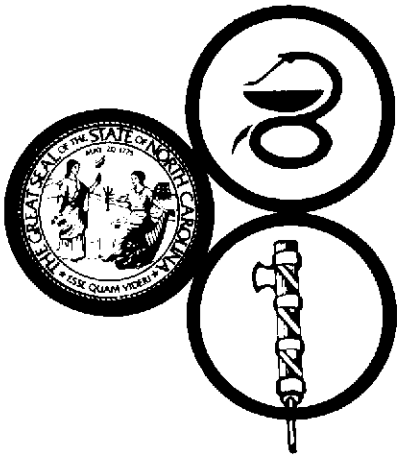
April, 1992



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 710 - Disciplinary Actions

November:

James M. Kinsland, Franklin. Obtaining and consuming controlled substances from the pharmacy stock without authorization. License suspended indefinitely with conditions.

Benjamin Scott Dinkins. Request for reinstatement of license granted.

Michael Lupton, Grantsboro. *Pre-Hearing Conference.* Filling and dispensing prescription medication without an authorized prescription. Recommendation: Letter of Reprimand and four extra hours of continuing education before renewal of 1992 license. Accepted by Board.

Griffin Wakefield, Charlotte. *Pre-Hearing Conference.* Engaging in activity which is a violation of the laws governing the practice of pharmacy and distribution of drugs. Recommendation: Letter of Reprimand and obtain six additional hours of continuing education in order to renew license for 1992. Accepted by Board.

January:

Donna H. Hamilton, Chapel Hill. Forging prescriptions, obtaining prescription drugs without authorization and pleading guilty to obtaining controlled substances by forgery. License revoked, stayed for two years with conditions.

Gregory K. Rice, Durham. License suspended indefinitely, stayed for five years with conditions.

Benjamin K. Mobley, Asheboro. Dispensing controlled substances without valid prescriptions. License suspended indefinitely, stayed for five years with conditions.

Philip B. Cates, Jr., Durham. *Pre-Hearing Conference.* Failure to detect difference between a brand name drug and a generic drug and failure to detect excessive high dosage for a child constituting negligence in practice of pharmacy. Recommendation: Board reprimand and caution. Accepted by Board.

John Kenneth Carter, Tabor City. *Pre-Hearing Conference.* Plea of guilty of driving while impaired. Recommendation: No action taken at the present time as long as John Kenneth Carter abides by the Board's prior Order of June 20, 1989. If violation of that Order occurs, then this plea of guilty of driving while impaired will be considered by the Board. Accepted by the Board.

Item 711 - Narcotics for the Terminally Ill

Press reports of a recent court case involving a judgment for $13 million against a nursing home for failure to administer pain medication to a resident has gained some attention. The Board staff investigated the situation, which occurred in the northeastern part of the state, and concluded that no disciplinary action was warranted against the pharmacist or pharmacy involved.

Since the public reports did not convey the complete story, many pharmacists are concerned about the excessive use of controlled substances, including narcotics, by people who are in the final years of their life. This item reminds pharmacists that their primary responsibility is the health of their patients or customers, and that the alleviation of pain through prescription drugs, including narcotics, is a normal part of medical care.

In short, pharmacists should not fear action from the Board of Pharmacy if they are dispensing substantial amounts of narcotics for a legitimate medical need, such as to relieve pain for patients who will not be with us six months or one year hence due to their deteriorating health.

National Pharmacy

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and can only be ascertained by examinin

CSA Violators - Loss of DEA Registration

On August 1, 1991, the Drug Enforcement Administration (DEA) announced in 56 *Federal Register* 36727-01 that it will clarify regulations proposed in the February 4, 1991 edition of the *Federal Register* to modify 21 CFR 1301.76(a) by adding additional grounds which would prohibit a registrant from hiring an individual for a position requiring access to controlled substances. The additional conditions extend this prohibition to any person who has been convicted of a felony relating to controlled substances, or who has surrendered a registration as a consequence of a controlled substance investigation.

Most of the comments received by the DEA regarding the changes proposed on February 4, expressed concern about the proposed rule's adverse impact on pharmacists who are successfully participating in a state-sanctioned recovery program for chemical dependency. Those commenting suggested that the proposed rulemaking include an exemption for individuals participating in monitored recovery programs.

