

Appreciation

This issue marks the completion of the thirteenth year of publication of *The Pharmacist Activist*. I remember wondering when I started the publication in January 2006 whether there were enough important issues about which I could write an interesting (and occasionally provocative) editorial every month. What I quickly realized is that my continually developing list of topics for editorials is much longer than I will ever have time to write. The Index for this Volume 13 (2018) is on page 4. All of the issues in Volumes 1 through 13 (2006-2018) are available on the website, www.pharmacistactivist.com.

I wish to express my deep appreciation to my friend and former student, Linda Corvari, who has provided financial support for publication of *The Pharmacist Activist*. Linda is the Founder and President of p-value communication (www.pvaluecomm.com), and her support reflects her commitment to advance the profession of pharmacy through stimulation of discussion/debate on important issues and challenges, and the provision of objective evaluations of new drugs. This support makes it possible to continue to make *The Pharmacist Activist* available free-of-charge via email to interested pharmacists and student pharmacists.

Appreciation is also extended to Jeff Zajac and Pat Polli of NEWS-Line Publishing, and the assistant editor and my wife Suzanne Hussar for their expertise and skills in editing, preparing, and distributing the issues of *The Pharmacist Activist*.

I am also very grateful to those who read *The Pharmacist Activist*, and to the many who provide thoughtful comments and recommendations. Your responses provide the motivation to continue with this initiative.

Best wishes for a blessed Christmas season and a healthy and enjoyable new year!

Daniel A. Hussar

The Pharmacist Activist

Editorial

For Those Without a Voice or Choice – A Gift of Life

As an advocate for smoking cessation I (author DAH), and others, have referred to smoking as the leading cause of preventable death. As important as this issue is, I was wrong. Abortion is the leading cause of preventable death.

We are opposed to abortion for ethical, moral, and religious reasons. Many terms have been used to identify the results of sexual intercourse including fertilized egg, embryo, conception, pregnancy, fetus, contents of the womb, unborn child, and baby. Regardless of the term used and how it is defined, or how one views the timing of when life and pregnancy begin, the unquestioned result of abortion is death. Voicing opposition to abortion often brings a response of whether there should be exceptions. For example, if a woman who is pregnant experiences a medical crisis for which the only intervention to save her life would result in the loss of her unborn child, how would we respond? Our immediate response is that every effort should be made to save the life of the mother, even if the unborn child does not survive.

Both those who support and oppose abortion have very strongly-held opinions. The ongoing debate is often characterized by anger and even hate. We do not anticipate that stat-

ing our opposition to abortion in this editorial or otherwise will change the opinions of those who support abortion. Rather, our hope is that those with very divergent opinions can continue to discuss this issue in a manner that is civil, tolerant, and respectful of those who hold different views.

I (DAH) write reviews about new drugs. In the package insert for every drug, there is a section on Pregnancy that includes summary information regarding the safety and risk of using the medication during pregnancy. For many years I used the most common terminology in describing the risk to the fetus or fetal harm. It occurred to me that the term “unborn child” was more personal and appropriate than “fetus” and “fetal,” and I began to use that term. I was contacted by the editor of one of the journals in which I publish about the terminology I had chosen. During our discussion she noted that she understood and personally agreed with my reasons for using the term unborn child. However, because of editorial policy (political correctness?), my use of that term would not be permitted. If anything, this experience increased my reluctance to use the terms fetus and fetal. As a compromise, I now describe the potential risk/safety of a drug causing “adverse developmental effects when used during pregnancy.”

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Mifepristone

Almost 20 years ago the Food and Drug Administration (FDA) approved mifepristone, also known as RU-486, the abortion pill, and by its trade name Mifeprex. Mifepristone is an antiprogesterone agent that is indicated, in conjunction with misoprostol, for the medical termination of intrauterine pregnancy through 49 days' pregnancy. I (DAH) wrote an editorial with the title, "Mifepristone – Controversy, Beliefs, and Politics – Issues for Everyone," in which I stated my opinion that the FDA had made the wrong decision. However, it was not my personal opposition to abortion that I used as the basis for my opinion but, rather what I considered the responsibility of the FDA to be.

In considering the application for the approval of a new drug, the FDA thoroughly evaluates the studies of its effectiveness and safety. There is no question that mifepristone is effective for the indication for which it has been approved and, although there are some safety concerns, it is considered safe enough for use by the women for whom it is prescribed. However, I took the position that the FDA not only had a responsibility to the woman who would take the medication, but also to the unborn child. That the FDA has this responsibility is evident in the often lengthy sections of package inserts that address the safety of use of a medication during pregnancy, and which primarily focus on the potential for harm to the unborn child and to a lesser extent, if at all, address any safety issue for the woman for whom it is prescribed. Mifepristone causes the death of the unborn child – the ultimate safety risk.

I planned to include this editorial in the publication for which I served as editor-in-chief at that time. However, the pharmacy organization that published this periodical refused to permit me to include it. To the credit of, and with appreciation to the late Harvey A. K. Whitney, Jr., the publisher and editor of *The Annals of Pharmacotherapy*, my editorial was included in this journal (Volume 35, March 2001, pages 373-375).

