JULY, 1981

North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 360—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

March: The members considered a request from a pharmacist who was appealing the results of a criminal trial in federal court to the Fourth Circuit Court of Appeals in Richmond. This was the second trial arising out of the same event since the first trial also produced an appeal and the case was returned to district court for a new trial. It was understood that the results of the appeal would be known in the fall of 1981 and no more unreasonable delay was expected. It was the decision of the Board to reconvene the hearing, which originally began in June of 1979, after the appeal has been cided.

A pharmacist appeared at this meeting to respond to charges of Medicaid fraud and it was stipulated that he had pleaded guilty to such charges in court. The pharmacist, represented by two attorneys, indicated that he had paid over $7500 in fines and restitution on a negotiated plea involving four offenses with a total amount of less than $60.00. The pharmacist also had affadavits of good character from 41 individuals in his community and his attorney stressed that the pharmacist had already been sufficiently punished for whatever wrongdoing that may have occurred. It was the decision of the Board to place the pharmacist on probation for three years.

April: A pharmacist appeared to respond to charges of allowing or permitting an unlicensed individual to dispense drugs. Testimony established that controlled substances were purchased on three occasions on prescriptions which were filled by the unlicensed individual. The pharmacist's attorney asked for the consideration by the Board that it was his first offense and cited many awards the pharmacist had received in the community. It was the Board's decision to place the pharmacist and the pharmacy under three years probation.

A pharmacist failed to appear before the Board for a hearing even though a return receipt from a certified letter giving notice was received. Testimony proceeded and evidence indicated that controlled substances were dispensed by an unlicensed individual on three occasions. It was the decision of the Board to issue an active suspension of the pharmacist's license for 10 days and an active suspension for the pharmacy (with a sign posted) for a period of six days, each to begin before June 1, 1981.

May: A pharmacist appeared before the Board to answer charges of allowing or permitting an unlicensed individual to dispense prescription drugs. Testimony and evidence indicated that prescription drugs were dispensed in response to a prescription on four occasions by an unlicensed individual. This was the third appearance before the Board for this pharmacist under similar charges. It was the decision of the Board to issue an active suspension of the pharmacist's license for thirty days and an active suspension of the permit (with sign posted) for a period of five days to begin not later than July 1, 1981.

A pharmacist-manager appeared before the Board to answer charges of allowing or permitting an unlicensed individual to dispense prescription drugs. Testimony and evidence indicated that a pharmacist terminated employment suddenly with very little notice which caused a gap in pharmacist coverage. An individual who is employed by the corporation who is licensed in another state but not in North Carolina filled approximately 11 prescriptions from 5 pm until closing. It was the decision of the Board to admonish the individuals involved and take no further action.

A pharmacist appeared before the Board to answer charges of allowing or permitting an unlicensed individual to dispense prescription drugs. Testimony and evidence from the Board showed that controlled substances were dispensed on several occasions by an unlicensed person. The pharmacist claimed that this occurred under supervision which was not visible from the test of the store. The Board directed the investigation to continue.

ITEM 361—DISCIPLINARY ACTIONS OF PHYSICIANS AND DENTISTS

R.G. Stuelke, M.D., Durham had the restoration of his Schedule III privileges endorsed by the Board of Medical Examiners on Sept. 17, 1980; and V.C. Lanier, M.D., Welcome, surrendered his Schedule II privileges on March 16, 1981.

L.T. Russell, DDS, Asheville, surrendered prescribing privileges for all controlled substances on November 26, 1980. J.F. Peppers, DDS, Marion, surrendered his Schedule II privileges on Jan.22,1981; and W.H. Fitts, DDS, Wake Forest has surrendered privileges in Schedule II effective April 27, 1981.

ITEM 362—WHAT CAUSES A PERSON TO HAVE THEIR LICENSES SUSPENDED OR REVOKED?

