

North Carolina Board of Pharmacy

). Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 579 — Disciplinary Actions

May: *William Andrew Merrill*, Morganton. Dispensing prescription drugs without valid prescriptions and failure to keep and maintain adequate records of dispensation of prescription drugs. License suspended for remaining period of court imposed probation, stayed for the period of said probation with conditions, one being an active 30 day suspension of license to practice pharmacy.

June: *Jimpsey Duward Fowler*, Jonesville. Unlawful refilling of a PRN prescription, attempted medical assistance provider fraud unlawful dispensing of a controlled substance. License revoked.

ed for ten years with active 120 days suspension and other conditions.

Larry James Toth, Morrisville. Request for license reinstatement. Granted effective October 18, 1988 with conditions.

Item 580 — Board Member Election

The Spring election of the Board for a position to begin in 1989 created one clear winner in May which was Jack Watts, and Mr. Harold Day prevailed in the runoff election held this Summer. The ballots were counted in the runoff election on Monday, August 22 at the Institute of Pharmacy with Mr. Day receiving 918 votes and Mr. Burleson receiving 848 votes. The Board of Pharmacy elections declared Mr. Day the winner on Tuesday, August 23.

Mr. Watts is a native of Tabor City, an alumnus of Wake Forest College (when it was in Wake Forest) and is a graduate of the University of South Carolina School of Pharmacy. He is well known in pharmacy circles in this state having served as a medical services representative for Eli Lilly & Company for many years and as President of the North Carolina Pharmaceutical Association. Jack is also a member of the Board of Trustees of Campbell University. The Board welcomes Jack, who will serve a term to begin the Spring of 1989.

Item 581 — 10,000 And 600

One milestone has recently passed with the Board and another about to occur this month. In July the Board issued license mber 10,000 to Michele Lyn Arling who is a graduate of the University of Illinois at Chicago College of Pharmacy. Michele was born in Joilet, Illinois and attended Northern Illinois University prior to her entering the College of Pharmacy in Chicago. She reciprocated to North Carolina in order to attend graduate school

at the University of North Carolina at Chapel Hill where she is a Ph.D. candidate in pharmacology. Her goal at the conclusion of her university studies is the pharmaceutical industry, possibly with a location in the Research Triangle Park. In her spare time, which is precious for a graduate student, she enjoys team sports and traveling.

On October 18 the Board of Pharmacy will hold its 600th meeting since its formation in 1881. While meetings were sporadic at the beginning, sometimes only once or twice during each year, the Board has moved to the point where we have 11 meetings to conduct business each year plus the meetings in connection with licensure examinations. President Lloyd said, in commenting on this event, that "I am especially pleased that the Board reached this milestone while I am President. This is just one of the many benchmarks which will be reached by the Board as it moves toward the 21st Century." Meetings of the Board are open to the public and usually are held on the third Tuesday of each month at the Board offices in Willow Creek Shopping Center in Carrboro:

Item 582 — Quarterly Query

A prescription for Winstrol,[®] #100 which is marked refill PRN may be refilled: 1. As needed. 2. Within dosage for one year. 3. Within dosage for six months. 4. May not be refilled.

Item 583 — Problems With Syrup Of Ipecac

You probably by now have heard of the recall of Syrup of Ipecac which occurred this Spring. If you haven't, please check your shelves for the Humco Brand of Syrup of Ipecac to be sure that it does not contain eucalyptus oil.

The Board has also received several separate complaints recently about the sale of Syrup of Ipecac in pharmacies. This is available over the counter and many pharmacies exercise little or no scrutiny over who purchases this product. On two occasions recently complaints have arrived in the Board office about the use of Syrup of Ipecac by people afflicted with anorexia nervosa. The purchasers, typically young females, acquire large amounts of the product, sometimes three dozen of the one ounce bottles at one time. The product is then used to induce vomiting which prevents the absorption of food and weight gain in the mistaken belief that the person is overweight. The complaints received in the Board

continued on page 4



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy C... and can only be ascertained by exami...

INSTITUTE FOR TEACHERS OF PHARMACY LAW

The following information was presented at the recent 1988 *Institute for Teachers of Pharmacy Law*, co-sponsored by the NABP Foundation and the American Association of Colleges of Pharmacy, and funded through a grant from Smith Kline & French Laboratories. For a copy of the *Proceedings* from the Institute, contact the NABP Foundation office, (312) 698-6227.

