January, 1991

North Carolina Board of Pharmacy

P.O. Box 459, 620H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 661 – Disciplinary Actions

July: **Richard D. Callicut, High Point.** Dispensing Darvocet-N 100 and Placidyl in excess of the five refills and for longer than the six months permitted for a Schedule IV controlled substances prescription and in significant excess of normal therapeutic use. License suspended ten (10) days, stayed one (1) year.

August: **Martha Ann Hobbs, Kinston.** Appropriating and consuming controlled substances for own use without valid prescription. License suspended indefinitely. Petition for termination of suspension and reinstatement to be considered by Board only after meeting certain specific conditions.

lliam Raymond Francis, Jr., West Jefferson. Failure to renew pharmacist license in a timely manner while continuing to practice pharmacy and failure to display a current license renewal; continuing as pharmacist-manager for a period of time without a valid pharmacist license thereby causing the pharmacies to be operated without a valid pharmacy permit. License suspended 30 days, stayed three (3) years.

September: **Harry Charles Woodfield, III, Raeford.** Appropriating and consuming Schedules II, III and IV controlled substances without a valid prescription. License suspended indefinitely, stayed for five (5) years with an active eight (8) month suspension commencing March 15, 1990 and other conditions.

Steven D. Kiser, Knoxville, Tennessee. Consuming controlled substances for which there was no valid prescription; violation of Board's Order reinstating license dated February 9, 1990. License revoked.

Noah Michael Sites, Raleigh. Appropriating and consuming controlled substances for own use without obtaining authorization from a physician. Current renewal certificate and wallet card shall remain in custody of the Board and Respondent shall not engage in practice of pharmacy in North Carolina pending further proceedings before the Board no earlier than November 20, 1990 and other conditions.

James Clark Cameron, West End. Obtaining all continuing education credits through non-contact programs. Respondent shall not practice pharmacy in North Carolina until he demonstrates compliance with the Board's continuing education statutes and regulations and other conditions.

Pre-Hearing Conference. September 18, 1990. Board accepted recommendation of Mr. Randall. David Montgomery, Kernersville. Misfilling of a prescription. Official Board reprimand.

October: **Teresa Z. Jones, Fayetteville.** Request for reinstatement of revoked pharmacy license. Petitioner has demonstrated that she can safely and properly engage in practice of pharmacy. License reinstated with specific conditions set forth.

Donald W. Beaver & Don's Discount Drugs #3, Kannapolis. Dispensing generic products without authorization. License suspended 60 days, stayed three years with an active seven-day suspension and other conditions. No action on pharmacy permit.

Benjamin Scott Dinkins, Monroe. Pleading guilty to four counts of the distribution of Schedule IV narcotics. License revoked, stayed for remaining period of criminal probation with conditions.

Thomas Andrew Hunter, Matthews. Action did not constitute violations of law and did not constitute a basis in fact for plea of guilty in criminal action. Charges dismissed.

Pre-Hearing Conference. November 20, 1990. Board accepted recommendation of Mr. Randall. P.L. Elvington, Fair Bluff. Plea of no contest to misdemeanor violations of state law involving Medicaid recipients. License suspended 60 days, stayed for the period of the court suspension, which is five (5) years from May 18, 1988.

Richard G. Brame, North Wilkesboro. While serving as pharmacist-manager, a large quantity of Diazepam 10mg was unaccounted for and adequate records had not been maintained; necessary inventory and control of dispensing of all drugs had not been done. License suspended 30 days for improper record keeping, stayed two (2) years with conditions.

Item 662 – New Rules on Pharmacist-Manager Responsibilities

Effective September 1, 1990, pharmacist-managers now have additional responsibilities as a result of the new rules adopted by the Board. When a pharmacy closes or discontinues business, the pharmacist-manager must notify the Board office in writing and specify the closing date. Also, pharmacist-managers must have a plan to preserve the prescription records and pharmaceuticals when there is warning of a natural disaster such as a hurricane.

