

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 494—BOARD MEMBER ELECTION

Ballots in the runoff election for the position on the Board from the North Central part of the State were counted on August 19th with the following results:

Evelyn P. Lloyd	896
Jack G. Watts	865

Elected for three-year terms to begin in the Spring of 1986 are **Harold Day** for the first ballot and **Evelyn Lloyd** in the runoff election. Members of the Board are: **Harold Vann Day**, President, Spruce Pine; **William Whitaker Moose**, Vice-President, Mt. Pleasant; **Joseph B. Roberts, III**, Gastonia; **Evelyn P. Lloyd**, Hillsborough; **William R. Tams, Jr.**, Wilson; and **William H. Randall, Jr.**, Lillington.

ITEM 495—BOARD DISCIPLINARY ACTIONS

May: **James D. Neal** and **Center Pharmacy**, Liberty. Dispensing controlled substances without a prescription. License suspended for 2 years, stayed 2 years with a 21-day active suspension and other conditions. No action taken on permit.

Robert Earl Baxley, Bladenboro. Personal consumption of drugs without a prescription. Official Board Reprimand with conditions.

Michael A. Boykin, Tarboro. Personal consumption of drugs without a prescription. License suspended 4 years, stayed 4 years with a 14-day active suspension and other conditions.

June: **Neal Jones Pharr**, Carolina Beach. Personal consumption of Schedule II controlled substances without a prescription and failure to keep accurate and adequate records. Official Board Reprimand with conditions.

No Disciplinary Hearings held in July, 1985.

At the August meeting the Board revoked one pharmacist's license and suspended the license of another with a stay order; however, they are not included in this issue since the time for appeal had not expired prior to the copy deadline.

ITEM 496—QUARTERLY QUERY

A pharmacist who receives a prescription from an optometrist has the responsibility to determine:

1. That the optometrist has been approved to prescribe.
2. That the optometrist has "communicated and collaborated" with a physician.
3. The extent of greater responsibility incurred by the pharmacist.
4. If the Rx is to correct, relieve or treat conditions of the eye.
5. That the Rx is not for a controlled substance.

ITEM 497—PHARMACISTS RESPONSIBILITY IN PRODUCT SELECTION

North Carolina statute conveys a high responsibility on pharmacists who engage in product selection by placing the determination of equivalency on the pharmacist who dispenses the drug. There is

no reference to a positive or negative formulary of any kind nor is there any mention of FDA Bioequivalency findings. This situation is more important with an influx of generic drugs where the brand name had only been available prior to this time. With the passage of The Drug Price Competition and Patent Term Restoration Act and the expiration of certain patents, opportunities for product selection will certainly increase in the future.

Generally, it is inadvisable to unilaterally change the drug dispensed to a patient who is effectively stabilized on a compound to treat conditions, afflictions or diseases which are likely to continue indefinitely. Pharmacists may not be aware of factors which could result in adverse consequences for the patient. The Board recommends that pharmacists exercise caution in switching patients to new generic drugs until more experience is available. Drugs in this category might include but not be limited to Amitriptyline, Diazepam, Digoxin, Furosemide, Methyldopa and Propranolol. There are also known problems with time released dosage forms which cause them to be sufficiently inequivalent to make them not suitable for product selection. Caution is also advised with insulin where there are now several different manufacturers, more sources (beef, pork, beef/pork, Human Recombinant DNA, Human-Pork Based) and a number of different purity levels of proinsulin. Changing from one brand to another or from a brand to a generic is best done after consulting the prescriber which is a good opportunity for pharmacist/physician communication in the best interest of the consumer.

This is just a reminder that, in order to comply with North Carolina statute, the two-line prescription form needs to be a format with the product selection permitted line on the lower left and the dispense as written line on the lower right. As noted in an earlier item (420), other formats do not comply with state statute and would usually allow product selection by the pharmacist. The answer to quarterly query is #4, "If the Rx is to correct, relieve or treat conditions of the eye."

