January, 1996

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

P.O. Box 459, Carrboro, NC 27510-0459
Carrboro Plaza Shopping Center, Highway 54 Bypass, Suite 104-C, Carrboro, NC 27510-1597

Item 859 – Disciplinary Actions

Pre-Hearing Conference

Tamala Jane Hartsell (DOB: November 17, 1961), Pharmacist-Manager, Pharmacy Services of America, Charlotte. Heard by Board Member Watts. Late renewal of permit to operate Pharmacy Services of America.

Recommendation: Permit suspended 15 days, stayed three years with the condition that the permit for Pharmacy Services of America be renewed by December 31 of each year of the Stay Order. Accepted by the Board and Ms. Hartsell.

September

William Timothy Walker (DOB: May 5, 1942) **and Pharmacy Land**, Eden. Allowing an unlicensed person to dispense a prescription drug without supervision; dispensing drugs in a non-safety closure container; violations of the patient counseling rule. Pharmacy failed to prevent the violations when the permit holder knew or should have known that the violations were occurring.

Mr. Walker's license suspended ninety (90) days, stayed five (5) years with active 45-day suspension and other conditions.

Permit for Pharmacy Land suspended thirty (30) days, stayed five (5) years with active three (3) consecutive day suspension and other conditions.

Pre-Hearing Conferences

Gordon Bryant Johnson (DOB: October 3, 1954), Charlotte. Heard by Board Member Watts. Consumption of Vicodin, Lorcet HD, Hydrocodone, and Fioricet without a prescription.

Recommendation: License suspended indefinitely, stayed five (5) years with active suspension of 90 days beginning on July 17, 1995, and other conditions. Accepted by Mr. Johnson and the Board.

Anthony Bryant Cameron (DOB: December 11, 1961), Fayetteville. Heard by Board Member Randall. Dispensed numerous prescription medications to himself and another family member without a prescription or authorization from a physician to include Percocet (Roxicet and Valium 10 mg [Diazepam]).

Recommendation: License suspended indefinitely and cannot petition Board for reinstatement for a period of three years from date of Order, which is September 30, 1995. Accepted by Mr. Cameron and the Board.

John Randall Martin (DOB: December 28, 1949), Clayton, Georgia. Heard by Board Member Lockamy. Failed or refused to renew the permit to operate Highlands-Cashiers Hospital for 1995 in a timely manner.

Recommendation: License suspended for 13 days, stayed three years with condition that the license of Mr. Martin be renewed by December 31st of each year during the stay period and other conditions. Accepted by Mr. Martin and the Board.

Highlands-Cashiers Hospital, Highlands. Heard by Board Member Lockamy. Jim Cothran, pharmacist-manager, present to represent the hospital. Failed or refused to renew the permit to operate Highlands-Cashiers Hospital for 1995 in a timely manner.

Recommendation: Permit suspended 13 days, stayed three years with condition that permit to operate Highlands-Cashiers be renewed by December 31st of each year during the stay period and other conditions. Accepted by Mr. Cothran for the hospital and the Board.

John D. Miller (DOB: August 25, 1940), Sherrills Ford. Heard by Board Member Moose. Dispensing error on a prescription for Vascor 200 mg.

Recommendation: License suspended 30 days, stayed two years with conditions. Accepted by Mr. Miller and the Board.

James Wood Oxendine (DOB: April 27, 1953), Charlotte. Heard by Board Member Lockamy. Neglection of duties as pharmacist-manager.

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharma
and can only be ascertained by exa

NABP Implements New Electronic Licensure Transfer Program

Pharmacists will soon be able to transfer their licenses across state lines even faster than before thanks to the Electronic Licensure Transfer Program (ELTP), a new computerized system being developed by the National Association of Boards of Pharmacy (NABP). The ELTP system will permit pharmacists and state boards of pharmacy to use state-of-the-art technology that includes electronic communication capabilities when processing applications to transfer licensure from state to state.

