



# North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 378--APRIL BOARD MEETING

This shall serve as notice of a change of the Board meeting in April to April 6th, 1982 at the Hyatt in Winston-Salem. This is at the same time and location as the Annual Convention of the North Carolina Pharmaceutical Association. The location of the meeting will be posted at the North Carolina Pharmaceutical Association Registration desk. The Board meeting is open to the public.

## ITEM 379--NEW REGULATIONS ON ELECTION OF BOARD MEMBERS, RECIPROCITY AND DEADLINE FOR EXAM APPLICATIONS

At the November meeting the Board of Pharmacy adopted new regulations on Board Member Elections and the other topic in this item. One substantial change is that all pharmacists in the state will be receiving ballots with the April issue of this *Newsletter* for election of a Board member. The person elected is scheduled to take office in April of 1983 which provides nearly one year to become acquainted with Board activities. The new regulations follow below:

**Exam Deadline:** All applications for examination shall be made on forms provided by the Board, filed with the Board 45 days prior to the date of the examination, and accompanied by the required fee.

**Reciprocity:**(a) An active competent practitioner in good standing is a person who is a graduate of an accredited school or college of pharmacy, and has been licensed for at least one year and demonstrates satisfactory performance in an examination on North Carolina Pharmacy Law. In lieu of holding a license for at least one year, a reciprocity candidate may take the Practical Examination as specified in 46.0405(a)(2) and, upon successful completion, be licensed by reciprocity.

(b) The North Carolina Board of Pharmacy interprets the phrase in G.S. 90-64(a)(1), "in good standing" and the phrase in G.S. 90-64 (a)(2) "valid license" as continuing requirements. Any interruption in the validity of such a license or the person's good standing in such other state from a disciplinary proceeding can result in ineligibility for licensure or renewal of licensure under this section.

(c) The term "disciplinary proceeding or unresolved complaint" interpreted in the judgment of the North Carolina Board of Pharmacy. The fact that such disciplinary proceeding or complaint has been finalized in another jurisdiction, either for or against the license, does not necessarily mean that it has been resolved to the satisfaction of the North Carolina Board of Pharmacy.

(d) The North Carolina Board of Pharmacy considers the follow-

ing criteria in determining if licensure requirements in another state are equivalent to or higher than requirements in this state:

(1) Was the applicant originally licensed by examination?

(2) If licensed after June 1, 1980, has the applicant achieved scores on an equivalent examination, such as the NABPLEX examination, which would qualify for licensure in this state at that time?

(3) Does the state in which the candidate was originally licensed deem licenses from this state to be equivalent to the extent that they are suitable for licensure in that state without further substantial examination?

A negative determination of any of the above criteria would preclude licensure under G.S. 90-64.

**Elections:** Board of Pharmacy Elections; Composition and Duties: The Board of Pharmacy Elections shall consist of all members of the Board of Pharmacy who are not nominees in an election and shall convene to accept nominations, count ballots and certify election results.

**Eligibility to Vote:** Eligible voters shall be the pharmacists licensed in North Carolina and residing in North Carolina as taken from the preferred mailing address on the most recent renewal on March 15 immediately prior to the election.

**Geographic Representations:** Members of the Board of Pharmacy shall be elected from five geographic areas of the state. From time to time the Board of Pharmacy Elections shall reapportion each geographic area for equal representation.

**Committee on Nominations:** The Board of Pharmacy Elections may appoint an Advisory Committee on Nominations in January of each year. Members of this Committee shall submit at least one name of an eligible candidate for election by March 1 for the next election.

**Nomination by Petition:** Nominations may also be made by the petitioner of ten (10) eligible voters from a geographic area as specified in 21 NCAC 46.1103, such document to be filed in the Board office or postmarked before March 10 for the next election. Nominations shall be closed on March 15th.

**Consent to Nomination:** A person's name shall not be placed on the ballot without their written consent.

**Ballots--Casting and Counting:** A ballot shall be mailed, with return envelope, to all eligible voters in April of each year. A brief description of a nominee's qualifications, provided by the nominee and edited, if necessary by the Secretary, shall accompany each ballot. Secret ballots shall be cast in the envelope provided before May 15. Ballots received shall be counted and certified by the

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# National Pharmacy

## TRANSFER OF CONTROLLED SUBSTANCES PRESCRIPTIONS BETWEEN PHARMACIES APPROVED

A new rule issued by the Drug Enforcement Administration now allows a legally refillable prescription for a controlled substance to be transferred by phone from one pharmacist to another. The rule sets forth the conditions which must be satisfied by the pharmacists participating in the transfer. These requirements include, among others, that the original prescription be marked void and transferred after the information is transmitted to the pharmacist who will refill it, that proper information about the pharmacist to whom the prescription is transferred be recorded on the back of the original prescription, and that all information required to appear on the original prescription be provided to the pharmacist receiving the transfer.

