The Pharmacist Activist

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Editorial

Strike 3 – CVS Should be OUT!

There are thousands of dedicated pharmacists and student pharmacists who work for CVS Caremark. I wish I could focus on their commitment to serve their patients, their company, and the profession of pharmacy. However, their management has betrayed their own employees, their customers, and our profession in so many ways that have seriously damaged respect for and credibility of CVS that these issues must command the attention of this commentary.

Strike 1

The terms and restrictions of CVS Caremark's prescription benefit programs are a disservice to patients and local pharmacies, and inequitable for pharmacies other than CVS (please also see "CVS Caremark – An Alliance that Must be Broken" in the May 2009 issue of *The Pharmacist Activist*, and "What are they Doing to our Profession? – And Who Cares?" in the November 2009 issue). For more than a year this situation has been the subject of an ongoing investigation by the Federal Trade Commission that involves both competition and consumer protection issues. Investigations have also been initiated by several Senate committees and approximately 25 states.

Most recently, six pharmacies in Texas have filed a lawsuit against CVS Caremark for trade secret misappropriation and violations of the Racketeer Influenced and Corrupt Organizations (RICO) Act (www.aprx.org). It is an embarrassment to our profession that RICO and one of the largest pharmacies in the country must be identified in the same sentence.

Strike 2

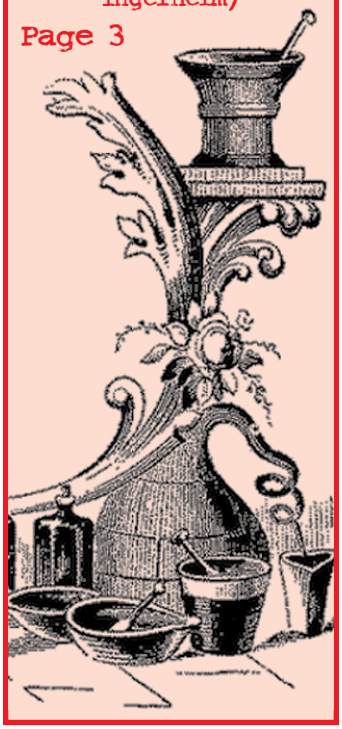
The May 28, 2010 issue of *The Wall Street Journal* included an article (page B4) titled, "CVS Cites Drug-Price Error." This story described how patients in one of CVS Caremark's prescription programs had been paying higher prices than they were promised when they signed up for the plans in late 2009. CVS Caremark attempted to explain this situation away by claiming it was a "computer error" (please also see "CVS Caremark's Participation in Medicare Prescription Programs Should be Terminated" in the June 2010 issue of *The Pharmacist Activist*).

Strike 3

The misuse of pseudoephedrine in preparing highly-addictive methamphetamine was the basis for the passage of the Combat Methamphetamine Epidemic Act of 2005. In addition to restricting the nonprescription sale of pseudoephedrine to pharmacies from behind the counter, this Act also established limits on the amounts of pseudoephedrine-containing products that could be purchased. On October 14, 2010, the U.S. Drug Enforcement Administration (DEA) issued a news release titled, "CVS to Pay Largest Ever Civil Penalty Under Controlled Substances Act." The following statements are among those included in this news release:

"In an agreement finalized late yesterday, CVS Pharmacy, Inc. the biggest operator of retail pharmacies in the United States, has admitted that it unlawfully sold pseudoephedrine to criminals who made methamphetamine. As part

Contents



of the agreement with federal prosecutors, CVS has agreed to pay $75 million in civil penalties and to forfeit the $2.6 million in profits the company earned as a result of the illegal conduct."

"CVS Pharmacy... failed to ensure compliance with laws limiting sales of pseudoephedrine, which allowed criminals to obtain a key ingredient used in the manufacture of methamphetamine from CVS stores... CVS supplied large amounts of pseudoephedrine to methamphetamine traffickers in Southern California, and the company's illegal sales led directly to an increase in methamphetamine production in California. CVS eventually changed its sales practices to prevent these illegal sales, but it did so only after it became aware of the government's investigation."

"The $75 million portion of the settlement represents the largest civil penalty ever paid under the Controlled Substances Act."

"CVS's flagrant violation of the law resulted in the company becoming a direct link in the methamphetamine supply chain."

"This case shows what happens when companies fail to follow their ethical and legal responsibilities. CVS knew it had a duty to prevent methamphetamine trafficking, but it failed to take steps to control the sale of a regulated drug used by methamphetamine cooks as an essential ingredient for their poisonous stew."

"The investigation into CVS uncovered thousands of violations of the Combat Methamphetamine Epidemic Act of 2005, which, among other things, limits the amount of pseudoephedrine that a customer can purchase in one day. In 2007, CVS implemented an automated electronic logbook system to record individual pseudoephedrine sales, but the system did not prevent multiple purchases by an individual customer on the same day. The government learned that violations occurred not only in California and Nevada, but likely also in 23 other states where CVS failed to implement appropriate safeguards. The settlement therefore addresses CVS's liability in a total of 25 states."

