October, 1996

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Item 889 – Disciplinary Actions

May:

Elizabeth M. O'Ham, Charlotte (DOB: October 21, 1962). License reinstated with conditions.

James L. Patterson, Jr., Statesville (DOB: April 30, 1952). Presence of a prescription medication in urine specimen for which there was no written prior prescription by a practitioner acting in the ordinary course of medical treatment constitutes violation of Board's December 18, 1995 Final Decision. License indefinitely suspended with conditions.

Pre-Hearing Conference Recommendations

Gregory Elkins, Charlotte (DOB: February 12, 1966), failed or refused to maintain security in the pharmacy as required by Board rule.

Recommendation: License suspended for a period of three years with conditions. Accepted by Mr. Elkins and the Board.

John C. Read, Asheville (DOB: September 30, 1952), negligent in practice of pharmacy.

Recommendation: Letter of Reprimand for negligence in the practice of pharmacy, and is admonished to be more careful to eliminate future errors. Accepted by Mr. Read and the Board.

Carl B. Tucker, Jr., Florence, SC (DOB: December 26, 1956), unlawfully obtained a Schedule III controlled substance while employed as a pharmacist at Rite Aid Pharmacy in Bishopville, SC.

Recommendation: Comply with all conditions as set forth in the Order entered by the South Carolina Department of Labor, Licensing and Regulation dated February 21, 1996. In addition, Mr. Tucker must notify the North Carolina Board of Pharmacy at least 30 days prior to accepting employment in North Carolina as a pharmacist. Accepted by Mr. Tucker and the Board.

June:

Lisa L. Angel, Raleigh (DOB: June 3, 1968); **Jeffrey Alan Bennett,** Fuquay Varina (DOB: May 1, 1962); and **Drug Emporium,** Raleigh. Failure to offer and provide patient counseling in violation of 21 NCAC 46.2504. License of Pharmacist Angel suspended for four consecutive days to begin no later than July 1, 1996; license of Pharmacist Bennett suspended for a period of seven consecutive days to begin no later than July 1, 1996. No action on the permit to operate Drug Emporium.

Russell V. Cobb, Mt. Airy (DOB: December 5, 1943), request for reinstatement of pharmacy license granted with specific conditions.

Sidney Lee Higbee, North Wilkesboro (DOB: April 24, 1951), request for reinstatement of pharmacy license granted with specific conditions.

John Wesley Saunders, Wendell (DOB: May 30, 1938), Summary Suspension of License entered.

Pre-Hearing Conference Recommendations

Mary Louise Dixon, Raleigh, (DOB: November 29, 1953), violation of Stay Order issued by the Board on March 19, 1991.

Recommendation: Stay Order of March 19, 1991 be lifted resulting in an indefinite suspension of the license to practice pharmacy, and no request for reinstatement of license would be heard by the Board for six months from the date of the Board approval of this agreement. Accepted by Ms. Dixon and the Board.

Harold Grey Smith, Gastonia (DOB: February 2, 1946), filled prescriptions for prescription legend drugs for himself without authorization.

Recommendation: License suspended 90 days, stayed for five years with conditions. Accepted by Mr. Smith and the Board.

July:

John C. Carter, Loris, SC (DOB: February 25, 1946), request for reinstatement of license granted with specific conditions.

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FDA Warns of Contaminated Liquid Acetaminophen

On July 19, 1996, the Food and Drug Administration (FDA) issued an import bulletin clarifying a June 26, 1996 Pan American Health Organization (PAHO) news release which reported on an epidemic of acute renal failure in Haiti that was attributed to contaminated liquid acetaminophen manufactured in that country. Laboratory analysis by the U.S. Centers for Disease Control (CDC) found diethylene glycol, an ingredient used in automobile anti-freeze, in two samples of acetaminophen products with the trade names "Afebril" and "Valodon." According to PAHO, 68 cases of renal failure have been reported, and at least 30 children have died. Affected patients ranged in age from one month to 13 years.

To the FDA's knowledge, these acetaminophen products are not distributed in this country. As a precautionary measure, however, the FDA has asked U.S. Customs agents to be alert for shipments of such products from Haiti.

