September 2006

Kansas State Board of Pharmacy

Landon State Office Bldg
900 Jackson, Room 560
Topeka, KS 66612
www.kansas.gov/pharmacy/

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

Case No. 05-60 – Pharmacist assessed a fine of $5,000 for filling prescriptions for himself and his wife that were not authorized by a practitioner.

Case No. 05-65 – Pharmacy fined $1,000 and ordered to install an operating alarm system. Pharmacy also ordered to adopt and enforce procedures requiring each person receiving narcotics delivered to store to sign his or her name to incoming invoice receipt.

Case No. 05-65A – Pharmacy fined $1,000 and ordered to install an operating alarm system. Pharmacy also ordered to adopt and enforce procedures requiring each person receiving narcotics delivered to store to sign his or her name to incoming invoice receipt.

Case No. 06-03 – Pharmacy fined $2,380 for operating without a pharmacist-in-charge (PIC) for a period in excess of 30 days.

Case No. 06-25 – Pharmacy fined $500 for failure to register pharmacy technician.

Case No. 06-33 – Pharmacy fined $500 for failure to register pharmacy technician.

Case No. 06-42 – Pharmacy fined $500 for failure to register pharmacy technician.

Case No. 06-48 – Pharmacy fined $500 for failure to register pharmacy technician.

(Specific information on these cases can be found in the Kansas State Board of Pharmacy minutes or on the Board's Web site.)

Pharmacy Technician Registration

Pharmacy technician registration will begin the first of September 2006. All technicians with an even-numbered registration number are required to renew their registration by October 31, 2006. The renewal fee is $25. Registration submitted after November 30, 2006, will result in an additional late fee of $25. The Board of Pharmacy is pleased to announce that they have partnered with Information Network of Kansas, Inc, to provide online renewals for pharmacy technicians this year. Pharmacy technicians are encouraged to register online. It is quick, easy, and safe. To renew simply go to the Board's Web site at www.kansas.gov/pharmacy. Go to the link on the left side of the page titled **"Online Renewals."** You can pay with either a credit card or check. A reminder will be sent to the pharmacy technician's home address regarding renewals. It is the technician's responsibility to let the Board know if they have changed addresses. Changes of address must be done in writing to the Board office. You can either e-mail the Board at pharmacy@pharmacy.ks.gov, send a fax to 785/296-8420, or send a letter to the Board at 900 SW Jackson, Room 560, Topeka, KS 66612-1231.

Training of Pharmacy Technicians

New technicians must be registered with the Board prior to entering the pharmacy and functioning as a technician. If unregistered individuals are found working in the pharmacy, the pharmacy will be fined $500. The pharmacy technician application is available on the Board Web site under the link for **"Applications and Forms."** Within 30 days of employment the PIC must give each **newly registered** technician an examination. The examination should test general and minimal legal requirements that relate to pharmacy law and pharmacy technicians. The pharmacy may either write their own examination and have it approved by the Board, or they may use Board-approved questions. The technician must have a passing score of at least 75%. The test must be maintained in the pharmacy file and be available to the inspector during a site visit. The PIC is no longer required to submit anything to the Board office signifying that the technician has passed the test. A pharmacy technician only has to take this test once. If they change jobs and already have their Board registration, they are not required to take the test again. It is a one-time test given when the individual is first registered. Technician registration numbers do not change and the individual will always have the same number forever. They do not have to fill out a new application with the Board when they change jobs. They just need to let the Board know that they have changed employment.

The PIC is required to design a pharmacy technician training course. The training manual shall be kept up-to-date for completeness. The Board inspectors will accept either a signed and dated statement, kept with the manual, that the manual has been reviewed annually or have an annually signed and dated list of functions that each technician has been trained to perform. The list of functions is found at K.A.R. 68-5-15. The PIC will need to have separate documentation that each

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Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion

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.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

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pharmacy technician has been trained within 180 days of his or her employment at your practice. This training is more in-depth than the initial training that is given to the technician within the first 30 days.

The PIC is also responsible for making sure that each technician is registered with the Board prior to their functioning as a technician. The technician should have a pocket card that is issued by the Board.

Kansas Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. The Committee on Impaired Pharmacy Practice (CIPP) is readily available for help. Pharmacists in Kansas may call the CIPP Help-Line at 1-800/279-9300. CIPP is supported by a grant from the Kansas State Board of Pharmacy and by donated time and services of pharmacists and pharmacy intern volunteers. All calls are confidential and are not known to the Board of Pharmacy.

Combat Methamphetamine Epidemic Act of 2005

Congress passed the new Patriot Act this year, which also contains the federal initiative to thwart the manufacturing and distribution of methamphetamine. There are portions of this law still to be proposed as regulations in the near future, but the federal law will require changes in how retail pharmacies and retail dealers (ie, grocery stores, general merchandise stores) sell ephedrine, pseuodephedrine, and phenylpropanolamine products. All forms of these products are covered under federal law. The law did not make these products a controlled substance but it designates all non-prescription drug products as "scheduled listed chemical products." Retail pharmacies and over-the-counter (OTC) retailers will be limited to selling no more than 3.6 grams per purchaser daily or 9 grams over a 30-day period regardless of the number of transactions. The limit for dosage units went into effect on April 8, 2006. Non-liquid forms (including gelcaps) must be sold in a 2-unit blister pack (with the exception that when a blister pack is not technically feasible, the product may be in unit dosage packets or pouches). Items that were exempt in Kansas (gelcaps and liquids) will now require additional information from both pharmacies and OTC retailers. The purchase must be reported in an electronic or written logbook and will include the product by name, quantity sold, name and address of purchaser, date and time of each transaction, the use of a photo identification for proof of identity, and the purchaser must sign the logbook. A notice must be available with the logbook that will notify the purchasers that any false statements in the logbook may result in criminal penalties. Training of personnel that assist in any transactions of these products will be required. Pharmacies and OTC retail dealers will have to verify online with the United States Attorney General that such training has taken place. A self-certification process will be required as well. Rules and regulations are currently being promulgated concerning the maintenance of confidentiality of the logbook information. Release of information to state, federal, or local law enforcement agencies in good faith will be immune from civil liability. The effective date of most of the provisions in the Act will be September 30, 2006.

Schedule V starch tablets must be logged in at the pharmacy. OTC gelcaps and liquids must be placed so that customers do not have direct access before the sale is made ("behind-the-counter placement") or in a locked cabinet that is located in an area to which customers do not have direct access.

The Board realizes that the federal law conflicts with the requirements of state law. The Board reviewed this issue at its September 2006 meeting to determine if additional consistency is necessary in state law. If you have any comments or concerns please let your Board members know.

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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