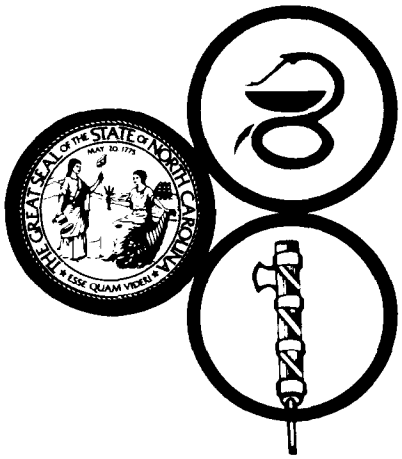
July, 1990



North Carolina Board of Pharmacy

P.O. Box 459, 620H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 643 - Disciplinary Actions

Pre-Hearing Conference: January 16, 1990. Board accepted recommendations by Mr. Randall.

William McLaughlin, Roanoke Rapids. Failure to keep adequate records. Seven-day active suspension of license and other conditions.

Clayton Sasser, Norwood. Dispensing of controlled substances without a prescription. Board reprimand which would be removed from record after one year of good behavior.

Lewis Summey, Dallas. Dispensing error. Letter of caution issued.

February: *James Dallas Neal, Liberty.* Emergency action by the Board to summarily suspend license to protect the public health, safety, and welfare.

Pre-Hearing Conference: February 20, 1990. Recommendation of Mr. Biggers presented to and accepted by the Board.

Mary Alice Greyer, Bryson City. Fraudulent prescriptions filled. License suspended 60 days, stayed two years, must take jurisprudence examination.

Gary A. Taylor, Greenville. Compounding prescription error. Letter of caution issued.

March: *Niven Drug Company, Charlotte.* Permitting an unlicensed person to dispense a prescription drug without the supervision of a licensed pharmacist. Permit suspended 30 days, stayed two years with conditions.

April: *William T. Boyd, Winston-Salem.* Mislabeling and misfilling prescription orders. License suspended indefinitely with specific conditions of reinstatement.

Marion R. McCurdy. Appropriating Schedule II controlled substances without obtaining authorization from a physician. License revoked.

Alpheus W. Benthall, Albemarle. Dispensing of Darvocet-N-100 in significant excess of normal therapeutic use. Official Board reprimand.

John Leroy Mattox, Sr. & Swain Drug Store, Bryson City. Dispensing of 71 unlawfull refills of three prescriptions for Xanax without valid prescriptions. License suspended one year, stayed for a period of five years with active suspension of 60 days and other conditions. Permit suspended 60 days, stayed five years.

Item 644 - Election Results

The Board of Pharmacy recently conducted its annual election. The ballots were counted on May 14th in Board offices in Carrboro. The election results were:

Bruce Canaday	679
Mike Morton	311
Bill Randall	888

Mr. Canaday has called for a run-off election. The ballot is enclosed with this *Newsletter.* Please return this ballot in the enclosed envelope prior to August 20, 1990. Ballots will be counted in a public session at the Board offices in Carrboro beginning at 3 p.m. Visitors are welcome.

Item 645 - Adams Named President

At the 86th Annual Meeting of the National Association of Boards of Pharmacy held in Phoenix, Arizona in May, 1990, it was announced that Mr. William R. Adams, Jr. will serve as the 1990-91 Honorary President of the Association. The honor is especially appropriate because Bill will be leaving the Board this spring after 15 years of service.

We are grateful for the many contributions Bill has made, and continues to make, to the examination process. Bill served both as chairman and member of the Advisory Committee on Examinations which has assembled the NABPLEX Examination for many years. Through his leadership of the NABPLEX Review Committee, he will continue to participate in examination matters at the national level. Every Tarheel should be proud of his accomplishments.

Item 646 - Reciprocity and Your Original License

From time to time, questions arise in the Board office regarding the necessity of keeping an original license renewed. The most common situation occurs when an individual has obtained a license in North Carolina through reciprocity, but does not wish to maintain his or her license in another state. Licensure by reciprocity, or by endorsement in some states, is based on an original license to practice that was obtained by examination. As a general statement, it is not possible to reciprocate a license obtained by reciprocity. One can only reciprocate a license obtained by exam.

If a pharmacist wished to obtain a license in another state, it would be necessary to produce a license in good standing obtained by examination. Thus, we recommend that licenses obtained by examination be maintained through the payment of necessary fees and meeting continuing education requirements, even though one may never intend to return to that state.

