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Louisiana Board of Pharmacy

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Board Mourns Robert L. Eastin, Sr. (99-07-46)

The Louisiana Board of Pharmacy and the profession of pharmacy lost a friend with the death of Robert L. Eastin, Sr. We knew him simply as "Bob," a kind and friendly man. Bob served on the Board of Pharmacy from November 9, 1996, until his death on March 9, 1999.

Through his leadership and dedication to the practice of pharmacy, Bob helped lay the foundation for pharmacy in the 21st century. He was an asset to the Board of Pharmacy, and a friend to all who knew him. Our condolences to his family.

A New Day! A New Executive Director (99-07-47)

The Louisiana Board of Pharmacy is pleased to announce its new executive director, Mr. Malcolm J. Broussard. Malcolm brings to the Board a vast array of pharmacy expertise. He has a passion and love for the profession of pharmacy. His contributions to the profession are too numerous to expand upon in this brief newsletter, but Malcolm has literally donated all of his energies and time to move the profession of pharmacy forward for everyone.

Malcolm has served our profession in a leadership and decision-making capacity on a state and national level through various associations. As executive director, he will bring those assets to the Board of Pharmacy. Malcolm, we thank you for accepting this challenge and best wishes from all of us!

I Enjoyed the Ride (99-07-48)

This will be my final *Louisiana Board of Pharmacy News* publication. I have resigned my position as executive director of the Board and state news editor of the newsletter. I would like to share with you the resignation letter I submitted to the Board on February 25, 1999:

The purpose of this letter is simple yet frustrating. I sadly but realistically submit to the Louisiana Board of Pharmacy my resignation as executive director, effective February 25, 1999. I offer my services, if legally allowable, to the Board during the necessary transition period.

Due to verbal concerns expressed by Walgreens, I swiftly requested, on December 23, 1998, an advisory opinion from the Louisiana Board of Ethics regarding whether any conflicts of interest are presented by my owning Mills' Cashway Pharmacy Inc., while serving as the executive director for the Louisiana Board of Pharmacy. On January 20, 1999, the Louisiana Board of Ethics issued such an opinion that would prohibit me from working and owning a pharmacy, including Mills' Cashway Pharmacy Inc., which is permitted or regulated by the Louisiana Board of Pharmacy, while serving as the executive director for the Louisiana Board of Pharmacy.

The opinion created an adversity I had to deal with head on. Do I continue to work in the government sector or retain a private business that I have owned for the past 18 years? For me the choice is business. I cannot sacrifice future financial opportunities available in the profession of pharmacy to serve exclusively as the executive director of the Louisiana Board of Pharmacy.

The events that have led to this choice cannot be controlled. Moreover, I am presently not in a position to legally question the opinion at issue.

I applied for this position of executive director with one major goal: to make a positive contribution to our proud profession of pharmacy. Together we have and will continue to pursue that goal. It was a privilege to represent the honor and tradition of the Louisiana Board of Pharmacy. I have met caring and kind professionals from near and far; their friendships will be everlasting. Helping consumers with complaints, fears, and problems was an opportunity to serve the great people of this state. Working with the two schools of pharmacy assured me that the future of pharmacy is solidly entrusted to our youth. Speaking to groups of pharmacists throughout the state reinforced my love for this profession. I thank the Board and staff for their support, guidance, trust, and love. I leave this office a humbled and appreciative person.

I have been blessed to know each of you!!

I conclude my farewell newsletter with this special message from an unknown author: Live life. Think freely. Practice patience. Smile often. Savor special moments. Live God's message. Make new friends. Rediscover old ones. Tell those you love that you do. Feel deeply. Forget trouble. Forgive an enemy. Hope. Grow. Be crazy. Count your blessings. Observe miracles. Make them happen. Discard worry. Give. Give in. Trust enough to take. Pick some flowers. Share them. Keep a promise. Look for rainbows. Gaze at stars. See beauty everywhere. Work hard. Be wise. Try to understand. Take time for people. Make time for yourself. Laugh heartily. Spread joy. Take a chance. Reach out. Let someone in. Try something new. Slow down. Be soft sometimes. Believe in yourself. Trust others. See a sunrise. Listen to rain. Trust life. Have faith. Enjoy wonder. Comfort a friend. Have good ideas. Make some mistakes; learn from them. Celebrate life.

