



North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 507: Disciplinary Actions

March: Joel Paul James & James Pharmacy, Angier: Dispensing prescription legend drugs in non-safety closure containers; improperly labeling prescription medication; dispensing prescription legend drugs without a valid prescription. License suspended five years, stayed ten years with an active 60 day suspension and other conditions.

John H. Carswell & Colonial Drug Company, Chapel Hill. Petition to reconsider Board's Order of January, 1986 denied. Failure to sign prescriptions for Schedules III, IV and V substances; failure to show the patient's address on prescriptions for Schedule III, IV and V substances; failure to mark prescriptions for Schedule III, IV and V substances with a red "C"; failure to record refill information on prescriptions; violations of the terms of the stay of the suspension of license set out in the Board's March, 1985 Order. License suspended for 90 days with other conditions.

No disciplinary matters in April or May, 1986.

Item 508: Reminder On Product Selection Law

Members of the Board have expressed concern that pharmacists in North Carolina need to be reminded about one specific section, with subsections, of the Product Selection Law. The pertinent part is G.S. 90-85.28(a) which can be found on page 14 of the green Law Book.

Without neglecting other sections of the statute, Board members feel the portion on a logo or other identifying mark on tablets and capsules, the section on adequate provisions for drug recall and also the part on return of outdated drugs deserve emphasis. Simply stated, a product in solid dosage form such as a capsule or tablet must bear a logo or other identifying mark in order for it to be used in product selection or substitution. Also, manufacturers must have a returned goods policy and a provision for drug recall which complies with the statutory standards for their products to be used in product selection.

A reminder to pharmacists: the Product Selection Law contemplates that the decision on using a brand or generic drug on any given prescription will be between the prescriber and the pharmacist. While it would be reasonable to expect that the consumer's wishes would be seriously considered, they are not the final arbiter of the drug to be used. State statute leaves this entirely to the prescriber and pharmacist. It is well known that there are some drugs with equivalency problems among manufacturers, see Items

367 and 497. Obviously the consumer is not always in the best position to make the product selection decision. This issue takes on more importance when it is realized that the equivalency decision is entirely the decision of the pharmacist and there is no statutory reference to FDA bioequivalence findings or any other standard. It is also important to remember that when a prescriber writes for a brand name drug and signs on the DAW line, the pharmacist needs to contact the prescriber for approval before dispensing a generic version of the drug.

Item 509: Clarifications Of PRN Refill Designation

Because of general confusion regarding the meaning of PRN when used as refill instructions, this subject was specifically treated in the Pharmacy Practice Act revision which became effective in 1982. This item is in response to questions that continue to be raised on this subject. The specific words of the Statute are "Prescriptions marked PRN shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified."

Board staff interprets this to mean that prescriptions marked PRN (or ad lib etc.) can be refilled for only one year without contacting the prescriber. Continued refillings could occur only after approval from the prescriber. Prescriptions for controlled substances must be brought forward in the file after six months for refill purposes. The Board has not ruled on prescriptions for non-controlled drugs as to whether they must be brought forward in the file or if a notation on the prescription would be sufficient. Under these circumstances inspectors will accept either procedure for non-controlled drugs.

In a case for a prescription marked for a specific number of refills, five for example, the refilling of the prescription could occur beyond one year but within the five refill limit. There are also occasions where prescribers would indicate "PRN for three years" in which case the prescription could be refilled for the designated three year period. In this context, pharmacists should also review sections .1801 and .1802 of Board regulations on refusing to fill or refill a prescription and refilling beyond dosage.

Item 510: October 12th-18th Is Pharmacy Week In North Carolina

The state-wide observance of Pharmacy Week is scheduled this year from October 12th to the 18th. Coordinators for this year's
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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy and can only be ascertained by examination)

Boards of Pharmacy Get Message on Health Fraud

The National Association of Boards of Pharmacy, during the week of May 17 to 21, held its annual meeting in Philadelphia. Board of pharmacy representatives from 44 states attended the meeting. The opening session addressed the issue of health fraud. Board of pharmacy attendees received a substantial amount of information on health fraud; information about issues that are not generally thought of when one speaks of health fraud. The emphasis was on pharmacist involvement, either intentionally or unwittingly, in issues of health fraud.

One of the speakers, Stephen Barrett, M.D., consumer advocate and editor, stated that only people who are grossly malnourished need multi-vitamin supplements. People who have a normal, everyday diet simply don't need this "nutritional insurance." Dr. Barrett said that pharmacists are actually engaging in health fraud by recommending and selling vitamin supplements.

According to Dr. Barrett, a second form of quackery involves stress formula vitamins. He said that there is not the slightest evidence that vitamins help one deal with stress or that stress induces a need for vitamin therapy in the human body. Pharmacists are often intentionally or unwittingly part of the problem by touting or just plain selling stress formula vitamins and other formulas that are unnecessary, according to Dr. Barrett.

