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Louisiana Board of Pharmacy

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Election of Officers (06-01-233)

The annual election of officers was conducted during the regular Louisiana Board of Pharmacy meeting held in Baton Rouge on November 9, 2005. The following members were elected:

Carl W. Aron, Monroe.....President
T. Morris Rabb, Monroe ..... First Vice President
Marty R. McKay, Woodworth.....Second Vice President
Joseph L. Adams, Mandeville.....Third Vice President
Reuben R. Dixon, New Orleans.....Secretary

Board Meeting Dates for 2006 (06-01-234)

The Board has set the following **tentative** meeting dates for 2006:

February 14-16	August 15-17
May 16-18	November 14-16

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

Board Member Appointments (06-01-235)

Board member appointments are made in accordance with LRS 37:1175, which provides that whenever a vacancy occurs among the members representing one of the eight districts, the registered pharmacists who are bona fide residents of the district in which the vacancy occurs shall nominate, from among their number, a representative to the Board. Whenever the vacancy will occur by reason of an expiring term, the nominations shall be made by mail at least 60 days in advance of the expiration date of the term.

The Board secretary is responsible for mailing a ballot, by United States mail, to each pharmacist holding an active license and residing in the district in which the vacancy will occur, at the last known address as indicated in the Board's records. The ballot, or another enclosed communication, will state the date, time, and place for counting ballots. At a gathering open to the public, the secretary and/or more persons designated by him or her will open and count the ballots. The secretary will then certify to the governor the names of the three nominees in each district receiving the highest number of votes.

The terms of six current Board members will expire on July 28, 2006. The ballots with necessary information will be mailed to pharmacists in the respective districts during the week of April 3, 2006. The ballots will be opened and counted during the week of May 8, 2006; information about the exact time and place will be included with the ballot.

Board member terms that will expire on July 28, 2006, and their districts, are:

1. **Joseph L. Adams**, Mandeville (District 1 – composed of the parishes of Jefferson and St Tammany);
2. **Richard J. Oubre,** LaPlace (District 3 – composed of the parishes of Ascension, Assumption, Iberia, Iberville, Lafourche, St Charles, St James, St John the Baptist, St Martin, St Mary, Terrebonne, and West Baton Rouge);
3. **Lois R. Anderson,** Shreveport (District 4 – composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster);
4. **T. Morris Rabb,** Monroe (District 5 – composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll, and Winn);
5. **Larry J. Lantier, Jr,** Lafayette (District 7 – composed of the parishes of Acadia, Calcasieu, Cameron, Jefferson Davis, Lafayette, and Vermilion); and
6. **Brian A. Bond,** Jena (District 8 – composed of the parishes of Allen, Avoyelles, Beauregard, Catahoula, Concordia, Evangeline, Grant, LaSalle, Pointe Coupee, Rapides, St Landry, and Vernon).

Should any pharmacist need a list of pharmacists in his or her own district for purposes related to this nomination election, the Board office will supply one complimentary list upon written request by the pharmacist.

Emergency Rule (06-01-236)

During its November 9, 2005 meeting, the Board voted to adopt an emergency rule that repeals certain requirements related to the nature of the practical experience earned by pharmacy interns during their academic rotation programs. Specifically, the Board voted to amend Section 705.C.1.b by removing the requirements for 300 hours of community pharmacy dispensing and 300 hours of hospital pharmacy dispensing within the academic rotation programs. The emergency rule went into effect on December 1, 2005; and further, the Board filed a Notice of Intent to make that amendment permanent. The public hearing for that proposal will be held on January 25, 2006, at the Board office.

Promulgation of New Technician Regulation Suspended (06-01-237)

We notified you last year of the Board's intent to change the technician regulation. As part of that process, we filed our Legislative Oversight Committee Report on August 25, 2005. Following the landfall of Hurricane Katrina on August 29, 2005, the governor issued several disaster-related orders and proclamations. One of the effects of that series of orders was to suspend the rulemaking process on our report. After consulting with the legislative and legal staffs, we have concluded the most equitable decision is to re-file the Legislative Oversight Committee Report as soon as the state of emergency is terminated by the governor. We will keep you

Continued on page 4

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and can only be ascertained by examining

DEA Releases Final Rule on Approved Narcotic Controlled Substances for Maintenance of Detoxification Treatment

According to the June 23, 2005 *Federal Register*, Drug Enforcement Administration (DEA) has amended its regulations (§1301 and §1306) to allow qualified practitioners not registered as a narcotic treatment program to dispense and prescribe to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment. This final rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to increase and improve the treatment of narcotic addiction. In addition, the final rule is intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic drugs approved for maintenance/detoxification treatment. This rule went into effect July 25, 2005.