The FDA has further determined that the glycerin used in the production of these products may have originated in China. Additional investigations regarding the actual manufacturer are being conducted. To assure that U.S. manufacturers do not receive contaminated glycerin, the FDA's Division of Import Operations and Policy is requesting that U.S. Customs agents flag all glycerin importations from China for sampling and examination.

Veterinary Drug Compounding Compliance Policy Guide Available

The Food and Drug Administration (FDA) published a notice in the July 3, 1996 *Federal Register* announcing the availability of a Compliance Policy Guide (CPG) entitled "Compounding of Drugs for Use in Animals," Section 608.400. The CPG contains the FDA's current position and interpretation of the soon-to-be implemented Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), which will allow the compounding and "extra-label" use of approved animal (and human) drugs.

The CPG specified four categories of compounding activities: 1) those that would likely indicate drug compounding subject to regulatory action and be considered "ordinarily of high regulatory priority," 2) those that would indicate excessive risk to public health or to animals or an otherwise adverse risk/benefit ratio and be considered "of high regulatory priority," 3) those that would indicate compounding subject to regulatory action and be considered "possibly of high regulatory priority," and 4) those that would not ordinarily be considered for regulatory action.

This CPG addressing the compounding of drugs for use in *animals* parallels the 1992 CPG addressing the compounding of drugs for use in *humans*. In that document, the FDA declared its intention to exercise its enforcement discretion and initiate federal enforcement actions against those whose activities raise "the kinds of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the [Food, Drug, and Cosmetic] Act." The 1992 CPG also listed the types of activities that would be considered in determining whether to initiate such action.

Single copies of the CPG section 608.400 entitled "Compounding of Drugs for Use in Animals" may be obtained by submitting a written request along with two self-addressed adhesive labels to the Industry Information Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

Comments may be submitted at any time to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857. For further information, contact Richard E. Geyer, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301/ 594-1764.

DEA Removes Pseudoephedrine Exemption

The U.S. Drug Enforcement Administration (DEA) published a final rule in the August 6, 1996 *Federal Register* that removes the exemption for certain products containing pseudoephedrine from the chemical control provisions of the federal Controlled Substances Act (CSA) and the federal Controlled Substances Import and Export Act (CSIEA).

These chemical control provisions, entitled the Chemical Diversion and Trafficking Act of 1988 (CDTA), which amended the CSA and the CSIEA, were passed by the U.S. Congress to control the diversion of certain chemicals necessary for the illicit production of controlled substances. The CDTA established a system of recordkeeping, reporting, registration, and notification requirements that allow the DEA and those in the chemical industry to identify those individuals attempting to divert chemicals for the manufacture of such illicit drugs as methamphetamine and methcathinone.

According to the DEA, evidence of illicit use of pseudoephedrine in the manufacture of controlled substances has risen since 1994, when single-entity ephedrine products became subject to registration, reporting, recordkeeping, and notification requirements pursuant to the Domestic Chemical Diversion Control Act of 1993. The Agency reported that in 1995 the identification of over-the-counter (OTC) pseudoephedrine

products seized from clandestine laboratories and the interception of such products from mail-order shipments increased dramatically.

Previously, the CDTA regulated bulk pseudoephedrine base weighing one kilogram or more, while pseudoephedrine products lawfully marketed or distributed under the federal Food, Drug & Cosmetic (FD&C) Act were exempted from regulation.

Under the final rule, the exemption has been removed for solid dosage form products containing pseudoephedrine alone or in combination with guaifenesin, dextromethorphan, or antihistamines, subjecting these products to the recordkeeping, reporting, registration, and notification requirements found in the CSA. Products containing pseudoephedrine in combination with therapeutically significant quantities of acetaminophen, aspirin, or ibuprofen remain exempt from these regulations. The one kilogram threshold has been reduced to 48 grams pseudoephedrine base (equivalent to 1,953 pseudoephedrine HCl 30mg tablets or 976 pseudoephedrine HCl 60mg tablets), which allows for the sale of a 244-day supply (240mg/day) without being subject to regulation. Additionally, the registration requirement has been waived for retail distributors of below-threshold quantities of regulated pseudoephedrine products to ensure the availability of the drug to legitimate consumers.

