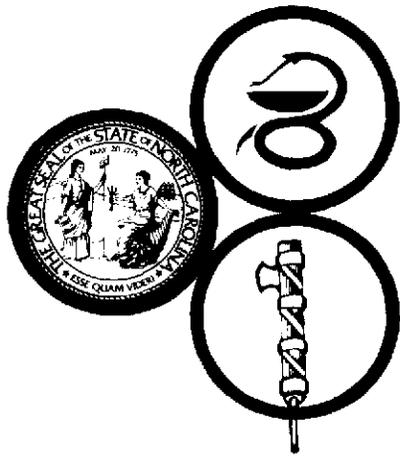


April '81



North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 349 — WE HAVE MOVED!!!!

As of March 1, 1981, our new address is 209 Carr Mill Mall in Carrboro. Our new mailing address is P.O. Box H, Carrboro, North Carolina, 27510. Please note this change for future correspondence with our office. Our telephone number 919/942-4454 remains the same.

ITEM 350—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

January: Two partners in a pharmacy appeared at a hearing in January for a shortage of over 8,000 dosage units of propoxyphene during an audit period of 1½ years. One of the partners was also pursuing the reinstatement of his license to practice pharmacy which had been suspended indefinitely in 1975. The Board placed the pharmacist on probation and directed him to submit a plan for recordkeeping and a controlled substances inventory. The Board reactivated part of the other partner's suspension which had been lifted in April of 1980 and did not reinstate his license.

Two pharmacists appeared at a hearing in response to charges of inaccurate records of controlled substances, specifically Meprbamate. Evidence indicated a large number of dosage units had been dispensed on "prescriptions" which the physician denied issuing. The pharmacists claimed approval had been obtained by telephone but offered no supporting evidence. Many alterations of refill records occurred which created confusion over exactly what transpired. An audit revealed a shortage of either 5,000 or 8,000 Meprbamate 400 mg. depending on which records were used. The Board suspended the license to practice pharmacy for 30 days for each pharmacist and added a 3 year probation.

ITEM 351 — YOU NEED A PUNCH

A three hole paper punch that is, if you don't already have one. Past issues of the *Newsletter* were punched for insertion and retention in the binder which has been distributed to all pharmacies. Future issues will not be punched and this item is useful for that purpose and easy retention of DEA or FDA publications. *Newsletters* are mailed to your preferred mailing address as indicated on your license renewal. If you want to receive the *Newsletter* at your pharmacy for retention in the binder, please so indicate on your license renewal.

ITEM 352 — PRESCRIPTION COPIES

North Carolina statute GS 90-106 provides that copies of prescriptions for controlled substances shall not be filled or refilled. It is the Board's position that copies of prescriptions for non-controlled drugs are also not valid in the same way that a copy of a check is not a check, a copy of a contract is not a contract, etc. If a pharmacist receives a prescription copy and feels that it should be filled (or refilled) the pharmacist should contact the prescriber and essentially obtain a new prescription and treat it as such in their prescription files. There is no provision in North Carolina statute or regulations for the transfer of prescriptions between stores.

ITEM 353— IDENTIFICATION REQUIRED

This item is to remind pharmacists that federal regulations require that every pharmacist, when dispensing a Schedule V drug without a prescription to a person not known to them, must obtain identification from that person. North Carolina pharmacists should be aware that they will be held to this standard in the event of a hearing before the Board.

In this connection, it may be advisable to confirm unknown customers or patient identification on all prescriptions for drugs subject to abuse including, but not limited to, Dilaudid, Preludin, Quaalude and Percodan. This is no more than what most pharmacists would do if such a person were presenting a check as payment for goods and services. It would seem that a pharmacist's care in dispensing drugs subject to abuse would be at least equivalent to that used in financial matters.

ITEM 354 — FACTS ON PHARMACISTS

The Health Services Research Center at UNC-CH has compiled statistics from data on license renewals submitted by pharmacists in North Carolina. Complete and reliable data was received from 2,848 pharmacists in the state. The data is from the 1980 renewal information and is specified for this state.

