The Pharmacist Activist

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The way of the guilty is devious but the conduct of the innocent is upright. Proverbs 21:8

Editorial

CVS Places Consumers at Risk of Harm, And is Destroying the Profession of Pharmacy! Part 2

Most of the responses I received to Part 1 of the series of editorials (February issue of *The Pharmacist Activist*) on this topic are from two groups of individuals. Current and former CVS pharmacists and technicians voice appreciation for the extended awareness and concern about the working conditions imposed by their management that increase the risk of errors. They also express their gratitude to Ellen Gabler, the New York Times (NYT) investigative reporter, for recognizing and exposing the stressful work environment they experience and the resultant risks for consumers. I also hear from many pharmacists at Rite Aid, Walgreens, and Walmart with the request, "Don't forget us – our working conditions are as bad as those at CVS." I recognize that and many of the comments that I make about CVS in these editorials apply equally to those chain stores. However, CVS, with its huge network of stores combined with its Caremark and Aetna components, is responsible for the greatest risk for harm for consumers and is the most potent destructive force in pharmacy.

Updates

Much has happened in the short period of time since I published Part 1 of this series. Ellen Gabler has published a follow-up report, "Walgreens Had Consultants Cut Staff Complaints About Errors," in a page 1 (A1) story in the February 22, 2020 print edition of the NYT. This story also addresses additional concerns involving CVS stores, as well as responses from CVS to the first story in the NYT. Hundreds, if not thousands, of comments have been posted on certain social media sites. And then, there is the editorial commentary in *Chain Drug Review*, "Retail pharmacies will overcome biased story." Although this latter commentary is supportive of the role of and trust in pharmacists, it includes the following comments that must be challenged:

Chain Drug Review (CDR): "As *The New York Times* has been doing of late with astonishing regularity and surprising frequency, the newspaper of record has at last gotten round to demolishing the retail pharmacy business."

The Pharmacist Activist (TPA): The NYT article pertains to concerns and errors in *chain* pharmacies, and does not focus on the entire "retail pharmacy business." The NYT article addresses errors in the context of "chaos" and working conditions in chain pharmacies. It provides readers with information that is important for them to know for their own protection. It is not an attempt to "demolish" chain pharmacies. To the contrary, any "demolishing" is self-inflicted by the chains. If they did that just to themselves, it would be for the betterment and safety of the public. However, unfortunately, the policies and actions of the chains are destructive for the entire profession of pharmacy, as well as for consumers.

CDR: "They (pharmacists) are, at times, overworked and overlooked, unreasonably and unfairly called upon to multitask."

TPA: "At times?" "Frequently" would be more accurate and some chain pharmacists would respond "all of the time."

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CDR: "When they (pharmacists) complain, as they frequently did in this article (NYT), it is often anonymously, at a time when using their name and identifying the retailer for whom they work might have helped curtail or control the mistakes that do occur."

TPA: Chain pharmacists who use their names and identify their employers will be terminated, but for an alleged violation of some company policy in an attempt to prevent the termination from appearing retaliatory. Even pharmacists who are no longer employed in a chain pharmacy are fearful of criticizing their former employers because of concerns they will find some way to retaliate.

CDR: "Typical of the *Times*, as it is much of print journalism, this article is long on criticism but woefully short on suggestions for appropriate action. The story leaves the cures for this unacceptable malady to the retailers…"

TPA: I fully agree that the current situation is "unacceptable." However, it is not the responsibility of the *Times* to provide suggestions for appropriate action. Chain pharmacies have created the terrible working conditions that increase the risk of errors and harm, and it is chain pharmacies that should take the appropriate actions. However, it is clear that they don't and won't, and they have no basis for the complaint that the *Times* is exposing the errors and other problems the chains want to cover up. It is also noteworthy that the CDR does the same thing for which it is criticizing the *Times* by not providing suggestions for appropriate action. However, *The Pharmacist Activist does* have recommendations for appropriate action which are provided later in this editorial.

CDR: "And if one patient passes on by swallowing a drug not prescribed or dispensed to treat the malady the proper drug is generally used to treat, that's reprehensible."

TPA: I fully agree, and "passes on" sounds so much better than "died" or "killed." The terminology is also a factor in identifying the frequency with which errors occur in CVS and other chain pharmacies. CVS contends that errors are "rare." The CDR commentary initially notes that errors occur "occasionally," and then "not often." There is a trend here and many CVS pharmacists would say that the most accurate designation is "frequently."

