October, 1993

North Carolina Board of Pharmacy

P.O. Box 459, Carrboro, NC 27510-0459
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Published to promote voluntary compliance of pharmacy and drug law.

Item 760 - Disciplinary Actions

May:

James Dallas Neal, Liberty; Date of Birth: January 19, 1944. Request for reinstatement of pharmacy license denied.

David R. Bowers, Statesville; Date of Birth: July 18, 1950. Order Modifying Final Order of October 10, 1992 entered, and reinstatement of license with conditions granted.

Emmanuel (Tripp) May, III; Date of Birth: May 9, 1940; and May Pharmacy, Burlington. Obtaining, consuming, and dispensing controlled substances without authorization. Respondent pharmacy - failure to prevent events described above when the permit holder knew or should have known the violations were occurring. Pharmacist May's license and pharmacy permit for May Pharmacy revoked, stayed for five years with active suspension of Pharmacist May's license for 30 days and other conditions.

June:

Quay H. Beck, Jr., & Skyland Pharmacy, Skyland; Date of Birth: October 11, 1949. Insufficient evidence to establish violations. No disciplinary action taken, matter dismissed.

Pre-Hearing Conference: **Roger L. Simpson; Date of Birth: July 21, 1954.** Heard by Board Member Watts. Positive result of urine test for barbiturates in November and December of 1992; three other such urine tests had revealed a negative result. Recommendation of Mr. Watts: Mr. Simpson have a urine screen following the pre-hearing conference and, if negative, continue Stay Order entered pursuant to administrative hearing held January 21, 1991. If the result of the urine test is positive then the matter would go before the full Board. Recommendation accepted by Mr. Simpson and the Board.

Pre-hearing Conference: **Samuel H. Price, Jr., Mooresville; Date of Birth: August 1, 1929.** Heard by Board Member Watts. Evidence presented of missing controlled substances from pharmacy in Mooresville; admitted use of injectable Talwin in the past. Voluntary surrender of license on May 20, 1993. Recommendation of Mr. Watts: accept the surrender of license and not reissue without a hearing before the full Board. Recommendation accepted by Mr. Price and the Board.

Pre-hearing Conference: **Allen D. Putnam, Shelby; Date of Birth: August 12, 1930.** Heard by Board Member Watts. Termination from employment for unauthorized refills on prescriptions; admission of improper documentation of refills. Recommendation of Mr. Watts: Board reprimand. Recommendation accepted by Mr. Putnam and the Board.

Item 761 - Letter from a Pharmacist

Some pharmacists have expressed a reluctance to comply with the Board's rule regarding patient counseling. What follows is a partial transcript of a letter sent to the Board office by a pharmacist in this state who had a prescription filled for her daughter. The author's name has been withheld, not by request, but as an editorial decision.

I am a licensed pharmacist in North Carolina. Since I teach at a local community college, I get my prescriptions filled like the rest of the public.

Today I took a prescription to my local pharmacy to be filled for my three-year-old daughter. The prescription was written for Pediazole one-and-one-half teaspoonfuls twice a day. The prescription was filled and labeled with Pediaprofen (ibuprofen) suspension, take one-and-one-half teaspoonfuls bid, instead of the antibiotic prescribed.

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National Pharmacy

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FDA Introduces MedWatch

The Food and Drug Administration (FDA) depends on pharmacists to serve as the frontline defense against adverse events and product problems with medications and devices. To encourage and facilitate the reporting of serious adverse events and important product problems, FDA has developed Med*Watch*, a new medical products reporting program.

While the FDA does not require reports on every adverse reaction observed, it would like to know about those serious events in which a device or medication, either prescription or OTC, has been associated with a death, life-threatening condition, initial or prolonged hospitalization, disability, or congenital anomaly. The FDA is particularly interested in reports involving a medication that has been on the market for a relatively short time, about three years or less, because historically that has been when the most critical problems have surfaced.

The Agency also wishes to learn about product quality problems for both prescription and nonprescription drug products, such as inaccurate or unreadable product labeling, packaging, or product mix-up, contamination or stability problems, and particulate matter in injectable products. Malfunctioning devices that are likely to result in death or serious injury if used in a patient should also be reported.