These responsibilities are in addition to those specified in .1317 and .2502 of the orange Pharmacy Law Book. If you are a pharmacist-manager and do not have a current (orange) law

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National Pharmacy

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and can only be ascertained by examin

Q and A from Rx Legend

In May 1990, *The Rx Legend*, the FDA's guide to statutes and regulations governing the practice of pharmacy, was revised and renamed *An Introduction to FDA Drug Regulation - A Manual for Pharmacists*. The new version does not include the question and answer section that appeared in the original. In response to a growing number of requests from our readers, we will publish portions of the omitted section in this and future "National News Sections."

Q Can a pharmacist accept and return to stock the unused portion of a prescription that a customer may return with a request for refund?

A It is a very dangerous practice to accept and return to stock unused portions of prescriptions (or for that matter, unused portions of over-the-counter drugs) that are returned by patrons. Many state boards of pharmacy have issued regulations specifically forbidding this practice, and FDA endorses the actions of these boards as being in the interest of the public health. Some boards permit return of drugs in unit dose containers which meet USP Class A or B requirements.

There is no doubt that the pharmacist is legally responsible for any hazards of contamination or adulteration that arise from mixing returned portions of drugs with shelf stock. Some investigated drug injuries have been caused by drugs returned by patrons and subsequently resold by the pharmacist.

Q Are investigational new drugs generally available to community and institutional pharmacies through commercial sources?

A An investigational new drug is not available to community and institutional pharmacies from commercial sources. Such drugs are distributed as outlined in the protocol of the investigational study. Under an investigational new drug exemption (IND), the drug may be shipped to the investigator or to a pharmacy working closely with the clinical investigator for dispensing on the orders of the clinical investigator.

Copies of *An Introduction to FDA Drug Regulation - A Manual for Pharmacists* are available from the National Association of Boards of Pharmacy, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068.

Nursing Home Repackaging

The FDA issued the following letter of clarification in response to an inquiry from Marilyn Mitchell, executive director of the Wyoming State Board of Pharmacy, about the repackaging of medications to unit dose containers in nursing homes.

FDA regards the practice of repackaging drugs from a prescription container (as dispensed by a pharmacist to the patient) into unit dose containers as a violation of the Food, Drug and Cosmetic Act, resulting in misbranded drugs.

The rationale for FDA's policy is spelled out in Compliance Policy Guide 7132b.10. Although each unit dose container is regarded as a drug in package form, subject to all requirements of the FD&C Act, the size of the container presents labeling problems. Therefore, FDA has specifically spelled out the labeling requirements that all establishments engaged in unit dose packaging must adhere to. For prescription drugs, they are listed in 7132b.10.

We would not allow the tablets, capsules, etc. in a patient's prescription container to be repackaged into unit dose containers in a nursing home (or anywhere else), even for dispensing to the same patient, because labeling requirements for expiration dates and lot or control numbers could not be met.

The expiration date requirements for unit dose repackaged drugs are listed in 7132b.10 and in 7132b.11. It would be impossible to establish an acceptable (i.e., meet the requirements) expiration date for the unit dose repackaged drugs since 1) the assigned expiration date on the manufacturer's package is unknown, and 2) the effect of the prescription container and environmental influences on the drug cannot be determined or calculated.

Also, since the manufacturer's label is more than likely not on the prescription container (although in some cases it may be, especially when the manufacturer's unit is dispensed), the manufacturer's lot or control number will be unavailable.

Regarding FDA's registration requirements for establishments that repackage drugs, the FDA does require such firms to register with certain exemptions which are identified by regulations 21 CFR 207.10. Please note that one of the exemptions applies to hospitals, clinics, and public health agencies regularly engaged in dispensing prescription drugs under state and local laws which regulate the practices of pharmacy and medicine.

In this regard, a nursing home may be considered similar to a hospital if such an operation is authorized under state law to dispense prescription drugs. Normally, if such an establishment were to repack drugs for use in the immediate facility with no further distribution, registration with the FDA would not be required.

