

North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 393 ELECTION RUNOFF

Enclosed with this *Newsletter* is a ballot, with envelope, for a position on the Board to begin in April of 1983. The two candidates who received the larger number of votes in the first election were Gilbert Hartis and Evelyn Lloyd. Please submit your ballots in the enclosed envelope prior to August 23, 1982.

ITEM 394—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

March: A pharmacist from the Winston-Salem area appeared before the Board on a charge of negligence for dispensing an optic solution of a prescription drug with labeled directions to place one drop in the right eye four times a day. Some evidence was introduced to indicate that little, if any, harm would have occurred if the patient had used the prescription as directed on the label; It was the board's decision to reprimand the pharmacist and urge that he use caution in future similar situations.

A pharmacist from Charlotte appeared to respond to charges of unauthorized personal use of controlled substances, meprobamate and propoxyphene. This activity was discovered during a routine visit by a Board Inspector. The pharmacist claimed exceptional stress in working 12 hour shifts, 7 days on and 7 days off as well as a physical problem with muscle spasms and pain. The Board issued a 30 day active suspension with a 5 year probation under certain conditions.

May: A pharmacist-manager from Wilkesboro appeared to respond to charges of Medicaid Fraud, unauthorized refilling of prescriptions for controlled substances and unauthorized dispensing of prescriptions not in safety closure containers. His plea of guilty to Medicaid Fraud and several instances of unauthorized dispensing of controlled substances in non-childproof containers were presented at the hearing. More than 20 character witnesses for the pharmacist, including several physicians, testified at the hearing. The Board ordered at least a 90 day active suspension of the pharmacist's license, which would be reinstated after he passed a Jurisprudence exam, and a 5 year probation.

A pharmacist from Landis appeared in a hearing continued on oral occasions from its origination in June of 1979. Delays occurred at the request of the pharmacist's attorney, primarily because of multiple trials and appeals in the Federal courts. The pharmacist was charged with the dispensing of controlled substances without a prescription on numerous occasions. During a 5 month period over 1,700 prescriptions for controlled substances from a nearby phy-

sician were filled at the pharmacy while the next nearest pharmacy filled less than 20 prescriptions during a similar period of time. It was the Board's decision to revoke the pharmacist's license to practice. The editor suggests that readers refer to Item 399 on corresponding responsibility.

A pharmacist from Murphy failed to appear for a hearing on charges of inability to account for controlled substances and personal use of drugs. Testimony tended to show unorthodox behavior of the pharmacist and significant shortages of Percodan, Tylox and Dilaudid. The Board ordered that the pharmacist's license be suspended indefinitely.

ITEM 395—WHY SAFETY CLOSURE CONTAINERS?

Aside from the federal law which requires their use, why are safety closure containers required for prescription drugs and some other items? One answer is that, according to the Consumer Product Safety Commission, they prevented nearly 200,000 accidental poisonings and almost 700 deaths among children from 1973 to 1978. Information like this can lessen the aggravation if these devices are explained to recipients. Patrons can request and receive non-safety closure containers on prescriptions but it is advisable, although not required, to have such a request signed by the customer.

ITEM 396—ETCETERA, ETCETERA

Did you know that the DEA number of a pharmacy is not required to be on a prescription label? . . . Many forged prescriptions have been found with the patient's address as "In Transit." The pharmacy at Duke University has notified the medical staff that this phrase is inappropriate on prescriptions.

Inspectors report that several original licenses issued in the late 1970's show signs of fading and pharmacists may want these replaced. Replacements can be obtained by completing a form and submission of \$10 to the Board office along with the defective certificate. Write the Board office for details if you are interested.

ITEM 397—DRUGS UNAPPROVED BY FDA AND SUBSTITUTION

A recent case in Ohio produced criminal (manslaughter) charges against a pharmacist when an unapproved generic furosemide was
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National Pharmacy

MISBRANDED DRUGS—FEDERAL FOOD, DRUG, AND COSMETIC ACT

By: Franklin Z. Wickham, Executive Director
Ohio State Board of Pharmacy

One of the more important aspects of the Federal Food, Drug, and Cosmetic Act, which is of concern to practicing pharmacists, is the section of law regarding the misbranding of a drug. Drugs which are dispensed by a pharmacist on a prescription are misbranded when they are recognized in an official compendium and **are not** packaged and labeled as required in the official compendium.