Under the Med*Watch* program, the FDA has consolidated the various forms previously used to report adverse events or problems with medications and devices into a single, one-page reporting form (FDA Form 3500). Pharmacists planning to file a report can find the new form in many publications, including the *FDA Medical Bulletin.*

The FDA has established a 24-hour, seven-day-a-week, toll-free telephone line for health care professionals wishing to request information, report quality problems, and receive a copy of the new form and the *FDA Desk Guide.* The *Desk Guide* contains examples of events that should be reported, completed sample forms, and blank forms with step-by-step instructions. The phone number is 1-800/FDA-1088. Reports can also be made on-line through a computer-to-computer interface by calling with a modem the FDA computer at 1-800/FDA-7737 and responding to the questions that appear on the screen. Completed report forms can also be faxed toll-free to FDA at 1-800/FDA-0178.

Because of different reporting requirements, problems with vaccines should continue to be reported to the Vaccine Adverse Events Reporting System (VAERS), a joint FDA/CDC project, at 1-800/822-7967.

Working together through the Med*Watch* program, FDA, pharmacists, and other health care professionals can safeguard the public health through the early detection and prompt reporting of serious adverse events and product problems.

In order to encourage participation in the program, the FDA will hold a special conference next year for health care practitioners and academia concerning medication-induced and device-induced problems. The Agency will also strive to keep health professionals informed about the use of Med*Watch* reports, and will urge medical, dental, nursing, and pharmacy schools to include lectures about adverse event and product problem recognition and reporting in their curricula.

DEA Creates Mid-level Practitioner Category

After several months of commentary and analysis, the Drug Enforcement Administration (DEA) has released its final rule amending Title 21, Code of Federal Regulations (CFR), Parts 1301 and 1304, regarding the definition and the registration of a new category of DEA registrants, entitled "mid-level practitioners (MLPs)," who are permitted to dispense controlled substances by the state in which they practice.

The final rule, which was published in the June 1, 1993 *Federal Register,* defines a "mid-level practitioner" as

> an individual practitioner [as defined in §1304.02(d)], other than a physician, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense [federal definition] a controlled substance in the course of professional practice.

The registration requirement applies to

> . . . any person who administers, prescribes, or dispenses directly, i.e., affects the physical delivery of a controlled substance to the ultimate user or its agent . . . unless exempted by law or pursuant to Title 21, Code of Federal Regulations (CFR), §1301.24-1301.29 . . .

Some examples of mid-level practitioners cited by the DEA are nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants. Because there are wide variations between states regarding the prescribing authority of various MLPs, the newly established category serves to eliminate any questions regarding the practitioner's medical practice or activities, and whether or not the individual is allowed to handle controlled substances by the state in which he or she practices.

According to the DEA, this category was created because the Agency felt it was important to alert the appropriate individuals who have the responsibility for verifying authorization to dispense controlled substances that there may be a restriction on the authority of the individual whose application they are reviewing.

"The final rule was instituted to define classification and establish an administrative mechanism for issuing the registra-

tion," explained Andy McFaul of the DEA's Office of Diversion Control, Policy Unit.

In order to separate the registrations of mid-level and traditional practitioners, the DEA added a new type of DEA number. Registration numbers issued to MLPs will now begin with the letter "M," while DEA numbers issued to traditional registrants will continue to begin with the letters "A" or "B." The "M" alerts pharmacists and wholesalers of the need to verify that the state authorizes these registrants to engage in specific controlled substance transactions.

A provision has also been included that requires MLPs to maintain documents required by the state in which the individual is practicing and that describe the conditions and extent of that individual's authority to dispense controlled substances. The documents should be kept readily available for inspection and copying by DEA authorities. Examples of such documentation are practice agreements, practice guidelines, and protocols.

An explanation of the conditions under which MLPs may conduct research as a coincident activity to their registration is included in 21 CFR, Part 1301. This rule states that,

> A person registered to dispense controlled substances in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances, except that a mid-level practitioner, as defined in §1304.02(f), may conduct research coincident to his/her practitioner registration only to the extent expressly authorized by state statute.

