



North Carolina Board of Pharmacy

P.O. Box H, Chapel Hill—Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 425—BOARD DISCIPLINARY ACTIONS

March: A pharmacist-manager and owner from Mount Airy was present for a disciplinary hearing for charges of refilling a prescription for Tylenol® No. 3 without authorization. Testimony of the Board's Inspector revealed such refills occurring on seven different occasions in May and June of 1982. One such refilling was accomplished by an unlicensed employee who was not under supervision. A significant number of recordkeeping violations were noted including failure to sign prescriptions for controlled substances, other refillings of controlled substance prescriptions beyond authorization, and the absence of patient addresses on prescriptions for controlled substances. The pharmacist in his defense noted that this was a first offense before the Board and that this activity was not a willful violation but the result of many years of negligent habits. It was the decision of the Board to place the pharmacist on probation for one year under certain conditions, among them the successful completion of a pharmacy jurisprudence examination.

April: A pharmacist from Welcome appeared in a hearing to respond to charges of dispensing a controlled substance, Darvon® Compound 65, without a prescription. Testimony from agents of the State Bureau of Investigation revealed that a prescription which had originally been conveyed by telephone in 1973 and that this prescription vial was refilled on two occasions in February and March of 1982 without any contact with the prescriber. The pharmacist testified that he was undergoing a great deal of stress with his mother's illness which eventually led to her expiration in February of 1982. The Board placed the pharmacist on probation under certain conditions, including the completion of a pharmacy jurisprudence examination before the expiration of one year.

A pharmacist from Rowland appeared to conclude an investigation which revealed substantial personal use of controlled substances and a shortage of Demerol®, Percodan® and Percocet® at one pharmacy where he had been employed. The pharmacist responded that he had been enrolled in at least two different treatment programs for his problem and also was a member of Alcoholics Anonymous. It was the decision of the Board to suspend the pharmacist's license for 60 days with the license reinstated only after successfully completing a pharmacy jurisprudence examination and other conditions including unannounced urinalysis for drug screening.

A pharmacist and owner from Madison appeared in response to charges of pleas of guilty in federal court to the charge of distributing Placidyl® and Phentermine without a prescription. Drugs had been distributed to a college student with whom the pharmacist

had a personal relationship. The hearing lasted over 6 hours and it was the decision of the Board to suspend the pharmacist's license for 60 days with reinstatement only after passing a pharmacy law exam, other conditions and 5 years probation.

ITEM 426—QUARTERLY QUERY

This issue of the Newsletter contains the first publication of a question which had been used (and may be used again in the future) on the licensure examination. The members of the Board felt this example might be interesting and useful for practicing pharmacists and noteworthy for pharmacy students. The question appears below and the correct answer can be found elsewhere in this Newsletter with a close reading of other items.

A pharmacist received a prescription with today's date for Percodan® No. 12, 1 every four hours for pain (apparently completed by the office nurse since the pharmacist knows the physician is in Europe for three weeks) which had the physician's true signature. Who bears the responsibility for this prescription under the Code of Federal Regulations, if it is filled under these circumstances?

1. The Physician
2. The Nurse
3. The Pharmacist
 - a. 1 only
 - b. 2 only
 - c. 3 only
 - d. 1 and 3 only
 - e. 1, 2 and 3.

ITEM 427— LABELING GENERICS

One common question from pharmacists is the proper labeling of prescriptions when a generic drug is dispensed. Pharmacists often desire to use a brand name on the label for ease of identification and this can present some serious litigation problems, unless properly labeled. See Item 432.

Problems arise in at least two different areas — misbranding where the label is false or misleading in any particular or a misrepresentation that a product is the brand name when a generic is dispensed. Using, for purposes of illustration only, the drug name Sumycin®, generic Sumycin, Sumycin G, Sumycin/Tetracycline, Sumycin (manu-

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National Pharmacy

OTC SALES OF ALUPENT WITHDRAWN

On May 17, 1983 Boehringer-Ingelheim, Ltd. of Ridgefield, CT announced that it is removing its product Alupent, a metaproterenol metered dose mist inhaler, from over-the-counter sales. The company is advising pharmacists to place the product behind the prescription counter and make it available to patients only on prescription. The Food and Drug Administration has indicated that it supports this decision by Boehringer-Ingelheim and by Dorsey Laboratories, a licensee, who has also returned its Metaprel inhaler to prescription only sale. FDA also has indicated that it will be publishing a Federal Register Notice formally withdrawing OTC availability of Metaproterenol metered dose mist inhalers.

