April, 1994

North Carolina Board of Pharmacy

P.O. Box 459, Carrboro, NC 27510-0459
602H Jones Ferry Road, Carrboro, NC 27510-2165

Published to promote voluntary compliance of pharmacy and drug law.

Item 780 – Disciplinary Actions

November:

Charles Edward Zimmerman (DOB: January 20, 1958) and Smith Drug - Rite #4, Rutherfordton. Obtaining, consuming, and dispensing legend prescription drugs and controlled substances without authorization; failure of pharmacy to prevent events from occurring when permit holder knew or should have known the violations were occurring. Pharmacist license revoked. Pharmacy permit suspended 60 days, stayed five years with conditions.

Due to inclement weather conditions, there was no January, 1994 meeting held by the Board of Pharmacy.

Item 781 – Prescribing Outside of Practice

Some pharmacists seem confused about the ability of some practitioners to prescribe certain drugs. A brief review of the legal and ethical considerations seems necessary.

In state and federal law, the phrase "in the ordinary course of professional practice" often appears in definitions or descriptions of the prescribing activity. A prescription is an individual order, and does not, in and of itself, limit the scope of prescribing. The practitioner's prescribing authority depends entirely on his or her license to practice, which is issued by a professional occupational licensing board.

In theory, physicians have unlimited prescribing authority for humans. Their fundamental prescribing authority includes all human drugs ranging from common antibiotics used for upper respiratory infections to chemotherapy for cancer patients and cylosporins as part of organ transplant therapy. But even physicians are not licensed to prescribe all drugs. For example, physicians cannot prescribe drugs for veterinary use.

Other practitioners are limited to their individual licenses to practice. Dentists, for example, cannot prescribe outside of treating conditions of the mouth. Under some circumstances, this can extend to such drugs as Nicorette® for smoking cessation if it would positively influence dental health. Some tranquilizers might even be justifiable if ordered for patients who experience high anxiety when visiting the dental office. Such authority is not a blanket matter, however, as illustrated in one question posed to the Board office about a dentist prescribing 10 mg. Valium® #100 for his mother-in-law, who lived with him and his family, for domestic tranquility.

Veterinarians are limited to the practice of veterinary medicine and the treatment of animals. Optometrists can prescribe drugs to treat conditions of the eye or the adnexa, which is the orb surrounding the eye. Many practitioners, including nurse practitioners and, soon, physician assistants, can prescribe controlled substances if they have DEA registration numbers.

Of course, all of this is tempered by the general principle and Board rule that pharmacists can refuse to fill or refill prescriptions for any valid reason. A pharmacist who questions a prescription for a good reason can decline to fill that order. While it may be legally possible for a dermatologist to prescribe amitriptyline or lithium, a patient would most likely be better served by obtaining such therapy from an practitioner in the mental health field. Board rule clearly states that a pharmacist has both the right and responsibility to decline to dispense a prescription that is judged to not be in the patient's best interest or is potentially harmful. However, a prescription from the same dermatologist for a broad spectrum antibiotic for an upper respiratory infection does not present the same potential problems even though it may not be clearly within the practice of dermatology. The prescriber's broad mandate under a license to practice medicine would certainly cover that kind of order, even though it may be outside of their ordinary practice.

Although this area requires the individual pharmacist's judgment, it is not as clear-cut as some may think. The key is **professional** judgment, which should be familiar territory for pharmacists as we establish patient counseling as standard procedure.

Item 782 – Change in PA/NP Prescribing

The Boards of Nursing and Medicine initiated a change in the rules for prescribing by nurse practitioners effective March 1, 1994. You should **share this information** with all pharmacists at your facility.

The revised rules essentially eliminate the approved formulary concept for prescribing. The formulary concept remains in effect for nurse practitioners dispensing drugs until the Board of Pharmacy changes its rules. As of March 1st, each nurse practitioner and certified nurse midwife will be able to prescribe those drugs and devices in written, standing protocols developed by the supervising physician and the nurse practitioner for activity at that practice site.

