July, 1995

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Item 829 – Disciplinary Actions

March: Pre-Hearing Conference

Jerry K. Adams, Marshall (DOB: May 7, 1947). Heard by Board Member Moose. Refilled prescriptions without authorization. License suspended 90 days, stayed five years with active 10-day suspension and other conditions. Accepted by Mr. Adams and the Board.

April:

James Weaver Kirkpatrick, Weaverville (DOB: January 5, 1944) and Rite Aid Pharmacy, Bryson City. Dispensing controlled substances without authorization and failing to maintain proper records. License suspended 30 months, stayed 30 months with a six-month active suspension of the license and other conditions. Pharmacy violated law in failing to prevent the events from occurring when the permit holder knew or should have known the violations were occurring. Board shall withhold entry of any disciplinary action against pharmacy permit for period of six months from date of Order, during which time the Board will conduct an inspection and audit of pharmacy to ensure compliance with laws and regulations governing practice of pharmacy and distribution of drugs. If pharmacy passes inspection and audit, the Board will take no further disciplinary action against pharmacy permit.

Joel A. Ragan, Pfafftown (DOB: February 22, 1949). Hearing continued until June meeting.

Pre-Hearing Conference Recommendations:

Mildred Matthews, Asheville (DOB: November 17, 1939). Heard by Board Member Biggers. Filling of forged prescriptions and refilling of controlled substance prescriptions without authorization. License suspended five years, stayed five years with active suspension of license from August 23, 1994 to June 1, 1995 and other conditions. Accepted by Ms. Matthews and the Board.

Brian R. Fulcher, Greenville (DOB: July 3, 1961). Heard by Board Member Moose. Unauthorized use of drugs to include cocaine, LSD, marijuana, IV Demerol, IV Valium, Stadol, Morphine, amphetamine, Percocet, Hydrocodone, and other drugs to the extent that it rendered him unfit to practice pharmacy. License suspended indefinitely. Accepted by Mr. Fulcher and the Board.

Item 830 – New Public Member

Timothy Rogers from Raleigh was appointed by Governor Hunt to a five-year term beginning on May 2nd of this year. Tim has worked for several associations in Raleigh, including the State Employees Association of North Carolina, the North Carolina Bankers Association, and the Association for Home Care. He recently joined Tar Heel Home Health Management as their director of regulatory policies and public education.

A 1983 graduate of UNC, Tim has a unique connection with pharmacy. While a student on the Chapel Hill campus, he lived at the Phi Delta Chi house, and recalls many of his pharmacy acquaintances from that time.

The public members on the Board of Pharmacy have included Mr. Joe Roberts, an attorney from Gastonia, and most recently Mr. Bill Biggers, a lawyer from Asheville. They have made valuable contributions to the work of the Board, and we welcome Tim to this common effort.

Item 831 – Nursing Rules for Implementing Prescribed Pharmaceutical Regimens Including Standing Orders

Questions arise from time to time about the authority of nurses to perform certain activities regarding patients. In a response from this *Newsletter* editor, the North Carolina Board of Nursing submitted the following text for publication in the Board of Pharmacy *Newsletter.*

According to the Nursing Practice Act (G.S. 90-171.20 (7) and (8)), a registered nurse or licensed practical nurse has authority to implement a pharmaceutical treatment regimen prescribed by a person authorized by law to prescribe such a regimen. Persons with authority to prescribe include physicians, dentists, nurse practitioners, certified nurse midwives, and physician assistants.

Prescriptions (or orders) for a pharmaceutical treatment regimen may be conveyed to a licensed nurse as a specific written or verbal order for a specific client, or as a standing order for patients whose

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National Pharmacy

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and can only be ascertained by examini

Guidelines Developed for Non-Traditional Pharm.D.