From comments heard by Board personnel from pharmacists about the *Newsletter*, one of the most closely read portions is that which describes disciplinary actions by the Board affecting pharmacists. It has been the Board's experience that the cause of the activity which produced the hearing is a lack of understanding of law or

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RETURN OF UNUSED Rx DRUGS TO PHARMACY STOCK PROHIBITED IN MANY STATES

A pharmacist should not return drug products to the pharmacy's inventory once they have been dispensed to a patient and are out of the pharmacy's possession. It could be a dangerous practice for practitioners to accept and return to stock the unused portions of prescription medications which are returned by patients. A pharmacist would no longer have any assurance of the strength, quality, purity or identity of the drug products. Many state boards of pharmacy have adopted regulations specifically prohibiting the practice, and FDA endorses such actions as being in the interest of public health. Some FDA investigations in the past have shown that drugs returned by patients and subsequently redispensed by the pharmacist were responsible for injuries.

The pharmacist or other dispensing practitioner is legally responsible for all hazards of contamination or adulteration that may arise should returned portions of drugs be mixed with shelf stocks or redispensed to another patient.

PPI REQUIREMENTS STAYED INDEFINITELY

The FDA's patient package insert rules were stayed indefinitely in accordance with the Executive Order on federal regulation. The requirement of PPIs for cimetidine, clofibrate, propoxyphene was scheduled to take effect on May 25, 1981 and the requirement of PPIs for ampicillin drug products and phenytoin was to become effective on July 1, 1981. FDA asked manufacturers and practitioners to help publicize the stay to avoid confusion on the part of patients as to whether they should be receiving PPIs for these drug products. FDA also advised that the agency will not consider products misbranded if new labeling referring to PPIs is used, even though the package inserts will not now be distributed by pharmacists dispensing the drugs.

ARTHUR HULL HAYES, M.D. APPOINTED COMMISSIONER OF FDA

On April 13, 1981, Arthur Hull Hayes, M.D., assumed official duties as Commissioner of Food and Drugs following announcement of his selection by Department of Health and Human Services Secretary Richard Schweiker earlier that month. Dr. Hayes prior to becoming the new Commissioner, was Professor of Medicine and Pharmacology at Pennsylvania State University College of Medicine.

As an eminent drug scientist whose area of special interest is cardiovascular diseases, Dr. Hayes has long been involved in work with direct relevance to the drug approval process. He is currently president of the American Society for Clinical Pharmacology and Therapeutics. With his impressive academic credentials and the support of many groups outside the agency, Dr. Hayes' appointment reaffirms the Department of Health and Human Services' committment to scientific excellence and responsible regulation in fulfilling its mission of protecting the public health.

TEMAZEPAM GIVEN SCHEDULE IV STATUS

Effective April 7, 1981, the Drug Enforcement Administration (DEA) adopted a final rule placing the drug temazepam into Schedule IV of the Controlled Substances Act. News of DEA's proposed rule was discussed in the 1980-81 fourth quarter issue of *National Pharmacy Compliance News* of the BVC state board newsletters. FDA issued a conditional approval on a new drug application (NDA) for temazepam on February 27, 1981. Approval was conditioned upon announcement of the scheduling decision by DEA in the *Federal Register.*

NCI CLINICAL TRIAL SHOWS LAETRILE INEFFECTIVE AS CANCER TREATMENT

A recently completed clinical trial of Laetrile and metabolic therapy treatment conducted by the National Cancer Institute did not observably cure cancer, improve symptoms of cancer, or extend the lifespan of cancer patients. The clinical trial was undertaken even though preliminary tests in animals and a retrospective study of human subjects failed to justify further evaluation in clinical trials. The study was conducted by NCI because of its concern that many people were being sidetracked from possibly effective therapy by the claims of Laetrile proponents.

The study was conducted at the Mayo Clinic, the UCLA Jonsson Comprehensive Cancer Center, the University of Arizona Health Sciences Center, and the Sloan-Kettering Memorial Cancer Center on 178 cancer patients for whom no other treatment had been effective.

DEA PROPOSES RESCHEDULING MAZINDOL FROM SCHEDULE III TO IV

A Drug Enforcement Administration proposal to reschedule the anorectic drug mazindol from CS-III to CS-IV was recently published in the *Federal Register.* The proposal resulted from a denial of a petition filed by Sandoz, Inc. to remove mazindol (Sanorex) from the list of substances covered by the Controlled Substances Act. In seeking a recommendation from the Department of Health and Human Services on whether to grant or deny the descheduling petition, the department's evaluation included a recommendation to remove the drug from CS-III and place it in

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CS-IV. Following review of comments submitted concerning the proposal, DEA will make a final determination on whether to reschedule mazindol in CS-IV.