Item 647 - Pharmacist Name on Prescription Label

The Board staff has received several reports that some computer systems do not provide for the printing of the name of the

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examining

FDA Responds to Some Misconceptions about the Generic Drug Approval Process

A recent article, "Generic Drugs: Potential Public Health Threat" (*Pennsylvania Medicine*, Jan., 1990) raised concerns about generic drugs and their approval process. In testimony before the House Subcommittee on Housing and Consumer Interests, Select Committee on Aging on March 1, 1990, Dr. Carl Peck, director of the Center for Drug Evaluation and Research, FDA, introduced the CDER review, stating,

> "We receive substantial data on the drugs whose applications have been submitted to us, and we investigate reports of product problems, defects, and alleged therapeutic failures for all drugs. On the basis of our critical evaluation of that information and the advice of many outside experts . . . it is our judgment that generic drugs as a class are safe and effective. Where we could no longer assure safety and effectiveness, we have taken, and will continue to take, decisive regulatory action."

Regarding the promotion of generic drugs as a cost-containment measure, the FDA pointed to its strong endorsement of

> "the concept that the physician has the ultimate authority as to whether the patient receives a brand or generic drug. The Federal MAC program does not mandate substitution and we are not aware of any state that requires substitution to take place without physician authorization. However, we are acutely aware that there is not uniformity among the state laws as to how the physician can prevent substitution. While we think uniform prescribing regulations might be desirable, the practice of medicine and the practice of pharmacy are regulated by the states and not by the Federal Government."

In responding to views that brand-name, originator products are inherently superior to generics, the CDER noted:

> "The argument that the originator product is superior to subsequently approved generic products because the former was the subject of a full NDA involving clinical trials and the ANDA products were approved only on the basis of chemical equivalence and bioequivalence is disingenuous. The innovator's product is often not the same product (same formulation) that was used in the clinical trials. There are routinely changes of scale of production run, equipment, manufacturing processes, formulations, ingredient specification, source of supplies, method of synthesis of the active ingredient, etc., between the initial clinical trial products and those intended for commercial marketing. The FDA does not require the innovator firm to conduct clinical trials again to show that the 'new' product was the same as the 'old.'"

Summarizing the FDA's criteria for establishment of therapeutic equivalence, the CDER said that FDA rates products as therapeutically equivalent if they meet the following criteria: (1) the products must be approved; (2) they are pharmaceutically equivalent (have the same active ingredient at the same strength in the same dosage form); (3) they are bioequivalent; (4) they are adequately labeled; (5) the products meet all of the compendia standards; and (6) they are manufactured in compliance with FDA's Current Good Manufacturing Practice regulations. FDA believes that products meeting the above criteria will have the same therapeutic effect when given to patients under conditions specified in the labeling. The CDER also reaffirms that:

> "FDA believes that the decision to permit substitution or practice drug product selection should be made by the physician, pharmacist, and patient and not a federal government agency.
>
> Those episodes of misconduct on the part of a few generic firms and a few former FDA employees were clearly reprehensible. FDA has moved swiftly to stop distribution of any drug approved on the basis of fraudulent studies and the three former FDA employees convicted of accepting gratuities are no longer with the Agency. The Agency has also embarked on an extensive program of inspections and laboratory testing to assure compliance with Good Manufacturing Practices regulations and with compendia standards."

CDRH Explains: Prescription Medical Devices Sold in Non-Pharmacies

The Device Registration and Listing Branch, Center for Devices and Radiological Health (CDRH) of the FDA issued the following explanation as to why prescription medical devices can be sold in non-pharmacies.

> "In the case of dispensing an Rx drug, the regulations are relatively specific. The pharmacist must have a written request from the practitioner authorizing the dispensing of the drug, or a verbal request from a practitioner or someone designated by the practitioner.
>
> The pharmacy maintains a record of the authorization to dispense, the instructions to the patient, and the amount of drug dispensed. Provided there are no extenuating circumstances, the pharmacy can account for all of the Rx drugs passing through its system.
>
> The situation with Rx devices is far more complex. There are devices that are not routinely sold through a pharmacy, yet carry a prescription legend. Prescription medical devices may be sold, for example, by a durable medical equipment outlet on the order of a physician or other practitioner licensed by the law of the state in which he or she practices. While not required, many prescription devices are sold only by registered pharmacies.
>
> Prescription medical devices can be sold directly to the consumer as long as an appropriate *order* covers the sale of that device. These retail establishments are not limited to

liance News to a particular state or jurisdiction should not be assumed
the law of such state or jurisdiction.)

registered pharmacies licensed by State law to dispense prescription pharmaceuticals. In most cases, we view the monitoring of the distribution of prescription devices at the intrastate level as matters for local authorities.

Many medical devices, such as X-ray equipment, dental equipment, diagnostic laboratory devices, etc., can only benefit a patient by way of a procedure performed by a practitioner.

