July, 1996

North Carolina Board of Pharmacy

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Item 881 – Disciplinary Actions

February 1996

Pre-Hearing Conference

Mary Martha Wall (DOB: July 27, 1961), Winston-Salem. Heard by Board Member Watts. Consumption of controlled substances without authorization. ***Recommendation:*** License suspended two (2) years, stayed two (2) years with conditions. Accepted by Ms. Wall and the Board.

March 1996

Brian R. Fulcher (DOB: July 3, 1961). License reinstated with conditions.

April 1996

Pre-Hearing Conferences

James Grant Dorough (DOB: March 28, 1959), Monroe. Many dispensing errors committed. ***Recommendation:*** License suspended thirty (30) days, stayed five (5) years with conditions. Accepted by Mr. Dorough and the Board.

Rhonda G. Hammond (DOB: July 25, 1959), Summerville, South Carolina. Received a disciplinary action from the South Carolina Board of Pharmacy which included the unlawful obtaining of controlled substances. ***Recommendation:*** License suspended indefinitely. Accepted by Ms. Hammond and the Board.

John P. Maffucci (DOB: December 7, 1959), Cary, North Carolina. Pled guilty to one misdemeanor and two felonies in North Carolina, both of which involved drugs. Other similar offenses have occurred in New York. ***Recommendation:*** License revoked. Accepted by Mr. Maffucci and the Board.

Item 882 – Election Results

In April 1996, ballots were sent to all North Carolina licensed pharmacists residing in the state. Two positions were up for election, one from the western part of the state and the other from the north-central part. All candidates had excellent credentials and would have served the public and pharmacy well.

The ballots were counted on the evening of May 13th in the Board's Carrboro office. The results are:

District 1:	Harold Vann Day	816
	Daniel G. Garrett	616
	Michael Overman	**1,006**
District 2:	Eugene L. Bristol	439
	Jack G. Watts	**1,969**

The Board of Pharmacy certified the election results as final at its regular meeting on May 14, 1996. Mr. Watts will continue his membership on the Board of Pharmacy, and Mr. Overman will begin his term in the spring of 1997.

Item 883 – Board Recognized by NABP

There is no doubt that health care, including pharmacy, is experiencing turbulent times. During this period of unrest, questions, such as what is the Board of Pharmacy doing, often arise.

The North Carolina Board of Pharmacy exists to protect the public from dangerous or wrong pharmacy practices; not to protect pharmacists from the public, competitors, or other groups as health care continues to evolve. The Board's primary purpose is to issue licenses to competent candidates so that they can practice pharmacy, and to issue permits to operate pharmacies at locations so that they can dispense prescription drugs. We also discipline pharmacists who misbehave.

As a recognition of its performance, the North Carolina Board of Pharmacy received the Fred T. Mahaffey Award at the Annual Meeting of the National Association of Boards of Pharmacy (NABP) in May, which took place in Boston, Massachusetts. Among the reasons cited for being honored with this award were the activities of former Executive Director H.C. McAllister and the late Bill Adams in the development of an integrated composite examination, which was the forerunner of the current NABPLEX exam used throughout the United States. Adams and McAllister also pioneered the use of an errors and omissions exam, which is used to measure a candidate's performance when acting as a pharmacist who checks a technician's work before a prescription is given to the patient. The North Carolina Board has also produced two Association presidents and has more NABP Distinguished Service Award winners than any other state board. These individuals are Bill Adams, Steve Hudson, H.C. McAllister, and David Work.

The North Carolina Board was the first board of pharmacy to require the reporting of deaths due to drugs dispensed from a pharmacy. This reporting requirement has led to the finding that patients have died because of their inability to read and understand prescription labels. The North Carolina Board is also unique because it hosts an annual leaders forum held in February,

Continued on page 4

FDA Issues Consumer Warning for Ephedrine-Containing Products

The Food and Drug Administration (FDA) has issued a warning to consumers not to purchase or consume ephedrine-containing dietary supplements due to significant health risks. Ephedrine, an amphetamine-like stimulant, can have potentially dangerous effects on the nervous system and the heart. Clinically significant adverse effects include myocardial infarction, stroke, seizures, psychosis, and death. Less significant effects include dizziness, headache, gastrointestinal distress, irregular heartbeat, and heart palpitations.

The dietary supplements noted in the consumer warning contain botanical, or "natural," sources of ephedrine. The labels on these products may list as an ingredient one of the following: ephedrine, ephedra, Chinese ephedra, ephedra sinica, ephedra extract, ephedra herb powder, ma huang, ma huang extract, or epitonin. The dietary supplements are marketed under a variety of brand names with labeling that claims or implies that the product produces such effects as euphoria, increased sexual sensations, heightened awareness, and increased energy.