"The new Licensure Transfer Program, which will be operational in February, is part of NABP's continuing efforts to expedite the licensure transfer process and facilitate the interstate mobility of pharmacists," announced NABP President Ruth A. Vandever. "The new ELTP system will also make it easier for state boards of pharmacy to obtain critical information when making licensure transfer decisions about the pharmacists seeking licensure there. In turn, individual pharmacists will find that the time it takes to transfer their licenses has been greatly reduced."

Utilizing the ability of the new ELTP system to allow groups of people to electronically access, track, share, and organize information contained in the database, much of the time-consuming paperwork to verify the critical licensing information that must be completed under the current licensure transfer program will be decreased or eliminated. Developed by Vector Research, Inc., a computer consulting firm headquartered in Ann Arbor, Michigan, the ELTP system is based on a customized version of Lotus Notes and a PC-based hardware platform. The new database will be maintained at NABP headquarters and will only be accessible off-site via workstations at state board of pharmacy offices.

"Access to information stored in the ELTP database will be restricted to authorized NABP and state board of pharmacy staff, who will enter the system through a protected password procedure," emphasized NABP Executive Director Catizone A. Catizone. "We will enforce strict protections in order to maintain the confidentiality and integrity of the data. Depending on the level of security clearance granted them, individuals having access to the ELTP system will be restricted to viewing only certain data or to performing specific functions."

The new ELTP system will also affect NABP's Disciplinary Clearinghouse Program, which maintains disciplinary information on the nation's pharmacists, pharmacies, interns, technicians, and wholesale distributors. Instead of issuing and receiving paper reports of disciplinary actions, the ELTP system will allow each state board to enter its disciplinary information directly into a pharmacist's or entity's file in the database. The data can then be immediately transmitted to other states in which the pharmacist or entity is licensed. Because of the stipulation requiring that the disciplinary record of each pharmacist and licensed entity be part of the historical information contained in the database, the new program will also combat public concerns and help to ensure that practitioners who have been disciplined in one state are not able to transfer their license to another state until their disciplinary record has been reviewed and evaluated.

NABP's fee for processing an application for licensure transfer and verifying an applicant's credentials remains at $250 per state to which the applicant wishes to transfer his or her licensure. Effective March 1, 1996, applicants wishing to transfer their license to two or more states will pay $250 for the first state and $50 for each additional state requested during the same transaction. Licensure transfer applicants who request an extension of time beyond the initial 90-day deadline for submission of the Official Application to the state, or a change of state from the original state to which transfer was requested, are charged $50 per extension or change.

For more information about the Electronic Licensure Transfer Program or the procedures required for pharmaceutic licensure transfer, contact NABP's Licensure Transfer Programs Department at 708/698-6227, or your state board of pharmacy office.

Unapproved OTC Drugs Still Marketed

This article was reprinted, in part, from the January 1996 *FDA Medical Bulletin*, with the permission of the FDA.

The Food and Drug Administration (FDA) has been reviewing the safety and effectiveness of marketed over-the-counter (OTC) drugs for many years. Those ingredients found acceptable appear in OTC drug monographs (e.g., aluminum hydroxide is included in the OTC antacid monograph). Those ingredients found unacceptable cannot be shipped in interstate commerce after the effective date of the regulation.

Most manufacturers reformulate their products but, in some cases, no ingredients are found acceptable and the entire OTC category is removed (e.g., OTC smoking cessation products). This orderly process has sometimes caused confusion in the marketplace. While the regulations prevent further interstate shipment of unacceptable ingredients and products after the effective date, FDA does not ordinarily call for removal of products already marketed. Hence, drug manufacturers need not recall products that have not been included in the monographs. In some cases, products may linger in the marketplace until supplies are exhausted. This decision by FDA is primarily based upon the lack of available resources for the agency to conduct an effective program for removal of the products already in the marketplace. The vast majority of OTC ingredients that have been removed are found to be ineffective and pose little safety risk. The following list highlights FDA actions against those OTC drug products which have been found to be unsafe and/or ineffective:

