



# North Carolina Board of Pharmacy

P.O. Box H, Chapel Hill—Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 417—INVENTORY OF CS

Federal regulations require that DEA registrants take an inventory of all controlled substances every two years on May 1st. For most registrants this occurs in odd numbered years. This is the responsibility of the registrant and pharmacist-managers should be mindful of their responsibility in this regard.

## ITEM 418—BOARD MEMBERS ELECTION

Enclosed is a ballot and envelope for pharmacists residing in North Carolina to vote in the annual Board Member Election. Ballots will be counted at the Institute of Pharmacy on May 9, 1983 at 5:00 p.m. in an Open Meeting. Eligible candidates must be from the Northeastern District of the State consisting of the following counties: Bertie, Camden, Chowan, Currituck, Dare, Durham, Edgecombe, Franklin, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Tyrrell, Vance, Wake, Warren, Washington, and Wilson.

## ITEM 419—DISCIPLINARY ACTIONS OF THE BOARD

**December:** A pharmacist at a pharmacy in Charlotte appeared for a hearing which revealed a substantial shortage of Talwin<sup>®</sup> and lesser amounts of Percodan<sup>®</sup> and Dilaudid<sup>®</sup>. Testimony indicated shipments of Talwin<sup>®</sup> and Tripeleminamine from Charlotte to Indianapolis, Indiana, which apparently came from this pharmacy. Other testimony revealed numerous refills of prescriptions for paregoric at another pharmacy where this pharmacist was employed. One witness subpoenaed was not able to appear because he was in the federal prison system and the hearing was continued to obtain the testimony of this witness.

A pharmacist who had pleaded guilty to charges of unlawful possession of controlled substances in Anson County Court appeared for a hearing. Testimony indicated many other items from the pharmacy where he had been employed were found at his residence. The Board issued an active suspension of 30 days, prohibited him from serving as a pharmacist-manager for 5 years and imposed other conditions.

**January:** A pharmacist from Kings Mountain appeared to respond to charges of unauthorized refilling of prescriptions and possible Veterans Administrative prescription fraud. Testimony and evidence was presented to establish numerous refillings of certain prescriptions, apparently without authorization. There was evidence of other violations of controlled substances regulations but the VA fraud

charge was disputed. The Board issued at least a 5-day suspension of the pharmacist's license with reinstatement conditioned upon his passing a jurisprudence examination.

A pharmacist currently serving a federal prison sentence for conspiracy to distribute Dilaudid<sup>®</sup> appeared for a hearing. After considering all relevant facts, the Board suspended the pharmacist's license for the duration of the prison sentence with his license reinstated only after passing certain board examinations.

A pharmacist now living in Sanford appeared for activity which had occurred in Oxford which produced a guilty plea to misdemeanor falsification of prescription records. Apparently non-prescription drugs were dispensed to pharmacy employees without prescriptions and were labeled as controlled substances. The Board issued a three-year probation.

**February:** A pharmacist from Greensboro appeared to respond to charges of diverting Placidyl<sup>®</sup> and Fastin<sup>®</sup> for personal consumption. After admitting certain matters the pharmacist was placed on probation for 5 years.

A pharmacist from Asheville appeared to respond to charges of unlawful possession of Phenaphen No. 3<sup>®</sup> and Lomotil<sup>®</sup>. The drugs were discovered in the glove compartment of his car after an incident with an undercover female police officer. Since the pharmacist had already effectively received a seven month suspension of his license, the Board decided that no further action was necessary.

A hearing was scheduled for a pharmacist in Cherryville on charges of allowing an unlicensed person to dispense prescriptions. The pharmacist failed to appear and the Board revoked his license and suspended the permit. The Board required the presence of a pharmacist before reinstatement of the permit.

## ITEM 420—BOARD INTERPRETATION OF PRODUCT SELECTION LAW

Since the enactment of the Product Selection Law effective January 1, 1980, pharmacists have had several questions regarding interpretation. The following text is the editor's compilation of the Board's interpretation of this statute. Product selection, or substitution, is voluntary and not mandatory for the pharmacist. Section 90-85.27 through 90-85.31 of the General Statutes should be reviewed in connection with this item.

The Statute plainly states that prescribers should indicate their instruction to the pharmacist by using a prescription blank with a

*Contd. on page 4*



# National Pharmacy

## TAMPER RESISTANT PACKAGING REQUIREMENT NOW IN EFFECT

The first phase of the tamper resistant packaging requirements developed by the Food and Drug Administration in response to the Tylenol tampering situation became effective February 7, 1983. As of that date, all manufacturers of over-the-counter (OTC) capsules, cosmetics, vaginal products, and contact lense products must be packaging their products in tamper resistant packaging. The FDA regulations do not specify any particular type of packaging that must be used by the manufacturers but allows manufacturers some flexibility in developing tamper resistant packaging for their products so long as that packaging complies with the tamper resistant regulations of FDA.