ITEM 498—CONTINUING EDUCATION FOR LICENSE RENEWAL

Time is growing short for pharmacists to obtain hours of C.E. to report on their license renewal application forms which will be mailed near November 1st. **DO NOT** send C.E. certificates with the license renewal form; just indicate the programs or courses and hours obtained. The Board has decided to allow the 60-day grace period for license renewal to also apply to continuing education for this year so pharmacists will have until the end of February to obtain credit and report it on the license renewal form. Pharmacists who plan to count hours obtained for serving as a preceptor need to be sure that the intern's Form 2 (Blue Form) has been filed with the

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National Pharmacy

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CONCERNS REGARDING INSULIN SUBSTITUTION SURFACE

The issue of the substitutability of insulin has been faced by a number of practitioners in a number of states and by a number of boards of pharmacy. Substitution of insulin is, of course, a concern to everyone involved: the patient, the pharmacist, the physician, various diabetes associations, and other health-related professionals.

When purified insulins were introduced in the United States in 1980, the Food and Drug Administration, based on clinical data, required that all insulins carry a boldfaced warning statement in the package literature. This warning reads in part: "any change of insulin should be made cautiously and only under medical supervision. Changes in refinement, purity, strength (U-40, U-100), brand (manufacturer), type (Lente, NPH, Regular, etc.), and species source (beef, pork, beef-pork, or human) may result in the need for a change in dosage."

Although insulin is, strictly speaking, an over-the-counter product, it is a very potent pharmaceutical and its misuse can have serious or fatal consequences.

The USP, in its *Dispensing Information*, cautions that the patient is to make sure they have the correct type and strength of insulin ordered by their physician; the patient is NOT to change the formulation type unless told specifically to do so by the physician; and is to visit the physician at regular intervals via office visits.

The therapeutic goal of the treatment of the diabetic patient is obviously to control the patient's blood glucose level and as a consequence thereof, prevent or minimize the major and serious complications associated with diabetes that is out of control. Pharmacists have a very important role to play in this arena and often fail to realize the rather great significance to the patient of rather minor changes in the insulin being used by the patient. Pharmacists should take the time to consult with their diabetic patients and urge the patient not to make any changes in their insulin without first consulting with their physician.

MORE ON THE DIVERSION OF LEGEND DRUGS

Since the last newsletter where the issue of the diversion of legend drugs was discussed, a number of important events have occurred concerning this same issue.

The most noteworthy of these events was an investigation completed and made public recently by the FBI and U.S. Attorney's office in Atlanta, Georgia, concerning diversion of legend drugs. At

last count some forty-five individuals including drug wholesalers, manufacturer sales representatives, pharmacists and physicians have been charged with various criminal violations arising out of the diversion, sale, and purchase of various legend drugs.

The basic scenario involved was the diversion of drugs ostensibly sold for use in hospitals and thus sold at a very low price. The drugs were diverted to drug wholesalers and retail pharmacies. The investigation was initiated by the Georgia Board of Pharmacy and the Georgia office of Drug and Narcotic Control.

The diversion schemes appeared to be divided into several types of operations.

Drug company representatives, instead of destroying outdated merchandise and drug samples, were instead repackaging and/or relabeling the products and in turn reselling them to wholesalers or retail pharmacies.

Nonprofit hospitals appeared to be ordering excessive amounts of drugs at the lower prices generally accorded hospitals by drug manufacturers and then were in turn reselling the drugs at profits to "drug wholesalers or brokers" who in turn resold them to legitimate wholesalers or retail pharmacies at a substantial profit but still below normal prices.

"Charitable organizations" appeared to be shipping quantities of legend drugs purchased at substantial discounts to sources outside of the country who then, rather than using them in Third World countries, shipped them back into the United States for sale to drug wholesalers and retail pharmacies at a substantial profit.

Physicians were allegedly involved in soliciting large amounts of drug samples from drug manufacturers and then in turn selling them or trading them to retail pharmacies.

Pharmacists were involved in purchasing questionable drugs from brokers and physicians and then repackaging them into a batch of legitimate drugs.

