

# North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## 1998 Board of Pharmacy Members



Seated, left to right: Jack G. Watts, president, Burlington; Albert F. Lockamy, Jr., vice president, Raleigh. Standing, left to right: Timothy R. Rogers, Raleigh; Wm. Whitaker Moose, Mt. Pleasant; Michael Overman, Asheville; and Robert L. Crocker, Farmville

## Item 952 – Disciplinary Actions Pre-Hearing Conferences – July

**B. Christopher DeCaron, Mooresville (DOB June 1, 1964).** Heard by Board member Watts. Misapplying and otherwise diverting controlled substances to his own use; indulgence of drugs to an extent that made his behavior a danger to the public; failing to maintain records of transactions involving controlled substances. **Recommendation:** License suspended indefinitely with conditions. Accepted by Mr. DeCaron August 19, 1997; accepted by the Board October 21, 1997.

**John C. Hood, Jr., Kinston (DOB May 9, 1924) and Hood Pharmacy, Kinston.** Heard by Board member Rogers. Dispensing prescription drugs without authorization of a person authorized to prescribe such drugs. **Recommendation:** License suspended five years, stayed five years with active five-day suspension to begin no later than January 1, 1998, and other conditions. Permit suspended three days, stayed three years. Accepted by Mr. Hood July 30, 1997; accepted by the Board October 21, 1997.

**Timothy P. Keisler, Hollywood, SC (DOB July 15, 1966).** Heard by Board member Crocker. Unlawfully obtaining and ingesting hydrocodone while involved in the practice of pharmacy. **Recommendation:** License suspended two years, stayed with conditions. Accepted by Mr. Keisler September 26, 1997; accepted by the Board October 21, 1997.

**James D. Luke, Pineola (DOB March 28, 1928).** Heard by Board member Watts. Failure to verify hours of continuing education necessary to renew his license to practice pharmacy for 1996. **Recommendation:** Obtain 20 contact hours of continuing education for the 1999 renewal of his license to practice pharmacy. Accepted by Mr. Luke October 22, 1997; accepted by the Board October 21, 1997.

**David E. Upchurch, Hillsborough (DOB August 2, 1959), Upchurch IV Therapy Corp. and Upchurch Drugs, Durham.** Heard by Board member Crocker. Ingestion of alcoholic beverages while performing acts that are within the meaning of the practice of pharmacy. **Recommendation:** License suspended two years, stayed with specific conditions. Accepted by Mr. Upchurch on September 23, 1997; accepted by the Board October 21, 1997.

## Full Hearing – October

**Robert R. Broyles, III, Gates (DOB November 13, 1963).** Order reinstating license entered with conditions.

**Jeffrey K. Galloway, Charlotte (DOB November 1, 1962).** Order reinstating license entered with conditions.

**Van Hill King, Jr., Wilmington (DOB July 11, 1934).** Obtaining and consuming prescription drugs, including controlled substances, from pharmacy stock without authorization. Request for reinstatement of license denied and license remains suspended indefinitely.

## Item 953 – Web Site Update

As announced in the October *North Carolina Board of Pharmacy News* (see Item 946), the Pharmacy Board now

Continued on page 4



# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy and can only be ascertained by examination)

## **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.

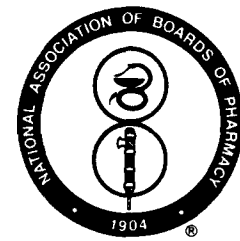
## **Recommendations to Fen-Phen and Redux Users**

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.

# Compliance News



...pliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

- ◆ 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 accidentally 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 (AACCP) 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).

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has a Web site, containing much information. Categories of information with selected topics are:

- “**About the NC Board of Pharmacy**” – The history and structure of the Board, Board hours, and how to contact the Board;
- “**New Developments**” – News about recent legal and policy changes;
- “**Frequently Asked Questions**” – Answers to questions about pharmacy legal matters, reciprocity, Board policies, and more;
- “**Calendar**” – Exam dates, Board meetings, reciprocity meetings, permit meetings, directions to the Board of Pharmacy offices;
- “**Literature**” – Download copies of brochures, notices, and the text of Board rules and regulations and other pharmacy-related laws.

