October, 1995

North Carolina Board of Pharmacy

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Item 844 – Disciplinary Actions

May

Pre-Hearing Conference Recommendations

Edward Ray Holder (DOB: October 28, 1948), Lillington. Heard by Board Member Moose. Practicing pharmacy without a valid license for most of the calendar year 1994; engaged in the unauthorized use of prescription drugs, including a controlled substance. License suspended ninety (90) days, stayed for five years with conditions. Accepted by Mr. Holder and the Board.

June

William H. Bradburn, Jr. (DOB: April 2, 1946), Shelby. Heard by Board Member Watts. Creating prescriptions without physician involvement resulting in improper record keeping. License suspended sixty (60) days, stayed four years with conditions.

John Thompson Simpson, Jr. (DOB: December 21, 1927), Statesville. Heard by Board Member Randall. Misdirections on a prescription and no patient counseling on this same prescription, which would have probably detected the wrong directions. License suspended thirty (30) days, stayed with a seven-active day suspension and other conditions. Accepted by the Board and Mr. Simpson.

Board Member Watts heard the cases involving the late renewal of the licenses and permits of the following individuals.

Pharmacist License Late Renewal

Mr. Earl Daniel Hart, Jr. (DOB: December 3, 1954), Fayetteville

Mr. Louis H. Weaks (DOB: January 18, 1944), Charlotte

Tara Correll Rhoades (DOB: February 14, 1955), China Grove

David G. Webster (DOB: August 15, 1951), Newton Grove

Linda Catherine Tucker (DOB: January 28, 1965), Laurinburg

Samuel L. George (DOB: April 23, 1945), Four Oaks.

Earle J. Stramoski (DOB: February 11, 1950), Greensboro

The recommendation for each of the above was that the license be suspended for the amount of time surrounding the late renewal of the 1995 license, stayed for a period of three years with the condition that the license be renewed by December 31st of each year of the Stay Order and other conditions. All were accepted by the Board and the pharmacists involved.

Pharmacy Permit Late Renewal

Constance Motlow (DOB: November 30, 1954), Pharmacist-Manager, Lexington Drug Company, Lexington

The recommendation was that the permit be suspended for the amount of time surrounding the late renewal of the 1995 permit, stayed for a period of three years with the condition that the permit for Lexington Drug as well as the license renewal of Ms. Motlow be renewed by December 31st of each year of the Stay Order and other conditions. This recommendation was accepted by the Board and Ms. Motlow.

Personal Pharmacist License & Pharmacy Permit Late Renewal

James Craig Bell (DOB: October 17, 1958) & Townsend Pharmacy, Red Springs

Ralph Harper, Jr. (DOB: February 18, 1942) & Harper's Prescription Pharmacy, Kings Mountain

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharm
and can only be ascertained by exami

DEA Final Rule Implements Domestic Chemical Diversion Control Act of 1993

On August 21, 1995, the Drug Enforcement Administration's (DEA) final rule establishing regulations to implement the Domestic Chemical Diversion Control Act (DCDCA) of 1993 took effect. Designed to provide additional safeguards against the diversion of such chemicals as ephedrine, the new regulations seek to detect and halt diversion by preventing illicit laboratories from acquiring the start-up materials needed for their clandestine activities.

Under the provisions of §1309.21(a) of the final rule, "Every person who distributes, imports, or exports any List I chemical" must register with the DEA. Not subject to these conditions are "those List I chemicals contained in a product exempted by §1310.01(f)(1)(iv)" of the rule. In addition, certain controlled substance registrants, including pharmacies, manufacturers, and wholesalers already registered with the DEA under the Controlled Substances Act, need not register again.

To guard against theft and diversion, the DEA built a number of general security provisions into the final rule. Such List I chemicals as single-entity ephedrine drug products in "retail settings open to the public" must be stocked behind a counter where only employees have access. Initially, the DEA had considered prohibiting the employment of individuals who have been convicted of a felony relating to controlled substances or listed chemicals, or who have been subject to denial, suspension, or revocation of a DEA registration. This position was rejected in favor of requiring the registrant to "exercise caution" when hiring persons who will have access to listed chemicals, who have been convicted of a felony, or who have had an application for a DEA registration denied, had a DEA registration revoked, or have surrendered a DEA registration for cause.

The final rule also underscores the role of the employee in reporting cases of diversion to the employer. In such cases, the employer is instructed to "treat such information as confidential" and to "take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information."