It should be noted by all practitioners that the procedure allowing transfer of prescription information for refill purposes is permissible only if allowable under existing state law. The new regulation was developed with the assistance of a DEA pharmacist's advisory committee, on which the National Association of Boards of Pharmacy is represented. Following publication in the *Federal Register*, the regulation became effective on October 5, 1981. After careful consideration, the DEA rejected a proposal to allow the retransfer of prescriptions under the new rule. The final order provides for transfer of original prescriptions for a controlled substance listed in Schedule III, IV or V.

The new regulation is found in Title 21 Code of Federal Regulations 1306.26 and reads as follows:

### 1306.26. Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word "Void" on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescrip-

tion;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date of last refill;

(v) Pharmacy's name, address, DEA registration number and original prescription number from which the prescription information was transferred;

(vi) Name of transferor pharmacist.

(3) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(d) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

[As added, 46 F.R. 48918, Oct. 5, 1981.]

## DEA PLACES HALAZEPAM IN SCHEDULE IV

Following FDA approval of a new drug application for halazepam in September, 1981, the DEA placed the new product in Schedule IV of the Controlled Substances Act. The therapeutic use of the drug is as an anxiolytic. It is marketed by the Schering Corporation under the name Paxipam<sup>®</sup> and is available in 20 mg. and 40 mg. tablets. Classification as a Schedule IV substance is based on DEA's findings that this drug has a low potential for abuse relative to the drugs in Schedule III, that there is a currently accepted medical use for halazepam in the United States, and that abuse of halazepam may lead to limited physical or psychological dependence relative to the drugs in Schedule III. The effective date of DEA's action was October 29, 1981.

## ALPRAZOLAM PLACED IN CONTROLLED SUBSTANCE SCHEDULE IV

A second new anxiolytic agent, alprazolam, has been placed in Schedule IV of the Controlled Substances Act by the Drug Enforcement Administration. The scheduling was effective upon publication in the *Federal Register* on November 12, 1981. Schedule IV was determined by the DEA to be appropriate because alprazolam has a low potential for abuse compared to the drugs in Schedule III, and abuse of the drug may lead to limited physical dependence compared to Schedule III drugs. Alprazolam is marketed by the Upjohn Company under the brand name Xanax<sup>®</sup> and is available in tablets of 0.25 mg., 0.5 mg., and 1.0 mg.

## FDA APPROVES HEPATITIS B VACCINE

A vaccine for the liver disease hepatitis B has been approved by the Food and Drug Administration and will be generally available in mid-1982. The vaccine will be the first completely new viral vaccine approved in the past 10 years and the first vaccine ever licensed in the U.S. that is made directly from human blood. This major advance was brought about by the cooperative effort

# Compliance News



of scientists in government, industry and the academic community.

Hepatitis B is a major health problem in the United States and an even greater one in some developing countries. It is estimated that there are 400,000 carriers and up to 300,000 new infections a year in the U.S., and 200 million carriers worldwide. Since hepatitis B has been linked to liver cancer, the vaccine may reduce the incidence of that disease. Though less common in the U.S., liver cancer is the most prevalent form of cancer in the world.

The FDA is currently recommending hepatitis B vaccination only for high-risk populations such as health care workers, laboratory workers, hemodialysis staff workers and patients, institutionalized mentally handicapped persons, some military personnel, contacts of known carriers, and persons with numerous sexual contacts. By treating high-risk groups, it is hoped that the chain of transmission of the virus will be broken.

Production and testing of the hepatitis B vaccine takes about 65 weeks, — longer than for any vaccine currently manufactured — because of the unique and complex production process and the necessary time for adequate testing. This process begins with the collection of blood plasma from chronic hepatitis carriers in specific FDA-licensed blood donor centers in major metropolitan areas across the country. The non-infectious hepatitis B particles are separated from the blood and purified by laboratory methods. The preparation is then treated with chemicals and enzymes to destroy the live virus.

The vaccine will be given in three 20 microgram doses, with the second dose given one month after the first, and the third, a booster shot, given six months after the first.

