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Kansas State Board of Pharmacy

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Fifty Years of Service

Congratulations to the following pharmacists who were honored in 2006 for completing 50 years of continuous licensed service to the citizens of Kansas and the profession of pharmacy. The Kansas State Board of Pharmacy is grateful for their years of contribution to the profession.

Con R. Spainhour ..... Winfield
Geraldine A. Liebert ..... Coffeyville
Eugene L. Kermashek ..... Bella Vista, AR
James F. Schneweis ..... Hoisington
Samuel R. Wagner ..... Harlan
James S. DeGoler ..... Mission

New Board Members

Governor Kathleen Sebelius has appointed three new members to the Board of Pharmacy. Frank Whitchurch, RPh, is the pharmacy manager and pharmacist-in-charge (PIC) for Prescription Solutions in Overland Park, KS. He was previously the pharmacy manager of Osco Drug in Kansas City, KS, and he served as a pharmacy operations specialist for Osco in Kansas and Missouri. Mr Whitchurch previously served on the Board of Pharmacy from 2002 until 2005 and is a current member of the Kansas Pharmacists Association (KPhA). He graduated from the University of Missouri School of Pharmacy in 1970. Mr Whitchurch and his wife Deborah live in Kansas City. Mr Whitchurch succeeds Merlin McFarland on the Board, and he is happy to be back serving the Board of Pharmacy.

Karen Braman, RPh, MS, has been appointed to her first term on the Board. She is the pharmacy director for Preferred Health Systems. Prior to that Ms Braman held leadership positions within the Kansas Health Policy Authority, was the deputy director of the Governor's Office of Health Planning and Finance and the Kansas Medicaid program director. She obtained her bachelor of science degree in 1991 and master of science degree in pharmacy in 1993 from the University of Kansas (KU) and completed an American Society of Health-System Pharmacists-accredited residency in pharmacy practice at the KU Medical Center in 1993. She has over 16 years of experience in pharmacy, prescription benefits management, and health policy, including 10 years with publicly funded health programs. Ms Braman and her husband, Keith, have two children and live in Lawrence, KS. Ms Braman succeeds Max Heidrick on the Board.

Nancy Kirk has been appointed as the public member of the Board of Pharmacy. Ms Kirk has a master's degree in social work from KU and she resides in Topeka, KS. She served 12 years in the Kansas House of Representatives and she serves on the Shawnee County Advocacy Council on Aging. She is a past board member of the YWCA and is a member of the Advisory Board of KU School of Social Welfare. She has also served on the Kansas Health Care Association Board of Directors. Ms Kirk was recently elected to the Topeka 501 School Board. Ms Kirk succeeds Howard Paul on the Board.

The Kansas State Board of Pharmacy staff welcomes all three Board members and wishes them great success and accomplishment during their tenure. The Board appreciates the leadership and years of dedicated service provided by the three outgoing Board members: Max Heidrick, Merlin McFarland, and Howard Paul.

Disciplinary Actions

Case No. 06-22 – A pharmacist in Kansas City, KS, was disciplined by the Board entering an order assessing an administrative fine of $500.

Case No. 06-49 – Walgreens Pharmacy #5539, 700 S Broadway, Salina, Kansas 67401, was assessed an administrative fine of $500 for failing to prepare an incident report.

Case No. 06-53 – A pharmacist in Ottawa, KS, was disciplined by the Board entering an order assessing an administrative fine of $1,000 and requiring the pharmacist to retake the PIC examination.

Case No. 06-55 – License is indefinitely suspended until further order of the Board.

Case No. 06-57 – Price Chopper Pharmacy, 7201 W 151st, Overland Park, KS 66223, was assessed an administrative fine of $500 for failing to prepare an incident report.

Case No. 06-59 – A pharmacist and PIC from Oberlin, KS, was disciplined by order of the Board assessing an administrative fine of $500 for approving a policy manual that did not comply with the pharmacy laws.

Case No. 06-61 – A pharmacist from Olathe, KS, was disciplined by order of the Board for diversion by requiring him to enter into the Kansas Pharmacy Impaired Provider Program for a period of no less than five years.

Case No. 06-67 – A pharmacist from Kansas City, KS, was disciplined by order of the Board requiring him to enter into the Kansas Pharmacy Impaired Provider Program for a period of no less than five years.

Case No. 06-74 – A pharmacy in Dighton, KS, was assessed administrative fines totaling $2,000 for failing to prepare incident reports regarding the mislabeling of drugs.

