April 1997

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Item 915 – November Disciplinary Actions

Pre-Hearing Conference Recommendations

James Howard Frazier, Greer, South Carolina (DOB: June 4, 1947). Board adopted Consent Order entered in South Carolina dated June 27, 1996, wherein Frazier admitted to diversion of a quantity of a Schedule III controlled substance for personal consumption. License in South Carolina suspended two (2) years, immediately stayed subject to specific conditions set forth by the South Carolina Board. Proposal to adopt South Carolina Consent Order for North Carolina accepted by Mr. Frazier and the Board.

Delton O. Jones, Fayetteville, (DOB: September 19, 1950). Failure to obtain required number of contact hours of continuing education for the 1996 license renewal.

Recommendation: License suspended seven (7) days, stayed three (3) years with conditions. Accepted by Mr. Jones and the Board.

Earl Lee Griffin, Asheville, (DOB: April 21, 1954). Dispensed Valium, Lorcet, and alprazolam without a prescription or authorization; failure to keep accurate prescription records, daily print-outs, and records of dispensing as required by law; and maintained the pharmacy where employed in a cluttered and unsanitary condition to the extent that an insect was once found in a stock vial.

Recommendation: License suspended thirty (30) days, stayed five (5) years with active ten (10) consecutive calendar day suspension and other conditions. Accepted by Mr. Griffin and the Board.

Full Hearing

Bobby K. Hinson, Pageland, South Carolina, (DOB: March 20, 1949). Entered into Consent Order with South Carolina Board of Pharmacy on June 27, 1996, admitting to unauthorized substitution and the failure to properly regulate his ingestion of drugs and alcohol. License in South Carolina was suspended three (3) years, stayed subject to several conditions.

One condition was an inpatient alcohol detoxification program within thirty (30) days which respondent failed to comply with; therefore, the South Carolina Board suspended his license by Order issued August 6, 1996. An accountability audit had been conducted by the South Carolina Department of Health and Environmental Control at Hinson's Pharmacy, and had revealed that Mr. Hinson had failed to make and maintain complete and accurate records of all controlled substances received and dispensed as evidenced by discrepancies.

A pre-hearing conference was held by the North Carolina Board regarding these matters on October 17, 1996, and continued until October 30, 1996, but Mr. Hinson did not appear for the continuance. A full Board hearing was therefore held on November 19, 1996, and evidence established that Mr. Hinson had not completed a detoxification program and remained in violation of the Consent Order of the South Carolina Board. License in North Carolina suspended indefinitely, effective thirty (30) days after service of Final Decision.

Ronald Lee Hobday, Harrisburg, (DOB: July 18, 1952). A Consent Order was entered November 19, 1996. Admission to obtaining and consuming cocaine from pharmacy stock of hospital where employed without authorization and had become dependent on cocaine. License suspended indefinitely.

James Grant Dorough, Monroe, (DOB: March 28, 1959). License reinstated subject to Dorough meeting specific conditions set forth by the Board but not before March 1, 1997.

Leonard W. Matthews, Madison, (DOB: January 6, 1941) and **Brown-McFalls Drug Company**, Madison. A Consent Order was entered January 21, 1997. Failure to prevent the dispensing of prescription drugs without pharmacist supervision when he knew or should have known vio-

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National Pharmacy

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

Research Study Addresses Prevention of HIV Transmission Through Increased Access to Sterile Syringes

The laws and regulations that restrict access to sterile syringes in the United States and its territories was the focus of an article in the January 1, 1997 issue of the *Journal of the American Medical Association (JAMA)*.[1] Researchers conducted a national survey of the pharmacy regulations and practice guidelines related to the sale of syringes. Results from three survey categories are listed in the chart below.

The article also discussed the following legal and public health proposals to increase the availability of sterile syringes as a preventive measure for human immunodeficiency virus (HIV) transmission for persons who continue to inject drugs: 1. clarify the legitimate medical purpose of sterile syringes for the prevention of HIV and other blood-borne infections; 2. modify drug paraphernalia laws to exclude syringes; 3. repeal syringe prescription laws; 4. repeal pharmacy regulations and practice guidelines restricting the sale of sterile syringes; 5. promote professional training of pharmacists, other health professionals, and law enforcement officers about preventing blood-borne infections; 6. permit local discretion in establishing syringe exchange programs; and 7. design community programs for safe syringe disposal.

The pharmacists' role in over-the-counter sales of syringes was also considered. "Pharmacists face substantial legal and professional hurdles in selling syringes to IDUs [injection drug users]," the authors stated. "Nationwide, pharmacists retain considerable discretion in deciding whether, and to whom, to sell syringes."

