The Pharmacist Activist

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Editorial

Pharmacists Be On Guard!

For the Protection of Your Patients and Yourselves

The July 20-21, 2013 edition of *The Wall Street Journal* includes an article (p. B3, Timothy W. Martin) titled, "CVS Sued by a Former Pharmacist." The article pertains to the experience of Joe Zorek, a pharmacist in Harrisburg, PA who had worked for CVS and its predecessors for 44 years from the time he was a student until the time his employment was terminated in July, 2012 (please also see my editorial, "Is Patient Safety at Risk at CVS? There is a Whistleblower!" in the June 2012 issue of *The Pharmacist Activist*).

Joe Zorek's most recent position at CVS was as pharmacist-in-charge, a responsibility that included supervision of 4 staff pharmacists and 21 pharmacy technicians in a 24-hour store that dispensed approximately 4,200 prescriptions per week, more than any other CVS store in its sales district. He was informed by his supervisor that, starting in January 2011, technician hours would be cut by approximately 20%. He responded that this action would likely endanger patient safety, but the reduction in hours was implemented. In the period following the reduction in technician hours Joe Zorek observed, and reported to his supervisor, that technicians were making a greater number of mistakes in filling and labeling prescriptions, and that there had been an increased rate of errors in dispensing prescriptions and a marked increase in the number of incident reports filed. The reduction in hours continued.

Joe Zorek's concern about errors and patient safety resulted in his making an extraordinary offer to his supervisor. He offered to reduce his own "base hours" from 50 to 42 per week so that the cost savings could be used to pay for the restoration of approximately one-half of the technician hours that had been cut. His supervisor agreed to this offer, Joe's salary was reduced, and the corresponding number of technician hours were restored. However, the store continued to be extremely busy even with approximately one-half of the technician hours that were cut being restored and Joe continuing to work 50-60 hours per week to fulfill his responsibilities even though his salary had been reduced as he had offered. Over the next several months repeated requests to increase pharmacy technician staffing were denied.

In early May of 2011 CVS increased the pharmacy technician hours to the number that had been available prior to the reduction of these hours. CVS also reinstated Joe Zorek to 50 hours of pay per week but kept his base hours at 42, resulting in a continuing

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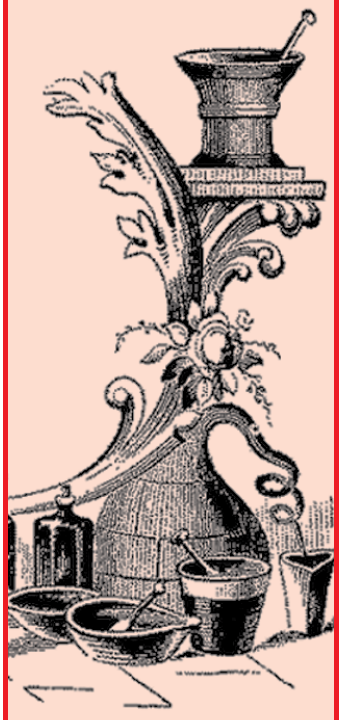

reduction of his accrual of benefits. In that same month the store received its highest score ever in the company's evaluation process, for which accomplishment Joe Zorek was congratulated by his regional sales manager. However, this restoration of the technician hours that had been cut lasted until only late June when Joe Zorek was informed that the technician staffing levels were to be cut again.

Protection of patients

Even under the best of circumstances, the use of every medication is associated with some risk. The admonition to physicians of "First, do no harm" is equally valid for the extremely important responsibility of pharmacists in preventing drug-related harm. Death or disability may be the consequence but these tragic events occur infrequently enough or have not been encountered in our personal responsibilities/experiences that we too often let our guard down. But we must stay on guard! We must not compromise our time and attention to maintaining, building, and applying our knowledge about the appropriate use and risks of the medications for which we are responsible. It is also essential that we assertively address the workplace and other factors that may increase the risk of errors and other drug-related problems. These factors most certainly include, but are not limited to, the level of staffing and the amount of time available to prepare and dispense a prescription, and counsel the patient regarding its appropriate use. We must take the time that is necessary to assure that the risk in using medications is at an absolute minimum for the patients who have placed their trust and confidence in us.

As in the situation Joe Zorek experienced as described above, many pharmacists will encounter resistance from their supervisors/management when they voice concerns about levels of staffing, patient safety, and a stressful workplace environment. In some circumstances, pharmacists may feel that their job would be in jeopardy if they voice such concerns. However, when patient safety is compromised, pharmacists must not remain silent! They must voice their concerns in the interests of their patients. Yes, we have a responsibility to our employer, but we have a greater responsibility to our patients in protecting them from harm that could have been avoided.

The extent to which dispensing errors and avoidable drug-related problems occur is unacceptable. Inadequate staffing of pharmacies can no longer be attributed to a shortage of pharmacists. In most areas the supply of pharmacists is sufficient to fulfill the basic responsibilities of our profession in assuring patient safety with respect to the use of medications. However, some chain pharmacies and some other pharmacy employers persist with inadequate staffing patterns and policies regarding dispensing prescriptions (e.g., signals/lights to indicate when "too much time" is being taken to complete a prescription, patients should not have to wait more than 15 minutes to receive their completed prescription). The amount of time that a pharmacist needs to appropriately fulfill her/his responsibility to a patient is not the same for every prescription. State Boards of Pharmacy should establish regulations that require pharmacies that have prescription dispensing policies that include a completion time expectation/deadline to submit such policies to the Board for approval with respect to patient safety considerations. Pharmacies that have such policies should also be required to submit reports to the Board of Pharmacy regarding dispensing errors and other drug-related problems, and lawsuits in which they are a defendant.

