

North Carolina Board of Pharmacy

P.O. Box H, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 384 — ALCOHOL WARNING LABEL ON PRESCRIPTIONS

On January 6th representatives of the Board of Pharmacy and the Pharmaceutical Association met with a subcommittee of the Mental Health Study Commission to discuss the practice of labeling certain prescriptions which could have an adverse reaction with alcohol. All present agreed that special diligence by pharmacists is warranted in this area. It was the consensus that this matter should be brought to pharmacists attention in this *Newsletter*. State law required that all prescriptions contain cautionary statements and this certainly applies to warnings on concurrent alcohol use. The Board advises that pharmacists need to use particular care to properly label prescriptions for sedatives, tranquilizers, antihistamines and other such drugs as well as personally speak with recipients of such drugs when necessary to convey the potential dangers if used with alcohol.

ITEM 385 — BOARD MEMBER ELECTION

The partial revision of the Pharmacy Practice Act by the General Assembly effective July 29, 1981 provided for election of pharmacist board members from all licensed pharmacists residing in the state. The position to be filled in this election is for a 3-year term beginning April 28, 1983. Accordingly, a ballot has been included with the mailing of this *Newsletter* listing the nominees pursuant to board regulations, as noted in the January, 1982 *Newsletter*. Also enclosed is a brief description of candidate qualifications and an envelope for returning the ballot to be cast.

Only ballots sealed in the envelopes provided will be counted in the election. They may be cast in person in the board office or by mail (affix first class postage, mail without postage is not delivered) before May 17, 1982. Results will be tallied on May 17th and ballots received after that date will not be counted in the election. Please complete the enclosed ballot, and submit it to the board office, sealed in the envelope provided, before May 17, 1982. The ballots will be counted in an open meeting beginning between 5:00 and 6:00 p.m. on May 17th at the Institute of Pharmacy and visitors are welcome.

The board has ruled that a majority of votes cast is required for election. In the event that no candidate receives a majority, a runoff will be held if called for by either of the top two candidates in the election within ten days of the election date. In the event that no candidate receives a majority and a runoff is not requested, the candidate receiving a plurality will be declared elected.

ITEM 386— NEW BOARD MEMBER APPOINTED

On February 5th, the Governor appointed Joseph B. Roberts, III as the first public member of the Board of Pharmacy. Mr. Roberts is an Attorney in Gastonia and has been active in civic affairs as a member of the Gaston County Board of Elections, serving as its Chairman in 1977 and was a member of the National Transportation Safety Board in 1976. He is a graduate of UNC, both undergraduate and law, where he was a William T. Phillips scholar, and has been active in local, state and national Bar activities. The board is pleased to welcome the addition of a person of his caliber and experience.

ITEM 387 — DISCIPLINARY ACTIONS OF THE BOARD

January: A pharmacist from Asheville appeared to clarify certain matters which arose from a prior hearing in November of 1981. The board had made a decision at that meeting, to be effective in January, on charges that he had made false statements to the board during the process of obtaining his license by reciprocity from Alabama. It was the decision of the board to change its earlier order and require a 60-day active suspension of his license with a 5-year probation.

February: A pharmacist who had received a temporary license in May of 1980 in pursuit of reciprocity had a hearing which began in November and reconvened in February. The pharmacist, his attorney and the pharmacist manager of a pharmacy formerly located in Hayesville appeared for the November session but failed to appear in February. Testimony and evidence revealed that large quantities of controlled substances (Dilaudid[®], Cocaine, Percodan[®], Quaalude[®] and Morphine) had been ordered by the pharmacy and large amounts of these and other controlled substances were missing at a later time. Quantities were in the range of ten times more than the average pharmacy in the area. A fire had occurred at the pharmacy and there were several alleged breakins not reported to DEA. Fire insurance coverage was increased one month before the fire and evidence of gasoline was found in the remains of the store. Testimony was heard from North Carolina State Bureau of Investigation Agents, Drug Enforcement Administration Agents and Board of Pharmacy Investigators from North Carolina, Georgia and South Carolina. The pharmacist, whose license had lapsed, was charged with giving false information in the process of obtaining a license by reciprocity and the board order that his license be revoked.

