



The Pharmacist Activist

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Editorial

Let Your Conscience be Your Guide! *(but some pharmacists are being denied this right)*

There are many situations in which the difference between right and wrong is clearly defined by laws. However, there are also numerous situations in which the difference between right and wrong is not definitively established and the admonition, "Let your conscience be your guide," has been frequently used to help individuals make the best decisions. "Conscience" is defined in *Webster's II New College Dictionary* as a.) the faculty of recognizing the difference between right and wrong with regard to one's conduct coupled with a sense that one should act accordingly, and b.) conformity to one's own sense of proper conduct. Conscience is personal and, sometimes, an individual may, in good conscience, do something that offends another's conscience.

Most current discussions of conscience with respect to the practice of pharmacy pertain to the use of emergency contraception (e.g., Plan B). The discussions of emergency contraception address many issues including, but not limited to, its mechanisms of action, whether the product may inhibit implantation of a fertilized egg (a secondary mechanism of action), when life begins, abortion, patients' rights, and pharmacists' responsibilities. Strong differences of opinion surround most of these issues. Some pharmacists who identify conscience as the basis for declining to dispense a prescription (i.e., conscientious refusal for ethical, moral, or religious reasons) for emergency contraception do so because they believe that life begins when an egg and sperm unite, and that an action to inhibit implantation of the fertilized egg terminates that life. Others disagree with this position.

Differences Can be Effectively Addressed

In 1998, the House of Delegates of the American Pharmacists Association (APhA) adopted the following policy that effectively addresses the rights of both patients and pharmacists:

"APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."

The objectives of this policy are not contradictory or mutually exclusive. Indeed, policies and procedures can be, and have been, developed that meet the needs of patients to obtain prescribed medications on a timely basis, ensure the right of pharmacists to exercise conscientious refusal, and address the interests of employers of pharmacists (e.g., chain pharmacies).

The Rhetoric and Pharmacist Bashing

Notwithstanding the opportunities to effectively address the needs/concerns of *both* patients and pharmacists (who wish to exercise conscientious refusal), as well as the switch of Plan B to nonprescription status for women 18 years of age and older, some have chosen to exaggerate and sensationalize a very small number of situations by using scare tactics that suggest a crisis exists. They bash pharmacists in general and vilify pharmacists

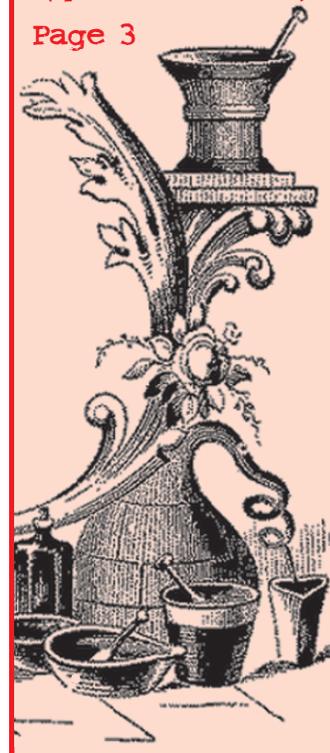
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who have exercised conscientious refusal. Chief among these critics of pharmacists are Planned Parenthood, NARAL (National Abortion Rights Action League), and the National Organization for Women (NOW). These organizations are very strong advocates for women having complete autonomy and unchallenged choices with respect to health, reproductive, and other issues. Therefore, it is contradictory that they are so critical of pharmacists who make a choice based on conscience with which they do not agree, to the point of urging that such pharmacists be fired or should change professions.

The following are examples of such activities of these organizations. In a negative campaign against at least one candidate in the 2006 elections, NARAL sent multi-color glossy mailings in which three of the panels showed a pharmacist addressing patients with the following messages:

“Sleeping pills?
I don't believe in sleeping pills.
Try counting sheep.”

“Viagra?
Not a chance.
Just try harder.”

“Pills for hair loss?
I don't believe in pills for hair loss.
How about a hat?”

Then the mailing shows a picture of the candidate with the message,

“Apparently Curt Weldon believes pharmacists should be allowed to refuse women birth control too.”

When I called NARAL to voice objection to this mailing, I was informed that “it was done as a joke.” When I noted that I considered it insulting to pharmacists, the response was “I can understand why you might feel that way.”

Another NARAL campaign urges women to participate in a letter-writing campaign to “thank” pharmacists who stock Plan B. If the initiative stopped there, no one would object, but it goes on to urge women to write letters to “spank” pharmacists who do not stock the product.

