December 2007

Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Spindletop Administration Building
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Happy Holidays!!!!
From the
Kentucky Board of Pharmacy
Board Members and Staff

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between **January 1 and December 31** pursuant to 201 KAR 2:015 Section 5(1). A pharmacist first licensed by the Board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2008 Pharmacist Renewals

Pharmacist licenses expire on February 28, 2008. The Board will send out a **postcard** the first week of January 2008 as a reminder (in addition, pharmacists that renewed online last year will be sent a reminder via e-mail). Again, this year you may renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site: *www.pharmacy.ky.gov*.**

Board Newsletter

The Board, at its July 11, 2007 meeting, voted to allow the *Kentucky Board of Pharmacy Newsletter* to be sent via an e-mail link beginning in 2008. Therefore, around March 1, 2008, each pharmacist will receive an e-mail from the National Association of Boards of Pharmacy® (NABP®) with a link to the *Kentucky Newsletter*, and will continue to receive e-mail alerts on a quarterly basis. If you wish to continue to receive the *Newsletter* by mail, please notify the Board in writing. If you have further questions, please contact the Board office at your convenience.

Pharmacist Recovery Network

Intervention: Breaking the Cycle of Dependency

Submitted by Patrick Clark, PharmD Candidate

Diabetes is a chronic disease that affects 7% of people nationally, and, as health care professionals, we have been trained very well on how to manage this disease state. Conversely, there is another disease state that affects 10% of the population, yet as a whole, we as health care professionals know very little about its treatment. The disease state I am referring to is addiction. Nationwide, one in 10 people suffer from some type of addiction, be it alcohol, illegal drugs, or prescription drugs. If left untreated, both disease states can be equally harmful to a patient or may even be fatal, resulting either as a direct effect or secondary effect of the disease. Yet we are trained very well on how to treat the diabetic patient and very little on how to treat the addicted one. So, why the disparity in the way we look at these diseases? Possibly the stigma of addiction, or the fact that we have far fewer "tools in the bag" when it comes to treating the disease. Both patient groups, diabetics and addicts, suffer from an incurable disease and both deserve our help as health care professionals.

Health care professionals are often confronted by addicts or drug seekers, and have an excellent opportunity to make an impact. One of the difficulties we face is distinguishing between those patients who have an abuse problem and those with an addiction/dependency problem. If a patient is suspected, Kentucky All Schedule Prescription Electronic Reporting (KASPER) is an important tool when screening for prescription drug-related problems. Another useful tool when assessing a patient is the **CAGE** questions, which follow:

- Have you ever felt the need to **C**ut down on your use of prescription drugs?
- Have you ever felt **A**nnoyed by remarks your friends or loved ones made about your use of prescription drugs?
- Have you ever felt **G**uilty or remorseful about your use of prescription drugs?
- Have you **E**ver used prescription drugs as a way to "get going" or to "calm down"?

Two affirmative answers to the above questions may indicate a possible drug addiction/dependency, while a single affirmative answer warrants further investigation. Also, watch for potential warning signs, ask frequency and dosage questions, and use clinical judgment.

Once you have determined a person may have a problem, you may take the responsibility to attempt to help the patient. You can help the patient determine the appropriate actions, advise them on the risks of not taking action, and advise them how to go about those actions. Patients should also be referred to a substance abuse specialist or treatment facility; however, health care

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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 "intrinsically 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.*

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professionals must be careful when recommending treatment facilities. It would be beneficial to educate the patient and the patient's family and/or significant other(s) on the nature of addiction, the effectiveness of treatment, and the prospects for recovery. There are some organizations that claim to cure addiction, and while this is the hope of the future, there is no proven cure to date. The addicted individual will need to continue to work in a program of recovery with a strong support system.

For more information, contact Brian Fingerson, RPh, via e-mail at KYPRN@insightbb.com or via phone at 502/749-8385.

2008 CAPTASA Conference

The 2008 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 25-26, 2008, at the Embassy Suites in Lexington, KY. For information on this conference please visit *www.CAPTASA.org* or contact Sandy Patrick via e-mail at sandy@captasa.org or via phone at 502/425-7761.

2008 Board Meeting Dates

Following are the dates and locations of the 2008 Board meetings:

January 9, 2008	Wednesday	Board Room
March 12, 2008	Wednesday	Board Room
May 14, 2008	Wednesday	Board Room
July 9, 2008	Wednesday	Board Room
September 10, 2008	Wednesday	To Be Announced
November 14, 2008	Friday	To Be Announced
December 10, 2008	Wednesday	Board Room

Following is the date and location of the 2008 Board Retreat:

Nov 15-16, 2008	Saturday/Sunday	To Be Announced

Contact Numbers of State Boards and Federal Agencies

Board of Dentistry	502/429-7280 502/429-7282(fax)
Board of Medical Licensure	502/429-7150 502/429-7158(fax)
Board of Nursing	502/429-3300 502/429-3311(fax)
Board of Optometric Examiners	859/246-2744 859/246-2746(fax)
Board of Respiratory Care	859/246-2747 859/246-2750(fax)
Office of Drug Enforcement	502/564-7985 502/696-3880(fax)
Food and Drug Administration (Cincinnati)	513/684-3501
Drug Enforcement Administration (Louisville)	502/582-5905

For more information on these and other state agencies please visit *www.ky.gov*, click on Government, and then click on State Agency List.

Errata

In the article "Pharmacist Interns" on page 1 of the September 2007 *Newsletter* there was a misprint. The *Newsletter* text read: "201 **Kansas** Administrative Regulation (KAR) 2:040 establishes the standards for training, qualifications, and registration of pharmacist interns." The text should have read "201 **Kentucky** Administrative Regulation (KAR) 2:040 establishes . . ." NABP regrets this error and apologizes for any confusion it may have caused.

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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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