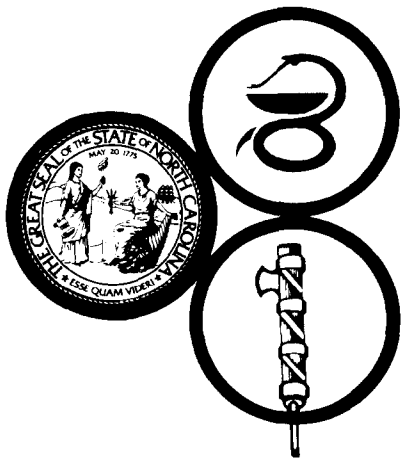
July, 1989



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.

Election Results

The Election to fill Board positions for terms beginning in the Spring of 1990 produced the following results:

District III: Gilbert Colina, 100; Tommy Dagenhart, 319; June McDermott, 421; Wm. Whitaker Moose, 758; and Ron Small, 198.

District IV: C. Foy Bradshaw, 86; Steve Dedrick, 330; Al Lockamy, 649; Christine Rudd, 221; Skip Sykes, 75; Jim Taylor, 100; and Julian Upchurch, 358.

Both Ms. McDermott and Mr. Upchurch have called for a ı-off. Their biographies, along with a ballot and envelope, ɔ enclosed. Please return the ballot before August 21 when they will be counted at an open meeting in the Board of Pharmacy office at about 5 p.m.

The General Assembly adopted a change in the Pharmacy Practice Act effective July 1, 1989 that extends Board terms from three to five years. Candidates elected on this ballot will serve five-year terms that will begin in the Spring of 1990.

Item 614 - Board Disciplinary Actions

February: Henry B. Ridenhour, Salisbury. Reinstatement of License granted with conditions.

Teresa Z. Jones, Fayetteville. Violation of terms and conditions of Board's Final Order of February 16, 1988; indulgence in the use of drugs to an extent that renders her unfit to practice pharmacy; appropriating controlled substances for her own use without obtaining authorization from a physician. License revoked.

Pamela Green, High Point. Indulgence in the use of drugs to an extent that renders her unfit to practice pharmacy; appropriating controlled substances for her own use without proper authorization from a physician. License suspended six months, stayed five years with conditions.

Charles P. Wilson, III, Arden. Reinstatement of License granted with specific conditions.

March: Jimmy Wayne Bryant, Charlotte. Dispensing escription drugs without valid prescription; dispensing of a prescription drug without the supervision of a pharmacist; pleading guilty to felonies in connection with the practice of pharmacy or the distribution of drugs. License revoked.

Steven D. Kiser, Tennessee. Request for Reinstatement of License denied.

April: James A. Sitison, Jr., Winston-Salem. Dispensing controlled substances without valid prescriptions. License suspended for three months, stayed for three years.

William B. Cheek, Hickory. Appropriating Schedule II and Schedule IV controlled substances for his own use without obtaining authorization from a physician. License indefinitely suspended.

Item 615 - Quarterly Query

Before we present the Quarterly Query, a clarification of Item 605 in the April, 1989 Newsletter is in order. Tom Thutt and others alertly pointed out that one response was incomplete because it failed to specify all exceptions under the Poison Prevention Packaging Act. The exceptions Nitroglycerin and Isordil were specified, but several other exemptions, including some effervescent aspirin tablets and some other specific drugs in particular packaging were inadvertently deleted. The Editor regrets the error.

True/False

Prescription labels for anabolic steroids must now bear the statement "**Caution: Federal law prohibits the transfer of this drug to anyone other than the person for whom it is prescribed.**" Answer on page 4.

Item 616 - National Health Practitioner Bank

The Medicare and Medicaid Patient and Program Protection Act of 1987 mandates that the U.S. Department of Health and Human Services establish a data bank containing information about all licensed health practitioners and health entities.

Beginning this summer, it is likely that all licensed health practitioners and health care entities will be required to file data about the following:

Disciplinary Actions - Health Professional Licensing Boards must report disciplinary actions taken against licensed practitioners and health entities.

