



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 541 — Disciplinary Actions

March: *Robert Ray Lucas*, Chapel Hill. Failure to record properly the sales of Schedule V controlled substances on the exempt narcotics register; dispensing Schedule V controlled substances for other than a legitimate medical purpose; dispensing Schedule IV controlled substances without a valid prescription; pleading guilty to a felony in connection with the practice of pharmacy and the distribution of drugs. License revoked, stayed ten years with 180 days active suspension and other conditions.

Edward Lowdermilk, Chapel Hill. Failure to record properly the sales of Schedule V controlled substances on the exempt narcotics register; dispensing Schedule V controlled substances for other than a legitimate medical purpose; serving as pharmacist-manager while permitting the dispensing of controlled substances without a valid prescription.

Ralph E. O'Harrow and Olde Towne Pharmacy, Belhaven. Marking prescriptions for Hycomine and Hycodan for five refills and refilling prescriptions for Hycomine and Hycodan without authorization from the prescribing physician. License revoked, stayed ten years with active suspension of six months and other conditions.

April: *Griffin Wakefield, William Turner Deavers, James Leonard Currence and Plaza Apothecary, Dalebrook Pharmacy, Biddleville Pharmacy*, Charlotte. In response to charges stemming from possession of a large quantity of samples, many of which were out of date, Mr. Wakefield, Mr. Deavers and Mr. Currence agreed to a 90 day suspension of their licenses, stayed for two years with an active 30 day suspension along with other conditions. The permits for each store specified above were suspended for ten consecutive days.

The February and May meetings of the Board of Pharmacy were cancelled.

Item 542 — Quarterly Query

A youthful person enters your pharmacy and requests a bottle of Novahistine DH. Remembering the federal regulations on Schedule V substances you request identification and he produces a drivers license showing a birth date of February 29, 1968. As the pharmacist you should:

1) Dispense the Novahistine DH since the person has shown identification establishing that he is over 18 years of age.

2) Decline to dispense the Novahistine DH since he has shown identification which establishes that he is not over 18 years of age.

3) Dispense the Novahistine DH, ignoring the identification.

4) Decline to dispense the Novahistine DH, since it was recently designated as a legend drug in North Carolina.

5) Decline to dispense the Novahistine DH because of insufficient proof of age.

Item 543 — Setting An Example For Continuing Education

During the licensure renewal period around the first of the year the Board staff regularly hears comments about difficulty in obtaining continuing education credits. Nearly everyone is able to attend local association meetings or programs at area health education centers which occur at convenient locations around the state. Some pharmacists accumulate more than enough credit with 70 to 80 hours and then there is York Garrett.

York, who was born on December 10, 1894, operates a one man pharmacy in Durham. He is one of the founders of the National Pharmaceutical Association and has met his continuing education requirement by attending their national conventions, in San Diego in 1986 and Houston in 1985. James Tison, executive director of the National Pharmaceutical Association, said that York "is a very active young man who has attended every NPA convention since its founding." It is obvious that York recognizes his seniority and sees the need to set an example for continuing education when some pharmacists who are 30 or 40 years younger claim to be unable to attend meetings. He is looking forward to the annual convention of the National Pharmaceutical Association this year in Kansas City in August.

If you have not attended a state or national convention, you should give serious thought to doing so as part of your professional responsibility. The North Carolina Pharmaceutical Association Convention is May 18th-21st, 1988 at the Grove Park Inn in Asheville. The North Carolina Society of Hospital Pharmacists is October 6th-8th, 1987 at the Mission Valley Inn in Raleigh and February 4th-5th, 1988 in Winston-Salem. The National Association of Retail Druggists has their annual convention in Las Vegas, Nevada from October 19th-23rd, 1987, the American Society of Hospital Pharmacists has their Mid Year Conference

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National Pharmacy

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

ANABOLIC STEROIDS

Increased interest over the use of anabolic steroids by amateur and professional athletes has cast a watchful eye towards the distribution of these drugs. The illegal manufacture, distribution and sale of prescription anabolic steroid drugs by body building clinics, gymnasiums, companies and individuals have become a major problem. The FDA has expressed great concern, and based on information obtained during investigations conducted in 1983-85, has requested that the Department of Justice conduct a nationwide investigation.

Black Market

Officials from the Justice Department, the Federal Bureau of Investigation and the FDA announced on May 22, 1986, a nationwide criminal investigation into the black market manufacture and distribution of anabolic steroids and other drugs used to enhance athletic performance.

The initial investigations resulted in the prosecution of seven individuals and one corporation with sentences ranging from a \$200,000 fine for one individual to a 4½ year jail term for another. The FDA also obtained control over an estimated \$2,000,000 worth of diverted, bogus, smuggled and counterfeit drugs destined for the black market.

Your Pharmacy?

