The Pharmacist Activist

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Editorial

Drug Shortages and High-Priced Generics — Pharmacy Should Establish Our Own Generics Pharmaceutical Company!

Prior to 2000, "drug shortages" seldom occurred. However, in recent years the number of drug shortages and the resultant concerns have sharply increased to the extent that the problem has been addressed by a Congressional committee, as well as President Obama in the form of an executive order. At various times there have been shortages of hundreds of medications, including drugs such as certain antibiotics, anticancer drugs, and general anesthetics for which the need is often urgent. Widely-used fluids such as Sodium Chloride Injection and Sterile Water for Injection have also been in short supply. Many of the medications for which there have been shortages are generic drugs that are administered by injection.

Drug shortages have resulted in the quality of care and safety of many patients being compromised. The American Society of Health-System Pharmacists, Institute for Safe Medication Practices, Food and Drug Administration, and other organizations have provided leadership in addressing these challenges and some progress has been made. However, serious problems continue to exist and receive prominent attention as reflected, in part, in the recent commentary, "The U.S. has a drug shortage – and people are dying," (*Fortune*, January 6, 2015, Mark Koba).

Many factors have been suggested as having contributed to the drug shortages experienced, including shortages of raw materials, manufacturing problems, supply and demand factors, business and economic issues, regulatory issues, and FDA enforcement actions. The solutions and strategies for preventing and resolving shortages is a much shorter list which some would suggest is limited to the requirement that manufacturers are now required to notify the FDA of potential shortages.

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High-priced generics

The word "generics" has been associated with an expectation of a low price for medications for which the patent has expired and they are now available from multiple companies in a competitive marketplace. Companies that have had billions of dollars of sales each year resulting from their exclusive marketing of drugs such as Lipitor and Prilosec recognize that, when the patents for such medications expire, equivalent generic products will become available at a much lower price and they will lose a large fraction of the revenue that the brand-name products had previously generated.

A high percentage of prescriptions and medication orders are for drugs that are available generically. The intensity of the competition in the generic marketplace and the relatively low profitability of many of the individual generic drugs have resulted in decisions and strategies designed to increase a company's financial success. Some of these decisions have resulted in companies discontinuing the marketing of certain medications that are no longer sufficiently profitable or part of the company's revised marketing focus. The reduced number of suppliers of certain medications is a contributing factor to the drug shortages that are experienced, as well as to the increased price that may result from less competition.

In some situations, only one company may supply a particular generic medication, even one that has been available for many decades. Without competition, some companies charge what the market will bear. As a consequence, the prices have skyrocketed for an increasing number of generic products that are inexpensive to produce.

Are there solutions?

The focus of this commentary is on the availability and price of generic drugs. A pharmaceutical company has the right to decide what medications it will market, assuming compliance with FDA and other pertinent regulations and standards. It is also the right of a company to establish the price it will charge for the drugs that it markets. However, these "rights" also lead to my opinion that it is unrealistic to expect that pharmaceutical companies, individually or collectively, will contribute to a resolution of drug shortages or resist the temptation to charge extraordinarily high prices for generic medications for which there is no or little competition. Accordingly, other alternatives must be identified.

The national pharmaceutical associations, representing pharmacists and organizations that dispense medications and serve the patients who are most disadvantaged by drug shortages and high-priced generics, can provide the leadership in addressing these challenges. Let's start with the American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), National Association of Chain Drug Stores (NACDS), and the National Community Pharmacists Association (NCPA). A group of pharmacists/leaders from these associations should meet with leaders of the generic pharmaceutical companies who are interested in discussing collaborative strategies that would effectively address the concerns identified.

Although I consider it important that a collaborative initiative first be explored, I do not anticipate that this will have a productive outcome. In some respects, related discussions have already been held in an effort to reduce drug shortages but these efforts can hardly be considered successful. In my opinion, the pharmaceutical companies involved will continue to be unwilling to relinquish any of their "rights" in determining the specific drugs they will market and the prices they charge, even if it is for the purpose of serving the "greater good" by meeting the needs of more patients. Therefore, another alternative must be considered.

American Generic Pharmaceuticals

I propose that the APhA, ASHP, NACDS, and NCPA establish a new pharmaceutical company that will manufacture and market generic products. We can identify a more creative name but, for now, let's call it American Generic Pharmaceuticals (AGP). The products to be initially developed would include those generic medications for which shortages have been problematic in recent years, as well as generic medications for which the marketplace has been exploited and the prices unreasonably high. The line of products can be subsequently expanded as additional opportunities are identified.

