April, 1995

North Carolina Board of Pharmacy

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P.O. Box 459, Carrboro, NC 27510-0459
Carrboro Plaza Shopping Center, Highway 54 Bypass,
Suite 104-C, Carrboro, NC 27510-1597

Item 816 – Disciplinary Actions

November:

Joel Allison Ragan, Pffaftown (DOB: February 22, 1949). Order Continuing Hearing entered. Pharmacy license surrendered to Board pending Final Order of Board.

James Gene Butler (DOB: July 29, 1935) and Medical Arts Pharmacy, Shelby. Consent Order Entered treated as a revocation. No action on pharmacy.

Stanley J. Gajdik (DOB: March 30, 1945) and Fairview Pharmacy Consultants, Fairview. Consent Order entered. License placed on probation for five years with active 90-day suspension of license and other specific conditions; permit suspended 90 days, stayed five years with active seven-day suspension and other specific conditions.

January:

Charles Dermont Duffey, Winston-Salem (DOB: September 16, 1949) and Community Drugs, Winston-Salem. Pleaded guilty to six felony charges. Pharmacy license of Mr. Duffey revoked. Permit revoked.

Pre-Hearing Conferences:

Billy D. Maddox, Asheville (DOB: December 13, 1943) and Pete Nick Sagonias, Asheville (DOB: August 13, 1940). Heard by Board Member Day. Dispensing of a prescription and failure to offer counseling. Recommendation: License suspended 30 days, stayed three years with active seven-day suspension and other conditions. Accepted by Mr. Maddox and Mr. Sagonias and the Board.

Allen T. Munday, Davidson (DOB: December 26, 1956), James Seymour Thomas, Charlotte (DOB: March 6, 1925), and Neil's Pharmacy, Davidson. Heard by Board Member Randall. Prescription filled for patient who had sensitivity to the product in the past and patient had reaction to the product; possibly no patient counseling or review of profile occurred prior to dispensing of product which resulted in direct cause of harm to the patient. Recommendation: Permit to operate pharmacy suspended seven consecutive days, stayed one year with Mr. Munday and Mr. Thomas being reprimanded and cautioned to establish working procedures that would prevent a similar incident from happening in the future and other conditions. Accepted by Mr. Munday, Mr. Thomas, and the Board.

Steven C. Armstrong, Fairview (DOB: November 29, 1952). Numerous prescription medications dispensed over a 90-day period for which there were no legitimate prescriptions; these orders placed into prescription record of several pharmacies in Asheville area even though a prescription order was never received and no attempt to secure an order was made. License suspended indefinitely, stayed one year with active seven-day suspension and other conditions. Accepted by Mr. Armstrong and the Board.

Larry Wayne Nichols, Taylorsville (DOB: October 14, 1943). Failure to offer to counsel a patient on a prescription for Doxycycline. Board Reprimand. Accepted by Mr. Nichols and the Board.

Dan G. McCrimmon, Jr., Pittsboro (DOB: May 11, 1960). Use of prescription medication for which no valid prescription existed and which rendered him unable to perform pharmaceutical services; failed to maintain biennial controlled substance inventory as required. License suspended indefinitely, stayed five years with 120-day active suspension and other specific conditions. Accepted by Mr. McCrimmon and the Board.

Item 817 – Committee to Revise the Practice Act

The Board has formed a committee to develop a proposed revision of the North Carolina Pharmacy Practice Act in response to a request from Dan Garrett, president of the North Carolina Society of Hospital Pharmacists, and Joe Edwards, president of the North Carolina Pharmaceutical Association. The committee has met several times and is considering changes in the Practice Act which would meet contemporary needs and future developments in health care.

Members of this committee are:

William H. (Bill) Randall, Jr., *Chairman*
P.O. Box 999
Lillington, NC 27546

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National Pharmacy

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and can only be ascertained by examini

Flu Vaccination Programs

An average of 20,000 deaths occur annually in the United States from influenza and influenza-related pneumonia, while an additional 40,000 deaths are attributed each year to pneumococcal pneumonia. As reported to the National Vaccine Program Office of the U.S. Department of Health and Human Services by the National Coalition for Adult Immunization, an estimated 50 million people are at high-risk for contracting these diseases. It is no surprise, then, that vaccines proven effective against both influenza and pneumococcal pneumonia are in great demand by a significant percentage of the population.

