The Pharmacist Activist

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Editorial

Dispensing Error — And a Pharmacist in Prison

Almost all pharmacists, as well as those in most other lines of work, have experienced days in which the scope and pace of our responsibilities have been extraordinarily intensive. However, at the end of the day, other than being stressed and exhausted, the experience has usually been relatively uneventful. Unfortunately, this is not always the case and, for some patients, there have been tragic outcomes. As "routine" as dispensing prescriptions may become, pharmacists must recognize that every prescription has "life or death" implications, and that errors can occur on "slow" days, as well as the hectic, stressful days. We must never let our guard down!

Two-year old Emily Jerry of Ohio died on March 1, 2006 as a consequence of an error made by a pharmacy technician and pharmacist. In preparing a solution for intravenous infusion, the technician used an excessive amount of a 23.4% solution of sodium chloride, and the pharmacist failed to recognize the error. This tragedy is discussed in detail in communications of the Institute for Safe Medication Practices (ISMP [www.ismp.org]) and in an article by Jesse Vivian in the November 2009 issue of *U.S. Pharmacist*.

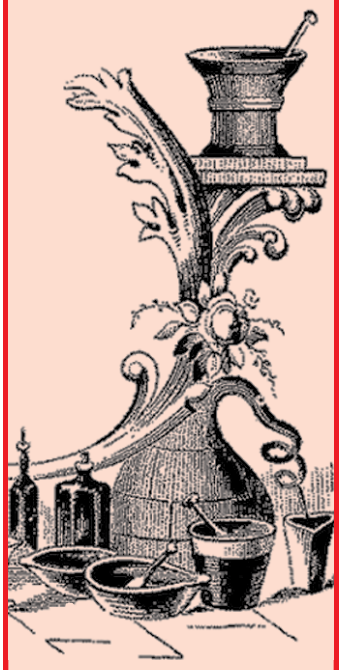
It is painful for me to even think of one of my children or grandchildren dying from any cause, let alone a cause that was preventable. Therefore, the emotions and anguish experienced by Emily's parents are beyond my experience and understanding, and extending heartfelt sympathy seems too inadequate.

There was an investigation following Emily's death and factors that contributed to the occurrence of the error were identified. The pharmacy computer was down for part of the day resulting in a backlog of orders, the pharmacy was short-staffed on the day of the error, the technician was distracted by other activities, and a call from a nurse suggested that the need for the medication was urgent. The importance of these and other system problems as contributing factors to the causes and occurrence of errors must be recognized and, to the extent possible, eliminated. However, as pharmacists we must be personally responsible and accountable for our actions, or lack thereof.

The other consequences

The pharmacist and technician were dismissed by the hospital at which they were employed. The pharmacist obtained employment in a community pharmacy and was reported to have been responsible for some dispensing errors in that setting. The Ohio Board of Pharmacy determined that the errors of the pharmacist represented unprofessional conduct in violation of state law, and took action to permanently revoke

Contents



his license. The vote of the Board has been reported to be six in favor of this action and two opposed.

The consequences for the pharmacist continued. He was charged with criminal actions and he pleaded guilty to a charge of involuntary manslaughter. In August, 2009, he was sentenced to six months in prison, six months of home confinement with electronic monitoring, 400 hours of community service, a $5,000 fine, and payment of court costs. His prison term concludes this month.

The penalty of permanent revocation of the pharmacist's license can be debated at length. Indeed, the Ohio Board of Pharmacy was not unanimous in this decision. However, it is the consideration of this event as a criminal matter and the resultant prison term that prompt my strongest objection and concern.

The dispensing error was a horrible mistake with the worst possible consequence, but it should not be considered a criminal action. Tens of thousands of deaths occur each year in the United States as a consequence of tragic, but accidental, medical errors. Should all of these errors be considered as criminal actions that will result in jail terms? Other than being able to quickly and specifically identify the cause of death and the individuals who made the error, what makes the tragic event in Ohio different from most of the thousands of other deaths that result from medical errors? Recently, a prominent Pennsylvania Congressman died. News reports indicate that he was admitted to the hospital to have "minimally invasive" gallbladder surgery. Unfortunately, during this surgery his intestine was "nicked." Complications set in and he died as a consequence. Should this surgeon be charged with a criminal action? My response is an emphatic "No!"

