



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—409 DISCIPLINARY ACTIONS OF THE BOARD

August: A pharmacist appeared before the Board who had pleaded guilty to five counts of felonious sale and delivery of controlled substances from a pharmacy in Thomasville. He explained that all the drugs went to one person for use in the family and there was no evidence of diversion to street use. He was sentenced in court to two years imprisonment, stayed for three years on the condition that he spend four consecutive weekends in jail which has been served. It was the Board's decision to suspend his license to practice pharmacy for at least one year with the license reinstated after passing a jurisprudence examination and other conditions.

A pharmacist currently living in Hamlet met with the Board to pursue the reinstatement of his license which had been surrendered in the Spring of 1982. The proceedings were continued until November when the Board reviewed the pharmacist's record of past appearances before the Board for shortages or problems involving Talwin® in Durham, High Point, Lexington and Raleigh. The pharmacist was not represented by counsel even though the proceedings had been continued at least partially for this purpose. The pharmacist would not admit or deny a problem with the personal use of Talwin®. It was the decision of the Board to lift a stay order on a decision reached in August of 1981 thus producing a revocation of the pharmacist's license to practice.

September: A pharmacist from Zebulon appeared to respond to charges of pleading guilty and no contest in Superior Court of Wake County to Medicaid fraud and the payment of over \$15,000 in fines. The pharmacist testified that the person who had prepared the Medicaid claim forms had a heart attack about 1 month before a routine audit revealed discrepancies. The pharmacist claimed that he knew there were inaccuracies in the claims after reviewing them but was instructed not to make any changes by the auditors. It was the decision of the Board to place the pharmacist on probation for approximately two years to run concurrently with a similar court order.

After an appeal to the Wake County Superior Court by a pharmacist from Asheboro of an Order of the Board in October of 1981 issuing a 60-day suspension of his license, the pharmacist was allowed to offer additional explanation in his defense. The pharmacist was represented by an attorney on this occasion even though he had not been represented by an attorney in October of 1981. Many letters of reference citing good character and reputation were offered to the Board in addition to further explanation of shortages at the pharmacy for which he was responsible which eventually produced the disciplinary action. It was the decision of the Board

to issue a 30-day active suspension in place of the original 60-day term.

October: A pharmacist practicing in Durham who lived in Raleigh at the time was the subject of a Board hearing on charges of personal consumption of Demerol® and pleas of guilty to misdemeanor larceny and obtaining controlled substances by forged prescriptions. Testimony indicated that he had consumed a small but significant quantity of Demerol® 100 mg. while on duty at the pharmacy in Durham. The pharmacist, through his attorney, offered in defense that he has been seeing a psychiatrist, has not consumed drugs since the offense was discovered and presented testimony of good character from one current and one former employer. It was the decision of the Board to suspend the pharmacist's license for three years, stayed under certain conditions including unannounced urine analysis tests and other conditions.

November: A pharmacist from Hickory was the subject of a hearing on charges of dispensing controlled substances on prescriptions that were not issued for a legitimate medical purpose in the course of professional practice and excessive refilling of a prescription for a controlled substance. The pharmacist claimed to be unaware of the "corresponding responsibility" section of Federal Regulations which places a duty on the pharmacist to determine the validity of prescriptions (See Item 311, November, 1979 and Item 399, July 1982). The Board staff's interpretation of refill instructions of the physician was disputed by the pharmacist. Testimony and evidence indicated a substantial increase in the filling of prescriptions for Talwin® during a certain two month period when the prescriber was under indictment for a violation of the controlled substances laws and that numerous prescriptions for controlled substances were filled from physicians a substantial distance away from this pharmacy while very few, if any, were found in other nearby pharmacies. The pharmacist also offered in his defense that he was afflicted with a debilitating disease which made attendance at continuing education programs almost impossible. After a hearing which lasted the entire day it was the decision of the Board to suspend the license of the pharmacist for 60 days and the permit to operate the pharmacy for 30 days both suspended for three years under certain conditions.

ITEM 410 — ACTIONS OF THE BOARD OF MEDICAL EXAMINERS

The Board of Pharmacy has been informed of activity from
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National Pharmacy

FDA PUBLISHES FINAL RULES REGARDING TAMPER-RESISTANT PACKAGING

On Friday, November 5, 1982 the U.S. Food and Drug Administration published its final regulations on tamper-resistant packaging in the *Federal Register*.