Pharmacists will be allowed to continue the retail sale of their current inventory that may still be on hand in non-tamper resistant packaging. As of February 7, however, all new purchases of capsule and liquid OTC products covered under the regulations must be in tamper resistant packaging. FDA's tamper resistant packaging requirements will expand to include tablet and suppository products on May 5 of 1983.

## U.S. CONGRESS TO CONSIDER ANTI-TAMPERING LEGISLATION

A bill which would make tampering with a consumer product a federal crime punishable by life imprisonment if the tampering results in either death or injury has been introduced recently by Senator Strom Thurmond (R-SC) and Senator Joseph Biden (D-DE). The legislation (S-216) is the same as that introduced in the final days of the last Congress by Senator Thurmond. Last year's bill, which was passed by the Senate but which died when the Congress adjourned also called for life imprisonment and included an amendment which provided for a penalty structure for those individuals who make malicious false statements relating to tampering. The new Thurmond/Biden bill, entitled "The Federal Anti-Tampering Act," would cover all foods, drugs, devices, cosmetics, and other items that may be produced or distributed for consumption by consumers, or which are intended for personal care use or household use. A similar bill (H.R. 778) has been introduced in the House of Representatives by Cardis Collins (D-IL) and has attracted close to twenty representatives who are interested in co-sponsoring this legislation.

## NO MICKEY MOUSE FOR THIS COURT

*By John F. Atkinson, NABP Counsel*

A pharmacy located in California filled 10,000 prescriptions during a 45-day period which prescriptions covered 748,000 dose units for four controlled substances commonly subject to abuse. Of these, 247 prescriptions were written by one individual who was later found to be an unlicensed practitioner. Prescriptions were written for patients with such names as "Henry Ford," "Fairlane Ford," "English Ford," "Glenn Ford," "Esther Williams," "Steve Allen," "Jerry Lewis," "Johnny Cash," "Terry Tune," "Van Johnson," "Pop Warner," "Sweet Tongue Hawkins," and "Pearl Harbor."

Antagonistic drugs were prescribed for the same person on the same day, and on certain days the same "patient" would have as many as three prescriptions filled.

Certain pharmacists employed at the store questioned the practice of dispensing these numerous prescriptions and called it to the attention of the pharmacist owner of the store who apparently did nothing to change the procedures being followed. The California Board of Pharmacy, upon learning of the dispensing practices, cited the pharmacist owner and three other employee pharmacists on charges of violating various sections of the California Health and Safety Code, the Business and Professions Code and of engaging in unprofessional conduct.

After hearing, the administrative hearing officer dismissed the charges against each of the pharmacists but the Board, exercising its discretion as provided under law, refused to accept his findings, made its own separate findings and revoked the license of the pharmacist owner, and her permit to operate the pharmacy. The Board also revoked the license of one of the additional pharmacists, cited and suspended the license of the other two. The Board decision was affirmed at the lower court level and the pharmacist appealed to the California Court of Appeals.

The pharmacists argued that the Board did not provide guidance in establishing those circumstances under which prescriptions, valid on their face, must be questioned by the dispensing pharmacist. They contended that their conduct under the circumstances of this case did not constitute conduct specifically deemed by the Board to be unprofessional.

In upholding the Board decision and the lower court, the Court of Appeals stated the following:

"The statutory scheme plainly calls upon pharmacists to use their common sense and professional judgment. When their suspicions are aroused as reasonable professional persons by either ambiguities in the prescriptions, the sheer volume of controlled substances prescribed by a single practitioner for a small number of persons or, as in this case, when the control inherent in the prescription process is blatantly mocked by its obvious abuse as a means to dispense inordinate and incredibly large amounts of drugs under the cover and protection of law, pharmacists are called upon to obey the law and refuse to dispense. To fail to do so is either gross incompetence, gross negligence or moral turpitude. (See Bus. & Prof. Code, 4380.5, defining misconduct as grounds for action by the Board.)

A profession is a vocation or occupation requiring special and advanced education and skill predominately of an intellectual nature. The practice of pharmacy, like the practice of medicine, is a profession. For this reason, society entrusts to persons in these professions the responsibility for control over a force which, when properly used, has great benefit for mankind, but when abused, is a force for evil and human destruction.

It follows that society cannot tolerate the presence of individuals within these professions who abdicate their professional responsibility and permit themselves to be used as a conduit by which these controlled substances reach the illicit market and become that force of evil to which we allude. More importantly, in this case, such prostitutes of their profession will not be heard to explain their dereliction by the juvenile-like complaint, "Nobody told

# Compliance News



me it was wrong! A true professional does not have to be told such things." Need I say more?

Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy of the State of California, App., 177 Cal Rptr. 807 (1981).