Thanks for the ride!!!

Fred H. Mills, Jr.

VIPPS Program to Provide Consumers with Information about Internet Pharmacies

As an increasing number of Internet pharmacies begin to introduce their services to the public, the National Association of Boards of Pharmacy (NABP) is completing development of its voluntary Verified Internet Pharmacy Practice Sites (VIPPS) program. Accessible through NABP's Web site at www.nabp.net, the VIPPS program will provide consumers with useful information about those on-line companies that are providing pharmacy services and have met the Association's criteria and requirements for program participation.

Through NABP's VIPPS seal (shown below), Internet users will be able to immediately identify VIPPS-approved on-line pharmacy sites. These Web sites will be required to display the seal and establish a hyperlink to the VIPPS screen, from which users will be able to view specific information about the site. Internet users can also log on to the VIPPS site to search for data about all of NABP's VIPPS-approved sites.

"Consumers are encouraged to look for the VIPPS seal when browsing on-line pharmacy Web sites, and to click on the seal to verify its authenticity through an established link to the VIPPS site," said NABP President Dyke F. Anderson.

In June, the Association began accepting applications from on-line pharmacy companies for admission to the VIPPS program. Since then, NABP has been verifying the data provided by applicants and conducting inspections of their operations to ensure adherence with the program's established criteria and requirements.

"As the first VIPPS seals are awarded, the VIPPS Web section will go live. Time projections indicate that the first seals will be awarded in August," Anderson said. "However, consumers should keep in mind that VIPPS is an evolving program. On-line pharmacy sites will be constantly added to the program as they are approved for participation."

Data gathered during the VIPPS application process includes licensure information for the on-line pharmacy; the types of services offered (e.g., dispense prescription medications and/or over-the-counter medications); and the company's written policies and procedures regarding drug utilization review, patient counseling, patient confidentiality, and quality improvement programs.

If the results from the application review are satisfactory, the on-line pharmacy enters into an agreement with the Association in which the pharmacy agrees to:

- adhere to the VIPPS criteria and program requirements;
- maintain all appropriate state and federal licenses in good standing;
- provide and allow certain information about the pharmacy to be posted and maintained for public access on the VIPPS Web site;
- facilitate and allow inspections of its operations, given reasonable notice and accommodation; and
- display and maintain the VIPPS seal, with a hyperlink on the pharmacy's Web site.

More information about the VIPPS program can be found at www.nabp.net. Questions should be directed via e-mail to vipps@nabp.net, or by calling Glenn Detweiler, NABP's licensure programs director, at 847/698-6227.

FDA Dietary Supplement Labeling Rule Goes into Effect

A new Food and Drug Administration (FDA) regulation implementing some of the major provisions of the Dietary Supplement Health and Education Act of 1994, went into effect March 23, 1999. The new regulation, intended to give consumers the information they need to make informed purchasing choices, requires consistent and more thorough labeling of dietary supplements.

Manufacturers are now required to include on labels a "Supplement Facts" panel, a clear identity statement, and a complete list of ingredients. The "Supplement Facts" panel must state the following:

- The manufacturer's suggested serving size;
- Information on nutrients (e.g., Vitamins A and C, calcium, and iron) when they are present in significant levels, and the percent Daily Value where a reference has been established – similar to nutrients listed on the "Nutrition Facts" panel on food labels;
- All other dietary ingredients present in the product, including botanicals and amino acids – those for which no Daily Value has been established.

A statement of identity must appear on the front panel of the product label and must use the terms "dietary supplement" or a term identifying the contents of the product, such as "Vitamin C supplement" or "Herbal supplement." Herbal products must be identified by the common or usual name and the part of the plant used to make the supplement (i.e., root, stem, or leaf).

The FDA plans to survey dietary supplements on the market for compliance with the new labeling requirements.

