



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 435 — DISCIPLINARY ACTIONS OF THE BOARD

May: A pharmacist-manager and owner from Elizabethtown appeared before the Board in response to charges of dispensing prescription drug without a prescription. Testimony indicated that Premarin® Vaginal Cream had been dispensed without a prescription on one occasion in December of 1982 and the pharmacist had a prior appearance for a similar violation in 1971. It was the decision of the Board to place the pharmacist on five years probation, require him to pass a pharmacy jurisprudence examination within four months and placed other conditions on his probation.

A pharmacist from Kinston appeared before the Board in response to charges of numerous refilling of prescriptions without authorization. The pharmacist had been alerted to this problem by a prior visit of the Board Inspector. It was the decision of the Board to suspend the pharmacist's license for thirty days, require that he complete a jurisprudence examination for reinstatement of his license and issued five years probation.

A pharmacist from Columbia appeared before the Board in response to charges of pleading no contest to obtaining controlled substances contrary to state law. He explained that his activity was caused by a problem with the personal use of drugs which he had but is now in the process of rehabilitation. After substantial testimony it was the decision of the Board to place the pharmacist under three years probation on condition of his continued rehabilitation through drug treatment and other conditions.

July: Two pharmacists who were managers for a pharmacy in Greensboro appeared before the Board in response to charges of pleading guilty to Medicaid fraud. Each pharmacist had a separate hearing and it was apparent that one individual was responsible for more activity than the other who had been employed at a Winston-Salem facility which was later consolidated into the Greensboro pharmacy. Upon inquiry the members of the Board discovered that the pharmacists were paid on a salary plus bonus which could have been enlarged by profits obtained through Medicaid fraud. It was the decision of the Board to issue a 60 day active suspension on the license of one pharmacist, a 15 day active suspension on the license of the other and impose other restrictions including a period of time when they could not act as a pharmacist-manager.

August: A pharmacist from the Asheville area appeared in response to charges of indulging in the use of drugs and other specific offenses which might have arisen because of his drug use. The pharmacist admitted the illicit use of drugs personally but denied any sale or dispensing to other individuals. Some testimony indicated that drugs had been altered or substituted in stock bottles and these

substituted drugs unknowingly dispensed to the public. The pharmacist presented significant evidence of participation in a rehabilitation program including testimony from the Director of the program. It was the Board's decision to issue an active suspension of the pharmacist's license for 120 days and other conditions were imposed on the continuation of his license after that time.

A pharmacist from Durham appeared in response to charges of pleading guilty to felony possession of certain controlled substances without a prescription. Testimony indicated that the pharmacist had been apprehended at the Raleigh-Durham Airport on his way to a musical concert in Washington, D.C. The drugs involved included Valium, Talwin, Dalmane, Tagamet and marijuana. It was the decision of the Board to suspend his license for 60 days beginning on the date of the hearing and imposed other conditions on the reinstatement of his license.

A pharmacy owner from Kinston appeared before the Board in response to charges of failure to promptly obtain a replacement pharmacist-manager. The owner appeared and testified that she had made every reasonable effort to obtain a new pharmacist-manager even though more than 2 months had elapsed until one was eventually employed. After some discussion it was the Board's decision to place the permit under an indefinite probation with certain specific conditions.

ITEM 436 — QUARTERLY QUERY

Which of the following statements concerning the product selection law is or are accurate?

- I. The manufacturer of a drug used in product selection must have adequate provisions for drug recall.
- II. Equivalent drug product means a drug product which the FDA has certified to be therapeutically equivalent.
- III. The name of the actual manufacturer of a product used, if different from its distributor, must appear on the label of the stock package.
 1. I only
 2. II only
 3. I and II
 4. I and III
 5. I, II and III

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National Pharmacy

MOST CONTROLLED SUBSTANCE DIVERSION IS AT THE RETAIL LEVEL

The Crime Sub-committee of the Judiciary Committee of the US House of Representatives recently received testimony from DEA and others regarding the diversion of controlled substances in the United States. DEA testified that diversion is now at the retail level rather than at the manufacturer or wholesaler level.

DEA testimony indicated that approximately 13,000 physicians and pharmacists (approximately 2% of the licensed physicians and pharmacists) are involved in some type of illicit practice that results in the diversion of controlled substances. This illicit practice can take the form of indiscriminate prescribing, dispensing of controlled substances without prescriptions, dispensing obviously forged prescriptions, etc.