Additionally, the ammended regulations require the practitioner to include on the prescription the identification number or written notice that the practitioner is acting under the good faith exception of §1301.28(e). In order to be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The prescription must also be dated as of, and signed on, the day issued and must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use as well as the name, address, and registration number of the practitioner. Practitioners are not normally required to keep records of prescriptions issued, but DEA regulations require records to be kept by practitioners prescribing controlled substances listed in any schedule for maintenance or detoxification treatment of an individual.

Any practitioner who dispenses or prescribes Schedule III, IV, or V narcotic drugs in violation of any of the conditions as specified in §1301.28(b), may have their practitioner's DEA registration revoked in accordance with §1301.36.

Due to the potential for diversion, and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

How FDA Reviews Drug Names

By Carol Holquist, RPh, FDA, Office of Drug Safety

FDA has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under FDA's Center for Drug Evaluation and Research. Ten clinical pharmacists and physicians make up OPDRA's medication error staff.

The Name Review Process

Since October 1999, OPDRA has reviewed approximately 400 drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk due to sound-alike and look-alike names. The process includes:

- *Expert panel review*. An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division of Drug Marketing and Advertising Communications, who rely on their clinical, regulatory, and professional experiences to decide on the acceptablilty of a proprietary name.
- *Handwriting and verbal analysis.* These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other United States drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- *Computer-assisted analysis.* Currently, OPDRA utilizes existing FDA databases to identify potential sound-alike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- *Labeling and packaging analysis*. OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each product to identify areas of potential improvement.
- *Overall risk evaluation.* This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

How Can You Help?

Pharmacists and other health professionals can assist FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800/FDA-1088), Web site (www.fda.gov/medwatch), and fax (1-800/FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA Form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (eg, pharmacist, nurse, physician) involved; medication involved; patient outcome; setting of the incident (eg, inpatient, outpatient); relevent patient information (eg, age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.

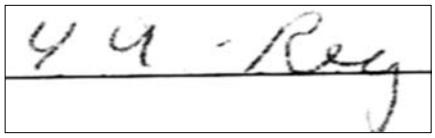
We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

What's wrong with "U?"

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 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.

The use of abbreviations is always problematic when communicating medical information. All too often, medical abbreviations hinder our understanding or are misread. Insulin errors are common and can cause significant patient harm. The cause of many insulin errors is related to the use of abbreviations when communicating prescription information. The abbreviation "U" to indicate "units" has contributed to many errors when it was misread as a zero (0) or a number 4.

Over the years, numerous reports have been received through the USP-ISMP Medication Errors Reporting Program that describe the occurrence of 10-fold or greater overdoses of insulin because the abbreviation "U" has been misinterpreted. It is not uncommon for a "U" to be misread as a zero (0). For example, prescriptions for "6U regular insulin" have been misinterpreted and administered as 60 units of regular insulin. In another report, a prescriber wrote an order for "4U Reg" (see photo); however, someone misinterpreted the "U" as a "4." The person who injected the insulin did not recognize that this was an excessive dose and proceeded to administer 44 units to the patient. The patient required glucose to reverse his acute hypoglycemia.



In order to prevent errors such as these, health care practitioners should **always** write out the word "units." Educate staff about the dangers involved with using this abbreviation. Practitioners must recognize the need for good communication skills and realize that the perceived time saved when using the abbreviation "U" for units may actually result in serious patient harm. Occasionally, while intending to do the "right thing," errors still can occur. This was the case when a physician wrote a sliding scale insulin order for a hospitalized patient with a blood sugar of 396 mg/dL. When writing the insulin order, the physician included the word "units." According to the order, this patient should have received 4 units of regular insulin subcutaneously. Unfortunately, because the letter "U" in units was separated from the rest of the word, "-nits," the nurse read the order as 40 units and administered the dose to the patient. His blood sugar dropped to 54 mg/dL and he required dextrose to correct the hypoglycemia. The error was realized when the nursing notes were reviewed and it was documented that 40 units was administered.

Pharmacy and nursing staff must carefully review insulin prescriptions, knowing that errors involving this abbreviation are common and can result in 10-fold or greater overdoses. Clarify any questionable insulin dosages and inform the prescriber of misinterpretations that could occur due to use of the abbreviation "U" for units. In addition, whenever possible, require an independent double check of insulin prescriptions before they are dispensed or administered.

Safeguards for Severe Acne Medication Announced

Because isotretinoin (Accutane®) carries significant risks of birth defects for women who are pregnant or might become pregnant, FDA has unveiled safeguards for its distribution. (See related article, March 2005 *NABP Newsletter*, page 61.) The manufacturers of isotretinoin are launching a program called iPLEDGE™ in which doctors and patients register with the program and agree to accept certain responsibilities as a condition of prescribing or using the drug. Wholesalers and pharmacies must also comply with the program to be able to distribute and dispense the drug.