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National ...acy Co...
and can only be ascertained by examini...

FDA SEEKS HELP OF PHARMACISTS

The increasing complexity of society, the growing proportion of elderly in the population, and the deadliness of new disease conditions all contribute to an expansion and even a redefinition of the pharmacist's traditional role. The value of some elements of that traditional role is being reasserted. The close patient-pharmacist relationship and the pharmacist's vital position as a final healthcare checkpoint have served as strong foundations for the argument that a move out from behind the dispensing counter is timely and necessary. Government agencies, including the Food and Drug Administration, are turning increasingly to pharmacists for assistance in determining and shaping what Americans in need of healthcare do.

For the past few years, the FDA has been conducting extensive research on and testing of condoms. The growth of condom use in response to the AIDS pandemic made such a study not only natural, but increasingly important. Because the effectiveness of condoms is directly related to their age, it is important to determine how old the condoms being stored in U.S. retail pharmacies are. The FDA decided that the Washington State Board of Pharmacy could gather such information, and accordingly contracted with the board to do so.

During 1987, the FDA's internal research and testing program evaluated the mechanical strength, leak integrity, and barrier capability of newly manufactured products. The test samples were unlike the latex condoms readily available to users, and the test results were, therefore, not necessarily generalizable to those products. Limited data suggests that condoms meeting the criteria of acceptability when manufactured, fail at an unacceptable rate when unpackaged. An abundance of anecdotal support for this data implies that the shipping environment and its effect on condom quality needs to be explored.

The FDA now requests the help of all state boards of pharmacy--and all pharmacists--in extending the knowledge that the Washington Board has provided. One objective of the study is to gather data on the age of condoms normally distributed within a state. Although it was initially believed that only limited numbers of older condoms would be available to consumers, preliminary findings indicate otherwise. In the State of Washington, condoms manufactured in 1976 were found in numbers sufficient to allow statistically valid laboratory testing of their residual material properties.

Several state boards of pharmacy are now being asked to direct a special mailing to all pharmacists within their state. The data will be summarized and pharmacists will be asked to furnish information about how many lots of condoms in their pharmacies were manufactured before January 1, 1983, and how many condoms each lot includes. The lot number information on the retail package should provide all the necessary information. Pharmacists participating in the survey are reminded not to limit their investigation to the stock available "on the shelf," because the oldest products are likely to be less accessible--perhaps in the back of storerooms. If a number of overage condoms are found--for instance, if 150 of a single lot were older than the expected shelf life--then the FDA would like to recover these for testing. The data thus derived will be added to the data base.

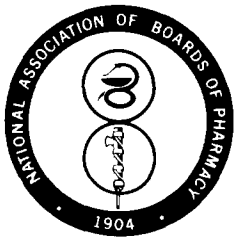
The FDA will compile all data and publish its findings, which will provide vital information. Participation in the survey, however, should demand only minimal effort. All the information gained by the Washington State Board of Pharmacy, for example, was acquired by mail and telephone.

Your state board of pharmacy will keep you informed of t project's progress. The FDA contacts for the study are: Richard E. Gross, Assistant Director, Office of Training and Assistance, Center for Devices and Radiological Health (HFZ-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3446, and Donald E. Marlowe, Director, Division of Mechanics and Materials Science, Center for Devices and Radiological Health (HFZ-150), Food and Drug Administration, 12200 Wilkens Avenue, Rockville, Maryland 20852, telephone (301) 443-7003

ILLEGAL SALE OF VETERINARY Rx DRUGS

Many distributing outlets offer over-the-counter (OTC) drugs intended for animals. No prescription or order from a licensed veterinarian is needed to purchase these drugs. The law stipulates that the drugs be clearly labeled with "adequate directions for use," and defines such directions as those that enable a layman to use the drug "safely and for the purposes for which it is intended." Adequate directions include:

- Statements of all conditions, purposes, or uses for which the drug is intended. These statements may not refer to conditions, uses, or purposes for which the drug can be used safely only under the supervision of a veterinarian.
- Quantity (dosage) of drug to be used.
- Frequency and duration of administration or applicatio including an appropriate withdrawal period, if this is indicated, for food-producing animals.



