March 2007

Kentucky Board of Pharmacy

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Spindletop Administration Building
2624 Research Park Dr, Suite 302
Lexington, KY 40511

New Board Member

Dr Anne Policastri was appointed to the Kentucky Board of Pharmacy effective January 1, 2007, by Governor Ernie Fletcher. The appointment shall be effective until January 1, 2011. Dr Policastri is a graduate of the University of Kentucky College of Pharmacy where she received a doctor of pharmacy degree in 1982. She recently accepted a faculty position at the University of Kentucky College of Pharmacy as a clinical assistant professor in the Department of Pharmacy Practice and Science. She serves as assistant director of experiential education.

Dr Policastri has been most active in a number of pharmacy organizations serving in various appointed and elected positions. She is one of only two pharmacists to have been elected as president of both the Kentucky Pharmacists Association and the Kentucky Society of Health-System Pharmacists. She has also served as a delegate from Kentucky to both the American Pharmacists Association and the American Society of Health-System Pharmacists. Dr Policastri has served on various pharmacy leadership and advisory councils.

When not busy with community and professional activities, Anne enjoys outdoor activities such as hiking, kayaking, sailing, bird watching, and wildlife/nature photography. She is an avid supporter of the Humane Society of the United States and has adopted three dogs and two cats that needed a good home.

Board Meeting Dates 2007

Following are the Board meeting dates for 2007:

- Wednesday, March 14, 2007
- Wednesday, May 9, 2007
- Wednesday, July 11, 2007
- Wednesday, September 12, 2007
- Friday, November 16, 2007
- Wednesday, December 12, 2007

All meetings will begin at 9 AM and will be held at the Board office, which is located at Spindletop Administration Building, Suite 302, 2624 Research Park Dr, Lexington, KY 40511.

Disposal of Patient Information

The Board office has recently been made aware of some news media reports concerning pharmacies that have become lax in their management of patient data and information. Numerous examples were found at pharmacies across the country of patient information discarded with the routine trash and left unsecured in outside disposal areas.

Each pharmacy should take appropriate measures to protect and maintain patient confidentiality through proper and appropriate disposal policies and procedures.

Pharmacist Intern Transferring Prescriptions

The Board of Pharmacy, at its December 13, 2006 meeting, approved a Board policy that the transfer of a prescription is a professional act; therefore, a registered pharmacist intern may transfer a prescription after he or she has successfully completed his or her first professional year of coursework toward a doctor of pharmacy degree program and is under the appropriate supervision of a pharmacist. Contact the Board office if you have any questions concerning this Board policy.

CAPTASA Conference 2007

Submitted by Jack Nicholson, BS, PharmD Candidate

On January 26-27, 2007, the seventh annual Clinical Applications of the Principles in Treatment of Addiction and Substance Abuse (CAPTASA) conference was held at the Embassy Suites Hotel in Lexington, KY. The purpose of the conference is to educate health care professionals as well as recovering professionals about addiction management. Treatment for addiction must be a collaborative effort involving all aspects of health care. This conference facilitates a means for this collaborative discussion to occur.

CAPTASA began based on a realization that health care professionals are as susceptible to addictive disease as the rest of the population. It was found that, contrary to wishful thinking, no special immunity to addiction existed in the health care community. The need for prevention, education, early identification, intervention, treatment, and supportive recovery programs was overwhelming. Initially, each profession responded depending on its sense of responsibility to its own members, its resources, and its leadership. Each program struggled, persevered, and evolved over the years. Health care providers determined that a collaborative meeting of the minds would result in more positive outcomes than by each unit functioning on its own. Thus, a planning committee was formed, and in February 2001 the first CAPTASA conference was held.

The two-day conference provides an excellent opportunity to network with other health care professionals involved with addiction management. It also provides a venue in which to learn about addiction prevention, education, and methods of recovery. Of more than 450 attendees, many were pharmacists in recovery, interested pharmacists, members of the Pharmacist Recovery Network committee, and members of the Kentucky Board of Pharmacy and staff.

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and can only be ascertained by examining

FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- One Touch Basic®/Profile®
  - Lot Numbers 272894A, 2619932, or 2606340
  - Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- One Touch Ultra®
  - Lot Number 2691191
  - Multiple Languages – English and French text on the outer carton
  - Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit *www.GenuineOneTouch.com.*

New DEA Number Assignments; Updated DEA Practitioner's Manual Released

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit *www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm.*

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at *www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf.*

Optimizing Computer Systems for Medication Safety

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.

