January, 1989

North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510 Published to promote voluntary compliance of pharmacy and drug law.

Item 589 — Disciplinary Actions Of The Board

September: *George Kennedy Cawthorne,* Raleigh. Failure to check ingredient labels and patient labels on prescriptions for two patients which resulted in death, constituting negligence in the practice of pharmacy. License suspended five years, stayed five years with active one year suspension and other conditions.

November: *William E. Evans,* Charlotte. Did not properly supervise and control the safety and security of Schedule II controlled substances, resulting in documented shortages of [illegible]. Failure to fulfill his duties as pharmacist-manager. License suspended 30 days and other conditions, appealed to Superior Court and Board required to make more specific findings which occurred at the November meeting.

Item 590 — Board Member Election

The Board will hold its annual election in the Spring of 1989 for two positions with terms to begin in the Spring of 1990. The northeastern part of the state is represented by Bill Adams and contains the following counties: Bertie, Camden, Chowan, Currituck, Dare, Durham, Franklin, Edgecombe, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Terrell, Vance, Wake, Warren, Washington and Wilson. Mr. Adams is not eligible to succeed himself in this position and it will be necessary to elect a new pharmacist to represent the northeastern part of the state.

The other position which will be up for election is that in the southcentral part of the state, now represented by Mr. Moose, containing the following counties: Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan, Stanly and Union. Mr. Moose is eligible for another term if he decides to run for re-election.

Pharmacists can become candidates for a position on the Board of Pharmacy in one of two ways. A committee is appointed by the President of the Board to nominate two individuals from each geographic area. The committees ordinarily meet in February and if you wish to have your name placed in front of either of these committees please forward appropriate information including a resume to the Board office prior to February 5th. It is also possible to become nominated by petition of ten pharmacists in the geographic area from which a member will be elected. These petitions need to be received in the Board office by March 10th. Ballots will be finalized at that time and will be distributed to all pharmacists licensed and residing in the state with the April Newsletter.

Item 591 — Quarterly Query

It is a violation of the Prescription Drug Marketing Act of 1987 to:

I. Sell samples.

II. To resell drugs purchased by a public or private hospital, with some specific exceptions.

III. To accept samples from a physician and credit his office or personal charge account.

1. I only.
2. II only.
3. III only.
4. I and II only.
5. I, II and III.

Item 592 — Uncommon Prescribing

During the Fall of 1988 the Board office had an inquiry from a pharmacist in Charlotte regarding the propriety of a dentist prescribing what appeared to be a large dose of Vistaril for a pediatric patient. The pharmacist was concerned about a possible overdose and called on the basis that it was unusual for a dentist to be prescribing Vistaril (hydroxyzine pamoate). After numerous telephone calls it was determined that the use of Vistaril (hydroxyzine pamoate) by dentists was part of the basis of a master's thesis at the University of North Carolina at Chapel Hill involving a study of Noctec (chloral hydrate) Vistaril (hydroxyzine pamoate) and Demerol (meperidine) during conscious sedation of pediatric dental patients. While the Board of Pharmacy is not the best source of information for this kind of question, it is a reasonable area of inquiry for pharmacists.

If you have a question of a similar nature the Board suggests that you contact any of the drug information centers which were

continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Co
and can only be ascertained by examin

CONDITIONS UNDER WHICH HOMEOPATHIC DRUGS MAY BE MARKETED

The following is the first half of a two-part article on the Food and Drug Administration's compliance policy regarding Homeopathic Drugs. This information was provided to NABP by FDA in response to a number of requests regarding FDA's policy on this subject. The second half of the article will appear in next quarter's newsletter. We hope that this information will minimize the confusion and misconceptions regarding homeopathic products.

BACKGROUND

The term "homeopathy" is derived from the Greek words *homeo* (similar) and *pathos* (suffering or disease). The first basic principles of homeopathy were formulated by Samuel Hahnemann in the late 1700s. The practice of homeopathy is based on the belief that disease symptoms can be cured by small doses of substances which produce similar symptoms in healthy people.

The federal Food, Drug, and Cosmetic Act (the Act) recognizes as official the drugs and standards in the *Homeopathic Pharmacopeia of the United States* and its supplements (Sections 201 (g)(1) and 501 (b), respectively). Until recently, homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years and have predominantly served the needs of a limited number of licensed practitioners. In conjunction with this, homeopathic drug products historically have borne little or no labeling for the consumer.

