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Kansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New Board Member Appointed

The 2009 Kansas Legislature increased the number of Kansas State Board of Pharmacy members from six to seven. The additional Board member must be a pharmacist. On July 10, 2009, Governor Mark Parkinson appointed David R. Schoech, RPh, to the Board of Pharmacy. David has been a pharmacist for 26 years and is owner and pharmacist-in-charge (PIC) of Columbus Family Pharmacy in Columbus, KS.

David received a bachelor of science from the University of Kansas School of Pharmacy in 1982. He is currently a district director of the Kansas Pharmacists Association and is the secretary of the Southeast Kansas Academy of Pharmacists. He previously served as a director and officer of the Kansas Pharmacy Service Corporation and is a member of the National Community Pharmacists Association. David is also on the University of Kansas School of Pharmacy Advisory Council. David was the Kansas Pharmacists Association 2006 Kansas Pharmacist of the Year and in 2007 was honored by the Kansas Pharmacy Service Corporation as a Distinguished Past Board Member.

David is active in his community, including serving on the board of directors of the Columbus Lion Club, the Columbus Chamber of Commerce, the Columbus Community Foundation, the Columbus Parks and Recreation Commission, and the Knights of Columbus. David and his wife Kathy have four children.

The Board of Pharmacy and staff welcome David and wish him great success and accomplishment during his tenure.

Continuous Quality Improvement

In July 2008, the Board of Pharmacy began requiring each retail pharmacy to establish a continuous quality improvement (CQI) program. Hospital pharmacies are exempt from establishing a CQI because they are already required to do so under risk management procedures. CQI works because it brings pharmacy errors into the open without fear of reprisal, and it is important because it places the patient first and stresses patient safety as the highest priority.

The Board's first step with this legislation was to amend the incident report regulation. Previously, a retail pharmacist was required to report all errors whenever they became aware of an alleged or real error in filling or dispensing a prescription. The amended regulation now defines a reportable incident as a preventable medication error involving a prescription drug in any of the following:

- the patient receiving the wrong drug;
- the patient receiving an incorrect drug strength;
- the patient receiving an incorrect dosage form;
- the drug being received by the wrong patient;
- inadequate or incorrect packaging, labeling, or directions; or
- the dispensing of a drug to a patient in a situation that results in, or has the potential to result in, serious harm to the patient.

An incident report must be filed as soon as possible after the discovery of the incident. The pharmacist shall prepare a report that contains the following information:

1. the name, address, age, and phone number of any complainant, if available;
2. the name of each pharmacy employee and the license or registration number of each employee involved;
3. the date of the incident and the date of the report;
4. the pharmacist's description of the incident;
5. the prescriber's name and whether or not the prescriber was contacted; and
6. the signatures of all pharmacy employees involved in the incident.

The incident report should no longer provide a description of the actions taken as a result of the incident and it should not state any steps taken to prevent a recurrence.

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Pharmaceutical Cargo Theft of Copaxone®

The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) reported that a shipment of approximately 14 pallets/994 cartons/5,962 packs of Copaxone® (glatiramer acetate) 20 mg, a non-controlled substance, was stolen during the week of April 13-17, 2009. The tractor trailer was recovered at a rest stop on the New Jersey Turnpike on April 20. Unfortunately the trailer was empty. Corporate security from Teva Pharmaceutical Industries Ltd recalled the remainder of lot #P53159, which has an expiration date of January 2011. If that particular product is found anywhere or offered for sale, it would be the stolen product.

Copaxone is a unique product and is used only to treat patients suffering from multiple sclerosis. If the product is not stored below 74º F and out of the sunlight, it becomes ineffective and may not be safe for use.

Immediately notify the FDA OCI if you are contacted by individuals offering to sell this product, if you have purchased this product, or if you know of anyone that may be involved with the theft and the distribution of this product.

Any information should be provided to Special Agent Gregg Goneconto or Special Agent Nancy Kennedy at OCI Headquarters (800/551-3989), or at *www.fda.gov/oci/contact.html*.

Failed Check System Leads to Pharmacist's No Contest Plea for Involuntary Manslaughter

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified Patient Safety Organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A former Ohio pharmacist will plead no contest to involuntary manslaughter of a two-year-old child who died in 2006 as a result of a chemotherapy compounding error.[1] The pharmacy board revoked the pharmacist's license and, after holding a criminal investigation, a grand jury indicted him on charges of reckless homicide and involuntary manslaughter. The pharmacist faces up to five years in prison.