What purpose was served by sending the Ohio pharmacist to prison? I can't identify any. Rather, for the following reasons, I would contend that society has been done a great disservice by this action. Many deaths are caused by medical errors but are not recognized as such. An environment that encourages the identification, causes, and candid discussion of errors will result in a greater awareness and understanding of these risks, and an opportunity to disseminate such information in an educational manner that will help other health professionals, and their patients, avoid such experiences. However, if the environment is one that threatens criminal action, prison terms, and permanent revocation of one's license for making an accidental but fatal error, can we realistically expect that health professionals will acknowledge errors they make if the cause of the death is not readily apparent and/or can be "covered up?" The experience of the Ohio pharmacist sends a chilling message that the penalties for dispensing mistakes may be very harsh. This is the wrong action and the wrong message.

Where are the pharmacy associations?

Over a period of many years, Michael Cohen and his colleagues at ISMP have provided exceptional educational programs and commentaries with a goal of preventing medication errors. Their analyses and warnings regarding errors and the tragedies that sometimes result have been of great value in identifying the medications and circumstances that are associated with the greatest likelihood of error. Tragedies are not reversible but, once they have occurred, what can be learned and communicated for the benefit of others so that the experience is not repeated? This is the commendable focus of ISMP's analyses and warnings. Without ignoring the importance of health professionals being accountable for their actions, this organization emphasizes the prevention of similar future errors, rather than focusing on blame and penalties. ISMP has been highly active in addressing the tragic error that took Emily's life, as well as the professional and personal circumstances of the Ohio pharmacist. But, to my knowledge our pharmacy associations, such as the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP), have been silent!

The implications of the Ohio experience are huge for pharmacists and our profession. I realize that I do not know all the details of the situation but, based on the information that is available, I have great concern about the criminal action pursued against the pharmacist and the resultant prison sentence because of his error. I would like to think that our professional associations would vigorously defend pharmacists against such punitive actions. They should do that even if the pharmacist charged is not one of their members, because the same risks and implications also exist for their members. Indeed, implications exist not only for pharmacists, but also for physicians, nurses, and other health professionals whose responsibilities involve life-or-death decisions and actions, that will sometimes result in errors. Our pharmacy associations should not only be actively addressing these situations on behalf of pharmacists, but should also be actively working with their counterparts in medicine and nursing to establish practice environments and policies that will keep errors to an absolute minimum, and to protect health professionals against criminal and punitive penalties for mistakes. It may be that APhA and ASHP have addressed the experience of the Ohio pharmacist and I am just not aware of their efforts. However, if they have done or said something, it has not been adequately publicized.

Personal responsibility and accountability

Our goal as pharmacists is to never make even one error! However, we will and do make errors, and can only hope

(Continued on Page 4)

New Drug Review

Iloperidone
(Fanapt – Novartis)

Antipsychotic Agent

New Drug Comparison Rating (NDCR) = 1

(important disadvantages) in a scale of 1 to 5, with 5 being the highest rating

Indication:
Acute treatment of adults with schizophrenia; association of the drug with prolongation of the QT interval will often lead to the conclusion that other drugs should be tried first; risk of orthostatic hypotension and syncope necessitates slow titration of dosage that delays onset of antipsychotic activity.

Comparable drug:
Risperidone (e.g., Risperdal).

Advantages:
- Less likely to cause extrapyramidal symptoms;
- Dosage adjustment is not necessary in patients with renal impairment (whereas a lower dosage of risperidone should be used in patients with severe renal impairment).

Disadvantages:
- May be less effective, particularly during the first two weeks of treatment, corresponding to and immediately following the dosage titration period;
- Not considered a first-line treatment;
- Labeled indications are more limited (risperidone is also indicated for the maintenance treatment of schizophrenia, for the treatment of bipolar disorder, and for the treatment of irritability associated with autistic disorder);
- Greater risk of QT interval prolongation (should be avoided in patients with risk factors for this response);
- Greater risk of orthostatic hypotension, necessitating slow titration of dosage that results in a delayed onset of action;
- Not recommended in patients with hepatic impairment;
- Administered twice a day (whereas risperidone may be administered once a day);
- Effectiveness and safety have not been established in pediatric patients (whereas risperidone has indications for use in children and adolescents);
- Fewer formulation options (risperidone is also available in an oral solution, orally disintegrating tablets, and an extended-release parenteral formulation).

