

# North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Item 549 - Disciplinary Actions Of The Board**

June: *Clarence Lee Swearngan*, Salisbury. Filling prescriptions when he knew or should have known that there was a question as to their validity. License suspended for one year, stayed for five years with 30 days active suspension and other conditions.

July: *Charles Peter Wilson, III*, Arden. Removing and dispensing to himself controlled substances from the pharmacy's stock without a valid prescription; conviction of a felony in connection with the practice of pharmacy or the distribution of drugs. License revoked.

## **Item 550 - Election Results**

The Spring Election for membership on the Board produced the following results: James W. Clow, 183; William H. Randall, Jr., 866; Bill Scarboro, 263; and George Willets, 400. These election results were declared as final at the June meeting of the Board and Mr. Randall has been elected to another three year term to begin in the Spring of 1988.

According to North Carolina statute and Board regulation any licensed pharmacist in the region designated for election can be a candidate. This can occur by nomination from a committee appointed by the Board or by petition of ten pharmacists from that region.

## **Item 551 - Prescription Forgeries**

Observant pharmacists will note in the disciplinary section of this newsletter, one action by the Board in June by the Board involving forged prescriptions. Another hearing with a different pharmacist occurred in July and is not printed since the time for appeal had not yet run by the copy deadline for this newsletter. In these two cases a total of 7,102 dosage units of Dilaudid 4 mg. were diverted from the close system of distribution through legitimate channels contemplated by the Controlled Substances Act. Pharmacists who fail to recognize prescription forgeries in a timely manner when they knew or should have known that suspicious conditions surround the prescription can expect similar treatment. In one of these cases the "prescriptions" were purportedly from dentists, an internist and a physician at a university student health center in Charlotte on the student health center's prescription blank and were filled in Fayetteville, often on the same day they were supposedly written. In another case the "prescriptions" were

written on photocopied blanks from an "Urgent Care Center" some 40 miles from the pharmacy where they were filled.

Pharmacists should understand that they are not expected to question every prescription for controlled substances from physicians. Inquiries should be made only if there is something additional which arouse suspicion such as an unusual distance from the prescriber, a large number of dosage units, the prescription is too legibly written, prescriptions are too frequent, or it is for an abusable drug for a new customer or other signs which might be questionable. Sensing and detecting forgeries is as much an art as a science and firm rules or checklists are not feasible.

Notice of the forged prescription problem has been given to pharmacists on many occasions, see Newsletter Items 250-September, 1976; 263-August, 1977; 269-January, 1978; 279-July, 1978; 327-April 1980; 366-October, 1980; 353-April, 1981; and 442-October, 1983. A recurring theme in these items is the matter of identifying the person presenting the prescription. Pharmacists can follow a procedure of treating a prescription for an abusable drug for a person not well known to them in the same way that they would a check and obtain identification from a driver's license or other document.

There are people who take advantage of pharmacists good intentions through one scheme or another to obtain drugs and divert them to their own purposes. This often means resale for "street use" the anathema of the purpose of drugs in society. Law enforcement agencies regularly report the illicit use of Dilaudid, Percodan and other easily identified brand name drugs. One source of these drugs, some say the primary source, is legitimate retail pharmacies with well intentioned (or naive or negligent) pharmacists who fail to recognize a scheme to obtain controlled substances under false pretenses.

The single most common scheme is forged prescriptions, usually presented by someone other than the patient for whom the prescription is written. It may be brought to the pharmacy by a member of the group that will ultimately obtain and redistribute the drug at the street level. Or it may be delivered to the pharmacy by a "runner" who is given the "prescription" sufficient cash to pay the normal retail price and a story from the organizers to say, if asked, that the prescription is for a relative who is dying of cancer.

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# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy and can only be ascertained by examining the original article.)

## **POISON PREVENTION IS A YEAR ROUND RESPONSIBILITY**

Pharmacists have a unique responsibility to protect the public health and ensure that all safeguards for the prevention of accidental poisonings are being followed.

