New Board Member (08-04-289)
As the pharmacists of District 6 may recall, the Louisiana Board of Pharmacy conducted a nomination election last year to choose a replacement for Ms Patricea Angelle. Governor Kathleen Blanco appointed Ms Elizabeth W. Barker to complete the remainder of the unexpired term. Ms Barker resides in Baton Rouge and practices pharmacy at River West Medical Center in Plaquemine, where she serves as the director of pharmacy services. As we welcome Ms Barker, we also thank Ms Angelle for her service to the Board and the citizens of the state.

Protect Your Patients and Customers – Be Sure Your Drug and Device Suppliers are Licensed (08-04-290)
Submitted by John Liggio, Executive Director, Louisiana Board of Wholesale Drug Distributors
The Louisiana Board of Wholesale Drug Distributors licenses and regulates drug and device wholesalers. In the ever growing market of counterfeit and adulterated drugs and devices, it is important to validate that your drug and device suppliers are properly licensed and inspected by the wholesale regulatory agencies to help protect your patients and customers from unscrupulous people that prey on the health care industry.

The Board of Wholesale Drug Distributors maintains a Web site that you can use to validate that your suppliers of drugs and devices are licensed to do business in Louisiana. That Web site is located at www.lsbwdd.org. If you are currently doing business with a supplier that is not listed on the Web site and not licensed by the Board of Wholesale Drug Distributors, please contact that board at 225/295-8567. Your participation in this process of verification will help identify, license, and protect the drug and device distribution chain that we all rely on and expect to be free from counterfeit and adulterated drugs and devices.

Regulatory and Legislative Proposals (08-04-291)
During its February 2008 meeting, the Board approved a number of regulatory and legislative proposals for further action during the calendar year. Regulatory Proposal 2008-1 ~ Practical Experience Requirements for Pharmacy Interns is intended to replace Regulatory Proposal 2007-3 of the same title, which was never promulgated. The Board authorized the promulgation of the newer proposal. You can view a copy of the proposal, as well as follow the progress of the promulgation process, by monitoring the Board’s Web site, in particular the Meetings & Notices section. The Board also approved four legislative proposals, relative to (1) electronic licensure renewals, (2) required notifications for interns, technicians, and technician candidates, (3) technicians in military service, and (4) an update of the state controlled substances list. The Board approved the filing of these measures during the 2008 regular legislative session. You can view a copy of the proposals, as well as follow the progress of the legislative process, by monitoring the Board’s Web site, in particular the Meetings & Notices section, as well as the legislative Web site at www.legis.state.la.us.

Louisiana Needs You! (08-04-292)
The Louisiana Department of Health and Hospitals, Office of Public Health recently launched its new volunteer management Web site. LAVA, or Louisiana Volunteers in Action, is the program responsible for recruiting the department's volunteer workforce (medical and non-medical). The LAVA Web site will allow individuals to register and volunteer to help the state during health emergencies and day-to-day activities. LAVA also provides Web-based emergency preparedness training to volunteers at no cost. Interested volunteers can sign up at www.lava.dhh.louisiana.gov.

The federal government requires states to operate emergency volunteer registries. LAVA is part of the federal program known as Emergency System for Advance Registration of Volunteer Health Professionals. For more information, please contact Ms Mardrah Starks-Robinson, program manager, at 225/763-3965.

Pain Management Clinics (08-04-293)
The 2005 Louisiana Legislature passed a law requiring the licensure of pain management clinics; it directed the Depart-
NABP Launches Pharmacy Curriculum Outcomes Assessment Program

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, www.nabp.net, or by contacting NABP Customer Service at custserv@nabp.net.

An e-Educated Consumer is Your Best Customer (Patient)

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

FDA Warns against Using OTC Cold Medicines in Babies

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of “serious and potentially life-threatening side effects.” FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

Bayer Diabetes Care Recalls Contour Test Strips

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in high glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms “bio-identical hormone replacement therapy” and “BHRT” to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of “bio-identical” as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.

