March 2008

Kansas State Board of Pharmacy

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900 Jackson, Room 560
Topeka, KS 66612
www.kansas.gov/pharmacy/

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

Registration of the following technicians has been revoked, and they are not eligible for employment:

Corey Gene Farley	Reg #14-03394	Kansas City, MO
Cindy L. Mares	Reg #14-06398	Frontenac, KS
Shawnna L. Marrs	Reg #14-03421	Overland Park, KS
Angela Walts	Reg #14-04891	Fort Scott, KS
Heather Williams	Reg #14-06836	Mulvane, KS
Lindsay Manning	Reg #14-05304	Topeka, KS

Tamper-Resistant Prescription Pads

Congress has delayed the implementation of section 7002(b) of the US Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007. The requirement that all written Medicaid prescriptions for fee-for-service program patients must be on tamper-resistant paper effective April 1, 2008. This is required by federal standards and includes prescriptions where Medicaid is the primary or secondary payer. Pharmacies that fill prescriptions written on noncompliant pads may have their reimbursements recouped and potentially be subject to other charges. The federal rules require that the tamper-resistant paper comply with one of the following criteria: (1) that it prevent copying – example, shows the word "void" when copied; (2) that it prevent altering – example, chemical stains or an altered background show attempts at ink or toner removal; and (3) that it prevent counterfeiting – example, prescriptions have a watermark and cannot be reproduced.

After October 1, 2008, prescriptions must comply with all three characteristics. This law does not apply to e-prescriptions, prescriptions transmitted to the pharmacy by facsimile, and prescriptions communicated by telephone. Records, including documents for noncompliant prescriptions must be kept for six years based on Department of Social and Health Services (DSHS) rules.

Special Notice about this Newsletter

The *Kansas State Board of Pharmacy Newsletter* has been designated as the official method of notification to pharmacists, pharmacy technicians, and interns licensed by the Kansas State Board of Pharmacy. These *Newsletters* will be used in hearings as proof of notification and are available for review on the Board's Web site at *www.kansas.gov/pharmacy.*

Board Position on Use of Medical Marijuana

The Board of Pharmacy passed a resolution on December 17, 2007, opposing the use of leaf marijuana for medicinal applications unless first approved by the United States Food and Drug Administration (FDA). The Board entered the resolution after reviewing whether there were any scientific studies supporting the use of marijuana for treatment in the United States. It determined that there were safer and more reliable medications that exist that are best for patients but that also provide compassionate symptom management.

Number for Reporting Adverse Events on Labeling for Human Drug Products

FDA published its interim final rule to codify the modified toll-free number proposed rule that became effective January 1, 2008. The interim rule published on January 3, 2008, is titled "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products." The interim final rule requires the addition of a statement on the labeling of certain human drug products for which an application is approved under the Federal Food, Drug, and Cosmetic Act. The added statement includes a toll-free number and advises that the number is to be used only for reporting side effects and is not intended for medical advice. The rule does not apply to over-the-counter drug products approved as new drugs under the act if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints. FDA anticipates that affected entities, including manufacturers, authorized dispensers, and pharmacies, will need time to update labeling and systems to comply with the new requirements. Therefore, FDA intends to exercise its enforcement discretion and not take enforcement actions with regard to these regulations until January 1, 2009.

Change of PIC Requires Inventory of Controlled Substances

The Board recently amended its regulations regarding the responsibilities of the pharmacist-in-charge (PIC) regardless of the setting or type of pharmacy. The PIC is now required to inventory all controlled substances (CS) in the pharmacy before leaving his or her position as PIC. To avoid problems with the employer it would be beneficial to take the inventory prior to submitting the PIC resignation to the employer. However, it needs to be taken as close to the resignation date as possible so that it is an accurate count at the time of leaving the position. The new PIC must take an inventory of all CS in the pharmacy within 72 hours of beginning his or her functions as the PIC. All records of inventory must be maintained for a period of five years.

NABP Testifies in Support of Proposed BTC Class of Drugs

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer

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 and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. 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.*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drugs names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site *www.med-errs.com* and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals

and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see ***ISMP Medication Safety Alert!® Community/Ambulatory Edition***, Volume 4, issue 5, May 2005, **Reminyl®/ Amaryl® Your Reports at Work.**) may "smell" safer, and therefore "sweeter." Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with "illegible or incomprehensible" labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at *www.fda.gov/cder/dsn/default.htm* and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at *www.fda.gov/medwatch/safety.htm.*

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services' (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, *www.nabp.net.*

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at *www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.*

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

To order the *Survey,* visit *www.nabp.net* and download an order form; the cost is $20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey,* please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Institutional Drug Room Regulations

The Board of Pharmacy has a public hearing scheduled on March 5, 2008, at 9 AM for institutional drug room regulations. The proposed regulation is on the Board's Web page under the link "Proposed Regulations." The Board is aware that many jails in the state are not properly registered as institutional drug rooms. If you are servicing a city or county jail and providing medications to the patients, you should make sure that the jail has been properly registered with the Board of Pharmacy. The application can be downloaded off of the Board's Web page under the link "Applications and Forms." The fee is $25. Please make sure that you are not sending any drugs to a jail that has not been registered with the Board of Pharmacy. If there are any questions regarding this matter please do not hesitate to contact the Board office at 785/296-4056 for further information.

Proper Disposal of Prescription Drugs

The Office of National Drug Control Policy (ONDCP) issued guidelines February 20, 2007, for the proper disposal of unused, unneeded, or expired prescription drugs. ONDCP, the US Department of Health and Human Services, and the US Environmental Protection Agency jointly released the new guidelines, which are designed to reduce the diversion of prescription drugs, while also protecting the environment.

The new federal prescription drug disposal guidelines urge Americans to:

- Take unused, unneeded, or expired prescription drugs out of their original containers.
- Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and put them in impermeable, nondescript containers, such as empty cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children or pets.
- Throw these containers in the trash.
- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so.
- Return unused, unneeded, or expired prescription drugs to pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal.

FDA advised that the following drugs be flushed down the toilet instead of thrown in the trash:

Actiq® (fentanyl citrate)
Daytrana™ Transdermal Patch (methylphenidate)
Duragesic® Transdermal System (fentanyl)
OxyContin® tablets (oxycodone)
Avinza® capsules (morphine sulfate)
Baraclude™ tablets (entecavir)
Reyataz® capsules (atazanavir sulfate)
Tequin® tablets (gatifloxacin)
Zerit® for Oral Solutions (stavudine)
Meperidine HCI® tablets
Percocet® (oxycodone and acetaminophen)
Xyrem® (Sodium Oxybate)
Fentora® (fentanyl buccal tablet)

Note: Patients should always refer to printed materials accompanying their medication for specific instructions.

Methadone Hydrochloride Tablets 40 mg (Dispersible)

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will instruct their wholesale distributors to discontinue supplying the formulation to any facility not meeting the above criteria. The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies.

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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