Anticholinergics in cough-cold products (includes atropine sulfate, belladonna alkaloids, etc. to "relieve excessive secretions of the nose and eyes"); **Antifungal diaper rash products** (antifungals should only be used under a doctor's supervision); **Antifungal nail products** (includes camphorated metacresol, chloroxylenol, nystatin, etc.); **Aphrodisiacs** (includes cantharides, ginseng, yohimbine,etc.); **Boil treatments** (includes ichthammol, juniper tar, calomel, etc.); **Camphorated oil drug products** (often mistaken for castor oil, resulting in a large number of accidental ingestions); **Digestive aids** (includes cellulase, garlic, ox bile extract, pancreatin, etc.); **Exocrine pancreatic insufficiency drug products**; **Hair growers and**

to a particular state or jurisdiction should not be assumed
he ... of such state or jurisdiction.)

hair loss prevention remedies (includes cantharides, ginseng, yohimbine, etc.); **Ingrown toenail relief** (includes chlorbutanol, chloroxylenol, sodium sulfide, etc.); **Nailbiting or thumbsucking deterrents** (includes denatonium benzoate and sucrose octaacetate); **Ophthalmic anti-infectives** (includes yellow mercuric oxide, boric acid for eyelid infections); **Oral treatment of fever blisters and cold sores** (includes lysine and Lactobacillus acidophilus); **Oral wound healing agents** (includes allantoin, carbamide peroxide in anhydrous glycerin for "minor oral injury"); **Products for oral use as insect repellents** (thiamine hydrochloride (vitamin B_1) has been used); **Products to relieve the symptoms of benign prostatic hypertrophy** (includes amino acids to relieve symptoms of urinary urgency and frequency, etc.); **Products marketed as daytime sedatives** (includes antihistamines, bromides, etc. for claims such as "simple nervous tension, helps you relax"); **Products to treat and/or prevent nocturnal leg muscle cramps** (includes quinine sulfate); **Products for the treatment of hyperphosphatemia/hypophosphatemia** (not amenable to self-diagnosis and self-treatment); **Products to prevent swimmer's ear**; **Smoking deterrents** (includes silver acetate, lobelia alkaloids, ginger, etc.); **Stomach acidifiers** (includes betaine hydrochloride, diluted hydrochloric acid, and pepsin to treat achlorhydria and hypochlorhydria); **Sweet spirits of nitre** (benefits insignificant compared to risks); **Theophylline-containing products to treat symptoms of asthma** (asthmatics require individualized dosing by a doctor); **Topical hormone products** (includes estrogens, progestins, androgens, etc. for claims, such as "removing wrinkles").

USP Urges Pharmacists to Report Packaging, Storage Problems

The United States Pharmacopeia (USP) Committee of Revision is seeking information and comments from pharmacists in order to compile a list of products which may have experienced packaging or distribution effects (e.g., damage, physical changes, temperature, and humidity effects) during shipment and/or storage. USP would appreciate receiving pharmacists' information and/or comments by May, 1996. The following letter from Lee T. Grady, PhD, USP's vice president and director of standards development, provides more information.

Dear Pharmacists:

As one of its responsibilities, the USP Subcommittee on Packaging, Storage, and Distribution establishes standards for the conditions to which pharmaceutical dosage forms are exposed during shipment and distribution. Similarly, the Subcommittee institutes standards for packages, including specific requirements for prescription dispensing containers, to assure that the quality of the drug is maintained until it is used by the patient. This is meant to include shipment from a pharmacy by mail, United Parcel Service, or other means of shipment and distribution. To assist the Subcommittee in meeting these responsibilities, USP requests your comments and assistance in identifying products that may be affected by temperature and humidity during shipment and/or storage.

Also of interest are reports you may receive from patients about products that appeared to be damaged when received. Samples of products which have shown physical changes upon arrival in the pharmacy after shipment, including those shipped to the patients and brought to the pharmacy, would be useful. USP is interested in products which may have experienced packaging or distribution effects as exhibited by perceptible attributes, such as unusual appearance, smell, etc.