1,000 Fraud–Related Inquiries Reported in Third Quarter

Consumer Affairs Officers at FDA's Office of Regulatory Affairs (ORA) responded to over 1,000 health fraud-related inquiries during the third quarter of 1990. As in the past, weight loss products accounted for the bulk of queries. ORA's "National Health Fraud Activity Report" specifically mentions the blatant ads which state that the mail-order product "Beldoxnol" is "FDA approved," and the heavy promotion for Cal-Ban 3000 which continues despite reports of illness and injury. The major weight-loss concern, however, involved the Phoenix Fiber Cookie.

To a lesser extent, consumers inquired about products promoted for reasons other than weight loss. Promoters of Matol Km purportedly made all kinds of claims for disease prevention and treatment, and in many parts of the United States CANCELL continued to be touted as a cancer cure, despite court actions in Michigan.

)RA found that herbal supplements are being pushed heavily a variety of health conditions, including body building and AIDS, and consumer affairs officers continued to receive reports about hair growth and skin rejuvenation claims for products marketed by NuSkin International in Utah and Global Esthetics in Canada.

In Minnesota, ozone generators prompted considerable concern, sparking complaints from the state chapter of the American Lung Association, the Attorney General's office, and the media. Promotion of the devices in Florida also raised questions amid claims of effectiveness for treatment of cancer, AIDS, diabetes, and other serious diseases.

MPPP Passes with Counseling Language Intact

Months of intense lobbying and hard work paid off for Sen. David Pryor (D-AR) and those organizations that represent pharmacists when Congress approved the Medicaid Prudent Pharmaceutical Purchasing Provisions (MPPP), formerly called the Pharmaceutical Access and Prudent Purchasing Act of 1990 (PAPPA), in the early morning hours of October 27, 1990.

The new law, which was tacked on to the Revenue Reconciliation Act of 1990, is the first piece of federal legislation to require patient counseling and prospective drug utilization and review since the ill-fated Medicare Catastrophic Coverage Act was repealed last year.

Designed to furnish Medicaid recipients with the prescriptions they need while providing them with the necessary knowledge to use the drugs effectively, the MPPP incorporates a unique, two-pronged approach. Drug availability is ensured by requiring drug manufacturers to give state Medicaid programs a specific schedule of rebates as a condition of coverage of their prescription drug products, and the DUR provisions will enable Medicaid patients to get the greatest benefit from their prescription drugs.

MPPP's drug utilization review language is both prospective and retrospective. Those provisions related to patient counseling require pharmacists to offer to counsel Medicaid patients "if in their professional judgment, the patient would benefit from their doing so." The content of the counseling has been left to the pharmacist's professional discretion.

In order to improve the counseling and dispensing practice of health professionals, the drafters of the legislation included an educational outreach program. In addition, the new law provides for demonstration projects on the effectiveness of on-line prospective drug utilization review in assisting pharmacists' fulfilling patient counseling requirements, and on the cost-effectiveness of pharmacists' providing cognitive (clinical) services to patients.

NABP, whose patient counseling guidelines formed the basis for the MPPP's DUR requirements, received special commendation from Sen. Pryor. Stressing the importance of the counseling provisions to the profession of pharmacy, the Senator said, "Pharmacy is the big winner. The inclusion of counseling language in this landmark legislation indicates that Congress recognizes that pharmacists can and do perform valuable health services to their communities."

National Data Bank Update

The National Practitioners Data Bank, which was established through Title IV of the Health Care Quality Improvement Act of 1986 to provide a central source of information about the malpractice, professional review, and licensure actions taken against the nation's physicians and dentists, became operational September 1, 1990.

The Medicaid Patient and Program Protection Act of 1987 served to expand the scope of the data bank to include other health care practitioners, including pharmacists. However, information concerning health care professionals other than physicians and dentists is not being collected as yet.

Those entities able to query the national system include hospitals, professional societies and other health care entities with formal peer review procedures, state licensing boards, a plaintiff's attorney with authorization from the Department of Health and Human Services, the individual practitioner who wishes to review his own file, and federal health care entities.