The personal side

Joe Zorek has multiple sclerosis (MS) that was diagnosed in 1989. In spite of this challenge, he was able to effectively fulfill his responsibilities and perform all essential functions of his pharmacist-in-charge position. However, from late 2010 through mid-2011 a cascade of events began to take its toll. These events included the high prescription volume, the installation of a new pharmacy dispensing system, a reduction in technician hours, demeaning comments, fear of losing his job, what he has described as harassment and retaliation, and others. In early July of 2011 he experienced a severe flare-up of his MS that his neurologist indicated was likely triggered by stress in the workplace and by sitting in the lift chair (that his supervisor required him to use) for extended periods of time. It is noteworthy that Joe Zorek had only experienced one prior flare-up (in 1995) that was minor compared to what he experienced in 2011.

Joe Zorek was on disability leave from CVS from July 6, 2011 to July 5, 2012. CVS allows its employees one year of such leave and, on July 5, 2012, CVS terminated his employment.

The lawsuit that Joe Zorek has filed against CVS includes charges of violations of the Americans with Disabilities Act, the Pennsylvania Human Relations Act, and Public Policy, including counts of failure to accommodate, hostile work environment, unlawful and wrongful termination, and retaliation.

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New Drug Review

Lorcaserin
(Belviq – Arena; Eisai)

Anorexiant

New Drug Comparison Rating (NDCR) = 4

(significant advantage[s]) in a scale of 1 to 5 with 5 being the highest rating

Indication:

An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m^2 or greater (obese); or 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

Comparable drug:

Phentermine.

Advantages:

- Has a unique mechanism of action (is a selective serotonin 2C receptor agonist);
- Is indicated for chronic weight management (whereas phentermine, when used as a single agent, is indicated for short-term treatment);
- Is less likely to cause sympathomimetic adverse events (e.g., CNS stimulation, increased blood pressure, increased heart rate).

Disadvantages:

- Has not been directly compared in clinical studies with other anorexiants;
- Is administered twice a day (whereas controlled-release formulations of phentermine are administered once a day);
- Is more likely to cause serotonergic adverse events (e.g., agitation, GI effects, hyperreflexia).

Most important risks/adverse events:

May cause fetal harm and is contraindicated during pregnancy (Pregnancy Category X); serotonin syndrome or neuroleptic malignant syndrome-like reactions (risk is increased by the concurrent use of other serotonergic drugs (e.g., selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, monoamine oxidase inhibitors, lithium, triptans, tramadol, tryptophan, bupropion, dextromethorphan, St. John's wort [concurrent use is best avoided]); valvular heart disease (should not be used in combination with serotonergic and dopaminergic drugs that are potent serotonin 2B receptor agonists [e.g., cabergoline]); cognitive impairment (caution should be exercised when operating vehicles or hazardous machinery); psychiatric disorders (e.g., euphoria, dissociation [is classified in Schedule IV], depression, suicidal ideation); priapism (has been associated with activation of serotonin 2C receptors; caution must be exercised with concurrent use of medications for erectile dysfunction); hypoglycemia (caution is needed in patients with type 2 diabetes treated with insulin or insulin secretagogues [e.g., sulfonylureas]); pulmonary hypertension; heart rate decreases; hematological changes (e.g., anemia, leukopenia); prolactin elevation; may increase the action of CYP2D6 substrates; use is not recommended in patients with severe renal impairment.

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A spokesman for CVS has denied the allegations and noted that CVS will defend the case vigorously. He further noted, "The health and safety of our customers is our number one priority and we have comprehensive policies and procedures in place to ensure prescription safety."

Protecting ourselves

Joe Zorek took extraordinary measures to protect the health and safety of his patients, even to the point of risking his own health and job, as well as his willingness to accept a reduction in his own salary to free up funding to support more technician hours. He has demonstrated courage and determination in doing what is right for his patients and for the profession of pharmacy.

Joe has protected himself in several ways. He has had a very positive attitude in responding to his illness/disability and considers himself to be "BLESSED" by being supported by so many individuals. His concerns are not for himself but for patients, as well as for pharmacists who fear for their jobs if they report errors or voice concerns about understaffed and stressful workplaces. He is a positive example and an advocate for pharmacists who place safety before profit.

Joe Zorek also protected himself by thoroughly documenting his experiences and observations. There is a saying, "If it isn't documented, it didn't happen." Joe has thorough documentation regarding the issues identified above, as well as for other concerns.

And for his lawsuit? I have full confidence that Joe Zorek will be successful.

Pharmacists who wish to contact Joe Zorek directly may reach him at jzorek52@yahoo.com.

Daniel A. Hussar

New Drug Review (cont.)

Most common adverse events:

In patients not having diabetes: headache (17%), dizziness (9%), nausea (8%), fatigue (7%), constipation (6%), dry mouth (5%); in patients with diabetes: hypoglycemia (29%), headache (15%), back pain (12%), cough (8%), fatigue (7%).

Usual dosage:

10 mg twice a day; if a patient has not lost at least 5% of baseline body weight by week 12, treatment should be discontinued.

Product:

Film-coated tablets – 10 mg.

Comments:

Lorcaserin is a serotonin 2C receptor agonist that is thought to reduce food consumption and promote satiety by selectively activating serotonin 2C receptors on anorexigenic proopiomelanocortin neurons located in the hypothalamus. When used in the recommended dosage, the new drug does not appear to activate serotonin 2B receptors. In placebo-controlled studies, approximately 50% of the patients who did not have type 2 diabetes lost at least 5% of their baseline body weight compared with approximately 25% of those receiving placebo. In patients with type 2 diabetes, approximately 38% of patients treated with lorcaserin and 16% of those receiving placebo lost at least 5% body weight.

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