



Pharmacists and Emergency Contraceptives: Controversies and Challenges

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In the practice of pharmacy, each day brings a set of unique and challenging situations requiring pharmacists to employ their scientific and clinical knowledge with truth and compassion in a world filled with diverse views on God and His creation. All medications possess both helpful (i.e., desirable) and untoward (i.e., adverse or undesired) effects. Understanding and balancing these effects in a manner that offers maximum benefit and minimum risk to the patient is our intended goal. Such is integral to our professional code of ethics. We are called upon to rely on the latest and most valid scientific evidence in making our decisions. Again, our professional code of ethics demands it. And, we should never aim for anything less. Whether we're helping a patient control his/her high blood pressure, treating a devastating invasion of cancer, or preventing the occurrence of H1N1 (aka, swine flu) viral infection, the patient's well-being is "at the center of professional practice."[†]

In most cases (e.g., those listed above), that which represents the well-being of the patient is relatively easy to discern. However, medications can be (and are) used in a multitude of ways (both legally and illegally) that raise tough questions as they abrasively challenge the ethical principles provided to us in God's word. A few of the issues often cast into this bucket include: euthanasia (aka, mercy killing), the use of psychotropic medications (e.g., in the treatment of depression, attention deficit hyperactivity disorder (ADHD) or schizophrenia), capital punishment (e.g., lethal injection), abortifacients (i.e., drugs used to induce abortion, such as RU486) or birth control pills (e.g., oral contraceptives). And, what about issues such as providing erectile dysfunction medications to registered sex offenders or HIV+ patients, or filling a prescription for a narcotic pain medication that you sense might be sold on the street for profit? And, the list goes on and on. Many times the ethical principles seem clear enough, but the science supporting our understanding of the issue is lacking. At other times both the science and ethics seem clear, but the government establishes laws that require a response that runs counter to the one we would prefer. To whom are we responsible?

We are licensed by our home state to engage in the practice of pharmacy, governed by the laws and rules established by the federal and state governments and various rules agencies (e.g., Food & Drug Administration; State Board of Pharmacy). We are guided by the Code of Ethics established and adopted by our profession, and us as professionals within it. Yet, as Christians, we are ultimately responsible to our Lord, Jesus Christ.



One of the truly exciting opportunities available to the faculty and students of the Cedarville University School of Pharmacy is the mission-driven ability and intention to address the tough questions facing the practice of pharmacy – and, healthcare in general – in a manner that fully prepares students to be excellent clinicians, and honors our Lord. Teaching students to effectively merge good science and practice with a kingdom perspective is our purpose and privilege.

One such issue requiring present and continued study pertains to the professional implications associated with the so-called “morning after pill” (aka, emergency contraceptives (EC) such as Plan B[®]/levonorgestrel)††. There’s insufficient space in this brief article to address all of the issues that might be associated with the topic, and many more questions than answers will be found (such is the nature of our work). This will likely leave you unsatisfied, and maybe uncomfortable. Welcome to the world of pharmacy. Let’s get started.

First, let me differentiate some terms: oral contraceptive and birth control pill. This level of differentiation is semantics to some. But it’s important to communicate in a clear and precise manner. Birth control pills (BCP) usually refer to medications used to prevent pregnancy, and oral contraceptives (OCs) are the most commonly used products in this category. What are the implications of these terms? It’s important to note at the very beginning that OCs are not universally accepted as being “OK” by Christians. For example, most Roman Catholics – as holders to “natural law” (i.e., sexual intimacy must allow for the potential for pro-creation, and should not be separated), are generally opposed to any form of contraception (preventing the fertilization of a female egg by a male sperm cell), whereas protestants are typically more willing to see contraception as acceptable. However, both groups generally believe that life begins at conception, and we have an obligation to protect the sanctity of human life from that point forward. Therefore, most Christians would agree that abortion (i.e., disrupting/ending the life/growth of a fertilized egg, ie., after conception) is considered morally wrong. So, what about so-called ECs (another form of BCP)? These hormone products are typically taken within 72 hours after sexual intimacy to prevent pregnancy; however, depending on the manner in which these medication work, and the definition of pregnancy, these products might not function as contraceptives, but as abortifacients.