Responding to these comments, the DEA indicated that the term "registration" was misinterpreted to include any form of regulation or licensure to practice pharmacy in a state. The proposed regulation refers only to individuals who have had a **DEA Registration** denied or revoked, or who have surrendered a **DEA Registration** for cause. Furthermore, since pharmacists are not DEA registrants, but rather agents of DEA-registered hospitals, pharmacies, or other entities, the proposed regulation does not alter current regulatory practices.

The DEA has also confirmed that the regulation would not affect an individual who voluntarily ceased practice (retirement, etc.), or who temporarily surrendered a state license while participating in a state-monitored recovery program. The DEA promises to issue a revised final rule.

FDA Issues Warning on Long-Term or High-Dose Corticosteroid Treatment

The Food and Drug Administration (FDA) has asked the makers of corticosteroid drugs to warn doctors that long-term or high-dose treatment with these products may place patients exposed to chicken pox or measles at increased risk of unusually severe infections or even death.

Commonly prescribed for children in the treatment of such chronic conditions as asthma, allergies, and juvenile arthritis, corticosteroids may suppress the human immune system. While this side effect has been reported with different dosage and treatment lengths, problems have most often been associated with either low-dose prolonged treatment or with moderate-to-high dose treatments of varying durations.

Because the Agency is concerned about this serious medical situation, FDA is requesting that all manufacturers of oral, injected, and inhaled corticosteroids include the following statement in the "Warnings" section of the physician labeling:

> Children who are taking immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chicken pox develops, treatment with antiviral agents may be considered.

FDA told the manufacturers that the "Precautions" section of the physician labeling of corticosteroids should also include the following information for patients:

> Patients taking immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles and, if exposed, to obtain medical advice.

Manufacturers of corticosteroids have been asked to incorporate the "warning" and "precautions" statements into their literature within 90 days.

Patient Counseling - A Must in 1993

As reported earlier in this *Newsletter* ("National New Section," 4th Quarter, 1991), the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) was signed into law on November 5, 1990, amending the 1965 Medicaid law. OBRA '90 conditions states' participation in the federal Medicaid program on the participation of drug manufacturers in state rebate programs, the development of drug use review (DUR) programs, and the implementation of patient counseling requirements.

State DUR programs must include both prospective and retrospective components to ensure that prescriptions for Medicaid patients are appropriate, medically necessary, unlikely to result in adverse medical results, and based upon predetermined standards. Medicaid prescriptions and drug use practices must be reviewed for therapeutic appropriateness, overutilization, underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of treatment, drug-allergy interactions, and clinical abuse/misuse.

Each state must also establish standards for pharmacists to counsel individuals receiving Medicaid benefits. The law specifically requires that the "pharmacist must offer to discuss with each individual receiving benefits under this title, or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long distance calls) who presents a prescription. . ." At a minimum, the pharmacist should discuss:

1. the name and description of the medication;
2. the route, dosage form, dosage, route of administration, and duration of drug therapy;
3. special directions and precautions for preparation, administration, and use by the patient;
4. common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
5. techniques for self-monitoring drug therapy;
6. proper storage;
7. prescription refill information; and
8. action to be taken in the event of a missed dose.

The pharmacist may supplement oral information with written information, but may not use written information alone to fulfill the counseling requirement. OBRA '90 further requires the pharmacist to extend the offer to counsel in person, whenever practicable, and make a reasonable effort to obtain, record, and maintain patient profiles which contain at least the following information:

1. name, address, telephone number, date of birth (or age), and gender;
2. individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
3. pharmacist comments relevant to the patient's drug therapy.

The National Association of Boards of Pharmacy (NABP) believes that Congress' intent in passing the patient counseling provisions of OBRA '90 was to ensure that the pharmacist personally interacts with the patient. The overwhelming majority of representatives participating in the NABP Task Force on OBRA '90 agreed that the pharmacist must personally offer to counsel the patient and cannot delegate this responsibility. **Pending publication of the final regulations from the Health Care Financing Administration (HCFA), the agency responsible for implementing the OBRA '90 requirements, the latest available information indicates that the posting of a sign, notice, or other impersonal means for indicating that the pharmacist is available for counseling are not appropriate and do not satisfy the intent or letter of the Act.**

NABP has been working with other national organizations and government agencies to draft model language to assist the states in implementing the patient counseling and prospective drug use review requirements of OBRA '90. Model regulations have been submitted to the state boards of pharmacy for their review and possible adoption. HCFA will be issuing regulations in the near future. States will need to institute regulations that conform to these requirements.

NABP has also advised states that the patient counseling and prospective DUR requirements should apply to all patients, not only Medicaid recipients, so as to avoid establishing a two-tiered system of health care.