The National Association of Boards of Pharmacy (NABP) presented its support of the rule in a December 6, 1995 letter to the DEA. The Public Comments section of the final rule highlighted NABP's comments:

> In response to the NPRM [Notice of Proposed Rulemaking], the National Association of Boards of Pharmacy (NABP) submitted a letter of strong support for the proposed regulations. NABP wrote that a nationwide federal effort, under the auspices of DEA, was necessary to deal with the diversion of such OTC products, and accordingly NABP supports the present effort to bring the diversion of drug products containing pseudoephedrine under control.

This final rule is effective October 7, 1996. For further information, contact Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, DEA, Washington, DC 20537; 202/307-7183.

President Signs MedGuide Legislation

On August 6, 1996, President Clinton signed an appropriations bill which contains a provision requesting that national organizations representing health care professionals, consumer organizations, and the pharmaceutical industry, among others, collaborate to develop a plan of action to achieve the goals of the FDA proposal entitled "Prescription Drug Product Labeling; Medication Guide Requirements" (MedGuide).

Published in the *Federal Register* on August 24, 1995, the MedGuide proposal urged private sector initiatives to "meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006." Should such initiatives not be achieved, the MedGuide proposal stated that "FDA would either: 1) implement a mandatory comprehensive Medication Guide program, or 2) seek public comment on whether the comprehensive program should be implemented, or whether and what other steps should be taken to meet patient information goals."

The recently signed bill requires that the submitted plan: 1) identify goals, 2) assess the effectiveness of current private-sector approaches to provide oral and written prescription information to consumers, 3) develop guidelines for providing such information consistent with assessment findings, 4) contain elements necessary to ensure the transmittal of useful information to consumers (e.g., accurate and comprehensive information; understandable, legible, comprehensible, non-confusing format), 5) develop a quality assessment mechanism, and 6) provide for compliance with relevant state board regulations.

The plan must be submitted to the Secretary of Health and Human Services within 120 days of this provision's enactment for review and acceptance, with implementation to begin within 30 days of acceptance. The legislation also requires a review of private-sector initiatives for achievement of information distribution goals before January 1, 2001.

NABP Home Page Accessible to Practitioners

The National Association of Boards of Pharmacy (NABP) recently opened a home page on Glaxo Wellcome's HELIX network, which provides pharmacists and other individuals with on-line access to such information as a weekly summary of the *Federal Register*, NABP's most recent press releases, and the Association's Mission Statement and Preamble.

Travelers on the Internet can find HELIX at http://www/helix.com/. "Clicking" on the button labeled "Professional Health Information" accesses a registration form that once completed, permits unlimited free use of HELIX. The registration form gives way to the Professional Health Content page, where a click on the "Professional Associations and Organizations" button opens NABP's home page.

HELIX represents NABP's initial introduction to the Internet. In the future, NABP plans to expand its menu of services on the HELIX Home Page.

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Charles Dermont Duffey, Winston-Salem (DOB: September 16, 1949), request for reinstatement of license granted with specific conditions.

Pre-Hearing Conference Recommendations

Robert E. Parrish, Raleigh (DOB: December 22, 1954). Failure to comply with the Board's rule on patient counseling.

Recommendation: Reprimanded and both Mr. Parrish and Eckerd Drugs emphasize their policy that will assure that all personnel employed in the pharmacy are aware of the requirements for patient counseling. Accepted by Mr. Parrish, Eckerd Drug Corporation, and the Board.

Item 890 – Tips on Patient Counseling

One of the most effective ways to counsel a patient who presents a new prescription was developed by the Public Health Service. It suggests such open-ended questions as:

- What did the doctor tell you the medication was for?
- How did the doctor tell you to take the medication?
- What did the doctor tell you to expect?
- Final verification: Just to make sure I didn't leave anything out, please tell me how you are going to take the medication.

Suggestions for refill questions include:

- What do you take the medication for?
- How do you take it?
- What kinds of problems are you having?

Item 891 – Prescribers Treating Family Members

The Board of Pharmacy regularly receives questions about prescribers who write prescriptions for their family members. The following material is presented from the North Carolina Medical Board and is provided for your practice guidance.

It is the position of the North Carolina Medical Board that generally a physician should not prescribe for family members. Treating one's family is not illegal, but the Board wishes to remind physicians that such treatment and prescribing practices may provide less than optimal care for a family member.