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

- Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to "overload" the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- Maximize a system's capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print "Topical or External Use Only" warnings on drug labels for all drugs that can be administered safely only by this route.
- Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer's alert system and the response to the alert.

Revised Coumadin Labeling and Medication Guide

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at *www.fda.gov/cder/Offices/ODS/medication_guides.htm.*

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit *www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin.*

FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for "hidden traps" by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to "Be smart, be skeptical!" and will be available in English, Spanish, and French. One component is a "teaser" Web site available at *http://wemarket4u.net/glucobate/index.html.* At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

FDA Implements Strategy for Phony Dietary Supplement Claims

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency's counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes (*www.fda.gov/diabetes/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html*), as well as more general health care information.

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At the 2007 meeting, various themes pertaining to addiction management were presented. Topics included "Update From The Human Genome: Mother Nature Versus Mother Nurture," "Principles of Pain Management for the Addicted Patient," and "Evidence of AA: It Works." Pharmacists who presented at the conference were Dave Sallengs of the Drug Enforcement and Professional Practices Branch of the Kentucky Cabinet for Health and Family Services and Brian Fingerson of the Kentucky Professionals Recovery Network (KYPRN), who is also an adjunct assistant professor for the University of Kentucky College of Pharmacy. Mr Sallengs spoke on the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system while Mr Fingerson spoke on "Oh No! Not My Kids! The Adolescent Challenge," which showed methods for decreasing addiction rates in the teenage population. Mr Fingerson also was master of ceremonies for the conference.

Thirteen hours of continuing education (CE) credit were granted for the conference by the Kentucky Board of Pharmacy. Thirty-six CE certificates were awarded to pharmacists for their attendance. For more information regarding past and future conferences, visit *www.captasa.org* or contact Sandy Patrick at the Kentucky Physicians Health Foundation at sandy@captasa.org or 502/425-7761.

For comments, questions, or concerns regarding drug or alcohol addiction, contact Brian Fingerson, RPh, at KYPRN at kyprn@insightbb.com or 502/749-8385.

DEA Jurisdiction

Submitted by Freda E. Lanham, Investigative Assistant, London Resident Office Diversion Group

Recently the Drug Enforcement Administration (DEA) London Resident Office took over jurisdiction of the entire Eastern District of Kentucky, which includes the following counties: Anderson, Bath, Bell, Boone, Bourbon, Boyd, Boyle, Bracken, Breathitt, Campbell, Carroll, Carter, Clark, Clay, Estill, Fayette, Fleming, Floyd, Franklin, Gallatin, Garrard, Grant, Greenup, Harlan, Harrison, Henderson, Jackson, Jessamine, Johnson, Kenton, Knott, Knox, Laurel, Lawrence, Lee, Leslie, Letcher, Lewis, Lincoln, Madison, Magoffin, Mason, McCreary, Martin, Menifee, Mercer, Montgomery, Morgan, Nicholas, Owen, Owsley, Pendleton, Perry, Pike, Powell, Pulaski, Robertson, Rockcastle, Rowan, Scott, Shelby, Trimble, Wayne, Whitley, Wolfe, and Woodford. Some of this area was previously handled by our counterparts in the Louisville office.

Michael J. Lowe is the group supervisor of the DEA London Diversion Group. He can be reached at 606/862-4503. Diversion Investigator Luis Altamirano can be reached at 606/878-3004; Diversion Investigator Brooke Blalock at 606/862-4510; and Investigative Assistant Freda Lanham at 606/878-3000. Any correspondence for the London Diversion Group, including DEA copies of Official Order Forms and Theft/Loss Reports should be sent to PO Box 5065, London, KY 40745. The fax number for the DEA London office is 606/862-8296.

Beware of Internet Prescriptions/Contracts

Recent investigations by the Kentucky Bureau of Investigation, Kentucky State Police, and Kentucky Board of Pharmacy have identified various out-of-state pharmacies contacting pharmacies in Kentucky asking them to become a member of their network. In the past couple of years, one such pharmacy in Kentucky voluntarily closed and another pharmacy was closed with the cooperation of federal and state agencies. These pharmacies utilize the Internet, in whole or in part, to fill prescriptions for Kentucky patients without having a patient/practitioner relationship. The Board is cautioning pharmacists regarding this type of practice. If you have any questions or concerns, please contact the Board office.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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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