Records of transactions involving List I chemicals must be maintained for four years and List II chemicals for two years. Records for over-the-counter (OTC) transactions should include the name, address, and, if required, the DEA registration number of each party to the transaction; the name, quantity, and form of packaging of the listed chemical; the method of transfer (e.g., "picked up by customer"); and the type of identification used by the purchaser and any unique number on that identification. For transactions that result from the dispensing of a prescription for a listed chemical, a pharmacy's prescription records have been deemed as meeting the record keeping requirement.

The final rule also requires that "for sales to individuals or cash purchases, the type of documents and other evidence of proof [of identity] must consist of at least a signature of the purchaser, a driver's license, and one other form of identification." A record keeping format suggested but not required by the DEA is a bound log book similar to those kept for Schedule V narcotics. The final rule also stipulates that submitted reports must include "a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual."

In response to public comments to the proposed rule, the DEA withdrew a proposed reporting requirement for ephedrine transactions involving the distribution of 375 dosage units or more of such drug products in a calendar month to a person who is not registered with the DEA to distribute or export a List I chemical. However, the DEA still views 375 dosage units as a good benchmark for reviewing whether a transaction involves an extraordinary amount based on the currently recommended dosing levels cited in such compendia as *Drug Facts and Comparisons*, the *USP-DI*, and the *American Pharmaceutical Association (APhA) Handbook of Nonprescription Drugs*.

The DEA noted that it is difficult to estimate how many parties will continue to handle regulated ephedrine products. In its notice of proposed rulemaking, which was published in the *Federal Register* in October, 1994 and became effective on November 10, 1994, the Agency cited several factors affecting their number: 1) a rapidly changing market for ephedrine affected by state laws restricting its availability; 2) the availability of unregulated alternatives to ephedrine; and 3) the intent of the DCDCA to eliminate sales to illegal laboratories.

Since the October announcement, 11 states have enacted provisions to control regulated ephedrine products by making them either prescription-only or controlled substances, and one state has implemented licensure and reporting requirements. Four more states have introduced legislation in this area.

Other reactions to the DEA's action include changes in product inventories by several wholesalers who formerly carried regulated ephedrine products and who now stock only the non-regulated ephedrine combination products. Recent reports indicate that the U.S. Food and Drug Administration is considering moving ephedrine to prescription-only status.

The final rule may be found in the June 22, 1995 *Federal Register*. For more information, contact G. Thomas Gitchel, chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; telephone (202)307-7297.

Research Studies Target Questionable Prescribing Practices and Medication Errors

The General Accounting Office (GAO) recently released the results of its study which found that about 17.5 percent of 30 million Medicare recipients who are not in rest homes or hospitals are prescribed drugs that are unsafe for their age group or that are inappropriate in relation to other prescriptions.

Such inappropriate drug use is common among the elderly, claims the GAO study, because the elderly take more prescriptions and are, therefore, more apt to develop adverse reactions.

The elderly are also more sensitive to some drugs, and the usual drug doses may be too strong for them.

At a news conference about the study, Rep. Ron Wyden (D-OR) blamed inadequate physician training in the treatment of elderly patients, the failure of health professionals to provide patients with complete information about their drugs, and the lack of coordination between physicians and pharmacists for the inappropriate prescribing of drugs to the elderly. "The tragedy in all this," said Wyden, is that the resulting "injuries, deaths, and costs are almost always avoidable."

The July 5, 1995 issue of the *Journal of the American Medical Association (JAMA)* contains two articles, entitled "Incidence of Adverse Drug Events and Potential Adverse Drug Events" and "Systems Analysis of Adverse Drug Events," that report on a six-month study conducted between February and July 1993 of the adverse drug events (ADE) and potential adverse drug events in two hospitals, Massachusetts General Hospital and Brigham and Women's Hospital. Researchers defined an adverse drug event as "an injury resulting from medical intervention related to a drug," and a potential adverse drug event as "incidents with potential for injury related to a drug."

The researchers found that of 4,031 admissions in adult, nonobstetric units during the six-month period, 247 ADEs and 194 potential ADEs had occurred at the two hospitals. Of the 247 ADEs, 70, or 28 percent, were preventable. These numbers translate to an average of 3,566 ADEs and potential ADEs, or approximately 10.9 percent of hospital admissions in the observed units, at each hospital in a one-year period.

According to the study, most errors occurred in the physician ordering stage (39 percent) and the nurse administration stage (38 percent). The transcription and verification stage accounted for 12 percent of the errors, while the pharmacy dispensing stage accounted for the remaining 11 percent. The report noted that,

> Among ordering errors, wrong dose was the most common, followed by wrong choice, known allergy, wrong frequency, and drug-drug interaction .... The most common transcription errors were wrong frequency and missed dose, while the most common dispensing errors were wrong time, wrong drug, and wrong dose. Among administration errors, wrong dose, wrong technique, wrong drug, missed dose, and wrong time of administration were most frequent.