Official compendia, recognized by the federal law, includes the official United States Pharmacopeia/National Formulary (USP/NF), official Homeopathic Pharmacopeia of the United States, and their supplements. If the drug is recognized in both, then the drug must be packaged and labeled according to the requirements stated in the United States Pharmacopeia.

The majority of oral dosage forms of drugs recognized in the U.S.P. have a packaging requirement only, while a large number of biologicals and injectables have both a packaging and labeling requirement. An example of an oral dosage form having both is Prochlorperazine Edisylate Oral Solution (Compazine®). The product is misbranded if it is not packaged and stored "in tight, light resistant containers," and is labeled to indicate that it is to be "diluted to appropriate strength with water or another suitable fluid prior to administration." Another product having similar requirements is Mellaril® concentrate.

A drug may also be misbranded, when dispensed by a pharmacist, if the prescription label is "false or misleading," or if the drug is "offered for sale under the name of another drug." Consequently, if the drug dispensed is different from that which is indicated on the container, the prescription is misbranded and in violation of the Federal Food, Drug, and Cosmetic Act. If the laws in your state permit pharmacists to dispense generically equivalent drugs, the prescription label should **clearly** indicate that the drug product dispensed is different from the product prescribed.

Most prescription drug products, and any products which contain controlled substances, that are in a dosage form intended for oral administration are misbranded unless they are dispensed in child-proof containers. The only exceptions are:

- (1) sublingual dosage forms of nitroglycerin;
- (2) sublingual, chewable forms of isosorbide dinitrate in strengths of five milligrams or less;
- (3) erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than eight grams of the equivalent of erythromycin;
- (4) anhydrous cholestyramine in powder form;
- (5) potassium supplements in individually-packaged effervescent tablet form, each tablet of which contains not more than 50 milliequivalents of potassium;

(6) sodium fluoride drug preparations, including liquid and tablet forms, containing no more than 264 milligrams of sodium fluoride per package;

(7) betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams of beta methasone;

(8) pancrelipase preparations in tablet, capsule, or powder form and containing no other prescription drug;

(9) mebendazole in tablet form in packages containing not more than 600 milligrams of the drug;

(10) methylprednisolone in tablet form in packages containing not more than 84 milligrams of the drug;

(11) colestipol in powder form in packages containing not more than five grams of the drug;

(12) erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin; and,

(13) those instances where either the prescriber or purchaser has requested that the drug not be dispensed in a child-proof container.

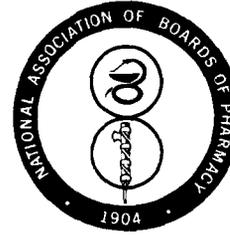
TEST YOUR FEDERAL DRUG KNOWLEDGE

Most states use an examination to test pharmacists on federal and state drug law knowledge. It is a means of insuring compliance with state and federal drug laws. NABP produces a federal drug law examination independently and also publishes a study guide that is distributed to all state boards using the exam. Example questions from the FDLE Guide appear below. Pharmacists are urged to answer the questions and grade themselves on their performance. Six out of eight questions answered correctly is a passing score.

1. Which of the following statements is true concerning newly scheduled controlled substances?
 - a. Inventories of the drugs should be reported to DEA within 30 days of publication of the regulation ordering scheduling.
 - b. Inventories should be taken within six months of scheduling.
 - c. Inventories should be taken during the next regular inventory, but invoices should be filed according to law.
 - d. Newly scheduled drugs are exempt from inventory.
 - e. Inventories should be taken upon the date of scheduling.

2. Several phrases and symbols associated with drug labels are listed below. Indicate the phrases or symbols associated with L¹rium®.
 1. "C-II"
 2. "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"
 3. "Caution: Federal law prohibits dispensing without prescrip-

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tion”

4. “C-III” or “C-IV”
 - a. phrase 1 only; b. phrase 2 only; c. phrase 3 only; d. phrases 3 and 4 above; e. phrases 2, 3, and 4 above

3. If a drug is found to be liable to deterioration by the Food and Drug Administration, and it is not labeled as prescribed for the protection of public health, the drug is said to be:
 1. adulterated
 2. counterfeit
 3. misbranded
 - a. 1 only; b. 2 only; c. 3 only; d. 1 and 2 above; e. 1 and 3 above