Case No. 06-93 – Denial of Reinstatement of License

Case No. 06-95 – A pharmacist from McPherson, KS, was disciplined by order of the Board imposing mandatory participation in an Impaired Provider Program.

Case No. 06-100 – Pharmacy technician, Leavenworth, KS. Registration revoked based upon a finding he diverted controlled substances (CS) and providing them to a third party.

FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

Changes in Medication Appearance Should Prompt Investigation

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

As the number of generic products continues 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. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. 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.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

Contingency Plan Allows Extension for NPI Compliance

Pharmacies that missed the May 23, 2007 deadline for using the National Provider Identifier (NPI) required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may be able to take an extension of up to one year. To be eligible, pharmacists must demonstrate "good faith" effort to come into compliance by developing and implementing a plan to enable them and their trading partners to move toward compliance. More information is available at *www.cms.hhs.gov/nationalprovidentstand*.

2007 Legislative Changes

The 2007 legislative session instituted several changes to the Kansas Pharmacy Act. House Bill 2096 made some technical amendments to how Board meetings operate. The amendment permits the Board to hold an annual election of officers at any time throughout the year. A second change deleted an outdated requirement that the Board hold an annual meeting for the purpose of examining applicants for licensure as pharmacists.

Senate Bill (SB) 63 amended KSA 65-1637(e) whereby it clarifies the refill limitations for a noncontrolled PRN prescription drug. A prescription for a noncontrolled medication written PRN will now specifically expire one year after the prescription was originally issued.

An amendment to KSA 65-2837a (b) was made in SB 62. Prescriptions for Schedule II, III, and IV, amphetamine or sympathomimetic amines will no longer require the diagnosis. Schedule III and IV prescriptions in this category may be faxed.

Several changes were made to the law regarding CS and paraphernalia and provided state law conformity with the Combat Methamphetamine Epidemic Act of 2005. One change was that the legislature established an 11-member Controlled Substance Monitoring Task Force to develop a plan for the creation and implementation of a prescription drug monitoring program. These programs require prescription data for CS to be submitted to a central database administered by the Board of Pharmacy. The program would help prevent and detect the diversion and abuse of pharmaceutical CS and is not intended to discourage or interfere with the prescribing of CS for legitimate medical purposes.

The second objective of the task force would be to create and establish a real-time electronic purchase log concerning the sales of ephedrine and pseudoephedrine.

Thirdly, the bill makes all forms of over-the-counter (OTC) ephedrine, pseudoephedrine, and phenylpropanolamine a Schedule V CS. Effective July 1, 2007, all OTC liquids and gelcaps will join the tablets as Schedule V substances and will only be sold at a pharmacy. Prescriptions remain exempt. It will be unlawful for customers to have direct access to any ephedrine or pseudoephedrine product, so it must be behind the pharmacy counter or stored in a locked cabinet. The law makes it a class A, nonperson misdemeanor for any person to purchase, receive or otherwise acquire more than 3.6 g in a single transaction or more than 9 g within any 30-day period of pseudoephedrine base or ephedrine base. The substance may be sold by a licensed pharmacist, a registered pharmacy technician, a pharmacy intern, or a clerk supervised by a licensed pharmacist. The seller must verify that the name entered in the log corresponds to the name provided on the identification. The purchaser must sign the log. The log must also show the person's address and the date and time of the sale. The log must have the name of the CS and the quantity sold. The log or database shall be available for inspection during regular business hours to the Board of Pharmacy and any law enforcement officer. The bill also provides immunity to the pharmacy employees who in good faith release information in the log to law enforcement officers. The federal law will continue to require a notice with the logbook that will notify purchasers that any false statements in the logbook may result in criminal penalties. For more specifics on these and other legislative changes go to the Board's Web site at *www.kansas.gov/pharmacy.*

The legislature also amended and created new requirements for wholesale drug registrants. A new registration was created for companies selling or leasing durable medical equipment.

Lastly, SB 11 will now permit a pharmacy student or intern who has an immunization certificate to immunize patients so long as he or she is working under the direct supervision of a pharmacist who also has an immunization certificate.

The Board amended the ratio regulation at the March Board meeting. The ratio shall not exceed two to one except for the following: the ratio may be three to one if at least two of the pharmacy technicians have a current certification issued by Pharmacy Technician Certification Board (PTCB) or have a current certification issued by another organization approved by the Board. The Board has approved PTCB and Institute for the Certification of Pharmacy Technicians at this time.

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