January, 1994

North Carolina Board of Pharmacy

P.O. Box 459, Carrboro, NC 27510-0459
602H Jones Ferry Road, Carrboro, NC 27510-2165

Published to promote voluntary compliance of pharmacy and drug law.

Item 769 – Disciplinary Actions

July:

Curtis D. Croft (DOB: May 18, 1923) **and Belmont Drug Company, Inc.,** *Belmont.* Allowing unlicensed personnel to dispense prescription drugs without supervision; failure of pharmacy to prevent events from occurring. Pharmacist license and pharmacy permit revoked.

Livvie W. Vann, III (DOB: November 8, 1946), *Burlington.* Order Modifying Final Order and Reinstating of License entered with conditions.

August:

Benford E. Morse (DOB: January 18, 1952), *Elizabethtown.* Obtaining and consuming controlled substances without authorization from hospital pharmacy stock. License suspended indefinitely, stayed five years with conditions.

Richard L. Mercer (DOB: January 19, 1952), *Hamlet.* Order entered denying reinstatement of license.

September:

Charles Edward Earnhardt, IV (DOB: September 26, 1956), *Salisbury.* Mislabeling and misfiling prescription orders; receiving and consuming prescription drugs without authorization of a physician. License revoked.

Sidney Lee Higbee (DOB: April 24, 1951), *North Wilkesboro.* Possessing and dispensing controlled substances illegally. License revoked.

October:

Susan R. Geer (DOB: August 26, 1968), *Charlotte.* Involvement in the illegal sales of controlled substances. License suspended five years, stayed five years with conditions.

Joel Paul James (DOB: June 7, 1943), *Chapel Hill.* License reinstated with conditions.

Gordon Bryant Johnson (DOB: October 3, 1954), *Belmont.* Obtaining, consuming, and dispensing prescription drugs without authorization. License suspended indefinitely, stayed indefinitely with conditions.

Item 770 – May 1994 Board Meeting Date Changed

Due to a scheduling conflict with the NABP Annual Meeting in May, 1994 in Portland, Oregon, the North Carolina Board of Pharmacy's regular meeting will be Tuesday, May 10, 1994.

Item 771 - Proposed Changes in Nurse Practitioner Prescribing

The Board of Nursing and Board of Medical Examiners held a public hearing on November 17, 1993 to consider proposed changes in their prescribing practices. No changes in their rules have been adopted as of the copy deadline for this *Newsletter*. We will keep pharmacists informed with developments in the April issue of the *Newsletter*.

Item 772 – Renewal Reminder

This shall serve as a reminder that any license or permit renewal that has not been received in the Board office by the end of February will be delinquent. The late renewal charge for pharmacy permits is $250, while licensed pharmacists must add $15 to their regular renewal fee if paid after March 1st. No additional notice will be mailed to licensees.

Item 773 – Control Room Temperature - New Definition

The United States Pharmacopeia has proposed a new definition for controlled room temperature as part of their efforts to harmonize standards with other countries, in particular the European community. The proposed new standard, which is scheduled to take effect on January 1, 1994, states that controlled room temperature is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20 to 25 degrees Celsius (68 to 77 degrees Fahrenheit), that results in a mean kinetic temperature calculated to be not more than 25 degrees Celsius, and that allows for excursions between 15 and 30 degrees Celsius (59 and 86 degrees Fahrenheit) that are experienced in pharmacies, hospitals, and warehouses.

Item 774 – Prescription Label

Beginning January 1, 1994, prescription labels must contain a discard date. This date is either the expiration date on the manufacturer's original container or one year from the date the drug is dispensed, whichever comes first. Please guide your conduct accordingly.

Item 775 – Board Hearing on Mail Order Pharmacy

On November 30, 1993, the Board of Pharmacy held a public hearing at the Institute of Pharmacy to consider proposed rules on mail order pharmacy, the confidentiality of prescription information, and the requirement of an appearance at the Board office to obtain a permit or dispensing approval. Most of the speakers at the hearing addressed the subject of mail order pharmacy.