Reprints of the *JAMA* article can be obtained by contacting the Centers for Disease Control and Prevention National AIDS Clearinghouse at 1-800/458-5231.

[1] Gostin LO, Lazzarini Z, Jones TS, Flaherty K. Prevention of HIV/AIDS and other blood-borne diseases among injection drug users: A national survey on the regulation of syringes and needles. J Am Med Assoc 1997; 277:53-62.

Continued Competency Assessment Scores to be Given Only to Pharmacists

The National Association of Boards of Pharmacy (NABP) has announced that the scores from the Association's new computer-administered, multiple-choice Pharmacist Continued Competency Assessment Mechanism will be reported only to pharmacists. Scheduled for implementation in 1999, the Assessment Mechanism will be used as a diagnostic tool to help pharmacists identify areas of practice that require their specific attention or additional education.

"As state agencies charged with protecting the public health and welfare, the boards of pharmacy recognize the importance of assuring the public that its pharmacists are competent and able to fulfill their professional responsibilities," stated NABP Presi-

State	DP Law*	SP Law**	PSS Law/Regulation***
AL	X		X
AK			
AZ	X		
AR	X		
CA	X	X	X
CO	X		
CT	X	X	X
DE	X	X	
DC	X		X
FL	X	X	
GA	X		X
HI	X		
ID	X		
IL	X	X	
IN	X		X
IA			
KS	X		
KY	X		
LA	X		X
ME	X	X	X
MD	X		X
MA	X	X	X
MI	X		
MN	X		
MS	X		
MO	X		
MT	X		
NE	X		
NV	X		X
NH	X	X	X
NJ	X	X	X
NM	X		
NY	X	X	X
NC	X		
ND	X		
OH	X		X
OK	X		
OR	X		
PA	X		X
RI	X	X	X
SC			X
SD	X		
TN	X		X
TX	X		
UT	X		
VT	X		
VA	X	X	X
WA	X		
WV	X		X
WI	X		
WY	X		

* Drug paraphernalia (DP) laws prohibit the sale, distribution, possession, manufacture, and/or advertisement of items known to be used to introduce illicit drugs into the body.

** Syringe prescription (SP) laws prohibit the sale, distribution, and possession of syringes without a valid medical prescription.

*** Pharmacy syringe sales (PSS) are restricted by state law or board of pharmacy regulation(s) or practice guideline(s).

Compliance News

dent Ralph E. Progar. "The philosophy guiding the development of NABP's Pharmacist Continued Competency Assessment Mechanism is one that stresses continuing education rather than punitive measures."

During the developmental phase of the Assessment Mechanism, NABP will convene a focus group to ensure the program accurately reflects current standards of practice. NABP will also work closely with the American Council for Pharmaceutical Education (ACPE) to facilitate the development of appropriate continuing pharmaceutical education programming that complements the blueprint for NABP's Pharmacist Continued Competency Assessment Mechanism.

"The addition of a continued competence assessment mechanism should promote the further development of curricular-based continuing education programs in accord with specified practice competencies," noted ACPE Associate Executive Director Kimberly Werner. "In concert with the Pharmacists' Learning Assistance Network (PLAN), an information service which assists pharmacists in planning an individualized continuing education strategy, the Pharmacist Continued Competency Assessment Mechanism has the potential to facilitate pharmacists' selection of continuing education offerings that address an area or areas in need of improvement."

States Continue to Enact Ephedrine Restrictions

In 1994, the Drug Enforcement Administration (DEA) enacted a rule subjecting all quantities of ephedrine to recordkeeping requirements under the federal Controlled Substances Act. The rule was established amid reports of increasing abuse and diversion of ephedrine to clandestine methamphetamine ("speed") and methcathinone ("cat") laboratories, where it was the primary precursor for the illicit production of these controlled substances.

With enactment of the DEA's rule, many states implemented their own regulations to control access to ephedrine. The National Association of Boards of Pharmacy (NABP) recently sought to update a survey it conducted in 1994 to determine how states are regulating ephedrine. With 40 states responding, the new survey indicates that efforts to limit access to ephedrine are continuing. Highlights from the survey's findings include:

- 21 states have placed some sort of restrictions on the sale of ephedrine-only products and 16 states have restrictions on the sale of ephedrine-combination products. These figures represent a significant increase over the 1994 survey when 14 states reported restrictions on ephedrine-only products and eight had restrictions on ephedrine-combination products.
- 11 states designate ephedrine-only products as controlled substances, while 10 states list them as legend drugs. In 1994, six states classified ephedrine-only products as controlled substances and eight states classified them as legend drugs.
- Eight states designate ephedrine-combination items as controlled substances and six states list them as legend drugs. This is a significant increase from two years ago, when only three states designated ephedrine-combination products as controlled substances and only two states as legend drugs.
- Five states are considering proposals to list ephedrine-only products as controlled substances, and three states are proposing to classify ephedrine-combination products as controlled substances. In 1994, two states reported considering proposals to list ephedrine-combination products as controlled substances and both have enacted their proposals.

