NEWS

October 2008

Louisiana Board of Pharmacy

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Appointments to the Louisiana Board of Pharmacy (08-10-304)

Governor Bobby Jindal recently announced six appointments to the Louisiana Board of Pharmacy:

- District 2: **Jacqueline L. Hall**, who practices at Walgreens Pharmacy in New Orleans, was reappointed.
- District 3: **Richard A. "Andy" Soileau**, who practices at Soileau's Pharmacy in New Iberia, replaced Fred H. Mills, who completed five-and-a-half years of service.
- District 5: **Carl W. Aron**, who practices at Aron's Pharmacy in Monroe, was reappointed.
- District 6: **Ronald E. Moore**, who is a consultant pharmacist for a number of hospital and institutional facilities, replaced Joseph V. Greco, who completed six years of service.
- District 8: **Marty R. McKay**, who practices at Pearson Drugs in Lecompte, was reappointed.
- **Sydnie M. Durand** is a new public member, and she replaced Alvin A. Haynes, who was appointed in 2005.

License and Permit Renewals for 2009 (08-10-305)

The renewal cycle for pharmacists and pharmacies will open on November 1, 2008. The Board will not automatically mail renewal applications to every pharmacist or pharmacy; instead, we will send a reminder postcard just prior to November 1. The postcard will remind you of the three options you have to renew your credentials: (1) visit the Board's Web site at *www.labp.com* and renew the credentials online using a credit card; (2) visit the Web site to download and print an application form, then complete and mail it with the appropriate fee using check or money order; or (3) send a written notice to the Board office (mail, fax, or e-mail) with your name, address, and credential number requesting the Board to mail an application form to you. For those credentials renewed online, we will mail those credentials within one or two business days; for those credentials renewed with paper applications, we will mail those credentials within two to four weeks, depending on the volume of paper applications received.

Any address changes received in our office after October 17, 2008, will not be reflected on your reminder postcard. If you do not receive your reminder postcard by November 15, 2008, then it becomes your responsibility to obtain a renewal application or renew your credential online.

The online renewal feature of the Web site will only be accessible from November 1, 2008 through midnight on December 31, 2008. While the Board makes every effort to maintain the online convenience during the renewal period, our service provider may experience weather-related or other unforeseen technical difficulties from time to time – as happened on the last day of the 2007 renewal cycle. You have 60 days to renew your credentials, and it is your choice as to when you renew your credential. If you choose to wait until the last day and the Web site is not available, then you will be responsible for the consequences of your failure to renew your credential in a timely manner. Why take a chance? Please do not wait until the last minute.

Pharmacist License Renewal

- Pharmacist licenses expire at midnight December 31, 2008. There is no grace period, and a pharmacist shall not practice with an expired license.
- If you elect to use a paper application, then we suggest you submit your completed application and $100 fee to the Board office no later than December 1, 2008. Please do not forget to sign and date the application and answer the questions at the bottom of the form – if they are not all answered, or if there is no supporting documentation with an affirmative response, then the application will be returned to you as incomplete, resulting in a delay in the renewal of your license.

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

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- The renewal of an expired license will incur a 50% penalty as well as a lapsed license reinstatement fee, resulting in a total charge of $350.
- If it is important for you to know when your paper application is received at the Board office, we suggest you use a mailing service with tracking options (United States Post Office, United Parcel Service, FedEx, etc).

Pharmacy Permit Renewal

- Pharmacy permits expire at midnight December 31, 2008. There is no grace period, and a pharmacy shall not operate with an expired permit. Recent history reveals the usual fine for this violation is $5,000.
- If you elect to use a paper application, then we suggest you submit your completed application and $150 fee to the Board office no later than December 1, 2008. Please do not forget to sign and date the application and answer the questions at the bottom of the form – if they are not all answered or if there is no supporting documentation with an affirmative response, then the application will be returned to you as incomplete, resulting in a delay in the renewal of your permit.
- The renewal of an expired permit will incur a 50% penalty as well as a lapsed permit reinstatement fee, resulting in a total charge of $412.50, which includes the Prescription Monitoring Program (PMP) fee.
- The renewal of an expired controlled dangerous substance license will incur a 50% penalty as well as a lapsed license reinstatement fee, resulting in a total charge of $237.50.
- If it is important to know when your paper application is received at the Board office, we suggest you use a mailing service with tracking options.

