The Pharmacist Activist

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Editorial

What are they Doing to our Profession? — AND WHO CARES?

Hardly a week goes by when there is not a prominent story in the news about a large chain pharmacy, a mail order pharmacy, a pharmaceutical company, or an insurance company with a prescription plan being engaged in fraud, deceptive practices, misleading promotions, and/or settling litigation/allegations for tens or even hundreds of millions of dollars. The specific problems vary widely with examples including deceptive marketing of prescription benefit programs, promotion of drugs for "off-label" uses, and the sale of products after their expiration date. However, there is a consequence that is common to all of these events – they all reflect very negatively on the profession of pharmacy! And, in almost all of these situations, the individuals who made the decisions that have resulted in the negative/harmful experiences and news items are not pharmacists! Usually they are anonymous executives and managers in a corporate bureaucracy who could care less about the image and reputation of pharmacy, and even their own pharmacists, as long as profits are meeting or exceeding expectations. The focus of this editorial will be on issues involving large chain pharmacies.

CVS Caremark

"CVS Caremark – An Alliance that Must be Broken" is the title of my editorial in the May 2009 issue of *The Pharmacist Activist* (www.pharmacistactivist.com) that voiced my concerns about what I consider to be manipulative and deceptive practices in their prescription benefit programs. Many of the responses that I received were from pharmacists who work for CVS Caremark who agreed with my concerns and were either frustrated in their unsuccessful attempts to address these issues within the company or did not raise their concerns because of fear of retaliation. Several of the responses I received were from patients. I would not have expected patients to have seen my editorial in a publication intended for pharmacists and pharmacy students, but they discovered it while doing internet searches and felt compelled to share their experiences. The following example from these experiences demonstrates how the provision of medications to patients is compromised and depersonalized, as well as the arrogance of those administering the prescription plan:

A patient was obtaining Enbrel (which she described as "a miracle drug") for almost five years from her neighborhood pharmacy in which she had the utmost confidence and trust. However, her health insurance provider changed to CVS Caremark for mail order prescriptions and she was soon informed that she would have to obtain

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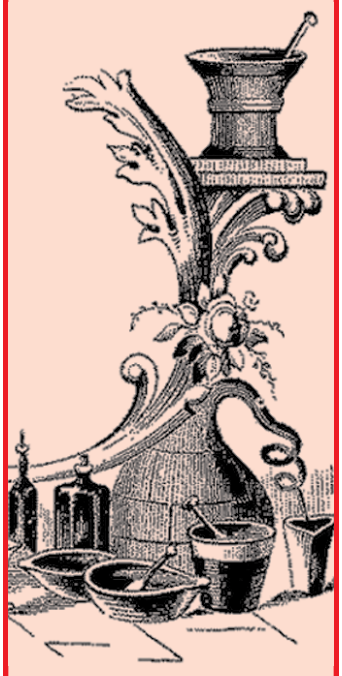

her Enbrel from its mail order pharmacy. Because of the expense of Enbrel, she was informed that it would only be dispensed in a 30-day supply instead of the usual 90-day supply from a mail order pharmacy for medications that are used for a chronic condition. Enbrel must be refrigerated which presented a particular challenge because the patient lives in a state in which the temperatures are often in the 90° – 100° range, she lived alone, and had a full-time job that precluded her from being home when the mail arrived so that she could promptly refrigerate the medication. She voiced her concerns to both CVS Caremark and her insurance company. There are no CVS pharmacies in her geographic region to which CVS Caremark might refer her (a concern in itself) and she was provided with the following options. She could have it delivered to a neighbor, or she could take a cooler to work and, because much of her work was conducted away from her office, she could instruct the person receiving the mail to place her package in a cooler. Both of these options are problematic but the third option was the height of arrogance. It was suggested that she could ask her local pharmacy (from which she could no longer obtain the prescription under the terms of her prescription plan) to accept the Enbrel shipment and keep it refrigerated until she could pick it up.

FTC investigation

In my May editorial I noted that the National Community Pharmacists Association (NCPA) had met with the Chairman of the Federal Trade Commission (FTC) and had urged that there be an investigation of anticompetitive practices and a reconsideration of the merger of CVS and Caremark. The documentation of problems experienced by numerous patients has been provided to the FTC, and CVS Caremark has recently acknowledged that the FTC is investigating some of its business practices. I fully expect that the FTC will confirm the existence of unacceptable problems that are already well known to patients and pharmacists. The FTC should withdraw its approval of the merger of CVS and Caremark and require that it be divided into two separate companies. It will not be enough for the FTC to require corrective actions and a financial settlement (that typically includes a statement that the company involved acknowledges no wrongdoing). Such settlements permit companies to continue to "push the limits" until they are investigated and caught again, and make a financial settlement in an amount that is less than what they received as a result of their inappropriate practices.

