



# North Carolina Board of Pharmacy

P.O. Box 471, Chapel Hill, NC 27514

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 332—CORRECTION— DISPOSAL OF CONTROLLED SUBSTANCES

In the January issue of the Newsletter Item 316 outlined the procedure for disposing controlled substances. A misprint occurred regarding the proper address for DEA and the corrected item follows below. Pharmacists should consider destroying out-of-date or otherwise unusable controlled substances. Forms are available (DEA-41) for this purpose in the Board office or DEA, 925 West Market St., Room 111, Greensboro, NC 27401. The forms must be completed in triplicate and either mailed with the drugs to be destroyed to the DEA office, 230 Houston Street, N.E., Suite 200, Atlanta, Georgia 30303 or held until a Board Inspector can destroy the drugs during a regular inspection visit. Board Inspectors destroy drugs as a service to pharmacists, and, although important, must have priority below investigations, audits and inspections, so please be patient if prompt responses are not possible. Each form has space for 32 line items.

## ITEM 333—PUBLIC HEARING SCHEDULED

The Board has scheduled a public hearing to be held at 4:00 p.m. on Tuesday, November 18, 1980 in Board offices in Chapel Hill for the purpose of revising Board regulations regarding examination and reciprocity. The examination proposal would allow individuals who have passed the practical examination to take only the theoretical exam at a future date. Currently candidates must either pass both examinations at one administration or first pass the theoretical and then pass the practical. The proposal regarding reciprocity would delete the requirement that a place of practice be established before an individual can obtain a temporary license pursuant to reciprocity. The current regulation provides that such a place must be obtained before the temporary license can be issued.

## ITEM 334—DISCIPLINARY ACTIONS OF THE BOARD OF MEDICAL EXAMINERS

The Board of Medical Examiners has reported that licenses to practice medicine have been surrendered by William Ricks Hanna, M.D., Lumberton and Richard D. Hamer, M.D., Charlotte. The

license to practice medicine of Edward L. Jones, M.D., of Thomasville has been revoked. The Board also took action against the licenses of John P.U. McLeod, M.D., of Marshville and Walter G. Lewis, M.D., of Gibsonville, however, each of these have been appealed. Lawrence C. McHenry, Jr., M.D., of Winston-Salem has surrendered DEA privileges in all schedules and Gary Gyan H. Kej, M.D., of Roanoke Rapids is under a three year probation with one condition being that he cannot prescribe or dispense Schedule II drugs from his office.

## ITEM 335—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

**May:** A pharmacist appeared to respond to charges of dispensing controlled substances without a prescription and refilling prescriptions without authorization of the physician. Evidence was introduced indicating numerous refills for Valium, Darvocet and Tylenol with codeine. Substantial discrepancies existed between the prescription records, patient medication records and receipts of the patient. The pharmacist stated that the discrepancies were because the patient often requested receipts for insurance purposes sometime after the prescription was filled or refilled. There were 72 questionable prescriptions over a six month period. The Board issued a 90-day active suspension on the pharmacist's license with a five year probation.

A pharmacist who had been found guilty of obtaining drugs by fraud appeared with his attorney and explained that he was under a great deal of personal stress due to illness and other personal problems. The pharmacist explained at length his conduct surrounding the use of drugs and it was the decision of the Board to place the pharmacist on five years probation.

**June:** A pharmacist employee appeared before the Board to respond to allegations of the illicit use of Hycodan<sup>®</sup> Syrup in a pharmacy. An audit by Board personnel indicated approximately 16 pints of Hycodan<sup>®</sup> had disappeared over a six-month period. Conflicting testimony was introduced by the Board and the pharmacist regarding the ultimate fate of the Hycodan<sup>®</sup> Syrup. After hearing all testimony, the members of the Board issued a suspension

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## DEA CENTRAL RECORDKEEPING REQUIREMENTS FINALIZED

Proposed amendments to the central recordkeeping requirements for controlled substances transactions reported in National Pharmacy Compliance News for the summer issue of your state board newsletter have been adopted in final form by the Drug Enforcement Administration. In response to a comment on the proposal, the 48-hour time period for delivery of records from the central location to the registered location, when requested by DEA, was changed to 2 working days to allow for holidays and weekends.