"As part of the agreement, the government has agreed not to pursue criminal charges against CVS, which has accepted responsibility for the illegal conduct and has agreed to implement a compliance and ethics program over the next three years. In addition, CVS has entered into a separate compliance agreement with the Drug Enforcement Administration that has a five-year term."

"...CVS, unlike other large chain retail pharmacies, allowed customers to make repeated purchases of pseudoephedrine that exceeded federal daily and monthly sales limits. ...For more than a year CVS failed to change its sales practices to prevent criminals from purchasing excessive amounts of pseudoephedrine in its stores."

"CVS has agreed to pay the $75 million civil penalty by tomorrow. The remaining $2.6 million in profits the company has agreed to forfeit to the government is due within 30 days."

Also on October 14, 2010, CVS Caremark issued a press release (www.cvscaremark.com) regarding this agreement that includes the following statements from its CEO:

"We are announcing today that we have resolved this issue, which unfortunately resulted from a breakdown in CVS/pharmacy's normally high management and oversight standards. While this lapse occurred in 2007 and 2008 and has been addressed, it was an unacceptable breach of the company's policies and was totally inconsistent with our values. CVS/pharmacy is unwavering in its support of the measures taken by the federal government and the states to prevent drug abuse."

"To make certain this kind of lapse never takes place again, we have strengthened our internal controls and compliance measures and made substantial investments to improve our handling and monitoring of PSE by implementing enhanced technology and making other improvements in our stores and distribution centers."

"CVS/pharmacy will continue to cooperate fully with the DEA and other law enforcement agencies in their efforts to keep PSE out of the wrong hands."

Some press reports have referred to the CVS response as an apology. However, words like "apology," "sorry," or "regret" are not included and I do not view the response as an apology. Rather, the primary concern of CVS is reflected in the subtitle of the press release that reads:

"Lapse in controls of PSE sales in certain CVS/pharmacy stores in 2007 and 2008 relates to electronic monitoring system flaw that has been corrected. Settlement amount fully reserved and previously disclosed; should have no further effect on company's financial results."

Several aspects of this situation warrant further questions. One part of the settlement is the forfeiture of $2.6 million in profits that CVS earned as a result of the illegal conduct. How many packages of pseudoephedrine-containing products were sold to make $2.6 million in profits? The number has to be HUGE. Why was there apparently no awareness and/or concern on the part of CVS managers, supervisors, and upper management about the extraordinary sales of these products, the purchases of which have been described by the DEA as "cleaning out store shelves?" Were bonuses based on sales provided to CVS employees in any of the CVS stores implicated in this debacle? Will the compliance and ethics program that CVS must implement over the next three years require the participation of its executives and upper management, as well as employees in the stores?

Why were no individuals at CVS held personally accountable by the DEA? Why were criminal charges not pursued? The charges by the DEA and the admission by CVS addressed in the settlement refer to the unlawful sale of pseudoephedrine. One

(Continued on Page 4)

New Drug Review

Dabigatran etexilate mesylate (Pradaxa – Boehringer Ingelheim)

Anticoagulant

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 stroke and systemic embolism in patients with non-valvular atrial fibrillation.

Comparable drug:

Warfarin (e.g., Coumadin).

Advantages:

- More effective in reducing stroke and systemic embolism;
- Has a different mechanism of action (thrombin inhibitor);
- Monitoring of blood tests is not necessary;
- Interacts with fewer medications;
- Not likely to interact with herbal products and dietary items (e.g., those containing vitamin K);
- Not likely to require dosage adjustment.

Disadvantages:

- Is administered twice a day (whereas warfarin is usually administered once a day);
- Shorter duration of action may be associated with an increased risk of problems when doses are missed or treatment is interrupted;
- Labeled indications are more limited (warfarin is also indicated for prophylaxis and/or treatment of thromboembolic complications associated with cardiac valve replacement, the reduction of the risk of death, recurrent myocardial infarction [MI], and thromboembolic events after an MI, and the prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism);
- Antidote is not available (whereas vitamin K is the antidote for an excessive response to warfarin).

Most important risks/adverse events:

Contraindicated in patients with active pathological bleeding; risk of bleeding (risk factors include the use of other medications that may be associated with bleeding events [e.g., heparin. antiplatelet agents]); missing doses or interruption of treatment may increase the risk of stroke; is a substrate for P-glycoprotein (P-gp) and action may be reduced by medications that are P-gp inducers (e.g., rifampin) – concurrent use should be avoided; dosage should be reduced in patients with severe renal impairment.

Most common adverse events:

Bleeding events, gastrointestinal adverse events (35%; include gastritis-like symptoms [e.g., gastroesophageal reflux disease, esophagitis, ulcer] and dyspepsia [e.g., abdominal pain]).