Today, the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products. Those products that are offered for treatment of serious disease conditions, must be dispensed under the care of a licensed practitioner. Other products, offered for use in self-limiting conditions recognizable by consumers, may be marketed OTC.

This document provides guidance on the regulation of OTC and prescription homeopathic drugs and delineates those conditions under which homeopathic drugs may ordinarily be marketed in the United States Agency compliance personnel should particularly consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy. If so, priorities and procedures concerning the agency's policy on health fraud would apply. (See CPG 7150.10 "Health Fraud-Factors in Considering Regulatory Action," 6/5/87).

DEFINITIONS

The following terms are used in this document and are defined as follows:

1. *Homeopathy:* The practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects.
2. *Homeopathic Drug:* Any drug labeled as being homeopathic which is listed in the *Homeopathic Pharmacopeia of the United States* (HPUS), an addendum to it, or its supplements. The potencies of homeopathic drugs are specified in terms of dilution, i.e., 1x (1/10 dilution), 2x (1/100 dilution), etc. Homeopathic drug products must contain diluents commonly used in homeopathic pharmaceutics. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are *not* homeopathic drug products.
3. *Homeotherapeutics:* Involves therapy which utilizes drugs that are selected and administered in accordance with the tenets of homeopathy.
4. *Homeopathic Pharmacopeia of the United States (HPU*
   A compilation of standards for source, composition, and preparation of homeopathic drugs. HPUS contains monographs of drug ingredients used in homeopathic treatment. It is recognized as an official compendium under Section 201(j) of the Act.
5. *Compendium of Homeotherapeutics:* An addendum to the PUS which contains basic premises and concepts of homeopathy and homeotherapeutics; specifications and standards of preparation, content, and dosage of homeopathic drugs; a description of the proving* process used to determine the eligibility of drugs for inclusion in HPUS; the technique of prescribing the therapeutic application of homeopathic drugs; and a partial list of drugs which meet the criteria of the proving process and are eligible for inclusion in HPUS and other homeopathic texts.
6. *Extemporaneously Compounded OTC Products:* Those homeopathic drug products which are often prepared by dilution to many variations of potency from stock preparations, and which: (1) have at least one OTC indication; (2) are prepared pursuant to consumers' oral or written requests; and (3) are not generally sold from retail shelves. Those products which are prescription drugs only cannot be provided to consumers as extemporaneously compounded OTC products, but may only be prepared pursuant to a prescription order.

* A proving is synonymous with the homeopathic procedure (identified in HPUS as a "Research Procedure") which is employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms.

DISCUSSION

Section 201(g)(1) of the Act defines the term "drug" to mean articles recognized in the official *United States Pharmacopeia* (USP), the official *Homeopathic Pharmacopeia of the United States* (HPUS), of official *National Formulary* (NF) or any supplement to them; and articles intended for use in the diagnosis, cure mitigation, treatment, or the prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any articles specified in the above. Whether or not they are official homeopathic remedies, those products offered for the cure, mitigation, prevention, or treatment of disease conditions are regarded as drugs within the meaning of Section 201(g)(1) of the Act.

Homeopathic drugs generally must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopeia. Section 501(b) of the Act (21 U.S.C. 351) provides in ant part:

> Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

A product's compliance with requirements of the HPUS, USP, or NF does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.

A guide to the use of homeopathic drugs (including potencies, dosing, and other parameters) may be found by referring to the following texts: *A Dictionary of Practical Materia Medica* by John Henry Clarke, MD, (three volumes; Health Science Press) and *A Clinical Repertory to the Dictionary of Materia Medica* by John Henry Clarke, MD, (Health Science Press). These references must be reviewed in conjunction with other available literature on these drug substances.

POLICY

LABELING

Homeopathic drug product labeling must comply with the ing provisions of Sections 502 and 503 of the Act and Part 201 Title 21 of the Code of Federal Regulations (CFR) as discussed below, with certain provisions applicable to extemporaneously compounded OTC products. Those drugs in bulk packages intended for manufacture or preparation of products, including those subsequently diluted to various potencies, must also comply with the provisions of Section 502 of the Act and Part 201 (21 CFR 201).