SODIUM FLUORIDE TABLETS EXEMPT FROM CHILD-PROOF PACKAGING REQUIREMENTS

The Consumer Product Safety Commission (CPSC) issued an exemption from child-protection packaging requirements for sodium fluoride drug preparations, including liquid and tablet forms, containing no more than 264 milligrams of sodium fluoride per package and containing no other substances subject to the requirements for special packaging under the Poison Prevention Packaging Act. The toxicity of sodium fluoride-containing tablets is no greater than the toxicity of equivalent dosages of the previously exempted liquid preparations. The CPSC believes that child-protection packaging for all forms of sodium fluoride containing no more than 264 mg. of sodium fluoride per package is unnecessary to protect 'dren from serious illness or injury, based upon the low toxicity or sodium fluoride and the lack of serious adverse human experience associated with ingestion of the drug. The Food and Drug Administration concurred with the Commission that an exemption should be granted, based on a lack of reported substantial hazard.

FDA REDUCES DISTRIBUTION OF IDL

In order to reduce Federal spending, the Food and Drug Administration has reduced public distribution of the Commercial Import Detention Lists (IDL). Anyone wishing to continue to receive the IDL on a monthly basis, a subscription service has been set up by the National Technical Information Service (NTIS) for a nominal fee. Any questions regarding the subscription service should be directed to NTIS. All questions regarding text of the lists should continue to be addressed to the Food and Drug Administration. (National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, phone: (703) 487-4650.

FTC TO STUDY DRUG PRODUCT SELECTION

In the near future, the Federal Trade Commission is scheduled to conduct a major study of the effects of drug product selection legislation on drug dispensing costs. The agency will also assess effect of "pass through" provisions of many state laws which require the pharmacist to pass on all savings to the consumer resulting from drug product selection. In its Model Drug Product Selection Law, the agency endorses the concept that pharmacists should not be required to make a complete "pass through" in order to give incentive for engaging in drug product selection.

NRC WANTS YOU -- AS ITEM WRITERS

There is a constant need for new questions in Math, Pharmacology, Chemistry, Pharmacy, and the Practice of Pharmacy to maintain the quality of NABPLEX. This article is an invitation to pharmacy professionals, especially practicing pharmacists, to write questions (items) for possible future use. No specific quantity of questions is required from item writers but you may be asked to submit up to 20 items once a year. If you are interested, please fill in the coupon below and return it to NABP Headquarters, Attn: NABPLEX Item Writers.

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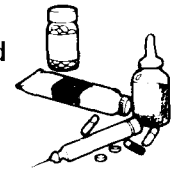
NABPLEX ITEM WRITERS, ONE EAST WACKER DRIVE, SUITE 2210, CHICAGO, IL 60601.

The BVC Readership Survey has been mailed to a sampling of practitioners in your state. If you have received a questionnaire, please complete and return it as soon as possible.



WHAT PHARMACISTS SHOULD KNOW ABOUT POISON PREVENTION PACKAGING BOOKLET AVAILABLE

The Consumer Product Safety Commission (CPSC) has available a booklet describing the responsibilities of pharmacists under the Poison Prevention Packaging Act. Copies may be obtained at no charge by calling the CPSC tollfree hotline 800-638-8326. In Maryland only the number is 800-492-8363 and in Alaska, Hawaii, Puerto Rico, and the Virgin Islands the number is 800-638-8333.

regulation, or an absence of concern about violations of law or regulations. Inspectors report with disturbing frequency, for example, that some pharmacists think 120 cc of a Schedule V product containing codeine can be dispensed once every 24 hours when regulations plainly state that the limit is 48 hours.

ITEM 363—DESTRUCTION OF CONTROLLED SUBSTANCES

This information supercedes that published in items 332 and 316. Unusable or out of date controlled substances can be destroyed by completion of proper forms (DEA-41) and mailing the drugs to DEA, 925 West Market Street, Room 111, Greensboro, NC 27401. Attention: Compliance. The drugs must be sent certified mail or registered mail, return receipt requested. Forms may be obtained from the Greensboro DEA office or the Board office and each set of forms has room for 32 line items.

ITEM 364—INTERESTED IN DRUG LAW?