Under the headline “IT'S OUTRAGEOUS,” Planned Parenthood states the following in materials it distributes: “A growing number of individual pharmacists across the country have refused to fill prescriptions for emergency contraception and other birth control pills. Some have even refused to return prescription slips to customers. The reason? They don't ‘believe’ in birth control.”

The new owners of an established pharmacy in Great Falls, Montana decided to no longer carry contraceptives. A letter to patients included the statement, “We will be happy to transfer your oral contraceptive prescription to another pharmacy of your choice in a timely manner.” The headline of one news commentary reporting on the situation noted, “Firestorm Ensues.” One recipient of the letter complained to Planned Parenthood of Montana that then launched a petition campaign against the pharmacy and alleged that it was lying about the drug.

Because the actual number of situations in which women have not been able to obtain emergency contraception immediately is so small, some organizations have resorted to conducting telephone “surveys” of pharmacies to obtain “results” that they use to suggest that pharmacists are ignorant regarding the actions and use of hormonal contraceptives, and that the access to emergency contraception is so limited that a crisis is imminent. These “results” are then further misrepresented in the media. Allegations of inappropriate behaviors by pharmacists (e.g.,

tearing up prescriptions) are made but not documented. The relative lack of actual experiences also results in the creation of hypothetical scenarios such as those in the NARAL political ad or allegations such as pharmacists that exercise conscientious refusal might decline to dispense antiretroviral agents to patients with AIDS because they disapprove of their lifestyle.

The Facts

The number of pharmacists who exercise conscience in declining to dispense prescriptions for certain medications is very small. Even in the settings in which these pharmacists practice, procedures/information are usually available that will facilitate patients obtaining these medications on a timely basis.

Emergency contraception is readily available.

The rhetoric and actions taken by those who have criticized pharmacists for exercising conscientious refusal has been excessive and misleading.

Some pharmacists have been fired or otherwise disciplined by certain chain pharmacies because they declined to dispense prescriptions for certain medications for reasons of conscience. A pharmacist who had inaccurately informed an individual that Plan B was not in stock in the pharmacy has been accused of “dishonorable, unethical, and unprofessional conduct...” and lying about the availability of the product in a case being considered by a state board of pharmacy.

In several states, governors, state legislators, and/or state boards of pharmacy have established requirements that prevent or restrict the opportunity for pharmacists to exercise conscience with respect to supplying emergency contraception.

Conscience Must be Protected

Some pharmacists who exercise conscientious refusal in declining to dispense emergency contraception do so because they believe that one of its actions will destroy a fertilized egg. They believe that a life is at risk. There is no more important reason for exercising conscience and taking appropriate action. Many others may feel just as strongly that the use of emergency contraception does not place a life at risk. However, this position should not be permitted to deny the right of individuals to exercise conscience.

This discussion has primarily focused on the use of emergency contraception and the differing opinions regarding the rights of pharmacists. However, the right of exercising one's conscience must be viewed in a broader and what, for some, will be a clearer context. This expanded context includes situations such as the use of medications for the execution of criminals via lethal injection, or for physician-assisted suicide or euthanasia. Clearly, these are life-or-death situations. Pharmacists (and others) must have the right to exercise conscience and to act on their beliefs. To deny this right because there is a difference of opinion regarding the particular issue will make it all the more difficult to protect this right with respect to other issues on which there is agreement among pharmacists.

The misleading and insulting allegations from those who would deny pharmacists the right to exercise conscience must be challenged. Legislators and members of boards of pharmacy must not be intimidated by those who would deny others the right to exercise conscience. Pharmacy organizations must demonstrate leadership in establishing and publicizing systems that ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal.

Daniel A. Hussar

New Product* Review

Levocetirizine dihydrochloride

(Xyzal – Sanofi-Aventis)

Antihistamine

**New Drug Comparison
Rating (NDCR) = 2**
*(significant disadvantages
in a scale of 1 to 5, with 5
being the highest rating)*

Indications:

In adults and children 6 years of age and older, for the relief of symptoms associated with seasonal and perennial allergic rhinitis, and for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria.

Most important risks/adverse events:

Contraindicated in patients with end-stage renal disease, patients undergoing hemodialysis, in patients 6 to 11 years of age with impaired renal function, and in patients with a known hypersensitivity to cetirizine; may cause a central nervous system depressant (CNS) action and patients should be cautioned about engaging in potentially hazardous activities; concurrent use with alcohol or other CNS depressants should be avoided.

