



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 - 564 Disciplinary Actions

October: *Anthony B. Cameron*, Sanford. Two counts of illegal sale of Valium (Diazepam), license ordered surrendered to the Board by the Courts. Request for reinstatement of license denied. November: *Henry B. Ridenhour*, Fontana Dam. Indulgence in the use of drugs to an extent rendering him unfit to practice pharmacy. Indefinite Suspension of pharmacy license with conditions.

William Paul Powell and *C.M.C.P. Inc. d/b/a Community Medical Center Pharmacy*, Mars Hill. Dispensing controlled substances to third parties without a valid prescription; failing to prevent the events described above, when the permit holder knew he should have known violations were occurring; violations of Board's order of September 19, 1984. Pharmacist license revoked, stayed indefinitely with a one year active suspension and other conditions. Pharmacy permit revoked.

January: *James Franklin Killian*, Rougemont. Indulgence in the use of drugs to an extent rendering him unfit to practice pharmacy. The license which was voluntarily surrendered to the Board in August of 1987 shall remain in the custody of the Board indefinitely.

Harry Cooper Lawrence, Monroe. Failure to perform adequately duties as pharmacist-manager. Official Board reprimand.

Teresa Z. Jones, Chapel Hill. Indulgence in the use of drugs to an extent rendering her unfit to practice pharmacy. License revoked, stayed ten years with conditions.

Larry Pope, Winston-Salem. Dispensing drugs without valid prescriptions and failing to maintain adequate records of dispensing prescription drugs. License suspended six months, stayed three years with conditions.

Allen D. Putnam, and *Hook-Superx, Inc. d/b/a Superx Drugs*. Consent Order Entered. Refilling prescriptions for prescription drugs without authorization of the prescribing physician; failing to maintain proper records regarding filling of prescriptions for controlled substances. License suspended six months, stayed two years with fourteen day active suspension and other conditions. No action on permit.

Item 565 - Correction To Item 559, Drug Information Centers

The January issue of this Newsletter contained Item 559 describing university based drug information services that was

inaccurate because it failed to include two services. The East Carolina University Drug Information Center in Greenville (919) 551-4257 and the Drug Information Service Center (DISC) at Bowman Gray North Carolina Baptist Hospital Medical Center, (919) 748-2037, should have been included in that group. The State Newsletter editor regrets his error.

Item 566 - Board Member Elections

Pharmacists residing in the state to have the opportunity to vote for pharmacist members of the Board in the annual spring election. As noted on the enclosed ballot, sent to all pharmacists residing in North Carolina, there are two positions up for election this spring. Please submit ballots to the Board office by May 16, 1988.

President Randall appointed two committees to present at least two names from each district for the ballot. Committee members for District 1, the western part of the state were T. Donald Marsh, Asheville; Jerry McKee, Shelby; Truman Hudson, Gastonia; and Charles Gillespie, Burnsville. This Committee met on Tuesday, February 23, 1988 at the Mountain Area Health Education Center in Asheville. The Committee for District 2 met on Monday, February 22, 1988 at Moses Cone Hospital in Greensboro and was composed of Bill Sawyer, Chapel Hill; Jean Douglas, Greensboro; David Claytor, Greensboro; and, Doug Sprinkle from Advance. Individual pharmacists can be candidates for the district where they live by a timely petition of ten licensed pharmacists.

The ballots will be counted in an open meeting beginning at 5 p.m. on Monday, May 16, 1988 at the Institute of Pharmacy in Chapel Hill.

Item 567 - Quarterly Query

The North Carolina Product Selection Law allows a pharmacist to use an equivalent drug under some conditions. Equivalency under this statute is determined by: I. FDA (Orange Book); II. The Pharmacist; III. Clinical Trials; IV. The Manufacturer; and V. The National Pharmaceutical Council.

Item 568 - Governor Martin Appoints William T. Biggers As Board Member

On February 5, 1988 Governor James G. Martin appointed William T. Biggers, an Asheville attorney, to serve as the public
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National Pharmacy

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DRUG SAMPLES — HANDLE WITH CARE!