A number of organizations have recognized this demand and have developed strategies for implementing widespread, low-cost vaccination programs designed to deliver the service outside of the physician's office in such convenient, neighborhood locations as pharmacies, fire stations, and even libraries. In its first year of implementing vaccination programs on a national basis, one such company, Nurses Prn Flu Central, administered a total of 221,176 immunization injections in the pharmacy departments of a major retailer with outlets in all 50 states. Nurses Prn charged $10 per flu vaccine in 1994, as compared to an estimated average of $40 for a visit to the physician's office that included a vaccination. To accommodate Medicare beneficiaries, Nurses Prn Flu Central billed Medicare directly.

When carefully administered, community-wide vaccination programs for influenza and other diseases can be effectively used to protect the public health and reduce health care expenditures. A key strategy of a plan developed by the National Vaccine Program is to improve overall vaccination levels through an "every resource/every setting" approach, which removes barriers to immunizations services, thereby making vaccines more available. To accomplish this goal, the plan advocates the development of innovative ways to reach more people, and according to a program spokesperson, proposes that "achieving high immunization coverage levels in children and adults will require collaboration between health care providers and a variety of groups with access to those populations."

One approach already discussed that is utilized to make influenza vaccinations more available to a large number of people involves providing vaccinations in community pharmacies. In providing the public with increased access to immunizations, it is essential to maintain the integrity and built-in safeguards of the current infrastructure for distributing and dispensing legend drugs. However, there is concern that some of the influenza immunization programs conducted during the autumn of 1994 may have violated federal and state requirements governing the distribution, possession, and dispensing of prescription drugs. The states reporting such activity note that one of the weak links in the plan appears to be the physician's immunization orders, which fall into two general categories: "blanket authorization" and "authorization after the fact."

In the "blanket authorization" scenario, vaccine manufacturers developed collaborative agreements with physicians to prescribe, and for nurses from such agencies as visiting nurse associations to administer, influenza vaccinations. The protocols typically utilized included the issuance of a standing order by a physician, the administration of vaccinations to patients by a registered nurse, and the delivery of service in pharmacies. Some state boards of pharmacy have reported that in some instances, the physician issuing the blanket authorization was not licensed in the state in which the vaccine was being administered.

In the "authorization after the fact" scenario, arrangements among manufacturer, physician, and nurse were equivalent to those employed under the "blanket authorization" plan, with one essential difference. Physicians involved in this type of program did not prepare a prescription until after the vaccine was administered to a patient. At that time, physician approval, usually *in absentia*, was provided and an individual order was then filed.

In a southwestern state, for example, the Board of Pharmacy identified a number of problems inherent with these immunization strategies. State statute prohibited the possession of prescription drugs by nurses. In addition, the vaccines were shipped into the state by unlicensed, out-of-state distributors. Once outside the normal chain of distribution, the integrity of the vaccines could not be assured. The state's medical board regulations also required that in order to prescribe a medication, a physician must know the patient. Standing orders or "blanket authorizations" for prescription drugs are not allowed. Finally, it was discovered that in a number of instances, these mobile vaccination clinics had no protocols in place for the emergency care of any patient who may have experienced an adverse reaction to a vaccination. Once the agencies conducting these types of vaccination programs were made aware of the problems and once the physician who was providing the blanket authorizations was advised of his liability exposure, they voluntarily withdrew their program from the state.

In another case, this time in a northeastern state, one of the private agencies conducting these mobile vaccination programs was informed by the state authority that regulates health care facilities that they needed to submit documentation for licensure in order to conduct mobile vaccination clinics. According to an official of the Board of Pharmacy, the agency conducting the vaccination program chose to ignore the licensure requirements and proceeded to conduct vaccination programs without the appropriate licensure. This investigation was turned over to the Bureau Chief of Health Care Facilities in the state's Department of Health and Human Services for further action.

Although most pharmacists welcome the opportunity to become involved in this important public health initiative, many community pharmacists are troubled by the fact that they had little or no advance information about a vaccination program being conducted at their site. In fact, many were unaware that their facilities would be participating in a vaccination

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program until the visiting nurses appeared and began preparing for immunizations.

It is clear that the dual incentives of increased public demand and high financial return will continue to make the provision of such vaccine programs attractive to a diverse group of organizations and businesses. To ensure the safety and protection of the public, however, these groups must become familiar with and work within the framework of the medical and pharmacy practice laws and regulations.

NABP Seeks Examination Item Writers

The National Association of Boards of Pharmacy (NABP) invites motivated pharmacy practitioners, educators, and regulators to indicate an interest in serving as item writers for one of the Association's three examinations: the NABPLEX, the Federal Drug Law Examination (FDLE), or the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

Participation in the item writing program allows pharmacy professionals from around the country to meet and share ideas with their colleagues while making a valuable contribution to the profession. With NABP's planned transition to computerized testing, this is an especially exciting time to become involved.