Written records should be maintained of all therapies, including but not limited to writing prescriptions for controlled substances and the medical indications for them. The purpose of a medical record is to provide accurate information regarding diagnosis and management of illness, but such recordkeeping is too frequently neglected when a physician manages illness in his or her family.

The Board urges physicians to delegate their own medical care and that of their family members to one or more of their colleagues in order to preclude involvement with governmental regulatory agencies that monitor physicians' prescribing practices. Furthermore,

1. the treatment of immediate family members should be reserved for minor illnesses, and temporary or emergency situations;
2. appropriate consultations should be obtained for the management of major or extended periods of illness;
3. any prescriptions issued should be within the scope of the physician's medical practice;
4. no Schedule II, III, or IV controlled substances should be given or prescribed for family members, except in emergency situations; and
5. appropriate records should be maintained for written prescriptions and/or administration of any Schedule II, III, or IV controlled substances.

Item 892 – Fraud Is Fraud

Many prescription reimbursements are paid by insurance programs, Medicaid, or some form of third-party payor. Every pharmacist knows and cringes at the possibility of a submission error, even one as small as a single-digit error, that can cause a claim rejection. Moreover, flawed claims, particularly monetary or quantity components, can become an issue of fraud. Just ask those pharmacists who failed to acknowledge a correct estimated cost (EAC) when billing Medicaid.

Now claims processors are demanding that a pharmacist submit a prescriber identification number for all practitioners. Unfortunately, a convenient, unique number for most, but not all, practitioners is the Department of Justice/ Drug Enforcement Administration's (DEA) registration number. Consequently, the DEA number is required for payment.

But not all prescribers are issued DEA numbers. When questioned about how to submit a claim with a non-DEA registered prescriber, payors responded with such answers as "make-up a false number," "use the supervising physician's number," or "use your pharmacy's DEA number." Isn't this a bit duplicitous? It seems that the payors are saying to never submit a flawed or fraudulent number that may result in non-payment of potential criminal action, except when the claims processor tells you that "to get paid, you'll have to have a fake DEA number to identify a practitioner." Who's committing the fraud?

(Reprinted from the July 1996 issue of the *Nevada State Board of Pharmacy Newsletter.)*

Item 893 – Do I Need Malpractice Insurance?

Most employed pharmacists believe their employer's insurance policy protects them from professional liability claims. This is often, but not always, the case. The

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employer's policy may or may not cover the pharmacist. The following are some interesting cases in which the pharmacist was not covered by the employer's policy.

- A hospital pharmacist worked in his friend's pharmacy for three hours one Saturday while his friend's wife was having a baby. When a mistake was made, the hospital pharmacist and his friend discovered the drug store policy did not cover "professional liability."
- A pharmacist gave advice to a neighbor at home. The advice was wrong and the employer's policy did not cover this incident because the pharmacist was off-duty at the time he gave the advice.
- Both a pharmacist and a hospital were sued for a drug error. By the time the matter went to court, the hospital was bankrupt. The pharmacist was informed that the hospital had not paid the insurance premium for several years so there was no coverage.
- A hospital sued its own pharmacist to recover $900,000 that the hospital paid because of the pharmacist error.

For your information, professional liability insurance is available through the North Carolina Pharmaceutical Association at 800/852-7343.

(Ken Baker, PhD, JD, General Counsel for Pharmacists Mutual Insurance Company, 800/247-5930, contributed to this item.)

Item 894 – Transfer Scam

The Board office was recently informed of a new scam involving the "transfer" of a prescription. It seems that a person had her prescription bottle in her purse at work. A co-worker obtained access to the woman's purse and took the information off the label. The co-worker went to a second pharmacy and asked for the prescription to be transferred. Although these drugs were obtained fraudulently, it was not discovered until the original patient went to obtain a refill and found that her prescription had been "transferred."

Item 895 – Prescription Load

As reported in the July *Newsletter,* the Board recently adopted a rule which provides that a pharmacist shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety.