The Regulation requires tamper-resistant packaging for all OTC drugs with the exception of dermatologics, dentifrices, and insulin and includes cosmetic liquid oral hygiene products and vaginal products. The regulation will also require manufacturers to include a statement in the labeling of the covered products that will alert purchasers to the tamper-resistant feature of the package. The regulations require that manufacturers have the tamper-resistant packaging in place by February 7, 1983 for most products and on May 5, 1983 for the remainder. Products at the retail level must be in tamper resistant packaging by February 6, 1984. Pharmacists thus will have approximately one year to sell or return all OTC drug products not currently in tamper-resistant packaging.

The regulations indicate that a tamper-resistant package is "one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred." In the regulations FDA has identified several different types of packaging systems that are currently available which would meet the agency's tamper-resistant packaging requirement. FDA has indicated, however, that it does not wish to inhibit manufacturers flexibility as to which methods of tamper-resistant packaging will be used for their particular products and thus are not requiring specific package types.

HHS Secretary Richard S. Schweiker summarized the intent of the regulation by saying "while it is virtually impossible to make any package tamper-proof, it is possible to manufacture packages in such a way that tampering is much more difficult, and that if a product is tampered with, it can more easily be detected by a careful consumer."

"The manufacturers of over-the-counter drugs have been extremely cooperative in moving quickly toward better protection. They have acted responsibly and in good faith, and I believe this regulation will give them the uniform national standards they need," said Schweiker.

LOOK-ALIKES BILL PASSED

The U.S. Senate passed a street drug "look-alikes" amendment intended to prohibit the manufacture and distribution of imitation controlled substances on September 30th. Offered by Senators John C. Danforth (R-MO) and Gordon J. Humphrey (R-NH), the amendment was accepted as part of the "Violent Crime and Drug Enforcement Improvements Act of 1982 (S.2572) which received the 95-1 vote.

The provision would amend the Food, Drug and Cosmetic Act making manufacturing, distributing and advertising an "imitation

controlled substance" a federal crime. Defining look-alikes as "any substance other than a controlled substance or prescription drug, or combinations of such substances, which is marketed, sold or distributed to encourage recreational drug use or abuse or similar non-medical purposes and (a) by representation of appearance (including color, shape, size and markings) would lead a reasonable person to believe that the substance is a controlled substance; or (b) purports to act, either alone, in multiple doses, or in combination with a substance or substances, like a controlled substance, either stimulant or depressant as defined in section 102(9) of the Controlled Substances Act."

Meanwhile, FDA is on the move to block illegal stimulants sale and distribution. FDA has taken two steps to cut this traffic off at its source by (1) declaring all phenylpropanolamine-ephedrine-caffeine combinations to be new drugs that require FDA approval before marketing; and (2) reviewing a new, multi-option strategy that could convert phenylpropanolamine from OTC to prescription-only status. FDA's Drug Listing Branch is compiling a list of these drugs and can act as a clearinghouse for the exchange of drug identification information. The FDA Drug Listing Branch in Rockville, MD, may be reached at (301) 443-6910.

Both FDA and DEA have encouraged state attempts to deal with the problem of look-alikes and have advised that activities of manufacturers of simulated controlled substances be brought to the attention of state boards of pharmacy for local action, referral to the proper federal agency, or both. (Reprinted by permission, NABP Newsletter, Volume 11, No 10 October, 1982.)

DEA PROPOSES TO ALLOW DISPENSING CS IN HOSPITAL EMERGENCY ROOMS

DEA has recently proposed to amend part 1306 of Title 21 of the Code of Federal Regulations to permit hospital emergency room personnel to dispense controlled substances to non-patients when alternative pharmacy services are not available. Under DEA's currently existing regulations, physicians, pharmacists, and agents or employees of the physician may dispense controlled substances (subject, of course, to more stringent limitations found in state law). Physicians currently are not allowed by DEA regulations to call a local hospital emergency room and make arrangements for personnel in the emergency room to dispense controlled substances to a patient whom the physician is sending over to the hospital for that particular purpose. Apparently, DEA has received a number of comments from the medical community regarding this situation and their proposal seeks to change that situation.

DEA proposes to permit hospital emergency room personnel to dispense controlled substances pursuant to prescriptions issued by practitioners outside of the hospital provided that certain conditions are met. The *Federal Register* of Friday, September 17, 1982 in-

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dicates that those conditions are as follows: First, the dispensing authorized by this regulation must be done by those permitted to do so under state law. Second, normal pharmacy services must not be available. It is not the intention of this regulation to substitute emergency services for those pharmacies, where the latter are available to serve the needs of the community. Third, the outside physicians must be properly registered to authorize the dispensing of the medication in question and, finally, all federal and state requirements for the issuing and filling of prescriptions and the maintenance of records thereon must be followed.