Let’s briefly review the physiology of the female reproductive system (to the extent that it supports the remainder of this discussion). Under the influence of Gonadotropin releasing hormone (GnRH; released from the part of the brain called the “hypothalamus”) the pituitary gland (also in the brain) releases follicle stimulating hormone (FSH) and luteinizing hormone (LH). FSH and LH, released in the early phase of the normal 28-day uterine cycle, cause the development of ovarian follicles. These are the sacs in the ovary (the organ that produces the female egg or “ovum”) within which the ovum resides. Each month one (usually) of the ova (plural of ovum) grows larger than the rest. The follicle of this maturing ovum secretes two additional hormones, estrogen and progesterone, which stimulate the lining of the uterus (endometrium) to thicken and make ready for the potential implantation and growth of the



fertilized ovum. The uterus is also referred to as the “womb”. When the ovum is ready to be released from the ovarian follicle, the brain releases a surge of LH which initiates rupture of the follicle and release of the ovum (“ovulation”) into the uterine tubes (aka, fallopian tubes) which connect the ovary to the uterus. For the next few days, the ruptured follicle (also called the “corpus luteum”) continues to secrete estrogen and progesterone, continuing the development of the endometrium.

Following sexual intimacy, sperm deposited in the vagina may pass through the cervix (the muscular closure restricting access into the uterus) into the uterus, and eventually into the fallopian tubes. It is here, usually, where one of the many sperm may enter the released ovum (this is called “fertilization”) creating what we refer to as an “embryo”. The embryo will then typically travel down the fallopian tube into the uterus and implant into the uterine lining, where it will reside and grow for the next 9 months. If implantation is successful, the embryo begins producing a new hormone, “human chorionic gonadotropin” (hCG), which continues to cause the corpus luteum to produce estrogen and progesterone in support of the developing embryo. Detecting the presence of hCG in the urine is the manner in which home pregnancy tests work. If, however, implantation does not occur, the corpus luteum will eventually cease its work, the endometrium’s development will collapse, and the recently thickened lining will slough (also called “menstruation”), and a new cycle begins.

Oral contraceptives are most commonly a combination of an estrogen and progesterone taken on a daily basis. These supplemental (i.e., more than normal) hormones essentially tell the brain to refrain from releasing GnRH, which means that the pituitary gland will not release FSH and LH, and the ovarian follicles will not be stimulated to grow an ovum for subsequent release and possible fertilization. In other words, OCs prevent ovulation. In addition, OCs appear to thicken the mucous that normally glazes the endometrium, thereby making it more difficult for sperm to make their way to the fallopian tubes. Each of these actions prevents conception (i.e., the fertilization of the ovum), which leads to their identification as “contraceptives”.

Emergency contraceptives are, essentially, high-dose OC taken within 72 hours after sexual intimacy. These products also work by derailing the normal hormonal cycle, and preventing ovulation. There is also some concern that a different mechanism of action may be at play, namely causing a thinning of the endometrium to a sufficient degree that makes it difficult for the fertilized ovum (embryo) to successfully implant and grow. There is limited, but intriguing, evidence for this effect. I will take the position that life (and, thus pregnancy) begins at conception – an event that takes place up to several days after ovulation and/or sexual intimacy when the sperm and ovum finally (and successfully) meet in the fallopian tube. So, if an EC acts, in some cases, by causing a new embryo to fail to implant in the uterus, then such a drug would be considered an abortifacient in those cases.

This is where things get really tough. Solid data indicating an abortifacient effect of ECs is lacking. It’s speculative, but not proven. But, they clearly have contraceptive effects...which are generally acceptable (unless you hold to natural law). Proving the presence or absence of an



abortifacient effect of ECs will be very difficult. One reason is that upwards of 75% of all fertilized ova (i.e., conception has occurred) never successfully implant in the uterus, and are simply passed during menstruation. It is very difficult to determine whether or not ECs increase this rate of embryo loss. Further, we are presently unable to readily determine when conception has actually occurred. And, given the fact that ECs act primarily by inhibiting ovulation, identifying the very small percentage of the time when they “might” act as an abortifacient is seemingly impossible.