General Labeling Provisions

Name and Place of Business: Each product must bear the name and place of business of the manufacturer, packer, or distributor in conformance with Section 502(b) of the Act and Part 201 (21 CFR 201).

Direction for Use: Each drug product offered for retail sale must bear adequate directions for use in conformance with Section 502(f) of the Act and 21 CFR 201.5. An exemption from adequate directions for use under Section 503 is applicable only to prescription drugs.

Statement of Ingredients: Ingredient information shall appear in accord with Section 502(e) of the Act and 21 CFR 201.10. Labeling must bear a statement of the quantity and amount of ingredient(s) in the product in conformance with Section 502(b) of the Act, as well as 21 CFR 201.10, expressed in homeopathic terms, e.g., 1x, 2x.

Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.

Established Name: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. Many homeopathic products bear Latin names which correspond to listings in the HPUS. Since Section 502(c) of the Act and 21 CFR 201.15(c)(1) require that all labeling be in English, the industry is required to translate these names from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first. It is permissible for industry to include in the labeling both English and Latin names.

Container Size - Labeling Exemption: For those products packaged in containers too small to accommodate a label bearing the required information, the labeling requirements provided under Section 502 of the Act and 21 CFR 201 may be met by placing information on the carton or outer container, or in a leaflet with the package, as designated in 21 CFR 201.100(b)(7) for prescription drugs. However, as a minimum, each product must also bear a label containing a statement of identify and potency, and the name and place of business of the manufacturer, packer, or distributor.

Language: The label and labeling must be in the English language as described and provided for under 21 CFR 201.15(c)(1), although it is permissible for industry to include foreign language in the labeling as well.

continued from page 1

listed in prior issues of our Newsletter and are reproduced for your information below.

Bowman Gray	919-748-2037
Campbell University	800-327-5467
Duke University	919-684-5125
East Carolina	919-551-4257
UNC	919-966-2373

Item 593 — Directory Available From The Pharmaceutical Association

The North Carolina Pharmaceutical Association published in its August issue of the Carolina Journal of Pharmacy a directory of useful addresses and phone numbers for important agencies, associations and groups. For further information about how to obtain this directory call, toll free, 1-800-852-7343.

Item 594 — Sign Available For Controlled Substances

The DuPont Company is making available to all pharmacies a sign which states "We verify all controlled substance prescriptions. Positive I.D. required." The Board office expects a supply of these items to be available from our office in February.

We will be compiling a list of people who wish to obtain one of these signs. Please write or call the Board office and ask for your name to be placed on this list and we will forward one to you as soon as they are available.

Item 595 — Disciplinary Actions Of Board Of Medical Examiners

Enclosed with this Newsletter you will find a list of the disciplinary actions of the North Carolina Board of Medical Examiners which was provided to the Board of Pharmacy in October of 1988. This material is provided only for your guidance in the practice of pharmacy and filling prescriptions from these individuals.

Item 596 — Topical Minoxidil Preparations

The Board has received questions from pharmacists regarding the extemporaneous compounding of minoxidil topical solutions. Rogaine topical solution has recently been approved by the Food and Drug Administration and is being marketed by The Upjohn Company. Prescriptions for Rogaine which are signed on the "Dispense As Written" line should be filled with Rogaine according to North Carolina law.

Also, any adverse reactions or side effects that might occur with the use of extemporaneous compounded minoxidil solution could be considered the compounding pharmacist's responsibility. If you have any questions about this matter please contact the Board office.

Item 597 — Drug Product Problem Reporting Program

Enclosed with this Newsletter is a sticker which gives the practicing pharmacist information about reporting problems with drug products. This information is being collected by the United States Pharmacopeial and we urge you to place the enclosed sticker in a prominent place in your practice. Please make use of this voluntary service and be an active participant in protecting the public health and safety.

Item 598 — When Is A Safe Not Safe Enough?

Pharmacists are constantly concerned about the matter of negligence and might want to be aware of a recent comment in court in Charlotte. During a court proceeding in which pharmacist negligence was a factor the judge reviewed the record which indicated that a safe in a pharmacy was in a "day lock" condition. That is to say the safe had its combination worked and the handle turned or ready to be turned, to the open position but with the safe door closed.