I hope you will be able to assist the Packaging, Storage, and Distribution Subcommittee by responding to this request for information. USP is grateful for your interest and assistance in improving product and packaging standards. Please contact Dr. Claudia C. Okeke at 301/816-8243 if you would like to discuss this matter further, and send all samples or information to Dr. Okeke at USP, 12601 Twinbrook Parkway, Rockville, MD 20852.

NABP Action Halts Use of Copyrighted Materials in Examination Review Courses

The National Association of Boards of Pharmacy (NABP), the developer and copyrighted owner of the National Association of Boards of Pharmacy Licensure Examination (NABPLEX®), has recently entered into a Settlement Agreement and Release relative to allegations of copyright infringement of the NABPLEX in various review courses held in the southeastern region of the United States. The Settlement Agreement and Release addresses NABP items used in review courses designed to prepare candidates for the NABPLEX. The Agreement encompasses a professor and university, and prohibits the utilization of NABP copyrighted materials in a review course or otherwise.

NABP continually monitors review courses and other programs which could impact its NABPLEX, Federal Drug Law Examination (FDLE), Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and other competency assessment programs offered to the state boards of pharmacy to ensure that its copyrighted materials are not infringed. General discussions related to education and preparing for state licensure examinations which do not involve the utilization of copyrighted NABP materials were not the issue at hand. Rather, NABP's action focused on protecting the integrity and confidentiality of its NABPLEX program and related materials.

The Association's monitoring efforts and security programs will continue to maintain the integrity and confidentiality of its competency assessment programs through the strict enforcement of all applicable rights under relevant federal and state statutes.

CE Articles in State Board Newsletters

You will notice that this issue of your state board of pharmacy newsletter contains a continuing education (CE) article that discusses medication errors. Renewing a successful 1992-93 project, the NABP Foundation, *U.S. Pharmacist,* and Glaxo Wellcome have joined together to produce another four-part CE article series which will run until December 1996. The series will focus on such issues related to medication errors as the legal aspects, external pressures in practice, and managing pharmaceutical care.

Continued from page 1

Recommendation: License suspended 15 days, stayed three years with conditions. Accepted by Mr. Oxendine and the Board.

David Lee Barker (DOB: March 5, 1939), Charlotte. Heard by Board Member Lockamy. Failing to counsel patients.

Recommendation: Letter of Reprimand and admonishment to be more diligent in providing counseling in the dispensing of pharmaceuticals to eliminate future errors. Accepted by Mr. Barker and the Board.

Larry Jackson Shelton (DOB: December 9, 1948), Hendersonville. Heard by Board Member Moose. Activity at Medicine Shoppe in Hendersonville involving a high school student employee stealing pharmaceuticals which were later consumed by teenagers.

Recommendation: Letter of Caution. Accepted by Mr. Shelton and the Board.

October

Pre-Hearing Conferences

Tamara Volk (DOB: May 29, 1966), Tempe, Arizona. Heard by Board Member Lockamy. Failure to verify continuing education hours necessary to renew her license to practice pharmacy for 1995.

Recommendation: License suspended seven days, stayed two years with conditions. Accepted by Ms. Volk and the Board.

Item 860 – Message from the VA

Steven C. Fulmer, the resident agent in charge of the Office of Inspector General for the Department of Veteran Affairs in Columbia, South Carolina, has requested that the following information be relayed to all pharmacists in North Carolina.

Please be aware that a number of Department of Veterans Affairs (VA) prescription pads have been stolen. As a result, a number of forged/ falsified prescriptions for scheduled drugs have been presented at commercial pharmacies across North Carolina. Since VA prescriptions are filled at VA pharmacies for a flat charge to the patient of $2 regardless of the medication dispensed, it is reasonable to expect something unusual, possibly criminal, when VA prescriptions are presented elsewhere. The VA Inspector General's criminal investigators want to locate these stolen scripts and, working with other enforcement agencies, prosecute those responsible for putting scheduled drugs on the streets. To help us with this problem, please:

1. Make a copy of any VA script presented, whether you decide to fill it or decline to do so;
2. Make a copy of all identifying information about the individual presenting the script; and
3. Fax the information or call the VA IG office in Columbia, South Carolina. The 24-hour fax and phone recorder lines are: FAX: 803/695-6708; Voice: 803/695-6707.

