July 1998

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 971 – Disciplinary Actions

February 1998

Granville R. Jones, Durham (DOB August 10, 1961). Consumption of crack cocaine. License revoked, stayed for 20 years with active indefinite suspension of the license and other specific conditions.

Jay Scott Major, Rocky Mount (DOB April 21, 1942). Dispensing controlled substances and other prescription medications without authorization. Consent Order Entered: License suspended two years, stayed two years with active suspension of 15 days and other specific conditions. Consent Order accepted by Mr. Major February 16, 1998. Accepted by the Board February 17, 1998.

February Pre-Hearing Conferences

F. Elizabeth Perry, Oriental (DOB March 18, 1951). Heard by Board Member Lockamy. Unlawfully obtaining and ingesting Stadol NS while involved in the practice of pharmacy. Consent Order entered: License suspended two years, stayed five years with conditions. Accepted by Ms. Perry February 12, 1998. Accepted by the Board February 17, 1998.

March 1998

Morgan Lewis Williams, Thomasville (DOB February 28, 1948). Order Denying Reinstatement of License Entered.

March Pre-Hearing Conferences

Robert Brent Clevenger, Huntersville (DOB December 31, 1958). Heard by Board Member Lockamy. Dispensing controlled substances and other prescription drugs without authorization; consuming prescription drugs, including controlled substances, without a lawful prescription; failure to make and keep records as required by the Pharmacy Practice Act. Consent Order entered: License suspended one year, stayed five years with active suspension of seven days and other specific conditions. Accepted by Mr. Clevenger March 11, 1998. Accepted by the Board March 17, 1998.

April Pre-Hearing Conferences

Allen Hardy Fish, Charlotte (DOB April 5, 1936). Heard by Board Member Lockamy. Errors committed in dispensing of prescription drugs and those errors were of possible harm to the public. Consent Order entered: License suspended seven days, stayed three years with conditions. Accepted by Mr. Fish April 20, 1998. Accepted by the Board April 28, 1998.

James Ronald Newby, Smyrna, Georgia (DOB March 8, 1953). Consent Order entered in lieu of an administrative hearing. Admission to violations leading to the entry of the Final Consent Order before the Georgia Board of Pharmacy. License is suspended 18 months, stayed 18 months subject to conditions set forth in the Final Consent Order and Order Lifting the Limit of Direct Supervision issued by the Georgia Board of Pharmacy. Accepted by Mr. Newby March 12, 1998. Accepted by the Board April 28, 1998.

Barry V. Watson, Lenoir (DOB October 8, 1941). Heard by Board Member Lockamy. Unlawfully obtaining and ingesting phentermine while involved in the practice of pharmacy. Consent Order entered: License suspended indefinitely. Accepted by Mr. Watson April 17, 1998. Accepted by the Board April 28, 1998.

Item 972 – Compounding Fen-Phen

The members of the Board of Pharmacy considered the situation that recently developed regarding fenfluramine and dexfenfluramine. At a recent meeting of the Board, it was moved, seconded, and adopted by a unanimous vote that the North Carolina Board of Pharmacy takes the position that pharmacists should not compound fenfluramine and dexfenfluramine products until there is medical evidence which indicates that patients would not be at risk in consuming these compounded products. The Board trusts that pharmacists will guide their conduct accordingly.

Item 973 – Counseling on Placebos

At another recent Board of Pharmacy meeting, the members considered a question regarding the proper patient counseling activities of a pharmacist when dispensing a placebo product. After much discussion, it was the consensus of the Board that counseling should occur on a placebo product as if the real active ingredient had been dispensed. Caution was also noted for those patients who may be lactose intolerant. There is a high likelihood that placebo doses would contain lactose, which could have serious consequences for some patients.

Item 974 – Inspection Statistics

During the first quarter of 1998, Board inspectors visited 172 pharmacies, which included 71 independents and 101 chain drug stores. The average number of pharmacists employed at each location was 2.03, and the average number of hours open per week was 85.31. At these stores, an average of 160.31 prescriptions

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FDA Acts on Modernization Act of 1997

The Food and Drug Administration (FDA) has been hard at work in response to the recent passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 809 of the FDAMA exempts compounding by pharmacists and physicians from FDA regulation, under certain conditions, and also maintains that compounding is appropriately regulated at the state level by the boards of pharmacy.

Advisory Committee Established

In accordance with the provisions of Section 809, the FDA has established a Pharmacy Compounding Advisory Committee "to provide advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners and to make appropriate recommendations to the Commissioner of Food and Drugs."

The March 10, 1998 announcement in the *Federal Register* states that the 15-member committee will include experts in pharmaceutical compounding, pharmacy practices specializing in compounding, general retail pharmacy practice, hospital pharmacy practice, fields of medicine in which compounding drugs or the use of compounded drugs is relatively common, pharmaceutical manufacturing, clinical toxicology, clinical pharmacology, chemistry, and related specialties.

The committee will also include a representative from the National Association of Boards of Pharmacy (NABP), the United States Pharmacopoeia (USP), a pharmacy organization, a physician organization, a consumer organization, and the pharmaceutical manufacturing industry.

