The Pharmacist Activist

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Editorial

Serious Medication Errors Must be Reported –

for Educational and Preventative Purposes!

No one is perfect. Everyone makes mistakes. We can only be as careful as possible and hope that our mistakes are very rare occurrences that don't have serious consequences. However, the practice of pharmacy is an area in which the risk of serious consequences from an error is much greater than in most other areas of responsibility. I urge my students to view every prescription as being associated with life or death implications.

How often do serious medication errors occur? There have been varying estimates but the truth is that no one really knows. There are no requirements that serious medication errors have to be reported and, if anything, there is a disincentive to share/communicate information that would reflect negatively on the individual responsible for an error. Sometimes an error and its consequences are so serious and obvious that the situation reaches the attention of the news media. In other situations, however, even fatal medication errors never become known to individuals other than those most directly affected because a lawsuit is filed, an out-of-court settlement is reached, and a condition of the settlement is that the terms be considered confidential.

I am directly aware of deaths resulting from preventable medication errors because I have been retained as a consultant or expert witness in the litigation that has resulted. Typically, I have been contacted by the attorney for the pharmacy/pharmacist who is a defendant in the lawsuit. However, in some situations I am contacted by the attorney for a patient, or the patient's family when the patient died as a consequence of a medication error. I dislike participating in support of a case against a pharmacy but have agreed to do so in several situations in which pharmacies and their attorneys have "stonewalled" the plaintiff by attempting to build a defense on the position that the only responsibilities of the pharmacist are to dispense the medication the physician has prescribed and to accurately place the physician's instructions for use on the label of the prescription container. Their position further

Contents

contends that the pharmacist has no responsibility to raise a question or otherwise intervene if there are questions regarding the appropriateness or the safety of the medication. In other words, the attorney for the pharmacy is attempting to minimize the scope of responsibility of a pharmacist and, if a judge or jury was to agree with this position, the professional role of pharmacists would be substantially devalued.

Very few of these lawsuits ever go to trial and they are settled out of court, typically with no acknowledgement of wrongdoing and agreement that the terms of the settlement are confidential. Circumstances and information that could be very valuable in preventing future tragedies if they were publicized in an educational context will "never see the light of day." How often do situations like this occur? No one knows. But my guess is it is far more often than we would like to think.

An interview

I was recently interviewed by an investigative reporter with Houston television station KHOU. The producer of the program was aware of a number of reports of errors made at chain pharmacies, as well as an initiative to increase the technician to pharmacist ratio in Texas. The story ("Pharmacists: Corporate greed putting patients at risk") addressed concerns about medication errors and the stressful pharmacy workplace environment that increases the pressure on pharmacists "to fill prescriptions faster, to do more with less, and with less qualified support staff." The story quoted Texas pharmacist Bill Bradshaw as follows: "Wrong patient names, wrong drug, wrong directions." "I have gone home and said a prayer asking God to please not let me have made any mistakes that could have caused harm to a patient." (I have heard similar comments from many pharmacists at the end of a 12- or 14-hour day that they describe as a blur.)

Pennsylvania pharmacist Joe Zorek, a former CVS Pharmacist in Charge who is now suing CVS for wrongful termination, was also quoted. He described being timed on how fast they filled prescriptions – "if he was too slow, his computer would give him a warning in red." When technician hours were reduced, "the result was an increased workload that led to a marked increase in prescription dispensing errors and a possible threat to his patients." "Speed often competed with patient safety."

Bill Bradshaw and Joe Zorek are to be commended for their courage in describing the workplace pressures that are putting patients at risk. In my opinion, the vast majority of chain pharmacists would quickly agree with the concerns they have voiced – if they could! However, many chain pharmacists fear retaliation, demotion, and termination if they voice their concerns even within the company. The tight employment situation for pharmacists in many parts of the country makes it difficult for a pharmacist to quickly identify another position. In addition, most chain pharmacies have policies that prohibit their pharmacists from being interviewed by members of the media. To do so would represent violation of a company policy and probable termination. Rather, chain pharmacists are expected to refer inquiries from the media to a spokesperson for the company.

The Houston TV story also included an interview with a patient for whom an antidiabetic medication had been dispensed instead of an antibiotic at a CVS store. CVS declined an on-camera interview but provided a written statement from its Director of Public Relations that included the information that CVS apologized to the patient who had received the incorrect medication. The CVS statement begins, "The health and safety of our customers is our number one priority . . . " I have seen this statement so often as CVS attempts to explain away errors or other problems that it would be laughable if the consequences of the errors were not so serious. This statement is NOT credible. In my opinion, errors have become just a cost of doing business. It would be interesting to know how many CVS pharmacists believe this statement made at the highest levels of the company. However, we will never know because CVS will never ask its pharmacists that question or let anyone else ask them.

The need for change

The reporting of medication errors is voluntary. Although the information supplied is very useful, it is also incomplete. The result is that most errors are not reported and we do not have a reliable awareness of the type and number of the errors that are occurring. The situations in some chain pharmacies appear to be going from bad to worse and it is my expectation that the frequency of medication errors will increase. In my opinion we have reached the point at which serious medication errors must be reported. However, I make this recommendation with

(Continued on Page 4)

New Drug Review

Bazedoxifene acetate/conjugated estrogens
(Duavee – Pfizer)

Agent for Menopause-associated Conditions

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

Indication:
In women with a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause, and the prevention of postmenopausal osteoporosis.

Comparable drugs:
Raloxifene (Evista).

Advantages:
- Labeled indications include treatment of vasomotor symptoms associated with menopause;
- Is the only combination formulation with an estrogen agonist/antagonist and estrogen.

