



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 525 — Disciplinary Actions Of The Board

August: *Donald L. Weathers*, Newton. Refilling prescriptions for controlled substances and legend drugs in excess of the authorized number; failing to maintain accurate, readily accessible records of refills of prescriptions; failure to indicate the name of the generic product on prescription labels and substituting generic products for brand name drugs without authorization from the prescribing physician. License suspended for 60 days, stayed for 5 years with an active 10 day suspension and other conditions.

September: *Joseph Donald Stone* and *Surry Drug Company, Inc.*, Pilot Mountain. Appropriating Schedule IV and Schedule V controlled substances for his own use without valid authorization from a prescribing physician; addiction to alcohol and controlled substances. License suspended 90 days, stayed 2 years with conditions. No action on the permit.

Jimmy Ray Nilew, Asheville. Appropriating Schedule IV controlled substances from store stock without authorization; dispensing Schedule IV controlled substances to family without obtaining a valid prescription; possessing a Schedule IV controlled substance with intent to deliver without valid authorization; falsifying prescription records at place of practice. License suspended 1 year, stayed 5 years, 6 months active suspension and other conditions.

October: *Jesse Oxendine* and *King's Drug Company*, Charlotte. Permitting an unlicensed employee to dispense prescription drugs without supervision by a licensed pharmacist. License revoked for 5 years, stayed for 5 years with 30 days active suspension and other conditions.

Item 526 — Pharmacist Found Guilty Of False Prescription Labeling

The statement above is from a newspaper headline which occurred in a medium sized town in North Carolina. The article indicated that the pharmacist dispensed Trifluoperazine and labeled the container Stelazine®, Hydrochlorthiazide and labeled it Hydropres® and Phenytoin and labeled it Dilantin®.

It also revealed that the pharmacist was found guilty of Medicaid violations which probably prompted the investigation. What is noteworthy about this case is that it illustrates that labeling generic drugs with a brand name is just as much a violation of law as Medicaid fraud. The essence of the violation is that a misbranding has occurred when the label is false or misleading in any particular.

The pharmacist was fined \$5,000, paid restitution of over \$4,300 and assessed court costs.

It is also possible that a brand name or trademark infringement can occur when a brand name is used on the label of a generic drug. A brand or trademark such as Coca Cola, Buick or Blue Cross is owned by the companies who have these products and they are quite careful about the use of such brands or marks. These are recognized as property by the courts and companies must protect these property rights if they are to maintain the worth of their brand name. Pharmaceutical manufacturers have gone to court in the past to protect their property rights (see Item 432 in the July 1983 Newsletter) and they can be expected to do the same in the future.

Item 527 — Quarterly Query

A prescription for Lomotil® marked for 10 refills can legally be refilled in North Carolina.

- I. Five Times
- II. Ten Times
- III. Not more than 6 months.
- IV. Not more than 1 year.
 1. I but III
 2. I but IV
 3. II but III
 4. II but IV
 5. II with no time limit

Item 528 — Regulations On Health Department Dispensing

At the November Meeting, the Board adopted regulations for dispensing of drugs in health departments. A pharmacy permit is required with a pharmacist-manager responsible to the Board for operating within statute and regulations. A copy of the regulations is available from the Board office on request.

Item 529 — Prescribing Of Oral Contraceptives By Physician Assistants Or Nurse Practitioners

In October of 1986 the North Carolina Board of Medical Examiners adopted a change in the Approved Formulary for nurse practitioners and physician assistants which allows prescribing of oral contraceptives with refills up to one year. No other changes were made in the Approved Formulary.

continued on page 4



National Pharmacy

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

Cyanide Study Called For

On October 27, 1986 President Reagan signed into law the "Anti-drug Abuse Act of 1986." Attached to that law was a provision that orders the Environmental Protection Agency (EPA) to determine the feasibility of tightening up registration requirements and recordkeeping of Cyanide and limiting access to supplies of the chemical and requiring distinctive coloration for the chemical. The new provision directs EPA to study the issues and report back to the Congress within six months on present sources of Cyanide and distribution and sales methods.

The Cyanide legislation was first introduced on July 30, 1986 by Senator Slade Gordon (R-Washington).

Sixteen deaths, involving the poisoning of food or drug products, have been attributed to Cyanide. Stricter controls over Cyanide distribution certainly seems to be in order. Hopefully the new Federal legislation will result in tighter controls for this chemical in the future.

When Compounding Becomes Manufacturing

Pharmacists are frequently asked by physicians — most commonly dermatologists — to compound and dispense special formulas for patients of those physicians. On occasion, this type of compounding can get out of hand and can result in the pharmacist being viewed as a manufacturer by FDA rather than a pharmacist compounding specially formulated prescriptions.

