



North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 368—CHANGES IN PHARMACY LAW FROM THE 1981 GENERAL ASSEMBLY

Several significant changes in pharmacy law were enacted by the General Assembly which recessed in July. Although the comprehensive re-write of the Pharmacy Practice Act (see Item 358) has not yet been adopted, it has passed the House and could be considered by the Senate in June of 1982. The proposal of the Sunset Commission, with some amendments, passed and produced several new features in the law which affect pharmacists.

The Board of Pharmacy now consists of five pharmacist members and one public member, all to serve no more than two complete consecutive three year terms. The pharmacist members will now be elected in a vote of all pharmacists licensed and residing in this state while the public member is selected by the Governor. Reciprocity requirements were also changed and there is no longer a temporary license in this process. The Board has also been given the power to discipline pharmacists for negligence. A change was also made which allows physicians in the armed forces or the Veterans Administration, who are licensed in any state, to prescribe controlled substances in this state for eligible beneficiaries of armed services medical care. The General Assembly also approved new fees for the Board as indicated in prior issues of the *Newsletter*.

ITEM 369—NOTICE OF PUBLIC HEARING

On Tuesday, November 17, 1981 at 4:30 p.m. a Public Hearing will be held at Board offices, 209 Carr Mill Mall in Carrboro, NC. Subjects to be considered will be regulations on reciprocity, the procedures for election of pharmacy Board members and the deadline for examination applications. Please submit comments in writing to the Board office or give notice of your intent to appear in person by November 12th. If the number of people giving notice of appearance seems to exceed the capacity of our meeting room the hearing will be held at the Institute of Pharmacy, Rosemary and Church Streets in Chapel Hill and those so indicating will be notified.

ITEM 370—NOTE FOR INTERNS/EXTERNS PRECEPTORS

Recently the Board has liberally interpreted its regulations on acquisition of experience to avoid inequities during a change in the examination cycle. The transition to a June and January cycle for the licensing exam has now been accomplished and all such

inequities have had the time to be remedied. On many occasions the Board has stated that on and after July 1, 1981 the regulations will be applied as they are written. The most common problem is the proper filing of forms.

Regulations provide that forms must be filed with the Board within five days of the beginning and ending of an experience period. Two separate forms must be filed, a (white) Form 1 within 5 days of the beginning of the experience and a (blue) Form 2 within 5 days of the end. Each form needs to be signed by the preceptor and Form 2 must be notarized. The timely filing of these forms cannot be overemphasized — 5 days is not 10 or 20 days.

Such experience may be obtained after admission to the School of Pharmacy and may occur after admission but before actual attendance of classes. Under these circumstances the pharmacist has a duty to bring this to the student's attention and provide assistance in completion of the forms.

ITEM 371—MESSAGES FROM INSPECTORS

Inspectors report that these issues are recurring problems and need attention by pharmacists. Federal regulations provide that prescriptions for Schedule III and IV drugs can be refilled for a maximum of 5 times and no longer than 6 months. Renewals of such prescriptions by the prescriber beyond these limits requires a new prescription, written or oral. Such new prescription needs to be treated as a fresh document by bringing it forward in the file with a new serial number and specifically **not** by a mere notation on the original document. In order to refill any prescription, controlled or non-controlled, the authorization must appear on the document.

They also report that frequently licenses and permits are not displayed as required by law. These should be on view for both the public and Inspectors at all times.

Another question which often arises is that of providing controlled substances to physicians for office use. **Do not** supply these items on a prescription. Schedule II drugs require the physician to complete a Schedule II order form and the article(s) should be provided with the original remaining in the pharmacy and copy 2 forwarded to DEA. Schedule III, IV and V drugs, should be supplied to a physician's office on a normal invoice, remembering to keep such records readily retrievable. Remember the 5% rule in these transactions; which provides that such transactions can occur without registration as a distributor if the yearly amount is less than 5% of the dispenser purchases of controlled substances.



National Pharmacy

RESULTS OF PPI STUDY ANNOUNCED

The Rand Corporation of Santa Monica, California in late summer announced the results of a study of patient package inserts (PPI's) — leaflets for consumers describing a prescription drug's purpose, directions for use, precautions and side effects. The three-year, \$525,000 study was performed under a contract with FDA.

A sample of 1,821 people having prescriptions dispensed for certain drugs at 69 Los Angeles pharmacies was recruited. Subjects were given one of several PPI's or served in a no-PPI control group. They were interviewed by telephone 2 to 3 weeks after receiving their prescriptions and also were sent a mail questionnaire.

