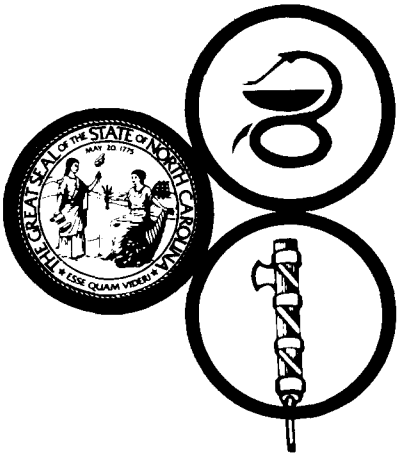
January, 1992



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 698 - Disciplinary Actions

August:

Rebecca Rowell, Durham. Failure to detect difference between brand name drug and a generic drug and failure to detect excessive high dosage for a child constituting negligence in practice of pharmacy. Board reprimand.

Dewayne P. Franzen, Greensboro. Failure to write own signature on prescriptions for controlled substances; dispensing controlled substances to a Medicaid recipient while suspended from the Medicaid program; violation of Pre-hearing Conference Agreement of June 13, 1989. License actively suspended for 30 days pursuant to violation of Pre-hearing Conference Agreement. Upon completion of active suspension, license suspended additional 30 days, stayed for five years.

September:

Robert B. Reaves, Fayetteville. Appropriating and consuming Schedules III and IV controlled substances without obtaining authorization from a physician. License suspended indefinitely, stayed for a period of five years upon Respondent passing a drug screen test and other conditions.

October:

Russell V. Cobb, III, Dobson. Failure to obtain during 1990 at least ten hours of continuing education credit, at least five contact hours, and maintain certificates of credit for continuing education establishing the required hours. License suspended indefinitely, stayed for 30 days with conditions.

Christine M. Dutton, Fayetteville. Excessive dispensings of Schedule V controlled substances; filling forged prescriptions. License suspended 120 days, stayed five years with active ten-day suspension and other conditions.

Item 699 - Notice: Public Hearing for Rule

In the October issue of this *Newsletter*, a notice was published on proposed rules with a public hearing scheduled for January 28, 1992 at the Durham Hilton. Circumstances require that the location of this hearing be changed to the Institute of Pharmacy, Rosemary and Church Streets, in Chapel Hill at 2:00 p.m. on the same day.

Proposed rules include those for patient counseling, another redefining internship hours, and a third, which would clarify the current rule on prescription transfer to allow electronic transfers under some circumstances. Copies of the proposed changes are available from the Board office and are printed in the *North Carolina Register*.

Item 700 - Local Alert System Encouraged

Some communities have an excellent telephone alert system to relay information about attempted forgeries, problem prescriptions, or other time-sensitive information to pharmacists in their area. This is usually accomplished through a "telephone tree," a concept in which the message has a common starting point and each pharmacist relays that item to two others until the information reaches every pharmacy in the community.

The Board staff believes that this is an effective way to communicate and encourages the establishment of an alert system in communities. If local associations have an interest in beginning an alert system, the Board staff is willing to assist when invited. Contact the inspector for your area or David Work at the Board office.

Item 701 - Keep Your Newsletter *for Reference*

The Board staff endeavors to include items pertinent to practice in this *Newsletter*. A binder for keeping a permanent collection of the *Newsletter* is available and is provided with each pharmacy permit. We expect to

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National Pharmacy

(Applicability of the contents of articles in the National Phar Comp
and can only be ascertained by examinin

Urine and Saliva HIV Screening Tests

Susan Gallinger, Director of Insurance for the Arizona Department of Insurance, contacted the Food and Drug Administration with regard to the Agency's role in the approval of test kits that identify the presence of antibodies to the human immunodeficiency virus (HIV). In her correspondence with Dr. Gerald Quinnan, Acting Director of FDA's Center for Biologicals Evaluation and Research, Ms. Gallinger indicated that, while she was given to understand that the only such test "approved and licensed" by the FDA is the test using blood and/or plasma specimens, her department had evidence of the increasing use by insurers of tests for HIV antibodies using other body fluids, in particular urine and saliva.

Listed below are the specific questions raised by Susan Gallinger and the answers provided by Dr. Quinnan.

1. Has the FDA reviewed and approved the regular use of body fluids other than blood or plasma for HIV antibody testing for the purpose of determining a person's actual HIV-infection status?

FDA has not approved the use of body fluids other than human plasma, serum, or dried blood spots for use with licensed HIV antibody test kits.

2. If the FDA has granted limited approval of the use of urine and/or saliva specimens for testing for the presence of HIV antibodies, what limitations have been placed on that use?

No limited approval has been granted. However, certain research or clinical investigations on the use of urine or saliva specimens for HIV antibody testing may be authorized pursuant to an Investigational Device Exemption (IDE) or Investigational New Drug (IND) application accepted by FDA. The use of specimen collection devices in investigations to determine the safety and effectiveness of urine or saliva specimens for HIV antibody testing must be pursuant to a protocol accepted by FDA and must be clearly labeled for investigational use.