It is possible to communicate with Board staff by e-mail. Pertinent addresses are:

**drwork@ncbop.org** (executive director, legal questions)

**csmith@ncbop.org** (reciprocity information)

**gbrantley@ncbop.org** (human resources, financial matters)

**dstump@ncbop.org** (examination matters, pharmacist address changes)

**rparis@ncbop.org** (pharmacy permit applications, pharmacy address changes)

**tdodson@ncbop.org** (DME permits, reciprocity information)

**wandrews@ncbop.org** (FNP/PA information, physician dispensing)

**hudson@twave.net** (investigations, inspections, complaints)

### **Item 954 – New Label, Old Directions**

A citizen brought to the Board staff's attention confusion regarding label instructions on refills for medications that require an initial tapering dose, such as prednisone. The physician and pharmacist understand that once the dose gets down to a certain level, it is to remain at that point until therapy is changed, but the patient is not always aware of this.

If there is not complete communication, or if there is no patient counseling, it is possible a patient would, upon refilling the prescription, see the tapering dose instructions again and begin with the high dosage regimen all over again. This underscores the importance of patient counseling and communication in providing optimum drug therapy.

### **Item 955 – Updated Oxygen Survey**

Thanks to El Niño, North Carolina had an uneventful 1997 hurricane season. However, there is potential for a rough winter throughout the state. With unpredictable weather patterns,

it is important for those patients on oxygen therapy that a sufficient back-up oxygen supply be maintained in the patients' homes to avoid interruption of oxygen therapy. As stated in an earlier article on the subject, the Durable Medical Equipment (DME) Subcommittee of the North Carolina Board of Pharmacy directed Board staff to conduct a survey on back-up oxygen supplies being provided to patients by DME suppliers.

The Board surveyed 25 percent of permitted DME suppliers throughout each region of North Carolina. Each DME company supplies an average of 121.14 patients with oxygen, with a minimum of four patients and a maximum of 578 patients. The company with the fewest number of oxygen patients is in Nash County, and the company with the largest number of patients is in Mecklenburg County. The average amount of back-up left with the patient is approximately 27 hours at two liters per minute, with one “E” cylinder the minimum amount provided and a liquid oxygen system the maximum.

Just under 75 percent of the companies had a written Emergency Disaster Plan in place in the event of a disaster. Of the facilities surveyed, approximately 17 percent were licensed to transfill oxygen by the Food and Drug Administration (FDA) and the North Carolina Department of Agriculture.

Companies maintained an average of 2.38 delivery vehicles. These vehicles ranged from vans, box trucks, and pickup trucks to four-wheel-drive station wagons and normal passenger vehicles. The average distance to the furthest oxygen patient was 50.26 miles, with a drive time of approximately 58 minutes. Approximately 35 percent of the companies were national suppliers and 65 percent were independent suppliers.

These survey results did not differ greatly from the survey previously conducted on the same issue. The Board reminds its members to keep in mind that the safety of the public of North Carolina is the ultimate goal.

### **1998 DME Subcommittee Members**



*Durable Medical Equipment Subcommittee members for 1998. Seated, left to right: Larry Lankford, Durham; Wayne Link, chairman, Lynn; Kathrine Noel, Oxford. Standing, left to right: Timothy Rogers, Raleigh; Wm. Whitaker Moose, Mt. Pleasant.*

### **Item 956 – “Sharps” Rules**

An inquiry from a county recycling department caused Board staff to look into local ordinances pertaining to disposal of “sharps.” Some cities and/or counties have local rules or ordinances pertaining to sharps, which include such items as needles used for injectables. An inquiry through the North Carolina Association of County Commissioners yielded some results but may not have been complete.

If you are aware of any rules or ordinances that exist in your county or community on the disposal of these items, please inform the Board office at your earliest convenience.

### **Item 957 – Acetaminophen Overdoses**

Recent news reports confirm that fatal liver damage from overdoses of acetaminophen is more likely to result from accidental use rather than from suicide attempts. The use of alcohol and acetaminophen together has been shown to be the biggest factor in liver injury.

The average accidental overdose for acetaminophen is 11 grams, while the average dose taken in a suicide attempt is 24 grams.

New labeling has also been approved warning citizens specifically about acetaminophen use in children. Several cases of liver damage and death from acetaminophen use have been reported in children in the United States.

### **Item 958 – Dental Problems from Drugs**

The Associated Press reported that an elderly man had tooth decay directly caused by the erroneous use of nitroglycerine tablets. He had gagged on his sublingual drug, so he stuck the tablets under his top lip, where they eventually ate a hole in his tooth.

Other potential dental problems arising from drug use include gum swelling in patients taking either calcium channel blockers or Dilantin. Cyclosporin can cause massive gum overgrowth.