One of the impetuses for a decrease in the number of accidental poisonings for children has been the Poison Prevention Packaging Act (PPPA) of 1970 which requires child-resistant packaging for products for use in or around the household. The regulation requires all human oral prescription drugs be dispensed in safety packaging, with few exemptions. Since the regulation was passed in 1974, childhood poisonings from prescription drugs have dropped markedly. Unfortunately, they have not been eliminated entirely. In fact, more than 60,000 prescription drug poisonings involving children under 5 were reported in 1985.

To investigate the matter further, the Consumer Product Safety Commission (CPSC) conducted a study of the reports received from the various poison control centers. The CPSC is responsible for the implementation of the Poison Prevention Packaging Act. The study found that of 306 child-resistant packages examined, 65 percent were not working properly, almost one-third of all medicines ingested were *not* in child-resistant containers and 17 percent of the drugs ingested were in no containers at all.

Additionally, over half of the non child-resistant containers had been dispensed to parents of a child under five and 18 percent had been dispensed for the child himself. The results of the study seem to indicate that pharmacists have not been complying with the PPPA.

In a recent move, the CPSC is working with the boards of pharmacy and other state agencies to obtain a memorandum of understanding that would have the CPSC and boards of pharmacy cooperatively enforcing the child protection packaging requirements of the PPPA. Through the agreement, the boards of pharmacy would assume the responsibility for the education of pharmacists and the enforcement of the PPPA standard for prescription drugs. Boards of pharmacy could easily and effectively accomplish these objectives during routine inspections or through educational programs organized by the board. The boards of pharmacy already have in place mechanisms to provide the assistance requested by the CPSC.

It would be advisable to confer with your board of pharmacy about this cooperative program and how it will affect you. In all cases, the pharmacist's responsibility to follow the PPPA and protect the public health from accidental poisonings is tantamount and year-round!

## **DEA: MULTI-YEAR REGISTRATION**

On July 1, 1987 the Drug Enforcement Administration (DEA) began the phase-in of a multi-year registration system for all retail

pharmacies, hospitals/clinics, practitioners and teaching institutions currently registered with the DEA or who will apply for registration. The purpose of the multi-year registration system is to reduce the paperwork burden on the public and the administrative burden on the DEA. It will be phased in so that the volume of registrations renewed annually will be reduced from the present total of 660,000 to 220,000.

The selection process for determining which current registrants will be renewed for a 1, 2 or 3 year period will be through sequential sorting. The active file of current DEA registrants will be divided into equal thirds. It will *not* be done by zip code sorting or selection. All new applicants for registration after July 1, 1987, will be registered initially for a period of 28 months to 39 months depending on when they apply. Their registration will require renewal every 3 years thereafter.

The fee for registration remains the same at \$20 per year for hospitals/clinics and practitioners. The fee for a 1-year renewal is \$20, for a 2-year renewal is \$40 and for a 3-year renewal is \$60. The correct fee and renewal period for each registrant will be preprinted on the renewal application forms issued to the registrants due for renewal. For additional information contact the DEA at:

Drug Enforcement Administration, Registration Unit - ODRR,  
1405 Eye Street, N.W., Washington, D.C. 20537, (202) 254-8255.

## **A SUMMARY: FDA DRUG APPROVAL PROCESS**

In order for a sponsor to proceed with clinical testing of experimental products for use in the treatment of any disease or condition, an Investigational New Drug (IND) application must be filed with FDA after completion of animal studies. The IND must contain information needed to demonstrate the safety of proceeding to test the drug in human subjects. In addition, assurance of informed consent and protection of the rights and safety of human subjects is required.

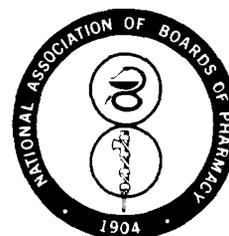
The initial clinical use of investigational drugs, Phase I, is intended to carefully assess the safety of the drug to determine any metabolic and pharmacologic effects that can be monitored, any side effects associated with increasing doses, and to gain very preliminary evidence of effectiveness. Small numbers of patients are entered into Phase I trials. As safety data are accumulated and reviewed, studies are gradually expanded in scope and size.