This puts significant pressure on the need for us to practice “evidenced based” medicine (i.e., ensuring that everything we do is scientifically valid). As with any medication-related decision, it becomes important for us to ensure that the patient is informed of the data, so that he/she can make an informed decision about their care.

In the past, there hasn’t been much evidence of the body’s recognition of pregnancy until after implantation of the fertilized egg. What we, as holders to the conception position of life/pregnancy, want to know is precisely when the fertilization occurs. Interestingly, there is some developing science that might help us. A hormone called Early Pregnancy Factor (EPF) has been identified as a substance produced by the fertilized ovum, apparently communicating important information to the body of this event. EPF is only found in minute, difficult-to-measure, quantities, but, it’s there! The fertilized egg is not a silent entity in the body. An ability to measure EPF may someday offer us a new tool in assessing pregnancy and appropriately employing ECs.

What about our obligations, as licensed pharmacists, to dispense a medication to which we have moral objection? Many professional organizations have developed, and states have enacted, “conscience clauses,” giving guidance and privilege to a pharmacist to refrain from participating in a medication use process to which he/she has cultural or religious objection. But, this is a state-by-state issue. In Illinois, for example, the governor enacted rules that require a pharmacist to dispense all such legally written prescriptions. A number of court cases are pending that involve the refusal of pharmacists to practice according to such a rule. But, as Christians, in those states where we might be forced to dispense a product with which we have moral objection, do we simply withdraw our influence in the profession (i.e., refuse to dispense the products and give up our license to practice), or work to change the rules that guide our work?

Even if we have the right of “conscience”, to what end should we go to thwart a patient’s attempt to have a valid, legal prescription filled? Should we refuse to locate another pharmacy or pharmacist that might help? Should we refuse to transfer the prescription refill to another pharmacy (which is the focus of additional court cases)? Most conscience clauses will say that the pharmacist can refrain from participating in the activity-in-question (e.g., dispensing ECs), but must not engage in any activity that gets in the way of the patient’s legal rights.



Another important consideration in such cases for pharmacists pertains to the policies of the employer. Most multi-location pharmacies will likely have consistent (i.e., same from one location to another) policies regarding which products will be stocked and dispensed – wanting their customers to receive consistent service. A pharmacist needs to understand the policies of the employer (hopefully prior to being employed) in order to assess compatibility with his/her personal perspectives on these ethical dilemmas.

What is the status of Plan B[®]? It was originally a prescription-only item (July, 1999), having gone through a crazy maze of hoops, roadblocks, hot-potato-style handling by our Federal government. Eventually the product was made available as an over-the-counter item for those 18 years and older. Petitions for this change were initiated in February, 2001 and were finally approved in August, 2006. In mid-2009 it was further approved for over-the-counter purchase by persons 17 years and older (the product is held behind the counter in pharmacies/clinics, and proof of age is required for purchase). It is still prescription-only for persons less than 17 years.

As pharmacists, how do we manage this OTC product? How do we ensure that the 24 year lady at our counter is truly purchasing the product (assuming that we're OK with anyone getting it) for herself? It's very possible that she's simply buying it for a 15 year old friend (maybe as a paid purchaser). What about selling the product to sexual predators who might trick or force victims into taking this medication? As it pertains to the prescription version (regardless of age) – we don't always work with a complete set of data about the patient. Typical OCs (dispensed without concern in most pharmacies) can be used as ECs, just by changing the dosing strategy used. Additionally, OCs are used for other (i.e., non-contraceptive) purposes, usually related to regulating the female menstrual cycle. Patients may not be taking these medications for contraception at all.

As Christians, how do we effectively engage our patients, and serve our profession? Our society? Our Lord? So many in our world are asking for “Plan B,” something far less than that which God has provided for them. We want to offer them Plan A. With love and compassion we need to offer them excellent care, truth and encouragement in a non-judgmental way (Romans 14).

† The Code of Ethics for Pharmacists, as published by the American Pharmacists Association, can be accessed via their website www.pharmacist.com (search “code of ethics”)

†† Plan B[®] is a registered trademark of Women's Capital Corporation, a subsidiary of Duramed Pharmaceuticals, Inc. Duramed is a subsidiary of Barr Pharmaceuticals, LLC