Drug Samples assumed a new meaning when the FBI undercover operation in Georgia (Pharmony) revealed an extensive network of drug diversion and corruption. The two year operation uncovered the fraudulent representation of samples for use in hospitals, nursing homes, clinics, pharmacies, foreign countries, and international non-profit organizations.

Defendants in the "Pharmony" investigations had engaged in selling expired drugs, causing the removal of the word "sample" imprinted on some of the capsules and tablets and purchasing sample drugs from physicians for the purpose of reselling those pharmaceuticals to drug stores.

In 1985, the FDA expressed its concern over the abuse and diversion of drug samples to the National Association of Boards of Pharmacy (NABP) in a memorandum. Since that memorandum, various state legislatures have taken action to tighten controls over the distribution of drug samples. At the national level, Representative John Dingell and other concerned legislators have structured House Bill HR1207, which would significantly control the distribution of drug samples.

Pharmacists should be aware of the existing state laws under which they must practice and impending federal legislation. Briefly, here is a summary of the existing state regulations:

Indiana: regulations against the sale of sample drugs and the distribution of expired sample drugs.

Oklahoma: prohibits the sale, barter or buying of any complimentary drug sample and requires recordkeeping for the distribution of samples through properly defined and regulated channels.

Washington: requires manufacturers that intend to distribute sample drugs to register annually and maintain proper record-keeping; provides requirements for the proper and secure storage of drug samples; provides requirements for disposing of surplus, outdated or damaged sample drugs; requires that drug samples can only be distributed upon written request.

Recently introduced state sample drug legislation:

Georgia: relates to the sale and distribution of dangerous drugs and prohibits the sale, exchange of, or offers to sell or exchange complimentary samples of dangerous drugs.

Massachusetts: prohibits the free distribution of medications and vitamins.

Oregon: no person may sell, purchase or trade or offer to sell, purchase or trade any drug sample.

As always, if you have a question about the distribution of drug samples in your state, please contact your board of pharmacy.

FDA PUTS FINAL TOUCHES ON EDUCATION CAMPAIGN

The Food and Drug Administration (FDA) is putting its final touches on a public education campaign on anabolic steroid abuse.

The educational program includes two posters, a brochure, a special bulletin to high school coaches, a radio public service announcement, and a video news release.

The first poster, done in cooperation with the Department of Education, was mailed in January to 91,000 junior high, senior high, and college coaches along with a background article. Also distributed in January was a radio public service announcement by TV wrestling commentator/movie actor/muscleman Jesse Ventura that went to 4,875 radio stations around the country. The FDA believes that its video news release will probably be offered to TV stations by satellite in February or March 1988. A special bulletin to coaches went out in late January as a four-page supplement to the National High School Coaches Athletic Association newsletter. FDA claims that it will reach some 95,000 coaches. A poster titled "Don't Pump Trouble; Stay Away From Steroids," featuring Ventura, will be the follow-up piece to the video and is planned as a September mailing to 91,000 coaches. The brochure, "Anabolic Steroids: Losing at Winning," is aimed at teenagers and will be available from FDA in early 1988. A total of 500,000 copies will be printed; orders for over 100,000 have already been received by the FDA.

CALCIUM CARBONATE TABLETS — BE SURE TO SPECIFY "USP"

Many pharmacists take for granted that the products they utilize in their practice have to conform to Pharmacopeial standards whether or not they bear the initials "USP" on their label. That is true for drugs, but not necessarily for food supplements. Federal and State Food and Drug Acts only recognize as directly enforceable Pharmacopeial standards for products labeled as drugs or drug products. If the item is not considered a drug, compendial standards are not automatically enforceable by law even though the item may be included in the USP or NF.

One of the most common types of products not automatically subjected to compendial standards are the dietary supplements. Dietary supplements are usually regulated as foods (unless they are labeled for therapeutic indications) and there is no food compendium like USP containing enforceable end product standards.