Another speaker, John Renner, M.D., Director, Kansas City Committee on Health Fraud and Abuse, and Director, SSM National Family Practice Research and Development Center, advised pharmacists to look at and think about some of the products that they are selling. Dr. Renner listed a number of worthless "quack" products that are commonly available in pharmacies such as Bee Pollen, Grapefruit Diet Formula, Alfalfa Tablets, Ginseng, Selenium, Zinc, Garlic, Bone Meal, Dolomite, Sea Salt, and others.

He urged pharmacists to make use of their knowledge, credibility and access to the public to get valid health information disseminated. Pharmacists should use bulletin boards, posters, etc. to set up "patient learning centers." Display a large sign indicating "we do not sell..." and then list all of the products in the previous paragraphs.

Dr. Renner further urged pharmacists to boycott pharmaceutical companies that sell quack products. Further, he urged pharmacists to discontinue sales of tobacco and alcohol because they are worse than quack products — they are anti-health rather than simply worthless.

DEA Speaks to Pharmacy Boards

DEA was also represented at the NABP Annual Meeting in Philadelphia. Ron Buzzeo of DEA restated DEA's support for multiple copy prescription blanks for Schedule II prescribers.

Buzzeo stated that 34 percent of all M.D.s in the country are now covered by multiple copy prescription blanks for Schedule II substances. The states of New York, Illinois, California, Texas, Idaho, Hawaii and Rhode Island currently require multiple copy prescriptions.

DEA has noticed a significant drop in the amount of Schedule II substance prescribing in states that have implemented multiple copy prescriptions. As an example, Schedule II prescribing in Texas dropped 60 percent with the implementation of multiple copy prescriptions. Schedule II prescribing in New York dropped 54 percent and 53 percent in Rhode Island when multiple copy prescriptions were required for Schedule II drugs.

Buzzeo indicated that DEA had noticed some shift to Schedule III and IV substances with the implementation of multiple copy prescriptions for Schedule II substances, however, not in equal quantities. The rise in Schedule III and IV substance use fell substantially short of making up for the fall in Schedule II use.

Attendees at the NABP meeting were also informed of DEA's plans to go forward with a three-year registration system starting this fall. This will be a significant change from the current registration system, and when it is implemented, practitioners will have only one registration number, not one registration for each separate location, as is now the case.

Pharmacists should be aware of this change not only for their own records but for the records they keep on prescriber DEA numbers.

A Look at Professional Responsibilities

NABP General Counsel, John F. Atkinson, recently reviewed for board of pharmacy members a 1985 court case entitled *Jones v. Irvin*. This case and the courts assessment of the duties of a pharmacist provide a rather shocking description of how at least one court views the profession of pharmacy.

The following is Mr. Atkinson's review of the case of *Jones v. Irvin*.

Carole Jones sought damages against K-Mart for alleged personal injuries she sustained from consuming an excessive amount of prescription drug, Placidyl[®], taken over a long period of time, claiming that K-Mart and/or its pharmacists were negligent in:

A) That it knew or should have known that Placidyl[®] is a drug of abuse and that it was being prescribed in massive amounts; that it should have notified either the plaintiff or the physician prescribing the drug that something was amiss.

B) That it knew the plaintiff was being prescribed massive doses of Placidyl[®], along with other drugs, and that it knew or should have known that the plaintiff was being overmedicated and that it had a duty to notify either the plaintiff and/or her physician of

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this problem.

C) That it knew or should have known that the various drugs being prescribed for the plaintiff in the quantities in which they were being prescribed could have adverse reactions and it failed to take any action whatsoever to notify the plaintiff or her physician.

K-Mart moved for dismissal of the negligence counts claiming that neither it nor its pharmacists had a duty to warn Ms. Jones or her physician of any of the above-listed dangers.

The Federal District Court for the Southern District of Illinois clearly recognized the issue to be determined; namely, "whether a pharmacist who correctly fills a prescription, is negligent for failing to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer."

The Court found that a pharmacist owes the patient the "highest degree of prudence, thoughtfulness, and diligence" but adopted the legal principals expressed in *Pysz v. Henry's Drug Store*, 457 So.2d 561 (Fla. Dist. Ct. App. 1984) that "a pharmacist who properly fills a prescription has no duty to warn the customer of the dangerous propensities of the prescription drug, or in the alternative to notify the physician of the dangerous propensities of the drug and/or the effect it is having on his patient."

The Court assessed the duties of the pharmacist, the physician and the patient as follows:

Based on the Court's analysis of the foregoing cases and general policy concerns, the Court holds that a pharmacist has *no duty to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over-medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer.* It is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug. Further, it is the duty of the patient to notify the physician of any adverse effects or other precautions that must be taken in administering the drug Cf. *Cruz v. Texaco, Inc.*, 589 F. Supp. 777 (S.D. III. 1984). *Placing these duties to warn on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability.* (Emphasis Added)

The Court recognized the responsibility of the pharmacist not to fill prescriptions calling for doses that are obviously fatal and that liability a pharmacist incurs for improperly compounding or filling a prescription. Surprisingly, it also found a duty in the pharmacist to warn a patient about the adverse reaction which may oc-

cur when the pharmacist fills a prescription and also sells the patient an over-the-counter drug that may interact.

