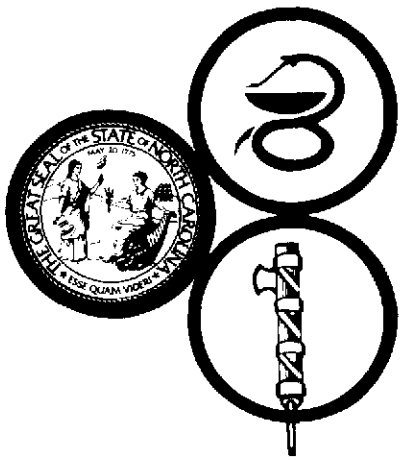
April, 1990



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 634 – Disciplinary Actions

November: *Barry Gene Wall*, South Carolina. Indulged in the use of drugs to an extent that renders him unfit to practice pharmacy; a physical or mental disability that renders him unable to practice pharmacy with reasonable skill, competence, and safety to the public; failed to comply with the laws governing the practice of pharmacy and the distribution of drugs; failed to comply with the rules and regulations of the Board. License ·ked.

·rry Thomas Murrell, Jr., Albemarle. Unlawful dispensing ·f controlled substances and embezzlement; pleading guilty to three felonies in connection with the practice of pharmacy and the distribution of drugs. License suspended five years, stayed five years with active suspension of one year and other conditions.

January: *Steve Kiser*, Knoxville, Tennessee. Request for reinstatement granted with specific conditions.

Larry Young, Morrisville. Failure as pharmacist-manager to maintain a perpetual inventory of cocaine at facility where employed; delay in notifying DEA investigators of possible theft of controlled substances; failure to comply with regulations and laws governing the practice of pharmacy. License placed on probation for two years. Should a violation of the laws governing the practice of pharmacy, or the distribution of drugs, or the engagement in any activity which is a violation of the rules and regulations of the Board occur during this probationary period, the license to practice pharmacy may be actively suspended for a period of 60 days at the discretion of the Board.

Joel Paul James & James Pharmacy, Angier. Pleading guilty to the felony of medical assistance provider fraud in connection with the practice of pharmacy; violation of Board's Order of March 18, 1986; failing to prevent the violations to occur when the permit holder knew, or should have known, the violations were occurring. Stay of the five-year suspension of license to ·ctice pharmacy imposed by the Board's Final Order of ·rch 18, 1986 is lifted and license to practice pharmacy is suspended for five years. The permit issued to Angier Pharmacy suspended for a period of one year, stayed for a period of five years.

Item 635 – Committee Selects Nominees

Each year the pharmacists of North Carolina have the opportunity to vote for at least one Board member selected from geographical areas of the state. According to Board rules, a person becomes a nominee for the position in one of two ways; a committee selects at least two candidates for the election, or a pharmacist can be nominated by a petition of ten pharmacists from the region.

Committee members Dan Teat, Bruce Canaday, and Keith Elmore met in Southern Pines on Friday, February 9. They recommended that three names be placed in nomination for a five-year term to begin in the Spring of 1991. The three candidates whose names appear on the ballot that is enclosed for North Carolina residents were selected by the Committee and approved by the Board as provided by regulation.

Ballots will be tallied in an open meeting on Monday, May 14, 1990, in the Board offices in Carrboro. Ballots submitted after that date will not be counted.

Item 636 – Quarterly Query

The Federal Food, Drug and Cosmetic Act regulates:

1. the mailing of prescriptions.
2. the taxation of drugs.
3. prescribing by physicians.
4. marketing of drugs.
5. the Use of drugs.

Item 637 – Replacing Auxiliary Labels

During the normal course of pharmacy practice, it is necessary to replace labels as current supplies are exhausted. When this occurs, you should consider replacing your current auxiliary supply with USP Pictogram Labels, which are designed to convey common prescription information to non-readers. Since over 800,000 people in this state have less than an eighth grade education, nearly every pharmacist has a substantial segment of his or her customers or patients who are poor readers. Informa-

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Com
and can only be ascertained by examinin

USP Addresses Dispensing Prescription Drugs from Containers without Expiration Dates

The following letter from Joseph G. Valentino, executive associate of the United States Pharmacopeial Convention, Inc., is in response to the article "Prescription Drugs - No Expiration Dates," which appeared in the last issue of the *Newsletter*.

I would like to elaborate from a USP perspective on the statement provided by Clifford D. Broker, chief of the FDA Policy and Guidance Branch, which appeared in the Winter issue of the NABP national newsletter section regarding the dispensing of prescription drugs from containers that do not bear expiration dates.

While it is true that FDA GMP requirements went into effect in 1979, USP-NF expiration date labeling requirements for official dosage forms went into effect in 1976. USP-NF labeling requirements are enforceable under the Federal Food, Drug and Cosmetic Act and comparable state requirements. Assuming they were not in violation when produced, official drugs that do not bear an expiration date may be at least 14 years old!

Starting in 1985, the USP-NF contained the statement:

> 'Where a dosage form is required to bear an expiration date, such dosage form shall be dispensed in or *from a container labeled with an expiration date*, and the date on which the article is dispensed shall be within the labeled expiry period.'