Robert O. Voy, MD, the chief medical officer and director of sports medicine for the United States Olympic Committee says he is incensed that today between 30 and 40 percent of performance-enhancing drugs are obtained from licensed physicians. During the last week of May 1986, the FDA Office of Compliance in the Center for Drugs and Biologics sent a Drug Alert to the Chief Executives of companies engaged in the manufacture and/or wholesale distribution of various anabolic steroid prescription drugs. The alert reminded them of their legal responsibility for marketing only in legitimate channels of commerce.

The Alert recognized legitimate medical purposes for the use of steroids; "Certain steroids have many useful anabolic and androgenic effects and are commonly used to supplement the body's own supplies and to take advantage of their abilities to counter certain serious disease conditions." However, it emphatically warned that their use "is limited and many side effects of the drugs are known. These include adverse effects on the liver including liver cancer, stimulation of cancer of the prostate, effects on serum cholesterol and blood clotting, inhibition of testicular function in men and irreversible masculinization in women. Steroid drugs require close monitoring, a knowledge of dosage limitations, contraindications and precautions to avoid potentially lethal consequences."

Public Attitude

More disturbing than figures estimating that nearly 100 million dollars per year are being spent by athletes for anabolic steroids is the prevailing attitude among some athletes and a large portion of the public. Athletes involved with or familiar with the use of steroids to enhance performance have indicated that they consider two questions before use: "Do steroids improve performance?" and "Are they harmful to healthy people?" Some of those surveyed also indicated that if the answer to the first question is yes, then the answer to the second question is not important. Too often, steroids have become an integral part of training.

Pharmacist Responsibility

With any prescription drug, it is the pharmacist's responsibility to ensure that prescription drugs are only dispensed pursuant to a bonafide prescription from a licensed practitioner. Making such a determination is not easy and requires open communication with the practitioner and patient. Finally, because steroids can cause serious damage when used inappropriately, the pharmacist should educate patients and other practitioners about their proper use.

THEFT AND LOSS OF CONTROLLED SUBSTANCES — DEA FORM 106

In the unfortunate event that your pharmacy or the pharmacy at which you are employed experiences a theft or loss of controlled substances, the registrant of the pharmacy shall notify the Regional Office of the DEA and complete DEA Form 106.

Recently, the DEA has received requests under the provisions of the Freedom of Information Act to release all 106 Forms filed for a geographic area by registrant category. For example, requests have been received for Form 106 for all thefts and robberies from pharmacies in Canton, Ohio. The Form contains confidential information about the pharmacy's security system, drug inventory and personnel. To date, the DEA has not released this type of information, as it relates to individual episodes.

DEA intends to continue to defend against the release of the 106 Forms and would appreciate your comments as to the advisement of releasing such information. Please send comments to Carmen Catizone at: NABP, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068.

OCTOBER IS "TALK ABOUT PRESCRIPTIONS" MONTH

The practice of pharmacy can no longer be defined as the simple dispensing of a drug product. It has evolved, both professionally and legally, into so much more and has adjusted to the increasing complexity of our modern health care system by expanding the patient oriented services a pharmacist is called upon to provide. At the heart of these expanded services is patient counseling, which should be encouraged at all levels.

Compliance News

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



October will mark the National Council on Patient Information and Education's second annual "Talk About Prescriptions" month. The council's objective in sponsoring this national event, whose theme is *Medicine: Before you take it, talk about it*, is to improve communications between patients and their health care providers. This year's campaign will focus on prescription drug information for older consumers; prescription drug information in chronic disease management; informing consumers on prescription drug use; compliance; organizing drug information and education in your community; and counseling on food/drug and drug/drug interactions.

NCPIE is preparing a "Planning Newsletter" and Poster Insert for distribution to its member organizations and to all interested parties. Pharmacists interested in participating in the program should write for more information to NCPIE, *Talk About Prescriptions Month*, 1625 "I" Street N.W., Suite 1010, Washington, DC 20006, or call (202) 466-7611.

In conjunction with "Talk About Prescriptions" month NCPIE is beginning a media based campaign to improve prescription drug use by older consumers. More materials for the health provider will be available at a later date.

DISCONTINUANCE OR TRANSFER OF BUSINESS

The National Association of Boards of Pharmacy (NABP) has received a number of inquiries regarding the discontinuance or transfer of business. A DEA registrant who is discontinuing business or discontinuing controlled substances business, shall return the certificate of registration and any unexecuted order forms to the Registration Branch, Drug Enforcement Administration, Department of Justice, P.O. Box 28083, Washington, DC 20005.

If a registrant discontinues controlled substances business and transfers such business activity to another person, the certificate of registration and any unexecuted order forms are also required to be returned. It is recommended unused order forms be marked "VOID" by the registrant prior to being sent to DEA. The new owner requires a new registration.

Any controlled substances in the registrant's possession may be disposed of in accordance with instructions under the section: Drug Destructions.