Abortion pill reversal

The concerns and emotional impact of the confirmation of an unplanned and unwanted pregnancy can only be fully understood by the woman experiencing it. A very hasty decision, sometimes strongly influenced by the husband/boy friend or parents, may be made to terminate the pregnancy with mifepristone. Following the administration of mifepristone, some women quickly experience regret, guilt, or other emotions resulting from the implications of their decision.

Because it is an antiprogesterone action of mifepristone that terminates a pregnancy, the timely administration of progesterone has been used to reverse the activity of mifepristone. The protocol for oral use is two progesterone generic (or Prometrium) micronized capsules (200 mg; i.e., 400 mg per dose)

as soon as possible and twice a day for 3 days. Treatment is continued with a dose of 400 mg at bedtime until the end of the first trimester, or for a duration of treatment based on the clinical judgment of the prescriber. This strategy has been used successfully to reverse/counteract the effect of mifepristone, with resultant full-term pregnancies and the birth of healthy babies (www.abortionpillreversal.com). A study evaluating the experience of 261 successful mifepristone reversals determined that the reversal success rate using oral progesterone was 68%, a significantly higher rate than the 25% survival rate if no treatment was provided. There was not an increased risk of birth defects or preterm births (<http://issuesinlawandmedicine.com/Delgado-Article>).

Some oppose the use of abortion pill reversal because extensive studies have not yet been conducted and this is an off-label use of progesterone. However, understanding and compassion for the woman who requests this intervention must be accorded the highest priority, and information regarding abortion pill reversal must be more widely communicated.

Adoption – A Gift of Life

One reason for which a woman experiencing an unplanned pregnancy would consider an abortion is that she would not be in a position to support and raise a child. There are many couples who would love to have children but, because of infertility or other reasons, are not able to have children of their own. The opportunity to adopt a baby would be a precious and wonderful gift for the new parents, as well as for the baby.

A story shared by a friend describes this experience best. As a teenager she became pregnant but did not marry the father. Abortion was an option but she chose to have the baby, a girl, for whom immediate adoption arrangements had been made. When the daughter was in her late teens, she sought out the identity of her birth mother. They met and embraced and one of the first things the young woman said to her mother was "Thank you for giving me life."

Daniel A. Hussar*, Suzanne F. Hussar**,
Eric F. Hussar***, and Terra L. Hussar****

"A baby is God's opinion that the world should go on."

– Carl Sandburg

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New Drug Review

Fremanezumab-vfrm (Ajovy – Teva)

Agent for Migraine

**New Drug Comparison
Rating (NDCR) = 3**

*(no or minor advantages/
disadvantages)*

*in a scale of 1 to 5 with 5 being
the highest rating*

Indication:

Administered subcutaneously for the preventive treatment of migraine in adults.

Comparable drug:

Erenumab (Aimovig); (galcanezumab [Emgality] has been subsequently marketed).

Advantages:

- May be administered less frequently (every month or every 3 months, whereas erenumab is administered every month);
- Product does not contain latex derivatives (to which some patients may be sensitive).

Disadvantages:

- May be more likely to cause injection site reactions (although incidence is similar to that with placebo, but may also be related to the larger volume of the dose [1.5 mL compared with 1 mL with erenumab]);
- May be more likely to cause hypersensitivity reactions.

Most important risks/adverse events:

Hypersensitivity reactions; clinical studies excluded patients with a history of significant cardiovascular disease, vascular ischemia, or thrombotic events, such as cerebrovascular accidents, transient ischemic attacks, deep vein thrombosis, or pulmonary embolism.

Most common adverse events:

Injection site reactions (45%, compared with 38% with placebo).

Usual dosage:

Administered subcutaneously; 225 mg once a month or 675 mg every 3 months (quarterly); the 675 mg dose is administered as 3 consecutive injections of 225 mg each.

Product:

Injection in single-dose prefilled syringes – 225 mg/1.5 mL (should be stored in a refrigerator and, prior to administration, should be allowed to sit at room temperature for 30 minutes protected from direct sunlight).

Comments:

Calcitonin gene-related peptide (CGRP) is a neuropeptide that is involved in the transmission of pain impulses, and elevated concentrations have been associated with migraine attacks. Fremanezumab is a human monoclonal antibody that binds to CGRP ligand and blocks its binding to the receptor. It is the second CGRP antagonist approved for the preventive treatment of migraine, joining erenumab.

The effectiveness of fremanezumab was demonstrated in two placebo-controlled studies. One study was conducted in patients with episodic migraine (i.e., 4 to 14 migraine days per month [MMD]). Patients treated with fremanezumab experienced, on average, one to two fewer MMD than those on placebo with dosages of both 225 mg once a month and 675 mg once every 3 months, over a 3-month treatment period. Approximately 46% of patients experienced at least a 50% reduction from baseline in MMD, compared with 28% of those receiving placebo. The second study was conducted in patients with chronic migraine (i.e., 15 or more headache days per month with at least 8 migraine days per month). Patients treated with fremanezumab (in both dosage regimens) experienced, on average, two fewer MMD, than those receiving placebo. Approximately 39% of patients experienced at least a 50% reduction in monthly average number of headache days of at least moderate severity, compared with 18% of those receiving placebo.

Daniel A. Hussar

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