Many state pharmacy statutes or regulations require pharmacists to comply with USP requirements upon dispensing. Even if such a provision is not present in a state law, one must ask whether such a practice, in view of the USP-NF statement and the apparent age of the product, constitutes good pharmacy practice.

FAX Machines: Progress or Peril

The emergence of the facsimile machine has been heralded as both a technological godsend, and a technological nightmare. Pharmacy, never exhausting its ready supply of controversial issues, once again finds itself in the midst of conflict and debate.

While pharmacists are seeking answers to some basic, but important questions, the state boards of pharmacy find themselves simultaneously accused of slowing the wheels of progress and opening the door to drug diversion and fraud. A recent article in the January issue of the *NABP Newsletter* summarized some of the recent policy and position statements that have been adopted by the state boards. Essentially, the boards have identified three areas of concern: drug diversion; the possible denial of a patient's freedom of choice; and prescription record maintenance.

A review of the policies and recommendations contained in the various state board newsletters revealed the following data:

	Use of FAX for Prescriptions	Schedule II	Schedule III-V
AL	Permitted	FAX not permitted for Sched. II.	Close surveillance should be paid to Scheds. III-V.
AR	Permitted.	May not use FAX for Sched. II.	Verify if validity is questionable.
CO	Permitted. Telephone verification required.		
GA	Prohibited for all prescriptions. FAX allowed only within hospital setting.		
ID	Bd. reviewing issue. Legality may be in question.		
MD	Prescriptions excluding CDS, may be transmitted via FAX.	Prohibited	Prohibited
ME	Bd. reviewing rule & reg. change to accommodate FAX.		
MN	FAX may be used in hospital setting only.		May be used for Sched. III-V only.
MO	Bd. does not recommend use of FAX for non-controlled prescriptions.	Prohibited.	
NV	Prohibited for all prescriptions.		
NJ	Reduce FAX to hard copy for permanent RX file.	FAX for Sched. II unacceptable for dispensing.	Original signed RX order required before filled prescription released to patient.
VA	Prohibited for all prescriptions.		

DEA Issues Position on FAX

The following sets forth the Drug Enforcement Administration's (DEA) position on the use of facsimile equipment to transmit a prescription for controlled substances from the prescriber to the dispenser. DEA opposes the use of a facsimile prescription for a Schedule II through V controlled substance for the reasons discussed below.

This issue was reviewed by several state pharmacy boards and by national medical and pharmacy associations. A recent national survey of states was made to determine which states have authorized the use of the facsimile machine to transmit a prescription from physician to pharmacy. This survey revealed that nine states presently allow a prescription for a non-controlled substance to be telefaxed to the pharmacy. One state allows the telefaxing of a prescription for a Schedule III through V controlled substance, provided the original prescription is 'ivered to the pharmacy before the medication is dispensed.

lthough existing regulations in the *Code of Federal Regulations* do not specifically address the use of the facsimile machine, they do allow a telephone prescription order for a Schedule III through V controlled substance. A telefaxed prescription provides an accurate copy of the original prescription compared to a phone-in prescription, reducing the chance of misinterpretation by the pharmacist. Use of a facsimile machine also provides additional time for the pharmacist to prepare the medication for the customer. However, the potential for diversion is increased since a patient in possession of an original prescription for a Schedule III through V controlled substance could transmit the prescription to several pharmacies. Also, the identification of a forged prescription becomes especially difficult since the telefaxed copy is less likely to show that the prescription has been altered.

In the case of a Schedule II controlled substance prescription, it has been suggested that the facsimile machine provides additional time for the pharmacist to fill the prescription before the customer arrives to purchase the medication. The original prescription in this instance is required by regulation before the medication can be dispensed. However, the use of a facsimile machine in this way allows for abuses of the system since the pharmacist may never see the original prescription before the medication is dispensed to the customer. From a practical point of view, the cash register clerk will interface with the customer ıd the original prescription will be made available to the ıarmacist only after the sale is completed. Even if the pharmacist reviews the original prescription prior to the sale, the pharmacist is less likely to conduct a thorough review for forgeries since time, effort, and inventory have already been invested.

Consequently, it is DEA's position that the use of a facsimile machine to transmit a controlled substance prescription to a pharmacy should be prohibited. For the foregoing reasons, it is apparent that the use of a facsimile machine for this purpose would increase the potential for diversion of not only a Schedule III through V controlled substance, but for a Schedule II controlled substance as well. The pharmacist has full responsibility to dispense only pursuant to a prescription which meets the requirements of **21 CFR 1306**, and the pharmacist must fully exercise his/her responsibilities under **21 CFR 1306.05(a)**.

North Carolina Develops Faxweb

North Carolina Board of Pharmacy Executive Director David Work has established "Faxweb," beginning with a telephone tree model to send facsimile transmissions to pharmacies across the state. The program, which disseminates information "over the state like a web," enables the Board to fulfill one of its primary responsibilities, communicating with the state's licensed pharmacists.