Pharmacists, Interns, Technicians, and Technician Candidates (08-10-306)

If you are a pharmacist-in-charge, you shall – at all times – ensure that all personnel you allow to perform professional functions in your prescription department are properly credentialed by the Board to do so. If you are a staff pharmacist or relief pharmacist, it is your responsibility to ensure that the employees assisting you in the prescription dispensing process are properly credentialed to perform those duties in your presence. In the event a compliance officer discovers one or more persons performing professional functions without the necessary credentials, you will be identified as the responsible person in the investigative report filed by the compliance officer. Further, in the event of a formal inquiry by the Board, you will bear the risk of potential disciplinary action.

Prescription Monitoring Program (08-10-307)

As required by Act 676 of the 2006 Louisiana Legislature, and as further authorized by Chapter 29 of the Board's rules, the Board has finally completed the development phase of the PMP. The state has finally approved the selection of a software vendor and data collection firm to help administer the Board's program. Health Information Designs, Inc (HID) is located in Auburn, AL; the firm currently supports PMP operations in Alabama, North Carolina, North Dakota, and South Carolina and is implementing new programs in Arizona and Vermont.

HID mailed a *Dispenser's Implementation Guide* to every pharmacy licensed by the Board (except charitable pharmacies, which are not permitted to dispense controlled substances) during the first week of September. This document, which is also available on our Web site, contains the technical specifications for dispensing software vendors to assist pharmacies and other dispensers to comply with their reporting requirements. The guide instructs dispensers how to contact HID and set up their accounts, as well as the various methods by which they may electronically submit their reports.

As provided in the enabling legislation, dispensers of prescriptions for controlled substances are required to report their eligible transactions on a periodic basis to HID. Eligible transactions include prescriptions for controlled substances in Schedules II, III, IV, and V. They also include "drugs of concern"; however, these drugs will need to be formally identified by regulation, and we will notify you when that happens. Dispensers do not include: (1) a pharmacy permitted as a hospital pharmacy that dispenses or distributes any controlled substance for the purposes of inpatient health care; (2) a practitioner who dispenses or distributes no more than a single 48-hour supply of a controlled substance to a patient prior to, or subsequent to, performing an actual procedure on that patient; (3) a practitioner who administers controlled substances to a patient; and (4) a wholesale distributor of controlled substances credentialed by the Louisiana Board of Wholesale Drug Distributors. With respect to hospital pharmacies, their permit enables them to dispense controlled substances for outpatient health care; therefore, hospital pharmacies are not exempted from the reporting requirement.

Pharmacies and other dispensers should be prepared to file their first report to HID after November 1 and before November 15, 2008. They will have until December 31, 2008, to file all eligible controlled substance prescription transaction data retroactively to June 1, 2008. HID anticipates opening the database to queries from authorized users on January 1, 2009.

As we move forward with the implementation phase of the PMP, we encourage you to look for communications from HID and the Board; they will contain time-sensitive information. We will also update the PMP section of our Web site, and we encourage your periodic review of that information.

Disciplinary Actions (08-10-308)

Although every effort is made to ensure this 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 6-7, 2008 meeting, the Board took final action in the following matters:

Dave's Village Drugs (Pharmacy Permit No. 219), Voluntary Consent Agreement: Permit revoked. *Charges*: 11 counts, including violation of existing probationary terms, failure to comply with sanitation code (water dripping from ceiling tiles, insufficient lighting of prescription department, and evidence of animals in prescription department), failure to maintain policy and procedure manual after repeated notice, failure to properly record receipts of controlled substances, failure to properly secure controlled substances, and the offering for sale of expired prescription and non-prescription drugs.

David Louis Matherne (Pharmacist License No. 9961), Voluntary Consent Agreement: License suspended for five years; following the completion of the first 90 days, the remainder of the suspension is stayed and the license placed on probation for the remainder of the five years, subject to certain terms; further, assessed $5,000 plus administrative and investigative costs. *Charges*: 12 counts, including violation of existing probationary terms, failure to complete continuing education requirements, acquisition of pharmacist license renewal by fraud or misrepresentation, and failure to perform required pharmacist-in-charge duties at Dave's Village Drugs.

GlobalNet Pharmacies (Pharmacy Permit No. 5668), Voluntary Consent Agreement: Permit suspended for two years, with execution thereof stayed, and then placed on probation for two years, to begin when permit is renewed, subject to certain terms; further, permit holder assessed $10,000 plus administrative and investigative costs. *Charges*: six counts, including the attempted acquisition of a pharmacy permit renewal by fraud or misrepresentation.