A pharmacist from Winston-Salem appeared to answer charges that he had sold Percodan[®] and Seconal[®] from the trunk of his car

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National Pharmacy

DEA WARNS OF LIABILITY

Stern warnings have been issued to the nation's pharmacists concerning their expected participation in the Drug Enforcement Administration's war against drug diversion. DEA officials have warned that "a pharmacist who deliberately closes his eyes when he has every reason to believe that the purported prescription order had not been issued for a legitimate medical purpose may find himself prosecuted, along with the issuing physician, for knowingly and intentionally distributing controlled substances, a felony offense which may result in the loss of one's business or profession." DEA also requires the pharmacist to exercise his own professional judgment concerning controlled substances prescriptions.

To assist pharmacists with identifying forged prescriptions, DEA has developed a checklist:

- Does the prescription order contain an indication different from the one(s) in the package insert?
- Does the prescriber write significantly larger numbers of prescription orders (or in larger quantities) as compared with other physicians in the area?
- Does the prescriber write for antagonistic drugs, such as depressants and stimulants, at the same time?
- Do patients appear to be returning too frequently?
- Do patients appear presenting prescriptions written in the names of other people?
- Do a number of people appear simultaneously, or within a short time, all bearing similar prescription orders from the same prescriber?
- Are numerous strangers suddenly showing up with prescriptions from the same prescriber?
- Are your purchases of controlled substances rising dramatically?

DEA warns that any of these symptoms could be a signal that drug abusers are tapping your pharmacy. DEA also asked that pharmacists who notice a pattern contact their state board of pharmacy or local DEA office.

ADVISORY FROM THE FDA

"We continue to receive a considerable number of inquiries from community and hospital pharmacists, state boards of pharmacy, purchasing agents, and others which suggest that there exists a noteworthy degree of misunderstanding about the status of certain single-entity and combination drug products which have yet unresolved questions of effectiveness under FDA's Drug Efficacy Study Implementation (DESI) program. In addition, we find there is a good deal of confusion regarding the significance of an NDA (New Drug Application) or ANDA (Abbreviated NDA) number assigned to a specific product by the FDA and the NDC (National Drug Code) number.

First, we should point out that NDA or ANDA numbers are

generally assigned by the FDA upon receipt of a submission for reference purposes only, and do not imply approval. There is no confirmation of the existence of an NDA/ANDA number as an assurance that the product has been approved. Inquiries to the FDA or product sponsors should specifically question the approval status, not the assignment of a number. Likewise, there have been questions regarding a product's NDC number and its significance. An NDC number only identifies the product and firm, but again, and this must be emphasized, it has nothing whatever to do with approval of the product.

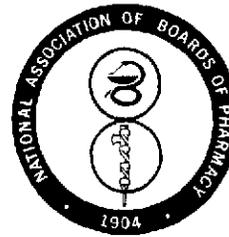
The second issue concerns the status of certain DESI products and an apparently growing degree of erroneous information that is circulating in the professional community. The type of inquiries we receive suggests that the most frequently misunderstood product is the chlorzoxazone-acetaminophen combination, yet its status reflects that of several other products for which the effectiveness is in question. The DESI drugs, which include chlorzoxazone-acetaminophen (specifically Parafon Forte), are those originally approved for marketing by the FDA between the years 1938 and 1962.

New provisions to our laws, passed in 1962, added the demonstration of effectiveness to our approval criteria. The 1938-62 products (including Parafon Forte) were approved **only** for safety, not for effectiveness. Therefore, under the DESI program, these products are now being evaluated for efficacy. Once the effectiveness issues and/or other matters are resolved, an ANDA may be approved for DESI products. However, provisions in the administrative practices and procedures are time consuming and have delayed resolution of many of these issues.

It is FDA's policy that Abbreviated New Drug Applications (ANDAs) for products pending final determination of effectiveness will not be accepted for review, unless such a provision or requirement is published in the *Federal Register* (FR). It is also our policy that until a final determination of effectiveness is published specifying the conditions for marketing, firms may continue to market these products without FDA approval, on their own responsibility. For example, Parafon Forte (chlorzoxazone-acetaminophen) has been classified under the DESI review as "probably effective." This indicates that the product has not been determined to be fully effective and the classification has not yet been finalized on a FR notice published. Until that time, we have deferred regulatory action on that product and other chlorzoxazone-acetaminophen combinations currently on the market. We are advising that those marketing "Parafon Forte generic substitutes" (and other unapproved versions of DESI drugs) do so on their own responsibility because we can neither comment on the quality aspects of the product nor guarantee that we will not seek regulatory action at some point in time. We are aware that states vary in positions on these products.

