The Pharmacist Activist

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Editorial

CVS has an Exceptional Opportunity but Rejects It –

To the Peril of its Customers and Frustration and Risk of its Pharmacists!

There is probably no other organization in American pharmacy that can match CVS with respect to the opportunity for having a strongly positive impact on the practice of pharmacy. It has approximately 10,000 pharmacies and extensive financial resources. It has thousands of highly capable pharmacists. Its leadership deserves credit for certain of the decisions that have been responsible for its growth and financial success. It has received accolades for its excellent decision to discontinue the sale of tobacco products.

But then I am pulled back to reality by headlines such as the following that appeared in the June 30th issue of *The Boston Globe* (Vivian Wang):

> "CVS pays $3.5m to settle claims it filled fake painkiller prescriptions"

The story reports on allegations by DEA investigators that pharmacists in 50 CVS stores in Massachusetts and New Hampshire dispensed forged prescriptions more than 500 times. CVS responded by agreeing to settle the claims for $3.5m and to improve training of employees to recognize forged prescriptions. It said that it settled the allegations to avoid the cost and inconvenience of further legal proceedings. Apparently $3.5m buys the conclusion of the investigation, but many questions remain such as the following:

Are the pharmacists about whom the allegations were made still employed at CVS? If so, did they receive any disciplinary action? Have any of the alleged actions been reported to the State Board of Pharmacy? If so, did the Board take disciplinary action? If it was an owner of an independent pharmacy against whom such allegations were made, it could be anticipated that her/his pharmacist license might be suspended and that the subsequent ramifications might necessitate sale or closure of the pharmacy. There is a gross inequity with respect to the consequences that an owner of an independent pharmacy might experience when compared with those of a chain pharmacist and her/his company. This inequity can be defined by the number of dollars it takes to settle the allegations.

I wish to be clear that I deplore every situation in which a pharmacist betrays the public and our profession by dispensing prescriptions that he/she knows or strongly suspects are forged. However, to what extent does a company's policies, culture, and work environment contribute to situations in which pharmacists make bad decisions? Related questions include: When a prescription is received, is there a specific period of time in which a pharmacist

is expected to complete and dispense it? What are CVS's expectations (quotas) regarding the number of prescriptions that must be dispensed before additional staffing (pharmacists and/or technicians) is provided? Is the number of prescriptions dispensed a factor in the determination of bonuses for pharmacists? What are CVS's policies and procedures with respect to how its pharmacists should respond when they suspect a prescription is forged? For example, should the prescriber identified on the prescription be contacted to confirm that it is valid? Should the police be contacted when it is known that a prescription is forged? When a pharmacist declines to dispense a prescription, do the policies and procedures keep the potential for retaliation at the lowest level possible? There is no reason to think that these questions were even considered by the DEA and/or other investigators. Reaching the settlement was apparently based only on dollars.

I raise these questions because I consider them very important, and not to make excuses for bad decisions of pharmacists. Pharmacists must give the highest priority to their responsibilities to their patients and to the laws and ethics of our profession, and must not use company policies and/or pressure as an excuse for compromise or inappropriate actions. It is noteworthy that a CVS pharmacist with a physician who is CVS's medical director have published an article in the *New England Journal of Medicine* (August 21, 2013) titled, "Abusive Prescribing of Controlled Substances – A Pharmacy Review." However, to my knowledge, CVS has been silent about the problems that have been identified in its own pharmacies. A title for such an article might be, "Abusive Dispensing of Controlled Substances – The CVS Experience."

Very regrettably, the situation identified above and as described in The Boston Globe is not an isolated experience. There are frequent reports in the news regarding errors, as well as problems pertaining to controlled substances involving CVS stores. These situations are almost always settled and I have heard the CVS standard response so often that I can anticipate it before they say it – *We acknowledge no wrongdoing. We are settling the matter to avoid the cost and inconvenience of further legal proceedings. The safety of our customers is our highest priority.* In the situations in which I am aware of some of the specifics, the truth is that there was wrongdoing, and customer safety did not have priority.