## INVENTORIES OF CS MUST BE TAKEN

For several years after the federal Controlled Substances Act became effective in 1971, DEA provided pharmacists with a booklet listing all available controlled substances that the pharmacist could use to take his biennial controlled substances inventory. The booklet not only made it easier for the pharmacist to take his inventory but it served as a reminder to him that the inventory must be taken. DEA has now discontinued sending the booklet to pharmacists. It is therefore appropriate to remind pharmacists that 1983 is the year in which the majority of pharmacists will be required to take their biennial inventory of controlled substances.

For those pharmacies who were in operation on May 1, 1971, the majority will be taking their biennial controlled substance inventory on May 1 of 1983.

For those pharmacies that opened for business for the first time since May 1, 1971, the controlled substances inventory will be taken on each two year anniversary of the opening.

As with many rules under which pharmacists operate the inventory requirement also has some exceptions. Pharmacists may take the required inventory either on May 1 of every odd numbered year (if they were open for business on May 1, 1971) or every two years from their date of first opening (if they first opened for business since 1971) or they may take the required inventory on their regular date for taking the physical inventory at the pharmacy or on any other fixed date so long as it is within six months of the May 1 date or their anniversary date. If a pharmacist chooses such an alternative date he must notify DEA of that date and must continue to take his inventory on that fixed date.

DEA does allow a pharmacist a four day leeway from his inventory date but again the pharmacist must notify DEA if he intends to make use of this four day leeway period.

A registrant may take his inventory either as of the opening of business or as of the close of business on the inventory date. The registrant must indicate on his inventory records whether the inventory is taken as of the opening or as of the close of business on the inventory date.

An inventory must be maintained in a written, typewritten or printed format. An inventory taken by the use of an oral recording device must be promptly transcribed.

When taking inventory an exact count must be taken of all Schedule II controlled substances. Schedule III, IV, and V controlled substances can be inventoried by taking an "eyeball estimate" of the number of dosage units on hand unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents is required.

Copies of the inventory need not be submitted to DEA but must be kept at the registered location in a readily retrievable fashion.

## FDA COMPLIANCE POLICY GUIDES—THE SALE OF R<sub>x</sub>-LEGEND VETERINARY DRUGS

The federal Food, Drug, and Cosmetic Act contains specific provisions in Section 503 which limit the dispensing of certain drugs intended for use by man to a prescription issued by a licensed practitioner. These provisions do not apply to drugs for animal use. Section 502(f)(1) of the Act requires that labeling of drugs, including veterinary drugs, bear adequate directions for use.

It is the interpreted view of Congress that a man has the right to treat his own animals with any product for which reasonably adequate directions for safe use can be supplied in labeling. Many animal drugs are available for sale to the layman bearing directions allowing the drugs to be used safely for the purposes for which they are intended. There are other animal drugs for which, because of their toxicity or other potential for harm, the method of their administration, or the inability of the layman to diagnose the conditions for their use, adequate directions for safe lay use cannot be prepared.

Regulations in 21 CFR require that veterinary drugs for which adequate directions for lay use cannot be prepared, and which therefore cannot be safely used except by or under the supervision of a veterinarian, must bear on their label this exact statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." Persons who distribute animal drugs are responsible under federal law for assuring that animal drugs bearing this "Caution" legend on their label are sold only to authorized recipients. Catalog sales should require evidence of proper licensing of the purchaser.

Occasionally, animal drugs may bear a label statement such as "sold only to licensed veterinarians." Such a statement has no basis in law, but is intended to reflect the sales policy of the manufacturer or distributor.

Prior to being sold or dispensed, animal drugs whose labels bear the legend: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" must remain in the possession of a person or firm regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of animal prescription drugs. They may be distributed only by persons or firms authorized by state or local laws to possess and dispense such drugs.

Sale (or dispensing, making shipment, or otherwise making available for use in animals) to the lay person of an animal drug whose label bears this caution legend may be only by or on the bonafide order of a duly licensed veterinarian. Such sale of a prescription legend drug must come about as a result of a proper doctor/client relationship, which cannot normally be established merely through letter or telephone communication between a veterinarian and a layman. Sale of an animal prescription legend drug to a lay person except on a prescription or on order of a licensed practitioner, results in the drug being misbranded within the meaning of 502(f)(1), since it fails to bear adequate directions for lay use. (Reprinted with authorization from the Arkansas State Board of Pharmacy.)

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**MOVED? LET YOUR PHARMACY BOARD KNOW WHERE!**

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two line form, the line of the left indicating that product selection is permitted and the one on the right directing the pharmacist to dispense as written. If the drug is prescribed by generic name then product selection can occur regardless of which line is signed. If the prescriber signs on the DAW line, the brand prescribed must be used in dispensing. A signature on the product selection permitted line allows the pharmacist to use a generic version of the drug but this is the decision of the pharmacist, not the customer or patient.

