



North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 467—DISCIPLINARY ACTIONS OF THE BOARD

June: **Wallace A. Johnson**, Mount Airy. Dispensed controlled substances without a prescription, failed to keep records of dispensing of Percodan®, Dilaudid® and Demerol®, generic drugs were dispensed and labeled as brand name drugs when brand name drugs were prescribed, and dispensed controlled substances pursuant to telephone prescriptions beyond that allowed in federal regulations. License suspended for two years, stayed to five years under certain conditions including a 30 day active suspension with his license returned only after passing a jurisprudence exam.

Wallace A. Johnson, Jr., Mount Airy. Dispensed controlled substances without a prescription, failed to keep records of dispensing of Percodan®, Dilaudid® and Demerol®, generic drugs were dispensed and labeled as brand name drugs when brand name drugs were prescribed, and dispensed controlled substances pursuant to telephone prescriptions beyond that allowed in federal regulations. License suspended for three years, stayed five years under certain conditions including a 45 day active suspension with his license returned only after passing a jurisprudence exam.

Wally's Pharmacy, Mount Airy. Note activity above — 5 day active suspension of the permit with a sign posted on the front door notifying the public of the suspension.

James C. Kiser, Cramerton Drug, Cramerton. Prescription legend drugs were dispensed without a prescription while he served as pharmacist-manager. License suspended for 30 days, stayed for two years under normal conditions.

Steven D. Kiser, Cramerton. Dispensed Dilaudid® on numerous occasions without a prescription, dispensed Quaalude® 300 mg. without a prescription, engaged in the manufacture of marijuana, and dispensed codeine without a prescription. License suspended for two years, stayed for five years under certain conditions including a 90 day active suspension with his license returned only after passing a pharmacy jurisprudence exam.

July: **Richard E. Jimmo**, Durham. Failure to comply with a stay order of the Board issued pursuant to a hearing in August of 1983.

License revoked, stayed for five years under certain conditions including an active indefinite license suspension, psychiatric rehabilitation and a stipulation that he may not petition the Board for lifting of the active suspension before February of 1985.

John A. Wilkinson, Shelby. Unauthorized Possession of Tuinal®,

Amytal®, Biphedamine® 20, Fastin®, Dexedrine® and Miltown®. License suspended for 90 days, stayed for five years under normal conditions.

Ozie Faison, Durham. License reinstatement. After being found guilty in Federal Court of conspiracy to distribute a Schedule II controlled substance, the Board revoked his license in January of 1983, stayed for six years under certain conditions, one of which was an active suspension concurrent with his period of incarceration in Federal Prison with his license returned only after completion of a pharmacy jurisprudence exam. Mr. Faison completed and passed the examination with the June administration of the licensure exam and after meeting with Mr. Faison at the July meeting, the Board reinstated his license to practice pharmacy.

ITEM 468—NORTH CAROLINA PHARMACY WEEK

Governor James B. Hunt, Jr. has signed a proclamation designating October 14-21 as North Carolina Pharmacy Week. Contact the North Carolina Pharmaceutical Association at P.O. Box 151, Chapel Hill, NC 27514, 919/967-2237 for further information on this event.

ITEM 469—QUARTERLY QUERY

A pharmacist licensed in North Carolina must notify the Board of:

- I. A change of mailing address.
- II. A change of practice site.
- III. A change of marital status.
 1. I only.
 2. II only
 3. III only
 4. I and II only
 5. I, II and III.

ITEM 470—CHILD RESISTANT PACKAGING

The Associated Press has reported on a recent lawsuit against an Iowa pharmacist in which the parents won \$160,000 for the death of their daughter allegedly as a result of the pharmacist's failure to comply with the special packaging standards of the Poison Preven-

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National Pharmacy

ILLEGAL SALE AND DISTRIBUTION OF VETERINARY DRUGS

The Food and Drug Administration's Center for Veterinary Medicine (CVM) is urging state regulators, pharmacy boards, and the veterinary profession to join forces in curbing the widespread illegal distribution of veterinary prescription drugs which threaten the safety of the nation's meat, milk and egg supply.

Pointing out in a recent speech that CVM cannot do the job alone, Dr. Lester Crawford, CVM director, expressed concern that consumers will suffer if illegal use of prescription veterinary drugs in animals is not halted. Residues of such toxic drugs as the cancer-causing chloramphenicol, for example, have been found by USDA's Food Safety and Inspection Service in their national tissue residue monitoring program.

The Center for Veterinary Medicine has stepped up its field enforcement against the wholesale and retail over-the-counter sale of prescription veterinary drugs that are being distributed through mobile vans, by mail order and other illicit means. At FDA request, the federal courts have enjoined several distributors against further violations.

The problem is not limited to selling veterinary prescription drugs without a prescription, however. Some veterinarians have been providing the drugs to livestock owners without establishing a valid veterinarian-client-patient relationship. Some distributors have even used a practitioner under retainer or a staff veterinarian as a facade where, in fact, no valid relationship exists.

In another yet related area, the FDA is taking action to curb illegal imports of bulk chemicals which later are diverted illegally for use by veterinarians, clandestine drug manufacturers, and by other manufacturers producing new animal drugs without FDA approval.

Last August, the Center for Veterinary Medicine announced that it was revising its policy on extra-label (off-label) use of veterinary drugs in treating food-producing animals. Before the change, CVM took the position that a licensed veterinarian could use legally obtained drugs in any treatment regimen without fear of FDA regulatory action, if no violative tissue residues were found in edible products. Under the revised policy, FDA will consider regulatory action on extra-label drug use in food-producing animals whether or not violative tissue residues occurs. Exceptions are permitted only under carefully defined and controlled circumstances, and on a case-by-case basis.

In recent months, however, FDA has begun an ambitious program to totally eliminate the use of chloramphenicol in food animals. In veterinary medicine, chloramphenicol is approved only for treating dogs and as an ophthalmic in cats.

A 1983 FDA survey sought to determine the degree of control the states were exercising over veterinary drug distribution. Of the 36 states responding, 21 indicated varying degrees of effort attempting to deal with illegal veterinary drug distribution. But there were

only four that reported aggressive programs. This year, however, many states are showing renewed interest, some even to the extent of seeking additional regulatory authority from their state legislatures.

In recent remarks before the Western States Veterinary Conference, Dr. Crawford said that "what we generally need from state to state are not necessarily more laws and more regulations or new laws and new regulations. What we need from state to state is more rigorous enforcement of *existing* laws and regulations." "FDA," he continued, "is ready to support the states in any way feasible." He said this can be done most effectively through interaction between FDA's regional offices and the states they encompass.

While the problem is national in scope, individual states have the most to lose because of the damage that can be done in the public mind if serious questions arise about the safety of the food being produced in a state.

Dr. Crawford has urged that all states require licensing of veterinary drug distributors. He said, "the states should have clear authority to halt illegal distribution of veterinary drugs, especially where such distribution threatens animal or human health or involves fraudulent representations." "The states," he continued, "also should provide adequate legal and enforcement personnel."

Illegal veterinary drug distribution can be an even greater threat to public health than the illegal distribution of human drugs. Use of dangerous, unapproved drugs in humans generally involves the informed consent of the patient, but the consumer of meat, milk and eggs has no way of knowing what hazardous substances may be present in those foods and must rely upon appropriate authorities to assure safety and wholesomeness.

"The states have a primary obligation to protect its citizenry against illegal veterinary drug distribution," Dr. Crawford said. "Failure of a state to join with the federal government in overseeing the safety of the food supply," he continued, "is an abrogation of moral as well as civic responsibility . . . It is my personal opinion that the only solution to our mutual problems is for us to work together—government, industry, medicine—for we all have a very large stake and responsibility in providing the American consumer with the safest, highest quality food supply we possibly can."

CONTROLLED SUBSTANCES ACT VIDEO TAPE AVAILABLE

The second in a series of three video tapes produced by the NABP Foundation focuses on one of the most important legal aspects of pharmacy practice—the Controlled Substances Act. The video tape emphasizes the importance of protecting the public from the diversion of abusable drugs while recognizing the harm to good health care caused by an over reaction to the problem of prescription drug abuse.

Compliance News



The goal of the video tape and the accompanying study guide is to assist participants in developing:

1. A good working knowledge of the Federal Controlled Substances Act (CSA) as it applies to the daily practice of pharmacy and other professions;
2. Familiarity with common abuse trends;
3. Recognition of frequently used methods of illegally obtaining prescription drugs for abuse purposes; and
4. Professional responsiveness and ethical considerations in addition to legal compliance with the Federal Controlled Substances Act.

Gene Haislip, Deputy Assistant for the Office of Diversion Control at the Drug Enforcement Administration states in the tape: "the agency (DEA) needs the assistance of the pharmacy profession and individual pharmacists in these efforts to fight prescription drug diversion. We are proud that pharmacy has recognized its responsibility and has—through its own initiative—developed programs like this video tape to encourage its practitioners to keep up-to-date on the controlled substances laws and the problems of drug diversion."

The format of the tape, which includes a historical perspective and several scenarios concerning compliance, has been praised as a dynamic educational tool. The program, assigned one contact hour (0.1 CEU) of continuing pharmaceutical education credit for pharmacists, was developed to be presented through Boards of Pharmacy throughout the United States. Involvement of representatives from the Board of Pharmacy makes possible augmentation of the taped portion with a question and answer session that addresses both state and federal issues. Ordering information may be obtained through the NABP Foundation or through state Boards of Pharmacy. The National Association of Boards of Pharmacy and the NABP Foundation are approved by the American Council on Pharmaceutical Education as providers of continuing pharmaceutical education.

METHAQUALONE TO BE PLACED IN SCHEDULE I

On June 29, 1984 President Reagan signed public law 98-329 which will move the drug Methaqualone from Schedule II into Schedule I of the Federal Controlled Substances Act.

Methaqualone is no longer manufactured by legitimate drug manufacturing companies in the United States. The Lemmon Pharmaceutical Company was the last legitimate manufacturer of Methaqualone in the United States and it discontinued production on November 14, 1983.

The new law accomplishing the rescheduling of Methaqualone becomes effective September 26, 1984. After that date the prescribing and dispensing of Methaqualone will ordinarily not be permitted.

CHILD RESISTANT PACKAGING FOR DIPHENHYDRAMINE

Effective August 13, 1984 all products containing more than 75 mg. of Diphenhydramine Chloride in a single package, which is in a dosage form intended for oral administration, must be packaged in child resistant packaging.

This requirement does not apply to products already on pharmacists' shelves but applies only to those products packaged after the August 13 date. Diphenhydramine is just one example of previous legend drug products now available OTC that the Consumer Product Safety Commission is concerned with. As more and more legend products become available OTC in certain dosage forms, the Consumer Product Safety Commission must act to establish dosage limits for the child resistant packaging requirement.

CORRECTION ON GENERIC SUBSTITUTION OF SCHEDULE II PRESCRIPTIONS

In the National Pharmacy News section of the last issue of the newsletter, we incorrectly reported on regulations of the Drug Enforcement Administration that permit pharmacists to change the dosage form of a prescribed Schedule II product.

The following corrects what was reported previously in the last issue:

Concerning generic substitution, the DEA will permit pharmacists if they have a stock problem to change the dosage form of a prescribed Schedule II product. For instance, if the prescription was written for 100 mg. tablets with the directions "one tablet four times a day," the pharmacist could dispense 50 mg. tablets with the direction of "two tablets four times a day." If done, it might be wise to inform the prescriber or arrange for a notation on the patient's medical records that a change was necessary although no change in net therapy was produced.

DEA'S OFFICE OF DIVERSION CONTROL MAKE PHARMACISTS MANUAL AVAILABLE

"Pharmacists Manual: An Informational Outline of the Controlled Substances Act of 1970" is available through the nearest regional office of the Drug Enforcement Administration. It was incorrectly reported in the last issue of the newsletter that the manual is available through the Drug Enforcement Administration in Washington, D.C.

The 38 page manual is an attempt to assist pharmacists in their understanding of the Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice.

The manual was produced by the Drug Enforcement Administration's Office of Diversion Control as a part of the DEA's Diversion Control Program.

tion Packaging Act. The news article states: "A Palo Alto County couple have been awarded \$160,000 in a lawsuit claiming a pharmacist was responsible for the death of their 11-month-old daughter because he failed to put a child-proof lid on a bottle of medicine. The suit was brought by Julie J. and Ricky D. Baas in the U.S. District Court in Cedar Rapids in connection with the death of their daughter, Jessica. She died in 1981 after taking some of her father's asthma medicine, Tedral. The parents sued Donald Hoye, owner of Hoye Super Rexall Drug in Estherville, and Robert H. Young, the pharmacist who filled the prescription. They had sought \$1 million in damages.