THE PRESCRIPTION DRUG MARKETING ACT OF 1987

As many of you are aware, after a series of hearings on the problem of prescription drug diversion, Representative John D. Dingell introduced the Prescription Drug Marketing Act of 1987. The Bill was signed into law on April 22, 1988. It amends the Food, Drug and Cosmetic Act by restricting or prohibiting certain distribution practices which resulted in adulterated, outdated and counterfeit medication reaching American consumers. The following is a brief summary of the major provisions of The Prescription Drug Marketing Act of 1987:

- Prohibits the reimportation of exported U.S. produced pharmaceuticals except by the original manufacturer.
- Prohibits the sale, purchase or trade or the offer to sell, purchase or trade any drug sample or coupon redeemable for a drug product. Prohibits the sale, purchase or trade or offer to sell, purchase or trade any drug:
 - which was purchased by a public or private hospital or other health care entity or
 - which was donated or supplied at a reduced price to a charitable organization.
- Establishes controls on wholesale distribution:
 - sales information requirements for wholesalers who are not authorized distributors of record for such drugs.
 - requires licensure by the State.
 - requires the Secretary of HHS to issue guidelines establishing minimum standards, terms and conditions for licensure including requirements for storage and handling of drugs and maintenance of records of drug distribution.
- Provides for strict controls on prescription drug sampling by the representative and by mail:
 - only practitioners licensed to prescribe such drugs may be sampled
 - requires written request and written receipt
 - requires establishment of strict accountability of samples delivered by representatives
 - requires annual inventory and balancing of representatives' sample inventories
 - requires written receipt of samples delivered by mail or common carrier and a system to detect patterns of non-return

— requires reporting of significant losses or any theft of drug samples to the federal authorities.

- Establishes penalties for violations.

For further information on the effects of the Act on the practicing pharmacist, please contact your local board of pharmacy.

RECENT CHANGES IN DEA REGULATIONS

Practitioner Registration — 21 CFR 1301.31

The DEA registration issued to a retail pharmacy, hospital, practitioner or teaching institution is valid for a period of three years. That registration is assigned to one of 12 groups, based on the name of the registration, which correspond to the 12 months of the year. The expiration date of that group will be the last day of the month designated for that group. Renewal applications will be sent to the registrant approximately 45 days prior to the expiration of that registration.

Physician Dispensing — 21 CFR 1304.03

A DEA registered practitioner is required to keep records of all controlled substances in Schedules II-V which are dispensed, other than by prescribing or administering in the usual course of professional practice. If a practitioner regularly engages in the dispensing and administering of controlled substances and charges his patients either separately or together with charges for professional services, then records of the dispensing and administering must be kept.

Public Interest Revocations — 21 CFR 1301.45

The public interest revocation authority (enacted in 1984) provides DEA with the additional grounds to revoke, suspend or deny a DEA registration because that registration is inconsistent with the public interest. This authority is used in cases in which the state cannot act, cases in which other prosecutorial or administrative avenues have been unsuccessful and if there is a history of violations.

Corresponding Liability — 21 CFR 1306.04

The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills the order.

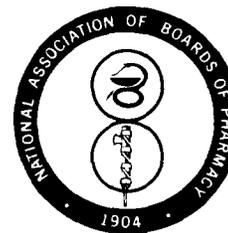
Proposals have been made to change the sections in the Code of Federal Regulations that pertain to the two following areas:

Refilling of controlled substance prescriptions and Transfer between pharmacies of prescription information for Schedule III and IV substances for refill purposes. 21 CFR 1306.22, 1306.26.

Recordkeeping procedures for Schedule II substances for patients in Long-Term Care Facilities and certain home health care situations. 21 CFR 1304 and 1306.

Compliance News

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



TIPS ON COUNTERFEIT DRUG DETECTION FOR THE PHARMACIST

In an effort to make pharmacists more aware of the types of deviations that the Food and Drug Administration has encountered in counterfeit drug investigations, and at the request of the National Association of Boards of Pharmacy, FDA has provided the following information which may help in identifying such counterfeit drugs. Pharmacists must be constantly alert to the variations in drug products, for it is often a pharmacist who first reports such variations, thereby initiating the action necessary to remove the counterfeit from the marketplace.

(1) Label Examination

- Major manufacturers maintain rigid specifications for color, format, print, etc., in the labeling of their products. Variation in the color or shade of ink used in the counterfeit label is common. Labels may occasionally fade, but specifications often include fade-resistant inks and exclusive individualized colors which may be difficult for counterfeiters to reproduce.

Minor deviations in format or print may be more difficult to observe when compared with an authentic article. Should these be found in labeling with the same revision date as an authentic, then this may be of enhanced significance when comparing the two.

Manufacturers may also use specific marks on labels for accountability purposes. The lack of such marks, notches, or perforations, when compared to the authentic product, should arouse suspicion.

- Lot numbers and expiration dates may vary in presentation in the counterfeit article. Variations may include the substitution of hyphens and comparable marks, indicating a break in series. The number of digits or alpha-numeric series in the lot number may vary. The presentation of the expiration date (abbreviated, unabbreviated, etc.) and its location with regard to the lot number sometimes varies with counterfeits. Type size and print should be compared.

(2) Container/Closure System

- The container/closure system is occasionally a tip-off when compared with an authentic. Examination should include the overseal, the plug, the cap liner, drying agent (if any), and container character. Such examination should include color, material, fabrication/assembly, and markings among characteristics for comparison to the authentic product.

(3) Dosage Unit

- Counterfeits have been found to vary in shape, color, uniform markings, friability, and odor. Duplication of composition and dosage characteristics is rarely achieved. Differences may become even more apparent as the product ages.