DEA also indicated that there are even "criminal financiers" who own clinics where physicians write prescriptions for drugs of abuse which are then purchased from pharmacies also owned by the financier. The "patients" in these situations are, obviously, not patients at all but simply drug abusers.

The house sub-committee also received testimony indicating that it is the practitioners themselves that must be controlled rather than DEA placing its primary focus on individual drugs. When one individual drug product is controlled another drug product will simply replace it.

Among the ideas discussed at the sub-committee were triplicate prescription forms for controlled substances, emergency scheduling powers for DEA, increased DEA authority in the registration of physicians and pharmacists, and increased penalties for diversion.

Pharmacists obviously have a key role to play in curtailing the diversion of controlled substances. As the primary supplier of controlled substances to the public through the filling of prescriptions issued by licensed practitioners; the pharmacist is in a unique position to monitor the use of controlled substances (as he is required to do under the regulations associated with the Federal Controlled Substances Act) and to report unusual prescribing on the part of physicians and unusual activities on the part of "patients" presenting controlled substance prescriptions.

FDA RE: "USP"

The Food and Drug Administration has recently issued a position statement regarding the issue of whether or not reference to "USP" in the labeling of a product automatically makes the product a drug.

FDA provides the following: "The term 'drug' as defined in section 201 of the FD & C Act refers to articles recognized in the USP, HF, and NF; however, section 201 further delineates the definition to mean articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal.

As related in the general notices section of the USP 'the designa-

tion USP in conjunction with the official title on the label of an article is a reminder that the article purports to comply with USP standards; such specific designation on the label does not constitute a representation, endorsement, or incorporation by the manufacturer's labeling of the information material contained in the USP monograph, nor does it constitute insurance by USP that the article is known to comply with USP standards.' This section further states that 'articles listed herein are official and the standards set forth in the monographs apply to them only when the articles are intended or labeled for use as drugs or medical devices and when bought, sold or dispensed for these purposes.'

Therefore, it our (FDA) opinion that articles bearing the compendial declaration such as purified water, cottonseed oil, etc., are not considered drugs unless the label or labeling or other circumstances clearly establish that the product is intended for drug use. In this regard please refer to 21 CFR Section 201.128 for further interpretation of the meaning of 'intended use'."

A review of the CFR section just referred to generally indicates that if the manufacturer or labeler of a product makes statement the labeling or advertising of the products or if his representative make oral statements regarding a product and its use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal the product is in fact a drug. Similarly, if the manufacturer knows or should have known that a product introduced in the interstate commerce by him is to be used for conditions or purposes or uses other than the one for which he offers it (i.e. drug purposes) he is required to provide adequate labeling for the product as a drug.

PROPOSAL WITHDRAWN BY DEA

In September of 1982 DEA proposed a change in the Federal Controlled Substances Act that would have provided a mechanism that would facilitate the dispensing of controlled substances by hospital emergency room personnel where community pharmacy services may not have been available. DEA intended that such hospital dispensing of controlled substances be limited to rural areas during off hours. DEA received a number of comments on the proposed rules which indicated that the perceived problems which prompted DEA to propose the rules may not have warranted a change in the regulation.

DEA indicated that the sole purpose of the proposed rule making was to provide a legal mechanism to allow the availability of controlled substances to non-hospital patients in hospital emergency rooms when community pharmacy services were not available. DEA further indicated that the rule making was proposed in the interest of good patient health care, assuring that no patient would go without necessary medication because of some real or perceived legal impediment.

The objections to the proposal received by DEA were summar-

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zed as follows in the *Federal Register* Vol. 48 No. 125 published June 28, 1983: 1. Pharmacy services are available in almost all rural areas. 2. Pharmacists are trained to determine if a prescription order is legitimate. Allowing emergency room personnel to dispense controlled substances via oral or written prescription orders would increase the risk of having controlled substances diverted. 3. If a true emergency exists, the patient should be examined by the emergency room physician. 4. Emergency room personnel do not have the training for dispensing controlled substances pursuant to oral or written prescription orders. Areas where expertise is needed include proper recordkeeping, label preparation, and dispensing the proper medication in accordance with the physician's instructions. 5. Having controlled substances dispensed from emergency rooms would increase the risk of armed robbery at these facilities. 6. Emergency rooms are already understaffed and overcrowded, and this provision would add to the problem. 7. The proposal would increase the chance for diversion by hospital employees. 8. Adoption of the proposal would lead to a breakdown of good security and pharmacy practice.

Additionally, a number of commentators felt that the proposed regulation was not specific enough and several state agencies, noting conflicting provisions of state law, felt that the proposed regulation would cause confusion.