The National Association of Boards of Pharmacy (NABP) recently convened a Task Force on the Development of an Equitable Degree Upgrade Mechanism to encourage the development of non-traditional programs for pharmacists with baccalaureate degrees seeking to earn a doctor of pharmacy degree. With the counsel of ACPE and the American Association of Colleges of Pharmacy (AACP), the Task Force prepared the following document entitled "Guidelines for a Uniform Method for a Baccalaureate Degreed Pharmacist to Earn a Doctor of Pharmacy Degree," as a blueprint for colleges and schools of pharmacy seeking to establish non-traditional degree upgrade programs.

I. Pharmacist holding a baccalaureate degree in pharmacy from an ACPE-accredited program who wishes to earn a doctor of pharmacy degree voluntarily makes application to the college or school from which he/she graduated or to another ACPE-accredited program. The application shall be assessed using a uniform guideline within the institution and among all ACPE-accredited pharmacy programs. The application would include the necessary identifier information as well as:
   1. Date of graduation;
   2. Date of original licensure as a pharmacist;
   3. Other educational experiences (including continuing education) and/or degree(s) earned; and
   4. Criteria - Appropriate and documented practical experience, based upon criteria developed with input from practitioners and boards of pharmacy, assessed individually.

II. Following the assessment of the pharmacist's application, professional skills, abilities, and knowledge and payment of appropriate fees, the college/school would select the appropriate procedure for the baccalaureate-degreed pharmacist to earn a doctor of pharmacy degree. The procedure would be one of the following:
   1. Completion of appropriate didactic work (e.g. continuing education courses - live or home study); or
   2. Completion of appropriate experiential rotation(s); or
   3. Completion of appropriate didactic work and appropriate experiential rotation(s); or
   4. No additional requirements.

Such a standardized mechanism shall be individually customized within the context of the following characteristics:

1. **ASSESSIBILITY:**
   A competency-based process (i.e. NABPLEX competencies) shall be conducted by a committee composed of faculty and practitioners.
2. **ACCESSIBILITY:**
   Accessibility is defined as a practical, non-disruptive program that will not require the applicant to relocate or significantly interfere with his or her practice.
3. **ACADEMICALLY SOUND:**
   An academically sound program is defined as a documented evaluation that does not disrupt or compromise accreditation standards.
4. **AFFORDABILITY:**
   An affordable program is defined as one which can be offered to the applicant at a reasonable cost and may be completed in a timely manner (generally one year).

Baccalaureate-degreed pharmacists interested in upgrading their degree to a Pharm.D. are encouraged to contact the college of pharmacy from which they graduated or their local college or school of pharmacy to inquire about non-traditional programming. NABP, AACP, ACPE, and your state board of pharmacy are committed to providing an opportunity for meaningful degree upgrade programs for those who wish to take advantage of them.

FDA Rule Protects Identities of Reporters to MedWatch Program

The U.S. Food and Drug Administration (FDA) published a final rule in the April 3, 1995 *Federal Register* that protects the identities of the reporters of adverse events and of the patients affected.

The final rule, which became effective on July 3, 1995, amends the public information regulations in 21 CFR §20.63 to help ensure that the identities of those who report adverse events associated with human drugs, biologics, and medical devices, and the identities of persons affected are held in confidence and are not disclosed by FDA or by manufacturers that possess these reports. The FDA took this action to maintain the agency's ability to collect information that pertains to the safety risks of FDA-regulated products. The FDA views this step as vital to the protection of the public health.

The final rule does not apply to the identities of those reporters who are required by federal statutes, such as the National Childhood Vaccine Injury Act or the Safe Medical Devices Act, to submit reports to FDA. Also, the final rule does not alter the disclosure requirements of such statutes.