Manufacturers to Restrict Distribution of Methadone

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see “Studies Show Increased Methadone-Associated Mortality Related to Pain Management” in the January issue of the NABP Newsletter, available on the NABP Web site at www.nabp.net.

New Compounding Standards Effective June 1; USP Offers Webinars

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, “Pharmaceutical Compounding – Sterile Preparations” on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See “Sterile Compounding Checklist Revised to Better Protect Patient Health” in the February 2008 issue of the NABP Newsletter.) The revisions are included in USP 32–NF 27 and in the second edition of the Pharmacists’ Pharmacopeia, published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

For more information on the Webinars and workshops, go to www.usp.org/hottopics/generalChapter797.html?hlc.

CMS Names MSAs, Products for Round Two of DMEPOS Bidding

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare’s DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at www.cms.hhs.gov/CompetitiveAcfdrm-dmepos.

Adverse Event Reporting Requirements in Effect for OTC Products

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marked without an Approved Application, is available via the FDA MedWatch site at www.fda.gov/medwatch/otc.htm.

FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer’s or distributor’s toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

mum of Health and Hospitals to promulgate a rule establishing standards of practice. The department published the final rule in January 2008, and it is currently accepting applications for licensure. Both the law and the rule place certain limits on prescriptions generated from these clinics: prescriptions for controlled substances shall authorize no more than a 30-day supply, and they shall not be refillable.

**Nomination Election for Board Members (08-04-294)**

Pharmacists should have already received Bulletin No. 08-01, which identifies the five members of the Board with terms expiring on July 28, 2008. Ballots were mailed to pharmacists in those five districts during the last week of March, and the deadline for their return is May 2.

**Collaborative Drug Therapy Management (08-04-295)**

The Board of Pharmacy and the Board of Medical Examiners have finally completed the rulemaking process to allow pharmacists and physicians to enter into collaborative practice agreements for the purpose of managing drug therapy of their mutual patients. All of the information you need can be found on the Board’s Web site, under the pharmacist link.

**Disciplinary Actions (08-04-296)**

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 November 15, 2007 administrative hearing, the Board took final action in the following matters:

- **April Nugent Benson (Technician Certificate No. 5513)**
  - Formal Hearing: Certificate revoked; further, assessed $5,000 plus administrative, investigative, and hearing costs. **Charges**: five counts, including failure to notify Board of employment change, and failure to submit to medical evaluation as directed by the Board.

- **Karen Rena Ross (Technician Certificate No. 7606)**
  - Formal Hearing: Certificate revoked; further, assessed $5,000 plus administrative, investigative, and hearing costs. **Charges**: three counts, including violation of probation.

- **Doreen Flettrich Korndorffer (Technician Certificate No. 1737)**
  - Formal Hearing: Certificate revoked; further, assessed $5,000 plus administrative, investigative, and hearing costs. **Charges**: four counts, including failure to submit to medical evaluation as directed by the Board.

- **Wendy Inez Aikens (Technician Certificate No. 6515)**
  - Formal Hearing: Certificate suspended for an indefinite period of time; further, assessed $500 plus administrative, investigative, and hearing costs; further, conditioned the acceptance of any future reinstatement application on certain terms. **Charges**: five counts, including failure to notify Board of employment change, and failure to submit to medical evaluation as directed by the Board.

- **Marilyn Joyce Felton (Pharmacist License No. 15321)**
  - Formal Hearing: License suspended for an indefinite period of time; further, assessed $5,000 plus administrative, investigative, and hearing costs. **Charges**: five counts, including failure to comply with continuing education requirements and failure to provide information requested by the Board.

During its February 21-22, 2008 meeting and administrative hearing, the Board took final action in the following matters:

- **Aaron Matthew Hare ( Applicant for Pharmacy Technician Candidate Registration)**: the Board denied the application and refused to issue the registration.

- **Sarah Mae Ardoin (Applicant for Pharmacy Technician Candidate Registration)**: the Board denied the application and refused to issue the license.

- **Kenneth Ray Richard (Pharmacist License No. 14439)**: Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective November 26, 2007.