The drugs chosen for the study were erythromycin, flurazepam and estrogens. Estrogen drugs are currently dispensed with an FDA required PPI. For the other two drugs, experimental PPI's were used. The principal findings of the study as reported by Rand scientists at a meeting of the American Psychological Association were:

- About 70 percent of patients said they read the PPI (more among first time users of the drug). Reading of PPI's was not limited to the younger or more educated respondents.
- About one-half of the subjects said they kept the PPI, and 20 to 30 percent said they read it more than once.
- People who received PPI's could answer more questions correctly about how to use a drug, its interactions and contraindications, than those who did not get PPI's.
- Few respondents changed their mind about whether to take a drug after reading the PPI.
- Only 3 of over 2,000 prescriptions dispensed with PPI's were returned for a refund.
- PPI's did not generally increase side effect reporting. People generally did not "imagine every side effect" listed in the leaflet. However, certain styles of presentation in which PPI's contain many specific instructions increased the reporting of side effects.
- People getting PPI's did not contact their physicians more often but were more likely to discuss drug safety and side effects with physicians during these contacts.
- Patients reported that PPI's helped them to understand their drugs, to follow their doctor's advice, and to know when to take their drug. The less educated respondents had the most favorable reaction.

The study is to be a factor in FDA Commissioner Arthur Hayes' decision on whether to proceed with a test program of PPI's for ten major drugs. Another factor is a public hearing held in Washington, D.C. on September 30, 1981. Dr. Hayes presided at the day-long hearing at which persons testifying were asked to address how the benefits of a patient information system can be measured against the costs; what alternative systems are available; and whether the system as developed by FDA provides sufficient information to permit an evaluation of the value of patient package inserts.

CPSC PROPOSES PACKAGING EXEMPTION FOR POTASSIUM SUPPLEMENTS

The Consumer Product Safety Commission has published a

Federal Register proposal to exempt all unit dose forms of potassium supplements, containing not more than 50 milliequivalents of potassium per unit dose, from the child-proof packaging requirements of the Poison Prevention Packaging Act. The action is based on the absence of adverse reactions in children from the ingestion of potassium supplements in all forms, including powdered and liquid potassium.

Currently the exemption covers only potassium supplements in effervescent tablet form. The proposed exemption includes unit dose vials of liquid potassium supplements and unit dose packets of powdered potassium. Comments on the proposed exemption were received by the CPSC through September 8, 1981. If the Commission issues a final regulation, it is expected to be effective on the date of publication in the Federal Register.

BIRTH CONTROL PILLS AND HEART ATTACK RISK

A study published in the *New England Journal of Medicine* suggests that the increased risk of heart attack associated with the use of birth control pills persists even after their use is discontinued.

The study showed that women who had taken the pill for ten or more years before discontinuing it had 2.5 times the risk of having a heart attack as women who never used the pill. The study found that those who had taken the pill for five to nine years before discontinuing it had 1.6 times the risk of heart attack as women who had never used it. There was no indication that the risk was increased in persons who had taken the pill for less than 5 years.

The study was supported in part by a grant from FDA and was carried out by scientists from the Boston University School of Medicine, Harvard School of Public Health, and University of Pennsylvania School of Medicine.

The authors caution that since the present data are the first to bear on the matter, they should be interpreted with caution until replicated in other settings and in other types of studies.

Current physician and patient labeling for oral contraceptives includes a warning that their use could increase the risk of heart attacks. The patient labeling now states that "... the use of oral contraceptives alone may double the risk of heart attack. However, the combination of cigarette smoking, especially heavy smoking, and oral contraceptive use greatly increases the risk of heart attack. Oral contraceptive users who smoke are about five times more likely to have a heart attack than users who do not smoke and about 10 times more likely to have a heart attack than non-users who do not smoke." The labeling warns that other risk factors in combination with oral contraceptive use can increase the risk of heart attack.

FDA is reviewing the paper and considering the need to revise physician and patient labeling to reflect that the risk of heart attacks may persist even after the use of the pill has been discontinued.

PUBLISHER OF MEDICAL TEXT NOT LIABLE FOR NEGLIGENTLY FAILING TO TEST

A woman who allegedly became addicted to diazepam could not recover against the publisher of the *Physicians Desk Reference* for

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failure to test and to warn. The publisher was not liable because it did not warrant the product or advocate its use and because the product descriptions that were carried in the text were considered to be advertisements. A publisher is not liable for the contents of an advertisement unless it shows reckless disregard for the truth.