Of the 4,106 pharmacists licensed in North Carolina, 3,351 are active and the remainder inactive or unreporting. By race, whites are the overwhelming majority of those reporting with 97%. Blacks report 1% with Asians, American Indians and others at lower numbers. Males outnumbered females 2,275 to 544 (81%). The data indicates that pharmacists spent most of their time in the follow-

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National Pharmacy

CPSC EXEMPTS POWDERED & EFFERVESCENT FORMS OF ACETAMINOPHEN FROM C-R-C REQUIREMENTS

A rule exempting specific dosage levels of powdered and effervescent forms of acetaminophen from child protection packaging requirements was issued by the Consumer Product Safety Commission. The exemption allows non-safety packaging of effervescent tablets or granules that contain less than 10% acetaminophen and which meet oral lethal dose and carbon dioxide release specifications. The exemption took effect on February 23, 1981 and is similar to the one previously provided for analagous forms of aspirin. Unit dose packages of acetaminophen except pediatric products, are also exempt if each individually packaged dose contains not more than 13 grains of acetaminophen.

Findings of the CPSC supporting the exemption of these dosage forms included the fact that the unpleasant taste of both powder and effervescent forms of acetaminophen would make it unlikely a child would ingest a harmful amount. The Commission also found that available injury data supported the safety of the exempted acetaminophen forms. With respect to the unpalatability of the product and its comparative risk with other unpleasant tasting products such as turpentine and insect repellent, the CPSC noted that the exempted forms of acetaminophen do not pose the type of risk presented by turpentine and insecticides because harmful amounts of these liquid products may be ingested before a child would react to the unpleasant taste.

CONTROLLED SUBSTANCES INVENTORY BOOKLET UNAVAILABLE FROM DEA

The Drug Enforcement Administration's supply of the Controlled Substances Inventory List (Revised January 1979) is exhausted. Due to federal budget cutbacks, the agency will not be reprinting the list. The biennial inventory requirement discussed in the 1980-81 third quarter issue of National Pharmacy Compliance News must still be met by all DEA registrants. A format similar to the DEA Inventory List is recommended.

PHARMACISTS URGED TO COUNSEL PATIENTS CONCERNING DMSO

The increasing use and promotion of dimethyl sulfoxide (DMSO) for uses for which it has not been shown to be safe and effective are of concern to FDA and boards of pharmacy. The agencies are particularly concerned about the use of the veterinary (90% solution) and industrial (99% solution) products by people treating themselves topically and orally for a host of conditions, including arthritis, bursitis, tendinitis, and muscular sprains and strains.

More information needs to be accumulated and analyzed concerning the effectiveness of DMSO in the many conditions for which it has been advocated. The issue of long-term safety also needs to be resolved. Meanwhile, FDA urges health professionals to counsel patients against purchasing DMSO of unknown quality and medicating themselves for purposes for which it has not been shown to be effective. They may also want to advise patients that when used at high doses for long periods, DMSO has not been shown to be without risk of eye injury.

Adverse effects of DMSO can include erythema, nausea, and the potential risk of blurring of vision or other eye problems. DMSO can also initiate the liberation of histamine and one case of severe hypersensitivity reaction has been reported after topical administration.

The more common outlets for the industrial solvent solution are hardware stores, mail order houses, and the backs of trucks operating near shopping centers or parking lots. Pharmacists may be approached to distribute DMSO marked "degreaser solvent." The FDA urges pharmacists to protect consumers by refusing to distribute this product.

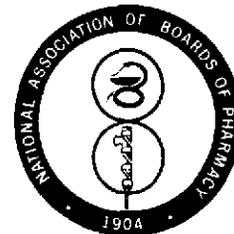
USP's D.I. GIVES INFORMATION FOR PATIENT AND PROFESSIONAL

The U.S. Pharmacopeial Convention, Inc. has published the second edition of *USP Dispensing Information*, the two-part volume that gives instructions for the use of pharmaceutical products. The first section, for the health practitioner, includes in each monograph categories of use, precautions, interactions, side effects, dosage, packaging, storage and consultation guidelines. The patient section contains much of the same in lay language and has been revised to meet FDA guidelines for patient package inserts (PPI). More than 1000 pages, the book covers some 2,000 drug dosage forms and several thousand brands. The 1981 USP DI's subscription price is \$18.75 and includes bi-monthly updates. To order, pharmacists can write to: 1981 USP DI, Publications Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852 or telephone (301) 881-0666.

FDA COMMEMORATES 75TH ANNIVERSARY OF PURE FOOD AND DRUGS ACT

The Food and Drug Administration this year is commemorating the 75th anniversary of the Pure Food and Drugs Act, the first federal law to provide protection to consumers from dangerous, adulterated and misbranded food and drug products. The anniversary year is being marked throughout the United States by scientific symposia on current and continuing problems, by pro-

Compliance News



grams at meetings of professional organizations, and by educational exhibits, including one at the Smithsonian Institution.

Poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines, led to enactment of the law, which was signed by President Theodore Roosevelt on June 30, 1906. The law was initially enforced by the U.S. Department of Agriculture. Today the successor to the Pure Food and Drugs Act of 1906, the Food Drug and Cosmetic Act of 1938, is enforced by the Food and Drug Administration, one of six agencies in the Department of Health and Human Services' Public Health Service.

In addition to the 75th anniversary theme at the scientific symposium, FDA will also participate during the anniversary year in meetings sponsored by the American Pharmaceutical Association, the American Institute of History of Pharmacy, the Association of Food and Drug Officials, the National Food Processors Association, the Animal Health Institute, the American Dental Association, the American Medical Association, and the American Academy of Pediatrics. Educational exhibits are also set up in the lobby of the Hubert H. Humphrey Building, which is the main building of the Department of HHS in Washington, and in the 32 cities where FDA has regional or district offices.

TEMAZEPAM TO BE SCHEDULE IV CONTROLLED SUBSTANCE

A Drug Enforcement Agency proposal to list temazepam as a depressant in controlled substances Schedule IV was announced in the *Federal Register* early this year. Listing the new drug in CS-IV is based upon a recommendation made by the assistant secretary of health on behalf of the secretary of DHHS. The findings of the secretary included that:

(1) based on information now available, temazepam has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III;

(2) temazepam will, upon issuance of a NDA by the FDA, have a currently accepted medical use in treatment in the United States; and

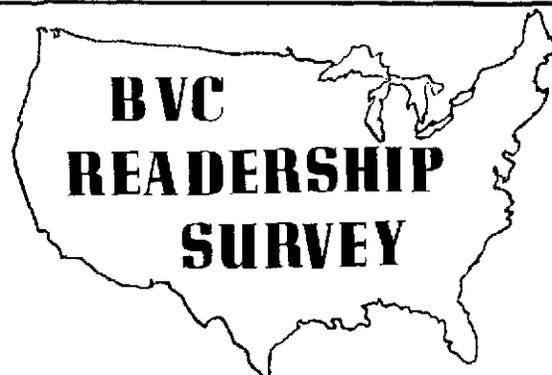
(3) abuse of temazepam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

CANDIDATE'S GUIDE TO NABPLEX AVAILABLE TO LICENSED PRACTITIONERS

The National Association of Boards of Pharmacy (NABP) has prepared a booklet to help candidates seeking licensure to practice pharmacy to prepare for NABPLEX — the *NABP Licensure EXam-*

ination. The booklet contains all the competency statements on which the examination is based as well as sample questions for each of the five tests which comprise NABPLEX. The competency statements describe the objectives of the examination in terms of the candidate's pharmaceutical education and experience. All examination questions are based on the competencies expressed in the statements. The subjects included in the five NABPLEX test sections are practice of pharmacy, pharmacology, pharmacy, mathematics and chemistry.

The 1981 *Candidate's Guide* is a useful reference for all pharmacists as well as applicants for licensure, but particularly for pharmacists who are preceptors or clinical instructors in internship and clerkship programs. The book provides insight into the required knowledge, skills and abilities necessary for the practice of pharmacy. Copies may be ordered from NABP, One East Wacker Drive, Suite 2210, Chicago, Illinois 60601. Orders must be prepaid. The single copy price is \$7.50.



BVC READERSHIP SURVEY

The Bureau of Voluntary Compliance will be sending out a Readership Survey to a random selection of licensees receiving the BVC State Newsletters. The purpose of the Survey is to provide information to state boards, the Bureau of Voluntary Compliance Committee, and the National Association of Boards of Pharmacy Foundation. This information will be used to aid in topic selection and in rating the state board newsletter in relation to other publications received. The importance of completing the form is in the random sampling. Only a selected number of pharmacists from each participating state will receive the survey and the accountability of the study will be based on the number of returns.

If you receive the survey, please fill in the information and return it without delay. Your suggestions and opinions will be an intricate portion of the study and will be included in the final report, as well as other BVC publications and presentations. For further information, you may contact Daniel J. Lambert, Director, Communications and Meetings, NABP Headquarters.

ing settings: Independent community—1120; small and large chains—1059; private and government hospitals 436; with other areas in lesser figures. It may be of interest to know that 751 pharmacists list themselves as owners or partners while 1932 state they are employees. It may be of a surprise to some pharmacists that more than 2000 of their colleagues work less than 40 hours per week with 647 working over 40 hours per week. Of the pharmacists who list themselves as inactive, about 10% state they are homemakers and not seeking employment. Less than 10% of those inactive are seeking employment.