The section also clarifies the exemption of MLPs in institutions and agents or employees of registered practitioners from the registration requirements. Generally, a mid-level practitioner may dispense, administer, and prescribe controlled substances under the registration of the hospital or institution where the MLP is employed without an individual registration to do so. This provision also applies to interns, residents, foreign-trained physicians, physicians on staff at a Veteran Administration facility, and physicians who are agents or employees of the Health Bureau of the Canal Zone government.

A related section of the rule addresses individual practitioners who are agents or employees of another practitioner registered to dispense controlled substances. When acting in the usual course of the individual practitioner's employment, such mid-level practitioners may administer and dispense controlled substances under the registration of the employer or principal practitioner if the individual MLP is authorized or permitted to do so by the jurisdiction in which he or she practices.

While this new DEA rule was in the proposal stage and open to commentary, a number of individuals raised concerns regarding its content.

A major area of concern was the definition of the term "dispense." The DEA clarified that the federal definition of the term "dispense," as specified in the Controlled Substances Act, applies in this ruling. The question of whether an individual who administers but does not prescribe controlled substances is considered to be "dispensing" was also addressed. According to the DEA, dispensing includes the acts of administering and prescribing controlled substances, either as individual or combined acts.

Another area addressed was the granting of controlled substance privileges to mid-level practitioners by providing them with a DEA registration number. The commentors held that MLPs do not have the education and experience to properly dispense controlled substances, that registering MLPs will overburden state regulatory forces, and that by issuing registration numbers to MLPs, the DEA is condoning the expanding privileges of MLPs in prescribing controlled substances.

In response, the DEA reiterated that the requirement for a registration issued to an individual whom the state has approved to handle controlled substances has already been established under federal legislation. Registration of MLPs by the DEA occurs after the state has made its determination regarding prescribing authority. The state is also given the authority to set standards for medical practice, such as educational standards.

The DEA expressed an interest, however, in the fundamentals through which state authority is granted. As noted in the June 1, 1993 *Federal Register,* the DEA "plans to work with the appropriate state authorities and industry to encourage consistency and clarity of standards of education, training, and the scope of controlled substance authority for MLPs."

Condom Brochure Available in Spanish

The Food and Drug Administration has announced the availability of a Spanish language pamphlet on condoms and sexually transmitted diseases.

Entitled "El Condon Proteccion Contra las Enfermedades de Transmision Sexual . . . Expecialmente el SIDA" (The Condom Protection Against Sexually Transmitted Diseases . . . Especially AIDS), the pamphlet presents facts about the effectiveness of male condoms in preventing these diseases. It includes information about choosing, handling, storing, and using a condom properly, and also discusses the use of spermicides and lubricants.

The pamphlet is available free of charge from the National AIDS Spanish Hotline, 1-800/344-7432. Large orders are available from the National AIDS Clearinghouse, 1-800/458-5231. An English version of the pamphlet, which was published earlier by FDA, is also available from the Clearinghouse.

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I did not receive counseling when the prescription was delivered to me, and I did not notice the error until I was home. I returned the ibuprofen to the pharmacy, and the prescription was rechecked to make sure that Pediazole had indeed been prescribed by my daughter's pediatrician.

I consider this error to be a potentially serious misfilling. If I had not recognized that the medication was not the prescribed drug, my daughter would not have received the anti-infective necessary to treat her documented infection. A delay in treatment could have resulted in serious consequences. A 12-day uninterrupted course of ibuprofen could have also been harmful, masking pain and fever in the absence of antibiotic therapy. The relatively high dose (150 mg) might have caused significant gastro-intestinal irritation.

While I realize that all of us are human and that mistakes do happen, I believe this error would never have occurred if I had received patient counseling. The pharmacist would have realized that an NSAID was not the intended medication if only rudimentary counseling had been provided.

Additionally, I was never offered an apology by anyone in the pharmacy.

Item 762 - Decision on Patient Counseling Violations

At the July and August Board meetings, the members considered a case in which Board inspectors presented three prescriptions for filling at a pharmacy, and no patient counseling occurred on any of these occasions. Prescriptions were presented for ampicillin, Indocin®, and Coumadin®. While ampicillin is a relatively popular drug with few side effects, the problems associated with Coumadin are well-known. The dispensing of a prescription for Indocin was the occasion for a well-known and precedent-setting case in this state regarding negligence.