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## MANUFACTURER TO VOLUNTARILY ISSUE PPI ON BENDECTIN®

Bendectin® will soon carry a patient package insert describing its effects. Merrill Dow Pharmaceuticals, the manufacturer, agreed to voluntarily issue the labeling, which was drafted in conjunction with FDA and was expected to be issued by late 1981. The insert will help explain important facts about the treatment of nausea and vomiting of pregnancy, including non-drug measures that may relieve symptoms, the effects of Bendectin® and the basis for the physician's decision to describe it.

The FDA's pilot program for PPIs for ten products, which included Bendectin®, was suspended earlier in 1981 and is currently under review by FDA. The manufacturer of this product agreed to proceed on an interim basis with the voluntary insert for Bendectin® until conclusions on the broader program are reached by FDA.

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## MAZINDOL TRANSFERRED FROM SCHEDULE III TO IV

The anorectic drug mazindol has been transferred by the Drug Enforcement Administration from Schedule III to the less stringent Schedule IV. The action was effective on November 27, 1981 and is based on information now available that mazindol has a lower potential for abuse than Schedule III anorectic drugs. The drug will

continue to be subject to the same manufacture, distribution, security, registration, inventory, records, prescription controls and criminal liability as in the past.

All labels and labeling for commercial containers shall comply with DEA regulations six (6) months after publication (Oct. 27, 1981), but DEA will entertain petitions for extensions of time if the effective date imposes special hardships on the manufacturer.

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## NO PPIs NEEDED FOR ORAL PROGESTATIONAL CANCER TREATMENT DRUGS

Oral dosage forms of progestational drug products used only in the treatment of advanced cancer have been exempted from the patient package insert distribution requirements for progestational drug products. The purpose of the regulation requiring PPIs for oral progestational drugs was to inform women with childbearing potential of the risks of in utero exposure of the unborn child to progestational agents. The Food and Drug Administration has determined, however, that this information is not relevant to the concerns of patients for whom progestational drug products are prescribed solely to treat advanced cancer. The exemption from the PPI requirement became effective December 29, 1981.

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## LOOK-ALIKE DRUG PROBLEMS INCREASING

The look-alike drug problem has grown tremendously in the last several years. The products contain the OTC ingredients caffeine, phenylpropanolamine, ephedrine, pseudoephedrine, acetaminophen, salicylamide, doxylamine, and chlorpheniramine, either alone or in combination. In color, shape and markings, the products are made to resemble such commonly diverted controlled substances as amphetamines, depressants, narcotics and stimulants.

These products have been distributed nationwide through ads in campus newspapers, the mails and handbills. Purchasers of large quantities of the counterfeits have been selling them without labeling as if they were the stronger controlled stimulants or depressants they look like. The widespread use of look-alike drugs is causing difficulties for physicians treating drug overdoses in hospital emergency rooms because of the confusion over what drugs were ingested. Look-alikes are also interfering with enforcement of current controlled substances laws because of the problems of false arrests. However, last fall at the request of the FDA and the Department of Justice, U.S. marshalls seized look-alike drugs and the equipment used to manufacture them at nine locations in five separate states. Seizures involved 15 million filled capsules and over 20 million unfilled capsules imprinted with counterfeit markings.

The FDA and DEA have encouraged and supported state attempts to deal with the problem, including state legislative action prohibiting the distribution and advertising of counterfeit, look-alike drug products. Currently thirteen states have under consideration or have passed such legislation. Promotional or distribution activities of look-alikes known to pharmacists should be brought to the attention of the state board of pharmacy for local action, referral to the proper federal agency, or both.

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Board of Pharmacy Elections at the regularly scheduled May Board Meeting. The Board of Pharmacy Elections shall determine the validity of any challenged ballot and mechanical devices may be used in compiling election results. The Secretary-Treasurer shall convey the certified election results to the Governor.

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### **ITEM 380—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY**

**August:** A pharmacist appeared before the Board to respond to charges of responsibility for losses of Talwin at pharmacies in High Point and Lexington. Evidence was introduced showing purchases of between 0 and 200 Talwin per month at the High Point store before and after his employment with purchases of over 1,000 per month during his employment. Dispensing records were constant at between 100 and 200 per month. A shortage of about 240 dosage units of Talwin was also established at the Lexington store over a period of three weeks. The Board revoked the pharmacist's license with a stay order conditional upon his enrollment in a drug treatment program, Board approval of all employment and other conditions.