ITEM 355—DISCIPLINARY ACTIONS—PHYSICIANS

The North Carolina Board of Medical Examiners has informed us of the following actions: Joseph A. Young, M.D., Newton has surrendered his license to practice medicine in North Carolina and prescribing privileges for controlled substances, November 18, 1980; Gilbert Silverman, M.D., Richmond, Virginia, has surrendered his license to practice medicine in North Carolina December 16, 1980; and Wallace E. Souther, M.D., Fletcher, has surrendered his license to practice medicine in North Carolina and his controlled substances registration, January 26, 1981.

ITEM 356—DISCIPLINARY ACTIONS—DENTISTS

The North Carolina State Board of Dental Examiners has informed us that Dr. L.T. Russell, Asheville, has surrendered his controlled substances registration and prescribing privileges in all schedules, November 26, 1980; and James F. Peppers, DDS, Marion, has surrendered his privileges to prescribe controlled substances in Schedules II, January 22, 1981.

ITEM 357—RESPONSIBILITY OF A R.PH.-MGR.

The Board issues pharmacy permits for places where drugs are dispensed to pharmacist-managers whom the Board holds responsible for the operation of the pharmacy or drug store in conformance with all applicable statutes and regulations. Every pharmacy must have a pharmacist-manager who countersigns the permit renewal for validation. The members of the Board consider this to be a serious and substantial responsibility. It is not a casual undertaking.

For example, it is a criminal offense for the pharmacist-manager to cause or permit an unlicensed person to fill a prescription, even if this occurs contrary to specific and written instructions from the pharmacist-manager. The Board has suspended or revoked licenses and permits under these circumstances. The Board also holds the pharmacist-manager responsible for any shortages revealed by an audit, regardless of his direct connection with the activities which produced the shortage.

It is a common practice of the Board to require that a pharmacist-manager be present at the location for which the permit is issued at least 32 hours per week or a majority of hours the pharmacy is open to serve the public.

ITEM 358—PROPOSED REVISED PRACTICE ACT

For nearly the past three years pharmacist representatives from the North Carolina Pharmaceutical Association, the North Carolina Society of Hospital Pharmacists and the Board of Pharmacy have participated in the development of a proposed revision of the Pharmacy Practice Act in North Carolina. Presentations were made in

more than 20 cities in the state during 1980 to explain the potential impact of the proposal which contains, among other things, a provision for pharmacists prescribing a third class of drugs. The Board, by statute, is prohibited from supporting or opposing legislation considered by the General Assembly. We have been informed that the North Carolina Pharmaceutical Association intends to pursue this proposal in the General Assembly during the Spring of 1981. For more information contact Mr. Al Mebane, Executive Director, North Carolina Pharmaceutical Association, P.O. Box 151, Chapel Hill, NC 27154, 919/967-2237. After being fully informed, you should be sure your legislators at the state level—both Senators and Representatives—know your opinions.

ITEM 359—LICENSE REINSTATEMENT

Occasionally the Board receives requests for reinstatement of licenses which have been suspended or revoked. The Board has a common practice which it uses in these situations. It follows below and is printed here for the information of the pharmacists of the state.

"Before reinstating any license or permit, the Board of Pharmacy considers each case on an individual basis. Ordinarily, a detailed record of positive accomplishments over a recent period of time would need to be demonstrated. Letters of recommendation would be considered for whatever merit they may have. However, the Board customarily would require more than a series of such letters and preferably an evaluation from an unbiased source or sources. Any significant evidence that the applicant is deserving of reinstatement would be considered. As a minimum the Board would look for evidence that the conduct which produced the revocation or suspension has been rectified, if it can be rectified, before a request for reinstatement would be seriously considered.

Although North Carolina statute allows the Board to reinstate licenses which have been revoked after a one year period, the Board does not consider itself under any obligation to reinstate a license at that time. By definition, revocation has more of a nature of permanence while suspension implies that reinstatement would be seriously considered at some time. Ordinarily, the Board does not consider requests for reinstatement more frequently than at six month intervals. After the Board has determined that an individual may benefit to have a revoked license reinstated, the individual must take and successfully pass the Board's regular practical examination to determine if such an individual has the ability to perform as a pharmacist as a condition of reinstatement."

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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