- **Charles Lafayette Mullins, Jr (Pharmacist License No. 16188)**: Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective November 29, 2007.

- **Jerry Dale Walters (Pharmacist License No. 16806)**: Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective January 15, 2008.

- **Scott Taylor Lovitt (Pharmacist License No. 17931)**: Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective February 7, 2008.

- **Brandy Nicole Bush (Technician Certificate No. 7306)**:
  - Board accepted voluntary surrender of the credential, resulting in suspension of the certificate for an indefinite period of time, effective February 7, 2008.

- **Clay Devoe Jones (Pharmacist License No. 15687)**:
  - Voluntary Consent Agreement: Granted request for reinstatement of the previously suspended license; placed reinstated license on probation for ten years, beginning February 21, 2008, subject to certain terms as enumerated in the agreement.

- **Gina Jo Palermo (Pharmacist License No. 16692)**:
  - Voluntary Consent Agreement: Granted request for reinstatement of the previously suspended license; placed reinstated license on probation for five years, beginning February 21, 2008, subject to certain terms as enumerated in the agreement.

- **Kerry Michael Finney (Pharmacist License No. 13535)**:
  - Voluntary Consent Agreement: Granted request for modification of probationary terms.

- **Kenneth Ralph Foster (Pharmacist License No. 9938)**:
  - Voluntary Consent Agreement: Granted request for modification of probationary terms.
Terry Ann Spears (Pharmacist License No. 8165), Voluntary Consent Agreement: Granted request for reinstatement of previously expired license, subject to completion of certain terms as enumerated in the agreement.

David Michael Pelous (Pharmacist License No. 11181): Denied request for reinstatement of suspended license.

Glenn Edwin Gough (Pharmacist License No. 11874), Voluntary Consent Agreement: Granted request for reinstatement of inactive license, subject to completion of certain terms as enumerated in the agreement.

Steve Patrick Michel (Pharmacist License No. 11999): Denied request for reinstatement of suspended license.

Mia Sunshine John (Technician Certificate No. 3957), Voluntary Consent Agreement: Granted request for reinstatement of expired certificate, subject to completion of certain terms as enumerated in the agreement.

Grand Coteau Prescription Shoppe (controlled dangerous substance [CDS] License No. C-001889), Board accepted voluntary surrender of the credential, resulting in the suspension of the CDS license for an indefinite period of time, effective November 26, 2007.

Pryce’s Pharmacy (CDS License No. C-000917): Board accepted voluntary surrender of the credential, resulting in the suspension of the CDS license for an indefinite period of time, effective December 12, 2007.

Mark Alan Parent, MD (CDS License No. 15811): Board accepted voluntary surrender of the credential, resulting in the suspension of the CDS license for an indefinite period of time, effective December 14, 2007.

Fyona Meshelle Daenen (Technician Certificate No. 7335): Board accepted voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective February 14, 2008.

Brittany Shanee Austin (Technician Candidate Registration No. 12288), Voluntary Consent Agreement: Registration revoked with permanent prohibition on any future application. Charges: six counts, including theft of controlled substances from employer pharmacy.

Megan Michelle Sturdivant (Technician Candidate Registration No. 12797), Voluntary Consent Agreement: Registration revoked with permanent prohibition on any future application. Charges: five counts, including theft of controlled substances from employer pharmacy.

Phil’s Pharmacy (Pharmacy Permit No. 2488), Voluntary Consent Agreement: Permit placed on probation for three years, beginning January 1, 2008; further, permit owner assessed $5,000 plus administrative and investigative costs; further, permit owner ordered to improve security of prescription department. Charges: seven counts, including accountability for shortages of controlled substances, including over 50,000 hydrocodone/APAP tablets during a one-year period.

Philip Wayne Beard (Pharmacist License No. 10513), Voluntary Consent Agreement: License assessed $1,000 plus administrative costs. Charges: seven counts, including accountability for shortages of controlled substances.

Alyson Beard McCleon (Technician Certificate No. 6568), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future application. Charges: six counts, including theft of controlled substances from employer, Phil’s Pharmacy.