**September:** A pharmacist who had a store in Elon College appeared to answer charges of pleading guilty to a crime involving controlled substances in federal court. Substantial shortages in Dilaudid 4 mg. and Biphedamine 20 were found in the store for which he was responsible as pharmacist-manager. Shortages in other controlled substance records were also found. It appeared that the pharmacist borrowed \$13,000 from another person to keep the business going but there was no specified interest and no repayment schedule. The creditor insisted on receiving drugs, perhaps as payment but with no specific credit given, in return for the loan. This accounted for the shortage and the Board suspended his license for 5 years with a stay order on the condition of a one year active suspension and other conditions.

**October:** A pharmacist who had been employed at a hospital in Goldsboro appeared to respond to charges of unauthorized use of drugs, specifically Dilaudid and Demerol. The pharmacist had surrendered his license for four years in an agreement that he not be prosecuted in state court. The Board ordered the acceptance of this surrender.

A pharmacist in Asheboro appeared in response to charges of failure to keep accurate records for controlled substances. An audit revealed shortages of Dexedrine, Biphedamine, Quaalude and Dilaudid over a 2 year period. The pharmacist admitted taking, for his wife, about 100 Dexedrine which was less than 10% of the amount missing. The Board suspended his license for 5 years, on the condition of a 60 day active suspension and other conditions.

A pharmacist from Rocky Mount appeared in response to evidence of double billing for Medicaid beneficiaries and other conduct contrary to the provider agreement. Evidence was offered to show repayment for double billing that occurred, apparently in error and other repayments. The Board censured the pharmacist for this activity.

A non-pharmacist owner and a pharmacist employee of a Charlotte pharmacy appeared to respond to charges of insufficient records for controlled substances. A former owner of the pharmacy had pled guilty to drug charges earlier this year. The pharmacy personnel described the corrective actions which had been implemented. The Board suspended the permit for one year stayed for one year which amounts to issuing a one year probation.

**November:** Five hearings were held in November with one being continued and another produced an order with an effective date in January of 1982. Summaries of the other three follow.

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A pharmacist from Rutherfordton was cited but failed to appear for a hearing on his negotiated plea of guilty in federal court to possession with intent to distribute Dilaudid. An audit revealed shortages of Dilaudid and Preludin, each in the thousands. The Board also revealed that 330 of 336 prescriptions were forged. The Board revoked the pharmacist's license.

A pharmacist from Winstom-Salem (Rural Hall) appeared to answer charges of allowing an unlicensed person to dispense drugs. Purchases of prescription drugs which are controlled substances were made on two occasions from an unlicensed person. Some testimony was presented which tended to explain one purchase. The pharmacy is now in bankruptcy. The Board ordered a two year suspension of the pharmacist's license, stayed for two years on condition of a active suspension of his license for 30 days and other conditions.

A hospital pharmacist from Roanoke Rapids, now in Fayetteville, appeared in response to charges of allowing unlicensed persons to dispense drugs and failure to keep accurate records for controlled substances. There were also some evidence of drug use by the pharmacist who described his condition at that time as manic depressive. An audit revealed significant shortages but testimony indicated some could have been attributed to another person. The Board ordered his license suspended for 2 years, stayed for 2 years on condition of a 15 day active suspension and other conditions.

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### **ITEM 381—POSTER ON RETURN OF PRESCRIPTION DRUGS**

The Board has a poster for use by pharmacists in explaining why the Board recommends that prescription drugs not be returned to the stock of a pharmacy. It is available free from Inspectors during their inspection visits.

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### **ITEM 382—LATE PENALTY FOR LICENSES AND PERMITS**

North Carolina statute provides for a 60 day grace period for the renewal of licenses and permits. Unrenewed licenses and permits are delinquent as of March 1st. Renewal after March 1st produces a substantial penalty, particularly with the revised fee structure of the Board. We hope this reminder will avoid such penalties.

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### **ITEM 383—DISCIPLINARY ACTIONS OF PHYSICIANS**

Alfred Lee Coles, M.D., Statesville had his license to practice medicine in North Carolina revoked November 5, 1981. John F. U. McLeod, M.D., of Marshville dropped his court appeal of April 3, 1980 and the revocation of his license is in force as of November 2, 1981; Robert D. Capell, M.D., of Rock Hill, SC voluntarily surrendered his license on October 15, 1981; and Heriberto A. Ferrari, M.D., of Charlotte voluntarily surrendered his license on August 11, 1981.

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