Each prescription from a nurse practitioner or certified nurse midwife must contain the six-digit prescribing number assigned by the Board of Medical Examiners, the nurse practitioner's name, and a telephone number. Prescriptions written for controlled substances must also have the nurse

Continued on page 4

National Pharmacy

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

Regulation of Dietary Supplements

As our nation's most accessible and respected professionals, pharmacists are frequently asked questions by consumers about the usefulness or safety of dietary supplement products. This article is intended to keep the practicing pharmacist abreast of current regulatory and legislative proposals governing these products.

Every year, millions of U.S. consumers purchase billions of dollars worth of dietary supplement products from their local food, drug, and health food stores. Most of these products are available in moderate potencies and are safe for their users. However, some products containing such ingredients as amino acids or herbs may provide little or no nutritional benefit and can be potentially harmful to their users. In addition, marketing strategies for such products may include scientifically unsubstantiated health claims.

Many cases have been documented in which product users have experienced serious adverse effects when using a specific dietary supplement. One of the most publicized cases in recent years, involving L-tryptophan, increased the U.S. Food and Drug Administration's (FDA) concerns about the safety of these products.

A report published by the FDA, entitled *Unsubstantiated Claims and Documented Health Hazards*, lists more than 500 dietary supplement products that are currently being marketed with unproven health claims. The report also lists the 188 FDA regulatory actions taken between November 1990 and June 1993 against manufacturers of dietary supplement products that made unsubstantiated claims about serious medical conditions. Thirty of these products were seized, and the manufacturers of the remaining 158 products were issued warning letters.

Although the FDA has issued enforcement actions against these dietary supplements, the Agency does not currently have the authority or means to extend its resources in order to better protect the public health and safety. This situation may change as a result of recently proposed regulations.

The Nutrition Labeling and Education Act of 1990 requires that foods bear nutrition labeling and that health claims for food products be backed by "significant scientific agreement." In response to this legislation, the FDA published a proposed rule in the November 27, 1991 *Federal Register* that submitted requirements for the listing of health claims on food product labels, including dietary supplements, that involved diet-disease relationships.

While this FDA process finalized regulations for nutrition labeling of food products in January of 1993, final labeling requirements for dietary supplements were not established because Congress enacted a one-year moratorium on the implementation of the dietary supplement regulations pending passage of the Dietary Supplement Act of 1992. When the Act's moratorium ended on December 15, 1993, the FDA published its final rule in the January 4, 1994 *Federal Register*.

Throughout the developmental stages of the FDA's final rule, consumer speculation surfaced about the impact of the final rule's provisions on an individual's access to dietary supplements. Many consumers believed that the FDA was planning to make all dietary supplements unavailable to the public, or that the Agency would remove dietary supplement products from store shelves and make them available only by prescription.

In response to these consumer concerns, the proposed Dietary Supplement Health and Education Act was developed. Provisions of both the U.S. House of Representatives and Senate versions of the proposed Act, which would limit FDA's authority over health claims made by manufacturers of dietary supplements, are currently being considered by Congress.

According to FDA Commissioner David A. Kessler, the provisions of these proposals "would eliminate the need of manufacturers to establish the scientific validity of a nutrient-disease relationship before making a health claim for an ingredient of a dietary supplement." Kessler also stated that, " If this legislation is enacted, FDA would only be able to take action after a claim was already on the product label and in stores."

In contrast, the FDA has proposed that the same standards and procedures that are currently being used for conventional foods also be implemented for dietary supplements. As stated in the final rule, the FDA would be given the authority to authorize claims based on,

> scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, and that the claim is supported by such evidence.

