October 1997

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 945 – Disciplinary Actions

June

Full Hearing

Charles E. Zimmerman, Kitty Hawk (DOB: January 20, 1958). Request for reinstatement of pharmacist license denied.

Sharon Spivey Davis, Asheville (DOB: January 6, 1954). Consent Order entered. License on probationary status for two years with conditions.

Rebecca B. Stryon, Pine Level (DOB: February 5, 1954). License to practice pharmacy reinstated with specific conditions.

Pre-Hearing Conference

Jeffrey K. Galloway, Wadesboro (DOB: November 1, 1962). Ingestion of controlled substances without a physician's order; failure to make and keep adequate records relating to the dispensing of controlled substances; indulgence in use of drugs to an extent that rendered him unfit to practice pharmacy. ***Recommendation:*** License suspended indefinitely. Accepted by Mr. Galloway May 8, 1997; accepted by the Board June 16, 1997.

Robert Earl Baxley, Bladenboro (DOB: February 24, 1944). Ingestion of controlled substances without a physician's order; failure to make and keep adequate records relating to the dispensing of controlled substances; indulgence in use of drugs to an extent that rendered him unfit to practice pharmacy. ***Recommendation:*** License suspended 90 days, stayed five years with conditions which included a 30-day active suspension of the license. Accepted by Mr. Baxley April 16, 1997; accepted by the Board June 16, 1997.

July

Full Hearing

Thomas James York (DOB: May 4, 1952). Committed numerous errors in the practice of pharmacy while employed at a pharmacy in North Carolina. License suspended indefinitely.

Item 946 – Board Web Site (www.ncbop.org)

By the time this newsletter reaches pharmacists, a Board web site for current information will be available. Pharmacists can find meeting schedules; examination schedules, including deadlines; an index to Board newsletters; material from the current "Pharmacy Laws of North Carolina" publication; and other updates on the site. We look forward to your response to this new service.

Item 947 – NTI Drugs

The General Assembly amended the Pharmacy Practice Act to provide for a class of drugs to accommodate the narrow therapeutic index concept. Patients consuming these drugs need to be treated somewhat differently than the average patient. If an individual is consuming one of these drugs, the pharmacist cannot substitute another manufacturer's product without receiving the consent of the prescriber and the patient. The April 1996 Board newsletter has a list of drugs which, although not under strictly the same category, should still be substituted with caution.

The Secretary of Human Resources, with guidance from the boards of pharmacy and medicine and the state health director, will determine what drugs are on the list. Although the list will be published in January, it will be available earlier on the Board's web site.

Item 948 – Drugs in Adult Care Homes

Pharmacists with the Division of Facility Services have called to our attention certain state rules which affect pharmacy practice in adult care homes. Problems continue to be found in labeling and relabeling pharmaceuticals in adult care homes. The labeling of these items is the pharmacist's responsibility and cannot be delegated to unlicensed personnel in adult care homes. Facilities must have a procedure in place to identify direction changes on medical labels and for relabeling needs to be within a 60-day time frame. This problem is most frequently found in community or retail pharmacies serving these facilities.

Problems continue to be seen in situations where patients take a "leave of absence," such as a home visit or vacation, from the adult care home. In such situations, pharmacists should not recommend to facility personnel that they prepare the medications for the leave of absence. Rather, pharmacists should dispense a separate supply of medication for that leave of absence.

Pharmacists may want to obtain a release for using non-child-proof containers since many of the "bingo cards" and other dispensing systems do not meet child-resistant packaging standards.

Apparently some labeling problems still occur with regard to generic and brand name products. If a generic drug is in the container, the Board staff's position is that the generic name must be on the label. This does not absolutely preclude the use of the brand name on the label, but it must be clear to everyone that the generic drug is in the container. One example is "Diazepam used for Valium." Regulations for long-term care facilities require the name of the drug dispensed and a statement of generic equivalency be placed on the label if a brand other than the brand prescribed is dispensed. Contact the Group Care Licensure Section Division of Facility Services at 919/733-6650 or 704/232-5084 with any questions.

