January 1998

# Louisiana Board of Pharmacy

5615 Corporate Blvd., Suite 8E, Baton Rouge, LA 70808 Published to promote voluntary compliance of pharmacy and drug law.

## Happy New Year (98-01-01)

Another year has gone by and we are still standing proud as pharmacists. We have maintained the honor of the public we serve. Together we have displayed our talents as valued members of the health care team and side by side we have proven the pundits wrong: pharmacy collaborative practice guidelines are drawing closer to becoming a reality, our two colleges of pharmacy work in unison with the Board, we accomplished all our legislative goals, and all state pharmacy associations participated in regulatory committee board meetings.

The Board's mission in 1998 is ambitious and daunting: we will continue to reach out to all disciplines of this diverse profession. Together we will strive to improve the health of Louisiana's citizens. In 1998, we must accept the ongoing challenge and defend our No. 1 ranking as the most trusted profession. We will accomplish this by protecting the public's health, safety, and welfare. As pharmacists we must never stop caring for the public we serve; that is why we are number one year after year.

From the Board of Pharmacy to you our dear colleagues, may you and your families have the happiest of NEW YEARS and may all your dreams come true!

## Board Elections (98-01-02)

The Board of Pharmacy elected the following officers for this year:

| | |
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| President | Carl W. Aron |
| First Vice President | Phillip C. "Pete" Aucoin |
| Second Vice President | Robert L. Eastin, Sr. |
| Third Vice President | Reuben R. Dixon |
| Secretary | Thomas J. "Pete" Chambliss |

## Regulation Changes (98-01-03)

On October 20, 1997, the Louisiana Board of Pharmacy promulgated seven regulations. Shortly thereafter, all permitted sites were mailed copies of these regulations, along with a summary of each regulation and information on the Pharmacy Technician Program. All pharmacists should read and review all information in this important mailing.

## Pharmacy Technician Program (98-01-04)

Plans have been finalized for the implementation of the Pharmacy Technician Program. Testing of pharmacy technician applicants will begin February 21, 1998. The Board office will continue to mail vital and timely information to all pharmacists-in-charge concerning the technician program. The Board office has received and responded to various questions related to the Pharmacy Technician Program. The following questions and answers will hopefully address those concerns:

**Question:** *I have been a support staff person for the past 10 years and I have successfully passed an association national technician exam. Do I still have to take the Louisiana test?*

**Answer:** Yes. Any person previously completing a support staff training program and having worked a minimum of 200 hours as a support staff person in a Louisiana pharmacy as of October 1, 1997, or before, shall be considered to have met the requirements of the didactic program and the on-site technician training program. An affidavit signed by the **pharmacist-in-charge** and the support staff person, properly notarized and attesting to the necessary facts, shall accompany the application for the pharmacy technician examination in order to obtain this exemption. This means you must pass the Louisiana Board of Pharmacy Technician Examination **regardless** of having passed a national technician exam.

**Question:** *As a current support staff person, if I do not pass the technician test by April 30, 1998, will I still be given credit for my previous support staff training and the hours I worked?*

**Answer:** NO! If you have not successfully completed the technician test by April 30, 1998, you then must successfully complete **all** minimal standards outlined in chapter 8, section 805, of the Pharmacy Technicians Regulation. This means you must go through a Board-approved didactic program, earn a minimum of 200 hours of experience, and successfully complete a test within a year.

**Question:** *I am a pharmacy technician from another state. Can I reciprocate?*

**Answer:** NO! All minimal education standards must be successfully completed in Louisiana. See the above answer.

**Question:** *Why is the Board changing from support staff regulations to the technician regulations?*

**Answer:** The mission of the Louisiana Board of Pharmacy is to protect the health, safety, and welfare of the citizens of Louisiana, and we must maintain and continue to elevate the practice of pharmacy. The purpose of this Pharmacy Technician Regulation is to ensure the standard of pharmaceutical excellence our citizens of Louisiana deserve and demand from this most trusted profession. This Technician Regulation expands the duties and responsibilities of present pharmacy support staff.

**Question:** *Once I successfully complete the Board requirements, will I get more money?*

**Answer:** That is a concern of most current support staff. This question will be answered only in due time by employers, not the

*Continued on page 4*

National Pharmac

(Applicability of the contents of articles in the National Pharm
and can only be ascertained by exami

## Pharmacy Compounding Legislation Adopted

The distinction between compounding and manufacturing was made clearer thanks to language included in the Food and Drug Administration (FDA) reform bill passed by Congress on November 9, 1997, and signed by President Clinton on November 21, 1997. The legislation incorporates provisions to reform FDA procedures, including language specifically exempting pharmacy compounding from several requirements of the Food, Drug and Cosmetic Act.