In addition to the many allegations of the DEA and other regulatory agencies, numerous lawsuits are filed against CVS, as well as other large chain and mail-order pharmacies, because patients have been harmed or died as a consequence of alleged dispensing errors, preventable adverse events and drug interactions, negligence, or other mistakes. I am sometimes contacted by attorneys involved in such litigation who request that I serve as a consultant and/or expert witness. Although the total number of lawsuits about which I have been consulted is relatively small, a number of them have involved CVS. In some of these situations, it has been my opinion that there is not sufficient basis for a lawsuit and I decline to participate further. In some other situations, I have worked with the attorneys who are defending CVS and its pharmacists. In a few situations in which patients have died or experienced severe harm, I have worked with the attorneys for the plaintiffs or their families who are suing CVS. I much prefer to not participate as an expert for plaintiffs in actions against pharmacists/pharmacies. However, when 1) it is absolutely clear to me that an error has been made and/or there has been serious negligence, and 2) the defendant pharmacy denies any wrongdoing or claims that its pharmacists have no responsibility to do anything other than dispense a prescription exactly as the prescriber has written it, I have agreed to work with the plaintiff's attorneys. The cases in which I have participated as a plaintiff's expert against CVS have involved deaths or serious/disabling, irreversible adverse events. In most lawsuits filed against pharmacies, very few people ever hear about tragedies that have occurred because these cases rarely go to trial where the news media would become aware of and publicize the circumstances. Rather, these lawsuits are almost always settled out of court and the terms of the settlement are classified as confidential.

As just one of the individuals who is contacted, I am aware of the specifics of a relatively small number of the lawsuits against CVS. However, it is my understanding that, at any given time, there is a very large number of active lawsuits against CVS. That this observation is accurate is essentially confirmed by CVS's refusal to identify the number and type of lawsuits it is defending. This information will remain secretive until some attorney identifies a strategy to obtain it, a whistleblower provides it, or a court or state board of pharmacy is sufficiently concerned to force CVS to reveal it.

What should CVS do?

I have the following recommendations for CVS:

1. **Get rid of Caremark!** In my opinion, it is a blatant conflict of interest for a corporation to own a pharmacy benefit manager/administrator (PBM) and a large chain of pharmacies, and the Federal Trade Commission should never have approved the acquisition of Caremark by CVS. Caremark's inequitable and anticompetitive terms, policies, procedures, and audits are strongly and almost universally criticized by pharmacies other than CVS pharmacies. Concerns about direct and indirect remuneration (DIR) fees imposed by PBMs on pharmacies are the subject of a recent communication from the National Community Pharmacists Association (NCPA). For some pharmacies these fees can total thousands of dollars each month, and pharmacists responding to a survey identify CVS Caremark and Aetna as being the most egregious in this area.

   For Caremark to be able to provide incentives to use its mail-order pharmacy to patients enrolled in the prescription plans it administers is anticompetitive. It is ironic that, in

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New Drug Review

Brivaracetam (Briviact – UCB)

Antiepileptic Drug

New Drug Comparison Rating (NDCR) = 2

(significant disadvantages)

in a scale of 1 to 5 with 5 being the highest rating

Indication:

Administered orally or intravenously as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

Comparable drug:

Levetiracetam (e.g., Keppra, Keppra XR).

Advantages:

- Reduced seizure frequency in some patients in whom previous treatment did not provide adequate control.

Disadvantages:

- Has not been directly compared with other antiepileptic drugs in clinical studies;
- Labeled indications are more limited (levetiracetam is also indicated for adjunctive treatment of patients with myoclonic seizures, and primary generalized tonic-clonic seizures);
- Has not been evaluated in patients younger than 16 years of age (whereas levetiracetam is indicated for younger patients, the age of which is based on the indication [one month of age or older for patients with partial-onset seizures]);
- Is administered twice a day (whereas the extended-release formulation of levetiracetam is administered once a day for patients with partial-onset seizures);
- Is included in Schedule V (whereas levetiracetam is not a controlled substance).

Most important risks/adverse events:

Hypersensitivity reactions (bronchospasm, angioedema; treatment should be discontinued if such events occur, and use is contraindicated in patients known to be hypersensitive to the drug); suicidal behavior and ideation; psychiatric adverse events (e.g., psychotic symptoms, irritability, depression); neurological adverse events (somnolence, fatigue; patients should be cautioned not to drive or operate machinery until they have gained sufficient experience with the medication); included in Schedule V under the provisions of the Controlled Substances Act; should only be used during pregnancy if the anticipated benefit justifies the risk to the unborn child; is metabolized, in part, via the CYP2C19 metabolic pathway, and action may be increased in patients who are poor CYP2C19 metabolizers, or who are taking a CYP2C19 inhibitor concurrently; action may be reduced by the concurrent use of rifampin; caution must be exercised when used concurrently with carbamazepine and/or phenytoin.

Most common adverse events:

Somnolence/sedation (16%), dizziness (12%), fatigue (9%), nausea/vomiting (5%).