The chart below provides information about which states currently have restrictions on the sale of ephedrine-only and ephedrine-combination products, and what type of restriction has been enacted in the state.

State	Any restrictions on the sale of products containing only ephedrine? If so, what type of restriction?	Any restrictions on the sale of "ephedrine-combination" products? If so, what type of restriction?
AL	No	No
AZ	Yes-controlled substance	No
AR	Yes-controlled substance	Yes-controlled substance
CO	No	No
CT	No	No
DE	No	No
FL	Yes-legend drug	Yes-legend drug
ID	Yes-legend drug	Yes-legend drug
IL	Yes-controlled substance	Yes-controlled substance
IN	No	No
IA	No	No
KS	Yes-controlled substance	No
KY	No	No
LA	Yes-legend drug	Yes
ME	No	No
MD	No	No
MI	Yes-legend drug	Yes
MN	No	No
MS	No	No
MO	Yes-controlled substance	Yes-controlled substance
MT	No	No
NE	Yes-controlled substance	Yes-controlled substance
NV	Yes-controlled substance	No
NH	No	No
NJ	Yes-legend drug	
NM	Yes-legend drug	Yes-legend drug
NY	No	No
ND	Yes-legend drug	No
OH	Yes-controlled substance	Yes-controlled substance
OK	Yes-controlled substance	Yes-controlled substance
OR	Yes-legend drug	Yes-legend drug
RI	No	No
SC	No	No
SD	Yes-controlled substance	Yes-controlled substance
TN	Yes-legend drug	Yes-legend drug
TX	No	No
VA	No	No
WA	Yes-legend drug	Yes-legend drug
WI	Yes-controlled substance	Yes-controlled substance
WY	No	No

40 states responded to the survey.

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lations were occurring; pharmacy failed to prevent events described from occurring when the permit holder knew or ›uld have known violations were occurring. License of Mr. Matthews suspended ninety (90) days, with active 30-day suspension of the license beginning February 1, 1997; after 30 days, license restored for period of three (3) years with conditions. Respondent Pharmacy shall surrender permit to the Board office on or before January 31, 1997. Such surrender shall be a permanent surrender of the permit to operate Brown-McFalls Pharmacy, Madison.

Item 916 – Board Interpretation of Prescription Pick-Up

Several years ago, the Board of Pharmacy ruled that prescriptions prepared and packaged by the pharmacist could be picked up by the customer while the store was open but after the pharmacy department had closed. For example, some businesses have been operating with the pharmacy open from 10 a.m. until 6 p.m., while the remainder of the business is open from 9 a.m. until 9 p.m.

At the January meeting of the Board of Pharmacy, the members voted to change this policy and require a pharmacist to be on duty when prescriptions are picked up. Among the members' reasons for changing this policy is that the prior policy could make patient counseling difficult, if not ir ssible.

The current ruling of the Board results in a situation where prescription pick-up must occur while the pharmacist is on the premises and available for counseling.

Item 917 – Pick a Language

A complaint has come into the Board office regarding a pharmacist who attempted to mix Spanish and English on one label. The essence of the problem was that the word "once" means one time in English and 11 in Spanish.

"Aplicarse once cada dia til rash is clear" – Incorrect phrase.

In the example above, the patient applied the cream 11 times per day and the product aggravated the patient's condition.

One can easily imagine the tragedy that could have occurred if the prescription had been for Lanoxin, methotrexate, or another powerful drug. There are computer programs which can type directions in Spanish or other foreign languages. Depending on their practice, pharmacists should familiarize themselves with these items.

Item 918 – Leaders Forum Recommendation

A number of North Carolina pharmacy leaders met during a weekend in early February. Among the topics discussed was patient counseling. It was the consensus of the group that if pharmacists short-cut patient counseling, then errors will increase. Everyone recognizes that patient counseling is where many dispensing errors are caught.