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## FDA LISTS GENERIC DRUGS MARKETED WITHOUT APPROVED APPLICATIONS

A list of widely prescribed generic drug products that lack FDA approval has been published by the regulatory agency. The first list was valid as of June 16, 1980. FDA announced in late August that it had prepared an update of the list and sent copies to all state boards of pharmacy and state drug officials.

Pharmacists may determine the status of any drug by calling their state board of pharmacy office or the FDA at (301) 443-1016. If the drug is marketed by a distributor and the manufacturer's identity does not appear on the label, the pharmacist should first find out who is the manufacturer of the drug in question by contacting the distributor.

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## PHARMACIST'S ROLE IN SOCIETY'S OVERUSE OF MEDICINES

In an interview with Wayne Pines, FDA associate commissioner for public affairs, FDA Commissioner Dr. Jere E. Goyan elaborated on his views on American society being overmedicated.

The interview appeared in the February 1980 issue of **FDA Consumer**, and excerpts from it on the responsibility of the pharmacist in educating the public on overuse of medication follow:

*Q. — What about pharmacists? As a pharmacist, what do you see as the role of this profession in cutting down on drug use?*

*A.—* The pharmacist has an important educational role to play. As a person with considerable knowledge about drugs and with direct access to the people taking them, I would hope that the pharmacist would spend more time counseling patients about proper drug use. This applies not only in the prescription drug area but also in the over-the-counter drug area. Pharmacists need to encourage consumers to come to them for assistance in selecting nonprescription drugs, and if the pharmacist thinks the consumer can get along fine without a drug, he ought to say so.

That may sound like turning down business, but pharmacists know that such advice builds respect and credibility—and brings back the customer when he or she really needs medicine.

*Q.— Can you summarize what you think the public can do about this problem?*

*A.—* Let me try to do it in a few sentences: People shouldn't insist on a prescription every time they visit a doctor. They should be conservative and cautious about anything they take into their bodies, and insist on knowing what the drug is for and what adverse effects it can have. People shouldn't take someone else's medicine or treat drugs casually. People should teach their children respect for medicines.

Those are some of the things I would tell patients to do. And that applies not only to prescription drugs but to nonprescription drugs as well. Aspirin can be as dangerous as any prescription medicine, if misused.

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## FEDERAL COURT DECISIONS SUPPORT FDA'S AUTHORITY FOR PRE-MARKET DRUG APPROVAL

Two recent federal court decisions should help FDA retain its ability to review generic and "me-too" drugs to assure they are safe and effective, and bioequivalent to the drugs for which they are designed as substitutes.

In November 1978, a pharmaceutical manufacturer sued FDA in federal district court seeking to enjoin the agency from instituting any regulatory action against it with respect to its generic drug, chlorpropamide. The company said the drug should not be considered a "new drug" and therefore was not subject to the new drug provisions of the FD&C Act. The manufacturer also sought a injunction restraining FDA from instituting any seizure action against its unapproved drugs on the market under the act.

The District Court for the Southern District of New York ruled in August 1979 that chlorpropamide was therapeutically equivalent to the pioneer product and therefore did not require FDA pre-market approval. In reaching his decision, the judge reviewed a bio-availability study conducted by the manufacturer, which had been found deficient by FDA, and found it sufficient to establish the therapeutic equivalence of the product.

FDA appealed the ruling and on July 29, 1980 the U.S. Second Circuit Court of Appeals reversed the decision, finding that the product did not meet the statutory test for escaping pre-market approval. The court stated "The mere fact that a pharmaceutical manufacturer purports to market a "me-too" product does not exclude the drug from the definition of "new drug". . . . Later developed "me-too" products. . . are required to apply for FDA approval for the undisputed reason that a difference in inactive ingredients, as exists here, when combined with the active ingredient, can affect the safety and effectiveness of the drug product."