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Compliance News



therefore, we strongly encourage pharmacists and other professionals who dispense, use and purchase them (or otherwise have a need to know), to consult with their individual state authorities to determine their positions regarding these products.

Ross S. Laderman
Director
Consumer and Professional Relations Staff
Bureau of Drugs (HFD-5)

DRUG PRODUCT PROBLEM REPORTING

The United States Pharmacopeial Convention (USPC) coordinates a simple and effective way to get direct health practitioner observations about product problems into the decision-making processes of industry and government. The practitioner reporting system is aimed at improving product quality and communicating health hazards to industry and government and funding is provided by the Food and Drug Administration. State and national organizations in various health care areas co-sponsor the two reporting programs: the Drug Product Problem Reporting Program (DPPR) and the Medical Device and Laboratory Product Reporting Program (PRP).

Problems may be reported by either providing a written statement or by calling the toll-free number. Copies of reports are forwarded to the FDA upon receipt by USP and manufacturers also receive copies as a service so that the firm may be aware of the concern. Basically, anything considered to be a problem should be reported. Drug problems include packaging and labeling complaints and poor pharmaceutical quality of drug products.

Although the primary purpose of the system is to improve the products utilized in health care, it also affords a vital means of quickly bringing health hazards to the attention of officials in government and industry. Without practitioner input, manufacturers, government, and the rest of the health care community may be unaware of problems that are experienced. For further information contact: **Drug Product Problem Reporting Program** or **Medical Device and Laboratory Product Problem Reporting Program, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852**; or call the toll-free number: **(800) 638-6725**; (except Alaska and Hawaii; in Maryland, call collect (301) 881-0256).

PHARMACY LAW PUBLICATION AVAILABLE

The American Society for Pharmacy Law (ASPL) is a national organization for those interested in the law as it relates to pharmacy. Some of its purposes are to communicate pertinent legal information to attorneys and pharmacists, to foster knowledge and education pertaining to the rights and duties of pharmacists, and to provide a

form for the exchange of information pertaining to pharmacy law. The Society publishes a monthly newsletter, *Rx Ipsa Loquitur*, which presents and discusses recent cases, statutes, and regulations in the area of pharmacy law. The Society meets on an annual basis usually in conjunction with the annual meeting of the American Pharmaceutical Association. The ASPL annual meeting includes presentations of papers on professional liability, health care law, and pharmacy regulations. The general session of the annual meeting usually includes a guest speaker or panel presentation discussing current items of interest to the membership. Membership in the ASPL is not limited to attorneys. Persons holding a professional degree in either pharmacy or law may attain membership by paying a \$15 yearly fee. Membership for pharmacist-attorneys is \$20 per year. Membership application or further information may be obtained by writing to Larry M. Simonsmeier, ASPL Secretary, College of Pharmacy, Washington State University, Pullman, WA, 99164-6510.

**Moved or Moving? Let Your
State Board Know Where!**

EXPIRATION DATES—OUTDATED DRUGS

One of the more important roles of the pharmacist is that of ensuring the quality of the drug product which is administered or dispensed to a patient. To assist the pharmacist in making this determination and assure that a drug product meets applicable standards of identity, strength, quality and purity, the Food and Drug Administration and the U.S.P. require that drug products bear an expiration date.

The expiration date identifies the time during which the drug product may be expected to meet U.S.P. or the manufacturer's standards of quality when the drug was manufactured, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the drug may be dispensed or used, and if stated only in terms of the month and year, the intended expiration date is the last day of the stated month.

Expiration dates have been required for all drug products manufactured since February 27, 1979 and pharmacists should regularly review their inventories and dispose of outdated products. The FDA recently reported that it's National Center for Drug Analysis has determined that samples of digitoxin, digoxin and sublingual nitroglycerin tablets which were undated and still in the marketplace pose possible health hazards due to product deterioration. Most of digitoxin tablets which were tested failed dissolution standards by substantial amounts. Pharmacists should examine their inventories of these products and dispose of those which do not bear an expiration date or are outdated.

without a prescription to a person who was an officer of the Winston-Salem Police Department operating in an undercover capacity. The pharmacist admitted some guilt but claimed he had been deceived by friends and responded to the officers request after several meetings where he was urged to sell such drugs. The officer contradicted these statements. The pharmacist pled for leniency and a probationary period, stating that he drank very little but occasionally used Marijuana. The board ordered a 90-day active suspension with a 5-year probation on certain conditions, one of which is that he must show any employer his record with the board and cannot be a pharmacist-manager for the entire 5-year period.

