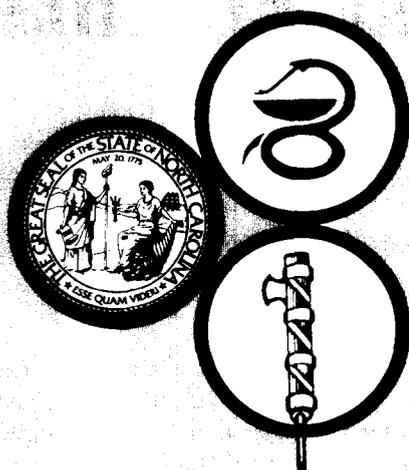


APRIL, 1980



# North Carolina Board of Pharmacy

P.O. Box 471, Chapel Hill, NC 27514

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 320—USP AND DISPENSING INFORMATION

The newly published USP/NF and a companion publication, Dispensing Information, deserves close scrutiny by all practicing pharmacists. Board regulation provides, among other things, that a pharmacy must have as Minimum Technical Equipment "a current edition of the USP or a standard commentary thereon." Possession of a current edition of the hard cover USP/NF would satisfy the regulation but some useful information which had been in prior USP publications is now printed in Dispensing Information, such as the usual adult dose. The additional publication also has new information on precautions, side effects and patient consultation which could be very useful. It is possible that pharmacists may decide that they cannot provide adequate information to practitioners and patrons without the supplemental soft cover book. These publications can be ordered either directly from the USP or through the North Carolina Pharmaceutical Association.

## ITEM 321—DISCIPLINARY ACTIONS OF THE BOARD OF MEDICAL EXAMINERS

The Board of Pharmacy has been informed of disciplinary actions involving the following physicians: The Board of Medical Examiners has endorsed the reinstatement of DEA privileges in Schedule II for Pressley R. Rankin, Jr., M.D. of Ellerbe; Joseph C. Fesperman, M.D. of Stanley, North Carolina surrendered his privileges in Schedule II on January 25, 1980; Samuel Allen Pope, M.D., Beulaville, surrendered his privileges in Schedule II on January 25, 1980.

## ITEM 322—DISPENSING DRUGS FOR VETERINARY PURPOSES WHICH WERE MANUFACTURED FOR HUMAN USE

Some pharmacists have a misunderstanding of statute and regulations when they dispense a prescription legend drug without a prescription for veterinary use. A veterinarian recently reported to the Board that a pharmacist had dispensed Depo Provera<sup>®</sup> injectable to the owner of a female dog for the purpose of delaying the onset of the dog's fertile season. One potential side effect of the drug is sterility which would certainly not be desired in this animal,

since it is a champion breeding dog. The veterinarian reported that this drug has not been used in animals for ten years. Fortunately, in this case, no harm was done. The dispensing of a prescription legend drug without a prescription is misbranding and subject to the provisions and penalties of both state and federal law.

## ITEM 323—HOW CAN I TELL IF A DRUG HAS A NDA OR ANDA?

Until recently this was a difficult question. You can find out by calling this telephone (301) 443-3700 in Maryland. The Food and Drug Administration has a service at this number which will obtain the answer to this item's title. An answering service will take the question and FDA personnel usually can provide responses in a few days.

## ITEM 324—RECENT RECALLS

All pharmacists should be aware of the recall of Selacryn<sup>®</sup> which occurred in January of 1980. If this matter has been overlooked, you should review your inventory for this product and if any is found you should contact a representative of Smith, Kline and French for return instructions.

Another recall in February received less publicity but is significant under the current Product Selection Act. A Telex message on the FDA system dated February 4, 1980 reported a recall of Beta-Val<sup>®</sup> Cream manufactured by Premo and distributed by H.L. Moore Drug Exchange of New Britain, Connecticut. On October 15, 1979 Premo notified H.L. Moore of the recall of this product and requested sub-recall to the dispensing level. H.L. Moore notified Premo they had no stock to return and refused to sub-recall. Subsequent requests by Boston district for the firm to sub-recall proved fruitless.

