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Kansas State Board of Pharmacy News

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Board Members Reappointed

Congratulations to pharmacists Robert "Bob" Haneke, PharmD, of Sylvia, KS, and Chad Ullom, RPh, of Topeka, KS, on their reappointment to the Kansas State Board of Pharmacy by Governor Sam Brownback. Bob is the current president of the Board, and his term expires on April 30, 2019. Chad is the current vice president of the Board, and his term also expires on April 30, 2019.

Red Flags for Pharmacists

Do you know what a doctor shopper looks like? Opioid abuse is now a nationwide epidemic, and the consequences are devastating and on the rise. Several factors have contributed to the severity of the problem, to include the drastic increase in the number of prescriptions written.

The Board understands that the greater responsibility lies with the prescriber, but pharmacists need to accept their responsibility and accountability for dispensing prescriptions that would not be considered legitimate when the totality of the circumstances are scrutinized. Kansas law defines valid prescription order to mean a prescription that is issued for a legitimate medical purpose by an individual prescriber who has a patient-physician relationship.

There are critical moments in the filling of a prescription when a pharmacist must make a decision based on the interaction with the patient as to whether a prescription is legitimate. K.A.R. 68-20-18 and 68-20-19 state that the responsibility for the proper prescribing and dispensing of controlled substances (CS) shall rest with the prescriber, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. Each pharmacist shall make a reasonable effort to ensure that any prescription, regardless of the means of transmission, has been issued for a legitimate medical purpose. Reasonable suspicion should be raised by red flag behaviors. It is simply not sufficient to contact the phone number on the prescription to determine whether a prescription is valid. Is the prescriber using his or her cell phone as the office number? Is the prescriber answering the phone directly? Contacting Drug Enforcement Administration and asking whether a prescription should be filled will not mitigate the pharmacist's responsibility if he or she is ignoring the red flags. The pharmacist has a duty to review the legal requirements of the prescription and to inquire further depending on the circumstances. Red flags may include a group coming in to the pharmacy carrying prescriptions for the same drug from the same doctor. Is the prescription being presented from a physician's office that is geographically located near where the patient lives? Where is the physician's office geographically located in relation to the pharmacy? Where is the patient geographically located in relation to the pharmacy? Is the patient paying cash for CS prescriptions? Has the patient been prescribed a variety of different CS? Is the patient calling ahead to determine whether you have the drug requested because he or she is sending in a group to have prescriptions filled?

In Kansas, oxycodone 30 mg is the most commonly requested drug because it is sought out by street dealers. Is the prescriber writing an abnormal amount of oxycodone when he or she is not a pain management doctor or in a specialty that would necessitate large amounts of this drug?

The Board has provided pharmacies with the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) prescription drug monitoring program to use as a tool to help formulate a decision. While it is not required that a pharmacist looks up each patient in the K-TRACS system, it may be an aggravating factor in a hearing if the pharmacist does not use the system and fills prescriptions that the K-TRACS system clearly would have identified as problematic, particularly when many red flags are present. Further, pharmacists can research many other states since Kansas uses the NABP PMP InterConnect® system. It is not acceptable for any pharmacy to continue to fill prescriptions when numerous patients from another state are coming to the pharmacy in groups to fill prescriptions from a physician located in a state that is different from the patients'. If the pharmacy is not monitoring the physical proximity of the patients and there is a disproportionate number of CS filled when compared to the total dispensed, these factors may be used in hearings.

Filling prescriptions that are not legitimate contributes to the scope and impact of the abuse of prescription opioids. The Board believes that there is sufficient information available in the Board *Newsletters,* on the Board website, and on the National Association of Boards of Pharmacy® (NABP®) website that provides guidance on the questions

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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you should ask when filling prescriptions for CS. If you are unfamiliar with these resources or you need additional education, contact your inspector and request guidance. Filling prescriptions that are clearly not legitimate will not be tolerated.

Official Method of Notification

The *Kansas State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacy interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kansas Pharmacy Law Book* for future reference.