Item 919 – Batch Mixing

It has come to our attention that problems may exist when mixing batches of prescription drugs under some circumstances. Some automated dispensing devices contain large quantities of tablets and capsules that could easily come from more than one batch. Any attempt at recall under these circumstances would certainly be incomplete. Therefore, Board staff recommends that pharmacists using automated dispensing devices make every effort not to mix batches in one bin.

Item 920 – Recommendation on Reducing Prescription Errors

The National Coordinating Council for Medication Error Reporting and Prevention has developed several recommendations in an effort to reduce drug errors. A copy of the Council's work from the *USP Review* is available from the Board office by sending a #11 stamped, self-addressed envelope.

Item 921 – Stadol Tampering

The editor has learned of a scheme to tamper with Stadol nasal spray. Pharmacists should be wary of any patient requesting a replacement of Stadol nasal spray (Stadol NS) due to a defective plunger on the container. Instances have been reported in which patients who have had legitimate prescriptions for this drug dispensed to them return to the pharmacy a short time later claiming the plunger on the container was defective and requesting a replacement. After replacing the container, the pharmacy discovered the drug in the old container had been replaced with a clear liquid. We suggest you report such instances to the prescriber.

Item 922 – Revision in Practice Act

A committee has met over the last two years in an effort to revise the Pharmacy Practice Act (see Item 865 in the January 1996 *Newsletter*). By the time you receive this publication, the results of this effort will be in front of the General Assembly.

The revision is not a complete change, but only a modification to certain, selected parts. There is a section revising the practice of pharmacy to include pharmaceutical care as well as the utilization of drugs under agreements similar to that which apply to physician assistants and nurse practitioners. Many states have adopted a similar procedure, including California, Florida, Indiana, Iowa, Kentucky, Michigan, Mississippi, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Tennessee, Texas, and Washington. Several other states, as well as North Carolina, are considering the matter at this time, including Delaware, Idaho, Kansas, Maryland, New York, Ohio, and Virginia. This means nearly

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half of the states have either adopted a procedure expanding the practice rights of pharmacists or are considering the matter at this time.

The revision includes a much needed section to repair the part of the statute referring to patient confidentiality, a portion requiring durable medical equipment (DME) registration for out-of-state suppliers in the same manner as out-of-state pharmacies, and other important matters. It is expected that the legislation will also contain a provision for dealing with impaired pharmacists and an arrangement to register pharmacy personnel.

Please make your feelings about these issues known to your representative in the General Assembly. If you are uncertain about who represents you in Raleigh, contact the North Carolina Pharmaceutical Association at 800-852-7343.

Item 923 – Designated Prescriber

Many prescription labels and computer programs have a built-in feature that designates the prescriber with either the title "Dr." or "MD." With the changing health care system, we also now have many new prescribers, including physician assistants, nurse practitioners, optometrists, etc. The net result is that a nurse practitioner can be indicated on a label as a physician when that is not the case. Technically, this is probably considered a "misbranding" because the label is misleading, which is one of the key definitions of "misbranding."

Board staff recommends that pharmacists take whatever steps are available to change their labels to indicate the proper title of prescribers.

Item 924 – May 1997 Board Meeting Cancelled

Due to a conflict in scheduling with the National Association of Boards of Pharmacy Annual Meeting, the regular monthly Board meeting for May has been cancelled.

Item 925 – Emergency Kits in Home Care

Representatives from the North Carolina Association for Home Care appeared before the Board at the February meeting to request a ruling on the use of emergency kits in home care. The Board thoroughly discussed the matter, which included an understanding on the limitation of the drugs involved in:

- **IV therapy:** diphenhydramine (Benadryl) 50 mg/ml, 1 ml syringe (1); epinephrine HCl 1:1000, 1 ml Tubex/Carpuject (1); furosemide 10 mg/ml, 10 ml vial (1); naloxone 2 mg/ml, 1 ml syringe (1); Tubex holder (1); NaCl 0.9% 250 ml bag (1); administration set (no filter) (1); NaCl 0.9% 10 ml vial (1); and syringe, (TB) 26 G, 3/8" 1 ml (1).
- **IM or SC therapy:** diphenhydramine (Benadryl) 50 mg/ml, 1 ml syringe (1); epinephrine HCl 1:1000, 1 ml Tubex/Carpuject (1); Tubex/Carpuject holder (1); NaCl 0.9% 10 ml vial (1); syringe, (TB) 26 G, 3/8" 1 ml (1); and hydration fluids as specified by the pharmacist.

The Board approved the use of emergency kits in home care, providing they are supervised and controlled by a consulting pharmacist.