This section exempts compounding performed by pharmacists and physicians, under certain conditions, from FDA regulation, and clarifies that compounding is regulated at the state level by the boards of pharmacy and medicine. The legislation also contains important protections for the compounding of positron emission tomography (PET) radiopharmaceutical drug products.

In an effort by the FDA to curtail the manufacturing of products under the guise of compounding, previous versions of the bill attempted to bring certain activities under the jurisdiction of the FDA. The National Association of Boards of Pharmacy (NABP) and practitioner groups urged that the legislation promote cooperative efforts between the state boards of pharmacy and medicine and the FDA.

In a letter to Senator Tim Hutchinson (R-AR), sponsor of the bill, NABP Executive Director/Secretary Carmen A. Catizone stated, "NABP supports ... legislation which will continue to recognize the authority of the state boards to regulate the practice of pharmacy, specifically the compounding of pharmaceuticals, as well as address the concerns of the FDA in regard to the manufacturing of products by entities trying to disguise themselves as legitimate pharmacies."

The new legislation allows for the compounding of drug products for identified individual patients based on the unsolicited receipt of a prescription authorized by the prescriber. The compounding of a product may also take place prior to the receipt of a valid prescription order based on a history of having received prescription orders for such products within an established pharmacist-patient or pharmacist-physician relationship.

This legislation also regulates the types and characteristics of bulk drug substances and ingredients that may be used in compounding, limits the amount of compounded product that may be distributed out of state, and places restrictions on the advertising and promotion of the compounding services offered.

The legislation mandates that an NABP representative be a member of an advisory committee that will assist the Department of Health and Human Services in developing regulations to implement the compounding legislation. NABP is also designated as the organization that will consult with the secretary of Health and Human Services to develop a memorandum of understanding for states' use when compounded drugs are distributed across state lines.

## FDA Advisory Against Compounded and Herbal Fen-Phen; HHS Recommendations to Users

The Food and Drug Administration (FDA) recently issued two advisories involving the popular anti-obesity drugs fenfluramine and dexfenfluramine (marketed respectively as Pondimin® and Redux®), which were withdrawn from the market in September. In one, the FDA expected pharmacists to refrain from distributing compounded fenfluramine (used in the "fen-phen" combination) and dexfenfluramine products to consumers. The other was a broad, public advisory to consumers stating that products marketed as "herbal fen-phen" could be hazardous to users' health.

### No Compounded Fen-Phen or Redux

The FDA has received reports that some pharmacists may be compounding fenfluramine and dexfenfluramine for their patients. The agency has issued a reminder of the serious health risks associated with these products, particularly the heart valvular abnormalities observed in 30 percent of subjects taking the medications, and has asked pharmacists to refrain from dispensing any compounded fenfluramine or dexfenfluramine products.

The FDA welcomes information regarding the manufacturers and/or sources of raw materials used to compound these products. This information may be provided to Robert Tonelli or Kathleen Anderson at the FDA, 301/594-0101. In addition, the FDA encourages pharmacists to share information about any known adverse reactions to compounded fenfluramine and dexfenfluramine products. These should be reported to the MEDWATCH program at 1-800/FDA-1088.

### Dangers of Herbal Alternatives to Fen-Phen

Products promoted as "herbal alternatives" to fen-phen have been commonly marketed on the Internet, at weight-loss clinics, in print advertisements, and at retail outlets. The main ingredients in these products are Ma huang (ephedra) in combination with St. John's Wort or L-tryptophan. In large doses, ephedra has been linked with an increased likelihood of heart attack, stroke, seizure, or death. The FDA has emphasized that the lack of known data demonstrating the efficacy of such herbal weight-loss products and their unknown quantities of ephedra raises concerns about product safety.

Moreover, the FDA, in a memorandum from its Non-Traditional Drug Compliance Team, stated, "Labeling OTC [over-the-counter] products as alternatives to anti-obesity drugs such as [fen-phen] is evidence that they are intended for the same use as the prescription drugs. Because these products are intended to treat obesity, they are drugs under the definition in section 201(g)(1)(B) of the Food, Drug and Cosmetic Act."