A law suit involving that issue recently came to light. In this particular case, Cedars North Towers Pharmacy (Cedars) prepares, packages, and ships certain medications formulated by a Dr. Fulton to physicians throughout the nation. FDA asserted in its action against Cedars that Cedars' activity makes it a drug manufacturer required to register with FDA. The government also claims that the medications being prepared by Cedars are "new drugs" and that Cedars is in violation of the Food, Drug and Cosmetic Act for manufacturing and selling drugs for which no new drug applications have been filed. Cedars argues that as a pharmacy it is exempt from regulation under Sections 355 and 360 of the Food, Drug and Cosmetic Act. The United States District Court for the southern district of Florida first referred the case to the Food and Drug Administration for an initial determination of the issue of whether the drugs in question were "new drugs" within Section 355 of the Act. Cedars petitioned the court to reconsider that action and the court granted Cedars' motion for reconsideration.

Section 360 (g) (1) of Title 21 United States Code, provides an exemption from registration to: "... (1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course

of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail."

The court stated that the facts were uncontested and required the conclusion that Cedars was compounding and selling drugs other than in the regular course of a pharmacy dispensing and selling drugs at retail. The court looked to previous court decisions and to the legislative history of Section 360, which together indicated that congress intended the act to have broad application. Congress stated that: "The purpose of the proposed legislation, as amended, is to strengthen and broaden existing laws in the drug field so as to bring about better, safer medicine and to establish a more effective system of enforcement of the drug laws." Congress also stated: "The Committee believes that drugs should not be on the market unless the Food and Drug Administration knows who is making them, and where they are being made, and is able to inspect the facilities in which they are being made. This will help to stop illicit and substandard manufacturers who do not follow the methods or established controls called for by good manufacturing practice." The court decided, therefore, that exemptions from registration must be narrowly applied to insure the Acts effectiveness in protecting public welfare.

The court determined that certain factors were relevant in deciding whether a pharmacy qualifies for the exemption contained in Section 360 (g) (1). Those factors were: (I) whether particular drugs are being compounded on a regular basis as opposed to periodic compounding of different drugs; (II) whether drugs are being compounded primarily for individual patient prescriptions as opposed to orders contemplating larger amounts for office use; (III) the geographic area of distribution; (IV) whether any form of advertising or promotion is being utilized; (V) the percentage of gross income received from sales of particular compounded drugs; and (VI) whether particular compounded drugs are being offered at wholesale prices.

The drugs which were the subject of the controversy in question were first developed by Dr. Fulton for use in treating patients who were suffering from Acne. Dr. Fulton enlisted the aid of Cedars in making the drugs more pharmaceutically elegant. Dr. Fulton, when attending various seminars and conventions, informed other physicians about his private formulations and of the fact that they could be obtained through Cedars.

Cedars provided literature describing each of the Fulton products to physicians who made inquiry about them. The literature provided information on each product's chemical composition, its possible uses, and, in some cases, how it is to be applied. Further, a price list advised that all listed products were available at wholesale prices, but that individual patient prescriptions and orders of less than \$30 would be sold at retail prices only. The list stated

Compliance News



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

that physicians desiring the product should submit a signed prescription for the amount required and should indicate on the order "for office use." Finally, the evidence disclosed that Cedars distributed those drugs to physicians throughout the United States receiving revenue in excess of \$10,000 per year for these Dr. Fulton drug items.

The court stated, "these facts indicate that this court is not presented with a situation requiring it to determine whether Cedars has come dangerously close to crossing the line separating a pharmacy, which is entitled to exemption, from a manufacturer of drugs, which is required to register. Rather, the facts compel the conclusion that Cedars has so clearly transended the level of normal pharmacy operation as to leave no question remaining regarding its possible exemption under Section 360 (g)(1). Bulk compounding of drugs at wholesale prices with national distribution is not the type of activity intended to be exempt from registration under Section 360 (g) (1). Protection of the public welfare requires this court to disregard the form of these transactions and find that their substance and effect is violative of the intent of the statute."

The court went on to find that the drugs involved in the case were, in fact, "new drugs" under the Food, Drug and Cosmetic Act.

The court thus granted the governments motion for summary judgment. Pharmacists should keep the facts and the court findings in this case in mind when compounding prescriptions, which are filled at the pharmacy doing the compounding. Compounding for the purpose of sales to other pharmacies or physicians takes the pharmacist out from under this exemption and makes him a manufacturer in the eyes of FDA.

Schedule II Order Forms

When a pharmacist issues an order form for Schedule II controlled substances and after the items are received the number of packages and the date such packages were received must be recorded on the copy retained by the pharmacist. A space is provided for this on the DEA order form. The order form must be completed properly and bear no material alterations or erasure.

Pharmacists are often negligent in recording the number of packages received and the date received on their copy of the order form. Failure to record this information could have serious consequences should an audit of controlled substances be conducted by DEA or Board of Pharmacy personnel.

Will Drug Diversion Bill Rise Again?

As Congress came down to the end of its recent session the bill to control drug diversion, which was sponsored by Representative John Dingell (D-Michigan), was the subject of some last minute negotiations between Dingell and his staff and the Pharmaceutical Manufacturers Association.