The safety and effectiveness of the metaproterenol inhalers when used as directed was not in question. The action withdrawing the inhalers from the OTC markets was taken as a result of many physician objections to the OTC marketing. The physicians argued that safe use required physician supervision.

The issue of the use of metaproterenol inhalers was discussed at a meeting of the FDA Pulmonary-Allergy Drug Advisory Committee. The Committee indicated that while they considered metaproterenol a safe and effective medication, there was concern about the possibility of overuse on the part of the public and of the potential for patients to fail to obtain needed treatment from their physicians. The Committee thus requested that the drug be returned to prescription only status until further studies could be completed.

Pharmacists are advised to restrict the sale of metaproterenol metered dose mist inhalers currently being marketed as Alupent and Metaprel to prescription only sales until further notice.

DEA PROPOSES TO INCREASE FEES FOR CONTROLLED SUBSTANCE REGISTRATION

In a recent Federal Register Notice of Proposed Rulemaking the Drug Enforcement Administration has proposed to adjust its fee schedule for DEA registration. DEA indicates that the current fee schedule has been in effect since 1971 and that it has been determined that it does not adequately recover the federal cost involved in the registration and control of manufacturers, distributors, and dispensers of controlled substances.

The Controlled Substances Act of 1970 requires DEA to annually register any person who manufactures, distributes, or dispenses a controlled substance. The Act authorizes DEA to charge "reasonable fees relating to the registration and control of the manufacturer, distribution, and dispensing of controlled substances."

Currently manufacturers are required to pay a fee of \$50, while distributors pay \$25, and hospitals, retail pharmacies, and practitioners pay a \$5 registration fee.

Last year, the general accounting office conducted a review of annual registration fees charged by DEA and determined that the existing fee structure did not adequately recover the cost incurred by the government. As a result of GAO's findings DEA proposes to adjust the fees charged its registrants. The proposed fee change would require manufacturers to pay a fee of \$250, distributors

\$125, hospitals, retail pharmacies, and practitioners \$20.

Final action on this DEA proposal is not expected before mid-summer. It is anticipated that DEA will notify all of its registrants of the fee change if and when it becomes effective.

USE OF PROGESTERONE IN TREATING PREMENSTRUAL SYNDROME

It is becoming increasingly common for a pharmacist to be contacted and asked to prepare prescriptions for progesterone suppositories for the treatment of premenstrual syndrome (PMS). Questions arise as to the status of progesterone suppositories and whether these large doses of progesterone can be legally dispensed.

FDA's Advisory Committee on Fertility and Maternal Health Drugs has met to consider the status of testing the progesterone for the treatment of PMS which is currently being conducted. The Committee has recommended that testing of progesterone by investigators in the United States be allowed to proceed using doses higher than the previous limitation of 200 mg. per day.

FDA has indicated that it will consider allowing dosages higher than 200 mg. per day after reviewing the results of studies aimed at determining the extent to which the drug in suppository form is absorbed in the body and what happens to it after it is absorbed.

In that FDA has not approved the use of progesterone suppositories in the commonly prescribed 400 mg. strength the question of how the pharmacist should proceed when he receives a prescription for this product arises. There is a fairly significant body of case law that has ruled that physicians have a right to prescribe an approved drug that is legally on the market for an unapproved use or in a non-approved dosage. Most health care practitioners and even the FDA itself are supportive of that position.

If a pharmacist is presented with a prescription for progesterone suppositories for the treatment of PMS the pharmacist would be well advised to bear in mind that the filling of a prescription for an approved drug but for an unapproved dosage and/or unapproved method of delivery places the pharmacist in a position of increased liability. The package insert accompanying any approved legend drug indicates the conditions under which the drug has been shown to be safe and effective by FDA. While physicians may prescribe and pharmacists may dispense outside of the approved indication, to do so is considered to be of an investigational or quasi-investigational nature and, should the patient suffer an untoward reaction, both the prescriber and the pharmacist may be called upon to justify their actions in prescribing and dispensing outside of the approved labeling recommendations.

It should be remembered that pharmacists are not required to fill any and all prescriptions that are presented to them. If, in the pharmacist's best professional judgment, it is determined to be inappropriate prescribing the pharmacist would be well advised not to fill the prescription. Pharmacists should use care in communicating this decision to the patient, however, in order not to interfere with the doctor/patient relationship.

