The Pharmacist Activist

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"…Wise men from the east came to Jerusalem and asked,
'Where is the one who has been born king of the Jews? We saw his star in the east and have come to worship him.'" Matthew 2:1

WISE MEN STILL SEEK HIM

Editorial

Importing Drugs from Canada is a Flawed "Solution" for Failures in the U.S.

Prices in the United States for many medications, primarily generic products, are reasonable and even inexpensive considering their value in maintaining and improving health. HOWEVER, the prices for many other medications are excessive and unjustifiable. It is the pharmaceutical companies that establish the initial list prices for these drugs, but health insurance companies and pharmacy benefit managers also extract large profits from the continued worsening of the drug pricing debacle. It is ironic that these industries take turns blaming each other for the high costs of drugs while, at the same time, all of them are being further enriched by the secretive and cyclical process in which they continue to increase the prices of drugs. The victims of this "system" are patients who often can't afford the medications, our society that must assume the financial burden for excessive drug prices, and the pharmacies that are not adequately compensated for their important role in the distribution and appropriate use of medications.

The recognition of these problems is not new. Indeed, the outrage, rhetoric, and debate regarding drug prices have continued for decades, but what has been accomplished? In a word, "NOTHING!" The financial interests, bureaucracy, politics, and lobbying of those who might lose a fraction of their riches have prevented any progress in developing better drug pricing, distribution, and availability strategies.

Because of policies and controls on drug prices that have been established in Canada, many drugs are available at much lower prices there than in the U.S. Approximately 15 years ago, there was strong activity on the part of patients and others in the U.S. to obtain drugs at lower prices from pharmacies in Canada. Although some were

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successful in this effort, there were also negative ramifications and, for the most part, this strategy failed. One might think that relatively recent experience would still be fresh in our memories. However, once again, some state and national government officials are actively developing plans to facilitate importation of drugs from Canada because we have failed to establish equitable drug pricing strategies in this country. There is a saying that those who ignore history are destined to repeat it. Importation of drugs from Canada was a flawed and failed strategy 15 years ago, and it will fail again now.

The importation of drugs from Canada is not only an unworkable and ineffective strategy, but it is also extremely unfair to inflict certain of the consequences of the drug pricing and distribution failures in the U.S. on our neighboring country. The population of Canada is far smaller than that of the U.S. and the supplies of medications in that country are also correspondingly smaller. If large quantities of certain individual or classes of medications were imported by the U.S. from Canada, this could create havoc in the supply and availability of these medications in Canada. As just one of the many potentially negative consequences of significantly expanded importation of drugs, we are not close to addressing the problems of shortages of important medications in the U.S., and it is inappropriate to burden our neighbor with the risk of consequences resulting from failures in this country to establish an adequate and equitable drug pricing and distribution system. These challenges originated in the U.S., and it is up to the citizens and government of the U.S. to resolve them in this country.

There are concepts and strategies that can greatly improve the affordability of drugs and the quality and effectiveness of the drug distribution system in the U.S. Although they are beyond the scope of this commentary, such strategies are identified in previous editorials in The Pharmacist Activist. However, the courage, will, and determination to take action are essential!

Daniel A. Hussar
danandsue3@verizon.net

Appreciation

This issue marks the completion of the fourteenth year of publication of *The Pharmacist Activist*. The index for this Volume 14 (2019) is on page 4. All of the issues in Volumes 1 through 14 (2006-2019) 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 the 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 (Publications Director) and Pat Polli (Publisher), and my wife and Assistant Editor 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 publication, and represent a substantial part of the content of the issues during the past year.

Each day when I pray, I thank God for the many blessings I have experienced. My "debt" of appreciation to my family, friends, students, and colleagues is also more that I can ever repay, but one of my goals for the next year is to call one of these individuals each day to voice my appreciation for their friendship.

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

Daniel A. Hussar

New Drug Review

Lefamulin acetate
(Xenleta – Nabriva)

Antibacterial Agent

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
Administered intravenously or orally for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.