A large number of devices, including implanted devices, replacement limbs, machined assistance devices such as braces and shoes, etc., cannot be used without intervention by a qualified practitioner.

The criteria as to whether a medical device is Rx or OTC seems simple on the surface. If adequate instructions for lay use cannot be written, the device is Rx. However, the existing regulations do not require a written prescription for the record. The terminology used in the regulations, 21 USC Section 801.109, is '. . . by or on the order of . . .' and the statement is to be completed by filling in the blank with the title of the licensed individual authorized to practice a profession under State law.

The concept of 'home health care' has caused another situation to contend with. For example, there are instances in which untrained individuals are adequately and properly using prescription medical devices at home with minimal instruction by a practitioner.

In summary, the pattern of distribution for medical devices is complex. Medical devices reach the location at which they are used, from and through many sources. Whether a pharmacy is involved or not, depends on a complex number of variables. Prescription devices, as defined in 21 CFR Section 801.109 are required to bear adequate labeling, as described in (b) of this section and a manufacturer is required to establish procedures which assure that persons receiving and using the devices have been given adequate instructions for their proper use.

The CDRH is presently unaware of intentional misuse of prescription medical devices by the general public."

The original legislation defining medical devices *(Medical Device Amendment of 1976)* did not create the same distinctions between Rx and OTC medical devices that exist for drugs. That flaw continues to cause ambiguity about what a legend medical device is and how pharmacists and state boards of pharmacy protect untrained individuals from misusing such products.

The problem has worsened with the growing popularity of home health care. Prescribers are giving these devices to patients for use at home with little supervision and minimal instructions for their use. NABP and the state boards of pharmacy have repeatedly asked the FDA to close this "regulatory gap" and assist the states in restricting the dispensing of legend devices pursuant only to the order of a licensed prescriber and through a licensed practitioner (pharmacist).

FDA Answers Questions about L-tryptophan

A recent FDA "Talk Paper" answered some frequently asked questions regarding the L-tryptophan recall and warning.

Q. There are a lot of popular milkshake-like products and other low-calorie items for weight loss on the market. Are they being recalled for L-tryptophan content?

A. FDA has not asked that they be. L-tryptophan does not seem to be a problem when it is part of a properly made mixture of amino acids and proteins. A small amount of L-tryptophan is used to improve the quality of the vegetable or other protein they contain. This is similar to the way L-tryptophan occurs naturally, and in this use, L-tryptophan is not considered a problem.

Q. If a product doesn't say L-tryptophan on the label, can I assume it is safe?

A. Generally, yes. Since L-tryptophan has been a selling point for products, it is unlikely a manufacturer would add the ingredient and not declare it, unless it's just in the minimal amounts needed to balance other amino acids in a balanced protein product.

Q. Why are you permitting L-tryptophan in infant formulas and medical foods?

A. The small amounts of natural L-tryptophan that are in mother's milk, cow's milk and other animal protein sources are needed for balanced nutrition. When a medical food or infant formula is made from hydrolyzed protein or derived from non-milk sources, small amounts of L-tryptophan are required. There has been no eosinophilia myalgia syndrome (EMS) associated with these products, and to eliminate these traces of L-tryptophan would make them unbalanced, would risk malnutrition, and in an infant, would result in poor development.

Q. I saw some products labeled as "natural" L-tryptophan supplements. Are they OK?

A. No. L-tryptophan is naturally present in the body, true, but the L-tryptophan in diet supplements, whether they call themselves "natural" or not, is manufactured. These products should be under recall and consumers should avoid them.

Prescription Drug Status of Pediatric Ibuprofen Suspension

The FDA's Consumer Safety Officer has issued the following warning concerning the placement and sale of ibuprofen pediatric suspension as an over-the-counter drug product.

"It has come to our attention that pediatric ibuprofen suspension (e.g. Children's Advil Suspension, Pedia-Profen) is being stocked outside of the prescription drug area of pharmacies and sold as an OTC product. Please note that these products are limited by Federal law to dispensing only on prescription. Sale of these products as OTC drugs is a violation of the Federal Food, Drug and Cosmetic Act and causes the products to be misbranded under sections 502(a) and 502(f)."

Continued from page 1

pharmacist who filled the prescription on the label. State statute plainly requires that all prescription labels bear the name, not just the initials of the practitioner who dispensed the drug.

Pharmacists using computer systems that do not provide this information must find other ways to comply with state statute. The first initial and last name would satisfy the Board staff.

Item 648 - Military Physicians and Controlled Substances

Questions have arisen about the authority of military physicians to prescribe controlled substances if they do not have a DEA registration. North Carolina statute specifically provides that a prescription for controlled substances include an order issued by a practitioner serving on active duty with the U.S. Armed Forces, providing the prescription is for an armed services medical care beneficiary.