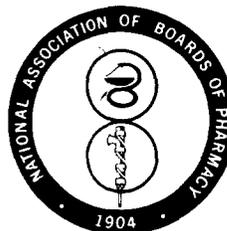
The second development since the last newsletter has been, not surprisingly, an increased interest in the investigation of this drug diversion phenomena by congressional investigative committees. Representatives Gerry Sikorski (D-MN) and John Dingell (D-MI) have been very active in congressional committee investigations into prescription drug diversion.

At least one source, the California-based Pharmacists Planning Service, Inc. (PPSI), alleges that the drug diversion problem is the result of unnecessary price discrimination by drug manufacturers. A spokesman for PPSI alleged that contrary to popular belief the preferential pricing participated in by most drug companies is designed to meet competition and is in fact not strictly limited to charitable institutions.

Regardless of the motivation for discriminatory pricing policies by drug manufacturers, pharmacists are cautioned to exercise con-

Compliance News

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cern and professionalism when purchasing drug products. Drugs that have travelled outside of the chain of legitimate distribution may appear to be a good deal financially but could have devastating consequences to the patient who ultimately receives the drug. Pharmacists should keep in mind that the potential for therapeutic failure is a significant possibility when medication is improperly stored, mislabeled, or is packaged under uncontrolled conditions.

The welfare of our patients should be of primary concern.

CONTROLLED SUBSTANCE DIVERSION FROM U.S. HOSPITALS

The Drug Enforcement Administration in its newsletter entitled *Registrant Facts*, recently reported on a study of controlled substance diversions from U.S. hospitals. In 1983, DEA testimony before the Crime Subcommittee of the Judiciary Committee of the U.S. House of Representatives, indicated that they felt that diversion of controlled substances was more serious at the retail level than it was at the wholesaler or manufacturer level. DEA indicated during that testimony that approximately 2% (13,000) of practicing physicians and pharmacists were involved in some form of illegal practice resulting in diversion of controlled substances. DEA's testimony indicated that indiscriminate prescribing by physicians, dispensing of controlled substances without prescriptions by pharmacists, and dispensing of forged prescription orders were the leading forms of activity that resulted in controlled substance diversion. The recent *Registrant Facts* article now indicates that internal diversion of controlled substances from hospitals may be a more serious issue than was previously believed.

DEA's data now suggests that more than 400,000 dosage units per year are diverted from all U.S. hospitals with 100 beds or more. An additional 50-100,000 dosage units a year likely disappear from U.S. hospitals with less than 100 beds. The top ten drugs diverted from hospitals in order of decreasing quantities are:

- diazepam
- hydromorphone
- meperidine
- cocaine
- morphine
- pentazocine
- oxycodone
- codeine
- methaqualone (now removed from the market) and
- propoxyphene

Registered nurses (RNs) were involved in nearly 70% of all reported incidences of controlled substance diversion from hospitals. Pharmacists and pharmacy technicians combined were responsible for approximately 10% of the reported incidences and physicians were responsible for approximately 3%. Other diverters reported included licensed practical nurses (LPNs), nursing unit clerks, and housekeeping personnel. Infrequently reported as involved in diversion were pharmaceutical sales representatives, patients, paramedics, and medical, pharmacy, and nursing students.

DEA reports that although nurses were most often implicated in the diversion of controlled substances, the total number of dosage units stolen by pharmacists and pharmacy technicians exceeded those stolen by nurses.

The DEA report indicates that nurses most frequently diverted meperidine (25.7%), diazepam (18.9%), codeine products (9.6%), flurazepam (6.6%) and morphine (6.5%).

In 1980, there were over 1,000 separate incident reports of meperidine diversion from 1,359 U.S. hospitals. Of these, over 80% involved registered nurses (RNs) and an additional 5% involved licensed practical nurses (LPNs).

Hospital pharmacists most frequently were involved in the diversion of stimulant drugs such as cocaine, amphetamines, and Ritalin. These stimulant drugs counted for over one-half of all controlled substance incidents involving pharmacists. The opiate narcotics were involved in an additional one-third of all reported incidents by pharmacists.

Hospital pharmacists in supervisory positions should keep these statistics in mind when setting up record keeping and drug control procedures in their hospitals in order to keep diversion of controlled substances at a minimum.