Compliance News



LEGEND TO OTC EQUALS CONFUSION

In recent months the Food and Drug Administration has approved a number of additional drugs for OTC marketing that were previously restricted to prescription only status. As more and more of these drugs previously available only as prescription items are being made available as over-the-counter medications with new packaging and labeling from the manufacturer, pharmacists are increasingly faced with decisions as to the handling of the medication already in their pharmacy stock.

The Food and Drug Administration reviews and approves all package labeling for legend drug products. It would be considered an act of misbranding for a pharmacist to, on his own, change that approved labeling information.

Once a medication packaged in legend drug packaging is received by the pharmacist that product must be dispensed only on prescription even if, at a later date, the product involved is approved for OTC sales. Only the new product packaging available from the manufacturer and labeled appropriately for over-the-counter distribution may be sold over-the-counter.

LITTLE KNOWN USES FOR THE U.S.P.

Pharmacists in community and hospital practice have, over the past years, seemingly developed a habit of complaining that the United States Pharmacopeia (U.S.P.) is not of value to them in their daily practice and should not be a required reference which it so often is.

The U.S.P. is a valuable reference text for the average pharmacist practitioner. As more and more pharmacists are required to utilize their expertise in decision making regarding generic substitutions, a need arises for a standard by which generically equivalent drug products can be measured. The U.S.P. offers that standard. If both a generic product and a brand name product are labeled as being U.S.P. quality, the pharmacist can rely on the generic product as having met specific acceptable standards for purity, disintegration, dissolution, and others. This information becomes invaluable in decision making regarding generic substitution.

Questions often arise in day to day pharmacy practice situations that call for a knowledge of the Federal Controlled Substances Act. The Federal Controlled Substances Act regulations are printed in the U.S.P. beginning on page 995.

With every prescription a pharmacist fills, a decision must be made regarding the type of closure, child resistant cap or non-child resistant cap, that will be dispensed. The Federal Poison Prevention Packaging Act, the act that requires the use of child resistant packaging, is found in the U.S.P. beginning on page 1020.

In daily pharmacy practice the question of when a drug becomes adulterated or misbranded frequently arises without recognition by the pharmacist of the derivation of these terms. The essentials of the Federal Food Drug and Cosmetic Act, which is essentially an adulteration and misbranding statute is found in the U.S.P. beginning on page 1017.

When a physician fails to indicate on the prescription the quantities of ingredients in certain products, the U.S.P. also comes to the

rescue: i.e., where propoxyphene hydrochloride, aspirin and caffeine capsules are prescribed without reference to the quantity of aspirin or caffeine a product containing 389 mg. of aspirin and 32.4 mg of caffeine should be dispensed. This information, too, is available from the U.S.P.

1982 EDITION OF NATIONAL DRUG CODE DIRECTORY AVAILABLE

The 1982 edition of the *National Drug Code Directory*, now available, has two volumes composed of four sections. Volume 1 contains an alphabetical index of all prescription drug products by product name. Volume 2 is composed of three sections: a numeric index of Rx drug products by drug class; a numeric index of Rx drug products by National Drug Code; and an alphabetical index of Rx drug labelers by short name and address. FDA plans publishing the *Directory* biennially and it can be obtained on subscription from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (Title: 1982 National Drug Code Directory; Order No.: 017-012-81002-1; Cost: \$90).

BENDECTIN PRODUCTION CEASED

In spite of clinical and epidemiological evidence demonstrating the safety of Bendectin, the manufacturer (Merrell Dow Pharmaceuticals) has ceased production of the drug due to the burdens created by litigation and publicity which have fallen on physicians, pharmacists, and patients as well as the company. Despite the decision to cease production, the company is attempting to assure that supplies of Bendectin in the marketplace are sufficient to fill the needs of patients currently completing therapy. The company has developed a policy which will apply to excess stock and reimbursement (from August 1, 1983–October 31, 1983) and has provided a toll free number for additional information: (800) 543-1970, in Ohio (800) 582-3109.

NABP NUMBER FOR PHARMACIES

Each pharmacy in the United States is identified by an individual number assigned for the National Association of Boards of Pharmacy by the National Council on Third Party Prescription Drug Programs (NCPDP). The number is used for filing reimbursement forms for third party payment programs by insurance carriers throughout the country. Recently, two additional companies have sent out letters to pharmacists concerning the use of the "NABP Number" when filing forms. It is used by some states as the official state I.D. number for a legally licensed pharmacy. To obtain information concerning your pharmacy's identification number, write or call: LeAnn Cleverly, Executive Director, NCPDP, 3900 East Camelback Road, Suite 506, Phoenix, AZ 85018. Phone: (602) 957-9105.