Under such circumstances pharmacists will need to consider whether this complies with the Product Selection Act which provides, in part, "(a) A pharmacist dispensing a prescription for a drug product prescribed by its brand name may select any equivalent drug product which meets the following standards: . . . (4) The manufacturer shall have adequate provisions for drug recall."



# National Pharmacy

## **d-PROPOXYPHENE: NARCOTIC STATUS PROPOSED RESCHEDULING PETITIONS DENIED**

The Drug Enforcement Administration has issued a notice of proposed rulemaking to classify dextropropoxyphene as a narcotic. The DEA proposal is based on a binding recommendation of the Surgeon General that the pain-reliever is an opiate and should be classified as a narcotic. The Surgeon General's recommendation concurred with the opinion of Dr. J. Richard Crout, Director, Bureau of Drugs, Food and Drug Administration.

Under the proposal, the drug will continue to be listed as a Schedule IV controlled substance and will not be placed under the stricter controls of Schedule II. This determination was made in response to two petitions received by DEA to transfer dextropropoxyphene from Schedule IV to Schedule II of the Controlled Substances Act. DEA's denial of the rescheduling petitions was supported by the findings of the Surgeon General that "there is insufficient evidence at this time to justify our recommending to you any change in the current scheduling of propoxyphene." The proposed narcotic status would apply to propoxyphene and all drug products containing propoxyphene and its salts.

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## **PEDIATRIC TETRACYCLINE USE**

Reports of adverse reactions in children given tetracycline liquid and tetracycline liquid congeners continue to be of concern to health professionals.

When pediatric tetracycline drops were withdrawn from the market in 1978, other liquid forms were allowed to remain, primarily because they were needed for geriatric patients.

However, the figures from the July 1978 to June 1979 **National Disease and Therapeutic Index** show that 60% of the prescriptions for tetracycline liquid are written for children from 0 to 9 years old, while geriatric patients over age 65 account for only 6% of the prescriptions. Similarly, 80% of the prescriptions for tetracycline congener liquid are written for children under the age of 9.

Tetracycline liquid and tetracycline congeners liquid may cause depression of bone growth and permanent discoloration of the teeth, as well as enamel hypoplasia, when given during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years). Therefore, tetracycline should not be used in this age group unless other drugs are not likely to be effective or are contraindicated.

Tetracycline congeners include: oxytetracycline, chlortetracycline, demeclocycline, doxycycline, methacycline and minocycline.

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**The Bureau of Voluntary Compliance welcomes pharmacists in Indiana, Michigan and New Jersey as new state board newsletter readers.**

## **UPDATE ON AMPHETAMINE ABUSE AND LABELING**

Amphetamine abuse remains a substantial medical and social problem despite regulatory actions over the last decade, according to analyses of updated information from the Drug Enforcement Agency, the National Institute on Drug Abuse, and the National Clearinghouse for Poison Control Centers.

Federal action has been successful in reducing the prescribing of amphetamines to about 25% of what it was in the 1960's, with an associated fall in the amount of abuse. Past actions have included putting the drugs in Schedule II under the Controlled Substances Act, mandating sharp reductions in production quotas, and limiting prescribing indications to narcolepsy, hyperkinesis, and short-term (a few weeks) treatment of obesity. The prescribing of amphetamines has continued to decline in recent years. But the rate of abuse, estimated by episodes reported to the Drug Abuse Warning Network (DAWN system) relative to prescription sales, has remained constant for several years.

A recent NIDA update indicated that stimulants account for more abuse than other other category of prescription drugs, that nonmedical use of stimulants is increasing among 18 to 25-year olds. In addition, within the class of anorectic drugs, amphetamines have abuse rates relative to prescription sales on the order of 10 times those of other drugs.

A significant amount of amphetamines used for non-medical purposes appears to come from legally manufactured, shipped, or prescribed supplies. High volume prescribers and dispensers of the drug for treatment of obesity account for a substantial amount of the abuse.