3. At this time, is a person justified in relying on the test results from tests using urine and/or saliva for the presence of HIV antibodies?

As stated above, FDA has not approved the use of urine or saliva for determining HIV antibody status. From its standpoint, therefore, relying upon urine or saliva as an acceptable specimen source for use in HIV antibody testing is not justified or prudent.

FDA addressed the use of urine or saliva specimen collection devices labeled for HIV antibody testing in a position paper dated August 23, 1991. In addition, an FDA "Talk Paper," which contained information about the marketing of an unapproved AIDS (HIV) test collection kit manufactured and commercially distributed by Epitope, Inc. of Beaverton, Oregon, was made available to the public on July 10, 1991.

More recently, an October 30, 1991 FDA "Talk Paper" revealed an October 29, 1991 seizure by U.S. Marshals and FDA officials of unapproved saliva and urine collection devices for AIDS antibody testing at Clinical Reference Laboratory, Inc., of Lenexa, Kansas. The company, which was marketing the devices for use in the screening of insurance applicants for evidence of the antibody to the AIDS virus, had failed to agree with the terms of an FDA request that it cease the illegal marketing and commercial use of the saliva and urine collection kits.

PDMA Enforcement

FDA is actively investigating the diversion of prescription drug products. Diversion activities being pursued include the sale, purchase, or trade of drug samples; the resale of prescription drugs purchased by health care entities; and misrepresentation by firms or individuals to prescription drug manufacturers and distributors in order to receive preferential pricing. The activities of wholesale distributors and manufacturers and their sales representatives, physicians, and pharmacists are included within the scope of these investigations. As appropriate, the Agency coordinates its investigative efforts with the Federal Bureau of Investigation (FBI), the Office of the Inspector General, and other federal and state drug regulatory agencies.

Several cases are either currently in Grand Jury as a result of these investigations or have been forwarded to the Department of Justice for Grand Jury referral. FDA anticipates further regulatory recommendations proceeding from these investigations.

Any questions or comments concerning FDA's enforcement of the PDMA may be directed to Jon May, PhD, RPh, Assistant to the Director, State Program Coordination Branch, Division of Federal/State Relations, 301/443-3360, Fax 301/443-2143.

Medicinal Oxygen and the PDMA

The treatment of Oxygen USP under the wholesaler guidelines (21 CFR Part 205) has raised serious concerns about the distribution of Oxygen USP and the FDA's labeling requirements for the drug product. More specifi

cally, does the FDA classify Oxygen USP as a prescription-only or an over-the-counter drug product?

In an October 3, 1991 memo, John D. Lipnicki, Consumer Safety Officer for FDA's Manufacturing Surveillance Branch, points out that Oxygen USP is a prescription drug. Although the issue of its labeling is being revisited, the Agency, at this time, considers the requirements of 21 CFR 201.100 to be satisfied if the article meets the ***labeling*** requirements described in the revoked *Federal Register* notice of March 16, 1972 (37 FR 5504). However, although the labeling requirements in the latter notice do not provide for the inclusion of the prescription legend, this accommodation for the emergency use of medicinal oxygen does not and never was intended to change the product's status as a prescription drug.

Therefore, as required by the "Guidelines for State Licensing of Wholesale Prescription Drug Distributors" (21 CFR Part 205), a wholesale distributor in a state that engages in wholesale distributions of prescription drugs in interstate commerce (including prescription drugs such as medicinal gases) must be licensed by the State licensing authority in accordance with these guidelines, unless they fall under any of the exclusions listed in 21 CFR 205.3(f).

In terms of dealing with any segment of industry that must be licensed pursuant to these guidelines, the Agency believes that the guidelines leave states sufficient discretion to determine appropriate structures for their regulation.

DEA Registration Number – Confidential?

Recently, several pharmacists in Kentucky complained to their state board of pharmacy about the use of the prescriber's DEA registration number by some third-party insurance providers in processing claim forms. The Kentucky Board of Pharmacy, in turn, contacted the DEA as to whether the third-party payers were inappropriately requiring the use of DEA registration numbers. The Board received the following response on October 9, 1991 from G. Thomas Gitchel, Chief Liaison and Policy Section, DEA Office of Diversion Control:

> The DEA system of registration was designed to establish a closed system of distribution of controlled substances from the ultimate user. DEA strongly opposes the use of a DEA registration number for any purpose other than to provide certification of registration in transactions involving controlled substances. The use of DEA numbers as identification numbers by the insurance industry is not a legitimate use of the system, and it in fact could lead to a weakening of the registration system. Instead, DEA encourages the development of an alternative identification system by the insurance industry for such purposes.

MPPP DUR Boards Clarification

Last quarter's National News article, "MPPP Implications for Practicing Pharmacists," included a discussion of the required composition of the individual state Drug Use Review Boards mandated by the legislation. Several readers have requested that we clarify and expand our explanation of this important component.