Consumers at risk

CVS places millions of consumers at risk of harm from inappropriate or less-than-optimal drug therapy by failing to provide them with the counseling and services its pharmacists are in a position to provide. CVS management denies this assertion or blames its pharmacists, but their denial is contradicted by the inadequate staffing of pharmacists and technicians, the stressful workplace environment, and the lack of adequate time for pharmacists to speak with patients. In the most serious situations, consumers experience adverse events, some of which are fatal, as a consequence of preventable errors and other drug-related problems.

Many errors are not even known or recognized, either because there are not consequences, or consequences occur but an error is not suspected and the resultant problem is attributed to another explanation. When errors are discovered but harm has not occurred or the consequences are considered "minor," consumers are placated with sufficient coupons for store merchandise or other incentives to "resolve" the experience.

Some errors that result in harm are so clear and indisputable that CVS will compensate the victims in an amount sufficient to avoid lawsuits. Errors that do result in lawsuits rarely become known to the media, the public, or even state Boards of Pharmacy, because they are settled out of court with the settlements being sealed with confidentiality restrictions. In some settlements the terms even permit the defendant chain pharmacy to "acknowledge no wrongdoing," the accurate translation of which would be "there *was* wrongdoing." While claiming that errors are "rare," CVS stonewalls requests to provide information/data regarding errors, as it did in responding to the reporter for the NYT. However, the outrage is increasing and the stone wall is starting to crumble. A rhyme comes to mind that is ripe for paraphrasing:

CVS sat on a crumbling wall;
CVS had a great fall;
All the CEO's millions,
And all the CEO's men and women
Couldn't put CVS together again!

Can a rhyme become reality?

Recommendations

Much more must be done to expose preventable medication errors and other drug-related problems, as well as irresponsible decisions of the executives of chain pharmacies. Ellen Gabler and the NYT have pulled open the veil of secrecy that has hidden these problems, but the momentum of increasing disclosure must not diminish. There are steps that can be taken now and the following recommendations are provided:

1. Pharmacies must report to the state Board of Pharmacy medication errors that cause harm and/or require increased patient monitoring. The definition of medication errors and risk assessment index established by the National Coordinating Council on Medical Error Reporting and Prevention (NCC MERP) should be used for the reporting of errors in the following categories to the Board:

   Category D: Errors that result in the need for increased patient monitoring but no patient harm;
   Category E: Errors that result in the need for treatment or intervention and caused temporary

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New Drug Review

Istradefylline
(Nourianz – Kyowa Kirin)

Antiparkinson Agent

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

Indication:
Adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes.

Comparable drug:
Dopamine agonists (with ropinirole used for comparison).

Advantages:
- Has a unique mechanism of action (adenosine A2A receptor antagonism);
- Is not likely to cause hypotension or somnolence;
- May be less likely to cause impulse control disorders/ compulsive behaviors;
- Dosage adjustment is less complex.

Disadvantages:
- Has not been directly compared with comparable drugs in clinical studies;
- Labeled indications are more limited (is not indicated as monotherapy, and ropinirole is also indicated for the treatment of patients with restless legs syndrome);
- May interact with more medications (e.g., CYP3A4 inducers and inhibitors);
- Should be used in a reduced dosage in patients with moderate hepatic impairment, and use should be avoided in patients with severe hepatic impairment.

Most important risks/adverse events:
Dyskinesia (may cause dyskinesia or exacerbate pre-existing dyskinesia); hallucinations/psychotic behavior (use should be avoided in patients with a major psychotic disorder); impulse control disorders/compulsive behaviors (e.g., intense urges to gamble, spend money, or binge eat; increased sexual urges); should not be used during pregnancy and women of reproductive potential should be advised to use effective contraception during treatment); action is decreased by strong CYP3A4 inducers (e.g., carbamazepine, rifampin) and concurrent use should be avoided; action is increased by strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole) and dosage should be reduced; action is reduced by tobacco smoking (20 or more cigarettes per day) and should be used in a higher dosage; should be used in a reduced dosage in patients with moderate hepatic impairment, and use should be avoided in patients with severe hepatic impairment.

Most common adverse events:
Dyskinesia (17%), dizziness (6%), insomnia (6%), hallucinations (6%), nausea (6%), constipation (6%)

Usual dosage:
20 mg once a day; may be increased to a maximum of 40 mg once a day, based on the need of the patient and tolerability; in patients with moderate hepatic impairment, or who are being treated concurrently with a strong CYP3A4 inhibitor, the maximum recommended dosage is 20 mg once a day; in patients who smoke tobacco in amounts of 20 cigarettes or more per day (or the equivalent of another tobacco product), the recommended dosage is 40 mg once a day.

