June 2012

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *www.kansas.gov/pharmacy/*

Drug Information Center

The University of Kansas (KU) Drug Information Center offers free drug information services to the pharmacy profession in the state of Kansas regarding drug information questions. Contact can be made by phone at 913/588-2328 or 1-800/232-3748 or e-mail at druginfo@kumc.edu.

Board Member Appointments

The Kansas State Board of Pharmacy recently added two new members to it ranks. Governor Sam Brownback appointed John Worden, PharmD, MS, and Mike Lonergan, RPh, to replace two members who have served admirably but whose four-year terms have expired. John Worden has been appointed to succeed Dr Shirley Arck. John currently serves as the director of pharmacy for McPherson Hospital in McPherson, KS. John is a native of Norton, KS, and he graduated from the KU School of Pharmacy in 2005 with a doctor of pharmacy degree. He earned a master's degree in hospital pharmacy administration from KU in 2007. He is also a Board certified pharmacotherapy specialist. John's term expires in 2016. Mike Lonergan has been appointed to succeed Michael Coast, RPh. Mike currently serves as the director of specialty pharmacy for Optum Rx in Overland Park, KS. Mike is a native of Iola, KS, and he received his bachelor of science in pharmacy from the KU School of Pharmacy in 1999. Mike is a certified pharmacist immunizer. Mike's term expires in 2016.

The Kansas State Board of Pharmacy staff welcomes the new members and wishes them great success and accomplishments during their tenure.

Fifty-Year Pharmacists

The Board congratulates the following pharmacists who were originally licensed in 1961, have continuously maintained their Kansas pharmacist license, and have devoted a half-century of service to the public and their profession:

Charles H. Herrelson..... Grove, OK
Waldo W. Hale ..... Lakin, KS
Robert A. Exon..... Topeka, KS
Jackson M. Gabelmann..... Bulverde, TX
Robert O. Iott..... Yakima, WA
Jack H. Klee ..... Olathe, KS
James C. MacDonald ..... Topeka, KS
Gary D. Pound..... Hutchinson, KS
Warren H. Robertson ..... Tribune, KS
Clifford A. Triplett .....Ozark, MO
Darryl D. Warren ..... Topeka, KS
Robert Kingsolver..... Garnett, KS

Revisions to the Pharmacy Practice Act and Controlled Substances Act

The 2012 Legislature amended K.S.A. 65-1637 so that a pharmacist may provide up to a three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply. "Psychotherapeutic drug" is not defined in the statute but generally are those prescribed for their effects relieving symptoms of anxiety, depression, or other mental disorders. This change takes effect on July 1, 2012. The complete legislation can be found in Senate Bill 211.

Senate Bill 134 has amended K.S.A. 65-4111 and 65-4113, respectively, to include carisoprodol to Schedule IV and ezogabine to the Schedule V controlled substance list. K.S.A. 65-1626 was amended by adding language that will permit a nonnarcotic depressant listed in Schedule V to be distributed as a sample. There are currently three drugs that meet this requirement. They are ezogabine, lacosamide, and pregabalin. No other controlled substances may be distributed as a sample in Kansas.

A prescription for a Schedule III, IV, or V controlled substance may authorize no more than five refills within six months following the date on which the prescription is issued. These changes are effective May 17, 2012.

Continued on page 4

DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

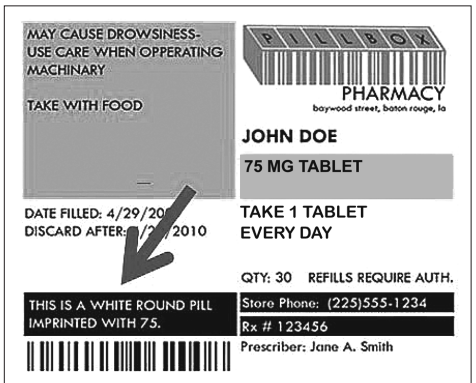
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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 an 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

A COLLABORATIVE SERVICE cpe monitor FROM ACPE AND NABP™

Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit ***www.MyCPEmonitor.net*** to set up your e-Profile and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

Continued from page 1

Several changes were made to the statute that applies to the K-TRACS Prescription Drug Monitoring Program. The Board is now authorized to accept grants, donations, gifts, or bequests that further the K-TRACS program.

The Board is authorized to provide data from the K-TRACS data to medical examiners, coroners, or other persons authorized under law to investigate or determine causes of death.

The K-TRACS Advisory Committee is now authorized to review and analyze data from K-TRACS for purposes of identifying patterns and activities of concern. If a review of the information appears to indicate that a patient may be obtaining prescriptions in a manner that represents misuse or abuse of controlled substances or drugs of concern, the advisory committee may notify the prescribers and dispensers. If there is reasonable suspicion of criminal activity the committee may notify the appropriate law enforcement agency.

The advisory committee may also establish criteria regarding appropriate standards of care and utilize a volunteer peer review committee of professionals with expertise in the particular practice in order to determine whether the standards for that profession have been exceeded. The committee is authorized to provide educational resources or professional advising to health care professionals when appropriate. The committee may also make referrals to regulatory or law enforcement agencies when warranted.

A person who knowingly, and without authorization, obtains or attempts to obtain prescription monitoring information shall be guilty of a severity level 10, nonperson felony. Changes to K-TRACS legislation are effective May 17, 2012.

Senate Bill 134 also made changes to the definitions in the Pharmacy Practice Act and the Controlled Substances Act related to electronic prescriptions. Definitions have been added to K.S.A. 65-1626 defining electronic prescriptions and electronic transmissions as well as other technical terms related to electronic prescribing. A "valid prescription order" has been defined to mean a prescription that is issued for a legitimate medical purpose by an individual prescriber licensed by law to administer and prescribe drugs and acting in the usual course of such prescriber's professional practice. A prescription issued solely on the basis of an Internet-based questionnaire or consultation without an appropriate prescriber-patient relationship is not a valid prescription.

Senate Bill 134 also amended the Pharmacy Practice Act so that there are definitions that relate to both written, oral, faxed, or electronically prepared and transmitted prescription orders. A major change is that prescriptions that are oral, faxed, or transmitted by the prescriber's agent shall now include both the first and last names of the transmitting agent. If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy.

An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to electronic transmission. An electronically prepared and transmitted prescription that is printed following electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

An authorization to refill a prescription order or to renew or continue an existing drug therapy may be transmitted to a pharmacist through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber. If the transmission is completed by the prescriber's agent, the first and last names of the transmitting agent need to be included in the order; the prescriber's signature is not required on the fax or alternate electronic transmission.

If the refill order or renewal order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order.

The Board is now authorized to conduct pilot projects related to any new technology implementation when deemed necessary and practicable, except that no state moneys shall be expended for such purpose.

Unrelated to pilot projects, the Board shall consult with industry and conduct a study on the issues of electronic transmission of prior authorizations and step therapy protocols. The report results shall be completed and submitted to the legislature no later than January 15, 2013.

House Bill 2523 amended K.S.A. 65-443 so that no person shall be required to perform, refer for, or participate in medical procedures or in the prescription or administration of any device or drug, which results in the termination of a pregnancy or an effect of which the person reasonably believes may result in the termination of a pregnancy, and the refusal of any person to perform, refer for, or participate in those medical procedures, prescription, or administration shall not be a basis for civil liability to any person. This law takes effect July 1, 2012.

The Board will post a complete copy of each bill on its Web site at *www.kansas.gov/pharmacy* under the link for Kansas Pharmacy and Related Laws if you would like to review a complete copy of each change.

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.

Debra L. Billingsley, JD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager