JANUARY, 1986

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 504—BOARD DISCIPLINARY ACTIONS

August:

James W. Woodard, Wilmington. Failure to provide supervision to unlicensed employees of Economy Drug Center, Wilmington. License suspended 90 days, stayed 2 years with a 21-day active suspension and other conditions.

Michael Gerald Beane, Lenoir. Dispensing controlled substances to third parties without a valid prescription; appropriating Schedule III and IV controlled substances for personal use without a prescription; removing prescription records from the files of a pharmacy; refilling prescriptions for controlled substances in excess of the amount authorized by law. Pharmacy License Revoked.

September:

'argo Fotos, Kitty Hawk. Board reviewed progress of pharmacist who had a, .red in front of the Board in November of 1984, at which time the case was continued indefinitely. After discussion, the Board determined that Ms. Fotos had complied with the terms of the Judgment and further action is unnecessary.

Anthony D. Batts, Wilmington. Dispensing a prescription drug without a valid prescription. License suspended thirty days, stayed for 1 year.

Kester Woody and Southern Pines Prescription Shoppe, Southern Pines. Permitting an unlicensed individual to fill prescriptions for controlled substances; refilling a controlled substance without proper authorization; dispensing a controlled substance without a valid prescription; improperly labeling containers for prescription medication; dispensing drugs in non-safety closure containers. License suspended 6 months, stayed for 3 years with an active 7-day suspension.

Ronald Ward, Southern Pines. Refilling a controlled substance without proper authorization; dispensing Valium without a valid prescription; improperly substituting generic drugs for brand name medication; dispensing prescription medication in improperly labeled vials. License suspended 6 months, stayed for 3 years with an active 7-day suspension.

October:

Milton Higdon and Smith's Drug Store, Forest City. Dispensing elixir of Terpin Hydrate with Codeine in excessive amounts beyond medical needs. License and permit for Smith's Drug suspended 10 days, stayed three years with certain conditions, one being to submit a written policy for determining when legitimate medical needs exist for Schedule V controlled substances.

ITEM 505—NEW REGULATIONS ON RECORDS, COMPUTERS IN PHARMACY, AND PRESCRIPTION TRANSFERS

Section 21 NCAC 46.1800 PRESCRIPTION REFILLS has been amended by adopting the following provision:

.1806 TRANSFER OF PRESCRIPTION INFORMATION

(a) The transfer of original prescription information for the purpose of re-.ispensing is permissible between pharmacies subject to the following re-quirements:

The transfer is communicated directly between two pharmacists and not by only one pharmacist gaining access to an information file containing data for several locations, and the transferring pharmacist must record the following information:

(1) The word "VOID" or its equivalent on the face of the invalidated prescription which invalidates any remaining refills.

(2) The name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information on the reverse of the invalidated prescription.

(3) The date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) The word "transfer" on the face of the transferred prescription;

(2) All information required to be on a prescription including:

(A) Date of issuance of original prescription;

(B) Number of refills authorized on original prescription;

(C) Date and time of transfer;

(D) Number of valid refills remaining and date of last refill;

(E) Pharmacy's name, address and original prescription number from which the prescription information was transferred;

(F) Name of transferor pharmacist;

(G) The manufacturer or brand of drug dispensed.

(3) Both the original and transferred prescription must be maintained for a period of three years from the date of last refill.

(4) Dispensing is permitted only within the original authorization for refills and no dispensing on such transfer can occur beyond that authorized on the original prescription. Any dispensing beyond that originally authorized or one year, whichever is less, can occur only on a new prescription.

(c) The requirements of (a) and (b) above may be facilitated by use of a computer or data system without reference to an original prescription document. The system must be able to identify transferred prescriptions and prevent subsequent prescription refills at that pharmacy.

(d) This section applies to the transfer of prescriptions issued by prescribers in other states, provided that the pharmacist receiving the prescription is reasonably satisfied that a viable physician-patient relationship exists and dispensing the drug is in the patient's best interests.

(e) All records pertinent to this section shall be readily retrievable.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.32; Eff. December 31, 1985.

Section 21 NCAC 46.2300 PRESCRIPTION INFORMATION AND RECORDS has been adopted as follows:

.2301 PRESCRIPTION/DRUG ORDER REQUIREMENTS

(a) Prescriptions or drug orders shall include, but not be limited to:

(1) date of issuance;

(2) name and, where required, the address of patient;

(3) name, address and telephone number of prescriber except that, indication of the name of the prescriber is sufficient if a data file specified in (b) below is current and in effect;

(4) Drug Enforcement Agency (DEA) number of prescriber in the case of controlled substances;

(5) name, strength, dosage form and quantity of drug prescribed;

(6) refills if authorized or, in institutions, the stop date, and route of administration of drug prescribed, if applicable;

(7) directions for use.

(b) Information in subsections (a)(2), (a)(3), (a)(4) and (a)(6) may be readily retrievable from a data file specifically compiled for use in the pharmacy and not a commercial publication.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.32; 90-106(h); Eff. December 31, 1985

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National Pharmacy

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SENTENCING OF THOSE INVOLVED IN DRUG DIVERSION SCHEMES BEGINS

Most of the individuals involved in the drug diversion scheme, that was recently brought to light in the southeast, are now beginning to make their court appearances and receive sentences for their participation in the various aspects of the drug diversion scheme.

A number of pharmacists, physicians, and drug wholesaler and manufacturer representatives have been sentenced. These individuals have been prosecuted for what the FBI terms "white collar crime."

The following pharmacists have been sentenced up to this time: Tom Atkinson, Atlanta (three years in prison, five years probation, $1,000 fine); Bill Cash, Roswell, GA (six months in prison, five years probation, $1,000 fine); Sam Eskenazi, Atlanta (four years probation, $1,000 fine); Clinton Harwood, Tucker, GA (two years probation, $1,000 fine); Will Maples, Fairfax, Alabama (three years probation, $1,000 fine); John Marzullo, Austelle, GA (eight years probation, $11,000 fine, and 16 hours per week of community service for one year); Richard Pawliger, Smyrna, GA (three years probation, $1,000 fine, and 16 hours per week of community service for six months); Charles Platz, Atlanta (two years probation and $1,000 fine); Jimmy Wilson, Atlanta (six months in prison, five years probation, and $1,000 fine).

Nine of the physicians involved in the drug diversion scheme have also been sentenced to terms of up to five years in prison for their roles in a scheme to sell sample prescription drugs intended for free distribution.

Of the physicians sentenced, the lightest sentence was one of eighteen months probation. Two physicians received substantial sentences. Dr. Carlos S. Contreras, of Dublin, GA was sentenced to five years in prison and $1,000 fine and Dr. Bill L. Wallace of Marietta, GA was sentenced to two concurrent five year terms in prison and $2,000 fine.

All but one of the physicians were required to spend half of their work days in community service treating the poor or training health care workers with no compensation being paid them.

Other individuals charged for their roles in the drug diversion scheme include Stephen Asher, former vice-president of Bindley-Western (a drug wholesaler), who was sentenced to three years in prison plus $1,000 fine; W. Michael Gemmill, former vice-president of Bindley-Western, who received three years in prison plus $1,000 fine; Harry Nail, sales manager of Bindley-Western, who received five years probation, $1,000 fine, and must perform 16 hours of community service per week for eighteen months.

Also sentenced was Thomas Hall, owner of C & H Wholesale Drug in Atlanta, who was sentenced to five years in prison, five years probation and $100 fine. Earl Joseph Coovert, president of Econo-Med, Inc. in Marietta, GA was sentenced to two three-year suspended prison sentences, three years probation, was confined to his home for three months, and ordered to do community service work two days a week for four months. He was also fined $1,000.

Other defendants in the drug diversion scheme will be sentenced in the future.

As can be seen from the above, prison sentences have been substantial as have the fines involved in most of the cases. In addition to the immediate consequences of sentencing, one must keep in mind that all of these persons are now convicted felons under federal law with all of the various legal consequences that stem from that categorization.

Pharmacists should keep in mind that any "deals" on the purchase of drugs that are "too good to be true" usually are.

HEALTH FRAUD, A MAJOR BUSINESS AND A MAJOR CONCERN

As the number of elderly in our population continues to grow, so does the problem of health fraud or quackery. Those involved in health fraud often aim their promotions at the elderly simply because the elderly have a relatively high proportion of health related ailments.

Quackery is not just involved with unapproved drugs, miraculous "cures," and other bizarre activities. Quackery also involves a large number of phony dietary claims and the use of unapproved medical devices.

Health fraud is a big business, a very big business. It is conservatively estimated that health fraud costs senior citizens ten billion dollars a year. The House Select Committee on Aging, chaired by Florida Congressman Claude Pepper, found that senior citizens, aged 65 or over, account for 11% of our population, but at the same time account for nearly 33% of our nation's total health care bill. The average senior citizen spends $3,000 a year on health care.

The Committee's breakdown of medical problems among the elderly gives a rather comprehensive list of the areas that those engaged in health fraud are most likely to zero in on.

> Eighty-four percent of the senior citizens have at least one chronic health problem. Forty-four percent have arthritis. Thirty-nine percent have hypertension. Twenty-eight percent suffer from hearing loss. Twenty-seven percent have a heart condition. Sixteen percent have orthopedic problems. Twelve percent have visual impairments. Eight percent have diabetes.

Because senior citizens often have mobility limitations and have greater difficulty shopping for their health care needs, they often shop through the mail. This reliance on mail order shopping makes them especially susceptible to purveyors of health fraud.

A study funded by the Administration on Aging and the Food and Drug Administration revealed that:

> Seventy-five percent of the U.S. population believes that extra vitamins give pep and energy. Twenty percent believe that ar...

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thritis and cancer are caused by vitamin or mineral deficiencies. Twelve percent have diagnosed their own ailments without consultation with a health professional. Four percent of our population is using a "cure" that was not obtained or recommended from a physician.

It is well known that the elderly have a greater number of medical problems than the population in general. The study referred to above indicates that the population as a whole has a willingness to experiment regarding cures for various diseases. There is yet another reason why many elderly Americans fall prey to medical quackery. That reason is trust. Our senior citizens were generally raised during a period of time when a person's word was his bond and when a handshake cemented many a deal. Other than perhaps at the Diamond Exchanges in Belgium, that situation can no longer be relied upon. Many senior citizens are all too likely to put faith in someone who has a quick smile and a firm handshake.

Further, many Americans, not just senior citizens, believe that if something is advertised on television or in the newspaper it must be t otherwise it would not be allowed to be advertised. The elderly would probably be better off if they had at least a small dose of the skepticism often exhibited by the younger members of our society.

Arthritis and cancer appear to lead the list of diseases where the elderly are particularly susceptible to quackery. It is perhaps that both of these diseases are difficult, if not impossible, to cure or control.

Among the "cures" that have been touted for arthritis are bee venom, snake venom, special diets, special water, copper bracelets, Miracle Mud, Moon Dust (in reality plain old worthless dirt), etc.

Some studies indicate that nearly 90% of all arthritis sufferers try at least one quack remedy.

Cancer is the second area that has been targeted by purveyors of health quackery. Nearly one-third of our population will likely develop cancer at some point in their lives and over 80% of all deaths caused by cancer will be people 54 years of age and older.

In recent years, legitimate scientific research has made enormous strides in fighting cancer, yet Congressman Pepper's Committee estimates that Americans are spending five billion dollars a year on worthless cancer cures.

Some cancer "cures" are simply ineffective while others are dangerous in and of themselves. Of primary concern to legitimate health care providers is the fact that when a cancer patient dabbles with these cancer "cures" they often forego legitimate cancer treatment regimens which have some proven value.

The Food and Drug Administration has primary responsibility for ɔrcement in the area of quackery but spends less than one one-thousandth of one percent of its budget in this area. There are too many quacks who are very skillful at avoiding prosecution. The FDA is simply overmatched. The FBI has done little in the area of health care fraud. The Postal Service, however, has done significant work in this area. Its Inspection Service Unit deals with medical quackery and has actively investigated cases and sought prosecutions where appropriate for various violations of postal service regulations.

Public education is the best tool for preventing health fraud. Pharmacists are in a position to be of great service to their patients in this area. Pharmacists should make every effort to discuss this issue with their elderly patients.

PHARMACISTS ROLE IN ACCIDENTAL POISONINGS

The Consumer Product Safety Commission is the federal agency charged with the implementation of the Poison Prevention Packaging Act of 1970. It is this act that has required child resistant packaging for all prescription drugs and for virtually all household products. The intent of this legislation was to reduce the accidental poisonings of children. Pharmacists, like other consumers, have no doubt struggled with the child-resistant caps on charcoal lighter, paint thinner, windshield washer solvent, and, of course, prescription drugs. While we may have been complaining about the difficulty in dealing with child-resistant caps from time to time, the statistics clearly indicate that the intent of the act has, for the most part, been met. A survey done by the Consumer Product Safety Commission on 1980 emergency room statistics from across the nation indicates that accidental ingestion of aspirin has decreased 65%; controlled substances 58%; and methyl salicylate containing products 61%. Ordinary prescription drugs, however, have declined in accidental ingestions by only 36%.

Does this statistic say something uncomplimentary about pharmacists?

Why is it that the accidental ingestion figures on prescription drugs have not declined to the same extent as for other products?

The CPSC provides several possible reasons for the smaller decline in poisonings from prescription drugs such as the availability of conventional packaging on request of the consumer, consumers leaving child-resistant caps off the container because of difficulty in manipulating them, consumers transferring the contents to a non-child-resistant container, and violations of the child-resistant container requirements by the dispensing pharmacist.