A registrant discontinuing controlled substances business altogether, or transferring it to another person, shall submit in person, or by registered mail, the following information to the nearest DEA office at least 14 days before the date of the proposed transfer: 1) The name, address, registration number of the pharmacy discontinuing business; 2) The name, address, registration number of the person acquiring the pharmacy; 3) Whether the business activities will be continued at the location registered by the person discontinuing business or moved to another location. If the latter, the address of the new location shall be stated; and 4) The

date on which the transfer of controlled substances will occur.

On the day of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken. This inventory shall serve as the final inventory of the registrant transferor and the initial inventory for the registrant transferee, and a copy of the inventory shall be included in the records of each person. It is not necessary to file a copy of the inventory with the DEA. Transfers of any substances listed in Schedule II shall require the use of order forms. The order forms of the transferee are to be used for the transfer.

On the date of transfer of the controlled substances, all records required to be kept by the registrant transferor, with reference to the controlled substances being transferred, shall be transferred to the registrant transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

PHARMACEUTICAL ALTERNATIVES NOT PHARMACEUTICAL EQUIVALENTS

The Director of the Kentucky Board of Pharmacy, Richard L. Ross, recently asked the FDA for clarification on the question, "are capsules and tablets considered different dosage forms and, thus, not substitutable one for the other?" Jon R. May, Ph.D., R.Ph., Assistant to the Director, State Services Branch, Division of Federal-State Relations, Office of Regional Operations, provided the following answer:

In the introduction to the 7th Edition (1987) of "Approved Drug Products with Therapeutic Equivalence Evaluations," the Agency defines several key terms: 1) Pharmaceutical Equivalents — Drug products are considered to be pharmaceutical equivalents if they contain the same active ingredients and are identical in strength or concentration, *dosage form*, and route of administration. They must be identical in strength, quality, purity, and identity, but may differ in color, flavor, shape, preservative, expiration time, and within limits, labeling; 2) Different dosage forms (e.g., capsules vs. tablets) and strengths within a product line by a single manufacturer are considered to be Pharmaceutical Alternatives; and 3) Therapeutic Equivalents — Drug products are considered to be therapeutic equivalents *when they are pharmaceutical equivalents that can be expected to have the same therapeutic effect* when administered to patients under the conditions specified in the labeling.

Only therapeutically equivalent products, as defined above, are considered interchangeable, and thus substitutable, by FDA. Since capsules and tablets are different dosage forms, they are pharmaceutical alternatives, not pharmaceutical equivalents, and are thus, not therapeutic equivalents. Therefore, FDA recommends that in filling prescriptions, capsules should not be substituted for tablets, and vice versa, unless the prescribing physician authorizes the change.

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in Atlanta, Georgia from December 6th-10th, 1987, and the American Pharmaceutical Association meets in Atlanta, Georgia on March 12th-16th, 1988.

Item 544 — Comments On Product Selection

While the Board of Pharmacy has generally followed a liberal interpretation of the Product Selection Law, there are some portions which apparently need to be highlighted for pharmacists. State law provides that, in order to be eligible for product selection, all oral solid dosage forms (tablets and capsules) must have an identifying mark or logo. Clearly stated this means that you can only use generic drugs in product selection which have an identifying mark or logo. Plain tablets or capsules are not eligible for use. In addition, the manufacturer must have a return goods policy. The Board has not ruled on what is an acceptable policy but is it obvious that a policy of not accepting returned goods would not qualify a company as being an acceptable provider.

Another issue in product selection is that of dosage form. The Board has recommended caution in this area, see item 376. This issue is currently presented in prescriptions for potassium when a physician prescribes for a micro-encapsulated tablet. It is the editor's opinion that a prescription for a micro-encapsulated potassium product must be filled with a micro-encapsulated potassium product and not a similar product which is not the same dosage form.

Item 545 — Pharmacist's Name On Label, Initials Are Not Enough

North Carolina General Statute 106-134.1(b) requires that the name of the pharmacist who fills the prescription must be on the prescription label. The Board has held the consistent opinion that initials are insufficient. Your editor believes that the pharmacist's first initial and last name would satisfy the statutory requirement but initials only or the absence of any indication would clearly violate state law.

Item 546 — Continuing Education Calendar

One complaint has been received by the Board regarding the continuing education calendar distributed with this Newsletter. This material is prepared by personnel at the University of North Carolina School of Pharmacy or Duke University as noted on each list. It is compiled far ahead of the actual program times and it may be necessary for a variety of reasons to cancel or move some programs. You should confirm each program prior to its date and it is always a good practice to pre-register for such events.

Item 547 — Pharmacy Change Of Address, Name Change, Etc.

State law requires that the Board be notified of all changes of pharmacy name or address or the closing of a pharmacy. Please notify the Board in writing with the name of the pharmacy, its address, DEA number and the appropriate change. Failure to do this can cause problems with pharmaceutical suppliers who confirm the existence of permits with the Board and the Drug Enforcement Administration.

Item 548 — New Supplement Available

The Board has printed a new supplement to the green Pharmacy Law Book and it is available from the Board office. Please send a self-addressed envelope with your request. The answer to Item 542, Quarterly Query is 1.

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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