While FDA policy regarding the disclosure of voluntarily submitted adverse event reports has been, and continues to be, that such reports are publicly available after identifying information has been deleted, the final rule does allow the disclosure of reporters of adverse events under certain limited circumstances. These exceptions are stated in 21 CFR §20.63(f)(1) as follows:

(1) *Exceptions.* (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither the FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the per-

son identified in the adverse event report or that person's legal representative; or (ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

The final rule preempts the establishment or continuation in effect of any state or local law, rule, regulation, or other requirement that mandates or permits disclosure of the reporters' identities. The incorporation of this exemption in the final rule signals FDA's commitment to protecting the identities of the voluntary reporter, the patient, and any other person identified in the report. Section 20.63(f)(2) of the final rule states:

(2) *Preemption.* No state or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided by this section.

It is important to note that the final rule does not preempt state or local laws that require disclosure of the substance of adverse event reports. FDA does not believe that disclosure of the substance of adverse event reports will impede its ability to collect such information. In fact, the FDA routinely releases the full substance of all voluntary adverse event reports upon request after deleting identifying information. The final rule also does not affect an individual's ability to obtain specific information about reports concerning his or her own reaction to a product, especially when the individual is a plaintiff in a medical malpractice lawsuit and discovery of the plaintiff's records is granted by a court.

Electronic Transmission of Prescription Orders/Patient Data

The electronic transmission of prescription orders from the prescriber to the pharmacist is an issue that many state boards of pharmacy are currently reviewing. Those reviewing the matter recognize that technological advances in telecommunication and computer systems are driving forward revolutionary changes in the traditional communications between practitioners and patients.

Data compiled by the National Association of Boards of Pharmacy (NABP) indicates that the state boards of pharmacy are receptive to the electronic transmission of prescription orders and patient data directly from the prescriber to the pharmacist, provided that security and confidentiality concerns are appropriately addressed. However, through a resolution adopted by delegates to NABP's 91st Annual Meeting held from April 29 to May 3, 1995, the state boards of pharmacy also expressed strong reservations about third-party payors intercepting and interfering with the transmission of prescription orders and/or patient data. This resolution states:

Whereas, optimal patient care requires close communication between the prescriber, pharmacist, and patient; and

Whereas, the patient has a right to confidentiality; and

Whereas, a patient's prescription is a confidential, professional communication of clinical information between a prescriber and a pharmacist; and

Whereas, technology will soon permit the transmission of prescriptions via electronic data interchange; and

Whereas, prescription information is being transmitted electronically across state lines; and

Whereas, the integrity of prescriptions transmitted via electronic data interchange can be compromised when allowed to be manipulated by other parties and may result in an altered or modified prescription; and

Whereas, pharmacists are charged with the responsibility of assuring the accuracy and integrity of prescriptions dispensed from the point of prescribing to the dispensing of medications and, ultimately, to ensuring the appropriate use of prescribed medications;

Therefore Be It Resolved that NABP establish a task force to prepare model regulations addressing these confidentiality issues and urge individual state boards of pharmacy to promulgate legislation and/or regulations to encourage the development of technology that will require that the transmission of electronic prescriptions from prescriber to pharmacist not be compromised by interventions, control, or manipulation of said prescriptions by any other parties.

NABP will review this resolution at a July meeting of its Executive Committee for further action.

Record Keeping Requirements for Sales of Single-Entity Ephedrine Products

As reported in the January-March 1995 edition of the "National Pharmacy Compliance News," all transactions involving single-entity ephedrine products are subject to federal record keeping requirements, regardless of the quantity involved.

Records for such ephedrine product transactions must be maintained for four years. Pharmacists should also be aware that **federal** record keeping requirements, which are set forth in 21 CFR §1310, apply to all single-entity ephedrine products, including injectable products and inhalers. Proof of identity in the form of a driver's license and one other form of identification, as well as the purchaser's signature must also be obtained. If the ephedrine product is dispensed pursuant to a prescription, regular prescription or hospital records are sufficient.

Any questions regarding these requirements or any others imposed under the federal Controlled Substances Act should be directed to the Diversion Group at your local DEA office.

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complaints, signs, and symptoms are consistent with a pre-established set of assessment data that must be collected prior to the implementation of the treatment regimen. The licensed nurse may only implement a written, verbal, or standing order that is complete and for which no further medical judgment is required prior to implementation.