The FDA is documenting information on OTC products promoted as alternatives to prescription anti-obesity drugs and is identifying the marketers of such products.

### Recommendations to Fen-Phen and Redux Users

The U.S. Department of Health and Human Services (HHS) has issued preliminary recommendations for counseling users of fenfluramine and dexfenfluramine. Developed jointly by the FDA, the Centers for Disease Control and Prevention, and the National Institutes of Health, the recommendations are based on current knowledge about the connection of these drugs to the development of heart valvular disease.

HHS recommends that anyone who has taken fenfluramine or dexfenfluramine for any period of time, either alone or with another drug(s), should:

- see his or her doctor for a medical history and physical examination to determine whether there are signs or symptoms of heart or lung disease.

- have an echocardiogram performed if the individual also has signs or symptoms of heart or lung disease, such as a new heart murmur or shortness of breath.
- have an echocardiogram BEFORE having any invasive procedure for which the American Heart Association recommends antibiotic prophylactic treatment to prevent the development of bacterial endocarditis. The echocardiogram will provide an accurate determination of whether the individual needs the antibiotic treatment.

## Study Recommends Counseling Parents on OTC Use for Children

A study published in the July 1997 issue of *Archives of Pediatric and Adolescent Medicine* found that even though a large number of caregivers administer over-the-counter (OTC) products to children, the caregiver's lack of knowledge about these medications, including the accuracy and correctness of the dosing, raises concerns about the children's safety.

In the study, investigators presented a mock scenario to 100 caregivers, who were asked to determine and measure a correct dose of acetaminophen for their child. A dose of 9 to 16.5 mg/kg was considered correct, and a measurement within +/-20 percent of the intended dose was considered accurate.

Only 40 percent of caregivers calculated an appropriate dose for their child and only 67 percent were able to accurately measure the amount of acetaminophen they intended. A total of 43 percent actually measured a correct amount of the drug, but almost one-third of that number did so accidently by inaccurately measuring an improper intended dose. Combining these results, only 30 percent of the caregivers were able to demonstrate both an accurately measured and correct dose for their child.

The study results show that improved caregiver education is necessary. Pharmacists should make every effort to counsel parents who intend to dose their children with OTC preparations.

## Non-Traditional PharmD Degree Upgrade Program Guidelines Revised

In 1995, this "National Pharmacy Compliance News" contained an article detailing "Guidelines for a Uniform Method for a Baccalaureate Degreed Pharmacist to Earn a Doctor of Pharmacy Degree," which was developed as a blueprint for colleges and schools of pharmacy seeking to establish non-traditional degree upgrade programs. Since that time, the National Association of Boards of Pharmacy (NABP) Executive Committee and member boards of pharmacy have continued to monitor the development of non-traditional doctor of pharmacy programs by the colleges and schools of pharmacy.

NABP's continued interest in the progress being made affirms the Association's desire for continued cooperation between the state boards of pharmacy and the colleges and schools of pharmacy in this critical area. Without such cooperation, practitioners interested in earning a doctor of pharmacy degree may face significant obstacles.

The following Guidelines, originally developed by NABP's Task Force on the Development of an Equitable Degree Upgrade Mechanism, are being reprinted to provide clarification in the "Affordability" section of the document. In response to comments from the American Association of Colleges of Pharmacy (AACP) and several colleges and schools of pharmacy, the clarification presents a more realistic time frame for completing a model program.

The Guidelines are only recommendations issued by NABP and its member boards of pharmacy. They are not legal or academic requirements. Practitioners are encouraged to contact their local college or school of pharmacy for more information concerning whether a non-traditional degree upgrade program is being offered and the specific requirements of those programs.

The "Guidelines for a Uniform Method for a Baccalaureate Degreed Pharmacist to Earn a Doctor of Pharmacy Degree" are reprinted below in their current form. The amended clause is highlighted.

I. A pharmacist holding a baccalaureate degree in pharmacy from an ACPE-accredited program who wishes to earn a doctor of pharmacy degree voluntarily makes application to the college or school from which he/she graduated or to another ACPE-accredited program. The application shall be assessed using a uniform guideline within the institution and among all ACPE-accredited pharmacy programs. The application would include the necessary identifier information as well as:
   1. Date of graduation;
   2. Date of original licensure as a pharmacist;
   3. Other educational experiences (including continuing education) and/or degree(s) earned; and
   4. Criteria - Appropriate and documented practical experience, based upon criteria developed with input from practitioners and boards of pharmacy, assessed individually.