A recent situation underscores the need for the FTC to take the strongest actions possible. Earlier this month, New York's Attorney General announced that CVS Caremark will pay $875,000 to settle charges that it sold expired products (e.g., OTC drugs, baby formula, milk, eggs) in 142 CVS pharmacies (60% of those visited) in New York state. Some of the products were more than two years past their expiration date. One of the things that CVS will do as part of the settlement is to post notices in its stores to remind customers to check products' expiration dates (does this suggest that the CVS stores are understaffed to the point that its own employees can't prevent this situation?). A CVS spokesman noted, among other things, that the settlement was not an admission of wrongdoing. Is this a bad joke? If CVS can't admit it did something wrong when it sold products two years past their expiration date, it can never be expected to recognize and acknowledge that anything regarding its prescription programs could be wrong. It is also noteworthy that the most recent settlement between the New York Attorney General and CVS Caremark also resolves an earlier lawsuit accusing CVS, in part, of violating a previous settlement in which it agreed to take actions to end such sales.

Additional poor examples

Concerns that are similar to some of those noted above have also involved other large chain pharmacies, and other concerns have also been identified. Selected examples include the following:

- The New Jersey Attorney General's Office reached settlements with Rite Aid for $475,000 and Target Stores for $375,000 for selling products past their expiration dates. The New York Attorney General's Office reached a settlement with Rite Aid for $1.3 million for the same reason.

- For many years Walgreens sold alcoholic beverages in its pharmacies in states in which this was legally permitted. The signage on the outside of its stores identified "Liquor" as prominently as it did "Pharmacy." However, a point was reached at which Walgreens removed liquor from most of its stores, presumably because the sale of liquor was not consistent with the healthcare image it wanted to promote. Recently though, it has been learned that Walgreens intends to start selling beer and wine in a majority of its stores. There is no question as to what motivated this decision (more money) but does this decision also send a message that a healthcare image is now less important? The number of prescription and nonprescription medications with which the use of alcoholic beverages should be avoided is so large that, to my knowledge, nobody has endeavored to count them.

When I attended the NCPA meeting in New Orleans last month my route to the convention center took me

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New Drug Review

Dronedarone
(Multaq – Sanofi-Aventis)

Antiarrhythmic Agent

New Drug Comparison Rating (NDCR) = 4

(significant advantages) in a scale of 1 to 5, with 5 being the highest rating

Indication:
To reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age>70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter of 50 mm or greater, or left ventricular ejection fraction <40%), who are in sinus rhythm or who will be cardioverted.

Comparable drug:
Amiodarone (e.g., Cordarone).

Advantages:
- Has a labeled indication for use in patients with atrial fibrillation and atrial flutter (whereas the labeled indications for amiodarone are for the treatment of ventricular arrhythmias);
- Less likely to cause pulmonary, thyroid, hepatic, or ocular adverse events;
- Has not been reported to cause blue-gray discoloration of skin;
- Is not likely to interact with warfarin;
- May be used in patients who are hypersensitive to iodine (whereas amiodarone is contraindicated because iodine is a component of its structure);
- Dosage adjustment is not necessary.

Disadvantages:
- Is less effective (based on the results of a study that directly compared the two drugs);
- Is not indicated for the treatment of ventricular arrhythmias;
- Increased risk of mortality in patients with severe heart failure (use is contraindicated);
- Is in Pregnancy Category X and is contraindicated during pregnancy (whereas amiodarone is in Pregnancy Category D);
- Has more contraindications;
- Is administered more frequently (twice a day whereas amiodarone may often be administered once a day).

Most important risks/adverse events:
Increased risk of mortality in patients with severe heart failure (boxed warning) and use is contraindicated in patients with NYHA Class IV heart failure or NYHA Class II-III heart failure with a recent decompensation requiring hospitalization or a referral to a specialized heart failure clinic; contraindicated in patients with second- or third-degree atrioventricular block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker), and in patients with bradycardia <50 bpm; may prolong the QT interval (concurrent use of other agents that prolong the QT interval is contraindicated, as is use in patients with a QTcBazett interval of 500 ms or greater; potassium and magnesium concentrations should be maintained in the normal range); action is increased by the concomitant use of a strong CYP3A inhibitor (e.g., clarithromycin) and concurrent use is contraindicated; is contraindicated in patients with severe hepatic impairment; may cause fetal harm (Pregnancy Category X) and use is contraindicated during pregnancy (women of childbearing potential should use effective contraception) and in nursing mothers; may cause a small increase in serum creatinine concentrations; action may be increased by CYP3A inhibitors (e.g., use of grapefruit juice should be avoided), and decreased by CYP3A inducers (e.g., rifampin, St. John's wort; concurrent use should be avoided); may increase the action of CYP3A substrates (e.g., simvastatin) and CYP2D6 substrates (e.g., fluoxetine); concurrent use with digoxin may increase the action of both agents (if digoxin treatment is continued, the dosage should be reduced by one-half); when a beta-blocker (e.g., metoprolol) or calcium channel blocker (e.g., diltiazem, verapamil) is to be used in a patient treated with dronedarone, they should be used initially in a low dosage.

