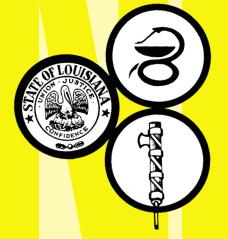
January 2005



Louisiana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537 www.labp.com

Election of Officers (05-01-201)

The annual election of officers was conducted during the regular Louisiana Board of Pharmacy meeting held in Baton Rouge on Wednesday, November 17, 2004, and the following members were elected:

Carl W. Aron, Monroe	President
T. Morris Rabb, Monroe	
Marty R. McKay, Alexandria	
Joseph L. Adams, Mandeville	
Reuben R. Dixon, New Orleans	

Board Meeting Dates for 2005 (05-01-202)

The Board has set the following tentative meeting dates for 2005:February 16-17May 11-12August 17-18November 16-17

The Board plans to hold the February meeting on the campus of the School of Pharmacy at the University of Louisiana at Monroe; all other meetings are planned for the Board office in Baton Rouge.

Certification of Pharmacist Preceptors (05-01-203)

The regulation for pharmacy interns requires their practical experience to be under the general supervision of a certified pharmacist preceptor. The practical application of this rule is limited to those interns earning hours of experience outside of their school curriculum. Any affidavits for such practical experience must now be signed by a certified pharmacist preceptor.

Pharmacists who wish to obtain certification as a preceptor must complete the certification training program offered by the University of Louisiana at Monroe and Xavier University of Louisiana schools of pharmacy and then submit an application to the Board for certification. The Board does not charge a fee for the certification, and it will be renewable every five years.

The January 2004 issue of this *Newsletter* contained information that this requirement would also apply to pharmacists training pharmacy technician candidates. Since the time of that publication, the Board has voted to delete that provision.

Out-of-State Pharmacies (05-01-204)

Section 2307 of the Board's regulations requires that the pharmacist-in-charge of an out-of-state pharmacy permit shall possess an active Louisiana pharmacist license. The Board delayed the implementation date for one year to give those pharmacists not already holding such a license an opportunity to obtain that license. That regulation became enforceable on January 1, 2005.

Electronic Transmission of Prescriptions (05-01-205)

The definition of **"prescription"** in the Louisiana Pharmacy Practice Act requires the communication of the prescription information from the prescriber to the pharmacy [LRS 37:1164(44)]. Section 1129 of the Board's regulations contains standards related to confidentiality. It provides that if confidential health information is not transmitted directly between a practitioner and a pharmacist, but is transmitted through a data communication device, then the operator of the data communication device may not access, maintain, or alter that information.

As vendors of prescription communication systems appear in the marketplace, dispensing pharmacists should consider the features and operations of such systems as they relate to the legal standards in Louisiana. Part of your due diligence should include your questioning of the vendor to ascertain whether or not the vendor's system has been certified by this Board as in compliance with existing state laws and regulations. To date, we have not certified any such systems.

New Regulations for Pharmacy Technicians and Technician Candidates (05-01-206)

The December 2004 Bulletin contained a notice that the chapter of regulations governing technicians and technician candidates has been revised. Persons and organizations holding a subscription to the *Louisiana Pharmacy Law Book* will receive an update in January; you may also access that new regulation on our Web site.

The revised regulation establishes new standards for the education of technician candidates. It also increases the number of hours of required practical experience, from 500 to 600. The final significant changes are the limitations on the scope of practice for both technicians and technician candidates.

Prescription Monitoring Program (05-01-207)

The Board has begun a collaborative dialogue with prescribers, dispensers, law enforcement, and substance abuse treatment professionals to consider the development and implementation of a prescription monitoring program, primarily for controlled substances. Such a program could serve multiple purposes including (1) the reduction of drug diversion, (2) the identification and intervention of individuals addicted to prescription drugs, and (3) support for the legitimate medical use of controlled substances. This will be a substantial project, requiring considerable resources from a broad spectrum of sources. We will keep you posted on our progress.



National Pharmacy (

(Applicability of the contents of articles in the National Pharmacy Compliar and can only be ascertained by examining t

The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin[®] in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone[®]) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- Persons aged 65 years or older;
- Children six to 23 months of age;
- Residents of long-term care facilities and nursing homes;
- Persons two to 64 years of age with chronic medical conditions;
- Health care workers involved in direct patient care;
- Household contacts and out-of-home caregivers of children less than six months of age;
- Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- Pregnant women.