Thank you for your concern,
Steven C. Fulmer
Resident Agent in Charge

Item 861 – Mexican Connection

All of us have heard stories about people who visit Mexico and easily purchase drugs which would have required a prescription in this country. In Mexico, these items are freely available in "pharmacies" that may not even have a pharmacist on duty. Generally, the focus of such a tale is the price, which is a fraction of the cost for the same drug in the United States.

James Robinson from Macks Pharmacy in Stoney Point related a different experience from one of his customers. A woman, who was consuming Levsin 0.125 mg, had visited Mexico and desired to take advantage of the lower prices in that country. She visited a pharmacy and requested Levsin but received Lanoxin 0.125 mg. Upon returning to the United States, she asked her pharmacist, Mr. Robinson, about the drugs. He explained the error which had occurred. The three times per day dose of Lanoxin, rather than Levsin, could have resulted in a disaster.

When you hear the usual story about lower prescription drug prices in Mexico, you may wish to relay the foregoing information.

Item 862 – Mailing Controlled Substances

Postal regulations were changed several years ago to allow the mailing of controlled substances, including narcotics. The following guidelines are offered to help you in your practice.

The inner container of any parcel containing controlled substances must be labeled as provided by the applicable statutes and rules, and placed in a plain outer container or securely over-wrapped in plain paper. The outside wrapper or container must be free of markings that would indicate the nature of the contents. **It is also a wise practice to send such items by certified mail, return receipt requested with restricted delivery.** In this way you can be certain that only the addressee can receive these controlled substances.

Item 863 – Teenage Delivery Drivers

While some people may think that the era of prescription delivery is long gone, that is not necessarily the case. There are still a number of independent pharmacies that offer this service. Please be aware that according to the Fair Labor Standards Act, anyone younger than 18 years of age is not allowed to drive a motor vehicle as part of their job. Violations of the Act

Continued on page 5

Continued from page 4

can result in penalties of $1,000 to $10,000, depending on the circumstances.

Item 864 – Proposed Rules

The Board of Pharmacy has proposed several amendments to its rules and some new rules which will be the subject of hearings in January and February. The January hearing is scheduled for Monday, January 22nd at 10 a.m. at the Institute of Pharmacy in Chapel Hill. The February hearing will occur on Tuesday, February 13th at 10 a.m. at the Mountain AHEC Auditorium in Asheville. A number of changes will be made ranging from simple technical matters, such as the Board's official address, to an entirely new section on rules for hospitals and other health care facilities, as well as proposed new rules for DME suppliers.

Item 865 – Committee to Revise the Practice Act

A committee to revise the Pharmacy Practice Act has been meeting for more than one year. The following are the members and alternate members of this Committee:

Committee to Revise the Pharmacy Practice Act

William H. Randall, Jr.
Chairman
P.O. Box 999
Lillington, NC 27546
(W) 910/893-4413
(H) 910/893-4154
FAX 910/893-2012

Walter Davis
Davis Mutual Drugs
2801 Brentwood Road
Raleigh, NC 27604
(W) 919/876-8806

Bill Harris
1130 Luther Road
Apex, NC 27502
(W) 919/681-2414
(H) 919/362-6751
FAX 919/681-3895

Tim Ives
5502 Bradshaw Quarry Road
Efland, NC 27243-9615
(W) 919/966-3711
(H) 919/563-2246
FAX 919/966-6125

Jimmy Jackson
Kerr Drugs
2522 South Tri Center Boulevard
Durham, NC 27713
(W) 919/544-3896, ext. 105
FAX 919/544-3796