Brian Gregory Bazajou (Pharmacist License No. 16814), Voluntary Consent Agreement: License suspended for an indefinite period of time; further, any future reinstatement application conditioned upon several terms, including five years of active suspension; further, assessed $5,000 plus administrative and investigative costs. *Charges*: nine counts, including acquisition of pharmacist license renewal by fraud or misrepresentation, failure to report adverse action by another state board of pharmacy, and failure to report prior criminal conviction.

Tashima Karvette Weary (Technician Candidate Registration No. 12573), Voluntary Consent Agreement: Board accepted voluntary surrender of the credential, resulting in the suspension of the registration for an indefinite period of time, effective June 4, 2008.

Tiffany LeBlanc Richard (Pharmacist License No. 15766): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective June 9, 2008.

Sharron Renee Barnes Michael (Pharmacist License No. 17155): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective June 13, 2008.

Glenn Morris Crochet, Sr (Pharmacist License No. 10340): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective June 10, 2008.

Larry James McManus (Pharmacist License No. 9716): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective June 30, 2008.

Nicole Colton Faust (Technician Certificate No. 5720): Board accepted voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective June 30, 2008.

Rebecca Shane King (Technician Candidate Registration No. 13772): Board accepted voluntary surrender of the credential, resulting in the suspension of the registration for an indefinite period of time, effective June 30, 2008.

Megan Elizabeth LaGrange (Intern Registration No. 45109): Board accepted voluntary surrender of the credential, resulting in the suspension of the registration for an indefinite period of time, effective July 15, 2008.

Derrick Lamar Franklin (Technician Certificate No. 7844), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future credential. *Charges*: six counts, including theft of Schedule III and IV controlled substances from employer pharmacy.

Zerina Faye Johnson (Technician Certificate No. 1519), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future credential. *Charges*: six counts, including prescription forgery for Schedule III controlled substance at employer pharmacy.

Gwendolyn Phillips Green (Technician Certificate No. 2928), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future credential. *Charges*: six counts, including prescription forgery for Schedule III controlled substance at employer pharmacy.

Yolanda Renee Turner (Technician Candidate Registration No. 12694), Voluntary Consent Agreement: Registration revoked with permanent prohibition on any future credential. *Charges*: six counts, including theft of Schedule III and IV controlled substances from employer pharmacy.

Amanda Marie Angell (Technician Candidate Registration No. 14222), Voluntary Consent Agreement: Registration issued on probation for one year, subject to certain terms as enumerated in the agreement.

Deidre Danielle Jones (Applicant for Pharmacy Technician Candidate Registration): Board denied the application and refused to issue the registration.

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Rachael Elizabeth Lassetter (Applicant for Pharmacy Technician Candidate Registration): Board denied the application and refused to issue the registration.

Michael David Quatrevingt (Applicant for Pharmacy Technician Candidate Registration): Board denied the application and refused to issue the registration.

Ronald Allen Barrett (Pharmacist License No. 11925): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective July 2, 2008.

Edward John Rabalais (Pharmacist License No. 9897): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective July 30, 2008.

Scott Taylor Lovitt (Pharmacist License No. 17931), Voluntary Consent Agreement: Board granted request for reinstatement of the previously suspended license, then placed the license on probation for 10 years, beginning August 6, 2008, subject to certain terms enumerated in the agreement.

Reynold James Serrette (Pharmacist License No. 14945), Voluntary Consent Agreement: Board granted request for modification of probationary terms, to permit the acceptance of an appointment as pharmacist-in-charge.

Mitchell John Kimball (Pharmacist License No. 13546), Voluntary Consent Agreement: Board granted request for modification of probationary terms, to permit the acceptance of an appointment as pharmacist-in-charge.

On these same dates, the Board also issued Letters of Warning to two pharmacy permit owners, as well as a Letter of Reprimand to one pharmacist. Finally, they granted two requests for the reinstatement of lapsed pharmacist licenses.

Calendar Notes (08-10-309)

The next Board meeting and administrative hearing will be November 13-14, 2008, at the Board office. The office will be closed November 4 for Election Day, November 11 for Veterans Day, November 27-28 for Thanksgiving, and December 25-26 for Christmas.

Special Note (08-10-310)

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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