National Pharmacy

(Applicability of the contents of articles in the National Pharma... com
and can only be ascertained by examinir

FDA Relaxes Standards for TV and Radio Promotion of Prescription Drugs

The Food and Drug Administration (FDA) published a proposed guidance in the August 8, 1997 *Federal Register* for television and radio advertising of prescription drugs. The new guidance will permit drug companies to notify consumers of a prescription drug's benefits if the company also provides information about any major risks and instructions on how consumers can easily obtain more detailed information about the drug's approved uses and risks.

Previously, drug companies could either name the prescription drug or identify the condition being treated, but could not do both in the same advertisement unless they also scrolled a brief summary of the prescribing information. This information included side effects, contraindications, and effectiveness. In its statement announcing the new guidance, the FDA acknowledged that "providing this amount of information in television and radio advertising is far more difficult [than in print advertisements] because of the time and space constraints."

"[The FDA's] action can help promote greater consumer awareness about prescription drugs," noted FDA Lead Deputy Commissioner Michael J. Friedman in the agency's statement. "By describing realistic standards for television advertising of prescription drugs, we hope to end the uncertainty which has plagued both consumers and industry about the use of this medium."

In its notice describing the new guidance, the FDA suggested one multi-faceted approach that drug companies could use to satisfy the legal requirements for their broadcast advertisements:

- A toll-free telephone number for consumers to promptly access detailed product information either by mail, fax, or phone.
- A reference to print ads that contain a brief summary of the product labeling. The broadcast ad could also reference brochures that contain similar information if they are distributed in a variety of publicly available sites, such as doctor's offices, libraries, and stores.
- An Internet web page address that provides full access to the approved product labeling.
- A statement that pharmacists and/or physicians can provide additional information about the drug product.

Advertisements for Glaxo Wellcome's Valtrex and Hoechst Marion Roussel's Allegra began airing soon after the FDA's announcement, with other drug products being considered for the new ad formats. Several drug companies are still reviewing the usefulness of the new formats. They are questioning the length and expense of the ads that would be required to meet the new requirements, the effectiveness of the advertisements in attracting consumers, and the benefits of broadcasting ads for drug products that have serious potential health risks.

The FDA will continue to evaluate the effects of its new guidance over the next two years to determine whether modifications are necessary. Individuals interested in commenting on the guidelines may write to the FDA at Dockets Management Branch (HFD-305), FDA, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857.

Senior-Adult Packaging Requirements Effective January 1998

Beginning January 21, 1998, all prescriptions, including those packaged by pharmacists, must be dispensed in accordance with the Consumer Product Safety Commission's (CPSC) new senior-adult, child-resistant packaging requirements.

As specified in Title 16 of the Code of Federal Regulations (CFR) Part 1700.15, the CPSC has revised the protocol standards used for product testing to include greater representation of senior adults, ages 50 to 70, in order to determine whether they can open the product more easily. The protocols will continue to include child testing to check if a package is also child-resistant.

When ordering packaging supplies, pharmacists must obtain assurances from their suppliers that the packaging has passed the CPSC's senior-adult testing protocols. The CPSC does not specifically approve packaging; instead, it establishes protocol requirements which must be met by packaging manufacturers.

The January 1998 effective date of the new packaging rule ends an 18-month stay of enforcement from the senior-adult requirements. Questions regarding the packaging rule should be directed to Laura E. Washburn, Division of Regulatory Management, CPSC, Washington, DC 20207; telephone 301/ 504-0400, ext. 1452.

Free Brochure Addresses Prevention of Inhalant Abuse

The U.S. Consumer Product Safety Commission (CPSC), in concert with the Partnership for a Drug Free America, has published "A Parents' Guide to Preventing Inhalant Abuse," a brochure which educates parents about the incidence, dangers, and prevention of inhalant abuse. The new publication was developed in response to reports from the National Institute on Drug Abuse that one in five teenagers have used inhalants to get "high."