How medical treatment orders or prescriptions may be conveyed to the licensed nurse is established through policy within each practice setting. This policy should include countersigning time for verbal orders whether or not orders may be conveyed via a person acting as a messenger for the prescriber, and requirements for completeness of orders that may be implemented by the licensed nurse. The common standard of practice for agencies utilizing standing orders is that they be reviewed and signed annually by the physician, dentist, or other person authorized to prescribe.

Nurse practice consultants are available to answer any questions you may have regarding the scope of practice for registered nurses and licensed practical nurses. You may contact a consultant at the Board of Nursing office by calling 919/782-3211.

Item 832 – More on the Pharmacist Recovery Network

For the past few months, a group of pharmacists have been meeting monthly in an attempt to revive the North Carolina Pharmacist Recovery Network (NCPRN). The purpose of NCPRN is to provide assistance to pharmacists, pharmacy students, and their families in identifying and treating impairment problems related to, but not restricted to, alcohol and substance abuse. Further, NCPRN will work to assure that if an impairment problem exists, those affected will receive careful consideration and an offer of assistance in an effective and confidential manner.

Issues currently being discussed include amending the present by-laws of the organization to better represent the focus of the program, enacting necessary legislation to provide civil immunity to anyone acting on behalf of NCPRN, developing a list of appropriate treatment centers throughout the state, recruiting and training other concerned pharmacists to act as interveners, and most importantly, searching out a source of continuous funding.

Current statistics say that roughly 10 percent of all pharmacists are either addicted or have the potential to become addicted. The profession must identify cases of impairment early in order to protect the public and rehabilitate impaired pharmacists and pharmacy students. Too much time and expense goes into the training and development of a pharmacist to allow the loss of their services without a concerted effort to rehabilitate.

If you or someone you know needs help or wants to help, please call Dave Marley at 910/785-4966 or Ken Keever at 910/887-8322. All calls are kept confidential.

Item 833 – Audit Tolerance

Rumors have been heard by Board staff that there is a specific percentage or number of dosage units used as "tolerance" in a controlled substance audit. While it is not unusual to find a few dosage units discrepancies in an audit, the Board staff has no specific guidelines on any "tolerance" which could be applied to any specific audit. Any statements that are circulating to the contrary have no basis in fact.

Item 834 – Equivalency of Morphine Sulfate Tablets

The Board of Pharmacy has received, through normal channels, a letter from the Food and Drug Administration noting the "Orange Book" ratings for long-acting morphine sulfate. Under the system used in the "Orange Book," products listed as Class A are therapeutically equivalent to other similar products, while those in Class B are not therapeutically equivalent. At the present time, the FDA has placed Oramorph SR and MS Contin in Class B. It is their opinion that these drugs are not therapeutically equivalent.

State law in North Carolina provides that the pharmacist makes such equivalency decisions; however, this information may be useful in arriving at individual dispensing judgments.

Item 835 – Change Begets More Change

The Board office recently received an inquiry from a Raleigh law firm regarding the propriety of "hospital consultant privileges" for pharmacists. Apparently the firm's client, a large hospital, was in the process of negotiating a contract with an HMO. One of the clauses in the contract would have the HMO pharmacist also approved for consulting privileges at the hospital.

The law firm inquired as to the propriety of such an arrangement. The response from Board staff was that nothing in state law prohibits such an arrangement. Under our system of law, activity which is not prohibited is therefore permitted, and it is assumed that such an arrangement would not be violative of state law.

Item 836 – Newsletter as Official Notice

This *Newsletter* is a publication of the North Carolina Board of Pharmacy and is intended to inform licensees about laws, rules, and pharmacy practice. Please read and keep these newsletters as they are official notification and are used in Board hearings to establish that a pharmacist knew or should have known certain information. Newsletter binders are issued with each new pharmacy permit and should be present at each location. The binders are available from the Board office for $4.24.