Although not appropriate for everyone, FluMist[®] (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu[®] (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza[®](zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- Washing your hands frequently to avoid the spread of viruses and bacteria;
- Avoiding contact with people who may be sick;
- Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- Covering your mouth and nose when coughing or sneezing;

 Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at <u>www.hhs.gov/nvpo/pandemic-plan</u>. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy[®] (NABP[®]) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – <u>www.fda.gov/oc/opacom/hottopics/</u><u>flu.html</u>.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – <u>www.cdc.gov/flu</u>.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra[®] (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at <u>www.pfizer.com</u> as well as FDA's distributed a press release that is now available at <u>www.fda.gov</u>.

Compliance News

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Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor[®] (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit <u>www.fda.gov/</u> bbs/topics/ANSWERS/2004/ANS01303.html.



Diabetes or Alzheimer's Disease?

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 (<u>www.ismp.org</u>) 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.

Several reports of mix-ups have been reported in which the antidiabetic agent AMARYL[®] (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication **REMINYL[®]** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access <u>www.ismp.org/Pages/</u> <u>FDAVideos.htm</u> for videos related to medication errors. See <u>www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm</u> for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's 2005 Survey of Pharmacy Law CD-ROM is now available. Eight new questions were added to this year's Survey; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from <u>www.nabp.net</u> and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at <u>www.nabp.net</u>, or contact NABP at 847/391-4406 or custserv@nabp.net.

Disciplinary Actions (05-01-208)

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 August 19, 2004 administrative hearing, the Board took final action in the following matters:

- Joan L. Blount (Technician Certificate No. 1653), Hearing: Certificate revoked; also fined \$5,000 plus administrative and investigative costs. *Charge*: (1) dispensing prescriptions in the absence of a pharmacist.
- Steven Louis Elliott (Pharmacist License No. 11805), Hearing: License revoked; also fined \$10,000 plus administrative and investigative costs. *Charges*: (1) has been convicted of a felony, and (2) violation of probation.

During its November 18, 2004 administrative hearing, the Board took final action in the following matters:

- Kerry Layne Nelson (Pharmacist License No. 16539), Voluntary Consent Agreement: License was suspended for 10 years, and further, reinstatement prohibited for at least one year; also fined \$10,000 plus administrative and investigative costs. Charges: (1) unlawful acquisition of controlled substances by forgery, (2) unlawful possession of Schedule III controlled substance.
- Charles Stuart Buck, Jr (Pharmacist License No. 11964), Voluntary Consent Agreement: License was revoked, with reinstatement prohibited for at least 10 years; also fined \$10,000 plus administrative and investigative costs. Charges: (1) dispensing prescriptions with suspended license, (2) unlawful acquisition of controlled substances by forgery, (3) diversion of controlled substances, and (4) violation of Board Order.
- Safescript Pharmacy No. 13 (Pharmacy Permit No. 5149), Voluntary Consent Agreement: Permit revoked; also fined \$50,000 plus administrative and investigative costs. Charges: (1) has committed repeated occasions of negligence or incompetence in the practice of pharmacy, (2) has assisted another person in evading any local, state, or federal laws or regulations pertaining to the practice of pharmacy, and (3) failure to maintain pharmacy records and furnish same upon request by the Board.
- Erica Sheree Guillory (Technician Certificate No. 4681), Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on reinstatement. Charges: (1) unlawful acquisition of controlled substance by fraud, (2) unlawful possession of Schedule III controlled substance.

- **Toccara Montrell Sykes (Technician Certificate No. 6316)**, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on reinstatement. Charges: (1) unlawful acquisition of controlled substance by deception, and (2) unlawful possession with intent to distribute a Schedule III controlled substance.
- Tiffany Weldon Toney (Technician Certificate No. 5669), Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on reinstatement. Charge: (1) unlawful acquisition of prescription drug by theft.

The Board also issued a Letter of Warning to one pharmacy permit. With respect to the reinstatement of lapsed credentials, the Board granted requests from one technician and one pharmacist. With respect to the reinstatement of disciplined credentials, the Board granted requests from three pharmacists. With respect to recovering practitioners, the Board accepted the voluntary surrender of license from three pharmacists and also granted requests for reinstatement from four pharmacists and one intern.

Calendar Notes (05-01-209)

The next Board meeting will be held February 16-17, 2005, on the campus of the School of Pharmacy at the University of Louisiana at Monroe. The office will be closed January 17 in observance of Martin Luther King, Jr Day, and February 8 in observance of Mardi Gras Day.

Special Note (05-01-210)

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.

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Malcolm J. Broussard, RPh - State News Editor Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor Reneeta C. "Rene" Renganathan - Editorial Manager

LOUISIANA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc 1600 Feehanville Drive Mount Prospect, IL 60056

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