II. Following the assessment of the pharmacist's application, professional skills, abilities, and knowledge and payment of appropriate fees, the college/school would select the appropriate procedure for the baccalaureate-degreed pharmacist to earn a doctor of pharmacy degree. The procedure would be one of the following:
   1. Completion of appropriate didactic work (e.g., continuing education courses – live or home study); or
   2. Completion of appropriate experiential rotation(s); or
   3. Completion of appropriate didactic work and appropriate experiential rotation(s); or
   4. No additional requirements.

Such a standardized mechanism shall be individually customized within the context of the following characteristics:

1. **ASSESSABILITY:** A competency-based process (i.e., NAPLEX competencies) shall be conducted by a committee composed of faculty and practitioners.
2. **ACCESSIBILITY:** Accessibility is defined as a practical, non-disruptive program that will not require the applicant to relocate or significantly interfere with his or her practice.
3. **ACADEMICALLY SOUND:** An academically sound program is defined as a documented evaluation that does not disrupt or compromise accreditation standards.
4. **AFFORDABILITY: An affordable program is defined as one which can be offered to the applicant at a reasonable cost and may be completed in a timely manner *(e.g., 36 semester hours).***

*Continued from page 1*

Board. The supply and demand of this field will dictate salary definitions. Please understand, the Louisiana Board of Pharmacy sincerely values your concerns, but our mandate is to protect the public's health, safety, and welfare.

**Question:** *When, where, and how often will the exams be offered?*

**Answer:** The first exam will be offered on Saturday, February 21, 1998, at various sites in the state. Future exams will be offered when necessary, as determined by the Board. The Board office will send notifications of future exam dates and locations to all permitted sites in Louisiana.

**Question:** *What can a technician not do?*

**Answer:** Only a pharmacist shall interpret, evaluate, and implement all prescriptions: written, oral, or otherwise. Only a pharmacist shall review the completed prescription for accuracy and compliance before the prescription is released from the prescription department. Only a pharmacist shall provide patient counseling and drug information, as necessary.

**Question:** *I am currently working as a support staff person, and I am terrified of taking exams. I am afraid of failing the test and losing my job.*

**Answer:** Rest assured, if you have worked and trained as pharmacy support staff in earnest, you should have no problem passing the test. Your pharmacist-in-charge should assist you as you prepare for this exam. Review sessions will be offered by Xavier University of Louisiana, College of Pharmacy, and Northeast Louisiana University, School of Pharmacy, if you feel you need refresher work. The Louisiana Board of Pharmacy will continue to answer your questions and alleviate your fears in this new process. We value your contributions and dedication to this profession that we together proudly serve.

## Board Member Appointments (98-01-05)

Six Board members' terms will expire July 28, 1998: Salvatore J. D'Angelo, District 1; Reuben R. Dixon, District 2; Thomas J. Chambliss, District 4; Carl J. Napoli, Sr., District 6; Allan L. Brinkhaus, District 7A; and Charles D. Trahan, District 7B.

In accordance with pharmacy law (on page 2 of the law book), some time in May 1998 we will mail nomination ballots to all pharmacists whose mailing address (with the Board office) is within the pharmacy district. For preliminary planning, should any pharmacist need a list of pharmacists in his or her respective district for purposes related to this nomination election, the Board office will supply said list one time only, upon written request. Further information will be provided in the April 1998 newsletter.

## Violations Hearing (98-01-06)

The Louisiana Board of Pharmacy held a violations hearing on November 10, 1997, at the First Circuit Court of Appeals, 1600 North Third Street in Baton Rouge. A synopsis of the hearings and results will appear in the Board's April newsletter.

## Preceptor Certification (98-01-07)

A preceptor is a Louisiana-licensed pharmacist who has been recognized as a certified preceptor qualified to proctor in the extern/intern practical experience program. Upon receipt of the properly completed preceptor application, and after verification by the Board that all requirements are satisfied, the Board may issue a preceptor certificate. This is not a renewable certificate. The certificate is valid as long as you are in good standing with the Board of Pharmacy. If you are not sure you are a certified preceptor, please contact the Board office and save yourself the paperwork.

## Lagniappe (a little extra!!) (98-01-08)

*Rarely does reality meet your dreams, quit waiting for utopia.*

## Special Note

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.

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