As of the deadline for this *Newsletter,* the two pharmacists involved in this hearing still had time to appeal. Therefore, no names will appear in this publication.

Pharmacists should find it useful to know, however, that the two pharmacists involved each received seven-day active suspensions, are required to pass the Board's law exam by March 1, 1994, and have a probationary period of five years. In addition, the permit received a 30-day suspension, stayed for a period of five years.

By this act, the members communicated to the people of the state, as well as to pharmacists, their serious intent to apply the patient counseling rule.

Item 763 - New Rules

The General Assembly has adopted several new statutes that affect pharmacy. The following summarizes these new rules.

- One statute calls for the revision of the Pharmacy Practice Act, specifically the section which provides for registration of mail-order pharmacies. This statute became effective on October 1, and the Board is in the process of adopting rules to implement this procedure. The rules are expected to be finalized in February or March of 1994.
- A change was made to the statutes pertaining to insurance that allows consumers to select the pharmacy of their choice. There are, however, several significant exceptions to the statute.
- Another amendment to the State Pharmacy Practice Act provides that the label of every prescription drug product dispensed shall contain the discard date, which will be one year from the date dispensed or the manufacturer's expiration date, whichever is earlier.

The Board has also adopted several new rules that affect the practice of pharmacy. Both these rules and the revised statute will be available in a supplement to the *Pharmacy Law Book*, which is scheduled for publication in December.

- The Board has adopted a procedure to be included in section .3001 regarding the disposal of prescription drugs. Although this does not yet apply to controlled substances, it is expected that the Commission on Mental Health, Mental Retardation, and Substance Abuse will consider this matter in the near future.
- Another section has been added to the definition section of our rules which defines a pharmacy intern. It states, among other things, that a pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision, perform all acts constituting the practice of pharmacy. Please note that the term "supervision" is used in this section and has a specific definition found elsewhere in the rules.
- A section of the rules was amended to specifically state that a pharmacist who has been found in violation by the Board or found guilty by a court for violating the laws, rules, or regulations governing the practice of pharmacy cannot serve as a preceptor without Board approval.
- Another provision was added to the Board rule which allows a pharmacist using professional judgment to dispense a quantity in excess of the face amount authorized for a non-controlled substance up to the total amount authorized. A pharmacist

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shall not dispense in excess of the face amount of the prescription for a controlled substance or psychotherapeutic drug without authorization from the prescriber.

- Another part of the rules regarding prescriptions allows a pharmacist to dispense a one-time emergency refill of up to a 72-hour supply, providing that the prescription is not for a Schedule II drug, that the medication is essential for the continuation of therapy, and if the interruption of therapy would likely produce undesirable health consequences.
- A section on continuing education was amended to specify the types of hours expected by the Board.

During the rule-making process, the Board declined to adopt a rule on self-inspection forms, and another amendment to the definition of supervision which would have allowed the Board to give approval for alternative supervision arrangements and other matters.

Item 764 – Simple Patient Literacy Test Available

A recently published article in *Family Medicine* (FAMMED 1993; 25:391-5) describes a simple, easy, and quick assessment of adult reading ability. The test is easy to administer and only requires one or two minutes to complete.

If you are interested in obtaining a copy of this article, please send a self-addressed envelope with 29¢ postage to the Board office, and it will be promptly mailed to you.

Item 765 – Thanks to Proctors

With the Board administering exams to a record 240 candidates for the June administration, it was of great assistance to have the proctoring services of Charlotte Mize, Ed Meade, and Dr. Jay Gross. These individuals, who are practicing pharmacists in the "real world," assisted the Board's efforts to administer the practical examination on June 21 and the NABPLEX on June 22. We appreciate and publicly acknowledge their help.

Item 766 – Task Force Reports Results

For reasons that are well-known and not necessary to repeat here, the Board adopted a rule about two years ago requiring the reporting of deaths due to drugs dispensed through pharmacies. At that time, both the president of the North Carolina Pharmaceutical Association (NCPhA) and the North Carolina Society of Hospital Pharmacists (NCSHP) called for the formation of a task force to examine the results of this reporting rule after it had been in effect for a reasonable period of time.