Prosecutors hold the pharmacist responsible for the toddler's death because he oversaw the preparation of her chemotherapy. A pharmacy technician mistakenly prepared the infusion using too much 23.4% sodium chloride. The infusion was administered to the child, who died three days later.

Though we cannot shed more light on the root causes of the error, our experiences with analyzing other errors strongly suggest that underlying system vulnerabilities played a role. Compounding the solution from scratch is error prone. Communication failures between technicians and pharmacists, IV compounder-related failures, inadequate documentation of the exact products and amounts of additives, and other system issues have contributed to numerous fatal errors. ISMP has also received reports of compounding errors and subsequent failed double-checks due to adverse performance-shaping factors such as poor lighting, clutter, noise, and interruptions. In fact, in this particular case, news reports suggest that the pharmacist felt rushed, causing him to miss any flags that may have signaled an error.[2]

Without minimizing the loss of life in this case, we continue to be deeply concerned about the criminalization of human errors in health care. Safety experts including ISMP advocate for a fair and just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public interest. Its potential impact on patient safety is enormous, sending the wrong message to health care professionals about the importance of reporting and analyzing errors. All professionals are fallible human beings destined to make mistakes and drift away from safe behaviors as perceptions of risk fade when trying to do more in resource-strapped professions. When warranted, licensing boards can protect patients from reckless or incompetent actions of health care practitioners by limiting or revoking licenses.

While the law clearly allows for the criminal indictment of health care professionals who make harmful errors, the greater good is served by focusing on system issues that allow tragedies like this to happen. Focusing on the easy target, the pharmacist, makes us wonder whether any regulatory or accreditation agency is ensuring that all hospitals learn from this event and adjust their systems to prevent the same type of error. If not, the death of this little girl is a heartbreaking commentary on health care's inability to truly learn from mistakes so that they are not destined to repeat.

References

1. McCarty J. *Eric Cropp, ex-pharmacist in case in which Emily Jerry died, is ready to plead no contest*. Cleve-

land Plain Dealer. April 19, 2009. Available at: *www.cleveland.com/news/plaindealer/index.ssf?/base/cuyahoga/1240129922221300.xml&coll=2*.

2. McCoy K, Brady E. *Rx for Errors: Drug error killed their little girl*. USA Today. February 25, 2008. Available at: *www.usatoday.com/money/industries/health/2008-02-24-emily_N.htm.*

NABP Wins ASAE's 2009 Associations Advance America Award of Excellence

In recognition of its efforts for educating patients on the potential dangers of buying medications online and empowering patients to make informed choices through its Internet Drug Outlet Identification program, the National Association of Boards of Pharmacy® (NABP®) recently received the 2009 Associations Advance America (AAA) Award from the American Society of Association Executives (ASAE) and the Center for Association Leadership in Washington, DC.

Launched in May 2008, the Internet Drug Outlet Identification program reviews and monitors Web sites selling prescription medications and distinguishes those sites that do and do not meet state and federal laws and/or NABP patient safety and pharmacy practice standards. Internet drug outlets that appear to be operating in conflict with program criteria, such as dispensing drugs that are unapproved and potentially counterfeit, frequently without a valid prescription, pose a significant risk to the public health. Such findings underscore the importance of this project and other efforts to contain the Web-based distribution of prescription drugs within the appropriate legal and regulatory framework.

"NABP is honored to have been selected for this prestigious award for our efforts to bring about positive change," says NABP President Gary A. Schnabel, RN, RPh. "This program represents a strong demonstration of our commitment to the NABP mission of assisting the state boards of pharmacy in protecting the public health."

NABP is one of only 21 organizations nationally to receive an award of excellence in the first round of ASAE's 2009 AAA Award program, an award that recognizes associations that propel America forward with innovative projects in education, skills training, standards setting, business and social innovation, knowledge creation, citizenship, and community service.

Consumer Directed Questions and Answers about FDA's Initiative Against Contaminated Weight-Loss Products

FDA has developed questions and answers to help consumers, health care practitioners, and the general public understand FDA's actions regarding weight-loss products contaminated with various prescription drugs and chemicals. Many of these products are marketed as dietary supplements. Unfortunately, FDA cannot test and identify all weight-loss products on the market that have potentially harmful contaminants in order to ensure their safety. FDA laboratory tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein in weight-loss products being sold over-the-counter. Enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight-loss products marketed to consumers on the Internet and at some retail establishments.