- Time of administration or application.
- Route or method of administration or application.
- Preparation for use.

As with any drug product, safe use of an OTC animal drug requires a user to **READ THE LABEL** and follow directions carefully.

Veterinary Rx drugs differ in that they require a prescription or other order from a licensed veterinarian. By definition, a layman cannot be given adequate directions for their use.

Often, a drug is assigned an Rx status because the disease that it treats is diagnosed with some difficulty. In other cases, use of the drug is exceedingly complex, and a layman lacks the requisite training and expertise to administer the drug properly. In addition, Rx drugs tend to be quite potent. The margin of safety for use may be narrow, and adverse effects may be common. There may be a great potential for misuse. These factors often prompt serious warning labels.

Animal owners are permitted to purchase only those Rx ıerinary drugs ordered or prescribed by a veterinarian who has diagnosed the animal to receive the medicine and instructed the owner in appropriate drug administration.

Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act requires that drug labeling include adequate directions for the drug's use. Since some animal drugs cannot be labeled with adequate directions for lay use, section 201.105 of the Code of Federal Regulations (by authority of section 502(f)(1) of the Act) establishes a category of Rx animal drugs exempt from this requirement. The regulation stipulates that such drugs must: (a) be in the possession of a person lawfully engaged in the manufacture, transportation, storage, or distribution of veterinary drugs; (b) be sold only to or on the prescription or order of a licensed veterinarian for use in his practice; and (c) bear the statement "Caution: Federal law restricts this drug for use by or on the order of a licensed veterinarian," thus providing safeguards against misuse of potentially dangerous products.

It is a violation of the Act -- and a *federal offense* -- to sell animal Rx drugs without a prescription or other order from a licensed veterinarian. The distribution of animal Rx drugs requires licensing or registration as required by state laws.

Complaints about the illegal distribution, sale, and use of animal Rx drugs should be reported to the nearest FDA office, which will be listed under "United States Government" in the telephone directory. If there is no FDA office in your area, rite the Center for Veterinary Medicine, Division of Compliance, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or call (301) 443-3336.

FDA'S DRUG QUALITY REPORTING SYSTEM

The United States Pharmacopeial Convention, Inc. (USPC) worked with the Food and Drug Administration for 17 years coordinating the publicity and report receipts of the FDA Drug Product Problem Reporting Program. In February 1988, USP-DPPR was born. In this drug problem reporting program, the USPC gathers information from health professionals and makes it available to subscribing manufacturers.

The FDA has reestablished its reporting program, which is now called the Drug Quality Reporting System (DQRS). The FDA has contracted with ERC International, and has announced its intention to target its program to provide more extensive publicity to all pharmaceutical practice specialties than the former system permitted.

Manufacturers affected by the reports are routinely provided with DQRS Reports without charge. As in the past, the Freedom of Information Act entitles anyone requesting a report to receive one. The USPC will distribute reports of product defects only to its subscribers. FDA will be receiving USP-DPPR reports and will follow up with the appropriate investigations.

Product problems can be myriad. The professional is the best judge of what constitutes a problem with a pharmaceutical product or device, and no list of possibilities can be exhaustive. However, some examples of defects are in order.

Wrong or deficient labeling should be reported. So should foreign or particulate matter in liquids and solids, imperfectly manufactured dosage forms, off-color, off-taste, and off-odor. It is also important to report questionable product stability, suspected subpotency or super-potency, defective ventilator valves, pinholes in tubing, occluded cannulas, collapsing catheters, and faulty syringe calibrations.

The primary purpose of the FDA Drug Quality Reporting System is to encourage improvement in the quality of pharmaceutical products and medical devices. The system has other merits, however. Through this reporting system, responsible officials in government and industry can be apprised of potential health hazards. Because pharmacy professionals participate so actively, the appropriate actions can be taken without delay. Defective products may be recalled or withdrawn from the market, or the manufacturing processes that led to the defect can be corrected.