Understanding this legal dichotomy is important to understanding the discrepancies in quality found by University of Maryland College of Pharmacy researchers in a study of the data on the quality of commercial calcium products. This October 1987 study was a follow up to one conducted and published in the February 1987 issue of American Pharmacy. The researchers concluded that a serious problem still exists. They found that a number commercial calcium carbonate tablets failed the USP dissolubility specification. Some products tested dissolved only two or three percent in 30 minutes. The Fifth Supplement to USP XXI

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requires that not less than 75 percent be dissolved in 30 minutes.

Pharmacists have a responsibility to ensure that the articles they purchase are of good quality. If the calcium carbonate tablets they are purchasing are not specifically labeled "USP," the pharmacist should insist on a statement in writing from the manufacturer that the lot does meet Pharmacopeial standards. Such a representation by a vendor might at least be enforceable under contract or commercial law principles in the event a problem should arise.

The USP is the mechanism by which the medical and pharmacy professions control the quality of the articles used in their practice — whether or not the article is technically classified as a drug or food supplement — and whether or not a governmental drug agency can legally enforce the standard under its governing statute.

Pharmacists need to be reminded to specify and insist on USP quality, since ordinary commercial law would then recognize that they did order and dispense an appropriate quality product.

MINOR CUTS, SCRAPES & BURNS — OTC ANTIBIOTICS

The Food and Drug Administration has approved combining antibiotics with anesthetics in first aid products. Although comments received during the rulemaking process expressed concern that the anesthetic component might mask the symptoms of infection and delay treatment by a physician, the FDA called the combination "rational" and noted there is not a single adverse reaction to any such combination products in the records of the FDA's Division of Epidemiology and Drug Surveillance.

Under the new FDA standards, the labeled uses for these combination products are limited to "first aid" for temporary relief of pain or discomfort in minor wounds, cuts scrapes and burns. The label must also warn; "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than one week unless directed by a doctor."

The five approved active ingredients are bacitracin, bacitracin-zinc, chlortetracycline hydrochloride, neomycin sulfate and tetracycline hydrochloride.

1988 EDITION OF USP DI PUBLISHED

The 1988 edition of the *USP DI* is now available. The latest edition includes four (4) new features:

1. The *Medicine Chart*, a full color, 16-page tablet and capsule identification directory has been added. The Chart contains actual size, color photographs of approximately 800 of the most widely used oral solid dosage forms.
2. The legal standards of quality for each drug product (but not the test methods) and the requirements for labeling, storage and

packaging, established in the *Pharmacopeia* itself and applicable to the dispensing situation are reprinted in the monographs of the *USP DI, Volume 1*.

3. Indications are separated by subheadings into "accepted" and "unaccepted" sections within each monograph.

4. *Volume 1* is now divided into two books for easier handling.

The *USP DI* is a comprehensive, clinically relevant, continuously updated reference of drug use information for the health care professional and the patient. In some states, the board of pharmacy requires each licensed pharmacy to keep a current copy of the *USP DI* on its premises. For more information please contact your state board of pharmacy. To order the *USP DI* contact the USP at 1-800-227-USPC.

LARGE VOLUME PARENTERALS (LVPs) — FDA INSPECTIONS

Under provisions of the Food, Drug and Cosmetic Act (the Act), firms (including pharmacies) manufacturing LVPs and distributing them without a prescription or conducting activities beyond the usual dispensing or selling of drugs at retail are required to register, the current good manufacturing practice (CGMP) regulations (21 CFR 211) apply and they are subject to regular inspections under Section 704 of the Act. Firms (including pharmacies) manufacturing LVPs and distributing them pursuant to a valid prescription are within the practice of pharmacy and are exempt from the registration requirements, not subject to biennial inspections or CGMP regulations.