While we hesitate in most instances to editorialize when reporting case law, we cannot help but comment on the broad legal principles expressed by the federal court in the Jones decision. While the facts of the Jones case may not have supported the negligence claim against either the pharmacist or K-Mart, the legal principals enunciated by the Court certainly seem to support the proposition that in most instances, a pharmacist need only be able to read, count and pour. Ironically, under the reasoning of the Jones case, a pharmacist may be well advised to do as little checking as possible in order to limit his liability exposure.

This attitude would certainly not be in synch with what we perceive to be the traditional professional responsibilities of a dedicated pharmacist."

Requirements For Computerization Of Prescription Information On Controlled Substances

The number of pharmacies becoming computerized is increasing on a daily basis. Also on the rise is the number of pharmacy computer systems available and the number of software programs that can be utilized by pharmacists in maintaining prescription records.

A review of the computerization requirements of DEA relative to the storage of prescription information on controlled substance prescriptions would seem to be in order. Please keep in mind that individual states may have additional or stricter requirements relative to computer storage of prescription information.

A pharmacy is permitted to use a data processing system as an alternative method for storing and retrieving prescription order renewal information for controlled substances in Schedules III and IV.

The computerized system must provide immediate retrieval (via CRT display or hard copy print-outs) of original prescription order information. Orders which must be readily retrievable from this type of system must include, but are not limited to, data such as: the original prescription number; the date of issuance of the prescription order by the physician; the full name and address of the patient; the physician's name and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed; the quantity dispensed, if different from the quantity prescribed; and the total number of renewals authorized by the prescribing physician.

In addition, the system must provide immediate retrieval of the current refill history for a Schedule III or IV controlled substance prescription orders that have been authorized for refilling during the past six months and backup documentation (stored separately in the pharmacy) to show that the refill information is correct.

event are Lorrie Tutterow in Winston-Salem, 919-922-4418, Charlotte Mize in Greensboro, 919-282-5449 and DeAnn Lagreque at 919-472-2000, ext. 2323.

Packets of information will be sent to members of the North Carolina Pharmaceutical Association and members of the North Carolina Society of Hospital Pharmacists. The material is available to pharmacists at no charge while supplies last by calling 1-800-852-7343 — toll free.

Item 511: Ask About The Grandchildren

As bothersome as child resistant closures are, everyone has to acknowledge that they have saved hundreds of thousands of lives, mostly children. Some people, particularly those at the age likely to have grandchildren, have great difficulty opening these containers and request non-safety closure packaging.

It is somewhat alarming that a Alabama study shows that 36 percent of ingestions by children of prescription drugs occurs in the home of grandparents. The Consumer Product Safety Commission suspect that this is due either to the use of non-safety closure containers or non-functioning containers that are re-used. See Newsletter Item 472, October, 1984.

Item 512: Continuing Education Note

Board Inspectors have been checking continuing education credits at random during regular inspection visits. Pharmacists should keep in mind that the continuing education regulation requires that they keep records at their regular place of practice. One convenient place to keep records is the inside front pocket of the yellow or brown loose leaf notebook for *Newsletters* present in every pharmacy. Pharmacists not in active practice at any one location may keep continuing education records at their home or any other place providing that they are readily retrievalbe.

Item 513: Dispensing Schedule V Drugs

Many pharmacists have commented to the office regarding disciplinary action for excessive dispensing of Schedule V drugs. The most common concern is "how often is too often" and would it lead to a hearing before the Board?

First of all, it must be remembered that the entire history is considered by the Board members during their deliberations. The Board considers the pharmacist's past conduct, the character of the drugs involved, the quantity and frequency of dispensing and any other pertinent information. All hearings held on this issue occurred only after warnings from inspectors, although this is not necessarily a pre-requisite for charges to occur. On the frequency

of dispensing issue, one Board member stated that once every two weeks would be normal, but more frequent dispensing should occur only after a demonstration of medical need.

Item 514: Regulation Amendment

Section 21 NCAC 46.1505 *EXAMINATION* has been amended to read as follows:

.1505 EXAMINATION

(a) The examination shall consist of testing in the following areas:

(1) theoretical examination including pharmacology, pharmacy, chemistry, mathematics and practice of pharmacy which may be reported separately or combined as one score.

(2) practical pharmacy examination which may be reported separately or combined as one score including: laboratory work, prescription reading and interpretation, drug identifications, determination of errors and omissions, pharmaceutical jurisprudence and such other reasonable tests of the applicant's ability to translate professional knowledge into terms of actual practice as the Board may see fit.

(b) The purpose of grading or rating the answers, which shall be legible, shall be valued by marks or points based on their importance, as determined by the judgment of the examiners.

(c) In order to pass, an over-all average of 75 is required on both the practical and the theoretical sections. Candidates who obtain a 75 on the practical pharmacy section or a 75 on the theoretical section are deemed to have passed the respective section provided that the candidate obtains a passing score on the remaining section in North Carolina within the next following two calendar years. A candidate who fails to pass both sections of the examination in the two calendar year period must retake and pass both sections of the examination.

History Note: Statutory Authority G.S. 90-85.15; 90-85.16 Eff. April 1, 1983; Amended Eff. December 31, 1985

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