"Where a dispute exists as to whether a drug product is 'generally recognized' by the experts to be safe and effective, the function of the district court is limited to determining that issue, not whether

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the product, including one claimed to be a 'me-too' drug, is in fact safe and effective. The latter issue is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue."

In another case involving related issues, a different manufacturer, on July 21, 1980, consented to the entry of a permanent injunction that bars the firm from marketing fifteen named unapproved new drug products. The company further consented to ship no other products without pre-market approval, unless FDA agreed that it was not needed, or, if FDA did not agree, the court resolved the question of the drug's status in favor of the firm.

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## DEA/PRACTITIONERS WORKING COMMITTEE ISSUES GUIDELINES FOR PRESCRIBERS

The Drug Enforcement Administration has jointly issued with its Practitioners Working Committee, "Guidelines for Prescribers of Controlled Substances." The guidelines are suggested principles for good prescribing practices. Their purpose is to provide a responsible professional standard which can be followed by prescribers of controlled substances.

There are six general guidelines for prescribing and eight specific guidelines for prescription orders in the statement. The guidelines support the use of controlled substances for therapeutic purposes, while at the same time caution on awareness of the potential for abuse.

Martin Golden, National Association of Boards of Pharmacy Executive Committee member, and its representative on the DEA/Pharmacy Working Committee, suggested the Guidelines for Prescribers be published in the national news section of the Bureau of Voluntary Compliance state board newsletter project.

The following comprises only the guidelines and does not include the preface and statement of purpose.

### General Guidelines

- Controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well being of patients.

- Prescribing controlled substances for legitimate medical uses requires special caution because of their potential for abuse and dependence.

- Exercise good judgment in administering and prescribing controlled substances so that diversion to illicit use is avoided and the development of drug dependence is minimized or prevented.

- Guard against contributing to drug abuse through injudicious prescription writing practices, or by acquiescence to unwarranted demands of some patients.

- Each prescriber is asked to examine his/her individual prescribing practices to ensure that all prescription orders for controlled substances are written with caution.

- Make specific effort to ensure that multiple prescription orders are not being obtained by the patient from different prescribers.

### Guidelines—Prescription Orders

The prescriber is granted through legal authority the right to prescribe medications that are necessary for the proper treatment of his/her patients. Prescribing is governed by laws and regulations which set minimum standards and requirements. These guidelines, tempered with good moral and ethical considerations, give guidance to going beyond the minimum requirements.

- The prescription order must be signed by the prescriber when it is written. The prescriber's name, address, and DEA registration number and full name and address of the patient must be given when prescribing controlled substances.

- The written prescription order should be precise and distinctly legible to enhance exact and effective communications between prescriber and dispenser.

- The prescription order should indicate whether or not it may be renewed and, if so, the number of times or the duration such renewal is authorized.

- Prescription orders for drugs in Schedules III, IV, and V may be issued either orally or in writing and may be renewed if so authorized on the prescription order. However, the prescription order may only be renewed up to five times within six months after the date of issue.

- A written prescription order is required for drugs in Schedule II. The renewing of Schedule II prescription orders is prohibited. Only in an emergency situation may oral orders for Schedule II drugs be accepted by a dispenser. Such oral orders must be followed up by a written order within 72 hours.

- Controlled substances which are prescribed without indication for renewal cannot be renewed without authorization by the prescriber. Prescribe no greater quantity of a controlled substance than is needed until the next check-up.

- Try to make prescription orders alteration-proof.

- When prescribing a controlled substance, write out the actual amount in addition to giving an Arabic number or Roman numeral in order to discourage alterations in written prescription orders.

- Prescribers are encouraged to consider placing a number of check-off boxes on their prescription blanks which show amounts within which the prescribed amount falls, i.e., 1-25, 26-50, 51-100, over 100. Use a separate prescription blank for each controlled substance prescribed.

- The use of prescription blanks which are preprinted with the name of a proprietary preparation should be discouraged.

- When institutional prescription blanks are used, the prescriber should print his/her name, address, and DEA registration number on such blanks.

- Institutions should discourage the use of institutional prescription blanks for prescribing controlled substances.