MOVED? LET YOUR PHARMACY BOARD KNOW WHERE!

facturer) or any other combination which would be misleading to the public or unfairly used the brand name which is a property right belonging to the company. One example which could be acceptable is the phrase "Tetracycline used for Sumycin®". Inspectors will be properly indicating the drug in each container.

ITEM 428— BOARD MEMBER ELECTION

A ballot was enclosed with the last issue of the Newsletter for all pharmacists in the state to vote in the Board member election. The ballots were counted on Monday, May 9th in an open meeting at the Institute of Pharmacy and Mr. William R. Adams, Jr. of Wilson was elected to another three year term on the Board. His term will begin in the late Spring of 1984.

ITEM 429— REPACKAGING OTC DRUGS

Some pharmacists engage in the practice of repackaging drugs for resale within their pharmacy. Federal statute and regulation requires that the following items appear on the label or labeling for each product: Identity of the product; place of business of the manufacturer, packer or distributor; net quantity of contents; statement of ingredients; adequate directions for use; caution and warning statement and a statement of content of habit forming drugs. Depending on the extent of such repackaging it may also be necessary to place an expiration date on the label based on stability studies. The absence of the above information could produce a charge of misbranding under either federal or state Food and Drug Law.

ITEM 430— BEYOND A BACHELOR'S DEGREE

The American Council on Pharmaceutical Education (ACPE), the accrediting organization in pharmacy, is in the process of revising its accreditation standards which will be applied to schools and colleges of pharmacy in the future. At a recent public hearing some concern was expressed that Schools of Pharmacy should make it possible for pharmacists to obtain degrees such as a Pharm.D. without resigning their job and moving to a university town. This might be feasible in North Carolina with its network of Area Health Education Centers (AHEC) already in place and functioning. Such an external degree program is not now available. Pharmacists who have opinions on this subject should send them in writing to the Board office, P.O. Box H, Carrboro, 27510. We will compile and forward them to the ACPE.

(The answer to Quarterly Query is (d), 1 and 3 only.)

ITEM 431 — THE COMPUTER AND ORIGINAL PRESCRIPTIONS

Board Inspectors have requested that material appear in this Newsletter to remind pharmacists that prescriptions still need to be given a serial number and filed in an organized fashion. Some pharmacists purchase a computer or data system and thereafter do not pay sufficient attention to their original prescription files. While it is true that many data systems can be used to retrieve information, the systems can ordinarily be used only for one purpose at any one time. If an Inspector needs information that is only available through the computer this could prevent the pharmacy from serving the public during that time.

This potential problem could be greatly alleviated by filing the

original prescriptions in a neat and retrievable fashion thereby keeping the data system free for maximum service to the public.

ITEM 432— B-W PROTECTS PROPERTY

Litigation came to a close this Spring between Burroughs Wellcome and a pharmacy in Federal Court in Ft. Lauderdale, Florida based on trademark violations. The pharmaceutical manufacturer brought a lawsuit alleging infringement on their trademark Actifed® when generic drugs were dispensed and labeled with the brand name. The federal court ruled in favor of Burroughs Wellcome and permanently enjoined the pharmacy from such conduct. This makes it clear that some companies will vigorously defend their brand names against trademark infringement.

ITEM 433 — PREPRINTED PRESCRIPTION BLANKS

Pharmacists should be aware that the North Carolina Drug Commission has adopted a regulation which prohibits the use of pre-printed prescription blanks for controlled substances. This regulation was effective April 1st and is brought to your attention at this time so that compliance may be obtained.

ITEM 434 — DISTINGUISHED SERVICE AWARD

This publication ordinarily does not contain notices of awards or other recognition. An exception is justified in the case of the Distinguished Service Award from the National Association of Boards of Pharmacy. Mr. William R. Adams, Jr., of Wilson, a member of the North Carolina Board for nine years was recently honored as the recipient of this award in Colorado Springs. This honor resulted from his service on and Chairman of the Committee which assembles and directs the national licensing examination used in all states and territories of the United States. Editor's Comment: Paraphrasing a currently fashionable advertising phrase "Bill did it the old fashioned way: he earned it!"

FOR YOUR INFORMATION

Our Newsletter masthead, designed by NABP, is composed of three symbols, each representing a facet of this publication's purpose. The bowl of hygieia, representing the profession of pharmacy, is combined with the Roman fasces, symbol of authority, and the seal of the State of North Carolina. Together the three emblems characterize the legal and professional duties entrusted by the citizens of this State to its registered pharmacists.

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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