The Board staff would very much appreciate hearing from pharmacists, **in writing,** about what they believe to be an excessive number of prescriptions per hour or per day. Please address all comments to:

David R. Work
Executive Director
North Carolina Board of Pharmacy
P.O. Box 459
Carrboro, NC 27510-0459

Item 896 – Refusing to Fill a Prescription

From time to time, it becomes necessary for a pharmacist to refuse to fill a prescription. One good example was brought to the Board's attention when a pharmacist refused to fill a prescription for Trisoralen written by a gynecologist. She suspected that the prescription had been written for use by the patient's husband, and that the physician had not examined his wife. The pharmacist noted the boxed warnings on the package insert and justifiably refused to fill the prescription. The physician involved was irate but eventually understood when the matter was explained to him by staff from the Board of Pharmacy.

Item 897 – Pharmacists in World War II

A study is now underway regarding the activities of pharmacists in World War II. A grant has been issued by the American Institute on the History of Pharmacy to research this subject.

If you have any information about pharmacists and pharmacies who were active during World War II, please contact:

Dennis B. Worthen, PhD
1723 Old Farm Drive
Loveland, Ohio 45140
Telephone: 513/583-5163
Internet connection: worthendb@aol.com

Item 898 – Media Reports

Many of you may have read the article in a recent issue of *U.S. News & World Report* that was critical of pharmacists who fail to catch drug interactions. This is a serious problem.

The Board has received complaints about this issue, and has noted at least one matter that deserves the attention of every pharmacist-manager. The updating of your drug interaction files on your computer is an important matter. The Board did see one case where a drug interaction was not included on the computer's file at all, but was ranked as the most serious interaction in a nationally recognized reference material. The reason for this discrepancy was that the drug interaction file in that pharmacy's computer was over 10 years old and had never been updated. This situation is an invitation for harm to the public and a justifiable malpractice suit. Remember, forewarned is forearmed.

Item 899 – October Board Meeting Date Changed

Due to a scheduling problem, the October meeting of the North Carolina Board of Pharmacy has been changed from October 15, 1996 to October 22, 1996. Please make note of this change.

Item 900 – DME Subcommittee Members Elected

In March 1996, ballots were sent to all durable medical equipment (DME) registrants in the state for representation on a DME subcommittee, which will consist of representatives from durable medical equipment, rehabilitation, and respiratory, along with two members of the Pharmacy Board. The ballots were counted on April 15 in the Board offices in Carrboro.

After certifying the results on April 16, the Board announced that Kathrine Noel will serve as the DME representative, Larry Lankford will be the rehabilitation representative, and Wayne Link will be the respiratory representative. All winners have excellent credentials and will serve their position well.

Item 901 – Limits to Power

Recently, inspectors have received comments from pharmacists regarding the Board's lack of action on fees paid by third-party payors. The North Carolina Board of Pharmacy's sole authority is to regulate pharmacy for the health and safety of North Carolinians. The Board has no jurisdiction over economic matters, and has no authority or power over fees paid by third-party payors. These matters need to be negotiated individually, or influenced through associations or group negotiators, such as the Pharmacy Network.

Item 902 – Two Common Questions

Among the most common questions received at the Board office are those involving the facsimile transmission of prescriptions and the partial filling of prescriptions.

- In the July 1994 *North Carolina Board of Pharmacy Newsletter,* an item appeared on page two that described the current rule on transmitting prescriptions via facsimile. Prescriptions for legend drugs and controlled substances in Schedules III, IV, and V can be transmitted by facsimile machines. It is generally not permitted to transmit Schedule II prescriptions via facsimile. Two exceptions to this rule are when the prescription is transmitted to a home infusion pharmacy, and when a prescription is transmitted to a community pharmacy for delivery to a long-term care facility.
- Most pharmacists are aware of the partial filling of Schedule II drugs and the 72-hour rule. An item in the October 1991 Board *Newsletter* describes an additional provision for the partial filling of Schedule II prescriptions. It is possible to partially fill prescriptions for Schedule II drugs for up to 60 days under two circumstances: 1) for patients in long-term care facilities, or 2) when the patient is terminally ill. In each case the pharmacist should note on the record that the patient is either in a long-term care facility or terminally ill. By using this provision of the federal rules, pharmacists can provide Schedule II prescriptions for people who are in need on a regular basis if the prescriber indicates a large enough supply to handle the situation.

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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