Comparable drug:
Moxifloxacin.

Advantages:
- Is the first pleuromutilin antibacterial agent to be approved for the treatment of a systemic infection;
- May be effective in some patients who have had an inadequate response to, or have experienced hypersensitivity or other risks with other antibacterial agents;
- Has not been associated with the occurrence of tendon problems, peripheral neuropathy, central nervous system effects, or exacerbation of myasthenia gravis (are the subjects of boxed warnings in the labeling for moxifloxacin).

Disadvantages:
- Is administered every 12 hours (whereas moxifloxacin is administered every 24 hours);
- Labeled indications are more limited (moxifloxacin is also indicated for the treatment of uncomplicated and complicated skin and skin structure infections, complicated intra-abdominal infections, acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and plague);
- Is more likely to cause gastrointestinal adverse events (e.g., diarrhea);
- Oral use is not recommended in patients with moderate or severe hepatic impairment, and dosage for intravenous use should be reduced in patients with severe hepatic impairment (whereas moxifloxacin use is not limited).

Most important risks/adverse events:
QT prolongation and increased risk of cardiac arrhythmias (use should be avoided in patients with known prolongation of the QT interval, ventricular arrhythmias, and in patients treated with other medications that may prolong the QT interval [e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, thioridazine, moxifloxacin]; concurrent use of tablets with sensitive CYP3A substrates known to prolong the QT interval [e.g., pimozide] is contraindicated; risk is increased in patients with hepatic impairment or patients in renal failure who require dialysis); Clostridium difficile-associated diarrhea; may cause adverse developmental effects if used during pregnancy (women of reproductive potential should be advised to use effective contraception during treatment and for 2 days after the final dose); lactating women should pump and discard milk for the duration of treatment and for 2 days after the final dose; effectiveness may be reduced by strong and moderate CYP3A and/or P-gp inducers (e.g., rifampin) and concurrent use should be avoided; action of lefamulin tablets may be increased by strong CYP3A and/or P-gp inhibitors (e.g., ketoconazole) and concomitant use should be avoided; oral use is not recommended in patients with moderate or severe hepatic impairment.

Most common adverse events:
Oral administration: Diarrhea (12%), nausea (5%), vomiting (3%); Intravenous administration: Administration site reactions (7%), hepatic enzyme elevations (3%), nausea (3%), hypokalemia (3%), insomnia (3%).

Usual dosage:
Oral: 600 mg every 12 hours for 5 days, administered at least 1 hour before a meal or 2 hours after a meal; Intravenous: 150 mg infused over 60 minutes every 12 hours for 5 to 7 days (may be switched to tablets during treatment); should be reduced to 150 mg every 24 hours in patients with severe hepatic impairment.

Product:
Tablets – 600 mg; single-dose vials – 150 mg in 15 mL (should be stored in a refrigerator); contents should be diluted in 250 mL of a citrate buffered solution that is supplied in infusion bags with product.

Comments:
Lefamulin is the first pleuromutilin antibacterial agent to be approved for treating a systemic infection. Retapamulin (Altabax) was the first pleuromutilin marketed for the topical treatment of impetigo. Lefamulin was evaluated in two clinical trials in which it was compared with moxifloxacin. In both studies, each agent was effective, as determined by early clinical response rates in approximately 90% of patients.

Daniel A. Hussar

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**All issues of The Pharmacist Activist are available without charge at www.pharmacistactivist.com*

Author/Editor – Daniel A. Hussar, Ph.D.
Dean Emeritus and Remington Professor Emeritus at Philadelphia College of Pharmacy, University of the Sciences
Assistant Editor – Suzanne F. Hussar, B.Sc. (Pharmacy)
Publisher - G. Patrick Polli II **Publications Director** - Jeff Zajac

The opinions and recommendations are those of the author and do not necessarily represent those of his former employer or the publisher.

The Pharmacist Activist, 620 Allendale Rd #60884, King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

NEWS-Line PUBLISHING