Disadvantages:
- Labeled indication for postmenopausal osteoporosis is limited to prevention (whereas the indication for raloxifene also includes treatment);
- Labeled indications do not include a reduction in risk of invasive breast cancer;
- Labeling includes a boxed warning regarding an increased risk of endometrial cancer;
- Bazedoxifene is only available in a fixed-dose combination product and not as a single agent.

Most important risks/adverse events:
Contraindications and other risks include problems that could result from the use of estrogen alone (i.e., the conjugated estrogens component); contraindicated in patients with undiagnosed abnormal uterine bleeding, known or suspected breast cancer or estrogen-dependent neoplasia, active or history of thromboembolism, hepatic impairment or disease, or during pregnancy (Pregnancy Category X); increased risk of stroke, deep vein thrombosis, dementia, and endometrial cancer (boxed warning); should not be used with additional estrogens (boxed warning) or with progestins or other estrogen agonist/antagonists; estrogen therapy has also been associated with an increased risk of hypertriglyceridemia, gallbladder disease, visual abnormalities, and hypothyroidism (thyroid function should be monitored).

Most common adverse events:
Muscle spasms (8%), nausea (8%), diarrhea (8%), dyspepsia (7%), upper abdominal pain (7%), oropharyngeal pain (7%), neck pain (5%), dizziness (5%).

Usual dosage:
One tablet daily (20 mg of bazedoxifene and 0.45 mg of conjugated estrogens); in the prevention of osteoporosis, supplemental calcium and/or vitamin D should be taken if daily intake is not adequate.

Products:
Tablets – 20 mg of bazedoxifene and 0.45 mg of conjugated estrogens.

Comments:
Estrogen is effective in reducing menopausal symptoms but, when used alone, it increases the risk of endometrial hyperplasia that may be a precursor to endometrial cancer. To reduce the risk of endometrial problems, a progestin has been used in combination with an estrogen, but additional risk may also be experienced. Bazedoxifene is an estrogen agonist/antagonist, also designated as a selective estrogen receptor modulator (SERM), that activates estrogen receptors in some tissues while inhibiting estrogen activity in others (e.g., the uterus). Its use in combination with conjugated estrogens provides the first combination product that includes an estrogen agonist/antagonist instead of a progestin to reduce the risk of endometrial hyperplasia.

The effectiveness of bazedoxifene/conjugated estrogens in the treatment of vasomotor symptoms was demonstrated in a placebo-controlled study in which the new product significantly reduced the number and severity of hot flashes. In studies in which it was evaluated for the prevention of postmenopausal osteoporosis, it significantly increased lumbar spine bone mineral density (BMD) and total hip BMD. When considered solely for the prevention of postmenopausal osteoporosis, the new product should only be used in women at significant risk of osteoporosis and non-estrogen medication should be carefully considered.

Other estrogen agonist/antagonists that are indicated for use in postmenopausal women include raloxifene that is indicated for the treatment and prevention of osteoporosis, and for the reduction in risk of invasive breast cancer, as well as ospemifene (Osphena) that was marketed in 2013 for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Daniel A. Hussar

an important condition, and that is that the information acquired be used for educational and preventative (i.e., prevention of errors) purposes, and not for punitive purposes against pharmacists who are responsible for the errors.

The State Boards of Pharmacy are the government agencies with the authority to regulate the practice of pharmacy. In 2013, the National Association of Boards of Pharmacy (NABP) identified research and other information that indicated that the use of metrics in pharmacies tends to increase errors. The NABP asked the State Boards to restrict, regulate, or prohibit their use, and this request was also noted in the Houston TV story. However, because State Boards of Pharmacy are the agencies that issue licenses to pharmacists and pharmacies, many pharmacists and their professional organizations may be opposed to submitting information regarding errors to these agencies for fear that actions might result with respect to their license.

The ISMP

The Institute for Safe Medication Practices (ISMP) has provided exceptional services to society and the health professions by collecting and disseminating information regarding medication errors and other health system-related errors that have great value in increasing awareness of and reducing the risk of errors. The philosophy of current ISMP programs is to identify and correct the underlying causes and related factors that contribute to the occurrence of errors, rather than assigning fault or blame to the individuals or organizations involved. This philosophy must be included as a basic component in an expanded program that would require the reporting of serious medication errors.

The State Boards of Pharmacy have the authority to require pharmacies to submit pertinent information regarding serious medication errors, and the ISMP does not have this authority. The ISMP has the expertise and experience in the collection, organizing, and communication of information regarding medication errors in an educational and preventative context that the Boards of Pharmacy do not have.

Proposed action

I urge that the State Boards of Pharmacy, ISMP, and NABP collaborate in the development of a program that will require the reporting of serious medication errors to ISMP. Provision should be made for individual pharmacists and pharmacy organizations to submit their ideas and opinions.

I recognize that this recommendation raises numerous questions that must be addressed. Examples that come quickly to mind include:

> What situations are considered to be medication errors? (e.g., dispensing errors, preventable adverse events, preventable drug interactions)
>
> How is "serious" defined? (e.g., death of a patient, actual or potential harm to a patient requiring medical consultation/treatment)
>
> What if there is potential or pending litigation? (e.g., a report must be submitted if an alleged error is the basis for litigation; a report must be submitted even if the litigation is settled out of court)

Dozens of other questions exist. However, the purpose of this editorial is to focus on a very important issue for which the profession of pharmacy must be more accountable to the public and to provide a recommendation that (as stated or improved) will be an initial step for positive action.

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