In Phase II studies, trials are conducted to evaluate the effectiveness of the drug for particular indications and to determine common short-term side effects.

Phase III studies are usually expanded controlled and uncontrolled trials involving larger numbers of patients, intended to gather additional information about effectiveness, to establish proper dosing regimens and parameters of use in order to prepare appropriate labeling, and to provide sufficient safety information

# Compliance News

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



to give a clear profile of the drug's potential risks in a larger population base. Often adverse reactions to a drug do not become recognized until the drug has been used in a large number of patients.

Once Phase III testing is completed, the sponsor submits all the test results to FDA in the form of a New Drug Application (NDA). FDA reviews the data submitted and then makes the decision on whether the drug may be approved for marketing.

## CONTROLLED SUBSTANCES ACT—RECORDKEEPING

The following excerpt is from a letter received by Marilyn Mitchell, Executive Director of the Wyoming Board of Pharmacy from the office of Chief Counsel, Drug Enforcement Administration, U.S. Department of Justice in response to a query concerning the recordkeeping requirements of the Controlled Substances Act.

“Very succinctly, the 1984 amendments to the Controlled Substances Act require that a practitioner: physician, dentist, veterinarian, or researcher; maintain complete and accurate records of all controlled substances dispensed (other than by prescribing or administering) by them. In this context the word “dispensed” means controlled substances given to a patient, ultimate user or research subject by the practitioner to be taken by the patient outside of the practitioner’s office.

“Complete and accurate records of all controlled substances given to a patient or research subject by a practitioner must be maintained regardless of their origin. Samples of controlled substances are *not* excluded from this requirement. If samples of controlled substances are given to a patient to be taken home by that patient, the practitioner must maintain a record of the dispensing of those controlled substances.”

## “CRUSHING” A TABLET OR CAPSULE CONTENT

At one time or another every pharmacist has had to respond to the question of whether a particular tablet or the contents of a capsule can be crushed for ease of administration. In responding, pharmacists must consider whether crushing will adversely affect the formulation, effectiveness or organoleptic properties of the medication. Advising patients or other health professionals to crush a medication is a recommendation that should be made after careful consideration of the individual drug product and individual patient.

In general, time release or slow release, enteric coated or any similar type of specifically formulated medication should not be crushed. Alteration of these special delivery systems could greatly affect the dose, absorption and side effects of the drug. Prior to crushing a medication, alternatives should be explored.

The following is a listing, *not all inclusive*, of some medications that should *not* be crushed:

Medication	Company	Formulation*
Ananase	Rorer	E-C Tab
Artane Sequels	Lederle	S-R Cap
Arthritis, Bayer Timed Release	Glenbrook	S-R Cap
Belladanal-S	Sandoz	S-R Tab
Bellergal-S	Sandoz	S-R Tab
Bisacodyl	(Various)	E-C Tab
Bronkodyl S-R	Winthrop	S-R Cap
Chlorpheniramine Maleate T-D	Lederle	S-R Cap
Chlor-Trimeton Repetab	Schering	S-R Tab
Choledyl SA	Parke-Davis	S-R Tab
Combid Spansule	SKF	S-R Cap
Compazine Spansule	SKF	S-R Cap
Constant-T	Geigy	S-R Tab
Contac	Menley James	S-R Cap
Diamaox Sequels	Lederle	S-R Cap
Dimetane Extentab	Robins	S-R Tab
Dimetapp Extentab	Robins	S-R Tab
Donnatal Extentab	Robins	S-R Tab
Donnazyme	Robins	S-R Tab
Drixoral	Schering	S-R Tab
Dulcolax	Boehringer	E-C Tab
Easprin	Parke-Davis	E-C Tab
Exotrin	Menley James	E-C Tab
E-Mycin	Upjohn	E-C Tab
Entozyme	Robins	E-C Tab
Eskalith CR	SKF	S-R Tab
Feosol	Menley James	E-C Tab
Feosol Spansule	Menley James	S-R Cap
Ferro-Sequels	Lederle	S-R Cap
Hydergine Sublingual	Sandoz	Subl. Tab
Indocin SR	MSD	S-R Cap
Isordil Sublingual	Ives	Subl. Tab
Theo-Dur	Key	S-R Tab
Theolair SR	Riker	S-R Tab
Thorazine Spansule	SKF	S-R Cap
Trilafon Repetab	Schering	S-R Tab
Tuss-Ornade Spansule	SKF	S-R Cap