The study also found that 101 different drugs were associated with the medication errors. The most common were morphine sulfate, which accounted for nine percent of all ADEs, meperidine (five percent), and oxycodone (four percent). The drug classes most often associated with ADEs were analgesics (30 percent) and antibiotics (24 percent).

In order to pinpoint the reasons for the medication errors, the researchers studied the proximal causes by individuals and practitioners involved in the drug delivery process. Overall, lack of knowledge about the drug and lack of information about the patient were the two most frequent proximal causes, accounting for 22 percent and 14 percent of all errors respectively. The most common proximal causes related to pharmacy dispensing were faulty drug identity checking (29 percent), and drug stocking and delivery problems (29 percent).

While the study recommended several ways to reduce medication errors, the researchers particularly emphasized the benefits of utilizing computer systems which provide both drug and clinical information to all individuals and practitioners who need the data for drug ordering and delivery. The study report stated,

> Physicians, nurses, and pharmacists need to have a great deal of information about drugs, including mechanism of action, side effects, dosing options, and interactions, to be able to use them wisely and safely. They also need ready access to patient information, such as blood levels, results of laboratory tests, and the amount of narcotics received in the preceding 24 hours. Both kinds of information must be available when they are needed and in a form that is useful .... These problems in information collection, retrieval, and display are those for which computers are particularly suited and about which considerable expertise exists.

The research study also mentioned another recommendation that has been implemented at some hospitals which enhances the pharmacist's role in the "patient care team" through such methods as participating in physicians' rounds.

Although implementing such recommendations would be beneficial, the researchers point out that "further research is needed to determine if such systems changes will, in fact, bring about substantial reductions in drug-related injuries."

FDA Final Rule Removes Theophylline from OTC Status

The Food and Drug Administration (FDA) published a final rule in the July 27, 1995 *Federal Register* that establishes cough-cold combination drug products containing theophylline (i.e. theophylline and ephedrine; and theophylline, ephedrine, and phenobarbital) as not generally safe and effective and, therefore, misbranded for over-the-counter (OTC) use. In addition, the final rule lists in regulation "all OTC bronchodilator ingredients that have been found to be not generally recognized as safe and effective and are misbranded."

Effective January 29, 1996, no OTC cough-cold combination drug products containing theophylline "may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application." The final rule also warns that any such OTC drug product that is in interstate commerce after the effective date will be considered not in compliance with the regulation, and will be subject to regulatory action.

For further information, contact William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; telephone (301)594-5000.

Continued from page 1

Samuel M. Cavanaugh (DOB: October 21, 1927) & Sam's Drug Store, Lumberton

Bradley A. Humphreys (DOB: September 11, 1948) & Northeastern Drug, Camden.

The recommendation for each pharmacy and permit involved was that the license and permit be suspended for the amount of time surrounding the late renewal of the 1995 license and permit, stayed for a period of three years on the condition that the license and permit be renewed by December 31st of each year of the Stay Order and other conditions. All were accepted by the Board and the pharmacists involved.

Joel Allison Ragan (DOB: February 22, 1949), Pfafftown. Removal of prescription drugs from pharmacy stock without authorization. License suspended ninety (90) days, stayed three (3) years with active 15-day suspension of license and other conditions.

Richard L. Mercer (DOB: January 19, 1952), Durham. License Reinstated.

Item 845 – Board Member Election

The ballots cast in the runoff election for District 5 were counted in the Board office on July 17th. The results were certified by the Board of Pharmacy elections as final and appear below.

Robert L. (Bob) Crocker	1,175
W.H. (Bill) Randall	1,005

Mr. Crocker will begin his five-year term in May, 1996.

Item 846 – Critical Doses

One recent report from the Board's rule on reporting of deaths due to drugs dispensed through pharmacies is worth every community pharmacist's close review. A patient received a prescription to treat psoriasis, which was written for Methotrexate 2.5 mg with the directions stating, "Two tablets every 12 hours for three doses each week." The patient who was marginally literate had her husband pick up the prescription. He customarily asked store clerks to make out his checks for him, which is one of the cardinal signs of a marginally literate or illiterate patient. There is no evidence of refusal to accept patient counseling, and the pharmacist had no specific recollection of the event. The patient consumed two tablets every 12 hours for six consecutive days until she was hospitalized. She eventually expired.

