January 2007

Louisiana Board of Pharmacy

NEWS

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537

Published to promote voluntary compliance of pharmacy and drug law. *www.labp.com*

New Board Members (07-01-259)

Governor Kathleen Blanco announced six appointments to the Louisiana Board of Pharmacy.

- **District 1:** Joseph L. Adams, who practices at Walgreens Pharmacy in Covington, LA, was reappointed.
- **District 3:** Blake P. Pitre, who owns and practices at Pitre's Pharmacy in Larose, LA, replaced Richard J. Oubre, who completed six years of service.
- **District 4:** Lois R. Anderson, who practices at Louisiana State University Medical Center in Shreveport, LA, was reappointed.
- **District 5:** T. Morris Rabb, who practices at Glenwood Regional Medical Center in West Monroe, LA, was reappointed.
- **District 7:** Chris B. Melancon, who practices at Melancon Drug Store in Carencro, LA, replaced Larry J. Lantier, Jr, who completed six years of service.
- **District 8:** Brian A. Bond, who is a consultant pharmacist for a number of hospital and institutional facilities, was reappointed.

Board Meeting Dates for 2007 (07-01-260)

The Board has set the following **tentative** meeting dates for 2007:

March 6-7	August 15-16
May 9-10	November 14-15

All meetings are planned to be held at the Board office in Baton Rouge, LA.

Illegal Generic Substitution (07-01-261)

The federal Food, Drug, and Cosmetic Act of 1938 established Food and Drug Administration (FDA) and then charged that agency to establish certain criteria for the approval of all drugs used in the United States. Drugs already on the market at that time were "grandfathered" and were allowed to remain on the market. Since these grandfathered drugs have never been approved by FDA, they do not appear in the listing of approved drug products with therapeutic equivalence evaluations (the "Orange Book"). Because these drugs do not appear in the "Orange Book," there are no FDA-approved therapeutic equivalent products available for generic substitution. Therefore, when a prescription is written for these products not listed in the "Orange Book" the pharmacist shall dispense it as written. The substitution of a different drug by the pharmacist would result in a misbranded prescription – a violation of federal and state laws.

For those drugs approved by FDA, not all generic products are rated by that agency as therapeutically equivalent and suitable for generic substitution. If the FDA rating begins with the letter "A," it is considered equivalent; however, if the FDA rating begins with the letter "B," it is not considered equivalent. Louisiana law prohibits the dispensing of generic substitutes that are not rated as equivalent by FDA.

We continue to receive complaints concerning illegal generic substitution of prescriptions with unapproved products. As economic pressures continue to increase, we encourage you to verify that all generic products you choose to dispense are listed, and appropriately rated, in the "Orange Book." If you do not have the printed version of that reference, you can verify a product's status at FDA's Web site at *www.fda.gov.*

Pharmacies and Pedigrees (07-01-262)

The 1992 amendments to the Prescription Drug Marketing Act (PDMA) of 1987 require that certain distributors provide a statement (also known as a pedigree) prior to each distribution of prescription drugs. The PDMA excludes manufacturers and "authorized distributors of record" (ADR) from the requirement to provide a pedigree prior to each wholesale distribution, and then defined an ADR as a distributor with an ongoing relationship with the manufacturer. FDA published its final rules for pedigrees in December 1999; however, due to concerns from the distributor segment of the pharmaceutical industry, the effective date of the laws and rules was stayed. In June 2006, FDA announced that the stay would end, and the requirement for pedigrees became effective December 1, 2006.