The FDA is concerned about this issue because a survey it conducted in the latter part of 1986 revealed a divergent scope of operations in the manufacture of LVPs. The Agency found that pharmacies were manufacturing LVPs both with and without valid prescriptions. The scope ranged from simple admixing to that of preparing LVPs with non-sterile components.

NABP SELECTS NEW EXECUTIVE DIRECTOR

The National Association of Boards of Pharmacy, the association for state regulatory pharmacy boards, has selected Carmen A. Catizone, M.S., R.Ph., as its new executive director. Catizone was chosen from a field of over 25 applicants, and assumed his new position in January of 1988. For two years prior to his appointment he directed NABP's Test and Measurement program, and was responsible for the NABPLEX national licensure examination, NABP's Federal Drug Law Examination, and the Foreign Pharmacy Graduate Equivalency Examination. Catizone succeeds retiring executive director emeritus Fred T. Mahaffey who has served the association and the profession of pharmacy for over 32 years.

NABP welcomes Gary Anderson, Ph.D., R.Ph. into the role of Test and Measurement Director.

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member of the Board of Pharmacy. Mr. Biggers' term will last until April, 1990. He replaces Joseph B. Roberts, III, a lawyer from Gastonia, who had served as the Board's first public member since February 5, 1982.

Mr. Biggers is a graduate of Western Carolina University and Wake Forest Law School and is in the general practice of law in Asheville. He served in Governor Holshouser's administration as Assistant Secretary in the Department of Administration with responsibilities which included the Administrative Procedures Act. He is married to the former Vicki Lineberger and they have two children, a boy, Taylor, age eight and a girl, Mary Frances, who is two years old.

Item 569 - Prescription Pick-Up After The Pharmacy Is Closed

The Board has regularly received in recent years the question, "Can a customer pick up a prescription which has been properly packaged and labeled after the prescription department is closed and a pharmacist is not on the premises?" After considering the matter at the August 18, 1987 meeting, the members decided that this activity was in the public interest, not prohibited by statute or regulation, and therefore permissible.

The short answer to the question above is "yes".

Item 570 - Preceptors Can Get C.E. Credit

April is a good time to finish your plans for this summer which could include continuing education credit. A pharmacist who serves as a preceptor for a student who obtains at least 400 hours of credit can get five contact hours of continuing education applied to Board relicensure. Forms must be completed at the beginning and end of the internship to be sure that credit is obtained for both preceptor and intern.

For further information, contact Dr. Dan Teat at Campbell University School of Pharmacy, (919) 893-4111, ext. 2262, or Mary Payton, (919) 962-0069 at the UNC School of Pharmacy.

Item 571 - Prescription Transfer Requires Cancellation

Prescription transfers are permitted according to regulations which provide for a significant amount of records at both pharmacies. It is useful to remember that a transfer is just that —

the moving of the prescription from one location to another — and requires cancellation of the prescription at the original location.

It is possible to transfer a prescription for a non-controlled drug as many times as refills are authorized. Controlled substance prescriptions may be transferred only once. The term "prescription copy" is misleading and should not be used. State statute specifically provides that "copies of prescriptions for controlled substances shall not be filled or refilled." The answer to Item 567, Quarterly Query is II., the pharmacist.

Item 572 - Prescriptions By Mail

The January issue of this Newsletter contained a notice of hearing for proposed rules, one of which pertains to prescriptions by mail. Whatever change in regulation the Board adopts, there will remain a prohibition in postal regulations on the mailing of narcotics. Please note that this applies to narcotics which cuts across Schedules but does not apply to all controlled substances.

The Board staff regularly hears vague reports of anecdotes about mail order prescription services. These include the late receiving of prescriptions, incorrectly labeled prescriptions, incorrect dosages or dosage forms, receiving the wrong drugs, unclear directions and receiving drugs not ordered. If you have any such examples — good or bad — of prescriptions by mail, please submit them in writing to the Board's office as soon as possible. As of the copy deadline for this Newsletter, the Board has not yet finalized the language for the new regulation and maximum input is desired.

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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