Installation of the Faxweb network was not without problems. Mr. Work encountered substantial delays in relaying information from one location to another and found that there were more instances in which the system failed to transmit the information than had been originally anticipated. In addition, he discovered that the copy quality of the faxed message diminished significantly after the first level. These problems were solved by sending single messages to each location.

During the past five months, North Carolina has sent 12 messages via the Faxweb communication system, notifying the state's pharmacists about Class I recalls; the recent developments in the generic drug issue, including changes in the classifications of individual products; and, most recently, disciplinary actions taken by the Board of Medical Examiners. On one occasion, the North Carolina Board took advantage of the Faxweb system to advise pharmacists of a continuing education program's cancellation due to Hurricane Hugo.

The costs attached to operating a facsimile communication system like Faxweb vary with the time of day and length of the transmission. In North Carolina, a three-page, daytime transmission to 66 locations costs slightly over $45. While it is obvious that economies are available," notes Mr. Work, "we could not find any way to send in-state fax messages for less than 14 cents." Interstate transmissions, however, ranged in cost from eight to nine cents.

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tion about these labels can be obtained from your wholesaler, or Pharmex at 1-800-233-0585.

Item 638 – Clarification of Generic Drugs for Medicaid Beneficiaries

For many years, the Board staff and Medicaid officials have had a difference of opinion regarding the requirement that generic drugs be used on some prescriptions for Medicaid beneficiaries. The addition of a phrase in the 1989-90 State Budget Act has made it clear that, when available in the pharmacy, generic drugs, rather than brand name drugs, shall be dispensed to Medicaid beneficiaries at a lower cost, unless the prescriber indicates DAW on the prescription in his own handwriting.

This change clarifies a situation that has existed since 1979 and, in the view of the Board staff, eliminates significant liability exposure for pharmacists. Benny Ridout, pharmacist consultant to the Division of Social Services, deserves full credit for this statute change.

Item 639 – Reminder about Prescription Transfers

Several recent inquiries to the Board office indicate that there is an incomplete understanding about the regulation involving prescription transfers. First of all, a transfer is just that – a transfer and not a copy. Transfers can only occur from pharmacist to pharmacist. According to Board rule, technicians or other unlicensed personnel cannot perform this function. While prescriptions for controlled substances can be transferred only once, other prescriptions can be transferred without limits, providing that refills still exist. It is wise to refer to the rule on this matter at section .1806 on pages 42 and 43 in the orange pharmacy law book and for both pharmacists to use a check list.

If you don't have an orange law book, you don't have the most current edition. An orange law book is available from the Board office for $5.00. Don't forget that, in order to prevent excessive refillings, it is the transferor pharmacist's responsibility to void the transferred prescription record.

Item 640 – Leaders Forum Produces Task Force

Each February, the Board organizes a Pharmacy Leaders Forum, which is composed of representatives from all the major groups in the profession in this state. The purpose of the gathering is to exchange views on important issues, to recognize legislative priorities, and to address any important matters facing pharmacy. On the second weekend in February, approximately 40 representatives of the Pharmaceutical Association, Society of Hospital Pharmacists, Campbell and UNC, wholesalers, manufacturers, chain pharmacists, government, and the Board of pharmacy assembled.

The group agreed that a task force should be formed to make recommendations on several critical issues in pharmacy. Accordingly, Board President Adams appointed a task force composed of four committees. A Committee on Standards and Practice will be chaired by Cindy Bishop, Gaston Memorial Hospital, and John Zatti of Glaxo will head a group that will consider the definition of pharmacy practice. The pharmacy technician issue will be considered by a committee chaired by Steve Dedrick of Duke University Medical Center, and Tom Wiser from Campbell will chair a group that will consider practice competency and the external Pharm.D. Board President Adams will co-chair the Task Force with Katherine Jefferson of the Pharmaceutical Association. Jefferson also serves as information liaison. Ex-officio members of the group are Al Mebane and David Work.

These committees, as part of the Task Force, will meet several times during the next year. We solicit your input in this effort and request that you contact the committee chairmen at the addresses noted above, or Chairman Adams. It is expected that the work of this group will result in changes to the Practice Act and regulations that will reflect current trends and future aspirations.

The answer to the Quarterly Query is #4, "The Marketing of Drugs."

Item 641 – Identification of Solid Dosage Forms

You may not be aware that the Food and Drug Administration identifies solid dosage forms as a service to professionals and the public. You may contact them through the Drug Listing Branch at (301) 295-8086, or write the FDA Drug Listing Branch, Solid Dosage Identification Source, 7520 Standish Place, Rockville, Maryland 20855. It is our information that identification can often be made within a few minutes from physical characteristics.

Item 642 – Honey and Infant Botulism

It has come to the Board's attention that honey and Karo syrup can have serious adverse effects if used in children under one year of age. According to articles in the *Journal of Pediatrics*, honey and Karo syrup may contain *C. botulism*, which causes infant botulism. It would be wise to avoid the use of either product in infants under the age of one year. Pharmacists should use special care not to recommend such a practice to improve palatability of medicine. Pharmacists should guide their practice accordingly.

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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