Thrift-T-Way Pharmacy of Lake Charles (Pharmacy Permit No. 1111), Voluntary Consent Agreement: Permit placed on probation for five years, beginning January 1, 2008; further, permit owner assessed $7,500 plus administrative and investigative costs. Charges: six counts, including accountability for shortages of controlled substances, including over 45,000 hydrocodone/APAP tablets during a one-year period.

Kenneth Ray Richard (Pharmacist License No. 14439), Voluntary Consent Agreement: License suspended for an indefinite period of time; further, assessed $1,000 plus administrative and investigative costs; further, barred acceptance of any reinstatement application until after January 1, 2009, and conditioned that acceptance upon certain terms as enumerated in the agreement. Charges: six counts, including diversion of controlled substances from employer pharmacy.

Gerald Edward Sargent (Pharmacist License No. 15503), Voluntary Consent Agreement: License suspended for an indefinite period of time; further, assessed $25,000 plus administrative and investigative costs; further, barred acceptance of any reinstatement application until after January 1, 2018, and conditioned that acceptance upon certain terms as enumerated in the agreement. Charges: 11 counts, including diversion of controlled substances from multiple employer pharmacies, and illegal possession of controlled substances in Schedules III and IV.

The Corner Drug Store of Ruston (Pharmacy Permit No. 2317), Voluntary Consent Agreement: Permit placed on probation for five years, beginning January 1, 2008; further, permit owner assessed $25,000 plus administrative and investigative costs; further, permit owner ordered to improve security of prescription department as well as upgrade the electronic record-keeping system. Charges: 36 counts, including re-dispensing of returned medications, dispensing of misbranded prescriptions, dispensing controlled substances not authorized by a prescriber, accountability for shortages of controlled substances, permitting technicians to process and dispense prescriptions without pharmacist supervision, unsanitary conditions in storage area, failure to properly secure prescription department, and improper records in prescription department.

Gilford Raymond Birch (Pharmacist License No. 9924), Voluntary Consent Agreement: License suspended for an indefinite period of time; further, assessed administrative and investigative costs; further, prohibited access to prescription department at The Corner Drug Store of Ruston during the period of suspension; further, barred acceptance
Continued from page 5

of any reinstatement application until after January 1, 2009, and conditioned that acceptance upon certain terms as enumerated in the agreement. Charges: 37 counts, including re-dispensing of returned medications, dispensing of misbranded prescriptions, dispensing controlled substances not authorized by a prescriber, accountability for shortages of controlled substances, permitting technicians to process and dispense prescriptions without pharmacist supervision, unsanitary conditions in storage area, failure to properly secure prescription department, and improper records in prescription department.

Grand Coteau Prescription Shoppe (Pharmacy Permit No. 1889), Voluntary Consent Agreement: Permit revoked, effective March 31, 2008; further, permit owner assessed $75,000 plus administrative and investigative costs. Charges: 16 counts, including dispensing over 25,000 Internet prescriptions during eight-month period, dispensing controlled substances pursuant to invalid prescriptions, and forgery and alteration of prescriptions.

Paul Willis Williams, Jr (Pharmacist License No. 11089), Voluntary Consent Agreement: License revoked, effective March 31, 2008; further, assessed $20,000 plus administrative costs; further, barred acceptance of any reinstatement application until after January 1, 2018, and conditioned that acceptance upon certain terms as enumerated in the agreement. Charges: 17 counts, including dispensing over 25,000 Internet prescriptions during eight-month period, dispensing controlled substances pursuant to invalid prescriptions, and forgery and alteration of prescriptions.

On this same date, the Board also issued a Letter of Warning to one pharmacy permit, as well as Letters of Reprimand to three pharmacists and one pharmacy permit owner. Finally, they accepted a voluntary surrender of license from a pharmacist, tendered for medical reasons.

Calendar Notes (08-04-297)
The next Board meeting and administrative hearing will be May 7-8, 2008, at the Board office. The office will be closed May 26 in observance of Memorial Day and July 4 in observance of Independence Day.

Special Note (08-04-298)
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.

Page 6 – April 2008

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