The Agency's concern focuses on the safety of dosage-related effects that can be seen with high doses of nutrients in non-food form and on the accuracy of any health benefit claims that are made. FDA does not believe it should presume that "all nutrients function in a nutritive manner regardless of their level unless it has proof to the contrary." The Agency believes that petitions for use of a nutritional supplement health benefit claim should include a basis for reaching a reasonable conclusion that the effect seen is nutritional rather than pharmacological. As stated in the

final rule background, once the "FDA determines that a health claim is valid, the agency will . . . authorize the use of the claim."

Unless there are subsequent developments, the Agency will begin to implement the final rule's provisions on July 1, 1995. If other initiatives prevail, the FDA could see its regulatory authority over dietary supplements severely diminished.

FDA Proposed Rule Would Preempt State Disclosure Requirements

The Med*Watch* Medical Products Reporting Program recently initiated by the U.S. Food and Drug Administration (FDA) relies heavily on health professionals' voluntary reporting of adverse medical events associated with drugs or devices.

FDA views the success of a program such as Med*Watch* as essential in fulfilling their responsibility to protect the public from potentially unsafe drugs and devices through ongoing post-marketing surveillance. Many significant adverse events or drug interactions not identified in tests conducted prior to a product's approval by FDA have historically been discovered through FDA's voluntary reporting mechanisms.

In response to concerns that this essential FDA role may be undermined by state laws or rules that permit or require the disclosure of patients' and/or reporters' identities, the FDA published a proposed rule in the January 27, 1994 *Federal Register* (pp. 3944-3950). If finalized, this proposed rule would protect the identities of both patients and health professionals involved in adverse medical events that have been reported either to manufacturers or directly to the FDA.

FDA attributes much of the voluntary reporting program's success to federal regulations that protect the confidentiality of individuals involved in adverse experience reports. Prior to any public disclosure of adverse event reports, these FDA regulations require deletion of the names and any information that would identify the person using the product, or any physician, hospital, or other institution involved with the report.

Although the identity of persons or institutions reporting directly to FDA is considered confidential and is protected from state disclosure requirements, such information in the possession of manufacturers is not. This lack of protection for manufacturers' information creates a problem because the FDA encourages reporters to allow the Agency to share the reporter's identity with the manufacturer in order to help FDA and the manufacturer perform the necessary follow-up procedures.

In recognizing litigants' concerns in malpractice cases, the background section for the proposed rule states that the Agency does not intend to frustrate or impede tort litigation in this area.

The proposed regulation has been drafted to permit any individual plaintiff who has experienced an adverse event and has subsequently become involved in medical malpractice litigation with the person who reported the event, to obtain all the information contained in the adverse event report. In this situation, where both parties to the litigation know each other's identity, the interests of the parties in protecting this information is minimized and, therefore, would not impose a significant disincentive to reporting.

For further information, contact Ilisa B. G. Bernstein, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (telephone, 301/443-2831).

DEA Begins Publication of Newsletter, Diversion Quarterly

The end of 1993 saw the publication of the first edition of the new DEA newsletter, entitled *Diversion Quarterly*. Issued by the Office of Diversion Control, this new DEA publication is aimed primarily at DEA diversion investigators.

Reviewing such topics as "Diversion Trends," "Clandestinely Manufactured Drugs," "Investigative Techniques," "New Treatment Approaches," "Legal Issues," and "Diversion's Most Wanted," *Diversion Quarterly* is intended to "help keep the men and women who make up the national diversion control community better informed," noted Gene R. Haislip, director of the DEA Office of Diversion Control, in his introduction of the *Newsletter*.

Comments and articles for *Diversion Quarterly* are invited. Interested parties may call 202/307-7297, fax a letter to 202/307-8570, or write to the Drug Enforcement Administration, Office of Diversion Control, Liaison and Policy Section, Washington, DC 20537.

NABP Number Reminder

The National Association of Boards of Pharmacy (NABP) office frequently receives phone calls from pharmacists seeking to obtain an "NABP Number" for their pharmacy. An "NABP third-party payment number," unique to each pharmacy outlet, is available through the National Council for Prescription Drug Programs, Inc. (NCPDP), located in Phoenix, Arizona, and not through the NABP offices. If you need to obtain an "NABP Number" for your pharmacy, please contact NCPDP at 602/957-9105.