(4) Secondary Packaging

- While often not available for pharmacist examination, deviations

are commonly spotted in secondary packaging. These include carton labeling, coding, and overwraps as well as the shipping container.

(5) Customer Complaints

- The customer who questions or complains of some "change" in a drug for which they have long-term experience should stimulate further inquiry. While these perceived differences often have other explanations, information leading to the detection of counterfeit drugs has occurred as a result of complaints and this may be a first clue to a potential problem.

(6) Significant Discount from Normal Price

- Diverted drugs, including counterfeits, usually cannot compete in the market unless they are (at one or more points in the distribution chain) offered at substantially reduced cost. Such offerings may be made commonly "off-the-street" sources rather than an authorized or otherwise established distributor. However, this is not universal. Any unusual conditions involving the offering for sale should be considered with suspicion.

(7) Contact the Authorities

- Ultimate confirmation of counterfeiting and the ability to act on a broad scale is dependent on contact with the authorities. Your report of suspect counterfeit drugs will be most helpful to State regulators and the Food and Drug Administration. The circumstances and records of sale may prove instrumental in ultimately tracing the drug to its source. A significant contribution to the integrity of this nation's drug supply can be made.

1988-89 SURVEY AVAILABLE

NABP's 1988-89 Survey of Pharmacy Law will be available from the NABP office in late September. The Survey contains current organizational, licensing, internship and drug law information from the 50 United States, Washington, D.C., and Puerto Rico. Census information, including

- total number of licensed pharmacists by state,
- total number of licensed pharmacies,
- number of licenses suspended, revoked, and reinstated, number of licensed hospital, community and chain pharmacies, is also listed.

New to this year's Survey is detailed information on prescribing authority in the various states.

Copies of the Survey of Pharmacy Law are provided free of charge to all last year pharmacy students by A. H. Robins. In addition, the publication may be purchased for \$20 per copy through the NABP Publications Desk, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068. Please send a check for \$20 with your order.

continued from page 1

office were from a mother, a psychiatric hospital and included an example of a young female going from store to store collecting Syrup of Ipecac ostensibly to assemble "babysitter kits". All that was really occurring was the collection of Syrup of Ipecac for her own use.

Pharmacists may wish to voluntarily place this product behind the counter for use only on request and in single package mounts.

Item 584 — PLAN

Glaxo and the American Council on Pharmaceutical Education have instituted a new program entitled Pharmacists Learning Assistance Network. This provides for a toll-free number accessible from 9 a.m. to 4 p.m. Central time to provide access to over 2,400 continuing pharmaceutical education activities. The number is 1-800-533-3606 and the entire program is underwritten by Glaxo. Pharmacists may wish to make use of this information in fulfilling their ten hours of continuing education required for license renewal in North Carolina.

Item 585 — It's Election Time Again

Every two or four years the time for state and national elections rolls around in the fall. This is a good time for pharmacists to talk to their legislators on matters they believe to be significant. For example, at the local level it is important to get the opinion of the individuals running for district attorney as to their position on forged prescriptions. Do they think this offense is serious enough to prosecute? Pharmacists constantly express their opinions about a number of other issues and any of these would be a fair question for a state legislator or other person running for a public office. The fall, prior to the election, is the time to make your inquiries.

Item 586 — Anabolic Steroids

The short session of the General Assembly adopted a change in the North Carolina Controlled Substances Act to add anabolic steroids to Schedule III. This includes methandrostenolone, stanozolol, ethylestrenol, nandrolone phenpropionate, nandrolone deconoate, testosterone propionate and chorionic gonadotropin. Pharmacists should be aware of this change in statute and guide their conduct accordingly.

Item 587 — Prescription Drugs And Physical Therapists

The members of the Board have discussed the issue of the use of prescription drugs by physical therapists during several recent meetings. At the June, 1988 meeting the Board resolved this issue by adopting a position. It is the position of the Board that pharmacists can provide prescription drug products to a physical therapist for use by that therapist in the treatment of a patient providing that a physician has ordered the drug.

This position adopted by the Board was in response to a specific request from a pharmacist in Gastonia. The answer to Item 582 is number 3. See Item 586.

Item 588 — Attention Directors Of Hospital Pharmacies-License Renewal And JCAHO Visits

Every year in January and February the Board gets regular telephone calls from hospital pharmacists concerned about an impending visit by a JCAHO survey team. The question which arises is "Is the pharmacy permit renewed and are all pharmacists licensees renewed?" While North Carolina state law does allow a 60 day grace period to renew your license this has proven to be a problem in some hospitals if the JCAHO visit occurs in January or February. For some reason some JCAHO personnel either do not understand or do not want to understand that a license is still in good standing during that period.

In order to avoid problems in this area it is best if the director of pharmacy makes certain that the permit to operate the pharmacy is renewed by January 1 of 1989 and all pharmacists have their 1989 renewals in hand as of the first of the year. It can save a great deal of anguish in January and February.

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
Carmen A. Catizone, M.S., R.Ph.—National News Editor &
Executive Editor
Nancy K. Loeb, M.E.E.—Editor