Libertelli v. Medical Economics Co., et. al.
(Dist.Court, Southern Dist., N.Y., No. 80 Civ. 5626)

ORAL CS-II Rx's VALID ONLY IN EMERGENCY SITUATIONS

A Schedule II controlled substance that is a prescription drug may be dispensed only with a written prescription from an authorized practitioner except in an emergency situation. In the latter instance, Schedule II substances may be dispensed by pharmacists who are orally authorized to do so by the prescribing practitioner, provided the four conditions of 21 Code of Federal Regulations (CFR) 1306.11(d) are met.

An emergency situation is not defined per se in the Controlled Substances Act regulations, but is in a cross-reference to the general drug regulations of the Secretary of the Department of Health and Human Services. The definition of an emergency situation is found in 21 CFR 290.10 and reads as follows:

Section 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Federal Controlled Substances Act, the term "emergency situation" means those situations in which the prescribing practitioner determines:

- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
- (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act, and
- (c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

REVIEW OF DMSO FOR SCLERODERMA

At the request of some members of Congress, the FDA has again reviewed the data in support of the use of DMSO in treating scleroderma and again has refused to approve the drug. Scleroderma is a condition characterized by hardening of the skin and ulcers on the arms, legs, feet and hands. In addition, internal organs are involved, but there is no suggestion that DMSO might be effective for this internal involvement.

FDA concluded the data in the NDA is inadequate to establish effectiveness because of inadequacies in protocol design and patient evaluation, documented inaccuracies in ulcer counts, and a lack of information as to how the counts were derived. Well designed, con-

trolled studies are required before conclusions can be reached that DMSO might provide some improvement with respect to loosening of the skin and increasing mobility of the fingers.

New studies on DMSO's use in scleroderma are being conducted this year by the Cooperative Systems Studies for Rheumatic Diseases group under support from the National Institutes of Health. The studies are expected to be completed in 1983.

FDA PUBLISHES NEW LIST

The Food and Drug Administration has advised all pharmacy associations and drug trade press of the forthcoming availability of the second edition of its *Approved Prescription Drug Products with Therapeutic Equivalence Evaluations*. The new edition will continue to list currently marketed prescription drug products which have been approved for both safety and effectiveness by the agency. FDA expects this list to be of value not only to large purchasers of drugs, such as state governments, but also to community pharmacists who want to dispense only those drug products approved by FDA. In addition, the publication contains therapeutic equivalence evaluations for multiple source drug products. These evaluations have been prepared to foster containment of health costs and to serve state health agencies in the administration of their drug product selection laws. The list will be available in late October from:

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402

The yearly subscription fee for the publication is \$45.00 which includes new monthly cumulative supplements. Because no stock number has been assigned, the list should be requested by name. Questions concerning payment and ordering information should be directed to the Order and Inquiry Desk, Government Printing Office, Phone: (202) 783-3238.

DRUG PRODUCT PROBLEM REPORTING

The United States Pharmacopeial Convention (USPC) coordinates a simple and effective way to get direct health practitioner observations about product problems into the decision-making processes of industry and government. The FDA, state and national organizations in various health care areas co-sponsor the two reporting programs: the Drug Product Problem Reporting Program (DPPR) and the Medical Device and Laboratory Product Reporting Program (PRP).

Problems may be reported by either providing a written statement or by calling the toll-free number. Copies of reports are forwarded to the FDA and manufacturers. Basically, anything considered to be a problem should be reported.

Although the primary purpose of the system is to improve the products utilized in health care, it also affords a vital means of quickly bringing health hazards to the attention of officials in government and industry. For further information contact: **DPPR** or **PRP, USPC, 12601 Twinbrook Parkway, Rockville, MD 20852**; or call the toll-free number: **(800) 638-6725**; (except Alaska and Hawaii; in Maryland, call collect (301) 881-0256).

ITEM 372—NOTE FOR HOSPITAL PHARMACISTS

Federal regulations provide that each registrant shall keep records of dispensing controlled substances. Records of billing patients for controlled substances do not always correspond to what was actually dispensed or administered to a patient and usually would not be a true reflection of activity with controlled substances. You should be aware that pharmacists have been prosecuted where only dispensing records were kept and an audit revealed significant discrepancies. It would be wise for Directors of Pharmacies in hospitals to evaluate their procedures for compliance.