After the rule was in effect for one year, the Board appointed a task force co-chaired by Bill Randall from the Board of Pharmacy and Cindy Bishop from NCSHP. Other members of the task force are Al Lockamy, Steve Dedrick, Wesley Byerly, Robert L. Crocker, Amy Brown, and Tom Thutt.

At the task force's first meeting on July 30, 1993, the members analyzed the results of the first reporting year from March 1, 1992 through February 28, 1993. The task force requested that an article concerning this topic be included in this *Newsletter*.

It is significant that of the 15 reported deaths, only one instance resulted in a hearing for a pharmacist before the Board. The message is that the reporting of a death due to a drug should not be considered a confession of wrong-doing by the pharmacist. In the majority of cases, no Board action could be justified against a pharmacist.

Several matters are of concern to the task force. Some of the 15 deaths reported during the year were due to devices. Others were deemed by Board staff not to be directly attributable to drugs, although drugs may have been a factor in the overall result. There were 10 clear-cut instances in which drugs dispensed through pharmacies actually caused deaths during this 12-month period. At least three and perhaps five of these deaths could have been prevented with patient counseling.

One surprising fact derived from this data is that over one-half of the reported cases came from the community or retail setting. This is information that the Board did not anticipate and came as a complete surprise. This figure is somewhat alarming since deaths involving retail pharmacies would naturally go unreported due to an absence of close and controlled contact with the patient.

It is worthwhile to note that some drugs deserve special scrutiny in this area. It was surprising that three of the 10 deaths reported for this time period were due, in one form or another, to procainamide. One was oral, the others intravenous, but the appearance of this compound in three out of ten deaths was certainly unexpected.

As part of the Board's overall effort during the first year, inspectors investigated deaths reported through the State Office of the Chief Medical Examiner. That office reports that each year about 100 deaths are due to therapeutic agents, which are often used for suicidal deaths. The top three drugs in this regard are imipramine, amitriptyline, and propoxephene napsylate. These three drugs account for the bulk of deaths that are due to drugs and deemed to be self-inflicted.

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One other matter deserves comment. Several instances have been reported during this first year, primarily in institutions, in which a drug was ordered intravenously at a specific strength and flow rate, and an error was made either in the strength or flow rate of a drug administered IV via infusion device. Whenever changes in drug concentration or IV flow rate occur, the potential exists for errors, and that has occurred causing deaths this year. This situation deserves the special attention of pharmacists and other personnel in hospitals, nursing homes, or other sites where intravenous fluids are commonly used.

The task force will meet regularly to determine if any trends or changes in pharmacy practice are warranted, such as counseling patients or asking patients about blood work if they are taking procainamide.

Item 767 - Thank Your Legislators

The North Carolina legislative process operates on a two-year cycle. In the odd-numbered years, which begin in January or February and usually end sometime in July or August, there is a long session in which members of the General Assembly conduct most of their business. The 1993 Session was no exception.

A number of bills were proposed which would have produced either a benefit or a detriment to pharmacy. One of the proposals, which would have resulted in a radical change to the Board of Pharmacy, did not occur.

Summaries of legislative changes and rule changes can be found on page four, Item 763 - New Rules, of this *Newsletter.* Several state legislators were especially helpful to the interests of pharmacy and the public in this session. They include Senator George Daniel from Yanceyville, Senator Alexander (Sandy) Sands from Reidsville, Representative Nelson Cole from Reidsville, Senator J.K. Sherron from Raleigh, and Representative John Gamble, MD, from Lincolnton.

A personal thank you from any pharmacist who knows these individuals is in order and well worth the time.

Item 768 - Board of Pharmacy Members

Wm. Whitaker Moose . . . . . President
A.W. Moose & Co., Mt. Pleasant

Al Lockamy, Jr. . . . . Vice President
Revco Discount Drug Center, Cary

Harold V. Day . . . . . .Pharmacist Member
Rite Aid Discount Drugs, Spruce Pine

Wm. H. Randall, Jr. . . . . .Pharmacist Member
Rite Aid Discount Drugs, Lillington

Jack G. Watts . . . . . .Pharmacist Member
Burlington

Wm. T. Biggers . . . . . Public Member
Asheville

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

National Association of Boards of Pharmacy Foundation, Inc.
700 Busse Highway
Park Ridge, Illinois 60068

NORTH CAROLINA BOARD OF PHARMACY

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