\*E-C = Enteric-Coated; S-R = Slow Release; Subl. = Sublingual; Cap = Capsule; Tab = Tablet

The above information was reprinted from “Correct Care,” a publication by the National Commission on Correctional Care (NCCC). The original article was written by Robert Hilton, Chair-Elect of the Board of Directors of the NCCC.

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The organizers wait outside and pay the runner as much as \$50 on delivery of the drugs and neither had seen the other before or since that time.

Pharmacists may not be aware of these schemes or that prescription blanks may have been reported missing by a physician. Indeed until this time, the fall of 1987, there has been no standard system to report lost or stolen prescription blanks in this state. The Board's publication described below is designed to assist pharmacists in identifying schemes to divert prescription drugs, usually controlled substances, before substantial quantities of drugs have escaped from legitimate channels of distribution.

A number of other schemes involving the passing off of a telephone number as that of a physician's office when it is a public telephone. Pharmacists could be suspicious when a physician answers his own office phone without a receptionist or nurse first taking the call. Some people will go to extreme lengths to obtain controlled substances and a recent newspaper story related another scam for this purpose. A young lady rented a nuns costume and attempted to pass forged prescriptions while wearing the habit. She apparently felt that the costume gave her better credibility but pharmacy personnel were suspicious of the jewelry she wore in addition to the nuns habit and she was apprehended by authorities.

### ***New Board Publication***

From time to time the Board office receives reports of prescription blanks which are missing and believed stolen from physicians offices. Up to this point there have been no organized effort to assemble this information and distribute it to pharmacists so they might be aware of "prescriptions" which may be invalid. Beginning this fall the Board office will collect this information in a publication titled *Report of Invalid Prescriptions (RIP)* and arrange for its distribution through wholesalers to pharmacies in the state. This distribution will be through pharmaceutical wholesalers with a pharmaceutical order, mailing or through their representatives. Physicians who believe that their prescription blanks are missing or have been stolen should contact the Board office at (919) 942-4454 and report this information as soon as it is discovered. Some standard information will be collected including the date of discovery and a sample of the missing prescription blanks marked void.

Pharmacists are cautioned that they should *not* attempt to apprehend individuals suspected of drug diversion. In more than one instance the Board staff believes that such diversion activity is the work of a significant group operating in many parts of the state and perhaps other states. For this reason we believe that early involvement of the State Bureau of Investigation Diversion Investigative Unit is important and urge that they be contacted in the normal course of events. If you have reason to believe that a drug diversion scheme has been tried or is in progress at your pharmacy the Board recommends that you notify: 1) local law enforcement (police or sheriff); and 2) the State Bureau of Investigation Diversion Investigative Unit at (919) 292-5320; 3) the Drug Enforcement Administration at (919) 333-5052; and 4) the Board of Pharmacy at (919) 942-4454.

### ***Item 552 - Transfer Of Prescriptions For Controlled Substances***

The Commission on Mental Health, Mental Retardation and Substance Abuse which has authority over the controlled substances regulations in North Carolina has amended its regulations on the transfer of prescriptions for controlled substances. As of August 1, 1987 it is permissible to transfer prescriptions in Schedules III, IV and V for refill purposes in the manner prescribed by federal regulations at 21 CFR 1306.26 which can be found on page 179 of the green pharmacy law book. This change in regulations now allows the transfer of prescriptions for both controlled and non-controlled substances pursuant to Board and Commission regulations.

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