After arguments were heard by counsel from both sides the judges opinion was that "common sense tells you it is negligence" for the safe to be in this condition. Please understand that this was *not* a decision of the Board of Pharmacy but the judge's opinion of that practice. The answer to Item 590, Quarterly Query is 5. I, II and III.

Item 599 — Physicians Win Suit Against Board

At the deadline copy for this Newsletter on the 1st of December, 1988 the Board learned that a Superior Court judge in Raleigh had ruled in favor of the physicians and against the Board in litigation which began about one year ago. What this means is the Board of Pharmacy is precluded from requiring a personal appearance for physicians to obtain a physician dispensing permit or charging a fee for such a permit.

You may remember that the General Assembly changed the Pharmacy Practice Act in 1987 to require a physician who dispensed drugs for a fee or charge to register with the Board of Pharmacy and the Board of Medical Examiners. It is now clear that if physicians are to be treated the same way as pharmacists under state law a change in statute will be necessary.

You should be aware that North Carolina State law prohibits the Board of Pharmacy from lobbying for or against legislation. G.S. 93(b) (6) plainly states that "Occupational licensing boards shall not use any funds to promote or oppose in any manner the passage by the General Assembly of any legislation." The organizations which engage in this activity in this state are the North Carolina Pharmaceutical Association (1-800-852-7343), the North Carolina Society of Hospital Pharmacists and the Chain Drug Store Committee of the North Carolina Merchants Association (1-800-662-7211). If you have opinions about this matter you should contact these organizations.

Item 600 — Board Penalty Guidelines

Several years ago the Board adopted its policy on dealing with pharmacists who have problems with drug abuse. At about the same time the Board recognized that guidelines were needed for certain types of conduct that might be analogous to the state's fair sentencing provisions for criminal conduct. The Board adopted the following guidelines which are reproduced below for your information.

Fairness in Pharmacist Penalties

Criminal Conduct

Illegal activity involving drugs, such as dealing in controlled

continued on page 5

continued from page 4

substances or large shortages of controlled substances. Normal ıalty — License revoked.

ıegligence, Careless Pharmacy Practice or Lax Recordkeeping

Examples would be failure to take a controlled substance inventory, failure to bring controlled substance prescriptions forward in the files, etc. First offense-short active suspension of 7 to 30 days with 2 to 5 years probation.

Second offense of aggravated circumstances on first offense — could produce a moderate to long suspension such as 30 to 180 days with 2 to 5 years probation.

Medicaid Fraud

Each case is viewed individually. If no significant unjust enrichment is present, probation or reprimand might be available. If practice involves billing for drugs not dispensed or billing for non-existent patients or significant billing for brand name when generic is dispensed, then some active suspension should be expected.

Personal Drug Abuse

THE IMPAIRED PHARMACIST

The North Carolina Board of Pharmacy has the gravest concern regarding the problem of the impaired pharmacist. The Board feels that steps should be taken to provide counselling, professional advice, as well as guidance and information for pharmacists 'h drug and alcohol problems. It is axiomatic to any type of ıtment or informational program that the anonymity of the ındividuals seeking assistance be maintained. Dealing with this problem is not a responsibility of the Board of Pharmacy. The Board can only consider the impaired pharmacist on a case by case basis when there has been an alleged violation of law or regulation.

The Board, on the other hand, is confronted with the impaired pharmacist who is alleged to have violated a law or regulation. Assuming that the competent evidence introduced at the hearing satisfies the Board that the pharmacist is guilty as charged, there are a number of factors which the Board may consider in reaching a decision. The Board feels that the pharmacy profession and the general public are entitled to know what those general factors are and why the Board considers them to be significant in reaching a decision in an individual case.

There are certain *mitigating* factors.