Finally, several of the objectors stated the belief that activities conducted pursuant to the proposed rule would place hospital emergency rooms unfairly in competition with community pharmacies in violation of the Robinson-Patman Act.

After assessing the comments and objections to the proposal, the Drug Enforcement Administration has determined that the need for the proposed rule change has not been clearly established and the proposal was withdrawn "for further study".

ETHATAB RECALLED

FDA recently announced a Class II recall for Ethatab, brand of Ethaverine HCl, 100 mg., a prescription antispasmodic in 100 count bottles. Ethatabs are manufactured by Glaxo, Inc., St. Louis, Missouri. Glaxo initiated the recall by letter on June 20, 1983 due to the discovery that some bottles of Ethatab tablets were mislabeled as Theobid Junior (Theophylline) 130 mg. capsules.

The recall affects 9,041 bottles of lot number 8211-918, 2351 bottles of lot number 8303-975 and 10576 bottles of lot number 8209-898A. Distribution was nationwide.

A ISSUES WARNING ON CHELATION THERAPY

The Food and Drug Administration recently issued a notice to state boards of pharmacy and state health officers relating to chelation therapy for arteriosclerosis.

Chelation agents are approved for treating poisonings with heavy

metals. One Chelating agent - EDTA - is being used in "chelation therapy clinics" for treatment of occlusive arterial disease (arteriosclerosis) and is advertised as an alternative to heart bypass surgery.

FDA advises that no IND or NDA for chelation therapy for arteriosclerosis has ever been filed with or approved by FDA. There is no scientific or medical evidence known to FDA that chelation therapy can have any preventative or protective benefit against the future development of arteriosclerosis.

Although a physician can use an approved drug for an unapproved or unlabeled purpose within the confines of his or her medical practice, the advertising of chelation agents for arteriosclerosis or any other unapproved medical purpose constitutes misbranding.

The paper released by FDA indicates that it has serious concerns about the commercialization of chelation therapy for arteriosclerosis for the following reasons:

(1) Arteriosclerosis, like cancer, actually is many different diseases. Therefore, claims that chelation therapy is broadly beneficial for arteriosclerosis patients should not be believed. Cholesterol buildup, for example, is a very common cause of arteriosclerosis and would not be helped by calcium-chelating agents.

(2) There is dissolved calcium circulating in the blood normally, which is necessary for heart, nerve and muscle function. EDTA can upset this electrolyte balance as it combines rapidly with the calcium in solution. The calcium is excreted through the kidneys, which also can be damaged by this therapy.

(3) EDTA's use against plaque can be life threatening if loosened material carried by the bloodstream lodges elsewhere, precipitating emboli, strokes or heart attacks. Thus, FDA believes that any chelation therapy should be conducted in a hospital, with treated patients remaining for observation after their intravenous injection. Unfortunately, most chelation therapy clinics for arteriosclerosis operate on an out-patient basis.

Pharmacists who are contacted by any individuals regarding arteriosclerosis and the use of chelation therapy in its treatment should advise patients to obtain consultation with their physician.

FDA APPROVAL WITHDRAWN

FDA published notice in the *Federal Register* of Friday, July 29 that it was withdrawing approval of Clistin R-A, Forhista Lontabs and Parafon tablets. A hearing was requested, however, for Parafon Forte Tablets and other drug products containing Chlorzoxazone 250 mg. and Acetaminophen 300 mg. Effective August 29, 1983 the Clistin R-A, Forhista Lontabs, and Parafon tablets can no longer be shipped in interstate commerce and are no longer approved for marketing. Parafon Forte tablets may continue to be marketed pending the outcome of the hearing that has been requested. FDA is withdrawing the approval due to their lacking substantial evidence of effectiveness.

ITEM 437 — NEWSLETTER ON MICROFICHE

The Board has available the issues of the Newsletter from 1976 through July of 1983 on Microfiche. An extensive index has been compiled and is included with the Microfiche which is available for \$2.00. If you desire such a Microfiche please send your request with a check for \$2.00 and it will be mailed to you promptly. The Board believes that this is one of the best tools for keeping current with pharmacy law in North Carolina.

ITEM 438 — CHANGE IN DRUG LAW

The North Carolina General Assembly adjourned in July after its longest session in history. A few changes occurred in the laws affecting the practice of pharmacy with the major change being the moving of Methaqualone from Schedule II to Schedule I effective October 1st. Notices have been mailed in September to all pharmacies in the State regarding the proper procedure to follow. Other changes involved the Controlled Substances Act placing stronger penalties on the practice of "doctor shopping" and the theft of controlled substances by employees of registrants. No other substantial changes in statute were produced from the 1983 session.