The Bureau of Drugs has initiated action to remove the prescribing indication for the management of exogenous obesity from the labeling of drug products containing amphetamine. An estimated 80% of legal medical use of these drugs has been for weight reduction. Amphetamines will remain on the market for use in the treatment of narcolepsy and the hyperkinesis syndrome in children.

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## **FDA ESTABLISHES RULES ON PERFORMANCE STANDARDS FOR MEDICAL DEVICES**

The Food and Drug Administration on February 1, 1980 established rules on how it will develop performance standards for medical devices. Under the rules, the FDA will rely mainly on voluntary standards developed by non-government standard-setting organizations. The agency will review these standards and, if satisfactory, will endorse them rather than developing its own. FDA will develop a mandatory standard only when needed for public health protection.

FDA expects manufacturers to comply with the voluntary

# Compliance News



standards because hospitals and other buyers of devices are likely to prefer products that meet FDA-endorsed standards. FDA will encourage manufacturers to identify on the label that the product meets the standard.

It is estimated that voluntary standards will eventually be developed for about 90% of the 1,200 types of medical devices for which standards are appropriate. Examples of such devices are electrocardiograph machines, glucose testing products and laboratory equipment calibrators. The standards will specify how the device is to perform, how to test its performance and how it is to be labeled.

In a release accompanying publication of this policy, Dr. Jere E. Goyan, FDA Commissioner, said: "The voluntary approach to standard-setting will adequately protect the public's health, while at the same time encouraging innovation in this important area. The approach adopted by FDA conforms to a policy recently announced by the Office of Management and Budget that encourages federal agencies to rely on voluntary standards whenever possible."

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## LAETRILE TRIALS IN TERMINAL CANCER PATIENTS APPROVED

The National Cancer Institute announced early this year that FDA had given it permission to proceed with a clinical trial of Laetrile in about 300 terminally-ill cancer patients, contingent on successful completion by NCI of two tests. The first test would be a pyrogenicity test in rabbits and the second would be to test the cyanide toxicity of Laetrile in six patients.

NCI estimates it would take at least three months for these tests to be completed. If they are successful and the clinical trial begins, it would be at least a year after that before any results are available.

FDA's conditional approval of the NCI request to test Laetrile does not alter the agency's position on the substance. FDA Commissioner Dr. Jere E. Goyan said "All the data to date suggests that Laetrile has no effect on cancer. But we will objectively and promptly evaluate any data that is produced by NCI's study. In the meantime, I caution cancer patients not to delay or abandon conventional cancer therapies by turning to Laetrile as an alternative."

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## USE OF "ROOM ODORIZER" AS A DRUG RAISES FDA CONCERN

Butyl nitrite, a chemical sold in various outlets across the country as a "room odorizer" is being investigated because it is increasingly being used improperly as a drug to provide a brief but intense "high" when inhaled, according to the Food and Drug Administration. Butyl nitrite is closely related chemically to amyl nitrite, a smooth muscle relaxant approved by FDA for prescription only

use in treatment of heart conditions. The "room odorizers" are currently being marketed under such brand names as Rush, Locker Room, Lockaroma, and Black Jack.

Side effects to the inhalation of butyl nitrite include headaches, dizziness, perspiration and a flushed face. Less common reactions include nausea, vomiting and fainting. Potentially more serious effects include the miscarriage of pregnancies, increased risk of tumor development and heart problems. The chemical is highly toxic if ingested.

FDA's position has been that since butyl nitrite is promoted solely as a "room odorizer" and not for any drug purposes, it did not come under the jurisdiction of the Food, Drug and Cosmetic Act. In view of the abuse problem, however, FDA's Bureau of Drugs will reevaluate that position to determine whether any actions could be taken under the federal Food, Drug and Cosmetic Act or other statute, and what regulatory actions would be appropriate. The reevaluation stems from FDA's concern about the drug-type abuse of any substance, no matter how it is promoted and sold.