The specific proposal is in pertinent part as follows:

Section 1306.06 Persons to fill prescriptions. A prescription for controlled substances may only be filled by: (a) A pharmacist acting in the usual course of his professional practice and either employed in a registered pharmacy or employed as a registered institutional practitioner, or (b) Emergency room medical personnel located within a facility registered as an institutional practitioner, if such personnel are so authorized in the jurisdiction in which they practice, and only if pharmacy services are not available. Controlled substances may only be dispensed pursuant to the prescription order of a properly registered practitioner. Requirements for filling such prescriptions are the same as those required of a pharmacist.

NEW TELEPHONE NUMBER FOR DEA'S REGISTRATION UNIT

The registration unit of the Drug Enforcement Administration is responsible for issuing and maintaining registration certificates for all legal handlers of controlled substances pursuant to the Controlled Substances Act of 1970.

Effective September 27, 1982, the telephone number for the registration unit of the DEA has been changed from (202) 724-1013 to (202) 254-8255.

Registrants should **not** call the general information number of DEA, (202) 633-1000, for Controlled Substances Act registration information.

Although the telephone number for the registration unit has changed, registrants should continue to send new and renewal application forms requests for order forms and general correspondence to DEA at the following address: United States Department of Justice, Drug Enforcement Administration, P.O. Box 28083, Central Station, Washington, DC 20005.

STARCH BLOCKER UPDATE

The following press release concerning starch blockers seizures was issued by FDA since the last Newsletter. At the request of the Food and Drug Administration and the Department of Justice, U.S. marshals have initiated nationwide seizures of "starch blockers" promoted for weight management.

On July 1, 1982, FDA stated that all starch blockers are unapproved new drugs, which had been marketed without the necessary scientific testing to prove their safety and effectiveness. FDA informed more than 300 manufacturers and distributors of starch blockers that they must stop manufacture and distribution of the products. Most have complied. However, a few firms have continued to manufacture and distribute starch blockers.

Seizures carried out since September 17 have involved products of the American Dietetics Co., at Cleburne, Texas, Orangeburg, NY, Ooltewah, TN, and Tulsa, OK; General Nutrition Corp., Arlington, TX, Nashville, TN and Pittsburgh, PA; Phoenix Laboratories, Deer Park, NY; Eden's Own Products, Inc., Tulsa, OK; Naturade Products, Inc., Tulsa, OK; and Holistic Products Corp., Tulsa, OK.

These first seizures netted tablets valued at approximately \$481,000 retail.

Starch blockers are prepared from raw beans, such as kidney and northern beans, and possibly other unknown ingredients. The products have been advertised and sold nationwide with claims that they block or impede starch digestion to help in weight control and weight reduction.

FDA continues to receive reports of adverse reactions from starch blocker users, generally consisting of nausea, vomiting, diarrhea, stomach pains and excess gas. In addition, the agency has investigated 27 hospitalizations associated with starch blocker use.

NABP FOUNDATION ANNOUNCES AVAILABILITY OF CE PROGRAM ON FEDERAL FOOD DRUG AND COSMETIC ACT

The NABP Foundation and the Foundation's Bureau of Voluntary Compliance have announced that a video tape presentation on the Federal Food, Drug and Cosmetic Act is now available for use by Boards of Pharmacy as the basis for developing a continuing education program on this subject matter.

The video tape presentation is designed to meet ACPE Standards of quality for continuing education programming and the NABP and NABP Foundation are ACPE approved co-providers. State and local pharmacy groups interested in a CE program on the Federal Food, Drug and Cosmetic Act should contact their state board of pharmacy to discuss the development of a CE program involving this video tape.

IS THIS NEWSLETTER IMPORTANT?—A recent survey of Louisiana pharmacists showed that 80.8% thought this newsletter was "good" to "excellent." Over 32% thought it the best thing the board does. Many state boards are now determining whether to continue the newsletter you receive. Your input may determine whether your state stays in the newsletter program. Take a moment this month to write your board office and give them your views.

the Board of Medical Examiners which affect the prescribing rights of certain physicians. The actions reported to the Board are: Oscar S. Cunanan, M.D., Cary, surrendered license to practice medicine February 18, 1982; Joe Dean Crawford, M.D., Asheville, surrendered license to practice medicine April 1, 1982; Lewis William Hagna, M.D., Marion, Board accepted retirement March 19, 1982; Melvin W. Webb, M.D., Burnsville, surrendered DEA privileges in all Schedules April 23, 1982; Luther T. Pennington, M.D., Ada, Oklahoma, surrendered license to practice medicine May 17, 1982; C. Clement Lucas, M.D., Edenton, surrendered license to practice medicine September 10, 1982; Hugh M. Clement, P.A., Greensboro, surrendered approval as a physician assistant September 24, 1982; Herbert Henderson, M.D., California, surrendered license to practice medicine September 24, 1982; Victor Gray Herring, III, M.D., Tarboro, surrendered license to practice medicine, October 21, 1982; Mark Williams Roberts, M.D., California, surrendered license to practice medicine, November 21, 1982.