In an attempt to answer a number of questions, FDA has published a guidance document. Some highlights include:

- *Are pharmacies required to provide a pedigree when they transfer drug products between pharmacies?* For transfers other than intracompany transfers, unless the transfer of a prescription drug product from one pharmacy to another is for a documented medical emergency, or the sale is of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use, retail pharmacies that are not ADRs for the prescription drug products sold or transferred to other retail pharmacies will have to provide a pedigree.
- *What are the record keeping requirements for pedigree recipients?* The pedigree must be retained by all distributors for three years. If the pharmacy receiving the pedigree will not itself engage in further distribution of the product to persons other than their patient, then the pharmacy is not required to maintain that pedigree; however, FDA encourages pharmacies to retain the pedigree in order to answer any question that may arise about that product that may have been dispensed to a patient.
- *Is a pedigree required for medical kits that contain prescription drugs, sometimes referred to as convenience kits?* Yes.
- *Is a pedigree required for prescription drugs that are returned from a pharmacy to a wholesaler?* A pedigree is required for returns from a pharmacy to a wholesaler unless that pharmacy is an ADR for those prescription drugs. FDA has indicated its intent to exercise enforcement discretion to allow pharmacies to return drugs that are expired, damaged, recalled, or in some other non-saleable condition, without having to provide a pedigree,

Continued on page 4

National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compli
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.

Continued from page 1

if (1) the pharmacies return the drugs to the source from which they purchased the drugs, or to a licensed reverse distributor for destruction, **and** (2) the pharmacies maintain for three years records that document each return and the source from which the pharmacies originally purchased the drugs.

We have posted the FDA Guidance for Industry document on our Web site, under Guidance Documents. If you have any further questions, we encourage you to review that document.

Disposal of Patient Information (07-01-263)

We have 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 have been discovered where medication vials, labels, and other patient information materials were discarded with routine trash and left unsecured in outside disposal areas.

We encourage you to take the appropriate measures to protect and maintain the confidentiality of your patients' protected health information through proper and appropriate disposal policies and procedures.

Disciplinary Actions (07-01-264)

Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information. During its October 5, 2006 administrative hearing, the Board took final action in the following matters:

The Medicine Shoppe of Slidell (Pharmacy Permit No. 3901), Voluntary Consent Agreement: Permit revoked; further, permit holder assessed $15,000 plus administrative costs. *Charges*: 35 counts, including active suspension of controlled substance (CS) registration by US Drug Enforcement Administration (DEA), improper storage and inventory of CS, improper transfer of CS, improper access to prescription records, improper prescription record keeping, improper packaging of drugs, misbranding of prescription drugs, and discrepancies on audits of prescription drugs.

Michael's Discount Pharmacy (Pharmacy Permit No. 5108), Voluntary Consent Agreement: Permit revoked; further, permit holder assessed $15,000 plus administrative costs. *Charges*: 41 counts, including active suspension of CS registration by US DEA, improper storage and inventory of CS, improper transfer of CS, improper access to prescription records, improper prescription record keeping, improper packaging of drugs, misbranding of prescription drugs, and discrepancies on audits of prescription drugs.

Michael Paul Hebert (Pharmacist License No. 13721), Voluntary Consent Agreement: License suspended for 10 years, beginning October 5, 2006; further, license to be automatically reinstated on probation, beginning April 5, 2007, and ending October 5, 2016, subject to certain terms as enumerated in the agreement; further, respondent assessed $15,000 plus $20,000 investigative costs plus administrative costs. *Charges*: 41 counts, including ownership of two pharmacies whose CS registrations were actively suspended by US DEA, improper storage and inventory of CS, improper transfer of CS, improper access to prescription records, improper prescription record keeping, improper packaging of drugs, misbranding of prescription drugs, and discrepancies on audits of prescription drugs.

Fallon Arlene Bobb (Technician Candidate Registration No. 11234), Voluntary Consent Agreement: Registration revoked, with prohibition on any future application for any credential. *Charges*: four counts, including theft of CS from employer pharmacy.

The Board also issued Letters of Warning to one pharmacist, one technician, and two pharmacy permit holders, as well as Letters of Reprimand to four pharmacists.

Calendar Notes (07-01-265)

The next Board meeting and administrative hearing will be March 6-7, 2007, at the Board office. The office will be closed February 20, 2007, for Mardi Gras Day.

Special Note (07-01-266)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

The *Louisiana Board of Pharmacy News* is published by the Louisiana 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.

Malcolm J. Broussard, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Editorial Manager

LOUISIANA BOARD OF PHARMACY

1600 Feehanville Drive
Mount Prospect, IL 60056

National Association of Boards of Pharmacy Foundation, Inc

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744