For this reason, a general view of the public was obtained. The following graph demonstrates the findings.

Graph 2

From the results, 45% of participants felt that Plan B was an abortive agent, 38% though it was not an abortive agent and 17% were undecided. The next question demonstrated that only 33% of participants felt that it was a form of contraceptive, 59% thought it was not a form of contraceptive and 7% were undecided. There were participants that thought that this medication was neither a form of birth control nor an abortive agent. It was apparent from the general consensus that there was a higher tendency for people to label Plan B as an abortive agent as opposed to a contraceptive agent. The FDA labels Plan B as an emergency contraception. It contains one of the same active ingredients used in ordinary prescription birth control pills – only in the case of Plan B – each pill contains a much higher dose and is taken in a different way.18
Like ordinary birth control pills, Plan B is currently available to all women as a prescription drug. This drug can now be sold over the counter in Canada and in eight U.S. States. Regardless, each person has their own definition of what human life is. It is this definition that will determine whether an individual views this drug as an abortive agent or a form of birth control. According to general medical definitions of pregnancy that have been endorsed by many organizations including the American College of Obstetricians and Gynecologists and the United States Department of Health and Human Services, pregnancy begins when a pre-embryo completes implantation into the lining of the uterus. This drug not only inhibits ovulation but it inhibits implantation as well. If it is believed that human life begins at conception, when the sperm joins with the ova then this medication can be viewed as an abortive agent. Since Plan B inhibits implantation, there is a chance that conception may have occurred before the pills were taken. Some individuals believe that baby would have been formed and by preventing implantation you, the baby by definition is aborted. If it is thought that human life begins when the baby is able to breathe and function on its own or when neurological activity in the cerebral cortex begins during the fifth month, then this agent could be regarded as a contraceptive since it was used as a preventative measure and no baby was created in the first place. On the other hand, this medication can inhibit ovulation, which may be categorized as a preventative contraceptive. The argument has been used that because many pregnancies are not viable, and these pregnancies are not usually clinically recognized, Plan B can therefore be regarded again as a preventative measure. In the end, it is a personal belief that will guide one decision in deciding to dispense this medication or not.

It was found that 74% of the participants said that they would dispense this medication (Plan B) to a 17 year old girl who came into the pharmacy with a prescription. 7% said they would not dispense this medication to the girl, those 7% were the same people that said they would not dispense the abortive agents. The next question went on and asked if the pharmacist should dispense Plan B to this girl if she repeatedly came into the pharmacy (about 3 times a year). A total of 48% of the participants said that they would not dispense this medication to the young girl but extensive counseling would be offered.

Approximately 62% of the participants felt that there should be no age limitation on the use of abortive agents. Even though some people felt that they would be more willing to dispense these medications to someone who is over 25.

The next prime area of the survey took into account the factors that played a key role in participant’s decision making. The number one factor that participants chose were morals, with 74% of participants choosing this category. The next factor that contributed were values (69%). The third factor that came into play in guiding decisions was the general norms of today’s society. (40%) Many people chose more than one of the options. Only 29% chose religion as a factor. Ethnicity (14%) and media (10%) were the factors that least contributed
to guiding decisions. Those participants that said that they would not dispense both the abortive drug and Plan B made it clear that their main factors in guiding their decisions included both moral, values and religion. Many factors play a key role in guiding decisions but what it came down to was that morals and values were the two main factors in the general population’s decision making.

Each pharmacist practices pharmacy with a certain code of ethics. It is this code that directs their decisions making and establishes a framework for professional behavior and responsibilities. It is expected that pharmacists apply moral and ethical principles conscientiously and consistently in making decisions. Patients expect pharmacists to use professional judgment to make objective and factual decisions that affect healthcare outcomes.

Through an interview process within the current pharmacy internship, three out of four pharmacists that were interviewed do not dispense abortive agents including the morning after pill. When asked why, all pharmacists demonstrated the same reasoning. It was against their moral and beliefs. They all felt that they have no right to interfere with God’s creation and therefore refrain from dispensing the medication. It is not their duty to impinge their beliefs on their patients so they do not take apart in dispensing this medication or counseling. Not only did they base their decisions on their religion but also on their morals, values and family ethics as well. Each patient has a right to autonomy - expressed by freedom of choice based on informed decision-making. For this reason, they felt it was mandatory that patients be referred to another pharmacy where they can get the proper medication they need. Patients have the right to make their own decisions just as pharmacists should. Therefore, pharmacists should have the right to refuse to dispense medications. There are those states that want pharmacists to put their own views aside and dispense medications even if it is against their will. Therefore, should physicians be made to prescribe abortive medications to every patient? Should they have the right to refuse to prescribe? When pharmacists refuse to dispense, the story is portrayed throughout the media.

Overall, pharmacists are faced with important decision making everyday. The question remains, how far will they let their ethics, moral and values guide them in their decision making. With the new conscience clauses being implemented, pharmacists are able to do what they feel is right without the social pressure and worry of being fired in most states. Certain regulation and procedures must be followed but in the end, it allows the pharmacist to practice pharmacy the best way they know how. The job of pharmacists in the end is to protect the patient. If the pharmacist feels that the drugs that they are dispensing are going to harm the patient in someway or goes against everything he/she believes in then it is only right that pharmacists do what they feel is the right.

Human beings are entitled to make choices that affect their lives, even though others may not agree with those choices. Pharmacists have the right to
personal beliefs and their own code of ethics, but interventions must be made to accommodate both the patient's needs and the pharmacist beliefs, without destroying the patient-pharmacist relationship.
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