In addition, the Drug Enforcement Administration (DEA) states that such physicians in military practice on a federally-owned reservation are exempt from registration with the DEA. Prescriptions issued by such prescribers should contain their branch of service and service identification number in lieu of the normal DEA number.

Item 649 - Leaders Forum Yields Task Force

Pharmacy leaders have met annually for the past seven years at a Leaders Forum held in early February. The Board has organized this meeting since the Forum's inception, and the Board President has traditionally presided at each meeting. This year's discussion covered four key issues. President Adams appointed a Task Force to consider and discuss each specific area and report back to the Leaders Forum in 1991.

Bill Adams (Wilson Memorial Hospital, P.O. Box 3161, Wilson, NC, 27895, 919/399-8341) will serve as the General Chairman of the Task Force with Kathryn Jefferson, director of professional affairs for the North Carolina Pharmaceutical Association (P.O. Box 151, Chapel Hill, NC 27514, 919/967-2237) serving as the Information Liaison. Al Mebane, from the Association, and David Work, from the Board of Pharmacy, will be present as ex-officio members.

The Committee on Practice Competency and the External Pharm.D., which is chaired by Tom Wiser (Campbell University School of Pharmacy, P.O. Box 1091, Buies Creek, NC, 27506, 919/893-4111), is responsible for identifying the competencies needed and developing a model external Pharm.D. program, including advanced placement for meeting certain competencies. Members of this committee are William Whitaker Moose from Mt. Pleasant; Ed Frenier from Carolinas Medical Center in Charlotte; Ralph Raasch from the UNC School of Pharmacy; Betty Rowe from Biomedical Home Care in Raleigh; and Ginger Nance, a UNC pharmacy student.

The pharmacy technician issue will be addressed by a committee headed by Steve Dedrick (Duke University Medical Center, P.O. Box 3089, Durham, NC, 27710, 919/681-2996). The Committee has the charge of defining the role of the technician in statute and regulation and constructing a position statement. Members of this committee are Al Lockamy from Revco in Raleigh; Harold Day from Spruce Pine; Gary Judd from Eckerds in Charlotte; George Hatfield from UNC Memorial Hospital in Chapel Hill; and Libby O'Ham, a Campbell pharmacy student.

The definition of the practice of pharmacy will be considered by a committee headed by John Zatti (Glaxo, 5 Moore Drive, Research Triangle Park, NC, 27709, 919/248-2113). The Committee will review current definitions of the practice of pharmacy compared to anticipated public health needs. They will then prepare a revised definition, noting any impact on regulations. Other members of this committee are Fred Eckel from the UNC Pharmacy School; Ginger Lockamy from Raleigh; Bill Randall from Lillington; Suzanne Wheatly from Cabarrus Memorial Hospital in Concord; and Scott Ballenger, a UNC pharmacy student.

Cindy Bishop (Gaston Memorial Hospital, 2525 Court Drive, Gastonia, NC, 28053, 704/866-2334) will chair a committee on standards of practice. Her committee will review current technology, the consensus statements from the 21st Century Conference, and other relevant material before recommending standards for the profession. Members of this committee include Dan Teat from Campbell University School of Pharmacy; Jack Watts from the Greensboro AHEC; Jim McAllister from Duke University Medical Center; Betty Broadhurst from Wilson Memorial Hospital; and Joe Moose, a recent Campbell graduate.

This very important task force will guide the Leaders Forum and may bring about proposals to change the law in North Carolina. The Board encourages input in this process. We suggest that you contact the committee chairmen if you have specific suggestions. You can, of course, contact Chairman Adams or Kathryn Jefferson for input you deem appropriate.

Item 650 - New Poster

A new poster, which conveys the message that pharmacists are willing to help illiterate patients by providing them with the special attention and counselling they need regarding the use of their medications, is available for use in pharmacies. This poster is a project of the Women's Auxiliary of the North Carolina Pharmaceutical Association and is spearheaded by its president, Betsy Mebane of Chapel Hill.

The specially-designed poster is available at no charge from the North Carolina Pharmaceutical Association at P.O. Box 151, Chapel Hill, NC, 27514. With over 800,000 people in North Carolina who have less than an 8th grade education, this item is certainly useful.

Item 651 - Note for Tuberculosis Patients

The Board has received information from Joy Wilson at the Guilford County Health Department through Charles Reed of the State Division of Health Services in Raleigh that some patients are not taking their tuberculosis medicine due to costs. If you are aware of any TB patients who cannot afford medication, please inform them that they can obtain free medicine at their local health department.

The North Carolina Board of Pharmacy News is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc., to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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