Warning Issued for Products Containing GBL

Reports of potentially life-threatening problems associated with the use of gamma butyrolactone (GBL) have led to a warning issued by the Food and Drug Administration (FDA) for a voluntary manufacturer recall of products containing GBL. Although labeled as dietary supplements, GBL-containing products are actually unapproved new drugs illegally marketed under various brand names, including Renewtrient; Revivarant or Revivarant G; Blue Nitro or Blue Nitro Vitality;

GH Revitalizer; Gamma G; and Remforce. These products claim to build muscles, improve physical performance, enhance sex, reduce stress, and induce sleep.

When taken orally, GBL is converted in the body to gamma hydroxybutyrate, also known as GHB, an unapproved drug which has also been illicitly distributed as a body-building, dietary supplement.

GBL-containing products have been associated with at least 55 reports of adverse effects, including one death. In 19 of those cases, patients became unconscious or comatose and several required intubation. Other reported effects included seizures, vomiting, and bradycardia.

GBL has been sold in both liquid and powder forms in health food stores, gymnasiums and fitness centers, and via the Internet. Consumers are advised to dispose of any GBL-containing products and to contact a physician if they experience any adverse effects. The FDA asks that adverse events be reported to MEDWATCH at 800/332-1088.

FDA Recognizes Pharmacists in New OTC Labeling Regulations

A final rule recently issued by the Food and Drug Administration (FDA) recognizes pharmacists' knowledge and contributions to patient care when it comes to over-the-counter (OTC) drug products. Published in the March 17, 1999 *Federal Register*, the rule establishes standardized format and content requirements for the labeling of over-the-counter (OTC) drug products, and is intended to assist consumers in reading and understanding OTC product labeling so they may safely and effectively use these products.

In the rule, the FDA recognizes that "pharmacists are knowledgeable about OTC drug products" and "are a valuable resource" for consumers. It is for these reasons that the new rule requires manufacturers to include on OTC product labeling the phrase, "Ask a doctor or pharmacist before use if you are ...," when addressing drug/drug or drug/food interaction warnings.

"The recognition of pharmacists as competent providers of OTC drug information has been a long time coming," said NABP President Dyke F. Anderson. "This regulation acknowledges the pharmacist's role as an integral member of the health care team."

The regulation also goes a long way towards providing understandable information to patients. A new "Drug Facts" box on each product will state the "Active ingredients," "Purpose" (pharmacological category), "Uses," "Warnings," "Directions," "Other information" (when appropriate), and "Inactive ingredients." The regulation also addresses minimum type sizes and other graphic features, including options for modifying the format for various package sizes and shapes.

Most OTC product manufacturers must comply with the new regulations within two years. All of the more than 100,000 OTC products must have compliant labeling within the next six years.

Risk Management Program Accompanies Approval of Fentanyl "Lollipop"

Accompanying the release earlier this year of a new fentanyl product developed specifically for breakthrough cancer pain was the requirement by the Food and Drug Administration (FDA) that a comprehensive risk management program be in place to prevent potentially dangerous misuse or abuse. The new product, oral transmucosal fentanyl citrate (Actiq®), comes as a flavored sugar lozenge that dissolves in the mouth while held by an attached handle.

The areas of potential misuse and abuse are three-fold, according to Anesta Corp., the product's developer, and Abbott Laboratories, its manufacturer and distributor. Concerns regarding accidental ingestion by children, diversion and abuse, and inappropriate prescribing for and use by patients who are not tolerant to the effects of opioids, have resulted in a risk management program that focuses on the safe storage, use, and disposal of Actiq, and instructs health professionals regarding proper patient selection and education.

For patients, a "Patient Leaflet" is available with detailed use, storage, and disposal information, as well as an "Actiq Welcome Kit," containing a child-resistant lock (for the home storage compartment), a child-resistant temporary storage bottle (to store partially used Actiq units), a portable locking pouch, and a demonstration video. For pharmacists, a dispensing checklist appears on the shelf carton, which directs the pharmacist to ensure that the patient is a chronic opioid user, and to counsel the patient on the safe use, storage, and disposal of Actiq, as well as its risks to children.