A pharmacist-manager from Greenville appeared to answer charges of dispensing controlled substances without a prescription. Testimony revealed substantial shortages of Paregoric, Butisol[®] Elixir and Ionamin[®] which apparently occurred during a period ending about one year ago. Testimony of the pharmacist indicated that the Paregoric and Butisol[®] were for personal use but there was no satisfactory resolution for the Ionamin[®] shortage. It was the decision of the Board to continue investigation of this matter to be certain that no such personal use without a physician's prescription occurs.

ITEM 388 — AUGUST BOARD MEETING

Due to a conflict in scheduling with other meetings, the board has set its August meeting for Tuesday, August 24, 1982 in the board offices in Carrboro.

ITEM 389 — STATUS OF PRESCRIPTION TRANSFER/PRESCRIPTION COPIES

Several pharmacists have noted some confusion between an article in the national news section of the January *Newsletter* and Item 352 addressing prescription copies. Although federal regulations allow the transfer of prescriptions for controlled substances, no such similar change has been made in North Carolina statute or regulation. Consequently, Item 352 in the April, 1981 *Newsletter* still prevails and the pertinent part is repeated for clarification:

North Carolina statute G.S. 90-106 provides that copies of prescriptions for controlled substances shall not be filled or refilled. It is the board's position that copies of prescription for non-controlled drugs are also not valid in the same way that a copy of a check is not a check, a copy of a contract is not a contract, etc. If a pharmacist receives a prescription copy and feels that it should be filled (or refilled) the pharmacist should contact the prescriber and essentially obtain a new prescription and treat it as such in their prescription files. There is no provision in North Carolina statute or regulations for the transfer of prescriptions between stores.

ITEM 390 — DRUGS AND THE ELDERLY

The present population of over 22 million elderly will double in the next fifty years, according to a recent NIH publication on the epidemiology of aging. These 22 million people over age 65 comprise 11% of the total U.S. population, yet they consume 25% of all prescription drugs sold in this country.

Because older people have a greater number of chronic diseases and take multiple drugs, the potential risk for drug interactions and adverse drug reactions is great. Physiologic alterations due to aging in gastrointestinal and renal function affect the absorption, distribution, metabolism, and elimination of drugs. Consequently the pharmacologic action of drugs taken by the elderly is exaggerated

at standard doses, and may result in undesirable effects. Drug interactions and adverse drug reactions are not only more likely to occur, they may be more difficult to detect in the older person.

The elderly are the group most likely to benefit from patient-oriented pharmacy services. Pharmacists should be particularly alert for potential drug-related problems in the elderly. For example, laxative abuse and nutritional deficiencies are not uncommon in this age group. Older people who live alone and cannot rely on family members to help with their medication regimen may benefit from large type prescription labels, a daily drug calendar, and easy-open containers. It is also important to make sure elderly patients understand the name of their prescription drug, its intended use, and the directions for use.

Another way pharmacists can help the elderly is in the area of drug product selection. Since many live on a fixed income, prescription drugs are often major expenses for retired older people. However, over 75% of people in the 65 and over age group are not willing to accept substitution of generically equivalent drugs. When generic substitution is not restricted by the physician, pharmacists can help educate the elderly to safety, efficacy, and potential cost savings of generically equivalent drug products.

ITEM 391 — COMPUTER CAUTION

At the February meeting members discussed with the Diversion Investigative Unit of the State Bureau of Investigation the use of computers to store prescription data. Serious concern was expressed that pharmacists may be misled that a computer or data system has been "approved" by DEA or the board when no such approval has been given to our knowledge. Also pharmacists may have been informed that a computer or data system avoids the necessity to keep original prescription documents when this is not the case. It is usually necessary to keep a manual system for verification and during "down" time. Remember, the board, DEA and the Courts hold the pharmacist responsible for maintaining and producing records, not the computer vendor! More about this in later issues.

ITEM 392—RECORDING REFILL INFORMATION

Inspectors report problems with some pharmacists neglecting to record sufficient information on the document when prescriptions are refilled. Refill information, including quantity if different from original, should be noted on each prescription and must be recorded for all CS. Failure to record refills can produce substantial shortages in an audit and result in disciplinary action even if the refills were authorized and drugs were actually dispensed in good faith. In order to be valid, all refill authorization must be prior to dispensing and it is this principle which prohibits the use of presigned blanks for discretionary use.

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