The Board office has received many inquiries about current information on drug law. The American Society for Pharmacy has a monthly publication, *Rx Ipsa Lonquitor,* which contains items of interest to both pharmacists and lawyers. Membership in the Society which includes the monthly publications, is $5.00 per year for students, $10.00 for pharmacists and $15.00 for pharmacist lawyers. Applications may be obtained from Larry Simonsmeier, College of Pharmacy, Washington State University, Pullman, WA 99164.

ITEM 365—HOSPITAL PHARMACISTS NOTE!

Many pharmacists have the impression that robberies or burglaries for drugs only occur in retail pharmacies. This is not the case. An article in the *American Journal of Hospital Pharmacy,* Vol. 38, May 1981, p.604 describes seven armed robberies in hospital pharmacies in recent months. As a commentary, this editor has visited numerous hospitals on speaking engagements for AHEC and passed security personnel with no questions asked or politely directed to the pharmacy. Others could easily do the same. Hospital pharmacists should seriously consider this situation.

ITEM 366—PRESCRIBING BY PA/NPs; CHAPTER TWO

In the January, 1979 issue of the *Newsletter,* the rights of PA/NPs to prescribe drugs was clarified in Item 298. Questions on this subject continue to arise and this is a second effort to resolve such inquiries.

One way to approach the subject is that, concerning PA/NPs who have received their six digit number from the Board of Medical Examiners, there are three classes of drugs. The first group is controlled substances. PA/NPs cannot issue prescriptions for the dispensing of controlled substances of any kind including Schedule V drugs. The second category are the drugs excluded on the formulary approved by the Board of Medical Examiners. PAs NP cannot prescribe these drugs on their signature alone but can prescribe these drugs if they are acting on the specific or direct order of the physician prior to the issuance of the prescription. In that case they should sign the prescription "Mary Jones, NP on the order of Dr. Smith" or "John Jones, PA on the order of Dr. Smith." (See Item 298). An example could be that a PA/NP could not prescribe Chloramphenicol or Pediatric Tetracycline on their own signature alone but could prescribe these drugs on the order of the supervising physician. The last group includes all other drugs — if a drug is not a controlled substance and not excluded through the formulary, the pharmacist can only assume that it is contained in the protocol or standing order and the PA/NP can prescribe the drug.

For your information, the formulary is aligned with categories in "Hospital Formulary Service" and differences of opinion regarding the proper therapeutic or generic category of a drug can be resolved by reference to that publication. PA/NPs cannot authorize refills on a prescription (see Formulary, other criteria) and the amount dispensed at any one time should not exceed 100 dosage units or a one month's supply. When a patient uses all of the first prescription and additional medication is needed, a second separate prescription may be written. Refills cannot be indicated on any prescription. In circumstances which would require parenteral drugs, such as a jaw injury, the Board of Medical Examiners may approve in the individual application, written standing orders to cover this specific situation. Pharmacists should understand that PA/NPs can only prescribe drugs according to the approved Formulary or specific written standing orders approved in the individual application on file with the Board of Medical Examiners.

ITEM 367—BIOEQUIVALENCE; PRODUCT SELECTION

Pharmacists participating in product selection (See Item 303 in August 1977 *Newsletter*) should be alert for drugs with documented or suspected bioavailability inequivalency. Twelve drugs (aminosalicylic acid, dexamethasone, dicumarol, digitoxin, digoxin, nitroglycerin, phenytoin, prednisolone, prednisone, quinidine, triamcinolone, warfarin) used in critical therapeutic situations and with evidence of inequivalency have been categorized as high risk potential by Wanke and Milne in *Contemporary Pharmacy Practice* 1:9 (Summer) 1978. An additional 42 drugs are listed as moderate risk potential.

Pharmacists should be aware of potential problems associated with inequivalent drug products and examine literature regarding bioavailability carefully before making product substitution. Three parameters that are considered important in evaluating bioequivalence are the peak concentration, time of the peak concentration and the area under the blood concentration-time curve. In addition, bioavailability data for time-release, enteric-coated, and injectable suspension preparations should be assessed carefully. A helpful resource is *The Bioavailability of Drug Products* published by the APhA, 1978, where a background review of bioavailability and selected monographs are presented.

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