The Board intends to adopt a rule on these subjects at its January meeting.

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy ...mp
and can only be ascertained by examinin

DEA Proposal Would Allow FAXing of Controlled Substance Prescriptions

The Drug Enforcement Administration (DEA) has published a rulemaking proposal (*Federal Register*, Sept. 23, 1993) that would amend its regulations to allow for the FAX transmission of controlled substance prescriptions from the prescriber to the dispenser. As proposed, the regulations would permit the FAX transmission of prescriptions for drugs listed in Schedules III and IV, and Schedule V drugs when a prescription is required. Upon receipt by the pharmacy, a facsimile would be treated as the original prescription and all current requirements (21 CFR 1306.05) regarding the manner in which prescriptions are to be prepared would continue to be applied in the case of a prescription FAXed by the prescriber to the pharmacy.

Currently a pharmacist may dispense Schedule II drugs only pursuant to a written prescription that has been signed by the prescriber. Orally transmitted prescriptions for Schedule II drugs are allowed only in emergency situations subject to certain specific limitations. Under the regulatory changes proposed by DEA, transmission of a Schedule II prescription from the prescriber to the pharmacy would be allowed, but DEA "would require that the original written prescription be presented and verified against the facsimile at the time the substances are actually dispensed, and that the original document be properly annotated and retained for filing."

The proposed rules would allow two exceptions to the requirements for Schedule II prescriptions. The first of these would apply to pharmacies providing home infusion/intravenous pain therapy, where it would "not [be] necessary for the original prescription to be delivered to the pharmacy either prior to or subsequent to the delivery of the medication to the patient's home." The facsimile of the prescription would be treated "as the original document by the home infusion pharmacy" and "must contain all information required by 21 CFR 1306.05(a) including the date issued, full name and address of the patient, and the name, address, and DEA registration number and signature of the prescribing practitioner," as well as any state labeling requirements. This exception would not be extended to oral dosage forms.

The second proposed exception applies to Schedule II prescriptions written for patients in long-term care facilities, which are filled and delivered to the facility by a consulting pharmacy. As in the case of the home infusion pharmacies' exemption, these facsimiles would be treated as original documents.

In proposing to grant each of these exemptions, DEA's intent is to facilitate the prescription communication process in both the home infusion and long-term care environments where patients' medication needs can change rapidly. Implementation of these proposed exemptions would eliminate the need to treat such long-term care and home infusion prescriptions as "emergency prescriptions," which, as defined by 21 CFR 1306.11(d), are limited as to the quantity that may be dispensed. Under current regulations, pharmacists are responsible for ensuring that controlled substance prescriptions "have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

According to DEA, if the proposed rule change becomes effective,

> Some measures to be considered in authenticating prescriptions received via facsimile equipment would include maintenance of a physician's facsimile number reference file, verification of the telephone number of the originating facsimile equipment and/or telephone verification with the physician's office that the prescription was both written and transmitted by the prescribing practitioner. Although such measures parallel efforts currently employed in verifying the authenticity of prescriptions transmitted by traditional means, the requirement of this proposal places an additional responsibility on the pharmacist to take efforts to ensure that the facsimile has been initiated by the prescriber.

DEA is now reviewing the information received during the comment period which ended November 22, 1993. It is anticipated that the Final Rule will be published in the *Federal Register* sometime during the first six months of 1994. Details of the Final Rule will be summarized in this *Newsletter*.

Practitioners should be aware, however, that where an individual state's law or regulations are more stringent than the Federal requirements, the state requirements would apply.

Pharmacy's License Disciplined for Patient Counseling Violations in Iowa

In a recent Iowa disciplinary action with far-reaching implications for the enforcement of OBRA '90's patient counseling mandates, the Iowa Board of Pharmacy Examiners disciplined the license of an Iowa pharmacy. No individual pharmacists employed by the pharmacy received formal discipline. Commenting on the case, the Iowa Board's Executive Director, Lloyd K. Jessen, noted that "this was the first case ever where the Board imposed the maximum fine of $25,000."