ITEM 439 — CAUTION PHARMACISTS!

Some reports have circulated in pharmacy journals that an insurance company has reported a number of claims in the past few years involving dispensing errors in which Inderal[®] was inadvertently dispensed instead of Lasix[®]. While this may seem unlikely it apparently does occur with growing frequency and there may be several explanations for this kind of error. In a pharmacy which has a section of drugs which are "fast movers" both Inderal[®] and Lasix[®] would normally be present in such a section. If the pharmaceuticals are arranged in alphabetical order then Lasix[®] and Inderal[®] would very likely be next to each other since there are few such drugs beginning with the letters "j" or "k". Also, patients using these drugs could be afflicted with the same illnesses and both are marketed in the same strength. Please note this potential problem and make whatever changes might be necessary in your pharmacy to avert such an error.

ITEM 440 — INSTITUTIONAL REGULATIONS

The Board held a public hearing on the adoption of proposed regulations for institutions on June 21, 1983 in Boone at the Continuing Education Center. After receiving many comments and suggestions for changes, President Adams recessed the public hearing until a later date. This date has been established and the hearing will reconvene on Tuesday, October 18, 1983 in Chapel Hill at 2:00 p.m. at the Institute of Pharmacy.

ITEM 441—UNAPPROVED USE OF APPROVED DRUGS

Pharmacists frequently express concern about physicians prescribing medication for uses not approved by the FDA. A physician may use a drug for any purpose, including an unapproved purpose, as long as he feels it is in the interest of the patient to do so. The authority of the FDA is to control the interstate marketing of drugs and approval or disapproval for certain uses applies only to its marketing and promotion. Although the package insert is the official information for drug use approved by the FDA, this does not preclude acceptable usage as described in other reference sources which are recognized by the health professions.

Since the physician may prescribe for any purpose, the pharmacist may dispense a drug for any purpose. Both, naturally, assume responsibility for their acts.

The issue of a pharmacist liability in dispensing a drug for a non-approved use has not been litigated. If a negligence case were established based on the prescribing of a drug for an unapproved use, it would seem reasonable that the pharmacist would be joined in liability. It is therefore important that the pharmacist exercise care in labeling the drug, in concluding that its use and dosage is safe, reasonable and rational and in providing information in response to physician inquiries.

If a pharmacist receives a prescription for a drug whose dosage is above the package insert recommendation, it is the responsibility of the pharmacist to check with the prescriber to determine if an error has been made relative to the use and dose. If the pharmacist dispenses the drug without checking and the patient is injured, the pharmacist may be liable since the pharmacist had the duty to question the dose and failed to do so.

(The correct answer to Item 436, Quarterly Query is 4, 1 and III.)

ITEM 442—WARNING FROM THE VA

The Board office has received a notice from George Methvin, Chief of the Pharmacy Service at the VA hospital in Asheville. He noted that some blank prescriptions had been illicitly obtained from the Veterans Administration and were prestamped with a VA DEA number. He notes that pharmacists should be alert for prescriptions written on VA prescription pads and particularly if they contain the Veterans Administration DEA number. If a physician in the Veterans Administration prescribes a controlled substance to be filled outside their facility the physician must use his own assigned DEA number and not that of the Veterans Administration. It is believed that several prescriptions may have been accepted at pharmacies for the drugs Amoxicillin and Dilaudid presented at the same time.

Pharmacists should be aware that there is now a section of Board regulation which provides for the right and responsibility to refuse to fill some prescriptions. Grounds for such refusal could be where there is a question as to the prescription's validity, when the pharmacist feels that dispensing the drug is not in the patient's best interests or if it would be harmful to the patient. This is brought to your attention since it is a recently enacted portion of Board regulations, effective in the Spring of this year.

ITEM 443—PUBLICATION FOR PHARMACISTS AND PHYSICIANS ON SAFETY CLOSURE LAW

The Consumer Product Safety Commission has developed a booklet for pharmacists and physicians which explains their responsibility under the Poison Prevention Packaging Act. The pamphlet answers typical questions about the need to use child resistant packaging to help prevent childhood poisoning. If you wish a copy or copies of this publication you should contact the Consumer Product Safety Commission, Southeastern Regional Office, 800 Peachtree Street, N.E., Suite 210, Atlanta, GA 30308, 404/881-2231.

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