The Dingell bill first called for a complete ban on sampling by drug manufacturers. As time needed for passage of the bill began to wane it became apparent that the powerful PMA lobby would kill the bill unless some compromise position could be worked out. Representative Dingell and his staff began attempting to negotiate a behind the scenes compromise with the drug manufacturers on the sampling issue in an attempt to get the much needed piece of legislation passed. The effort to obtain a compromise position was derailed when the Pharmaceutical Manufacturers Association decided that it was unable to accept the stiff corporate penalties for sampling abuses that Dingell and his staff wanted included in the bill.

PMA opposition to the sampling provisions virtually guaranteed that the bill would not pass this session. That is indeed what happened.

The question now is whether Representative Dingell and his subcommittee will take up the issue again when Congress reconvenes. If the issue does resurface it will be interesting to see if the Chairman follows through on a previous threat to go back to the total ban on sampling position if a compromise could not be worked out.

Should sampling of physicians by manufacturers ultimately be banned pharmacists could find themselves with a new role to play during the introduction of new drug products by the drug manufacturers.

In Appreciation...

The NABP Foundation's Bureau of Voluntary Compliance (BVC) has announced the stepping down of David Holmstrom, J.D., RPh., as National News Editor.

"We owe him a great deal of appreciation," said David Work, chairman of the BVC. "His insightful and provoking articles have brought the State Newsletter Project much acclaim."

This issue marks the last national section to be produced by Holmstrom. Beginning in March, the national section will be coordinated by Carmen Catizone, B.S., RPh., Test and Measurement Director at the National Association of Boards of Pharmacy (NABP), in collaboration with other members of the NABP staff and BVC Chairman Work.

Catizone says he will attempt "to maintain the high standard set by Holmstrom over the past four and a half years."

Information and story ideas for the national section may be submitted to Carmen Catizone, NABP, 1300 Higgins Road, Suite 103, Park Ridge, Illinois, 60068.

continued from page 1

Occasionally questions have arisen regarding certified nurse midwives and their prescribing ability. This group of practitioners was originally included in the nurse practitioner group for approval from the Board of Medical Examiners. In 1983 the General Assembly separated this group of practitioners and gave them the title of Certified Nurse Midwives who have the same prescribing privileges as nurse practitioners.

Item 530 — Reciprocity And Original License

Reciprocity is the honoring of a license in one state by another state based on the candidate meeting similar requirements and that each state will issue licenses to licensees of the other state without substantial examination. Currently the reciprocity of pharmacy licenses is now in effect among all states except Florida and California. About one year ago Hawaii began reciprocity for the first time. Reciprocity in North Carolina, and in most states, is based on licensure by examination. It follows, then, that the license in another state is based on licensure by examination in the original state.

The question has arisen from time to time regarding whether licensees by reciprocity in North Carolina must maintain their license in their original state. The issue has taken on more importance with differing continuing education requirements and potential multiple licenses.

The Board has not ruled on the necessity of maintaining the original license by examination and, under these circumstances, it would not be required by the Board staff. Pharmacists should understand that the Board could require an active license in the original state of licensure at some time in the future. With some states this can require paying all back renewal fees and/or obtaining all back continuing education which may be a significant task.

Item 531 — May Board Meeting Cancelled

Due to a conflict with the Annual Meeting of the National Association of Boards of Pharmacy, the regular May meeting of the North Carolina Board of Pharmacy is cancelled.

Item 532 — Equivalency And Product Selection

Pharmacists are reminded by this item that product selection can occur only with drugs that are equivalent. The Board has taken the position that the equivalency of the drug is the individual pharmacist's decision while noting certain drugs or categories of drugs where problems may arise. Because product selection is the pharmacist's responsibility it naturally follows that the pharmacist is

legally responsible for the product's equivalency.

Prior notations have been made in the board Newsletter on equivalency in items 367, 476 and 497. The Board recently received information regarding problems associated with the equivalency of levothyroxine and Synthroid®. A comparative study using the current USP Assay method showed some products to be subpotent long before their expiration date. Variability was noted both within products and between products which would make product selection inadvisable.

In this connection it should also be remembered that, in order to be used in product selection, a drug product must have a printed logo or identification mark on each tablet or capsule. This means that plain, unmarked tablets or capsules cannot be used in product selection. Companies must also have a returned goods policy in order for their product to be used in product selection. While the Board has not decided what is or is not an acceptable returned goods policy, it is clear that refusing to accept returned goods for credit would be unacceptable. The answer to Item 527, Quarterly Query is 5.

Item 533 — Board Presentations For Local Associations

City and County Associations can obtain a program from the Board of Pharmacy for continuing education credit. It consists of a review of Board activities and a slide series on the licensure exam. If you want to arrange for a Board Member and/or the Executive Director to make this presentation call 919/942-4454

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, J.D., R.Ph.—State News Editor

David Holmstrom, J.D., R.Ph.—National News Editor

Fred T. Mahaffey, Pharm D.—Executive Editor

Yetta Matturro, M.S.J.—Editor