Guidelines for Industry Available

In the March 13, 1998 *Federal Register,* the FDA announced the availability of a guide for the pharmacy industry entitled "Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Administration Modernization Act of 1997." The guidelines clarify FDA policy with respect to the implementation of certain FDAMA amendments to the Food, Drug and Cosmetic Act. The amendments addressed by the guidelines document include those which require that labels of prescription products, prior to dispensing, contain at a minimum the statement "Rx only" instead of "Caution: Federal law prohibits dispensing without prescription." Also addressed are those amendments that repeal the requirement that the labels of certain habit-forming drugs bear the statement "Warning – May be habit forming."

The guidelines describe the new prescription drug labeling requirements of the Food, Drug and Cosmetic Act as amended by FDAMA and advise manufacturers, packers and distributors of the policy that the FDA will follow in implementing the requirements of Section 126. The guidelines may be found on the Internet at http://www.fda.gov/cder/guidance/index.htm. Written requests may be submitted to the Drug Information Branch (HFD-210), CDER, FDA, 5600 Fishers Lane, Rockville, MD 20857. Include a self-addressed stamped envelope with each request.

FDA Declares OTC Quinine Misbranded

In response to concerns about the use of over-the-counter (OTC) quinine for the treatment and/or prevention of malaria, the Food and Drug Administration (FDA) published a final rule in the March 20, 1998 *Federal Register* establishing that OTC drugs containing quinine for the treatment and/or prevention of malaria are not generally recognized as safe and are misbranded. This action reclassifies quinine as a new drug within the meaning of the Federal Food, Drug and Cosmetic Act and requires that FDA approval be obtained for marketing.

The decision to classify OTC quinine as unsafe was based on data and information examined by the FDA while it was reviewing OTC quinine for the treatment and/or prevention of nocturnal leg cramps. Quinine was removed from the market for this indication due to the lack of substantial evidence of effectiveness, along with evidence of toxicity at the doses recommended. Additionally, the FDA expressed serious safety and efficacy concerns with regard to the continued OTC availability of quinine for the self-treatment of malaria without the care and supervision of a physician.

This final rule became effective April 20, 1998. For further information, contact John D. Lipnicki, CDER (HFS-560), FDA, 5600 Fishers Lane, Rockville, MD 20857: 301/827-2222.

NABP Survey Indicates Increased Telepharmacy Regulation

Over the past few years, a growing number of pharmacists have been providing pharmaceutical care across state boundaries, using increasingly sophisticated telecommunications technologies that allow cost-effective, rapid transmission of information over long distances. While these pharmacists provide such pharmaceutical care services as drug use evaluations and medication information, they do not dispense medications. As "telepharmacy" becomes more common, boards of pharmacy have begun to look at ways to regulate the practice.

Earlier this year, the National Association of Boards of Pharmacy (NABP) conducted a survey of the state boards

of pharmacy to discover how they were regulating telepharmacy. Although none of the 30 responding states have implemented a nonresident pharmacist registration requirement as recommended by NABP's Task Force on Telepharmacy, 10 to 13 percent appear to be applying their current laws and regulations to the practice of telepharmacy. Moreover, another 23 to 33 percent of the responding states indicated that they would be addressing the telepharmacy issue in the near future. "These regulatory efforts are significant because they recognize pharmaceutical care as a health care service provided by pharmacists," said NABP Chairman Franklin Z. Wickham. "The regulations also serve to protect patients from providers who have previously been outside the states' jurisdictional authority."

The survey results show that states applying their current laws and regulations to telepharmacy generally require full in-state pharmacist licensure for nonresident pharmacists who provide only pharmaceutical care, not pharmaceuticals, to their citizens. Another survey result, however, counters the philosophy that a pharmacist provides a service rather than just dispenses a drug product. About 23 percent of the responding states noted that their current nonresident pharmacy regulations require the locations from which these pharmacists provide services to be registered as nonresident pharmacies. This requirement would apply even though the pharmacists were not dispensing drugs into the state and even though such locations as home offices would be affected. Similarly, about 23 percent of the responding states would require locations that provide pharmaceutical care services within the state to be registered as pharmacies.

Licensure/registration was addressed by NABP's 1996-97 Task Force on Telepharmacy, which determined that a registration requirement should be established for nonresident pharmacists, as opposed to nonresident pharmacies, that provide pharmaceutical care to in-state citizens. The Task Force noted that such a registration requirement would allow states to identify those persons providing pharmaceutical care to their citizens, bring those providers under the state's jurisdiction, and ensure the providers' familiarity with the state's pharmacy practice laws.

NABP's telepharmacy survey presented the state boards with questions related to four telepharmacy practice scenarios reflecting actual questions the Association has received from pharmacists or pharmacies with regard to activities they would like to perform or are currently performing. A complete chart summary of the scenarios and the state boards' responses can be found on NABP's Web site, www.nabp.net.