4. According to the United States Postal Regulations, all of the following prescriptions can be mailed by a community pharmacy to the ultimate patient EXCEPT:
 - a. Demerol[®] 50mg X 30 tablets
 - b. Percogesic[®] X 100 tablets
 - c. Quaalude[®] 300mg X 100 tablets
 - d. Ritalin[®] 10mg X 50 tablets
 - e. Valium[®] 10mg X 200 tablets

5. If a Schedule II drug is dispensed via a telephone order in an emergency situation, the prescriber must deliver a signed prescription within what time period?
 - a. 2 days; b. 3 days; c. 4 days; d. 5 days; e. 10 days

6. Which one of the following items is NOT required by federal regulations to be included on Schedule II prescription orders?
 - a. date issued; b. name of prescriber; c. address of prescriber
 - d. DEA registration number of prescriber; e. prescriber’s telephone number

7. According to the DEA, the six months or five refill limitation applies to which one of the following?
 - a. telephoned Schedule III, IV, and V prescriptions only
 - b. emergency telephoned Schedule II prescriptions
 - c. telephoned Schedule III and IV prescriptions only
 - d. all Schedule III and IV prescriptions
 - e. all Schedule III, IV, and V prescriptions

8. According to federal law, which of the following prescription refill actions would be illegal?
 1. The refilling of a prescription marked “refill prn” after the death of the prescriber
 2. Authorization transmitted by the office receptionist to refill a prescription upon the direction of the prescriber
 3. Authorization by telephone by the prescriber to refill a Schedule III controlled substance
 - a. 1 only; b. 2 only; c. 3 only; d. 1 and 2 above; e. 1 and 3 above

ANSWER SECTION

- 1 (A) (B) (C) (D) (E)
- 2 (A) (B) (C) (D) (E)
- 3 (A) (B) (C) (D) (E)
- 4 (A) (B) (C) (D) (E)
- 5 (A) (B) (C) (D) (E)
- 6 (A) (B) (C) (D) (E)
- 7 (A) (B) (C) (D) (E)
- 8 (A) (B) (C) (D) (E)

Six out of eight questions answered correctly is a passing grade. The Answer Key appears at the bottom of this column. If you fail to get a passing score, you may want to review both your state and federal drug and pharmacy laws. Contact your state board of pharmacy for information.

MOVING? LET YOUR STATE BOARD KNOW WHERE AND WHEN

FDA URGES HALT OF REVITAL SALES

Drug stores across the nation have been urged to halt the sale of Revital powder and gel as a result of FDA tests indicating that these over-the-counter products are “heavily contaminated” with disease-producing organisms. Promoted for a variety of conditions from acne and surgical wounds to ulcers and herpes, the drug is being recalled by the manufacturer voluntarily (Salisbury, Maryland-based Robertson Resources Ltd.). In announcing the Class I recall, FDA stated that the levels of bacteria found in the product are “capable of causing serious injury and perhaps death.”

BENZYL ALCOHOL CAUSE OF FATAL TOXIC SYNDROME

Sixteen deaths have been reported in neonates in whom normal sodium chloride containing 0.9 percent benzyl alcohol has been used for flushing intravascular catheters or when bacteriostatic water was used to dilute or reconstitute medications. In the two medical centers reporting most of the cases of benzyl alcohol toxicity to date, no additional cases of the toxic syndrome has been seen after the use of benzyl alcohol containing solutions was eliminated.

The fatal toxic syndrome consists of metabolic acidosis, CNS depression, respiratory distress progressing to gasping respirations, hypotension, renal failure, and sometimes seizures and intracranial hemorrhages. Hospital pharmacists are warned that reports suggest that benzyl alcohol, present as a preservative in some small multiple-dose vials of bacteriostatic sodium chloride or bacteriostatic water for injection, has caused the syndrome in premature infants.

1. E; 2. E; 3. C; 4. A; 5. B; 6. E; 7. D; 8. A

FEDERAL DRUG LAW ANSWER KEY

dispensed and the patient expired. News reports indicate that the pharmacist was found not guilty on the manslaughter charge but was convicted on other charges and was sentenced to 60 days in jail. It is conceivable that similar conduct could produce a hearing before the Board in this state on a negligence charge. This general subject has appeared in this *Newsletter* on several prior occasions and should be of concern to pharmacists. Information on the approval status of a drug can be obtained by calling the FDA at 301/443-1016.