Item 926 – Child Support and Your License

A statute adopted by the General Assembly effective in the fall of 1996 now provides that professional licenses can be suspended or revoked for non-payment of child support. The Board has not yet received any notification of a failure or refusal of a pharmacist to make such payments.

In the event the Board is officially notified of such a delinquency, it is required by statute to suspend or revoke your license to practice pharmacy. This could also include a permit to operate a pharmacy if the individual involved is a pharmacist-manager.

This *Newsletter* item is for your information and to encourage parents to comply with court orders on this subject.

Item 927 – Big Judgment in Negligence Case

In October 1996, a South Carolina court issued a judgment for more than $16 million against a pharmacy for, among other things, understaffing its pharmacy. This is the case of Hundely v. Rite Aid and Jones (Court of Common Pleas, York County, South Carolina); 95-CP-46-405 and 406. The court found that the plaintiff had incurred physical injuries, including brain damage, and suffered severe emotional trauma.

The patient, a seven-year-old child, had been prescribed Ritalin for attention deficit disorder but was erroneously dispensed Glynase 6 mg tablets. The child received a dose more than 16 times the recommended starting dose for adult diabetics that caused her blood sugar to drop, resulting in seizures and coma that produced permanent brain damage.

The plaintiffs alleged that the pharmacist failed to perform mandatory checking procedures. The plaintiffs also alleged that the employer failed to maintain proper policies and procedures for filling prescriptions and supervising its pharmacists, retained the defendant pharmacist despite a record of misfilled prescriptions, and caused its pharmacies to be understaffed.

The defendant denied the prescription had been misfilled and denied the pharmacy was understaffed. The jury returned a verdict of $16,020,000.

Item 928 – Preprinted Prescription Blanks

A rule under the North Carolina Controlled Substances Act prohibits the use of preprinted prescription blanks for

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controlled substances. This means no prescription blanks can be preprinted with the name of the controlled substance, such as those often distributed by pharmaceutical manufacturers. The Board believes this is intended to avoid the possibility of prescription forgeries and applies to "rubber stamp" prescriptions.

It is the Board's interpretation that individually generated prescriptions, such as those from computer programs or those that are typewritten, are not "preprinted" within the meaning of this rule. Prescribers who use any preprinted system should be made aware of this rule, and that pharmacies routinely turn down such prescriptions as not being in compliance with North Carolina state law.

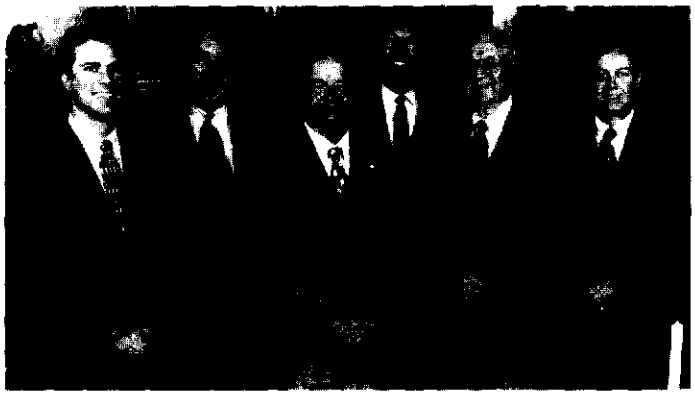
Item 929 – Dispensing by PAs and NPs

North Carolina statute provides that physician assistants (PAs) and nurse practitioners (NPs) can dispense drugs under rules published by the Board of Pharmacy. The Board recently revised its rules to provide that such dispensing can occur, and that there is no longer a formulary which once existed. PAs and NPs can dispense drugs listed in the written standing protocols or instructions between the physician assistant/nurse practitioner and supervising physician.

The new rules require the services of a consulting pharmacist with contact on a weekly basis for compliance with retrospective drug utilization review, cost effectiveness, and optimal drug therapy. Factors considered in this review would be the need of the drug and its effectiveness, including efficiency, toxicity, pharmacokinetic properties, and bioequivalence. Risks to be considered could include adverse drug reactions and potential for error in prescribing or ordering such drugs. Each location must also have a pharmacy permit from the Board.

Full text of the rule, which became effective April 1, 1997, is available from the Board office.

Item 930 – Pharmacy Board Members



Left to right: *Timothy R. Rogers, public member, Raleigh; William Whitaker Moose, member, Mt. Pleasant; Harold Vann Day, president, Spruce Pine; Albert F. Lockamy, Jr., member, Raleigh; Jack G. Watts, vice president, Burlington; and Robert L. Crocker, member, Farmville.*

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