The defendants contended they were under no obligation to use a child-proof lid and that the child's parents contributed to her death by leaving the medicine within her reach. The defendants also claimed that if they were found liable they should be reimbursed by James L. Coffey, M.D., and Patricia Nystrom, family nurse practitioner. The nurse practitioner allegedly failed to give proper instructions when Julie Baas called Coffey's clinic to report the child had taken some of the father's pills. The seven-person jury returned a verdict after deliberating about six hours. They found Hoye and Young negligent, but not the doctor or the nurse." (Reprinted from *Rx Ipsa Loquitur*.)

ITEM 471— RESPONSES TO MISCELLANEOUS QUESTIONS

One issue which frequently arises is the question of the validity of a physician prescribing for himself or his family. Such prescribing of controlled substances, in order to be valid, must be within the ordinary course of professional practice and also must be part of a physician/patient relationship. A relationship of an individual with himself is not possible and certainly questionable when applied to a family situation. If such individuals need or desire controlled substances on prescription they need to obtain the order from another prescriber. The principle of prescribing within one's professional practice also applies to prescribing by dentists, optometrists, veterinarians or other similar health professionals. If these individuals attempt to prescribe outside of the limitations of their practice, the prescription is invalid.

Pharmacists also need to be aware that, as far as the Pharmacy Practice Act is concerned, a prescription order also includes an order from a practitioner who is not licensed in North Carolina. One needs to be careful in this regard, however, since an out-of-state physician who is visiting your community who attempts to prescribe a drug can also be practicing medicine in this state and needs to have a valid North Carolina license in order to prescribe while in the state.

Prescription legend drugs which are not controlled substances need to be authorized for refills in order to be refilled. Some question has arisen in this regard and pharmacists are referred to G.S. 106-134.1 which specifically states that no refills can occur on prescription legend drugs unless specifically authorized by the prescriber.

Pharmacists are occasionally confronted with a situation where a patient on maintenance medication requests a refill after the authorization has expired (more than one year later on a prescription marked PRN) and when the physician is not available for consulta-

tion. It is the editor's opinion that one refill under these circumstances would probably be in the best interest of the patient with the clear understanding that any more refills must be approved by the prescriber prior to dispensing.

Inspectors occasionally describe a situation where pharmacists have not obtained a signed Schedule II prescription after dispensing a Schedule II drug pursuant to an oral (emergency situation) authorization. Pharmacists need to understand that they are clearly at risk under these circumstances unless they have followed the procedure according to federal regulations. On page 174 of the New Pharmacy Law Book 21 CFR 1306.11(d)(4) states that if the pharmacist has not received the written prescription within 72 hours, the nearest office of the Drug Enforcement Administration must be notified. The telephone number for the Atlanta office of the Drug Enforcement Administration is 404/221-4412.

ITEM 472—REUSE OF GLASS BOTTLES FOR PRESCRIPTION DRUGS

The Consumer Product Safety Commission has issued the following advisory regarding the reuse of glass bottles for prescription drugs which we felt should be brought to your attention. "Section 17.0015(c) of the standards promulgated under the Poison Prevention Packaging Act specifically prohibits the reuse of special packaging in the refilling of prescriptions for drugs subject to the standards. The reason for this prohibition is that plastic closures and containers in which the prescription was originally dispensed to the consumer might well be worn or otherwise damaged within the home to the extent that the original effectiveness specifications might be compromised but not to the extent that such wear or damage would be noted by the pharmacist prior to refilling the prescription."

"While this prohibition is certainly significant in the case of plastic closures fitted on plastic containers, the possibility of wear or undetected damage to glass containers is negligible. Therefore the use of a glass bottle in the refilling of a prescription would not appear to compromise the child-protection embodied in the Poison Prevention Packaging Act. We would not object to such reuse of glass bottles in the refilling of prescriptions, provided that a new plastic closure meeting the standards would be provided with the refilling." (*Apharmacy Weekly*, Volume 20, No. 11). The answer to Quarterly Query is 4., I and II only.

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