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of the pharmacist's license to practice for sixty days with a stay order for two years with the net result being a two year probationary period.

**July:** A pharmacist who has been pursuing reciprocity on a one year temporary license appeared to answer charges that he had consumed injectable Demerol while working in a pharmacy. Evidence was offered to establish that the pharmacist had collapsed from the use of injectable Demerol while working a shift in a community pharmacy and the pharmacist admitted this had occurred on two separate dates, approximately two weeks apart. The pharmacist asserted that these were isolated instances and he was not guilty of habitual use. He also stated that the problems which led to the attempted overdoses had been resolved and assured the Board it would not happen again. It was the decision of the Board to issue an active suspension of the pharmacist's license for thirty days and continue the one year probationary license an additional year.

A pharmacist-manager appeared before the Board to respond to charges of dispensing a prescription legend drug, Tussionex<sup>®</sup> without a prescription and failure to keep accurate records of the dispensing of controlled substances. Testimony and evidence was introduced, including a tape recording of a telephone conversation, which tended to establish that Tussionex<sup>®</sup> had been dispensed pursuant to an order which the pharmacist knew was invalid from the outset. There were also numerous instances of duplicate prescription numbers on prescriptions for different individuals from different physicians with wide variations in date of filling and one occasion of a triplicate number on three different prescriptions for different individuals from different physicians. It was the decision of the Board to suspend the pharmacist's license for ninety days followed by a probation of five years.

A pharmacist appeared before the Board to respond to charges of allowing or permitting an unlicensed individual to dispense prescription drugs, including controlled substances. Testimony and evidence was introduced that established the dispensing of prescription legend drugs and controlled substances by a person who is not licensed as a pharmacist on three occasions over eight days. After hearing all the testimony and receiving evidence, and considering a plea offered by the pharmacist at the August meeting, it was the decision of the Board to suspend the permit to operate the pharmacy issued to the pharmacist for fifteen days to begin not later than January 15, 1981 and to issue an active suspension of the pharmacist's license to practice pharmacy for thirty days beginning on January 15, 1981.

**August:** A pharmacist appeared before the Board to respond to allegations of Medicaid fraud and a certified copy of a plea of guilty to this offense was presented to the Board. The pharmacist explained that he had made restitution of approximately \$16,000 to the State and had served an active sixty day jail sentence for this crime. The pharmacist pleaded for leniency from the Board and it was their decision to suspend his license to practice pharmacy for a period of sixty days with a stay order for the same period as court's probation.

A pharmacist owner appeared in response to charges of dispensing a controlled substance without a prescription. The pharmacist claimed he had received a copy of the prescription from another pharmacy although the original prescription for the controlled substance was over one year old. The pharmacist admitted not

having contacted the prescriber and filled the prescription with the patient eventually being admitted to an emergency room for an overdose. It was the decision of the Board to suspend his license to practice pharmacy for ninety days with a two year stay order on this suspension with the net result being a two year probationary period.

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### ITEM 336—NEW TACK IN FORGERY

The Board Inspectors have reported several instances of prescriptions being presented, and occasionally filled, written on blanks from a medical center for "Hydromorphone" and specifying a patient's address as "in transit." Apparently forgers have had some success with this tactic and pharmacists should be alert for prescriptions and question validity where appropriate. Since individuals who have a bonafide need for Dilaudid have usually been ill for a long period, it would only seem reasonable to question prescriptions for the drug presented by someone you have not seen before.

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**ITEM 337—** Each pharmacy has a binder intended to contain all current Board Newsletters. Board Inspectors expect to find this binder, with Newsletters, in every pharmacy.

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### ITEM 338—RETURNING DRUGS TO A PHARMACY'S INVENTORY

The following is a reprint from a Food and Drug Administration publication, Compliance Policy Guides, November 7132.09 which may be helpful to pharmacists in conversation with patrons.

A pharmacist should not return to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, since he would no longer have any assurance of the strength, quality, purity or identity of the articles. Many state boards of pharmacy have issued regulations specifically forbidding the practice. We endorse the actions of these state boards as being in the interest of public health.

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.

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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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