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## SCHEDULE II CONTROLS ORDERED FOR PHENYLACETONE

Due to increasing evidence that the substance phenylacetone is being used as the principal compound in the illicit manufacture of amphetamine and methamphetamine, the Drug Enforcement Administration has placed the chemical into Schedule II of the Controlled Substances Act. The DEA's investigations have documented 268 illicit methamphetamine and 45 illicit amphetamine laboratories seized from 1975 to November 1979. The effect of the DEA's final order is to provide regulatory controls on the manufacture, distribution, importation and exportation of phenylacetone. The requirements include DEA registration of purchasers and sellers of the substance.

Because phenylacetone was determined to be an immediate precursor of two controlled substances, formal agency rulemaking procedures were not required and the scheduling was effective on February 11, 1980.

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The logo for the 1980 Census, featuring the word "CENSUS" in a bold, sans-serif font above "'80" in a larger, stylized font. A pencil is shown writing the number "0" in the "80".

**We're counting on you.  
Answer the census.**

### **ITEM 325—AUDITS FOR DRUGS; BRAND/GENERIC**

Mr. Keith Bulla, Supervising Agent of the Diversion Investigative Unit of the State Bureau of Investigation has indicated that pharmacists need to be aware of their audit methods. Before beginning an audit the agent will determine whether to survey prescriptions and records for all controlled substances, those in a particular schedule or schedules, or selected controlled substances. Most agents prefer the last procedure since it involves fewer records but any of the three may be selected. During the audit, each prescription amount would be logged and separate entries made for brand name drugs and generic drugs. The net result of this is that the records in a pharmacy could show substantial discrepancies if generic drugs are used to fill brand name prescriptions and no record of generic use is made on the brand name prescription. If records are kept in conformance with the current Product Selection Act, this will not occur.

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### **ITEM 326—JOINT MEETINGS CAN HELP SOLVE PRODUCT SELECTION PROBLEMS**

The enactment of the Product Selection Act has "changed the rules" for pharmacists and physicians in the area of prescribing and dispensing. Any significant change such as this can produce confusion and misunderstanding in the health professions. In order to clarify the new law, several communities in the state have held joint meetings of physicians and pharmacists to bring everyone up to date. At one meeting recently a physician was pleased to learn that prescription labels are required to contain the name and strength of the drug unless the prescriber has contrary instructions. Although this was not part of the Product Selection Law discussed it is only one example of matters which need clarification. The Board encourages participation by pharmacists in such meetings.

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Contact us at 919/942-4454 in Chapel Hill if we can assist you in the voluntary compliance of pharmacy and drug law.

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**NORTH CAROLINA BOARD OF PHARMACY**  
P.O. Box 471  
Chapel Hill, NC 27514

### **ITEM 327—PHARMACISTS SHOULD USE CARE WITH CERTAIN DRUGS**

Most pharmacists are aware that drug abusers have made frequent attempts to obtain Dilaudid<sup>®</sup> and Preludin<sup>®</sup> by forged prescriptions or otherwise. In this connection, pharmacists should take particular care to verify, where appropriate, prescriptions for either of these drugs for patients who are not well known to them. Incomplete or inadequate information on the prescription regarding the prescriber's name, address and telephone number should be cause for immediate suspicion and verification. (See Item 311 regarding the pharmacists and the physicians responsibility).

Recently, instances of illicit attempts to obtain Tussionex<sup>®</sup> by at least two methods have occurred. A person will present two prescriptions, one for Tetracycline and another for Tussionex<sup>®</sup> with one refill. Shortly after getting the prescription filled, the person will return for a Tussionex<sup>®</sup> refill, claiming the bottle has been dropped and broken. Checking with the prescriber reveals the "prescriptions" to be forged. In other situations, three individuals will enter a pharmacy and two will distract the pharmacist attempting to lead the pharmacist away from the prescription department. Once this has occurred, the other participant makes a dash for the prescription department to pick up as much Tussionex<sup>®</sup> as possible and run from the pharmacy.

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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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