Mike James
Person Street Pharmacy Inc.
702 N. Person Street
Raleigh, NC 27604
(W) 919/832-6432
FAX 919/833-7581

Whit Moose
P.O. Box 67
Mt. Pleasant, NC 28124
(W) 704/436-9613
(H) 704/436-9921
FAX 704/436-6512

Helen Deere Powell
201 Trotters Ridge Drive
Raleigh, NC 27614-9621
(W) 919/733-7461

Jack Watts
444 Tarleton Avenue
Burlington, NC 27215
(W) 910/574-7396
(H) 910/226-5861
FAX 910/227-9662

Peggy Yarborough
6845 Flat Rock Road
Sims, NC 27880
(W) 919/399-9332
(H) 919/237-8730
FAX 919/972-0419

Committee Alternates

Ross Brickley
15 Seven Oaks Drive
Clayton, NC 27520-8024
(W) 800/735-9111
FAX 800/628-0662

Pam Joyner
2100 Carpenter-Upchurch Road
Morrisville, NC 27560-9710
(W) 919/250-8018
FAX 919/250-8523

Steve Novak
Gaston Memorial Hospital
Box 1747
Gastonia, NC 28053-1747
(W) 704/834-2234
FAX 704/834-3030

Continued on page 6

Continued from page 5

Larry Swanson
Campbell University
School of Pharmacy
(W) 800/334-4111
FAX 910/893-1476

Tim White
1328 Duplin Road
Raleigh, NC 27607
(W) 919/832-4641
FAX 919/832-4643

If you wish to make your voice heard on any issue that you believe should or should not be part of the revised Pharmacy Practice Act, please contact anyone included in the list.

Item 866 – Confidentiality and Patient Counseling

Pharmacists should use care when counseling patient or their representatives about certain conditions. The Board office has received complaints regarding patients who were very upset that a pharmacist disclosed their medical condition to another person who was picking up their prescription.

There are a number of sensitive subjects which pharmacists should realize are best discussed only with the patient. Conditions involving mental illness, sexually transmitted diseases, AIDS, or Alzheimer's Disease are a few of the subjects which deserve caution. Any doubt regarding the proper disclosure of these conditions to people other than the patient should be resolved by speaking directly with the patient.

Item 867 – Board Member Election

There are two member positions open on the Board of Pharmacy for an election in the spring of 1996 to serve five-year terms beginning in the spring of 1997.

One nominee must be from the north central part of the state, which consists of the counties from Surry and Yadkin going east to Person and Orange. The other nominee must be from the western part of the state which includes all counties west of Gaston, Lincoln, Catawba, Alexander, Wilkes, and Alleghany. Nominees must consent to their nomination, and petitions must be received at the Board office by March 1, 1996. Members spend about 50 days per year on Board business and away from their other everyday activities.

Item 868 – Check Your Trash

A pharmacist has reported a clever scheme used by drug abusers who wish to get access to pharmaceuticals. He reported that an incident had occurred in which an individual had requested a refill on a prescription for a controlled substance. Personnel in the store knew that the individual was not the one for whom the prescription was written. Further checking into the situation revealed that the individual had sorted through the pharmacy's trash to find prescription containers with labels indicating that a controlled substance prescription had refills left. The individual then presented a request for that refill, hoping to get whatever controlled substance was prescribed for the other person.

If this scheme shows up in your area, it may be worthwhile to check IDs of individuals not known to you who pick up prescriptions for controlled substances.

The *North Carolina Board of Pharmacy News* is published by the North Carolina 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.

David R. Work, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh - National News Editor & Executive Editor
Anna Geraci - Editorial Manager

This Newsletter *is printed at a cost of $.10 per copy.*

National Association of Boards of Pharmacy Foundation, Inc.
700 Busse Highway
Park Ridge, Illinois 60068

NORTH CAROLINA BOARD OF PHARMACY

Nonprofit Organization
U.S. Postage
PAID
Park Ridge, Illinois
Permit No. 75