The Pharmacist Activist

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Editorial

Is Patient Safety at Risk at CVS?

There is a Whistleblower!

CVS EMPLOYS MANY EXCELLENT PHARMACISTS who are committed to provide high-quality services for their patients, and who are dedicated to represent their employer in as professional a manner as possible. Unfortunately, their efforts are often undermined by the policies and actions of executives and other managers of their company who have a singular focus – *MONEY!* It is not sufficient to just be profitable – the goal appears to be as profitable as possible. This obsession places customers at greater risk of harm and death, creates a stressful workplace environment, and seriously compromises the opportunity for pharmacists and other employees to derive professional fulfillment from their responsibilities.

CVS has acquired so much money, power, and influence that their management must feel that they are immune to any challenge or concern. There seems to always be an amount of money that can be paid by the company to escape with a settlement in which it does not have to acknowledge any wrongdoing.

Just within the last two years, there have been numerous situations in which CVS and, as a consequence our profession of pharmacy, have received very negative national publicity. On October 14, 2010, the Drug Enforcement Administration (DEA) issued a news release regarding CVS' agreement to pay $75 million in civil penalties because of its illegal conduct in selling pseudoephedrine to criminals who made methamphetamine (for a more detailed discussion, please see my editorial, "Strike 3 – CVS Should be OUT!" in the November 2010 issue of *The Pharmacist Activist* at www.pharmacistactivist.com).

In February of 2012 the DEA moved to suspend two CVS pharmacies in Florida from selling controlled substances, noting that the two pharmacies purchased approximately 3 million oxycodone tablets in a year (compared with approximately 69,000 tablets a year in an average pharmacy). The DEA further noted that the pharmacies are an "imminent danger" to the public (for a more detailed discussion, please see my editorial, "CVS – Criminal Charges

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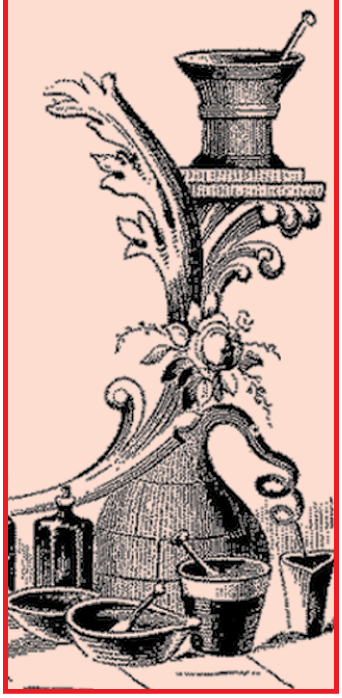

are Needed!" in the February 2012 issue at www.pharmacistactivist.com).

Some individuals *die* as a consequence of abuse of methamphetamine and oxycodone. Although the consequences for the purchasers of these agents in the CVS pharmacies implicated in the above situations are not known, the possibility that some of these individuals died can't be ruled out. I am personally aware of the death of an individual as a consequence of use of huge quantities of a narcotic analgesic that were obtained from a CVS pharmacy. The family of the individual is suing CVS and my prediction is that the lawsuit will be settled out of court for a very large amount of money with the terms of the settlement declared to be confidential. The situation will just "disappear" with the likelihood that neither the State Board of Pharmacy nor the DEA will learn of the circumstances of the death.

The drug mix-up

In March of 2012 it became known that a CVS pharmacy in New Jersey had mistakenly dispensed tamoxifen instead of chewable fluoride tablets to children in as many as 50 families over a period of several months. I was one of the individuals interviewed by an Associated Press reporter regarding the extent of the risk for the children who had received the wrong medication. I responded that the risk of harm from limited exposure to tamoxifen was very small as this is a hormonal anticancer drug and not one that destroys cells. I did not feel that the mistake should be the basis for undue alarm although I encouraged the reporter to request information as to how the mistake occurred so that the information could be used to help prevent future errors. The reporter also interviewed a CVS spokesman who said that the company is "actively investigating this matter to determine how the mistake occurred in order to take corrective actions to prevent this from happening again."

Several days after my discussion with the reporter I called the office of the CVS spokesman. I was told that he was not available at that time and I explained that I had been interviewed and quoted in the same story as the CVS spokesman had been. I noted that I felt I had been helpful to CVS by making comments intended to allay concerns and avoid alarm about the error. I further noted that I anticipated being interviewed further about the error and I wanted to learn more about CVS' investigation as to how it occurred. I emphasized that I considered it important that I speak personally with the CVS spokesman and I was assured that he would be given my message and contact information. I have not received the courtesy of a response and the strategy becomes clear. CVS wants this story to go away! They do not want to disclose any more information than they might be obligated to provide to a regulatory agency or office that is investigating the situation.

However, this story is *not* going to go away! It is my understanding that CVS personnel reviewed procedures and actions in a number of its pharmacies with respect to the factors that might have been responsible for the drug mix-up. I do not expect the results of this review/investigation to be made available; however, unexpectedly, I learned of another drug mix-up that was identified in this investigation. What did CVS management learn from the earlier tamoxifen/fluoride tablets mix-up and what "corrective actions" have been taken? It is my understanding that, in the second mix-up, none of the patients have been notified and the pharmacists have been sworn to secrecy about the error. Is the outcome of the earlier error an action that CVS should do more to "cover-up" subsequent errors? This situation is *shocking* and must not be tolerated! State Boards of Pharmacy and other pertinent regulatory agencies should conduct investigations of CVS with respect to errors, patient complaints, lawsuits filed against it, and adequacy of staffing.

