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Kansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Fifty Years Of Service

Congratulations to the following pharmacists who were honored in 2005 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.

James R. Sellers ..... Cheney
Lowell R. Macy..... Vermillion
Edith E. Crouse ..... Kansas City
Ralph I. Bretches..... Newton
John W. Heavin ..... Joplin, MO
Roger B. Miller ..... Bonner Springs
Richard L. Marquardt..... Hugoton
Robert E. Learned, Jr ..... Manhattan
William H. Hoffman ..... Westmoreland
William G. Hawes..... Smith Center
Elizabeth M. Burger..... Bartlesville, OK

Disciplinary Actions

Case No. 05-36 – Nonresident pharmacy fined $500 for failing to have consumer toll-free number on label.

Case No. 05-38 – Christine Carrell, RPh – Board accepted licensee's voluntary surrender of license.

Case No. 05-43 – Pharmacist fined $1,000 for permitting pharmacy technicians in pharmacy when pharmacist was not on premises. Pharmacy technicians required to take pharmacy technician examination within 30 days.

Case No. 05-67 – Pharmacy fined $500 for failure to file incident report.

Case No. 06-02 – Pharmacy fined $500 for failure to register pharmacy technician.

Case No. 06-04 – Pharmacy fined $500 for failure to register pharmacy technicians.

Case No. 06-08 – Pharmacy fined $1,460 for operating without a pharmacist-in-charge (PIC) for period in excess of 30 days and $500 for failure to register pharmacy technician.

Case No. 06-09 – Pharmacy fined $1,340 for operating without a PIC for period in excess of 30 days.

Case No. 06-11 – Pharmacy fined $1,740 for operating without a PIC for period in excess of 30 days.

Case No. 06-12 – Pharmacy fined $1,780 for operating without a PIC for a period in excess of 30 days.

Case No. 06-27 – Jonathan A. Zanders, #14-03442 – Pharmacy Technician, Junction City. Registration Revoked for Drug Diversion.

Pharmacy Technician Registration

In 2004, the Board of Pharmacy began registering all pharmacy technicians working in Kansas. K.S.A. 65-1663 states that it shall be unlawful to function as a pharmacy technician in this state unless such person is registered with the Board. The technician must have the registration card in his or her possession before they can function as a pharmacy technician. The technician registrations are issued every two years based on whether or not the registration is an odd or even number. The renewal is sent to the pharmacy technician's home address so the Board office should be notified whenever there is a change of address. The technician registration renewals are due October 31, 2006. Please mark your calendars to check that your technician has appropriately renewed his or her registration with the Board to prevent a fine against the pharmacy.

2006 Legislative Changes

The 2006 legislative session instituted several changes to the Kansas Pharmacy Act. House Bill (HB) 2830 amended existing pharmacy law regarding the registration of pharmacy technicians to require technicians to pass a Board-approved examination within 30 days of registration with the State Board of Pharmacy. Previously, an applicant for registration would have to pass the examination prior to registration. With this change the PIC will not have to certify on the pharmacy technician application that the applicant took and passed an examination. The test must be given within 30 days of the technician being registered with the Board and the test results shall be maintained at the pharmacy in a manner available for inspection by a Board representative. This change should

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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provide for smoother transition in training technicians before they are required to pass an examination.

HB 2830 also added a provision to K.S.A. 65-1663, which will require any change to the pharmacist-to-technician ratio in the prescription area to be adopted by a vote of not less than five members of the Board.

HB 2678 repealed K.S.A. 65-1661, which required Medicare-approved renal dialysis facilities that kept prescription drugs as part of their services, to be registered with the Board of Pharmacy. This statute was enacted in 1998 and none of the facilities ever applied for licensure or complied with this law. Therefore, the legislature determined that the Board would no longer be responsible for these facilities.

As of the writing of this *Newsletter* there are several bills that are still in conference committee. The Wholesale Licensure and Prescription Medication Integrity Act is one topic that remains in committee. The original bill was introduced by Pfizer and mandated the Board of Pharmacy to implement paper pedigree and then electronic pedigree requirements in the state. It also included licensure provisions for prescription drug distributors rather than registration. After much debate, many meetings, sub-committees, and many amendments, the final language would require the Board of Pharmacy to conduct a study on the issue of licensing wholesale prescription drug distributors and the use of pedigree for prescription drugs and the penalty aspects for violation of any pedigree requirements. The results of such study shall be completed and presented along with a licensing and pedigree plan and recommendations for licensing and pedigree legislation to the legislature no later than January 15, 2007. Regardless of whether or not this bill becomes law the Board will conduct a study and present the legislature with proposed bill language next year. The pedigree requirement and wholesale prescription distributor licensing will help combat counterfeit drugs that gain access through the secondary drug distribution system. The Board supports this type of legislation and looks forward to the opportunity of drafting language that will revise our wholesale distributor requirements in a manner that will protect the public from counterfeit drug products.

CEU Approval Requirements

K.A.R. 68-1-1b sets out the requirements for continuing education (CE) approval. The Board approves all CE programs that have been recognized by Accreditation Council for Pharmacy Education. Any requests made to the Board for CE approval shall be submitted at least 120 days in advance of the event for approval. CE credit shall not include in-service programs, on-the-job training, orientation for a job, an education program that is open to the general public, cardio pulmonary resuscitation (CPR), basic cardiac life support, code blue, or testing out of a course. Please keep these requirements in mind before submitting any requests for approval.

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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