The FDA is currently investigating the production and marketing of these ephedrine-containing dietary supplements, which appear to target adolescents and young adults, and are portrayed as alternatives to such illicit street drugs as "ecstasy," or MDMA (4-methyl-2, dimethosyamphetamine), a substance that produces euphoria in its users. The FDA considers the promotion and claims made for these dietary supplements to be in violation of the Federal Food, Drug, and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994, which governs the U.S. marketing of dietary supplements.

Under present regulations the FDA has the legal burden to demonstrate that these products are unsafe. Therefore, the agency is urging consumers who have been injured or have suffered an adverse effect after taking a dietary supplement to call 1-800/FDA-4010. The FDA also asks health care professionals who have treated patients injured by these products to report the incident to the FDA's Med*Watch* adverse event and product problems hotline at 1-800/FDA-1088.

Action Taken on Flunitrazepam Abuse

On March 5, 1996, the United States Treasury Department announced that the U.S. Customs Service would begin to confiscate all quantities of the drug flunitrazepam, commonly known by its trade name "Rohypnol," brought into this country by travelers, in commercial shipments, or by mail.

Flunitrazepam's alleged illicit use and abuse and reportedly high levels of importation have prompted the Drug Enforcement Administration (DEA) and several state boards of pharmacy to consider rescheduling the drug, which is a Schedule IV benzodiazepine, as a Schedule I controlled substance. At the National Association of Boards of Pharmacy's (NABP) Annual Meeting in May 1996, an informal poll of the meeting delegates revealed that an overwhelming majority supported the rescheduling of flunitrazepam to Schedule I.

While not available or approved for medical use in the United States, flunitrazepam is widely marketed outside of this country under a variety of trade names. The pharmacological effects of flunitrazepam are similar to those of other benzodiazepines. Its appeal to illicit users seems to come from the drug's sedative effects. For this reason, flunitrazepam is generally prescribed for insomnia.

Flunitrazepam can also potentiate the intoxicating and depressant effects of alcohol, giving it the reputation of being a "party drug." When combined with alcohol, it can impair judgment, motor control, and behavior, as well as cause profound sedation and anterograde amnesia. These incapacitating effects have reportedly caused this drug to be used to aid in the commission of rape by sedating and causing amnesia in the victim.

Several states have taken steps to tighten regulations controlling the use of flunitrazepam. Both Idaho and Oklahoma have moved the drug from Schedule IV to Schedule I. Florida has attempted to enact stricter regulations. A House bill which would have kept flunitrazepam in Schedule IV but imposed Schedule I penalties for violations, and a Senate bill which would have moved the drug to Schedule II did not receive the necessary votes to pass.

National efforts to impede the abuse of flunitrazepam are also underway. In the U.S. Congress, Rep. Gerald Solomon (R-NY) has introduced a bill entitled the "Drug-Induced Rape Act of 1996," which would impose a fine of up to $2 million for an individual defendant and would mandate imprisonment for a minimum of 20 years. Even though this bill does not specifically address flunitrazepam, it would, if enacted, provide an enhanced penalty for those convicted of distributing **any** controlled substance with the intent to facilitate a rape or sexual battery.

FDA Issues Final Rule Regarding Labeling of Sodium-Containing OTC Products

The U.S. Food and Drug Administration (FDA) published a final rule in the April 22, 1996 issue of the *Federal Register* amending the general labeling provisions for over-the-counter (OTC) drug products to provide for uniform sodium-content labeling. The final rule includes the following requirements regarding OTC drug products intended for oral ingestion.

(1) The product must have a sodium content declaration if it contains 5mg or more of sodium per single labeled dose (which may involve one or more dosage units, e.g. tablets, teaspoons);
(2) The product must bear a sodium warning if it contains more than 140mg of sodium in the labeled maximum daily dose. The warning states: "Do not use this product if you are on a sodium-restricted diet unless directed by a doctor.";
(3) Manufacturers may use the following descriptive terms for sodium content: "sodium-free" for products containing 0mg of sodium in the labeled maximum daily dose; "very low sodium" for products containing 35mg or less; and "low sodium" for products containing 140mg or less.

According to the final rule, the total sodium content (including both active and inactive ingredients), in milligram per dosage unit, will be rounded to the nearest whole number. The declaration of sodium content expressed in milligram per single dosage unit (e.g. tablet, teaspoon) will be listed on a separate line after the heading "Sodium Content" as the last statement in the ingredients section. These requirements apply to all OTC drugs intended for oral ingestion, including gum or lozenge dosage forms, whether marketed under an OTC drug monograph, an approved application, or no application.

The final rule is effective immediately. However, the FDA is still considering whether this final rule should be amended to include sodium content labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products. For further information, contact William Gilbertson at 301/827-2304.

WHO International Guidelines for Drug Donations

While reaffirming the essential benefits of international humanitarian relief efforts to provide appropriate medicines in emergency situations, the World Health Organization (WHO) notes that their experience has indicated that such donations often prove to be more harmful than helpful. The drugs may not be relevant to a particular emergency situation, or may not comply with local drug policies and standard treatment guidelines. Many donated drugs arrive unsorted, or labelled in a language that is not easily understood in the recipient country.