Pharmacists have both a moral and a legal responsibility to fulfill their role in the prevention of accidental poisonings. Pharmacists who fail to comply with the requirements leave themselves open not only to disciplinary action by boards of pharmacy and the CPSC but to some potentially devastating lawsuits.

Pharmacists should keep in mind that the Poison Prevention Packaging Act does not require that the patient request a child-resistant cap. The law requires that the pharmacist provide a child-resistant cap unless a non-safety cap is requested. The statistics appear to show that pharmacists can do more than they currently are doing in the area of poison prevention.

(continued from page 1)

.2302 RECORDS OF DISPENSING

(a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years and shall include, but not be limited to:

(1) quantity dispensed, if different;
(2) date of dispensing;
(3) serial number (or equivalent in an institution);
(4) the identification of the pharmacist responsible for dispensing;
(5) records of refills to date;
(6) documentation of satisfaction of state requirements for drug product selection.

(b) Records in Institutional Pharmacies may be made and kept as part of the patient's medical record.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.26; 90-85.30; 90-85.35; Eff. December 31, 1985

.2303 RECORDS OF PRESCRIPTION FILLING AND REFILLING

In a pharmacy with a manual system, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with a computer or data system, a designation of the dispensing pharmacist accompanied by the daily signature of the pharmacist filling or refilling each prescription is required as noted in .2304(3)(a) or (3)(b). Information must be kept for three years. This does not preclude the use of unlicensed personnel entering information in a data system providing that supervision is maintained pursuant to Board regulations.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; Eff. December 31, 1985

.2304 AUTOMATED DATA PROCESSING SYSTEMS

As an alternative to procedures in Section .2301 and .2302, an automated data processing system may be employed as a record keeping system if the following conditions are met:

(1) the system shall have the capability of producing sight-readable documents of all original and refilled prescription information. The term sight-readable means that a regulatory agent shall be able to examine the records and read the information. During the course of an inspection, the record may be read from the cathode ray tube, microfiche, microfilm, printout or other method acceptable to the Board.

In the case of administrative proceedings before the Board, records must be provided in a readable paper printout form.

(2) such information shall include, but not be limited to the prescription requirements and records of dispensing as indicated in Sections .2301 and .2302 of this regulation.

(3) the individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacy shall have the option of either:

(a) providing a printout of each day's prescription information. That printout shall be dated and the individual pharmacist shall verify that the information indicated is correct and sign the printout in the same manner as a check or legal document (e.g., J.H. Smith, or John H. Smith). Such printout must be maintained three years from the date of last dispensing; or

(b) maintaining a log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of three years after the date of last dispensing.

(4) Documentation in (3) above must be provided in the pharmacy within 72 hours of date of dispensing.

(5) An auxiliary record keeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. When the automated data processing system is restored to operation, the information regarding prescriptions filled, refilled or transferred during the inoperative period shall be entered into the automated data processing system within the time equal to number of inoperative days times three; for example, if the system were inoperative for 5 days then all interim data shall be entered within 15 days of the last inoperative day. However, nothing in this section shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety. The auxiliary record keeping system shall be backed up at least weekly at the discretion of the pharmacist-manager.

(6) Any pharmacy using an automated data processing system must comply with all applicable state and federal laws and regulations.

(7) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.

(8) Pharmacist-Managers in pharmacies with computers or data systems acquired before January 1, 1986, shall comply with these regulations by July 1, 1987. Pharmacist-Managers in pharmacies with computers or data systems acquired after January 1, 1986 shall comply with these regulations immediately.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; 90-107; Eff. December 31, 1985

.2305 SECURITY

To maintain the confidentiality of patients' prescriptions or drug orders, there must exist adequate safeguards or security of the records.

History Note: Statutory Authority G.S. 90-85.6(a); 90-85.36; Eff. December 31, 1985

Please note that the Commission on Mental Health, Mental Retardation and Substance Abuse has a regulation that prohibits the transfer of prescriptions for controlled substances.

ITEM 506—BOARD MEMBER ELECTION

Pharmacist members of the Board are elected for 3-year terms and all licensed pharmacists residing in the state are eligible to vote.

Two terms will expire in the Spring of 1987 and the elections are held year in advance to give any newly-elected member some time to attend Board meetings as an observer. Candidates for these positions must be from either the eastern part of the state which is now represented by Bill Adams or the south central part now represented by W. Whitaker Moose. A committee will consider nominations in February and anyone interested should submit a resume to the Board office prior to February 15.

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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