ITEM 398—FACTS ON PHARMACISTS

Pharmacists information from the last year revealed some interesting facts for those licensed in the state. About 90% are active with 10% inactive while 96.5% are white and 2% black, indicating slight changes from last year. Those under 31 were 32.7%; 31 to 40—28.8%; 41 to 50—16.6%; 51 to 60—15.4%; 61 to 70—5% and 71 and over — 2%. The notable part of these numbers is that pharmacy in North Carolina is a young profession with over 60% less than 40 years of age.

Licensees indicated their activity in community pharmacies — 1085, down slightly from last year; small and large chains —1181, up slightly from last year, with private and government hospitals at 539, up roughly 25% from last year. Of the entire group, 23% listed themselves as owners or partners and 65% were employees. Perhaps the most significant statistics involve the balance of male/female registrants. Males comprised 76% of the group, down 5% from last year with females at 24%, up 5% from prior figures. With the substantial number of females entering the profession from schools of pharmacy, this trend is likely to continue.

ITEM 399—SECOND, AND FINAL, NOTICE ON CORRESPONDING RESPONSIBILITY

On the front page of the November, 1979 *Newsletter*, pharmacists were notified of the corresponding responsibility of pharmacists in filling prescriptions for controlled substances. This *Newsletter* was included with the 1980 license renewal for each pharmacist in the state. Claims by a pharmacist that such notice was not received when their license was renewed on the renewal in the same envelope will be judged on whatever merit they may or may not have.

The publication of the American Society for Pharmacy Law states that "a pharmacist who deliberately closes his eyes when he has every reason to believe that the purported prescription order has not been issued for a legitimate medical purpose may find himself prosecuted, along with the issuing physician, for knowingly and intentionally distributing controlled substances, a felony offense which may result in the loss of one's business or professional license." Pharmacists are directed to 21 CFR Part 1300 to End which is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC. The April, 1981 issue cost was \$4.75.

ITEM 400—TRAVELING SECRETARY

During the past several months the Board Secretary accompanied each Inspector for two days of regular inspection visits. This included visits to Charlotte, Taylorsville, Statesville, Lumberton, Eden and Greensboro. While no problems sufficiently serious to require a hearing were noted, several matters deserve closer attention by pharmacists. First, generic drugs should not be placed in brand name stock containers — if they are, the article is misbranded under state and federal law. Failure to record receipt of Schedule II

controlled substances on the Schedule II order form is another common error easily corrected by a minor change in habit. A rather surprising number of outdated pharmaceuticals were found in prescription departments, the dispensing of which would be misbranding. In one large city almost one third of the pharmacies visited were either in, or very close to, violation of the Board's regulation requiring that a pharmacy be kept in a clean, orderly and sanitary condition. Pharmacists should correct these matters if they exist at their location.

ITEM 401--REPORTING DRUG PROBLEMS

The Medical Device and Laboratory Product Problem Reporting Program and the Drug Product Problem Reporting Program are two important surveillance programs of which pharmacist and other health professionals should be aware. Both were initiated in the early 1970's and are coordinated by the United States Pharmacopeia. The programs are endorsed by numerous pharmacy organizations across the country and are sponsored by the FDA.

The purpose of the programs is two-fold: to improve the products (drugs, devices) utilized in the health care system and to bring any problems with these products to the attention of government and industry. The USP takes problems reported into account when revising or devising standards for drug products. Examples of problems that have been reported include, improper or incomplete labeling, broken or discolored dosage forms, defective laboratory kits and infusion pump dysfunction. These problems are published in a periodic report available from the USP.

Programs such as these can work effectively if the pharmacist and other health care personnel, use them to report anything that is considered to be a problem with the products concerned. Industry can use the data collected to identify trends not detected with marketing testing and the FDA can use the data as a source for regulatory experience for the development of future standards.

For further information contact: Drug Product Problem Reporting Program or Medical Device and Laboratory Product Problem Reporting Program, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852; or call the toll free number anytime: 800-638-6725.

ITEM 402--FREQUENCY OF RECIPROCITY TO NC

The partial revision of the Pharmacy Practice Act changed reciprocity somewhat and temporary licenses are no longer issued. Applications are reviewed and candidates considered on the Monday prior to the third Tuesday during odd numbered months; January, March, May, etc. If you are aware of a person desiring to reciprocate to this state, please instruct them to contact the North Carolina Board first. Please note that candidates for reciprocity must meet the same theoretical standards applied to licensees by examination in this state.

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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