Inhalant abuse is the deliberate inhalation of common household products to obtain a "high." Such abuse can lead to permanent brain damage, loss of muscle control, and destruction of the heart, kidneys, liver, and bone marrow. Commonly abused products include glues/adhesives, nail polish remover, marking pens, paint thinner, spray paint, butane lighter fluid, gasoline, propane gas, typewriter correction fluid, household cleaners, cooking sprays, deodorants, fabric protectors, whipping cream aerosols, and air conditioning coolants.

"A Parents' Guide to Preventing Inhalant Abuse" is available free of charge. Up to 200 copies may be obtained from the National Inhalant Prevention Coalition at 1-800/269-4237. To order more than 200 copies, write to Publication Request, U.S. Consumer Product Safety Commission, Washington, DC 20207, and request Item #389. The brochure is also available on CPSC's web site (http://www.cpsc.gov) in the "What's Happening" and "Consumers" sections.

USP Offers Medication Counseling Behavior Guidelines

The U.S. Pharmacopeia (USP) has developed Medication Counseling Behavior Guidelines to assist health care providers in effectively communicating important drug information to their patients. The Guidelines provide definitions of counseling terms and discuss patient outcomes, skill evaluation, curricula, current practices, incentives and barriers, and patient perceptions and needs, particularly the needs of special population groups. They can also serve as a baseline for measuring the communications capabilities and effectiveness of health care providers.

According to USP Executive Vice President Jerome A. Halperin, the Guidelines support the goals of the Action Plan put forth by the federally appointed Steering Committee for the Collaborative Development of a Long Range Plan for the Provision of Useful Prescription Medicine Information.

The Guidelines can be accessed on the Internet at http://www.usp.org, or copies can be requested by contacting the Division of Information Development at 301/816-8351.

FDA Warns Consumers About Dietary Supplements Containing Digitalis

In June 1997, the Food and Drug Administration (FDA) issued a warning to consumers not to purchase or ingest certain dietary supplements containing "plantain." The warning cautioned that the products may contain digitalis, the botanical source of the active ingredient found in the cardiac glycoside drug, digoxin.

The FDA detected digitalis in samples of raw material labeled "plantain" that had been used by various manufacturers as a dietary supplement ingredient and that had been distributed to retailers for use in tea products. The effects of digitalis ingestion may include nausea, vomiting, dizziness, headache, confusion, hypotension, vision disturbances, and abnormal heart rate and rhythm.

To obtain information about distributors or manufacturers of bulk single-ingredient plantain and trade-name products which may contain digitalis, as well as retailers that have purchased suspect plantain, contact the FDA's consumer hotline (1-800/FDA-4010) or access the Dietary Supplements section of the FDA "Foods" website on the FDA homepage (http://www.FDA.gov/).

More States Grant Pharmacist Collaborative Practice Agreements

The National Association of Boards of Pharmacy (NABP) recently conducted a survey of the boards of pharmacy which found that in the past year, more states have taken legislative measures to provide pharmacists with collaborative practice and/or prescriptive authority.

Compared to early 1996 when, as reported in this "National Pharmacy Compliance News," 10 states had granted their pharmacists some form of collaborative practice and/or prescribing authority, NABP's survey found that 18 states now grant such authority to their pharmacists. Fifteen of these 18 states are allowing their pharmacists to develop collaborative practice agreements with prescribers, which allow pharmacists to initiate or modify patients' medication regimens pursuant to an approved protocol. As for the remaining three states, Florida grants pharmacists independent authority to prescribe medications from a limited formulary, Indiana allows pharmacists in hospital settings to adjust certain drug therapies pursuant to hospital protocols, and Michigan allows "prescribers" to delegate prescribing authority to "other licensed health professionals." In addition, 15 states or jurisdictions (i.e., Puerto Rico) are currently developing or reviewing proposals to grant pharmacists some level of collaborative practice or prescriptive authority.

The chart below provides a complete listing of those states that currently allow pharmacists collaborative practice or prescriptive authority and those states considering proposals for such activities.