Concerns of CVS pharmacists

To their credit, an increasing number of CVS pharmacists are voicing concerns to their management about inadequate staffing of pharmacists and technicians, scheduling problems, and policies that require a prescription to be dispensed in a certain number of minutes and telephone calls to be answered in a certain number of seconds (as one pharmacist questions, "When did pharmacy become a race?"). These policies and pressures converge in a manner that jeopardizes the safety of patients, and this has become a great concern for pharmacists who recognize the

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New Drug Review

Aflibercept
(Eylea – Regeneron)
Agent for Macular Degeneration

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

Indication:
Administered by ophthalmic intravitreal injection for the treatment of patients with neovascular (wet) age-related macular degeneration.

Comparable drug:
Ranibizumab (Lucentis).

Advantages:
- Administered less frequently (every 8 weeks for maintenance use compared with every 4 weeks that is recommended with ranibizumab);
- Has a unique mechanism of action (acts as a decoy receptor that binds vascular endothelial growth factor-A and placental growth factor).

Disadvantages:
- Labeled indications are more limited (ranibizumab also has a labeled indication for macular edema following retinal vein occlusion).

Most important risks/adverse events:
Contraindicated in patients with ocular or periocular infection, or active intraocular inflammation; endophthalmitis; retinal detachment; increased intraocular pressure.

Most common adverse events:
Conjunctival hemorrhage (25%), eye pain (9%), cataract (7%), vitreous detachment (6%), vitreous floaters (6%), increased intraocular pressure (5%).

Usual dosage:
2 mg (0.05 mL) by intravitreal injection every 4 weeks (monthly) for the first 3 months, followed by 2 mg once every 8 weeks (2 months).

Product:
Single-use vials – 2 mg in 0.05 mL (should be stored in a refrigerator).

Comments:
Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can activate certain receptors with resultant neovascularization and vascular permeability. Aflibercept is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. It acts as a decoy receptor that binds VEGF-A and PlGF, thereby inhibiting the binding and activation of these receptors.

The effectiveness of aflibercept was demonstrated in two studies in which it was compared with ranibizumab. The primary efficacy endpoint was the proportion of patients who maintained vision at week 52 compared to baseline. Approximately 95% of patients maintained visual acuity and the patients in the groups treated with aflibercept 2 mg every 4 weeks and 2 mg every 8 weeks experienced efficacy that was clinically equivalent to the patients treated with ranibizumab 0.5 mg every 4 weeks. Additional efficacy was not demonstrated when aflibercept was administered every 4 weeks compared with every 8 weeks.

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safety of their patients to be their highest priority. One pharmacist notes:

> "All corporate calls reference is capturing new business, increasing the volume, developing new business opportunities. The only thing I have never heard mentioned is patient care. I will have to say that they are genius to obtain pharmacists who do give that extra care because of their own personal ethics, but they then exploit that service for their own gain…..They administer through fear."

As more CVS pharmacists are voicing their concerns about dispensing errors and patient safety, there is increasing awareness of the indifference of management to their concerns. The word "indifference" is actually an understatement as some CVS pharmacists characterize management's response to their concerns about patient safety as their HIT strategy – Harassment, Intimidation, and Termination.

The whistleblower

Joe Zorek is a highly experienced pharmacist whose responsibilities have included service as the pharmacist-manager at one of the busiest CVS pharmacies in the Harrisburg, Pennsylvania area. About a year ago, a management order to reduce staff hours triggered a sequence of events that resulted in complaints from patients about waiting in lines, critical comments from supervisors because of the complaints from patients, a high level of stress for the staff, and mistakes on prescriptions. Joe voiced repeated concerns about patient safety that were ignored. His manager tried to demote him but he refused.

The increased stress and complications of his multiple sclerosis have resulted in his taking medical leave. Because he believes that CVS has attempted to take actions against him because of the concerns he has raised about patient safety, he has filed a whistleblower lawsuit.

CVS has denied wrongdoing and its spokesman issued a statement that included the observation that the chain's "number one priority" is the health and safety of its customers. Based on my awareness of errors that have occurred at CVS and how they have been handled, I consider the statement of the CVS spokesman to be a blatant *lie*.

Joe Zorek has demonstrated the courage of his convictions and has taken a stand in support of the safety of his patients. He considers this to be so important that he has placed his own health and job at risk. It is very unfortunate that such an adversarial relationship would develop between a pharmacist and his employer. But there can be no better reason for a pharmacist to take a strong stand than to protect the safety of his patients, and Joe is to be commended for taking this action. Even when CVS loses or settles this lawsuit, there is little reason to be optimistic that its policies and actions will change. However, the courageous action taken by one pharmacist may provide the impetus for others who have the same concerns to do likewise. State boards of pharmacy and our professional associations must also develop programs through which pharmacists who are willing to be strong advocates for the safety of patients can be protected from retaliation by their employers.

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