ITEM 411 – INSTITUTIONAL REGULATIONS COMMITTEE

A Committee has been appointed to recommend regulations to the Board for the dispensing of drugs in institutions, primarily hospitals but which may also include nursing homes and other similar facilities. The Committee has had several meetings and plans to continue into 1983. Its members are James McAllister, Chairman; William Adams, Vice-Chairman; Harold Day; Edward Frenier; Robert Dever; John Smothers and Jack Upton. If you have comments or suggestions please forward them to the Board office.

ITEM 412 – CHECK INVENTORY ON DIGOXIN, DIGITOXIN AND NITROGLYCERIN

Earlier this year the Food and Drug Administration noted that samples collected of digoxin, digitoxin and nitroglycerin which were outdated or had no expiration date often failed to meet minimum standards and could be potentially quite dangerous if dispensed. Pharmacists are urged to review their inventory of these items to be certain that current dating exists. Pharmacists are reminded that prescription drug products without expiration dates were probably manufactured before 1975 and products currently approved by the Food and Drug Administration have expiration dates not exceeding five years from the date of manufacture.

ITEM 413 -- INTERNSHIP FOR STUDENTS

Traditionally pharmacy has voluntarily assumed a portion of the responsibility for training potential licensees beyond the classroom. This training has evolved from an apprenticeship or clerkship to the current intern or academic extern designation. Students have reported some difficulty in obtaining such positions and the Board urges all pharmacists to consider their responsibility to the profession in this area. Experience in pharmacy is an invaluable part of student development and if it is not generally available we can expect that academia will take its place.

In this connection please note that it is the student (or candidate) who has the responsibility of filing their forms with the Board of Pharmacy within five days of the beginning and end of each period of experience. If an intern leaves forms for a pharmacist's completion and the forms are not filed in a timely manner it can result in the denial of part or all of the experience obtained as credit for the practical examination. Please file such forms properly to avoid any unfortunate results.

If you are interested in serving as a preceptor you should contact Dr. Jack Wier, UNC School of Pharmacy, Room 117, Beard Hall 200H, Chapel Hill, North Carolina, 27514; (919) 962-0097 or Mr. Al Mebane, Executive Director, North Carolina Pharmaceu Association, P.O. Box 151, Chapel Hill, NC 27514; (919)967-22...

ITEM 414 – INFLUENCING BOARD MEMBERS

The Members of the Board of Pharmacy hear disciplinary hearings nearly every month. Occasionally a pharmacist who will be the subject of a hearing in the future contacts individual members of the Board to "plead his case" before the actual hearing. Other individuals may contact members of the Board in an attempt to persuade them on the guilt or innocence of a person who will be the subject of a hearing.

Please be aware that when this activity occurs the individual members of the Board frequently disqualify themselves from the hearing. The net effect, then, of such attempted persuasion is to essentially nullify any progress which the appealing person may have intended. In order to avoid charges of prejudgment (or prejudice) and possible adverse rulings on appeal the Board must be as impartial as possible when the hearing occurs.

ITEM 415 -- DISPENSING EPINEPHRINE

In 1981, the General Assembly changed state statute to allow individuals who have completed a training program to administer epinephrine. This training program may be part of an emergency medical technician program or another program which does not produce technicians. Individuals who have completed such a program have received a certificate of "Approval to Administer Epinephrine" signed by a member of the Board of Medical Examiners. The current member signing or stamping such certificates is Frank N. Sullivan, M.D.

Epinephrine may be legally provided to approved individuals on the presentation of the certificate. This should be handled in the same way a pharmacist would distribute prescription drugs or other supplies to a physician's office for example. We understand that such items are available in kit form and can be obtained from pharmaceutical wholesalers.

ITEM 416 – NEW GREENSBORO DEA ADDRESS

We have been advised as of December 1, 1982 all correspondence mailed to the Drug Enforcement Administration, Greensboro, NC office should be mailed to their new address as follows: Drug Enforcement Administration, 2300 West Meadowview Road, Suite 224, Greensboro, NC 27407.

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