Most common adverse events (in patients aged 12 years and older):

Somnolence (6%), fatigue (4%), nasopharyngitis (4%), dry mouth (2%).

Usual dosage:

5 mg once a day in the evening in patients 12 years of age and older; dosage should be reduced in patients with impaired renal function; 2.5 mg once daily in the evening in children 6 to 11 years of age.

Products:

Tablets – 5 mg.

Comparable drug:

Cetirizine (Zyrtec).

Advantages:

- Dosage adjustment is not necessary in patients with impaired hepatic function.

Disadvantages:

- Has not been directly compared with cetirizine in clinical studies in patients with allergic rhinitis;
- Is not indicated in patients less than 6 years of age (cetirizine is indicated in children as young as 2 years of age with seasonal allergic rhinitis, and as young as 6 months of age for the other indications);
- Contraindicated in patients with end-stage renal disease or undergoing hemodialysis;
- Available in fewer dosage forms (cetirizine is also supplied in syrup and chewable tablet formulations);
- Not available in a combination formulation with a decongestant (cetirizine and pseudoephedrine are available in a combination formulation [Zyrtec - D]).

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New Product* Review (cont.)

Comments:

Cetirizine is a racemic compound that is an active metabolite of hydroxyzine (e.g., Atarax, Vistaril). The antihistaminic activity of cetirizine is attributed to its R enantiomer (levocetirizine) whereas the S enantiomer has little or no antihistaminic activity. Because levocetirizine is already available as the pharmacologically active component of cetirizine, it is not a new *drug**; however, it is the first *product* to contain just the single active enantiomer.

The indications for levocetirizine are the same as those for cetirizine and include the relief of symptoms associated with seasonal allergic rhinitis (SAR, hay fever, outdoor allergies) and perennial allergic rhinitis (PAR, indoor allergies), and the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria (CIU, hives of unknown origin). The effectiveness and safety of levocetirizine have not been evaluated in children less than 6 years of age whereas cetirizine is indicated for the treatment of PAR and CIU in children as young as 6 months, and SAR in children as young as 2 years.

The effectiveness of levocetirizine has been demonstrated in placebo-controlled studies. It has not been directly compared with cetirizine in clinical studies, with the exception of one small study in patients with CIU, in which the clinical efficacy of the two products was reported to be comparable. Because levocetirizine is the active component of cetirizine, the new product would be expected to be similarly effective to, but not more effective than, cetirizine when they are used in the recommended dosages that represent the same amount of levocetirizine (i.e., a 10 mg dose of cetirizine represents 5 mg of levocetirizine).

Both levocetirizine and cetirizine are considered to be low-sedating antihistamines that are more likely to cause sedation than the nonsedating antihistamines (loratadine [e.g., Claritin], desloratadine [Clarinox], fexofenadine [e.g., Allegra]), but less likely to cause sedation than antihistamines such as diphenhydramine (e.g., Benadryl). Somnolence (6%) and fatigue (4%) are the adverse events most often associated with the use of levocetirizine.

Levocetirizine is primarily excreted in unchanged form by the kidneys and its contraindications and risks in patients with impaired renal function are more extensive than those included in the labeling for cetirizine. However, in patients with impaired hepatic function, a reduction in the dosage of cetirizine is recommended whereas this is not considered necessary with the use of levocetirizine.

The recommended dosage of levocetirizine in adults and children 12 years and over is 5 mg once a day in the evening and the usual dosage of cetirizine in the same patient groups is 10 mg once a day. In children 6 to 11 years of age, the recommended dosage of levocetirizine is 2.5 mg (one-half tablet) once a day in the evening and the recommended dosage of cetirizine is 5 mg or 10 mg once a day. The 2.5 mg dose of levocetirizine should not be exceeded because the systemic exposure with a 5 mg dose is approximately twice that of adults. Cetirizine is also indicated for use in children as young as 6 months (depending on the indication), is available in syrup and chewable tablet formulations, and in a combination formulation with pseudoephedrine.

The disadvantages of levocetirizine when compared with cetirizine (and the nonsedating antihistamines) significantly outweigh its limited advantage. There is no reason to use it as the first-choice treatment for allergic disorders.

Daniel A. Hussar

*Although new drugs are generally reviewed in this column, an exception is being made in reviewing levocetirizine so that pharmacists will be prepared to compare this product with cetirizine and other antihistamines. The patent for cetirizine will expire soon and it will be available in less expensive generic formulations, and is also expected to be switched to nonprescription status. It is anticipated that levocetirizine will be extensively promoted for prescription use when it becomes available during the 2007 fall allergy season.