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Kansas State Board of Pharmacy News

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Safe Use Initiative: Acetaminophen Toxicity

In partnership with the National Association of Boards of Pharmacy®, and as part of its Safe Use Initiative, Food and Drug Administration (FDA) is encouraging pharmacies to stop using the abbreviation "APAP" and to spell out acetaminophen. This is suggested in response to numerous acetaminophen toxicity cases. As explained in an FDA drug safety notice, liver injury due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are assisting patients who may not be familiar with the APAP abbreviation. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug, which can lead to an overdose.

The Kansas State Board of Pharmacy does not mandate that pharmacies alter their prescription labeling to meet this change. However, the confusion regarding acetaminophen labeling highlights the importance of patient counseling. The Board strongly encourages pharmacists to address the acetaminophen issue during patient counseling or to change their labeling. Letting patients know that their prescription medication contains acetaminophen is essential and recommendations can be made during counseling regarding over-the-counter alternatives to acetaminophen that are therapeutically appropriate.

Disciplinary Cases

Angela E. Fuller, Pharmacy Technician Registration 14-09794: Registration revoked based on unauthorized refills of her own prescription.

Travis J. Fyler, Pharmacy Technician Registration 14-05982: Registration revoked based on diversion of controlled substances from employer.

Kansas State Board of Pharmacy Unveiling Statewide Prescription Drug Monitoring System

The Kansas State Board of Pharmacy will be unveiling a new Internet-based prescription monitoring database that provides prescribers and dispensers with accurate and timely prescription history data for their patients. The state's secure database, known as the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) system, will contain all entries representing controlled substances (Schedule II, III, and IV) and drugs of concern dispensed in Kansas from August 2010 and after. KSA 65-1683 requires any dispenser who delivers a controlled substance or drug of concern to report such dispensing to the K-TRACS database. K-TRACS will begin collecting dispensing information in February 2011, and will allow prescribers access to the database in April 2011. Dispenser guides for reporting will be made available in December 2010. The Board began holding prescription monitoring program informational/educational sessions across the state in November 2010. If you are interested in holding an educational session in your area, please contact the Board of Pharmacy directly.

The goal of developing this electronic system for reporting the dispensing of these prescriptions is to make information from the K-TRACS available to health care professionals who are seeking to improve patient care. All prescribers and pharmacists will have access to accurate and timely prescription history data to help determine appropriate medical treatment and interventions. In addition, the data may help to identify patients who could benefit from referral to a pain management specialist of those who are at risk for addiction and may be in need of substance abuse treatment.

For more information on the K-TRACS database, your possible reporting requirements, and to register for access

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.*

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.*

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.*

Safeguards to Implement with 'High Alert' Medications

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.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag

check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

Additional cognitive checks:

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- A thorough explanation of all expanded access programs available
- Links to key references and resources that are relevant to the slide content
- Selected virtual meeting presentations from ASCO Annual Meetings
- Helpful resources to use with patients

The program is available at *http://university.asco.org/Expanded Access* and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admissions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at *www.samhsa.gov/newsroom/advisories/1007140544.aspx*.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at *http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d*.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- Recommendations: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm*.
- Response Letter: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149*.
- Scope of Contemporary Pharmacy Practice, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150*.

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to the database information, please visit the Kansas State Board of Pharmacy Prescription Monitoring Program Web site at *www.kansas.gov/pharmacy/KSPMP*, e-mail Christina.morris@pharmacy.ks.gov, or call the agency directly at 785/296-8717.

Role of Authorized Agent in Communicating Controlled Substance Prescriptions

Drug Enforcement Administration (DEA) issued a policy statement on October 6, 2010, that provides guidance regarding the proper role of an authorized agent of a practitioner. Under the current law the only persons who may lawfully manufacture, distribute, and dispense controlled substances are those who have obtained a DEA registration authorizing them to do so. To be eligible for a DEA registration as a practitioner one must be a physician, dentist, veterinarian, hospital, etc. To be valid a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. DEA expects the practitioner to determine in his or her professional judgment whether a legitimate medical purpose exists for a controlled substance prescription; an agent may not make this determination. The core responsibilities pertaining to prescribing may not be delegated to someone else, however, an individual practitioner may authorize an agent to perform a limited role in communicating prescriptions to a pharmacy in order to make the prescription process more efficient. Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III through V by conveying all of the prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey the prescription information to the pharmacist. The prescriber must manifest assent for a certain person to act on his or her behalf. Therefore, it is important for a practitioner to decide who may act as his or her agent. It is also important for the pharmacist to inquire on the legitimacy of the prescription under certain circumstances.

The policy statement outlines the proper role of agents in situations where an individual practitioner and a long-term care facility nurse have taken affirmative steps to establish a valid agency relationship. Regardless of the setting it is the practitioner's sole decision whether or not to designate an agent to act on his or her behalf and subject to his or her control. DEA believes that it is in the best interests of the practitioner and the agent that the designation of those persons authorized to act on behalf of the practitioner and the scope of the authorization be reduced to writing. DEA has provided an example in their policy statement which can be found on the Board of Pharmacy Web site at *www.kansas.gov/pharmacy* under the link DEA Publishes Policy Change On "Agent of the Prescriber."

Special Notice About the Kansas State Board Newsletter

The Kansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter and* keep it for future reference because the *Newsletter* may be used in hearings as proof of notification of its contents. Please contact the Board office at 785/296-4056 if you have any questions about the articles.

FDA Adverse Events Toll-Free Number

The Board of Pharmacy would like to remind community pharmacists that every prescription dispensed after July 1, 2009, is required by FDA to contain the statement, "Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088." This statement may be distributed to patients in one of five ways:

- on a sticker attached to the unit package, vial, or container of the drug product;
- on a preprinted pharmacy prescription vial cap;
- on a separate sheet of paper;
- in consumer medication information; or
- in the appropriate FDA-approved medication guide that contains the side effects statement.

Calendar Notes

The next Board meeting will be December 2-3, at the Board office building in Topeka, KS. The office will be closed on December 24, 2010, for Christmas. The Board meetings for 2011 are March 9-10 at University of Kansas School of Pharmacy in Lawrence, KS; June 8-9 in Topeka, KS; September 8-9 at Via Christi Hospital in Wichita, KS; and November 30-December 1 in Topeka, KS. All meetings are open to the public.

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 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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