Most important risks/adverse events:
Increased mortality in elderly patients with dementia-related psychosis (boxed warning; is not approved for the treatment of dementia-related psychosis); cerebrovascular adverse events; QT interval prolongation (should not be used in patients at risk including those who are taking other medications that are known to cause QT prolongation [e.g., certain antiarrhythmic agents, moxifloxacin (Avelox)]); orthostatic hypotension and syncope (dosage must be slowly titrated); priapism; neuroleptic malignant syndrome; tardive dyskinesia; hyperglycemia and diabetes mellitus; leukopenia, neutropenia, and agranulocytosis; hyperprolactinemia; disruption of body temperature regulation; dysphagia; seizures; potential for cognitive and motor impairment (patients should be cautioned about engaging in activities requiring mental alertness); suicide (risk is inherent in psychiatric illness); use is not recommended in patients with hepatic impairment; is a substrate for CYP3A4 and CYP2D6 and action may be increased by the concurrent use of other medications that inhibit these metabolic pathways; may increase the action of central nervous system depressants and antihypertensive medications.

Most common adverse events (at the incidence reported with a dosage of 20-24 mg/day):
Dizziness (20%), somnolence (15%), tachycardia (12%), dry mouth (10%), weight gain (9%), nasal congestion (8%), fatigue (6%), orthostatic hypotension (5%).

Usual dosage:
To reduce the risk of orthostatic hypotension the dosage must be titrated slowly; the recommended initial dosage is 1 mg twice a day with daily adjustments made to 2 mg twice daily, 4 mg twice daily, 6 mg twice daily, 8 mg twice daily, 10 mg twice daily, and 12 mg twice daily on days 2, 3, 4, 5, 6, and 7, respectively; the maximum recommended dosage is 12 mg twice a day; when used concomitantly with a CYP3A4 inhibitor (e.g., clarithromycin) or CYP2D6 inhibitor (e.g., paroxetine), the dosage of iloperidone should be reduced by one-half.

that our errors will not have serious consequences. We sometimes have a false sense of assurance that our employer provides the needed insurance and support to protect us in the event of an error. In the Ohio experience, the hospital fired the pharmacist and technician. We must protect our patients, and ourselves, against stressful working conditions that increase the risk of errors. If you find yourself in such an employment situation, I urge you to communicate your concern to your manager and/or employer, and document your discussion. If no action is taken to reduce the stress and risk in your practice responsibilities, I urge you to seek employment elsewhere. The risks and potential consequences are too important, first of all for the patients we serve, and then for ourselves, to continue to be part of an unacceptable practice situation that we might forever regret.

Emily

In my passion to be an advocate for and to protect pharmacists, I must not forget Emily. She is the inspiration for this commentary regarding the need to design better systems that will increase the effectiveness and safety of health care and drug therapy, and the importance of pharmacists being more accountable. Emily's death has also been the inspiration for the enactment of Emily's Law in Ohio that establishes standards for pharmacy technicians.

Daniel A. Hussar

Author/Editor
Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia

Publishers
Christopher J. Polli • G. Patrick Polli II

Assistant Editor - John Buck

Publications Director - Jeff Zajac

Graphic Artist/Designer - Joe Monte

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The Pharmacist Activist
661 Moore Rd., Ste. 100, King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

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New Drug Review (cont.)

Products:

Tablets – 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg.

Comments:

Iloperidone is an atypical antipsychotic agent that is classified as a benzisoxazole derivative. Its properties are most similar to those of risperidone, paliperidone (Invega; the active metabolite of risperidone), and ziprasidone (Geodon). Other atypical antipsychotic agents include aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), asenapine (Saphris), and clozapine (e.g., Clozaril). The efficacy of these agents is thought to be mediated through a combination of antagonist activity at dopamine type 2 (D2) receptors and serotonin type 2 (5-HT2) receptors. In a 6-week study in which patients received iloperidone, risperidone, or placebo, the new drug was determined to be superior to placebo but less effective than risperidone, at least during the first two weeks of the study. It has been suggested that this difference in efficacy is attributable to the slow titration of dosage with iloperidone, compared with the more rapid titration that is possible with risperidone. Although the efficacy of maintenance dosages of the two agents is likely to be similar, the delay in attaining the full clinical benefit of iloperidone is an important disadvantage, particularly because it is used for the acute treatment of schizophrenia. The delayed onset of action, as well as the potential for QT interval prolongation, warrant consideration of other antipsychotic agents before using iloperidone.

When used in a dosage of 12 mg twice a day, iloperidone was associated with QTc prolongation of 9 msec although no severe cardiac arrhythmias were observed in the clinical studies. The use of the drug should be avoided in patients treated with other medications know to prolong the QT interval or who have other risk factors for QT prolongation. In patients treated with iloperidone in a dosage of 20-24 mg/day, 18% experienced at least a 7% increase in body weight, compared with 4% of those receiving placebo.

Daniel A. Hussar