NABP Launches Pharmacist and Pharmacy Achievement and Discipline Database on Web Site

On June 1, 1998, the National Association of Boards of Pharmacy (NABP) launched its Pharmacist and Pharmacy Achievement and Discipline™ (PPAD™) database on the Association's Web site at www.nabp.net. The database provides information regarding those disciplinary actions imposed by state boards of pharmacy that affect a pharmacist's ability to practice, and highlights the positive steps taken by pharmacists to enhance their ability to practice pharmacy.

Visitors to NABP's Web site may search the PPAD database by the pharmacist's name and state of residence or licensure. The database does not specify any additional identifying information, such as the pharmacist's address and phone number.

The following data is provided for disciplined licensees: the state or states in which the pharmacist is licensed and the license number(s), the state imposing the disciplinary action, the action imposed, and the effective date of the disciplinary action or the date NABP received notice of the disciplinary action from the board of pharmacy. The database does not disclose the reason that the board imposed the disciplinary action.

Actions reported in the disciplinary database are limited to license revocation, suspension, surrender of licensure, probation, termination of probation, and reinstatement of licensure. Minor actions, such as a censure, reprimand, fine, or monetary penalty, are not reported on the database. In the future, disciplinary information pertaining to pharmacies, interns, and technicians will be added.

NABP plans to expand the database to include information about the certification and accreditation achievements awarded individuals, such as successfully completing the Pharmacist Applied Knowledge and Judgment Assessment™ (PAKJA™), formerly known as the Pharmacist Continued Competency Assessment Mechanism™ (PCCAM™). PAKJA is a voluntary competency assessment tool scheduled for implementation in late 1999.

"The PPAD database was implemented to assist the state boards of pharmacy in fulfilling their responsibilities to protect the public health by providing access to crucial disciplinary information about their pharmacists," said NABP President Kevin E. Kinkade. "Pharmacy should be commended for taking the lead among the allied health care professions and making this important information available to consumers."

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were filled per day. Board staff believes this is a fairly accurate cross section of retail stores in the state.

The number of pharmacists at each location ranged from one to five, while the spread of prescriptions per day was between five and 500. The minimum number of hours a store was open per week was 42, with a maximum of 110.

Pharmacists can use these numbers as guidelines to judge their own situation.

Item 975 – DME Prescription Requirements

With the ever-changing format of Certificates of Medical Necessity (CMN), the Durable Medical Equipment (DME) Subcommittee wishes to emphasize the importance of suppliers obtaining the correct information to have a valid prescription. Section .2301 of the North Carolina Board of Pharmacy Rules and Regulations outlines the requirements for a Prescription Drug Order.

.2301 Prescription: Drug Order Requirements

(a) Prescription orders shall include, but not be limited to:
- (1) date of issuance;
- (2) name and address of patient;
- (3) name, address, and telephone number of prescriber, except that indication of the name of the prescriber is sufficient if a data file specified in (b) of this Rule is current and in effect;
- (4) Drug Enforcement Administration (DEA) number of prescriber in the case of controlled substances;
- (5) name, strength, dosage form, and quantity of drug prescribed;
- (6) refills if authorized or, in institutions, the stop date;
- (7) route of administration of drug prescribed; and
- (8) directions for use.

A CMN or any other document is not considered a prescription order if the above information is not included. This information is required for DME, devices, and especially oxygen orders.

Item 976 – Durable Medical Equipment Rules Seminar

Many pharmacies and durable medical equipment (DME) suppliers have received a notice from Medicare's National Supplier Clearinghouse concerning their noncompliance with Medicare standards. Registration with the Board is the first step toward complying with those standards. For the next step, all pharmacies and DME suppliers registered with the Board must comply with Board rules.

To assist you in your compliance, the Board has scheduled a seminar to explain the rules concerning devices and durable medical equipment. The seminar will be from **10 a.m. to 3 p.m. on September 10, 1998,** at Guilford Technical Community College in Jamestown, NC. While advance registration is not necessary, the Board would like to have an idea of how many will attend. Please contact Steve Hudson at 828/465-2324 if you plan to attend the seminar.

Item 977 – NCPRN Update

The North Carolina Pharmacist Recovery Network, Inc. (NCPRN), a non-profit organization dedicated to addressing the issue of impairment within the profession of pharmacy, has gotten off to a successful start to its collaboration with the Board of Pharmacy. In the first three months since opening its new office, NCPRN has taken on 16 new cases, and currently has a caseload of 42 pharmacists and one pharmacy student.

These numbers are quite significant when you consider NCPRN only had a total of five new cases in 1995 and 1996, and 16 cases in all of 1997. If the current pace continues, it will have taken on over 60 new cases in 1998, with a total caseload of almost 100 by the end of this year. Probably the most significant statistic, though, is that NCPRN has helped four independent store owners not only recover from the disease of addiction, but also keep their stores open.

If you or someone you know needs help, contact NCPRN at:

Phone:	336/774-6555
Fax:	336/774-9010
E-mail:	ncprn@msn.com
Web page:	www.ncprn.org
Pager:	336/208-6442

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