The patient obviously understood the directions as two tablets every 12 hours each day in contrast to what the physician had intended. The prescriber meant for her to take two tablets one day in the morning, then two tablets 12 hours later in the evening, and two tablets the next morning. The directions were obviously unclear and subject to several different interpretations. The patient's death was due, at least in part, to Methotrexate toxicity.

This incident brings to mind another occurrence which happened shortly after the Board adopted its rule on the reporting of deaths. In that case, a prescription for Melphalan whose directions were for the patient to consume six tablets for four days each month was incorrectly understood by the patient. The decedent took two consecutive courses for a total of 48 doses, and expired due to the Melphalan overdose.

This underscores the importance of pharmacists counseling patients on prescriptions for anti-neoplastic drugs and other bold therapy with interrupted courses of treatment. Patient counseling will save lives.

Item 847 – Read Prescriber's Prescriptions Carefully

Keith Stewart from Fremont Pharmacy reports that he received a prescription, which was first read as Neurotin 400 mg. A call to the prescriber confirmed the order should have been for Noroxin 400 mg. He accurately pointed out that there is a high potential for confusion between these two drugs, particularly with the similarities in spelling and doses when a prescriber has handwriting which is difficult to read. See the next item.

Item 848 – Stop, Look, and Listen!

The United States Pharmacopeial (USP) has printed a one-page document listing more than 250 drugs with similar names which could cause confusion and dispensing errors. You can receive a copy of this document by sending a postage-paid envelope to the North Carolina Board office at P.O. Box 459, Carrboro, NC 27510.

Item 849 – Faxing Prescriptions

This notice serves as a reminder that Board rules permit the faxing of prescriptions from the prescriber to the pharmacist. With all the potential problems of telephone prescriptions (see previous items), the transmission of prescriptions by fax certainly has much merit. It also gives the pharmacist a paper trail of prescriptions and refill authorizations which might not otherwise be available.

According to the DEA, prescriptions for Schedule II drugs cannot be transmitted by fax. The only exception to this rule is long-term care facilities, which can receive faxes of Schedule II drugs under DEA's rule.

Item 850 – Hurricane Alert

In August of this year, the Board staff sent the following memorandum to many pharmacies located in the eastern part of the state in anticipation of a hurricane. Although the hurricane did not come inland, the concern about proper pharmaceutical procedures remains.

Please review this information because there is still some time left for hurricane season after the arrival of this *Newsletter.* It is also useful to file this information for next year, just in case other such natural disasters come our way.

Continued on page 5

Continued from page 4

August 16, 1995

MEMORANDUM

TO: Pharmacist-Managers

FROM: D.R. Work

SUBJECT: Hurricane Alert and Comment

Weather reports indicate a hurricane offshore that may come inland and do substantial damage. This has the potential to disrupt normal activities in many respects, including health care. The following comment on Board statute and rules is intended to help you respond to any unorthodox situations which may arise. It should be remembered that the purpose of your license is to protect and serve the public, and citizens' needs should be met if at all possible.

Board Rule 21 NCAC 46.1809 specifically provides for an emergency prescription refill of up to a 72-hour supply of maintenance medication or other drugs where the interruption of therapy would produce undesirable health consequences. This applies to all drugs except Schedule II controlled substances. It does not specify that the original prescription needs to be on file at your location, and I believe that the Board would interpret this rule generously under hurricane conditions. Specific provisions are found in the rule and you should refer to that section on pages 64 and 65 of the blue pharmacy law book. **If you wish copies of complete sections** of any statute or rule mentioned in this memorandum, **please fax a request to 919/967-5757,** and one will be provided to you promptly.

The Board's rule on computer records specifies that in the event of down time, a manual system must be implemented. This can be found on pages 77 and 78 of the blue law book.

Pharmacist-managers have a responsibility under section .2502(i) to have a plan to safeguard prescription records and pharmaceuticals in the event of a hurricane. The Board does not expect perfection in this regard but some plan does need to be in place. Chain drug pharmacists or others in large organizations should contact their supervisor to determine company policy on this issue.

Lastly, and we hope this does not occur, the Practice Act provides at G.S.90-85.25 that any disaster or emergency which may affect the strength, purity, or labeling of drugs or devices should be reported to the Board. If this does occur in your pharmacy, you should contact the Board office to obtain a form for such report.

This memo is being sent by fax to all pharmacies in the eastern part of the state who have fax numbers on file with us. **Please share this information** with others in your community who may not have fax capability.