Pharmacist Collaborative Practice and/or Prescriptive Authority

States with Enacted Provisions	States with Proposed Provisions
Arkansas	Alabama
California	Arizona
Florida	Delaware
Hawaii	Idaho
Indiana	Louisiana
Iowa	Maryland
Kansas	Minnesota
Kentucky	New Jersey
Michigan	New York
Mississippi	Ohio
Nevada	Oklahoma
New Mexico	Pennsylvania
North Dakota	Puerto Rico
Oregon	South Carolina
South Dakota	Tennessee
Texas	
Vermont	
Washington	

Item 949 – Practice Act Changes

A number of changes have been made to the Pharmacy Practice Act, including one which allows the Board to contract with an organization to assist impaired pharmacists. You can expect to hear more from the Board on this change in the near future.

Other changes in the Practice Act include a revision of fees. The new fees are listed below.

Examination:	$ 110 (plus cost of test material)
License Renewal:	$ 110
Reciprocity:	$ 400
Original Pharmacy Permit:	$ 350
Permit Renewal:	$ 175
Dispensing Physician:	$ 50
Dispensing Physician Assistant:	$ 50
Dispensing Nurse Practitioner:	$ 50
Change in Pharmacist Personnel: (includes pharmacy technicians and change in pharmacy manager)	$ 25
Duplicate License:	$ 25

You may notice there are new fees for the registration of physician assistants, nurse practitioners, dispensing physicians, and pharmacy technicians. It will now be necessary for physician assistants, nurse practitioners, and dispensing physicians to pay registration fees to the Board. There are also extensive new rules requiring a consulting pharmacist for physician assistants and nurse practitioners who dispense. Pharmacists need to review these provisions if requested to provide this consultation service.

Item 950 - Counseling is a Lifesaver

The Board of Pharmacy's special projects consultant, Shelly Myott, has compiled a summary of the information received from 1992-96 as a result of the Board's rule requiring the reporting of deaths due to drugs dispensed through pharmacies. Some very interesting data was revealed in this summary, such as the drugs frequently mentioned in reports and the causes of patient expirations. The drugs involved in more than one report are Activase (alteplace), Dilantin (phenytoin sodium), Diprivan (propofol), methotrexate, morphine, procainamide, and protamine. Omniflox would have made the list if it had not been withdrawn from the market.

Conditions and frequency of causes were hypoxemia (2); Stevens-Johnson Syndrome (3); toxic epidermal necrolysis (3); hemorrhage (6); anaphylactic reactions (9); and overdose/possible suicide (12). There are at least two pieces of good news that can be derived from this data. First, patient counseling saved lives. In the first year, there were five death reports where, by staff analysis, it was apparent that the life could have been saved if patient counseling had occurred. There were no such deaths in 1996. Since the reporting rule went into effect prior to the patient counseling rule, we can see that this rule has saved lives.

It is also noteworthy that reporting of such deaths is not a confession. Only one of the many reports resulted in a Board hearing and disciplinary action involving a pharmacist.

The information from all reports was shared with the appropriate occupational licensing boards from other professions for any actions which might have been deemed appropriate. All health professionals should note that the Board amended its rule to provide that, in case of a disciplinary hearing, proper and timely reporting would be a mitigating factor while failure to report would be an aggravating factor.

Item 951 – DME and Hospital Rules Seminars

The Board has scheduled several seminars around the state to explain Board rules on devices and medical equipment (DME) supplied by registrants and pharmacists. Hospital rules will be considered from 9-11:30 a.m. and DME matters from 1-4 p.m. Pharmacists in the DME business need to be aware that they will be held responsible for the extensive rules on these items.

Seminars are scheduled as follows: **October 27** at Guilford Technical Community College, Jamestown, NC; **October 30** at McDowell Technical Community College, Marion, NC; **November 5** at Campbell University, Trustees Room, Buies Creek, NC; and **November 6** at Pitt Community College, Greenville, NC.

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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This Newsletter *is printed at a cost of $.10 per copy.*

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NORTH CAROLINA BOARD OF PHARMACY

Bulk Rate
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744