The data bank will store only those actions that have been taken since the September 1 opening date.

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book in your pharmacy, you should obtain one from the Board office.

Item 663 – Late Renewals

Licenses and permits issued by the Board expire December 31st of each year. However, there is a 60 day grace period provided by statute. Since some pharmacists are habitually late, even with the grace period, Board staff brought this to the Board members for guidance. The members directed that such cases be brought to hearings. Two such cases occurred this year and one is reported in the disciplinary section of this *Newsletter.*

The message is that problems can be avoided by timely renewal of your license or permit.

Item 664 – CE Audit Yields Suspension

For the last two years, the Board has conducted a random audit of pharmacists renewing their license to confirm the validity of the CE claimed on their license renewal. The Board rule requires ten hours of continuing education credit with no more than half of these hours in correspondence courses. The last audit discovered one pharmacist who had more than sufficient hours, but all were in correspondence courses. A hearing was held in September and disciplinary action taken as noted in this *Newsletter.*

Item 665 – Device Rules

Board staff, in conjunction with the North Carolina Society of Hospital Pharmacists, participated in a series of three programs in November 1990 on new rules for dispensing prescription devices. The intent of these rules, effective in September 1990, is to begin the process of controlling prescription devices in generally the same way prescription drugs are controlled. These rules apply only to drugs whose label bears the statement, "Caution: Federal law restricts this device to sale by or on the order of a physician." Dispensing such items requires a device dispensing permit for locations where non-pharmacists engage in this activity. Since a pharmacy permit includes a device dispensing permit, no additional registration is necessary in that case.

If you know of people or businesses in your community where such device dispensing occurs, you should consider notifying them of the new requirement or informing the Board office of the situation with specific information about the devices dispensed.

Item 666 – Interns and Telephone Prescriptions

The question occasionally comes to the Board office concerning the ability of pharmacy students to take new prescriptions by telephone as part of their internship experience. A large part of pharmacy practice involves telephone communication and it is part of the licensure exam in this state. The Board staff considers this to be part of the normal educational process and has no objection to students receiving new prescription orders by telephone or participating in the prescription transfer process.

Please note that prescription transfers involving technicians are not permitted and could produce a disciplinary action against the pharmacist-manager.

Item 667 – Liability for Forgeries

A recent court case in New York describes a situation that is pertinent to North Carolina pharmacists. A state law similar to North Carolina's, requires that a physician's name be printed on the prescription blank.

The litigation occurred when a widow sued a pharmacy alleging that her husband died at the age of 27 due to addiction to prescription drugs. Some prescriptions filled by the pharmacy were forgeries and did not have the printed name of the physician on the blank.

The case has been dismissed in a lower court, but this appellate court ruling, which will allow the case to continue to trial, does set precedence for responsibility in such cases.

Item 668 – Pharmacy Exhibit in New State Museum

The new state museum in Raleigh, which is now being built across the street from the Legislative Building, has plans for a 1925 era pharmacy. This plan was envisioned by W.J. Smith, chairman emeritus of the Pharmacy Museum Committee which is not headed by Milton Whaley. The Committee is seeking authentic items or artifacts which existed and would likely be found in a pharmacy in the 1920s. If you are aware of any such items that are in good condition, you should contact Milton Whaley at 3705 St. Markes Road, P.O. Box 51099, Durham, North Carolina 27717. They are especially interested in any inventory records from that time which include product brand names.

The Museum plans to have educational programs in connection with the pharmacy exhibit, including information on what items were present and why they were in the pharmacy. They expect to have a series of programs with classes on historical matters. These would include the development of pharmacy in this state.

Item 669 – Pharmacists in Saudi Arabia

We are aware that some pharmacists have been sent to Saudi Arabia as part of their military obligation, but we do not know the names of all such individuals. We would appreciate knowing which pharmacists have been stationed overseas pursuant to the Kuwait crisis and their mailing address. Please contact the Board office if you have any information on this matter.

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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