Usual dosage:

Starting dosage – 50 mg twice a day; based on individual patient therapeutic response and tolerability, dosage may be reduced to 25 mg twice a day, or increased to 100 mg twice a day; in patients with any stage of hepatic impairment, the recommended starting dosage is 25 mg twice a day and the recommended maximum dosage is 75 mg twice a day; when rifampin is used concurrently, the dosage of brivaracetam should be increased to up to double the usual dosage; when oral administration is not feasible, may be administered intravenously over 2 to 15 minutes at the same dosage and same frequency as with oral administration (the experience with the intravenous use of the drug is limited to 4 consecutive days of treatment); when treatment is to be discontinued, the drug should be withdrawn gradually.

Products:

Tablets – 10 mg, 25 mg, 50 mg, 75 mg, 100 mg; oral solution – 10 mg/mL (may also be administered using a nasogastric tube or gastrostomy tube); single-dose vials – 50 mg/5 mL.

Comments:

Brivaracetam is an analog of levetiracetam and their effectiveness in the treatment of seizure disorders is thought to be due to their affinity for synaptic vesicle protein 2A in the brain. The effectiveness of brivaracetam in reducing the frequency of seizures was demonstrated in three placebo-controlled studies in patients who were also taking other antiepileptic drugs concomitantly. Levetiracetam was a concomitant medication in approximately 20% of the patients in two of the studies, and brivaracetam provided no added benefit in these patients. Brivaracetam and levetiracetam have not been directly compared in clinical studies.

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2004, the CEO of CVS at that time stated, "We are opposed to forcing patients to use a mail order service and then dictating which mail order pharmacy to use."

2. **Walk your talk and actually give a high priority to patient safety!** CVS's hypocrisy with respect to its stated concern for patient safety is not acceptable. It is my understanding that the number of errors of commission and omission that occur in CVS pharmacies is astounding. Most of these errors are never known to anyone outside of CVS. However, as noted earlier, some have resulted in deaths and serious, irreversible harm.

3. **Value your pharmacists!** CVS is fortunate in that it employs thousands of highly capable pharmacists. However, a large number of these pharmacists feel they are important to management only because of the license they hold and not because they are skilled professionals who could provide comprehensive services for patients and make recommendations that would improve employee morale and contribute to the success of the company.

   Many CVS pharmacists have strong concerns about their work schedules and what are often very long days in an understaffed and stressful environment in which they are expected to simultaneously manage lines of patients with prescriptions, telephone calls, the drive-through window, and requests for immunizations. The result is that pharmacists become disillusioned, demoralized, resentful, and burned out. They feel trapped by company policies and metrics. This situation is a recipe for errors, and errors occur. There are statistics but they are known only to CVS, and CVS will not reveal them. However, statistics and evidence of errors are not needed because sound judgment dictates that there is an increased risk of error in an understaffed and stressful workplace in which pharmacists have so little time to commit to each prescription and to speak with patients.

   As noted earlier, when serious errors occur CVS will have enough money (sometimes in the millions) to reach a settlement. However, the pharmacist involved in the error can be at risk of having her/his license suspended or revoked.

   How should CVS pharmacists respond? Many leave and find another position but this is increasingly difficult to do at a time in which the supply of pharmacists exceeds the number of positions available in many parts of the country. If employment conditions do not significantly improve, I anticipate that CVS pharmacists will form a national union or related organization that will include both the pharmacist store managers and staff pharmacists.

4. **A pharmacist should personally speak with every patient with a prescription!** The "sign here" charade must be abandoned.

5. **Other pharmacies/pharmacists should be viewed as colleagues with mutual interests rather than competitors!** CVS is intensively competitive, as are other large chains such as Walgreens and Rite Aid. In communities where these chains coexist, they are in very close proximity to each other, often just across the street or within the same block. I am aware of a situation in a mid-size community in Pennsylvania in which a CVS and Walgreens were essentially right next to each other and both were open 24 hours a day. However, no other CVS, Walgreens, or other pharmacy for miles around is open 24 hours a day. CVS and Walgreens give higher priority to competing with each other rather than serving the needs and interests of the community. In my community, CVS opened a pharmacy directly across the street from an independent pharmacy that had been in that location for decades.

Five recommendations are enough for now. I expect that the upper management of CVS will not agree with many or all of my observations. If that is the response, I offer to conduct a survey in which CVS pharmacists can respond anonymously to determine the extent to which they consider my comments to be valid.

CVS has an exceptional opportunity! At the present time it is not respected by many within the profession and by many even within its own company. However, it could regain the respect and positive reputation it enjoyed when the company started. At that time it promoted the professional role of the pharmacist and provided their pharmacists with the time to speak with patients and provide comprehensive professional services.

I am available to help as an unpaid consultant.

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