For more information about the Actiq risk management program, log on to the Actiq Web site at www.abbotthosp.com/PROD/PAIN/actiqprod/act001.htm or call 1-888/818-4113.

Web Site Offers Pain Management Policy Information

For those interested in pain management and the effects of government regulation on the practice, the University of Wisconsin's Pain & Policies Studies Group (PPSG) Web site offers a wealth of information. Dedicated to facilitating public access to information about pain relief and public policy, the site features pain-related laws, regulations, and medical board guidelines for each state; articles about trends in pain policy; policy alerts; and a large section on international policy and opioid consumption trends. The PPSG's Web site can be found at www.medsch.wisc.edu/painpolicy/.

The PPSG studies the extent to which the regulation (or the perception of regulation) of drugs and professional practice affects pain management. Much of its work focuses on identifying and addressing the barriers to medical use of opioid analgesics essential to chronic pain management and palliative care, and the effects of prescription monitoring and health insurance on pain management.

Technician News (99-07-49)

A certificate that is not renewed by July 15, 1999, shall be null and void, and the certificate holder shall not be in good standing as a pharmacy technician in the state of Louisiana.

Future Pharmacy Technician Examination Dates

October 9, 1999
January 8, 2000

Disciplinary Actions (99-07-50)

The Louisiana Board of Pharmacy held an Administrative Hearing on May 6, 1999, at the First Circuit Court of Appeal, 1600 North Third St., Baton Rouge, LA, and acted on the following:

Robert N. Hall, #9994. Reinstatement requested; request approved pending completion of 16 hours American Council on Pharmaceutical Education (ACPE) credit, successfully completing the Multistate Pharmacy Jurisprudence Examination™ (MPJE™). License is to be reinstated on probation with conditions ending March 5, 2007.

Phillip A. Hughes, #10610. Probation modification requested to become pharmacist-in-charge at Excelth Network Desire Pharmacy, 2727 Louisa Street; Board granted request.

Antoinette L. LaCour, CPT #1771. Continued until next Administrative Hearing by motion of the Board.

Patrick B. Landreneau, #9437. Reinstatement requested; denied as premature based on plea agreement with the U.S. District Court, Western District of Louisiana, dated July 22, 1996.

Roy M. Montalbano, (aka Rosario Michael Montalbano) #9434. Reinstatement requested; action postponed until all matters with Board of Medical Examiners are resolved.

Leonard J. Sullivan, #9488. Continued until next Administrative Hearing by motion of the Board.

Gailyn Betts Young, #11653. Reinstatement requested; request approved.

The following **Voluntary Consent Agreements** were accepted by the Board:

Kay L. Kemp, CPT #1667. Voluntary surrender of Technician certificate accepted, resulting in an indefinite suspension; may not seek reinstatement of certificate prior to January 1, 2001. *Charges:* Unprofessional conduct, violating pharmacy laws, and violating technician regulations.

James A. Lancaster, #8482. License placed on probation for one year and assessed $250 in administrative costs. *Charges:* Failure to provide patient counseling while practicing in Kentucky.

Tyler Downtown Drugs, Inc., #1117. Permit placed on probation for five years with conditions, assessment of $2,000. *Charges:* Conduct endangering public health or safety; violation of pharmacy laws; inadequate pharmacy department security; and failure to maintain accurate and readily retrievable records resulting in an audit shortage.

The following Interlocutory Hearing Decree was continued until the next Administrative Hearing of the Board:

Jason C. Dove, #15811. License remains suspended until matter is heard by the Board at the next Administrative Hearing.

The Board received one voluntary surrender of license, reinstated three pharmacists' licenses, and accepted two voluntary consent agreements under the Louisiana Board of Pharmacy Impaired Pharmacist program.

Lagniappe (99-07-51)

This one is for my dear friend:

"Don't write anything you can phone, don't phone anything you can talk face to face, don't talk anything you can smile, don't smile anything you can wink, and don't wink anything you can nod."

– Earl Long, Former Governor of Louisiana.

Special Note (99-07-52)

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacists licensed by the Louisiana Board of Pharmacy. **These newsletters will be used in hearings as proof of notification.** Please read them carefully and keep them 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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