If the prescription is on a one line blank the pharmacist may use product selection unless the prescriber indicates DAW in his handwriting. In the case of oral (telephone) prescriptions it is the prescriber's duty to indicate DAW or otherwise. In the absence of such instruction it is the pharmacist's choice as to the drug used. Product selection must be tablet for tablet, capsule for capsule and the price must be less to the patient than it would have been had the brand name been dispensed.

Please see Item 376 in the October, 1981 Newsletter for the Board's opinion on product selection with timed released medication. Drugs used need to be therapeutically equivalent to that prescribed and this determination is the pharmacist's responsibility.

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### ITEM 421—NEW REGULATIONS

Notice was given of proposed new regulations in the October Newsletter and a public hearing was held on November 17, 1982. The Board adopted regulations at its January meeting and they will be available soon in published form. Specific new regulations which deserve the attention and study of all pharmacists are printed in the following paragraphs.

**1309—Indulgence in the Use of Drugs—** "Indulgence in the use of drugs" means the use of narcotic drugs or other drugs affecting the central nervous system or the use of intoxicating beverages to an extent as to deprive the user of reasonable self control or the ability to exercise such judgment as might reasonably be expected of an average prudent person.

**1310—Supervision—** "Supervision" means that the responsible pharmacist physically reviews the order and the dispensed product before such product is delivered to the patient or person acting on the patient's behalf.

**1312—Pharmacist Manager—** "Pharmacist Manager" means the person who accepts responsibility for the operation of a pharmacy in conformance with all statutes and regulations pertinent to the practice of pharmacy and distribution of drugs by signatures on the permit applications, its renewal or addenda thereto. A person cannot serve as pharmacist manager at more than one pharmacy at any one time except for limited service permits which may be considered on an individual basis.

Whenever a change of ownership or change of pharmacist manager occurs the successor pharmacist manager is responsible for an inventory of all controlled substances in the pharmacy within ten days. A written record of such inventory, signed and dated by the responsible pharmacist manager, shall be maintained in the pharmacy with other controlled substances records for three years.

**1801—Right to Refuse a Prescription—** A pharmacist has the right and responsibility to refuse to fill or refill a prescription if, in his judgement, it would be harmful to the recipient, is not in the recipient's best interests or if there is a question as to its validity.

**1802—Prescription Refills—** Authorization for prescription refills is presumed to be within the prescribed dosage or normal therapeutic use. Refilling prescriptions more frequently than the prescribed dosage would require, or refilling prescriptions in sig-

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nificant excess of normal therapeutic use may be considered as negligence under G.S. 90-85.38(9).

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### ITEM 422—PRODUCT CHANGE

The Board has learned that Winthrop Laboratories plan to change its formulation of Talwin<sup>®</sup> by adding Naloxone to one dosage forms and changing the product name to Talwin NX<sup>®</sup>. Until prescribers absorb this change, pharmacists will probably receive some prescriptions written for Talwin<sup>®</sup> and have only Talwin NX<sup>®</sup> in inventory. During this interim period it is the editor's opinion that Talwin NX<sup>®</sup> may be dispensed on such a prescription and pharmacists should personally inform the recipient of the formulation change and its possible effect. Personal communication is especially important when Talwin NX<sup>®</sup> is dispensed on a refill when Talwin<sup>®</sup> was dispensed on prior occasions. Pharmacists will probably need to remind some prescribers who write for this drug of the changes in formulation.

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### ITEM 423—SIGNS AVAILABLE

The Board of Pharmacy has produced two posters for display in pharmacies which are intended to convey certain messages to the public. One involves the return of prescription drugs to the pharmacy and the other explains why the recipient of a prescription must often wait for it to be refilled. The text of these two posters follows: "Please understand. . .Occasionally a pharmacist receives a request to return a prescription drug after it has left the pharmacy. Your pharmacist has the responsibility to maintain certain standards of purity and safety of all prescription drugs dispensed. In order to insure that those standards are maintained, the North Carolina Board of Pharmacy recommends that a pharmacist decline to accept any prescription drug for return once it has left the pharmacy." The other poster reads "Your Prescription—What's the Delay? You may not be aware that your pharmacist must follow a strict set of laws and regulations. These laws place specific limits on prescription refills which may require prior contact with your doctor. Your pharmacist may also need to clarify or confirm the contents of a prescription before its filling. If your pharmacist needs to follow such procedures this could delay the filling of your prescription. We trust that you will understand this is being done for your protection."

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### ITEM 424 — NOTIFY BOARD OF CHANGES

State law now requires pharmacists to notify the Board of any change of mailing address or change of place of employment within 30 days. Pharmacist managers must notify the Board of any change in pharmacist personnel within 30 days.

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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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