June 2005

Kansas State Board of Pharmacy

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www.accesskansas.org/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Senate Bill (SB) 27: Methamphetamine Precursor Substances

The State of Kansas' precursor law was passed during the 2005 legislative session and published on April 21, 2005. This law should have a significant impact on the availability of precursor chemicals for illegal purposes. The one need that persisted for clandestine methamphetamine (meth) makers was the need for products that contain ephedrine and pseudoephedrine (PSE). These products remained widely available in common cold and flu remedies that could be found on store shelves.

Effective June 1, 2005, single and combination products that contain any amount of ephedrine or PSE that are in starch tablet form or gel-coated starch tablet form are now Schedule V. A limit of three boxes within a seven-day period now exists for the sale of these products. The size of the box is not specified in the statute. Each purchaser must provide a photo identification that shows the purchaser's date of birth and the purchaser must sign a log book. The other requirements of a Schedule V log book can be found at K.A.R. 68-20-22. Single ingredient PSE or combination ephedrine and PSE products that are in liquid form or gel-filled capsules are exempt and may be sold over the counter.

The new law requires the Kansas State Board of Pharmacy to gather information and detect trends with regard to the types of illicit drug activity in your community so that recommendations can be made regarding future controls of abused chemicals. Your continued vigilance and support in reporting drug activity would be greatly appreciated. Each pharmacy has a unique opportunity to make a positive difference by providing roadblocks to meth makers' access to their active ingredients. You will also be promoting a positive impact on the livableness of our state. For more information on what SB 27 requires, see the Board's Web site at www.accesskansas.org/pharmacy.

Other Legislative News

The 2005 legislative session was very busy. Clarification was made regarding what type of disciplinary action the Board could take against a pharmacy technician. Additional language was added that would permit the Board to limit, suspend, or revoke a pharmacy technician registration. Please report technician problems to the Board so that his or her registration may be limited, particularly if the individual is unqualified or unprofessional in his or her practice. The law also removed the technician-to-pharmacist ratio authority from the statute and placed it with the Board's regulatory authority. The Board will be drafting regulations regarding the technician ratio in the near future. The Board will accept public comment regarding the regulation once it is drafted. Your input is important to the Board regarding this and any other matter of mutual concern. Please review the Board meeting agendas for issues and topics being discussed.

The legislature also provided a mechanism in House Bill (HB) 2155 for pharmacists to refill a prescription order on an emergency basis without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgement, continuation of the medication is necessary for the patient's health, safety, and welfare. The pharmacist can provide a sufficient amount to the patient, but in no event shall he or she provide more than a seven-day supply or one package unit. The one package unit was intended to cover those types of medications such as inhalers that do not come in a seven-day supply. The pharmacist should contact the physician on the next business day or as soon thereafter as possible.

A third change in the law is HB 2077, which creates a cancer drug repository program. The Board of Pharmacy will establish the cancer drug repository program through rules and regulations so those drugs may be donated and dispensed to cancer patients. Only cancer drugs in their original sealed and tamper-evident unit-dose packaging may be accepted and dispensed. This program will be voluntary to all participants and will provide some much-needed relief to cancer patients burdened with the high costs of pharmaceuticals.

If you would like to see copies of the bills that were passed this session, they are available on the Board's Web site under the link "Hot Topics."

Board Honors 50-Year Pharmacists

Congratulations to the following pharmacists who have been licensed in good standing with the Kansas State Board of Pharmacy for 50 years. The Board of Pharmacy is grateful for their years of contribution to the pharmacy profession.

Albert L. Park .....Osage City

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National Pharmacy C

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and can only be ascertained by examining

Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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Rebecca J. Griswold ..... Goddard
George E. Sims ..... Kansas City
Thomas C. Schermuly..... Wichita
Myron E. Kelso..... Coffeyville
Milton N. Hogue ..... Albuquerque, NM
Robert E. Galvin .....Fort Scott
Walter W. Ritzman ..... Estes Park, CO

Disciplinary Actions

Bryan T. Simpson, RPh, Joplin, MO – disciplined by Order of the Board.

John C. Preble, RPh, Prairie Village – disciplined by Order of the Board because of an order entered by the Colorado State Board of Pharmacy.

Rachelle Lechtenberg, RPh, Lawrence – disciplined by the Board for failure to comply with a requirement of a Board order.

Pamela L. Stoddart, RPh, Platte Woods, MO – indefinite suspension.

Reinstatements

Michael L. Linder, RPh, Hutchinson – Order of Reinstatement.

Continuing Education Reminder/License Renewal

Kansas pharmacist license renewals for licenses ending in an odd number were sent out in May of 2005. Pharmacists need 30 hours of continuing education (CE) credits, for each biennial period, that are dated June 1, 2003, or later. They must be Accreditation Council for Pharmacy Education, Continuing Medical Education-Category I, or Board of Pharmacy approved. You may also renew online. Ten percent of licensees will have their CE credits audited and they are randomly selected. You will be notified via a letter in August advising that you have been selected for a CE audit. The Board will also post a list of persons who are being audited on our Web site. If you do not receive an audit letter but see your name on the Web site you will need to contact the Board office. Failure to provide the Board with proof of CE compliance within 30 days of the request will result in an automatic late fee of $200.

Upcoming Board of Pharmacy Meetings

The Board of Pharmacy is encouraging all pharmacists to mark their calendar for the following meeting dates in 2005.

June 7-8 ..... Topeka
September 20-21 ..... Topeka
December 6-7 ..... Topeka

Board meetings are open to the public and pharmacists are encouraged to attend. While the meetings have a formal structure there are public comment periods for the agenda items. If you would like to be placed on the meeting agenda distribution list, please contact Karen Hollon at the Board Office at 785/296-6504. This is a great opportunity to help the profession progress.

Kansas Committee on Impaired Pharmacy Practice

Confidential assistance for anyone needing help or having concerns about drug- or alcohol-related problems involving himself or herself, a colleague, an employer, employee, or family member can be found by calling toll-free at 1-800/279-9300. Your call will be answered by a professional who can give you confidential guidance or a referral. The Committee on Impaired Pharmacy Practice (CIPP) program is supported by a grant from the Kansas State Board of Pharmacy and by donated time and services of pharmacists and pharmacy intern volunteers. Together, pharmacists and CIPP can work toward overcoming chemical dependence.

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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