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New Drug Review

Olodaterol hydrochloride
(Striverdi Respimat – Boehringer Ingelheim)

Bronchodilator

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:
For oral inhalation for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Comparable drugs:
Other long-acting beta2-adrenergic agonists (LABA) for oral inhalation: salmeterol (Serevent), formoterol (Foradil), indacaterol (Arcapta), vilanterol (available only in combination with other agents).

Advantages:
- Is administered once a day (compared with salmeterol and formoterol that are administered twice a day; indacaterol and vilanterol are administered once a day);
- More convenient administration and lesser likelihood of problems associated with administration (compared with formoterol and indacaterol that are supplied in capsules that are placed in a device for oral inhalation).

Disadvantages:
- Has not been directly compared with other agents in clinical trials;
- Labeled indications are more limited (salmeterol and formoterol are also indicated for the prevention of exercise-induced bronchospasm, and in combination with other agents [e.g., an inhaled corticosteroid] for the treatment of patients with asthma that is not controlled with conventional therapy);
- Is not available in combination formulations (compared with salmeterol, formoterol, and vilanterol that are available in combination formulations with an inhaled corticosteroid [Advair, Symbicort, and Breo Ellipta, respectively]; vilanterol is also available in combination with umeclidinium [Anoro Ellipta]).

Most important risks/adverse events:
Increased risk of asthma-related death (boxed warning; is not indicated for asthma; contraindicated in patients with asthma without use of a long-term asthma control medication); should not be used for relief of acute symptoms; treatment should not be initiated in patients with acutely deteriorating COPD; paradoxical bronchospasm (treatment should be immediately discontinued); may increase pulse rate and blood pressure, prolong the QT interval, and cause hypokalemia (must be used with caution in patients with cardiovascular disorders); may increase the possibility of exacerbations of seizure disorders, thyrotoxicosis, and diabetes; should not be used concurrently with another long-acting beta2-agonist and must be used with caution in patients who are being treated with another adrenergic agonist; concurrent use with a beta-blocker (e.g., metoprolol) may reduce the effects of both drugs; hypokalemic effect may be increased by the use of xanthine derivatives, corticosteroids, and certain diuretics (e.g., thiazides, loop); concurrent use of an antiarrhythmic agent, tricyclic antidepressant, or monoamine oxidase inhibitor may increase the risk of arrhythmia.

Most common adverse events:
Nasopharyngitis (11%), upper respiratory tract infection (8%), bronchitis (5%), cough (4%).

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(Generics - continued from Page 2)

The primary goal of this initiative is to effectively serve the drug therapy needs of patients whose care is now compromised by drug shortages and/or reduced availability of generic medications at reasonable prices. The pharmacy associations that will have ownership of AGP will be providing a valuable service to patients and society by contributing to the quality and safety of their drug therapy in a much more cost-effective manner. They will also be advancing the role and services of the profession of pharmacy and individual pharmacists. This initiative also has the potential to be of humanitarian benefit in helping to meet the drug therapy needs of patient populations in the United States and other countries who currently do not have access to or can't afford medications.

This initiative will require substantial commitment and resources. However, AGP can be developed and managed in a way that will generate income and not operate at a loss. Whether AGP is established as a nonprofit or for-profit entity can await further discussion, but the potential exists for income for the associations that will contribute to the resources that can be used to expand services and programs for the benefit of their members.

I recognize that the scope and implications of what I am proposing are formidable, and that there are numerous financial, legal, professional, and other issues that must be addressed. Will our professional associations actively consider the establishment of AGP? If they choose not to, I am optimistic that there are entrepreneurs in our profession who would recognize and act on the opportunity.

Daniel A. Hussar

New Drug Review - *continued*

Usual dosage:

5 mcg (two actuations of the inhalation device) once a day at the same time of day via oral inhalation.

Product:

Aqueous solution in an aluminum cylinder for use with the Striverdi Respimat inhaler as an oral inhalation spray; each actuation from the mouthpiece contains 2.5 mcg of olodaterol; inhalation unit must be primed when used for the first time or if the unit is not used for more than 3 days.

Comments:

Olodaterol joins salmeterol, formoterol, indacaterol, and vilanterol in the class of long-acting, beta2-adrenergic receptor agonists (LABA) bronchodilators that are administered by oral inhalation. Arformoterol inhalation solution (Brovana) is also available for use by nebulization.

The effectiveness of olodaterol was demonstrated in studies that included more than 3,000 patients with a diagnosis of COPD, and in which patients treated with the new drug showed improved lung function (e.g., improvements in forced expiratory volume in one second [FEV_1]) compared to placebo. In addition to the improvement in FEV_1, patients treated with olodaterol used less rescue albuterol during the studies compared with the patients receiving placebo.

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