Collaborative Agreement Update

In July 2014, the Kansas State Legislature authorized the Board of Pharmacy to adopt rules and regulations related to collaborative agreements between pharmacists and physicians. The law required that the Kansas State Board of Healing Arts nominate three physicians to serve on an advisory committee to assist with the rule writing process. The Board of Healing Arts recently nominated Dr Joseph Spurlock of Wichita, KS, Dr Robert Moser of Lawrence, KS, and Dr Myron Leinwetter of Rossville, KS, to serve on the committee. The committee had its first meeting on June 26. The committee outlined draft regulations that would provide for cooperative management of patients' drug-related health care needs specific to drug-related regimens and monitoring of drug therapy. The first draft was reviewed at the Board of Pharmacy's July meeting. The individuals serving on behalf of the Board of Pharmacy are Dr Jim Garrelts of Wichita serving as chairperson, Dr Lyndsey Hogg of Wichita, Rick Couldry, MS, BS, of Kansas City, KS, and Dr Tiffany Shin of Wichita.

Drug Supply Chain Security Act

By Brendan Handy, PharmD candidate

As the concern about the safety of prescription drugs has continued to rise in the last few years, many people felt it was about time to implement a program that would be able to track these prescription drugs on their way to the consumer. Many customers wonder where they are receiving their drugs from, and with the numbers of counterfeit drugs continuing to increase, it is safe to say that something needs to be done in order to eliminate this problem in the United States. As members of the pharmacy community, it is important to know that consumers are receiving the highest quality prescription products while also receiving the highest of care. Because of this growing concern, the government has implemented the Drug Supply Chain Security Act (DSCSA), a plan that is going to track prescription drugs from the manufacturer all the way until the point of dispensing.

The DSCSA was signed into law by President Barack Obama on November 27, 2013, as Title II of the Drug Quality and Security Act. Through the implementation of the DSCSA, the main objective is to develop an electronic system that will identify and track prescription drugs as they are distributed through the US. Potentially dangerous drugs will be eliminated from the drug supply chain. By doing so, consumers will be better protected from possible counterfeit, stolen, contaminated, or harmful prescription drugs. Although the implementation process is targeted as a 10-year process, consumers should know that the beginning steps are already being made to help make the drug supply chain process safer and more efficient.

Various guidance documents have been released that explain the new compliance rules. Over the course of the 10 years, the goal is to have requirements implemented for the following: product identification, product tracing, product verification, detection and response, notification, wholesaler licensing, and third-party logistics provider licensing. For product identification, using a unique identifier on drug packages, such as a bar code, would allow for easy tracking through an electronic system. With product tracing, having the manufacturers, wholesale distributors, repackagers, and dispensers provide information about the drugs, as well as documenting who handled the drugs, would be essential for proper tracking. In verification, each entity involved with the prescription drugs would need unique systems in which they would verify their specific goals and duties. Detecting and responding to a prescription drug issue would be important because this step would require the investigation of a drug that was labeled as "suspect," showing that it may be counterfeit or dangerous in some way. The notification process would require the specific entity to contact the proper authorities, such as Food and Drug Administration (FDA), immediately to figure out a potential problem, while also attempting to get it solved as quickly as possible. Lastly, the licensing component would involve wholesalers and third-party logistics providers having to obtain a federal or state license under the rules of the DSCSA. Guidance documents pertaining to this law can be found on the FDA website at *www.fda.gov.*

Useful Contact Information

Kansas State Board of Pharmacy.....785/296-4056
1-888/792-6273
K-TRACS.....785/296-6547
Kansas State Board of Healing Arts.....785/296-7413
1-888/886-7205
Kansas Dental Board.....785/296-6400
Kansas State Board of Nursing.....785/296-4929
Kansas Board of Examiners in Optometry.....785/832-9986
DEA (Kansas City).....913/825-4200
Food and Drug Administration, Center for Drug Evaluation and Research.....1-855/543-3784
Kansas Pharmacists Association.....785/228-2327
Kansas Council of Health-System Pharmacists.....785/271-0208
Kansas Pharmacists Recovery Network.....785/217-7091

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