First, whether this is the first time the pharmacist has been charged;

Second, the gravity of the offense, such as insignificant shortages of drugs which are diverted for the sole use of the pharmacist;

Third, the pharmacist acknowledged his responsibility for the shortages at an early stage in the investigation and assisted investigating officers thereafter;

Fourth, the pharmacist is aware and acknowledges his drug or 'ohol problem or dependency and has independently sought .ective assistance prior to the hearing and the positive attitude the pharmacist has towards recognizing the problem and rehabilitation;

Fifth, there is evidence that the pharmacist is taking positive steps to control the problem and there is not a substantial likelihood that the offense or violations will be repeated in the future;

Sixth, the history of the pharmacist including his activities in his profession and community;

Seventh, the psychological harm which might result from a revocation or long term suspension of the pharmacist's license.

These are not all but some of the major mitigating factors which the Board considers in reaching a decision.

Some of the *aggravating* factors which the Board considers are as follows:

First, the likelihood that the pharmacist will continue to be a hazard to the general public health.

Second, the severity of the offense. This includes, but is not limited to, whether there are substantial shortages over a long period of time, falsifying records or concealment of offense;

Third, whether the drugs illegally obtained by the pharmacist were diverted not only to his use but to the use of any third person;

Fourth, whether there is a history of prior offenses;

Fifth, the refusal of the pharmacist to acknowledge that a problem exists and past unwillingness to seek effective help or assistance;

Sixth, the likelihood that the pharmacist will in the future continue to violate the law and regulations of the Board;

The presence of one or more mitigating factors and the absence of any aggravating factors usually results in a stay of the suspension of a license thereby producing a period of probation. It is the Board's desire to give an offending pharmacist who has a drug or alcohol problem an opportunity to prove that the problem is being resolved. Often the Board will require unannounced urinalysis tests and have the Board's investigators and inspectors routinely check to see that the pharmacist is abiding by the terms of the Board's judgment which often includes a direction to continue effective help, counselling or attending AA meetings.

If there are one or more aggravating factors present with the absence of any mitigating factors, the Board generally will impose a more severe judgment, possibly including the revocation of a license.

The Board considers the above approach to be consistent with that mandated by the North Carolina General Assembly and the people of North Carolina in the establishment of the fair sentencing program. The Board feels that it is also consistent with prior decisions of the Board. This is a fair and equitable approach consistent with the maintenance of the Board's duty to protect the public health.

Additional Factors

In any or all of the above situations the Board might require taking an examination such as the Jurisprudence Examination, or the Practical Examination or other examination prior to reinstatement of any license. Active disciplinary actions on permits to operate pharmacies are uncommon but can occur when aggravated conduct is involved, repeat offenses occur at the same locations or there is other information available to the Board to indicate that the premises tends to attract trouble or problems over a long period of time.

continued on page 6

continued from page 5

Item 601 — A Small Town Practice

There are many small cities and towns in North Carolina and it is easy to become very familiar with your friends, neighbors and customers. Nearly every pharmacist has been cautioned about allowing people in the prescription department who are not store employees for security reasons. This caveat was remembered after the fact earlier this year in a case which occurred in Chadbourn.

The pharmacist noticed that Dilaudid was missing from his pharmacy and a brief investigation revealed that the responsible person was the city executive for a local bank. The banker frequented the pharmacy and was one of the "friendly visitors" to the prescription department on a regular basis. He apparently pilfered the Dilaudid when the pharmacist left the prescription department to serve other customers.

Item 602 — National Practitioner Data Bank

Beginning sometime in 1989 the federal government will begin to compile information in a National Practitioner Data Bank. Public Law 99-660 later amended by Public Law 100-177 and Public Law 100-93 have established a National Practitioner Data Bank to be operated by a contractor with the government. Agencies and organizations will be required to report information to this Data Bank which will include any malpractice payment made by a licensed health practitioner from a court judgment or out of court settlement and disciplinary actions of licensure boards. Health care entitites such as hospitals must report any adverse actions taken against health practitioner clinical privileges which lasts more than 30 days and professional societies must rep adverse membership data such as actions taken by an eth committee.

All hospitals must query the Bank every two years for health professionals they employ and also must check the Bank for information when negotiating to bring someone on staff. There are other provisions to the law but this gives you an idea of the scope of this effort. As originally written the law applied only to physicians and in some cases to dentists but the amendments caused the law to be applied to all licensed health professionals including pharmacists and nurses.

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, J.D., R.Ph.—State News Editor

Carmen A. Catizone, M.S., R.Ph.—National News Editor & Executive Editor