CONTROLLED SUBSTANCES ACT VIDEOTAPE

The second of two videotapes produced by the National Association of Boards of Pharmacy Foundation focuses on one of the most important legal aspects of pharmacy practice—the Controlled Substances Act.

The videotape emphasizes the importance of protecting the public from the diversion of abusable drugs while recognizing the harm to good health care caused by the over-reaction to the problem of prescription drug abuse.

Information concerning the videotape can be obtained from NABPF, O'Hare Corporate Center, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068.

(continued from page 1)

Board office. A copy of that form with hours of credit indicated is forwarded to each preceptor for their records.

Common Questions & Answers on C.E.: Q: How can I get C.E. when I'm living in another state? A: For pharmacists who reside outside of North Carolina, the Board will accept any programs which meet the C.E. standards in the state where they reside or practice.

Q: If I got 20 hours of C.E. at a convention this year, can I count 10 this year and 10 next year? A: No.

Q: I have taken a correspondence course which states that it is qualified for "contact hour" credit with ACPE. Does this count for contact hour credit for my N.C. license? A: No. The Board expects actual attendance at meetings or programs with personal communication between attendees and speakers for contact credit.

Q: Can I get an inactive license if I pay the fee but don't get C.E.? A: No. You can let your license lapse by not renewing but, under present standards, you would need to obtain at least 10 hours of C.E. before reinstatement.

City, county or regional associations and others who are planning programs in the state need to submit their material to the Continuing Pharmaceutical Education Panel, P.O. Box 151, Chapel Hill, North Carolina 27514, at least 30 days prior to its scheduled date.

ITEM 499—UNAPPROVED USE OF APPROVED DRUG

Questions regularly arise about the use of drugs in a fashion that has not been approved by the Food and Drug Administration. The Food and Drug Administration has the power to regulate the distribution of drugs in interstate commerce and their labeling which includes any promotional material. The "approved use" status of a drug with the Food and Drug Administration only means that the agency has approved its labeling, advertising or promotion for such purposes. The use of the drug for unapproved indications may be harmful or harmless but for one reason or another it has not been approved for that purpose.

There is not anything necessarily improper about a physician prescribing or a pharmacist dispensing a drug for an unapproved use. Judgment does need to be used however and a pharmacist needs to ascertain that no unforeseen harm comes to the patient or that the risk is worth the potential benefit. Hospital pharmacists or those servicing nursing homes need to take particular care that, when drugs are prescribed for an obviously unapproved use, they make an appropriate entry in the patient's chart as now required by statute. Pharmacists serving health care facilities now have an affirmative duty to make such entries when this situation arises.

ITEM 500—NOTICE OF PUBLIC HEARING ON PROPOSED REGULATIONS

A Public Hearing was held on Tuesday, October 15 at the Institute of Pharmacy when the Board considered proposed rules and regulations on:

1. Computers in Pharmacies.
2. Prescription Transfers.
3. Examinations.

Proposals 1 and 2 emanated from a Committee appointed by the Board (see July, 1985 *Newsletter*) and proposal 3 is from the Board Staff to accommodate the new format of the National Exam.

ITEM 501—DOROTHY MC ALLISTER

On July 11th, Dorothy Lassiter McAllister died after an illness that lasted some time. As an employee of the Board for over 20 years she was well known to students and pharmacists alike. The family requests that any contributions be made to the Thompson Children's Home, Box 25129, Charlotte, North Carolina 28229. Mr. H. C. McAllister is in decent health for a man in his 70s and the Editor believes he would appreciate written messages from friends and acquaintances at his address, P.O. Box 264, Chapel Hill, NC 27514.

ITEM 502—MAY BOARD MEETING

This shall serve as public notice that the May, 1986 Meeting of the North Carolina Board of Pharmacy has been cancelled.

ITEM 503—CONTROLLED SUBSTANCES REGULATIONS AVAILABLE

The most recent publication of the Controlled Substances Regulations is now available. To obtain a copy, write the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; ask for 21 CFR Parts 1300 to End and enclose a check or money order for \$5.50.

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