Products:
Film-coated tablets – 20 mg, 40 mg.

Comments:
The combination of levodopa and carbidopa is the most effective treatment for the motor symptoms of Parkinson's disease, but its effect diminishes with long-term use (e.g., 3-5 years). As the extent and duration of benefit of levodopa/carbidopa decreases, patients experience more and/or longer "off" episodes, representing periods during treatment in which there is an increase in Parkinson symptoms such as tremor and difficulty walking. Other medications that have been used as adjuncts to levodopa/carbidopa include dopamine agonists (e.g., pramipexole, ropinirole), monoamine oxidase type B inhibitors (selegiline, rasagiline, safinamide [Xadago]), amantadine, and catechol-O-methyltransferas e (COMT) inhibitors (e.g., entacapone).

Istradefylline is a xanthine derivative that has a unique mechanism of action as an adenosine A2A receptor antagonist. Its effectiveness was evaluated in four placebo-controlled clinical trials. Compared with placebo, patients treated with istradefylline experienced a significant decrease in the percentage of daily awake "off" time, and an increase in "on" time without troublesome dyskinesia.

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patient harm;
Category F: Errors that result in initial or prolonged hospitalization and caused temporary patient harm;
Category G: Errors that result in permanent patient harm;
Category H: Errors that result in a near-death event (e.g., anaphylaxis);
Category I: Errors that result in patient death.

Boards of Pharmacy must be accountable in enforcing the reporting of errors, assessing the risk factors, and taking appropriate action.

2. Standards/guidelines must be established to assure the level of staffing of pharmacists and pharmacy students and technicians that is appropriate for the number of patients served and/or prescriptions dispensed during a specified period of time. There are too many variables to establish specific quantitative *requirements* of this type, but the appropriateness of the level of staffing must be assessed as a potential contributing factor when errors occur. The number of patients served during a particular period of time, whether or not a prescription is dispensed for every patient, would be the best parameter to assess whether a pharmacist has sufficient time to fulfill her/his responsibilities to patients. However, this parameter is not used in current pharmacy practice, and the number of prescriptions dispensed during a particular period of time should be used initially as a less satisfactory but adequate measure. I propose the following guidelines:

   An average of 15 prescriptions per hour per pharmacist (i.e., one every 4 minutes, 120 in 8 hours, 150 in10 hours, 180 in12 hours) should be identified as the number of prescriptions that can be dispensed by a pharmacist that is consistent with obtaining and reviewing pertinent patient information, accurate preparation and dispensing of the prescription, patient counseling, phone calls, supervision of pharmacy students and technicians, and other responsibilities.

   Some will respond that this number is too high and some will respond that is too low. The number should be applicable whether the pharmacist is working alone, or with any number of pharmacy students and technicians whom the pharmacist must supervise.

   The proposed average of 15 prescriptions per hour per pharmacist *can be*, but would *not be required* to be a criterion for an employer to determine the number of hours of staffing of pharmacists and pharmacy students and technicians. However, when a medication error in one of the above categories occurs and is reported to the Board of Pharmacy, the description of the error must be accompanied by documentation regarding the number of prescriptions dispensed on the date the error occurred and the number of hours of staffing of pharmacists. In addition to any disciplinary actions taken by the Board with respect to the nature and severity of the error, additional penalties/actions should be imposed if the average of 15 prescriptions per hour per pharmacist is exceeded by more than 20%.

3. Pharmacists who are employed by for-profit corporations that are not owned by pharmacists should not be eligible to serve on a state Board of Pharmacy. The responsibilities of members of a Board of Pharmacy are to protect the interests and safety of the citizens of the state with respect to the licensure and practices of pharmacists and pharmacies, and conflicts of interest can occur when the priorities of a corporation are not consistent with those responsibilities.

4. A communications network should be established in which chain pharmacists can participate anonymously (i.e., Chain Pharmacists Anonymous Network [CPAN]), because of their fear of retaliation if they voice concerns. This initiative should start with CVS pharmacists and subsequently be expanded to include pharmacists employed at other chains.

5. The profession of pharmacy should appeal to the Federal Trade Commission and Department of Justice to require divestment of Aetna and Caremark from CVS, as well as similar actions for other corporations that have acquired anticompetitive and excessively dominant positions in pharmacy and health care.

Part 3 of this series will focus on the experiences of CVS pharmacists and technicians, and the destructive effects that CVS has had on the profession of pharmacy."

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