Item writers typically attend a weekend workshop at NABP's headquarters, where they learn the skills necessary to write test items for their designated examination. Applicable expenses for this workshop are paid by NABP. After completing the workshop, item writers will receive periodic requests to develop new test items that will be considered for inclusion in the exam. This work is done at home and requires no travel.

Interested individuals should send a letter of interest and a current resume or vita to ACE Chairman, 700 Busse Highway, Park Ridge, IL 60068.

NABP/HCFA Establish MOU

Signalling a strong effort to discourage the widespread fraud and diversion by durable medical equipment suppliers that has been reported across the country, the National Association of Boards of Pharmacy (NABP), the Health Care Financing Administration (HCFA), and CIGNA/DMERC, HCFA's claims processor for durable medical equipment, prosthetics, orthotics, and supplies in the western region of the United States, have joined forces and agreed to a Memorandum of Understanding (MOU) which initiates a program to organize and readily provide important information concerning the distribution of prescription drugs by medical equipment suppliers.

The first such agreement of its kind, the MOU creates a cooperative partnership to assure that pharmacies and suppliers submitting claims on behalf of Medicare beneficiaries comply with state and federal laws. This can be best evidenced by the possession of the appropriate license in the state(s) where they do business.

Primarily affected by the MOU at this time are those states within CIGNA/DMERC's jurisdiction. CIGNA/DMERC processes claims in Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. Although NABP will circulate information to all states, CIGNA/DMERC data will focus on those states listed above.

For some time the state boards of pharmacy have voiced concern about the increasing incidence of fraud and diversion by medical equipment suppliers. Abuses affected the entire gamut of distribution and reimbursement for services. Investigative data from the boards reported on situations where suppliers were housed and were distributing supplies and prescription medications from garages or warehouses found to be outside state licensing laws and safe operating standards.

Other information indicated that some suppliers were ordering prescription drugs from pharmacies and dispensing them to patients directly without appropriate licensure or safeguards for public health. HCFA's interest in this particular scenario concerns the large mark-up for services. Some suppliers are billing government reimbursement programs for the services provided after they receive the supplies and prescription medications and dispense them to the patient. In some cases, the services were either absent or below the actual level of care billed for.

Determined to confront these problems, several boards of pharmacy met with HCFA representatives to discuss their concerns, and to explore ways to seize control of the problem. It was agreed that a necessary first step would be the sharing of information to help the states identify those entities who distribute prescription drugs and may not be licensed with the state boards.

To ensure its successful operation, the MOU requires joint participation by HCFA, CIGNA/DMERC, NABP, and the state boards of pharmacy. CIGNA/DMERC will provide NABP with quarterly lists of suppliers who are billing Medicare for prescription medications. NABP will incorporate that data into the Disciplinary Clearinghouse that the Association maintains for pharmacists, technicians, interns, and wholesalers, and will forward the listings to the state boards. The boards are asked to review the information, check if the listed suppliers are required to be licensed in their state, and, if so, are in fact licensed in the state. In some cases, these determinations will require on-site inspections by the board of pharmacy. NABP will forward the data to CIGNA/DMERC and HCFA, and will assist in follow-up actions taken by the boards, HCFA, or CIGNA/DMERC.

Initially, state boards will be able to identify entities that are dispensing prescription medications without a pharmacy or wholesale distributor's license. When the program is fully operational, the cooperative effort between the state boards of pharmacy and HCFA is expected to result in legal and disciplinary actions against those medical equipment suppliers who are engaging in fraud and diversion. The program will also make HCFA aware of entities that are dispensing medications without a license. With this information, HCFA will be able to proceed with legal actions.

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Members:

North Carolina Pharmaceutical Association

Mike James
702 North Person Street
Raleigh, NC

Alternate: Pam Joyner
2100 Carpenter's-Upchurch Road
Morrisville, NC 27560-9710

North Carolina Society of Hospital Pharmacists

Bill Harris
Route 3, Box 121A
Apex, NC 27502

Alternate: Steve Novak
P.O. Box 1747
Gastonia, NC 28053-1747

North Carolina Society of Consultant Pharmacists

Helen Deere-Powell
201 Trotters Ridge Drive
Raleigh, NC 27614-9621

University of North Carolina School of Pharmacy

Tim Ives
5502 Bradshaw Quarry Road
Efland, NC 27243-9615

Campbell University School of Pharmacy

Peggy Yarborough
6845 Flat Rock Road
Sims, NC 27880

North Carolina Board of Pharmacy

Jack Watts
444 Tarleton Avenue
Burlington, NC 27215

Wm. Whitaker Moose
P.O. Box 67
Mt. Pleasant, NC 28124

North Carolina Association of Independent Pharmacists

Walter Davis
Davis Mutual Drugs
2801 Brentwood Road
Raleigh, NC 27604

Alternate: Tim White
1328 Duplin Road
Raleigh, NC 27607

Chain Drug Stores

Jimmy Jackson
Kerr Drugs
P.O. Box 61000
Raleigh, NC 27661

Ex-Officio Members

Dean Ronald Maddox
Campbell University
School of Pharmacy
Buies Creek, NC 27605

Dean William Campbell
University of North Carolina
School of Pharmacy
Beard Hall, CB 7360
Chapel Hill, NC 27599-7360

Al Mebane
P.O. Box 151
Chapel Hill, NC 27514

Frances Gualtieri
P.O. Box 968
Chapel Hill, NC 27514

David Work
P.O. Box 459
Carrboro, NC 27510-0459

Some legislation may be presented to the 1995 session of the General Assembly. However, a complete review and revision of the statute will probably need to wait until the 1997 session.

Item 818 – Confidentiality and Patient Counseling

Common sense would dictate that pharmacists be sensitive to their surroundings when counseling patients. It's often necessary to discuss very private information with patients as part of the patient counseling procedure. A recent column by Joe and Teresa Graedon, which was in response to a letter from one of their readers, highlighted that fact.

Some locations have set aside private areas for counseling even though it is not required by rule. There is no doubt that patients as well as pharmacists would be much more receptive to counseling in a private and quiet atmosphere.

Item 819 – Preceptor Responsibilities

While preceptors have many responsibilities for the instruction of interns, the filing of forms is not one of those duties. It is the **student's responsibility** to file forms with the Board within five days of the beginning and ending of each experience period. This gives the student a ten-day window at the beginning and end of each work segment to submit the forms to the Board office.

It is worthwhile to remind interns at the beginning of their experience, preferably on day one, that form filing is their responsibility under Board rules. In the past, cases have arisen in which a student has left forms to be completed by the preceptor, and these documents were not filed in a timely manner. Hours of experience can be, and have been, denied under these circumstances if they are submitted significantly more than five days after the experience ends.

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Item 820 – Choking from Oral Syringes

Two types of syringes are used to administer oral medication: the standard hypodermic syringes without a needle, or syringes specifically designed for oral administration of medication. Both syringe types are supplied with caps that should be removed before the medication is drawn into the syringe or given to the patient.

Trying to administer oral medication through a syringe with the cap in place is potentially life-threatening. This could result from filling the syringe and replacing the cap, or filling a capped syringe. **In both cases, inadvertently attempting to administer medication could blow the cap off the end of the syringe into the patient's throat.**

FDA has received four reports about infants choking on plastic caps from syringes. Reports in the literature also describe syringe cap aspiration.

In response to these events, FDA recommends the following precautions:

- Remove and discard syringe caps before providing syringes that are specifically made for oral medications to patient caregivers.
- Caution caregivers of your patients to discard caps from syringes that they buy OTC.
- Report any problems encountered with syringe caps to FDA's MedWatch (1-800/FDA-1088) program.

Reprinted from the *FDA Medical Bulletin*, September 1994.

Item 821 – The Morphine Double Effect, Ethics or Accident?

It was surprising, although it should not have been, to read an opinion piece in the Op-Ed section of the November 1, 1994 *New York Times*, "Killing Pain, Ending Life." This thoughtful essay dealt with the use of morphine drip and euthanasia for patients who were near the end of their life with no realistic chance of survival. This was explained as the double effect of morphine drip with the intent to relieve pain with death as a foreseen but unintended consequence. Even the Catholic Church has noted, "It is not euthanasia to give a dying person sedatives and analgesics for the alleviation of pain," says a 1975 directive from the National Conference of Catholic Bishops, "even though they may deprive the patient of the use of reason, or shorten his life."

Observers of health care have seen this kind of activity long before Dr. Kevorkian came on the scene. Certainly nothing sinister could be attributed to those cases in which the recipient was in severe and intractable pain with no known chance for survival.

Different situations arise, however, and at least two have come to our attention through our death reporting rule. In one case, a 22-year-old obese female who had minor surgery on her elbow, had morphine 10 mg. I.M. administered every three hours as part of a recovery process. After two such doses, the next drug administered was Dilaudid 4 mg. I.V. Shortly thereafter, the patient experienced breathing difficulties and expired two days later. The medical examiner report indicated "anoxic brain injury," probably due to respiratory depression from the opiate injections and obesity.