Pharmacists can advise patients to help protect themselves from harm by consulting with their health care professional before taking dietary supplements to treat obesity or other diseases. Patients should be advised of the following signs of health fraud:

- Promises of an "easy" fix for problems like excess weight, hair loss, or impotency
- Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient," and "ancient remedy"
- Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight-loss product
- Claims that the product is safe because it is "natural"
- Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results
- Promises of no-risk, money-back guarantees

More information is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm.*

Jury Trial Set for Doctor Charged with Bringing Misbranded Foreign Cancer Drugs into US

A jury trial to hear the case of *USA v. Vinod Chandrashekm Patwardhan, MD* was set to begin on April 21, 2009, in the US District Court for the Central District of California. Patwardhan, an Upland, CA doctor who specialized in treating cancer patients, was arrested in August 2008 by federal authorities after being charged with introducing foreign misbranded drugs into interstate commerce. These drugs reportedly were sometimes diluted when they were administered to his patients, according to a news release issued by Thomas P. O'Brien, US attorney for the Central District of California, on the day of the arrest. The charge of delivering misbranded drugs into interstate commerce with the intent to defraud or mislead carries a penalty of up to three years in federal prison.

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The incident report must be maintained for a period of five years and be made available to the Board or its representative within three business days upon request.

The preparation of the report fulfills the requirement related to incident reports and it is the responsibility of the pharmacist involved in the incident and the PIC to see that the report is completed in a timely manner.

The second portion of the pharmacy's responsibility is to develop a CQI program. The Board drafted the minimum requirements of a CQI program. It requires the retail pharmacy to have a meeting every quarter to review all incident reports generated during the last quarter. The Board has required that each pharmacy conduct a meeting by September 30, 2009. As the Board could not anticipate the size of each pharmacy and the number of employees at each pharmacy, the minimum requirement is that the meeting be attended by the PIC. The Board envisioned that the meeting would be attended by not only the PIC, but the pharmacy manager, the quality supervisor, staff pharmacists, and pharmacy technicians. Each incident should be reviewed and discussion should ensue to determine what steps should be taken to avoid such a recurrence in the future. A report of the meeting should be documented with at least a minimum of who attended the meeting, the list of incident reports reviewed, and a description of the steps taken or to be taken to prevent a recurrence of each error.

Obviously, the regulation can only provide guidance for minimum requirements in order to provide best practices to the pharmacy community. The products that are being dispensed have the ability to cause serious harm and many patients cannot fully appreciate the risks associated with taking medication. Some negligence in the course of human endeavors is predictable and expected. Each pharmacy has a responsibility to develop and maintain a comprehensive CQI program even though the Board is legally requiring the minimum. There are tools available, such as continuing education, that will assist pharmacies in developing a CQI program that will contribute significantly to patient safety. Training materials will not only address staffing issues, workflow issues, communication issues, formulating solutions, process improvements, etc, but will also assist the pharmacy in providing assistance with their documentation. The records that a pharmacy maintains can make a difference in avoiding misunderstandings and ultimately medication errors. Therefore, the Board encourages every retail pharmacy to use risk management techniques and tools when forming their CQI program. A team approach gives everyone an opportunity to express ways to improve their system. This will provide for the health, welfare, and safety of the patient as well as protection to the pharmacy from avoidable litigation.

In conclusion, it will help the pharmacy if everyone understands their role in the process, how errors are made, and what improvements can be made to prevent medication errors. CQI requires commitment in order for it to be successful.

Prescriptions for Sympathomimetic Amines

Prescriptions for phentermine no longer require a diagnosis. The phentermine prescription can be phoned, faxed, or handed to the patient for a 30-day supply with no refills. The pharmacy cannot fax for refills because the patient needs to be seen by the prescriber before a new prescription can be issued.

Disciplinary Case

Heather Ann Lindsay, Technician, Registration Number 14-05233: Registration revoked, diversion of controlled substances (hydrocodone) from employer.

Special Notice About Newsletter

The *Kansas State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. We encourage you to keep them for future reference. They are also maintained on the Board Web site at *www.kansas.gov/pharmacy/* under the link for Newsletters.

Kansas Committee on Impaired Pharmacy Practice

The Committee on Impaired Pharmacy Practice (CIPP) is a voluntary program established by the Kansas Pharmacists Association. The purpose of CIPP is to assist any pharmacist or pharmacy intern whose health and/or professional effectiveness has been, or is likely to be, impaired by the disease of chemical dependency or other physical or mental disability. If you have a problem, or you are concerned about someone who does, remember, you are not alone. CIPP can help. All calls to CIPP at 785/217-7091 are confidential.

The *Kansas State Board of Pharmacy News* is published by the Kansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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