ITEM 373—IS THE LABEL SUFFICIENT?

This section of the *Newsletter* does not deal with a matter of law or regulation but that of the pharmacist's duty to act in the interests of public health and safety. Some pharmacists may be surprised to learn that about 20% of the American public are functionally illiterate. This figure is significantly higher in two areas; the south and rural parts of the country. Depending on the circumstances, this could have more or less significance to individual pharmacists.

The Adult Performance Level Project conducted at the University of Texas and supported by the US Office of Education found some revealing shortcomings. For example, more than 1/4 of the American public does not know normal body temperature. It is all too easy to assume that others comprehend common prescription directions such as "Take one or two tablets every four hours for fever." These directions assume that the reader knows a body temperature significantly above average is a fever which may not be true, especially if the person doesn't know normal temperature. About 1/2 of those with lower incomes do not understand advertisements for common non-prescription pain relievers which reinforces the need for pharmacist advice in using OTC drugs. Conscientious pharmacists would be wise to consider these findings in their everyday activities.

ITEM 374—PRESCRIPTION LABELS FOR THE BLIND

Recent reports in the trade press have noted the availability of braille prescription labels for the blind. For more information contact the American Foundation for the Blind, Customer Service Department, 15 West 16th Street, New York, NY 10011 or by telephone (212) 620-2172.

ITEM 375 —QUOTE WITHOUT COMMENT

A short time ago a news wire service article reported that high school students had shut down the computer system at a university during the week of registration in Chicago. As a result, course registration was shut down, data could not be retrieved and student tuition payments were not recorded. Chicago police investigator Douglas Ellis is quoted as saying "Think of the medical profession. Suppose the same kids went into the Michael Reese Hospital computer and started screwing around, mixing up prescriptions. We're not talking about money, we're talking about human lives". This editor feels the quotation is sufficient without comment.

ITEM 376 —PRODUCT SELECTION ON TIME RELEASE CAPSULES OR TABLETS

The Board has received a request for a declaratory ruling on the equivalency of time release capsules and tablets. Several states have ruled that brands or generics are not equivalent in time release form

and should not be interchanged or used in product selection.

The North Carolina Board denied the request but stated in carefully worded language that "there is a variance between time released dosage forms from one manufacturer to another manufacturer and in situations where a significant change in drug levels could be critical the patient should remain on the same dosage form. The members individually recognized that all time release dosage forms are not equivalent but did not feel that they could declare that no such dosage forms would be equivalent." Pharmacists should guide their conduct in product selection accordingly.

ITEM 377 WHAT ABOUT DMSO?

The Board office has received numerous calls recently regarding the status of DMSO. The FDA has approved its use in a 50% solution for use in the urinary tract for treatment of interstitial cystitis and a 90% solution for topical use in nonbreeding dogs and horses. It is also available in a 99% solution as an industrial solvent.

Pharmacists should understand that it is not "illegal" in the criminal sense to sell DMSO as a solvent, but this does not mean that a pharmacist incurs no liability by selling this chemical for human use other than in the urinary bladder. Please note the FDA Drug Bulletin, Volume 10, Number 3, November, 1980, has a lengthy article on DMSO which contains the following phrase:

"prolonged use in animals causes opacities in the lens" of the eye.

At the time of this publication we were informed by FDA that the primary manufacturers of DMSO in the United States will only ship the chemical to bona fide purchasers in the future. It is possible that pharmacists could be defendants in negligence suits if persons who use the chemical are injured by it. Presently there are a number of such suits on a similar legal basis involving manufacturers of DMSO. Fortunately for pharmacists in that case, the manufacturers have retained fiscal solvency long enough to be defendants. It is not easily predicted if the manufacturers or distributors of DMSO will exist long enough for the detrimental results, if any, but pharmacists who sell this chemical for human use certainly will be defendants. Most large pharmacy corporations would probably decline to sell DMSO for this reason.

Lancet, an authoritative British Medical Journal, reported in its November 8th, 1980 issue that an elderly couple had become very ill after DMSO injections for arthritis. The wife vomited blood, had severe kidney damage and a small stroke. Liver damage may also have been involved. There has also been one death in the United States during intravenous administration of DMSO but there was no evidence that the expiration was directly related to DMSO use. The *Lancet* article suggests that "intravenous DMSO is potentially dangerous and should not be used for the treatment of arthritis."

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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