Continued from page 1

practitioner's DEA number, with quantities limited to a one-week supply and refills excluded. Refills for controlled substance prescriptions can only be authorized by the supervising physician and must be indicated as such on the label. Refills for other legend drugs cannot exceed one year.

The North Carolina Board of Pharmacy was concerned about the expansion of prescribing practices, particularly with controlled substances, when public policy seems directed towards limiting drug use. Board representatives testified at hearings on this subject in November and January, and progress temporarily stopped on the rule. After clarification was obtained, the path was cleared for the rule to be adopted. The North Carolina Board of Pharmacy was the only group to testify in opposition to this change.

Item 783 – Many Springtimes

Although this *Newsletter* is being assembled during some bad weather at the end of February, the splendid spring of the south should be in full bloom by the time it reaches pharmacists. The pharmacist among us who has the most springs to his credit is York Garrett, who operates Garrett's Biltmore Drug in Durham. York was a 1920 graduate of Howard University, and last December he celebrated his 99th birthday. While he no longer keeps long hours, York still runs his own pharmacy and is able to obtain his continuing education through the National Pharmaceutical Association. He serves as a good example for the youth in our profession, which is everyone except him.

Item 784 – Discard Date

Beginning January 1, 1994, prescription labels must contain a discard date, which is either the expiration date on the manufacturer's original container or one year from the date the drug is dispensed, whichever comes first. Please guide your conduct accordingly.

Item 785 – B.S./PharmD Issue

Much discussion has occurred over the last several years about the proposed move from the B.S. degree to the PharmD degree as the standard for pharmacy practice. The North Carolina Board of Pharmacy's position on this issue was published in the April, 1991 issue of this *Newsletter*.

The American Council on Pharmaceutical Education, the accrediting group in pharmacy, has announced that it intends to accept only PharmD curricula for accreditation by the year 2000 or as soon thereafter as possible. Some pharmacists have expressed their concern to the Board regarding the status of their license if this change occurs.

Pharmacists should be reassured that they will not be required to go back to school to retain their license to practice pharmacy. Currently, all that is necessary to maintain a license is meeting the continuing education requirements and payment of the renewal fee. Future changes would apply only to new licensees and not to current holders of licenses to practice pharmacy.

Item 786 – Close Move

The Board of Pharmacy will be moving its offices in the spring of this year. As of deadline for this *Newsletter*, the move is scheduled to occur on or about April 1, 1994. Our new location is not far away in Carrboro, and our mailing address will remain the same. However, our new physical location is: Carrboro Plaza Shopping Center, Highway 54 Bypass, Suite 104B, Carrboro, NC 27510. Our mailing address remains the same: North Carolina Board of Pharmacy, P.O. Box 459, Carrboro, NC 27510-0459.

Item 787 – DEA Registers Mid-Level Practitioners

A new category of practitioners is now receiving DEA registration numbers from federal authorities. This category includes optometrists and will also apply to nurse practitioners and physician assistants in the future. This change does not limit their prescribing authority, but is merely a technical change to accommodate a new category at the federal level. Please note this change in your practice because some registration numbers will certainly change.

Item 788 – New Law Book Available

The latest edition of the *North Carolina Pharmacy Law Book*, which should be kept in all pharmacies, is now available. The *Law Book* is current through April 1, 1994, and can be obtained by sending a request and a check for $8.48 to the Board office, P.O. Box 459, Carrboro, NC 27510-0459.

State law requires each pharmacist to notify the Board of any change in practice or home address within 30 days. Such information should be communicated to the Board office at 919/942-4454 or P.O. Box 459, Carrboro, 27510-0459.

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

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

Nonprofit Organization
U.S. Postage
PAID
Park Ridge, Illinois
Permit No. 75