Item 837 – Communication Suggestion

Dr. Bill Heller, retired executive director of USP, has offered the following suggestion to maximize the effect of patient counseling. Dr. Heller noted that it would improve the relationship between the pharmacist, physician, and patient if the prescriber was aware of the information that the pharmacist conveyed to the patient as part of the prescription dispensing activity. He also stated that communication could be improved if when the patient is about to visit the physician, the pharmacist mails or faxes the patient information leaflets to the prescriber just prior to the office visit.

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By following this suggestion, the prescriber and the pharmacist can do a better job of serving the patient. This added communication can only improve interprofessional relations.

Item 838 – Suggestions to Avoid Dispensing Errors

1) If you have interns or technicians, you are responsible for checking the product and the order prior to dispensing, and you assume total responsibility for their duties in dispensing prescriptions.
2) When you have any questions about a prescription, call the physician.
3) Check the name and strength of the drug three times: when taking the drugs off the shelf, prior to counting/pouring, and after affixing the label to the container. Check the NDC number on the computer screen against the NDC number on the stock bottle label.
4) Repeat the patient's and doctor's names to the person who is picking up the prescription.
5) When a patient orders refills, record the prescription number, patient name, and drug name to facilitate cross-checking.
6) On the first refill of a prescription, refer to the hard copy to verify the accuracy of the computer information.
7) When possible, have someone check your work.
8) Separate drugs with similar looking or sounding names. For example, place such drugs as Lasix and Lanoxin, Zantac and Xanax, in different areas of the prescription department.
9) Use colored stickers on stock bottles to warn of expiration dates.
10) When consulting with patients and explaining directions for use, recheck the label and contents for errors. It is better to find the error at the time of consulting than to find it after the patient has left the pharmacy.
11) Ask the patient to read the label back to you to determine if the recipient is able to read the label. Any hesitancy about such reading should produce a more thorough consultation by the pharmacist. With one out of every five citizens being functionally illiterate, there is a good chance that the person you are dealing with cannot understand the label.
12) Fight monotonous routines by varying your dispensing procedure.
13) Do not rush your work.

Item 839 – August Board Meeting Canceled

Pharmacists should be on notice that the August meeting of the North Carolina Board of Pharmacy has been canceled. The Board ordinarily meets on the third Tuesday of each month, and that will continue beginning on September 19th.

Item 840 – Sale of Ephedrine - New DEA Requirements

According to the Drug Enforcement Administration (DEA), ephedrine is the primary chemical precursor used in the clandestine synthesis of methamphetamine and methcathinone. DEA has had record keeping and reporting requirements for facilities that sell quantities of ephedrine in excess of one kilogram. Unfortunately, some entities have avoided these requirements by purchasing ephedrine in amounts of less than one kilogram.

To combat this practice, DEA adopted amendments, which became effective on November 10, 1994, that make the record keeping and reporting requirements applicable to all transactions (sales) of ephedrine, even for quantities as small as one dosage unit. This amendment also includes bulk ephedrine and single-entity ephedrine drug products.

These new requirements apply to all facilities involved in the sale of ephedrine, including pharmacies. Therefore, if a pharmacy is selling single-entity ephedrine drug products, the pharmacist needs to be sure that the pharmacy is registered and that proper records are being kept.

Registration – Ephedrine is not listed by DEA as a controlled substance but as a chemical precursor requiring a chemical registration. However, DEA has proposed rules to exempt persons, including pharmacies, that are registered to handle controlled substances from separate chemical registration to handle chemical precursors, such as single-entity ephedrine drug products. This does not and will not exempt pharmacies from the requirement that records be kept for all transactions involving ephedrine.

Records – Records must be kept for all single-entity ephedrine products. Although most commonly marketed for oral and injectable use under the generic name "ephedrine," some brand names do exist. DEA has advised that even the nasal dosage forms, such as Pretz-D Nasal Spray, Vicks Vatronol Drops, and Kondon's Nasal Jelly, are included. Record keeping requirements for these products depend on whether the product is dispensed pursuant to a prescription or, if properly labeled by the manufacturer, it is handled as an over-the-counter (OTC) sale.