In the wake of a February 2004 joint meeting between FDA's Drug Safety and Risk Management Advisory Committee and Ophthalmic Drugs Advisory Committee, major improvements were recommended for the restricted distribution program for isotretinoin, which has proven effective in treating severe recalcitrant nodular acne. Under the recommendations, patients who could become pregnant are to have negative pregnancy testing and birth control counseling before receiving the drug. In addition, patients must complete an informed consent form and obtain counseling about the risks and requirements for safe use of the drug. Starting December 31, 2005, all patients and prescribers must register and comply with requirements for office visits, counseling, birth control, and other program components. After October 31, 2005, wholesalers and pharmacies were required to register with iPLEDGE in order to obtain isotretinoin from a manufacturer.

Program information and registration is available at www.ipledgeprogram.com or 866/495-0654.

For the purpose of increasing available information about isotretinoin and its associated risks, FDA also issued a Public Health Advisory and revised the Patient and Health Care Provider Information Sheets that detail the new patient and practitioner restrictions and responsibilities under the program. A reporting and collection system for serious adverse events associated with the use of the drug has also been established. Pregnancy exposures to isotretinoin must be reported immediately to FDA at the MedWatch phone number (1-800/332-1088), the iPLEDGE pregnancy registry (866/495-0654), or on the iPLEDGE Web site.

Besides approving the iPLEDGE program, FDA approved changes to the existing warnings, patient information, and informed consent form to help patients and prescribers better identify and manage the risks of psychiatric symptoms and depression before and after taking the medication.

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posted on our progress. Until that process has concluded, the existing regulations found in *Chapter 9 – Pharmacy Technicians* of the *Louisiana Pharmacy Law Book* are still in effect.

Unusual Role for Board of Pharmacy (06-01-238)

Following the landfall of Hurricanes Katrina and Rita, the Louisiana Department of Health and Hospitals (DHH) obtained an authorization of financial support from the Federal Emergency Management Agency (FEMA) for several projects, one of which is the reimbursement to pharmacies dispensing certain prescriptions to certain hurricane evacuees and victims. DHH requested that the Board assume the role of claims administrator for this project; specifically, the Board was asked to communicate project information to all in-state pharmacies on a timely basis, to collect claims from all in-state pharmacies pursuing reimbursement, and finally, to process the payments for those claims when finally approved by DHH and FEMA.

We have distributed informational bulletins to all in-state pharmacies as soon as DHH and FEMA have provided their information to us. As this *Newsletter* was written, the current plan was to reimburse pharmacies for services rendered through January 15, 2006. However, given the dynamic nature of this entire project, we encourage you to visit our Web site on a regular basis to obtain the most current information.

Disciplinary Actions (06-01-239)

Although every effort is made to ensure that 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 November 9, 2005 meeting, the Board took final action in the following matters:

Tabatha Leanne Hammock (Technician Certificate No. 5859), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application.

Shaina D. Wade (Technician Certificate No. 3565), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application.

Lynnie M. Murphy (Technician Certificate No. 4040), Voluntary Consent Agreement: Accepted voluntary surrender, resulting in the indefinite suspension of the certificate, effective September 8, 2005.

Gary Charles Richardson (Pharmacist License No. 10910), Voluntary Consent Agreement: Accepted voluntary surrender, resulting in the indefinite suspension of the license, effective November 9, 2005.

Medicap Pharmacy of Slidell (Pharmacy Permit No. 5330), Voluntary Consent Agreement: Accepted voluntary surrender, resulting in the indefinite suspension of the permit, effective November 9, 2005.

Medicap Pharmacy No. 338 of Slidell (Pharmacy Permit No. 5253), Voluntary Consent Agreement: Accepted voluntary surrender, resulting in the indefinite suspension of the permit, effective November 9, 2005.

Advanced Pharmacy of West Monroe (Pharmacy Permit No. 5565), Voluntary Consent Agreement: Accepted voluntary surrender, resulting in the indefinite suspension of the permit, effective September 30, 2005.

The Board also issued a Letter of Reprimand to Warning to one pharmacy permit holder, as well as Letters to five pharmacy permit holders. With respect to the reinstatement of lapsed licenses, the Board granted requests from two pharmacists and two technicians, and then denied a request from one pharmacist. With respect to impaired practitioners, the Board accepted the voluntary surrender of credentials from one pharmacist and one technician, granted requests for reinstatement from three pharmacists and one pharmacy intern, and granted one request for probation modification from a pharmacist.

Calendar Notes (06-01-240)

The next Board meeting will be held February 14-16, 2006, at the Board office. The office will be closed January 2, 2006, for New Year's Day; January 16, 2006, for Martin Luther King, Jr Day; and February 28, 2006, for Mardi Gras.

Special Note (06-01-241)

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.

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LOUISIANA BOARD OF PHARMACY

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