Item 851 – Special Coverage

The following item has been printed at the request of Roy Shackelford, provider relations manager for the Depr ment of Environment, Health, and Natural Resources.

The North Carolina Department of Environment, Health, and Natural Resources operates five programs that cover pharmacy services for low-income individuals who do not have Medicaid or insurance. The HIV Medications Program covers anti-retroviral drugs, Bactrim, Septra, and Dapsone; the Kidney Program covers prescription drugs and OTC items related to end stage renal dosage; the Sickle Cell Program covers drugs related to sickle cell disease; Migrant Health covers drugs prescribed by a physician; and Children's Special Health Services covers drugs and supplies related to chronic illnesses.

Participation in these programs is voluntary, and enrollment is not necessary. If an eligible individual names your store as his preferred provider, you will receive an authorization entitled "Reply to Authorization Request," which tells you what is approved for coverage and for what length of time. Payment is at the Medicaid rate of reimbursement for prescription drugs and medical supplies. OTC items are paid at your usual charge.

For more information, you may obtain a "Pharmacy Billing Guide" from Purchase of Medical Care Services, EHNR, P.O. Box 27687, Raleigh, NC 27611-7687; telephone 919/733-3091.

Item 852 – National Pharmacy Week

You are encouraged to participate in National Pharmacy Week, which is scheduled for October 22-28, 1995. You can obtain information about National Pharmacy Week from several national organizations, including the American Pharmaceutical Association - 202/628-4410, NARD - 703/683-0085, and the National Council on Patient Information and Education - 202/466-6711.

Item 853 – Caffeine Count

Which has more caffeine, Coca-Cola or tea? Pharmacists are asked such questions but often do not have a good reliable source to use for response. One good reference is Bowes and Church's Food Values of Portions Commonly Used, J.B. Lippincott, 1994. It reveals that 12 ounces of Coca-Cola has 46 milligrams of caffeine, while Pepsi has 38 milligrams for the same quantity. Six ounces of brewed coffee has 103 milligrams, and various forms of cappuccino, vienna, chicory, etc., range down to about 25 milligrams. Black brewed tea has 36 milligrams for six ounces, and instant powdered tea has 31 milligrams per one teaspoonful.

Chocolate also has its share of caffeine with six ounces of semi-sweet chocolate chips containing 105 milligrams of caffeine. The amount of caffeine in other forms of

Continued on page 6

Continued from page 5

chocolate ranges down to Hershey's Mr. Goodbar which has five milligrams per 1.75 ounce bar.

Item 854 – Preceptors with Charges

If a student comes to you and requests that you serve as a preceptor, please understand that the Board now has a rule which could affect the credit given to that student. If you have had charges brought against you by the Board in the past or have had court action based on your practice as a pharmacist, the student may not be able to use you as a preceptor.

It is your responsibility to check this matter prior to the student's actual beginning of experience under your supervision.

Item 855 – Late Renewals

The Board office mails out both license and permit renewal forms on or about the first of November. Licenses and permits expire on December 31st of each year. While pharmacists can take advantage of a grace period, it is recommended that you renew your license and permit in a timely manner.

This issue of the *Newsletter* contains disciplinary actions for those pharmacists who did not renew their licenses last year but continued to practice pharmacy in this state. The lesson to be learned is that you need to renew your license on time to avoid getting your name in the *Newsletter.*

Item 856 – DME Inspections

Beginning this fall, all device and medical equipment (DME) permit locations will receive an inspection from Board Investigator Tim Jones. He will review specific areas listed in the Board rules for compliance.

This is a new activity for the Board and its staff, and we trust that it will be implemented with a minimum of problems.

Item 857 – Medicaid Provider Enrollment Information

The Enrollment Section of the Medicaid Pharmacy Program urges all providers to notify them of any changes if they are enrolled in the Medicaid program. Such changes would include IRS number, as well as changes in store name, address, ownership, lease, or management.

If any of these changes occur, it is imperative that you notify the North Carolina Department of Human Resources, DMA, P.O. Box 29529, Raleigh, North Carolina 27626-0529. These changes must be brought to the attention of the Enrollment Section.

Item 858 – Fax Number on Renewals

There is a space on every pharmacy permit renewal form for a fax number at that location. This information was essential when distributing the material contained in Item 850, which discussed procedures during hurricanes and other natural disasters.

It is important that all pharmacist-managers complete the information for all direct-line fax machines. If it is necessary to go through an attendant or manually answer the fax machine at your location, please so indicate on your permit renewal. This procedure will make it possible for the Board office to convey printed information to individual pharmacies in the most efficient manner.

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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