Most common adverse events:
Diarrhea (8%), asthenia (7%), nausea (5%), dermatologic effects (5%–e.g., rash, pruritus), abdominal pain (4%), bradycardia (3%).

Usual dosage:
400 mg twice a day with the morning and evening meals.

Product:
Film-coated tablets – 400 mg.

Comments:
Dronedarone is a benzofuran antiarrhythmic agent that has structural and pharmacological properties that are most similar to those of amiodarone. It exhibits electrophysiologic effects that include characteristics of all four Vaughan-Williams classes of antiarrhythmic agents. It is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation or atrial flutter (see indication above). The labeled indications for amiodarone are the treatment of recurrent ventricular fibrillation and recurrent hemodynamically unstable ventricular tachycardia, although it is often used "off-label" for the treatment of patients with atrial arrhythmias. The effectiveness of dronedarone was demonstrated in studies in which it reduced the combined endpoint of cardiovascular hospitalization or death from any cause by 24% when compared to placebo. The benefit of the drug was entirely attributable to its reduction of cardiovascular hospitalization. In one study that included patients with severe heart failure, the trial was terminated because of a higher mortality rate (8%) in patients treated with dronedarone compared with a rate of 4% in those receiving placebo. In a study in which it was directly compared with amiodarone, dronedarone was considered less effective in reducing recurrences of atrial fibrillation but was better tolerated, as reflected by fewer discontinuations of treatment because of the occurrence of adverse events.

Dronedarone is less likely than amiodarone to cause pulmonary, thyroid, hepatic, and ocular adverse events, and skin discoloration. However, it is more likely to cause serious complications in patients with severe heart failure and its use is, therefore, contraindicated in such patients. Both drugs interact with numerous other medications. Dronedarone undergoes extensive presystemic first-pass metabolism and its absolute bioavailability is 4% when it is administered apart from food. It should be administered twice a day with the morning and evening meals.

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past a CVS "pharmacy." However, the promotion and space devoted to the sale of alcoholic beverages were much more extensive and prominent than messages pertaining to healthcare or the pharmacy department that was located in the back of the facility. The facility would have been identified more accurately as a liquor store rather than a pharmacy.

- Many chain pharmacies have promoted free or discounted prescriptions for certain generic drugs and coupon programs designed to steal patients from other pharmacies. "Cheap drugs" is the message being sent and these chains insult their own and other pharmacists by ignoring the importance and value of the role, advice, and services of the pharmacist.

- I am aware of the specifics of a number of lawsuits that have been filed against chain pharmacies because of alleged negligence/errors. Of great concern to me is how certain chains and their lawyers will develop a defense that essentially sends a message that their pharmacists have no or extremely limited responsibility in raising a question with a prescriber or in taking other steps to assure the appropriateness of the prescribed drug therapy. These legal deliberations usually are viewed as highly confidential, and most pharmacists working with the chains who present such a defense have no idea how their own employer has insulted them and demeaned their role.

Who cares?

With the exception of the NCPA, there is little evidence that our national pharmacy associations are addressing these issues. Some will say that these issues/examples are not ones in which their members are involved. I would respond by saying that what happens in the community practice of pharmacy has an impact on all areas in which we practice the profession of pharmacy.

The pharmacists who should care the most about these issues are the ones who are employed by the chain pharmacies that are engaged in the activities of the type described. Although many chain pharmacists find fulfillment and enjoyment in their responsibilities, many others are disillusioned and frustrated. They should not take it any longer! They should be activists in pursuing progressive change within the organization. They should expose wrongdoing when they become aware of it. They should actively explore opportunities with another pharmacy or in another area of pharmacy practice.

And all of us should care about the question of whether pharmacists can continue to justify the status of healthcare professional in the light of how pharmacy is "practiced" in far too many places today. We must take back our profession from those who are exploiting us!

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