These issues are best dealt with by the pharmacist during patient counseling.

### **Item 959 – It’s Just an Antacid; What Could Go Wrong?**

Plenty, it seems, as there have been at least 14 deaths and other hospitalizations and disabilities linked to magnesium poisonings since 1968. Magnesium is a common ingredient in antacids, and pharmacists should offer counseling to patients who commonly use these over-the-counter medications.

Magnesium is an important nutrient in foods and drinking water, but overdoses can produce symptoms such as clumsiness, weakness, paralysis, drowsiness, confusion, and coma.

### **Item 960 – Who Can Prescribe What?**

Questions arise occasionally in the Board office about which professionals can prescribe what drugs. Physicians, of course, can treat their patients with any prescription drug on the market and can issue prescriptions to be compounded. Some caution needs to be exercised with certain drugs that have limiting labeling from the Food and Drug Administration (FDA) (see Item 896) and, of course, it always needs to be in the ordinary course of professional practice.

Physician assistants and nurse practitioners can prescribe in a manner very similar to physicians as long as they are treating their patients. They can only operate under protocols, but most pharmacists have no way of knowing exactly what is in such documents. Physician assistants, nurse practitioners, and certified nurse midwives are limited in their prescribing of controlled substances to a seven-day supply, although nurse practitioners can prescribe Ritalin for up to 30 days. Professionals in all three categories can prescribe controlled substances in Schedule IV in the same way that a physician can, including refills.

Osteopathic physicians in North Carolina must pass the same licensing exam as regular physicians and are treated the same way in this state.

Dentists can prescribe to treat dental conditions, podiatrists can prescribe for conditions of the foot, optometrists can prescribe to treat conditions of the eye, and veterinarians can prescribe for animals under their treatment.

### **Item 961 – A Taxing Matter**

Questions continue to arrive in the Board office regarding the proper application of sales tax in health care.

Several devices and prescription drugs are exempt from the North Carolina Sales and Use Tax. G.S. 105-164.13 exempts the following items from the North Carolina Sales and Use Tax:

Therapeutic, prosthetic, or artificial devices, such as pulmonary respirators or medical beds...that are sold on the written prescription of a physician, dentist, or other professional person licensed to prescribe, and crutches, artificial limbs, artificial eyes, hearing aids, false teeth, eyeglasses, ground on prescription of a physician or an optometrist, and orthopedic appliances designed to be worn by the purchaser or user [and]...[m]edicines sold on prescription of physicians, dentists, or veterinarians; insulin whether or not sold on prescription.

Thus, any medicines prescribed by a physician as well as the other devices and articles listed above are exempt. Also note, there is no sales tax on insulin.

Over-the-counter medicines and devices not listed above will be subject to the sales and use tax. Exemptions in the sales tax statute are strictly construed in favor of imposing tax and against allowing an exemption.

## **Item 962 – Tax on Sales to Physicians**

The Board has received several comments from pharmacists who have been visited by agents from the North Carolina Department of Revenue. A little-known provision of the law states that the sales tax exemption for prescription drugs applies only to purchases made by patients. If such purchases are made from a pharmacy by physicians, their office, clinic, or other similar entity, sales tax should be applied to that transaction and remitted to the North Carolina Department of Revenue.

## **Item 963 – Discussions with Board Members May Jeopardize Cases**

Occasionally a licensee attempts to communicate directly with a member of the Board of Pharmacy to discuss a pending case. Such *ex parte* communications can result in the contacted Board member being unable to participate in the hearing on the matter.

Generally the caller just wants to get an impression regarding Board opinion or to confirm that the Board has all the facts. It is important to understand, however, that Board members acting as individuals have no authority to act on any matter on behalf of the Board or to direct staff to take specific action. The Board is authorized to act only during lawfully convened meetings when a quorum is present. A Board member who is contacted directly may be forced to disqualify himself from the discussion or from the vote on the matter.

If you have an issue before the Board and wish to obtain general information, please contact the Board office. Although the staff will not be able to tell you how the Board will decide a specific case, they can provide general and historical information, possible alternatives, and information on procedural steps. The Board operates under the North Carolina Administrative Procedures Act.

### **Special Note About this Newsletter**

The *North Carolina Board of Pharmacy News* is considered an official method of notification to pharmacists licensed by the Board. These newsletters have been and will continue to be used in hearings as proof of notification. Please read them carefully and keep them for future reference.

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