DQRS reports can be submitted to FDA by mail or by telephone. The FDA DQRS 24-hour, toll-free telephone number, is 1-800-FDA-1088.

Continued from page 1

Malpractice - Any entity (insurance company, self-insured hospital, etc.) that makes a malpractice payment on behalf of any licensed health practitioner as a result of a court judgment or out-of-court settlement must report such information to the national data bank.

The data bank will store information about adverse clinical privilege actions taken against physicians or dentists by health care entities, if the duration of such action is thirty days or more. If it wishes, the health care entitiy may also report actions taken against any other health practitioner.

Professional societies of physicians and dentists that assess competency and/or professional conduct are required to report any adverse action taken against one of their members. The professional societies of other health practitioners may, if they choose, report to the National Health Practitioner Bank adverse actions taken against their members.

Health practitioners may obtain copies of their records from the data bank at no cost. The law provides that a copy will be automatically provided to each individual every time data is entered into his or her data bank file. Only state licensing boards, hospitals, and health care entities are permitted to routinely access the data bank.

The law requires hospitals to determine whether data has been filed with the data bank concerning a member of their medical staff or staff holding clinical privileges every two years, and they must determine what data is stored for a physician or dentist granted such privilege. Hospitals may access the data bank as they wish to determine whether health practitioners other than physicians and dentists have had data filed concerning their licenses, competency to practice, and/or professional conduct.

Item 617 - C.E. Audit

For the first time, the Board is auditing a random sampling of 250 pharmacists who renewed their licenses in 1988 to confirm that they actually completed sufficient hours of continuing education to lawfully renew. While the Board has not made a policy decision in the matter, it is reasonable to expect that an annual audit will be conducted. If it is determined that a pharmacist has renewed a license to practice by misrepresenting continuing education hours, the Board will proceed to a hearing or decline to renew that pharmacist's license for the following year for falsification of the renewal application. Retain your continuing education certificates for hours completed so that you may respond to future audits.

Item 618 - Dilaudid Scam

There is an especially clever group of prescription forgers that has operated successfully in North Carolina at least three times over the past several years. In the beginning, the ruse is benign. A "physician" from 15 to 40 miles away from the pharmacy calls ahead about a prescription for a patient. The "doctor" is supposedly out of town and wants to be sure the pharmacy has the drug and is prepared to fill the prescription when it arrives. The forgers use real prescription blanks stolen from physicians' offices and, in one case, from an urgent care center.

The first prescriptions to arrive are for an antihistamine, a cough syrup and tetracycline prescribed for a chest condition. The "prescriber" always calls ahead, always talks with the pharmacist, and always provides normal and proper responses to any questions raised. The prescriptions are picked up by a man or woman in the late twenties or early thirties for an aunt or mother-in-law. They converse with store personnel, purchase health products appropriate to their relative's condition, and always pay with cash.

The scheme gradually progresses from antihistimines/cough syrup/antibiotics to Tussionex. At about this time, the "prescriber" confesses to missing a diagnosis of lung cancer. The patient is described as terminal and the orders move to Dilaudid 2 mg and then to Dilaudid 4 mg, which is the ultimate goal of the scheme.

The set-up time may be as long as one year. The fraud is usually discovered when the pharmacist attempts to call the "physician" and finds that the actual physician does not know the patient.

If you believe this scam is being perpetrated at your pharmacy, contact your local law enforcement agency without delay. Do not attempt to apprehend these individuals. Pharmacists fooled by this scheme have received probation from the Board, but DEA civil fines in federal court have been assessed up to $10,000. For further information, contact Keith Bulla, Supervisor of Agents, Diversion Investigative Unit, State Bureau Investigation.

Answer to the Quarterly Query: False.

Anabolic steroids are in Schedule III in state law, so federal law on labeling does not apply.

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 with 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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