On occasion, practitioners may issue prescriptions or medication orders for ephedrine to be dispensed or administered to specific patients. Such prescriptions or medication orders must be properly issued by a practitioner for a legitimate medical reason.

When this occurs, the prescription or hospital records that are kept in compliance with Board rules are considered adequate records for the sale or use of ephedrine. If any of these generic or brand name single-entity ephedrine drug products are sold OTC, the pharmacy must keep a written record of the transaction. The record shall include:

1) the name and address of each party (i.e. the pharmacy and the purchaser);
2) the date of the transaction;
3) the name, quantity, strength, and dosage form of the product;
4) the method of transfer to the purchaser (i.e. picked up by the purchaser, delivery by company vehicle, etc.); and
5) the type of identification used by the purchaser and any unique number on that identification. For sales to an individual, proof of the identity of the purchaser must consist of at least a signature of the purchaser, a driver's license, and one other form of identification.

Reports – Pharmacists must report to DEA the purchases of extraordinary quantities of ephedrine or any unusual

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circumstance which may indicate that the ephedrine will be used as a precursor chemical. In addition, the unusual or excessive loss or disappearance of ephedrine from the pharmacy must be reported to DEA.

(From the April, 1995 *Alaska Board of Pharmacy News;* reprinted with permission.)

Item 841 – Stadol Information Needed

The North Carolina Controlled Substances Regulatory Branch, located in the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, is requesting that anyone with information concerning the history and current pattern of abuse for Stadol (Butorphanol Tartrate) injectable and nasal spray to write or call Mr. John Womble, North Carolina Controlled Substances Regulatory Branch, 325 N. Salisbury Street, Suite 666, Raleigh, NC 27603; 919/715-0652.

The data that is collected about the abuse of this substance will be used in a recommendation to the North Carolina Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services, concerning whether this substance should be scheduled in the North Carolina Controlled Substances Act and Regulations.

Item 842 – Errors and Interruptions

Although there is no data in the Board office to support the premise, it is commonly accepted that interruptions of a pharmacist's tasks can contribute to prescription errors. One chain pharmacy (Wal-Mart) is testing a prototype layout which consists of a pharmacy with two levels. The pharmacist on the lower level or first floor performs all the counseling on prescriptions filled and has a computer terminal to review patient files during this process. On the upper or second floor, the pharmacist and technicians work in a quiet, uninterrupted environment, which that company believes will reduce the chance for dispensing errors.

As of the press time for this publication, the company planned to open a prescription department containing this floor plan in Smithfield.

Item 843 – Quinine Sulfate for Leg Cramps

On February 22, 1995, the Food and Drug Administration (FDA) issued a final rule requiring drug manufacturers to stop manufacturing and marketing over-the-counter (OTC) quinine sulfate for nocturnal leg muscle cramps. FDA stated the ruling was due to a lack of adequate data to establish a general recognition of safety and effectiveness of quinine for this indication.

As a result of the FDA rule, all OTC quinine sulfate products carrying a label indication for nocturnal leg cramps are now considered misbranded products. Pharmacists providing such products to their patients would be violating both federal and Kentucky law.

Pharmacists may continue to dispense quinine prescriptions for malaria, which remains the only approved indication for the drug. Pharmacists should contact physicians continuing to treat nocturnal leg cramps via prescription, and should inform them that the FDA has published the preceding rule. Decisions concerning quinine therapy should be accurately noted in the patient medication records.

Manufacturers have already started reformulating their OTC leg cramp products without quinine. Pharmacists should alert their patients that the OTC product they previously used may have the same product name but new therapeutic entities.

(From the June, 1995 *Kentucky Board of Pharmacy News;* reprinted with permission.)

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