



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.

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- Tom Frazier, RPh, Pratt785/231-8822
- Melissa Martin, Kansas City 785/220-2463
- Reyne Kenton, Dodge City..... 785/633-1043

Disciplinary Actions

The following technician registrations have been revoked, and the technicians are not eligible for employment:

Shannon Laymon	Reg # 14-04195	Lyons, KS
Debra Krueger	Reg # 14-00864	Kansas City, KS
Donna S. Muniz	Reg # 14-01499	Garden City, KS
Stacy Burgess	Reg # 14-03181	Topeka, KS

The following pharmacist no longer holds a pharmacist license: Jean Appelhanz, Lic # 1-12661; Lawrence, KS; Voluntary Surrender.

The Kansas State Board of Pharmacy has taken action against other licensees for the following violations:

- ◆ Failing to record the name of the person who phoned in a prescription
- ◆ Failing to fill prescriptions in strict conformity with directions of provider
- ◆ Unregistered technicians
- ◆ Operating more than 30 days without a pharmacist-in-charge

The Kansas State Board of Pharmacy renewed pharmacy technicians' registrations. At this time all technicians should be registered or renewed. Please check to make sure that your pharmacy technicians have registration expiration dates of either 2008 or 2009. A technician who has not renewed his or her registration may not work in the pharmacy until his or her

registration has formally been renewed by the Board. To renew in December, the pharmacy technician is required to pay the renewal fee and a \$25 late fee. For further information on Board disciplinary actions check the Board of Pharmacy Web site at www.kansas.gov/pharmacy/.

Internet Faxes

The Board office has received numerous complaints from physicians and pharmacists in Kansas concerning faxes that are being transmitted from an Internet company to business fax machines in Kansas including medical clinics and pharmacies. The faxes indicate that you can now order prescription medication without a prescription. They state that the patient can just fill out an online questionnaire and one of their doctors will write a prescription. Prescriptions are then sent electronically from the Web-based company to a participating pharmacy. The advertisement states that the online pharmacy will fill the order and ship it overnight to the patient's door. Weekly specials usually include generic Ultram® (tramadol), generic Soma® (carisoprodol), and generic Fiorcet® (butalbital, acetaminophen, and caffeine). Various Web sites are: MyPharmaCentral.net, MyPharmaUSA.biz, MyFirstPharma.com, MyPharmaStop.net, MyRXUnited.com, MyPharmaCentral.com, MyPharmaNow.com, MyDrugstore1.net, MyPharmaUnited.com, MyPharmacyWorld.net, Medicaltouch.net, and Checkuplink.com.

Beware of the dangers associated with starting business affiliations with Web-based companies that generate prescriptions on the basis of a questionnaire and not a patient-physician relationship. The Web-based companies are attempting to legitimize prescriptions by using a duly licensed pharmacy to supply the medications. Do not jeopardize your license by filling these types of prescriptions.

The Kansas State Board of Pharmacy is working with the Attorney General, Food and Drug Administration, and other state boards of pharmacy to stop this activity.

Valid Signature on a Prescription

Prescriptions that are handed directly to a patient must be manually signed by the prescriber. If a patient arrives with a prescription that has a computer-generated signature or a rubber-stamped signature, it is not valid and must be verified prior to dispensing.



Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at www.fda.gov/cder/meeting/medication_guides_200706.htm.

Reporting Makes a Difference



*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.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System*, and *Identifying and Preventing Medication Errors*, the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- ◆ Losec[®] (error reports indicating mistaken as Lasix[®]) to Prilosec[®],
- ◆ Levoxine (error reports indicating mistaken as Lanoxin[®]) to Levoxyl[®],
- ◆ Reminyl[®] (error reports indicating mistaken as Amaryl[®]) to Razadyne[™] (and unfortunately new error reports show Razadyne being mistaken as Rozerem[™])



◆ and the most recent, Omacor[®] (error reports indicating mistaken as Amicar[®]) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit www.ismp.org and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review www.fda.gov for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites[™] program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at www.cfsan.fda.gov/~dms/dscgmps7.html and a fact sheet at www.cfsan.fda.gov/~dms/dscgmps6.html.

More information is available on the FDA Unapproved Drugs Web site at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

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 be on tamper-resistant paper has a new effective date of April 1, 2008. This change was implemented to reduce fraud and abuse. Reimbursement will not be made on Medicaid prescriptions unless the prescription was executed on a tamper-resistant pad. While the law requires that physicians comply with the requirements of using tamper-resistant pads, the penalties for violations may fall on the pharmacists who knowingly fill prescriptions that are written on incorrect forms and then bill Medicaid for the drugs. This applies to all outpatient drugs, including over-the-counter drugs in states that reimburse for prescriptions of such items. The limitation does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy telephonically by the prescriber.

Kansas Board of Pharmacy Meeting Dates

December 11-12, 2007	Topeka
March 4-5, 2008	Lawrence
June 10-11, 2008	Topeka

The Board office will be closed December 24-25, 2007, for a state holiday.

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 of Pharmacy Task Force

Board of Pharmacy members and staff participate in a variety of task forces involving the future of pharmacy. One task force was mandated by the Kansas Legislature and is working toward development of an electronic pseudoephedrine purchase report-

ing system and a prescription drug monitoring program. This group consists of numerous interested professionals that have met several times. The members will have a report for the legislature documenting the outcome of the meeting and recommending suggestions.

A second task force has been working on classifying pharmacies. The members have determined that the current statutes and regulations are designed for the typical retail pharmacy and medical care facility. This group is working toward recommending regulations that fit the different varieties of pharmacy.

There is a group working on the importance of continuous quality improvement and making those records protected or non-discoverable.

Lastly, a task force continues to work on the pedigree issue. The Board hopes to draft regulations that will protect the public from the risk of counterfeit drugs making their way into the drug delivery system.

The Board will continue to work toward relevant issues that are facing pharmacy today. These meetings are open to the public, and anyone is welcome to attend. If you have an interest in participating in any task force, the meeting dates are noted on the Board's Web site.

Do You Know a Pharmacist or Intern/Student Who Needs Help?

If you or a pharmacist you care about is suffering from chemical dependency or stress related issues, there is a solution. Call the Committee on Impaired Pharmacy Practice help line at 913/236-7575. All calls are confidential.

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KANSAS STATE BOARD OF PHARMACY

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