In order to avoid these problems and to better align drug donations with the needs of the recipients, WHO has developed the following International Guidelines for Drug Donations, which they hope will improve the quality of drug donations both in acute emergencies, as well as in development aid programs.

1. All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without the prior consent of the recipient.
2. All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or if a national list is not available, on the WHO Model List of Essential Drugs unless specifically requested otherwise by the recipient.
3. The presentation, strength, and formulation of the donated drugs should, as much as possible, be similar to those commonly used in the recipient country.
4. All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country.
5. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.
6. After arrival in the recipient country, all donated drugs should have a remaining shelf life of at least one year.
7. All drugs should be labelled in a language that is easily understood by health professionals in the recipient country. The label on each container should at least contain the International Proprietary Name (IPN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, and expiration date.
8. As much as possible, donated drugs should be presented in larger quantity units and hospital packs.
9. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by IPN, dosage form, quantity, batch number, expiration date, volume, weight, and any special storage conditions.
10. Recipients should be informed of all drug donations that are being considered, prepared, or actually underway.
11. In the recipient country, the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or if such information is not available, on the wholesale world-market price for its generic equivalent.
12. Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

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which is attended by representatives from all facets of pharmacy who meet to discuss important issues. Whit Moose founded this meeting and continues to be involved with its activities.

The North Carolina Board of Pharmacy is also the first board to adopt a rule which provides for disciplinary actions against pharmacists and/or owners who dispense prescription drugs at such an excessive rate per hour or per day that it poses a danger to the public health and safety. The Board adopted this rule at its April meeting, and it is expected to take effect on July 1, 1996.

Criticism is easy. We felt that the pharmacists of North Carolina needed to know about achievement in this era of constant change.

Item 884 – Correction to Item 870

From time to time the Board staff does make a mistake and one occurred in "Item 870 – Rule Change on PA/NP Prescribing" in the April 1996 *Newsletter*. The information was correct in that nurse practitioners can now prescribe up to a 30-day supply of Dextroamphetamine, Methylphenidate, and Pemoline for the treatment of attention deficient disorders. However, as of this date, **physician assistants** have **NOT** been given permission to prescribe these drugs in those quantities. While this may occur sometime in the near future, we unintentionally represented this as the current rule in the April *Newsletter*. Other prescriptions for Schedules II and III drugs are still limited to a seven-day supply.

Item 885 – August Board Meeting Cancelled

The August Board of Pharmacy meeting has been cancelled. The next regularly scheduled meeting will occur on September 17th, with reciprocity scheduled for September 16th. As usual, the subsequent meetings will occur on October 15th and November 12th, with reciprocity on November 11th.

Item 886 – Rules

Public hearings were held in January and February of this year to consider proposed rules, including hospital rules, with a possible effective date of May 1st. After much consideration and after receiving comments from interested parties, the Board has not adopted any new hospital rules as of this writing. Some rules which were considered at these hearings have been adopted, with proposed effective dates of July 1st and August 1st. Any other rules, including hospital rules, would become effective at a later date. Check the October *Newsletter* for any update on the adoption of additional rules.

Item 887 – Methotrexate Survey

In the October 1995 *Newsletter*, "Item 846 – Critical Doses" reported serious problems resulting from a methotrexate prescription written for a malliterate patient. Malliteracy is the status where a person has limited reading ability and is not able to understand the meaning of commonly used phrases. In that case the patient died, causing the Board to conduct a survey of all methotrexate prescriptions dispensed during the last three years in Buncombe, Haywood, and Henderson counties.

It is worth noting that the drug methotrexate is believed to not be widely used; however, over this three-year period in the counties involved, methotrexate was dispensed more than 15,200 times. During this time period, over 211,000 dosage units were prescribed and dispensed. These are much larger numbers than the Board staff anticipated at the beginning of this survey.

The Board did find one additional death that the staff believes was due to methotrexate toxicity. This finding tends to confirm the belief that for each report of a death due to a drug, there is at least one other similar event that went unreported. The Board receives more than 20 reports each year, indicating that the actual number of yearly occurrences is greater than 50. The Board staff is further analyzing the survey results for additional information.

Item 888 – Lockamy, Pharmacist of the Year

At the annual convention of the North Carolina Pharmaceutical Association (NCPhA), Board Member Al Lockamy, of Raleigh, was named the 1996 Pharmacist of the Year. He will be honored at a dinner later this year in Raleigh, which has traditionally been held in July, August, or September. No specific date had been set as of this *Newsletter* deadline. Anyone interested in attending should contact the NCPhA at 1-800/852-7343.

Lockamy's honor creates a rather unique situation since his selection as Pharmacist of the Year coincides with the honor received by Board of Pharmacy members and the executive director as recipients of the National Association of Boards of Pharmacy's Fred T. Mahaffey Award.

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.

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