MPPP requires each state to establish a DUR Board either directly or through a contract with a private organization. Appointments to these boards must include health care professionals who have recognized knowledge and expertise in one or more of the following areas: 1. Clinically appropriate prescribing of covered outpatient drugs; 2. Clinically appropriate dispensing and monitoring of covered outpatient drugs; 3. Drug use review, evaluation, and intervention; 4. Medical quality assurance.

OBRA '90 specifies that the membership of the DUR Board "shall be made up of at least one-third, but no more than 51 percent of licensed and actively practicing physicians and at least one-third licensed and actively practicing pharmacists." The rest of the Board must include non-physician and non-pharmacist members who have expertise with the DUR process.

FDA Toll-Free Phone Line for Health Professionals

FDA's toll-free telephone service established for health professionals began operating on September 16, 1991. Physicians, pharmacists, and nurses, as well as researchers, clinicians, and veterinarians can use it to ask questions about the agency's policies on medical advertising, marketing, and promotion and to discuss activities and practices that may require regulatory attention. The main number is 1-800 AD-US-FDA (1-800/238-7332).

The 800 number will be answered by the Medicine Staff in FDA's Office of Health Affairs during normal business hours. Calls requiring any additional professional expertise will be referred internally to the appropriate Center. Automatic answering equipment allows callers to record requests for information or leave messages at other times. Names of persons who call and information discussed are confidential. Telecopier (FAX) machines are available to permit the prompt transmission of documents during and after business hours.

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find this binder, complete with recent *Newsletters*, in each pharmacy.

Item 702 - Note for C.E. Program Planners

The Board accepts continuing education from ACPE-approved providers and others, including programs sanctioned by a panel formed by the North Carolina Pharmaceutical Association. This item is intended to convey two important points - local associations or others seeking approval from the panel must submit their programs at least 30 days prior to the event, and pharmacists should determine if credit is available prior to the meeting.

Item 703 - We Need Your Zip +4

New procedures adopted by the United States Postal Service strongly encourage the use of Zip+4 designation on all mailings. Therefore, we need your proper Zip+4 designation on all mail material. This includes your practice address, home address, and preferred mailing address. Please include this information on your renewals or drop us a post card with the accurate information.

Item 704 - Insulin Substitution

Although insulin is not a prescription drug, it is a vital medication for diabetics. Because it is an injectable, great care should be used prior to changing a patient from semi-synthetic to human insulin and vice versa. The same principle applies to human insulins which are produced by different processes. This is a decision best made in conjunction with the treating physician, patient, and the pharmacist in an effort to arrive at the optimum therapy.

A decision based only on price is one which is nearly impossible to explain if detrimental results occur.

Item 705 - New Law Book Available

The latest edition of the *North Carolina Pharmacy Law Book*, current through December 31, 1991, is now available. All pharmacies should have this publication. It can be obtained by sending a request and a check for $8.00 plus tax to the Board office, P.O. Box 459, Carrboro, NC 27510-0459.

Item 706 - Note For Preceptors

Occasions have arisen when preceptors have supervised several students and claimed many contact hours of continuing education credit for this service. At the October, 1991 Board meeting, the members voted to accept up to a maximum of five contact hours in any one year for serving as a preceptor for at least 400 hours of credit obtained by a student.

During the fall of 1991, the Executive Director visited all ten AHEC locations to speak with preceptors on issues of concern to the Board. The primary focus of each visit was candidate performance on the errors and omissions examination. Preceptors were encouraged to highlight errors or omissions found while interns are present, regardless of who is responsible; and to stress the importance of detecting them before patients are harmed. With a telephone prescription as part of the errors and omissions exam, preceptors were encouraged to give students appropriate experience in receiving such prescriptions.

Item 707 - Pharmacist I.D. on Prescription

Most pharmacists know that prescriptions for controlled substances must be signed and dated by the pharmacist who fills the prescription. Some pharmacists seem to be unaware, however, that prescriptions for other drugs must also indicate the pharmacist who fills or refills the prescription. While, in some cases, this may be accomplished by computer, it, nevertheless, is a requirement that should not be overlooked.

Item 708 - Rule On Reporting Deaths

At the November meeting of the Board of Pharmacy, the members adopted a rule that requires pharmacists to report deaths resulting from drugs which are dispensed through a pharmacy. This report needs to be on a form provided by the Board. Such forms will be available by March 1, 1992, the effective date of the rule. Pharmacists should understand that this is not necessarily a "confession" of negligence on the part of the pharmacist or the pharmacy, and each case will be looked at individually. In the past, Board inspectors have performed investigations involving deaths due to drugs which have not been the result of pharmacist negligence.

Item 709 - Last But Not Least

The Board will not send out reminder cards for delinquent renewals, so please be sure to renew your license before the end of February when the grace period expires.

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 laws. 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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