Usual dosage:

150 mg twice a day; in patients with severe renal impairment (creatinine clearance of 15-30 mL/minute), the recommended dosage is 75 mg twice a day; capsules should be swallowed whole as chewing, breaking, or emptying the contents of the capsule may result in increased exposure to the drug; if a dose is not taken at the scheduled time, the dose should be taken as soon as possible on the same day (the missed dose should be skipped if it cannot be taken at least six hours before the next scheduled dose; the dose should not be doubled to make up for a missed dose); the product labeling should be consulted for recommendations for converting from or to warfarin, or from or to a parenteral anticoagulant.

Products:

Capsules – 75 mg, 150 mg.

Comments:

Patients with atrial fibrillation are at greater risk of developing blood clots and at an estimated five-fold increased risk of experiencing a stroke. The vitamin K antagonist warfarin has been the standard treatment for preventing these problems but its use is associated with serious adverse events and drug interactions, and requires close monitoring. Dabigatran is a direct thrombin inhibitor and is the first of a group of investigational oral anticoagulants to be approved in the United States. It is absorbed as the dabigatran etexilate ester that is then hydrolyzed to dabigatran, the active moiety. Dabigatran is metabolized to four different acyl glucuronides that have pharmacological activity that is similar to that of the parent compound. Its effectiveness and safety were evaluated in a clinical trial that included more than 18,000 patients, in which patients received warfarin, dabigatran 150 mg twice a day, or dabigatran 110 mg twice a day. When used in the dosage of 150 mg twice a day, dabigatran reduced stroke and systemic embolism by 35% beyond the reduction attained with warfarin. The risk of major bleeding events was generally similar in the two groups. The 110 mg twice a day regimen of dabigatran was determined to be noninferior to warfarin, and less likely to

clear message of this settlement is that, if enough money can be paid, criminal charges will not be pursued. The amount of $75 million is stunning for most. However, the CVS response to this situation suggests that this amount hardly creates a ripple in its financial results. If the owner of one pharmacy admitted to such unlawful activity and wanted to reach a financial settlement, would the DEA not pursue criminal charges? If the DEA will not pursue criminal charges against CVS, particularly considering how much pseudoephedrine was sold, how can it pursue criminal charges against anyone engaged in such activity?

Out!

Within just one year, CVS has had three strikes, and some would say the actual number is much higher. Some of its actions, or lack thereof, have been disgraceful and an embarrassment to the profession of pharmacy. When the law was passed that resulted in pseudoephedrine being available without a prescription only from behind the pharmacy counter, our profession was provided a great opportunity to demonstrate that we could provide effective control of the distribution and use of a medication with a potential for misuse. Pharmacy has had the exclusive authority for recommending and providing the most effective oral nasal decongestant and for assuring its appropriate distribution. However, CVS has failed miserably in this responsibility and its failure also reflects very negatively on its employees and the entire profession.

Some have concluded that limiting the nonprescription availability of pseudoephedrine to behind the pharmacy counter is not effective. The state of Oregon requires a prescription for pseudoephedrine and a commentary in the November 15, 2010 issue of *The New York Times* ("How to Kill the Meth Monster") recommends that this be the policy in every state. I do not agree with this strategy, in large part because the greatest penalty/disadvantage will be for consumers who will no longer have convenient access to a medication that is both effective and safe when used properly.

The repeated misrepresentations and unlawful activities of CVS require more severe action. Instead of permitting CVS to buy its way out of criminal charges, such charges should have been pursued and CVS should have been put OUT of its pseudoephedrine business by banning the sale of these products in CVS stores (e.g., for at least two years). Because of its lack of compliance with multiple federal laws and policies, CVS should be put OUT of federal government-funded prescription benefit programs (e.g., for at least two years).

I began this editorial by recognizing the thousands of dedicated pharmacists and student pharmacists who work for CVS Caremark. Regrettably, the reputations of these individuals can also be tainted by their association with a company whose misrepresentations and unlawful actions have been widely publicized. Even in a tight job market, it may be time for some to consider another opportunity with an employer that complies with laws, and values and promotes its privilege of being associated with the profession of pharmacy. For some, opening your own pharmacy or buying an existing pharmacy will provide that opportunity. Instead of striking out on the CVS team, you can hit a home run for yourself and for our profession.

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New Drug Review (cont.)

cause bleeding events. However, this regimen is not identified in the dosage recommendations in the labeling and the available capsule potencies do not facilitate the use of doses of 110 mg. The concern underlying the FDA decision to not approve, at least initially, a product containing 110 mg is that some prescribers may be overly cautious and not prescribe the 150 mg twice a day regimen that provides the greatest benefit in reducing the risk of stroke.

The risk of major bleeding events was generally similar with dabigatran (150 mg twice a day) and warfarin, with the exception of patients aged 75 years and older in whom there was a higher incidence of bleeding with dabigatran. There was also a higher rate of major GI bleeding events in patients treated with dabigatran.

In contrast to the recommendations with the use of warfarin, treatment with dabigatran does not require monitoring of blood tests and resultant dosage adjustments.

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