Among the violations cited were insufficient staffing levels and adverse working conditions that created an environment

as observed by Board investigators, where staff pharmacists could not possibly comply with Iowa pharmacy statutes and rules. This situation was brought to the attention of the Board by pharmacists employed at the pharmacy.

Staffed by pharmacists and technicians experienced in handling a high volume of prescriptions, the pharmacy's activity averaged 2,000 prescriptions per week. Early in 1993, all three of these experienced pharmacists resigned their positions within one month. They cited the adverse working conditions as the reasons for their resignations. The Iowa Board was not notified of these resignations. Pharmacists hired to replace those who resigned subsequently complained that the pharmacy was severely understaffed for the volume of prescriptions, that the staff could not comply with OBRA '90 or Iowa law, and that dispensing errors were being made. The new pharmacist-in-charge and both new staff pharmacists all resigned.

In their "Conclusions of Law," the Iowa Board cited all applicable sections of the state statute and Board rules pertinent to the case. Among these were Iowa's pharmaceutical care requirements for patient records, prospective drug review, and patient counseling. Other violations included failure to notify the Board of the pharmacy's staffing changes and failure to operate a pharmacy in compliance with applicable laws and rules.

The evidence presented in this case established that the pharmacy violated Iowa Code when changes in pharmacist staffing were not promptly sent to the Board. The changes in staff were not reported until after a Complaint and Statement of Charges was filed. The evidence also established that the pharmacy violated Iowa Code when it allowed severe understaffing of the pharmacy and adverse working conditions, which resulted in the inability of staff pharmacists to comply with the mandates implementing OBRA '90, and caused dispensing errors.

The Decision and Order suspended the license of the pharmacy for a period of 90 days. The suspension was stayed and the pharmacy was placed on probation for a period of three years under the following terms and conditions:

- A civil penalty in the amount of $25,000;
- Submission of monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the pharmacy are maintaining and reviewing patient records and providing patient counseling as required by Board rules. The reports shall include:
  - The weekly work schedule for all pharmacy staff (pharmacists and supportive personnel), and the total number of hours worked by every registered pharmacist and pharmacy assistant each day.
  - The total number of new and refilled prescriptions filled each day.
- The Board is requiring that these monthly reports be submitted during the first year of probation and, thereafter, as directed by the Board.
- The pharmacy must notify the Board if the level of staffing falls below 175 pharmacist hours per week.
- The pharmacy shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.
- The pharmacy shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.
- No pharmacist employed by the pharmacy may supervise any registered intern or act as a preceptor.

In commenting on Iowa's overall OBRA '90 enforcement to date, Jessen noted that, "In Iowa we are making every effort to educate pharmacists about OBRA '90 requirements as part of the inspection process. To date, only a small number of pharmacists have received warnings for failure to comply with Iowa's rules implementing OBRA '90."

Pharmacists Provide Most MedWatch Reports

Since the Food and Drug Administration (FDA) initiated its Med*Watch* voluntary reporting program last July to monitor the safety of regulated medical products, 3,323 reports of serious adverse events and important product problems have been filed with the agency. Of these, 1,838, or 55 percent of the reports, were made by pharmacists. Pharmacists have also accounted for the majority of serious reports. Of the 1,851 reports categorized as "serious," 1,067 were reported by pharmacists.

As a consequence of the Med*Watch* reports, FDA may take a variety of actions. These include "Dear Health Professional" letters; labeling or packaging changes; product recalls; or product withdrawals.

The Med*Watch* 24-hour, seven-day-a-week, toll-free hotline is 1-800/FDA-1088. Reports of adverse events and product problems can also be made on-line through a computer-to-computer interface by calling the FDA computer via a modem at 1-800/FDA-7737 and responding to the questions that appear on the screen. Completed report forms can also be faxed to FDA at 1-800/FDA-0178.