In another case, a male in his 30s had surgery for a facia injury, which resulted in much blood loss. The patient had a history of sleep apnea, and morphine 2 to 10 mg. I.V. drip every hour PRN was ordered. Six hours later, the patient expired, apparently due to respiratory depression of the morphine, the anemia from blood loss, and the propensity for sleep apnea.

These two incidents are shared in general terms so that pharmacists may properly guide their practice, particularly with prospective drug use review as required under OBRA '90. No pharmacy disciplinary actions resulted from these activities.

Item 822 – Rules Notice

In the March issue of the *North Carolina Register*, the Board of Pharmacy gave public notice of two rules hearings scheduled in April and May. The first hearing is set for Tuesday, April 18, 1995 at 2 p.m. at the Institute of Pharmacy in Chapel Hill, and the other is scheduled for 3 p.m. on Friday, May 19, 1995 at the Grove Park Inn in Asheville.

Many of the rules deal with device and medical equipment suppliers, but there are several other proposals which could affect pharmacy. Among these are a provision for pharmacists to administer drugs, a change in the Board rules on drugs that can be dispensed by PAs and NPs, a rule limiting the dispensing of veterinary prescription drugs to pharmacists or veterinarians, a rule allowing a $20 charge for returned checks, and a requirement for a compounding log in a pharmacy which shows who compounded what products and other proposed rules. To receive a copy of the proposed rules, please send $1.50 in postage or a check to the Board office to cover mailing expenses, and one will be sent to you.

Item 823 – Drug Disaster and Loss Report Form

North Carolina General Statute 90-85.25 requires that the pharmacist in charge of a pharmacy shall report to the Board within ten (10) days of the event of any disaster, accident, theft, or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy. Federal regulations require the reporting of any theft of controlled substances to the Drug Enforcement Administration.

The Board has developed a form for reporting such disasters, etc. The form is available from the Board office. This item is a reminder to promptly report such incidents to the Board.

Item 824 – Biennial Inventory

The customary biennial inventory date of May 1st is fast approaching. This shall serve as a reminder that an inventory of controlled substances needs to be taken at least once every two years, and for many pharmacies the date is on or about May 1st.

While you may estimate counts of open containers of Schedules III and IV drugs, it is necessary to make an exact count of all drugs in Schedule II.

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Item 825 – Limit on Schedule II

Pharmacists should be aware that there is no quantity limit for a prescription for a Schedule II drug dispensed from a community pharmacy. There is also no time limit between the time that the prescription is written until it can be filled.

There is a 72-hour limit for partial filling of normal Schedule II prescriptions, and a 60-day limit on partial filling of Schedule II prescriptions for patients who are terminally ill.

Just because a prescription is technically and legally valid does not mean you are required to fill it. You can still use judgment in dispensing such prescriptions, and that is up to each individual pharmacist.

Item 826 – Phone List

The following list of frequently called phone numbers is provided for your reference.

North Carolina Board of Pharmacy	919/942-4454
	Fax: 919/967-5757
North Carolina Pharmaceutical Association	919/967-2237
	1-800/852-7343
	Fax: 919/968-9430
North Carolina Society of Hospital Pharmacists	919/933-6760
North Carolina Chapter, American Society of Consultant Pharmacists	1-800/735-9111
Board of Medical Examiners	919/828-1212
Board of Nursing	919/782-3211
Board of Dental Examiners	919/781-4901
Veterinary Medical Board	919/733-7689
Board of Optometry	910/285-3160
Drug Enforcement Administration (Greensboro Office)	910/547-4219

Item 827 – May Board Meeting

The date of the regular Board meeting in May has been moved to **Friday, May 19, 1995 at the Grove Park Inn in Asheville,** and will be held in conjunction with the NCPA Annual Convention.

Item 828 – Board Member Election

Ballots for the election of a Board member have been distributed separately by mail to all licensed pharmacists residing in North Carolina. Please note that the results of this election will be tallied on Friday, May 19, 1995 at the Grove Park Inn in Asheville. Ballots must be received in the Board office by Wednesday, May 17, 1995, to be counted in this election.

Candidates for the election are:

William H. (Bill) Randall, Jr.
Margaret (Maggie) Carpenter
W. Timothy Giddens
Robert L. (Bob) Crocker
C. Barry Paoloni
Ernest G. (Ernie) Hargett

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.

David R. Work, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh - National News Editor & Executive Editor
Janice Teplitz - Editorial Manager

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700 Busse Highway
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