CPSC Surveys Pharmacy Compliance of PPPA

The Consumer Product Safety Commission (CPSC) recently released its findings from a national survey conducted in 1990 to determine the compliance rate of the nation's retail pharmacies with regard to the mandatory safety standard (16 CFR 1700.14(a)(10)), entitled "Substances Requiring Special Packaging - Prescription Drugs," which mandates that child-resistant packaging be used for dispensing prescription drugs to consumers.

The survey found that approximately 45,500 pharmacies nationwide, or 82 percent, were subject to the child-resistant packaging requirement. About 3.2 percent, or 1,460 of these pharmacies, were considered to be noncompliant with the packaging requirements. Approximately 1,310 of the noncomplying pharmacies were located in the eastern United States.

CPSC's objectives were to assure that U.S. pharmacies are dispensing prescription drugs in compliance with the Poison Prevention Packaging Act's (PPPA) standard for oral prescription drugs; to determine the rate of compliance with the PPPA by making undercover purchases of prescription drugs in approximately 200 randomly-selected pharmacies nationwide; and to make statistical projections of the nationwide compliance of pharmacies with the PPPA based on the survey results.

CPSC's recommendations emphasize the importance of complying with the special packaging standard for prescription drugs. The Commission held that pharmacies in violation of PPPA should, to the extent possible, be subject to enforcement actions. The CPSC also urges that licensees in violation of the packaging requirements of the PPPA be disciplined by the state boards of pharmacy.

Item 712 – Quarterly Query

New Board rules on fax transmission of prescription orders allow:

1. The transmission of new prescriptions.
2. The transmission of prescription refills.
3. Refill authorizations.
4. Prescription transfers.
5. All of the above.

Item 713 – Confidentiality of Prescription Records

The Board receives inquiries from time to time about the status of the confidentiality of prescription records. North Carolina general statute provides that prescription records are not public records and can only be divulged to specific people under certain circumstances.

A substantial list follows in the statute (G.S. 90-85.36) and includes a practitioner who is treating the patient, an insurance company who is insuring the patient, Board inspectors, and researchers who have received Board approval.

This issue was of recent concern with a contract circulated by a third-party payor which had a provision stating that the insurance company had access to "all records" in the pharmacy. By signing such a contract, the pharmacist was agreeing to violate state law at the insurance company's request.

The moral of this story is to be sure to read all contracts before you sign them. If you feel any uncertainty, contact a lawyer before entering into such agreements.

Item 714 – Diversion Scheme

DEA officials requested that we alert pharmacists to potential diversion by service personnel who visit pharmacies regularly. One recent incident occurred when a soft drink delivery man routinely stopped in the prescription department for a conversation with store employees. He always attempted to prolong the conversation until he had an opportunity to divert Dilaudid and was successful about half the time.

Although this diverter was caught, others may still be active. You should review your procedures to guard against such activity.

Item 715 – Board Adopts Some Rules, Holds Others

At the February Board meeting, the members adopted two rules which were the subject of a public hearing in January. These rules addressed the number of experiential hours needed by students and a "housekeeping" change to the rules on hospital pharmacies. Neither of these adopted rules have a significant effect on practicing pharmacists.

The Board also postponed action on the proposed rules on patient counselling and on the electronic transfer of prescriptions. Members expressed concern about confidentiality issues regarding prescription transfers. An effort may be made to go to the General Assembly in the short session to change the statute as it pertains to the Board's authority over patient counseling.

Item 716 – Report Thefts, Robberies, Etc.

This is just a reminder that all thefts or robberies of controlled substances should be reported to the Board of Pharmacy and to the Drug Enforcement Administration. You can obtain information about each of these procedures from the Board at 919/942-4454 or the DEA Greensboro office at 919/333-5052.

In addition, all disasters which may affect the strength, purity, or labeling of drugs and devices in a pharmacy need to be reported to the Board without delay.

The answer to the Quarterly Query is 5. All of the above.

Item 717 - May Board Meeting Moved

Although the Board ordinarily meets on the third Tuesday of each month in Carrboro, the May meeting has been planned for Wednesday, May 20th, to coincide with the North Carolina Pharmaceutical Association Convention in Pinehurst. A specific location will be available from the Board office by May 1st.

If you plan to attend, contact NCPA at 1-800/852-7343 for room reservations. Reciprocity will still take place on Monday, May 18th in Chapel Hill.

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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