Item 776 – Students Attend Board Meetings

For the past several years, the Board has held its fall meetings (September, October, and November) at a location convenient for students to attend its meetings. This arrangement, which was suggested by Professor June McDermott from the UNC School of Pharmacy, enables students to observe Board activities as part of their educational experience.

Item 777 – Product Selection Opinion

At the Board of Pharmacy's October meeting, Board members were asked to render an opinion on the equivalency of products which differ only in alcohol content. That is, the primary active ingredient in two products would be the same, except that one would have alcohol and one would not. After discussing the matter, the Board decided that such products are not equivalent and, therefore, not interchangeable.

Item 778 – Board Disciplinary Actions

Board investigations have several potential results. First of all, an investigation can reveal that no violations of statute or rules occurred. When this happens, the case is marked closed. If, however, violations are found, there are a number of possible courses of action.

If the matters are minor in nature and relatively easy to correct, it is possible that a letter from the Executive Director to the pharmacist will be all that is necessary to solve the problem. For the least serious matters, a letter of caution is ordinarily issued. For more serious matters, an administrative reprimand is issued.

More serious matters that require some proceeding but not necessarily a full Board hearing can be handled with a Pre-Hearing Conference. This procedure consists of a Board of Pharmacy member hearing the results of an investigation, discussing the matter with the pharmacist, and making a recommendation to the Board for some type of action. This action may be the issuance of a probationary period, a short suspension, or a requirement that the pharmacist pass a jurisprudence exam, etc. This often occurs by a consensus agreement that the pharmacist has agreed to before presentation to members of the Board. The pharmacist always has the right to a full hearing if he or she feels that the Board member's proposal is not acceptable.

The most formal proceeding that can occur is a hearing in front of the entire Board. Disciplinary hearings are conducted during regular meetings, usually the third Tuesday of each month, at the Board's office at 602-H Jones Ferry Road in Carrboro. Members of the Board have no knowledge of any case prior to hearing the material presented at the meeting. This is the only way to ensure that the members maintain the impartiality necessary to make a fair judgment. Prior contact with members by pharmacists or their friends attempting to plead a case will, ordinarily, not be productive. Members who feel that they have been unduly pressured in any given case may, and often do, disqualify themselves from the hearing.

Board actions can range anywhere from the dismissal of charges to the revocation of a license or permit. The Board only has the authority to take action on licenses or permits but does, from time to time, issue a stay order or a suspension under certain conditions, which usually yields a probationary period providing that certain conduct occurs. This conduct ranges anywhere from remaining drug-free, not violating Board statute or rules, passing certain exams such as a law exam, and other conditions. The Board can suspend a license for a specific period of time or indefinitely as it may choose. The term "suspension" generally means that it is temporary in nature, and either for a specific period of time or, if indefinite, reinstatement will be seriously considered at a future date. Revocation is intended to be permanent, although on rare occasions the Board has reinstated such licenses for good cause shown.

Item 779 – Drug Destruction Forms Now Available

Record of Drug Disposal forms for prescription drugs and controlled substances are now available from the Board office. This form may be duplicated and used for community pharmacies' destruction of controlled and non-controlled drugs. Hospitals, clinics, and nursing homes may use this form for non-controlled drugs only. Board staff approval of witnesses and of the method of disposal can only be obtained by returning the form to the Board office. Once this is accomplished, the form will be returned to the pharmacy by the Board and the disposal of the drugs may take place. After approval and destruction of **controlled** drugs have taken place, a copy of the form should be mailed to the Drug Enforcement Administration.

For controlled drugs destruction in hospitals, nursing homes, and clinics, contact Johnny Womble of the Controlled Substances Branch at 325 North Salisbury Street, Raleigh, North Carolina, 27603, 919/715-0652.

To receive a copy of this disposal form and procedures to follow, you may call the Board office at 919/942-4454.

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