

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 451—VOTE AND ELECTION

Pharmacists licensed and residing in North Carolina will receive a ballot with this issue of the *Newsletter* for casting their vote in an election for a position on the Board of Pharmacy. The position is for a three year term beginning in the Spring of 1985. A ballot is enclosed for this purpose along with an envelope for return to the Board office. Ballots will be counted on Monday, May 21, 1984 at 5:00 p.m. in the Institute of Pharmacy in Chapel Hill. Observers are welcome at that time.

Pharmacists should be interested in knowing how an individual comes a candidate for election to the Board. Two provisions in statute exist, one through petition of 10 pharmacists and another by way of a Committee. Mr. William H. Randall, Jr. and Mr. C. Louis Shields were nominated by a Committee consisting of 6 pharmacists from the southeastern part of the state. Van H. King, III was nominated by petition. This open position is designated to be filled by a pharmacist from the southeastern part of the state. Members of the Committee were Herman Lynch, Chairman, Dunn; Fred Parker (Kerr Drugs) Jacksonville; Bill Oakley (Craven County Hospital) New Bern; Les Collins (Revco) Wilmington; and Sara Hackney (Hedgpeith Pharmacy, Inc.) Lumberton. The Committee met on February 16th in Goldsboro and arrived at the two names specified above. Similar procedures are planned for future years in different areas of the state as terms come up for election.

ITEM 452—WE'VE MOVED AGAIN

As of March 1, 1984 the Board office has a new location in Willow Creek Shopping Center in Carrboro. Our mailing address (P.O. Box H, Carrboro, 27510) and telephone number (919/942-4454) remain the same at our new location. The office is located at the intersection of Highway 54 Bypass and Jones Ferry Road in Carrboro.

ITEM 453—DISCIPLINARY MATTERS

January, 1984: Lucius Cooke appeared before the Board in response to a citation letter charging felony violations of North Carolina Statute on Medicaid fraud. Testimony indicated that Mr. Cooke had dispensed generic drugs and billed Medicaid for brand name drugs on several different occasions producing a fine of \$6,500 and restitution of \$2,500 in court proceedings. Mr. Cooke's lawyer offered on his behalf numerous letters of good character and the fact that Mr. Cooke had not had any prior problems with the Board.

It was the decision of the Board to suspend Mr. Cooke's license for six months, stayed for a period of four years producing a net period of four years of probation.

Raymond Gerald Mizelle appeared before the Board to request reinstatement of his license which had been suspended by the Board at its October meeting. Mr. Mizelle produced evidence that he had met the conditions specified for reinstatement such as enrollment in a drug treatment program, several consecutive clean urine screens and other conditions. It was the decision of the Board to reinstate Mr. Mizelle's license to practice under the remaining conditions specified in the October Order.

Russell V. Cobb, III from Dobson appeared before the Board in response to charges of Medicaid fraud at Dobson Drug Company. Testimony from Mr. Cobb indicated that while he was in the process of purchasing the pharmacy his Medicaid claims were processed by a company in Tennessee and submitted to North Carolina Medicaid using brand name drugs. The reason for billing for such brand name drugs was that the prior owner had used brand name drugs while Mr. Cobb did not beginning with the purchase agreement thus producing billings for brand name drugs while generic drugs were dispensed. Mr. Cobb indicated that he ceased this practice as soon as it was brought to his attention. The Court proceedings produced fines of \$7,000 plus \$2,500 in court costs. It was the Board's decision to continue the matter for 12 months for further review and if no further problems occur then the matter be dismissed. Mr. Cobb was admonished to keep his record clear in the future.

The Board accepted the surrender of the license to practice pharmacy held by Fredrick Ray Locklear. The Board also lifted a stay order on a prior revocation thereby revoking his license.

February: Mr. Lawson Stroupe appeared before the Board in response to charges of failure to keep accurate records for controlled substances and dispensing prescription drugs without a prescription. Testimony and evidence indicated that Mr. Stroupe while at Piedmont Pharmacy in Lawndale used an unorthodox method of filling and refilling prescriptions which involved the indication of monthly refills for prescriptions over a six month period at their initial presentation. The prescription document would then show refills monthly even though such refills might not have been obtained. There were also instances of dispensing prescription drugs purportedly prescribed by a physician who was in South America at the time. Mr. Stroupe, who was represented by counsel, assured the Board that these practices had terminated and things were now in order. It was the decision of the Board to continue the matter pending further review.

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National Pharmacy

CLARIFICATION RE: PARAFON FORTE APPROVAL

In the October 1983 *Newsletter*, the following article was published which apparently has caused some confusion:

"FDA published notice in the Federal Register of Friday, July 29, that it was withdrawing approval of Clistin R-A, Forhista Lontabs and Parafon tablets. A hearing was requested, however, for Parafon Forte tablets and other drug products containing Chlorzoxazone 250 mg. and Acetaminophen 300 mg. Effective August 29, 1983 the Clistin R-A Forhista Lontabs and Parafon tablets can no longer be shipped in interstate commerce and are no longer approved for marketing. Parafon Forte tablets may continue to be marketed pending the outcome of the hearing that has been requested. FDA is withdrawing the approval due to their lacking substantial evidence of effectiveness".

Some confusion has resulted from our final quarter 1983 newsletters as to whether FDA has withdrawn approval of Parafon Forte Tablets. Approval was withdrawn for Parafon Tablets, not Parafon Forte Tablets. The drugs listed: Clistin R-A Tablets (not Clistin Tablets), Forhista Lontabs, and Parafon Tablets, were the subjects of FDA withdrawal action because they lacked substantial evidence of effectiveness.

METHAQUALONE MANUFACTURING HALTED

The Lemmon Company of Sellersville, PA, the only legal manufacturer of Methaqualone, or Quaalude, in the United States, has halted the manufacturing of the drug and stopped distributing it January 31, 1984. While still considering the sedative-hypnotic product to be safe and effective, the company did acknowledge that Methaqualone has been widely abused, particularly over the past few years by so-called "stress clinics." Lemmon said the decision was made to abandon the continued production of the drug after discussions with FDA and with the Drug Enforcement Administration. Since its categorization as a Schedule II controlled substance, in 1973 the production quota for Methaqualone, which is based on anticipated legitimate use, has been steadily reduced. Statistics show that legitimate prescriptions for Methaqualone declined from more than four million in 1973 to less than 300 thousand in 1982. This reduction of more than 90% has taken place in spite of the large volumes of prescriptions written for ostensibly legal purposes in the "stress clinics".

Even if Lemmon had not taken its action to stop the production of Methaqualone, it is conceivable that the drug would have met a similar fate through the passage of legislation reported by the US House Committee on Energy and Commerce which would have outlawed Methaqualone.

1984 CANDIDATES GUIDE AVAILABLE

The latest edition of the NABPLEX® *Candidate's Guide*, the official guide to the National Association of Boards of Pharmacy standardized licensure examination now used in 49 states, the District of Columbia, Puerto Rico, and the Virgin Islands, now is available from NABP's Publication's Desk. The *1984 Guide* is 56

pages of information geared to prepare last-year pharmacy students for NABPLEX®. Guide contents include detailed information on how to prepare for the examination, new and revised competencies effective for the June, 1984 test administration, 378 sample questions from the actual pool of examination questions, procedures with relation to the actual test administration, and complete listings of all boards of pharmacy.

NABPLEX® will be administered throughout the United States with the exception of California on uniform testing dates in the 1983-1984 testing year. Competency statements on which questions are based are included in the new Guide and are applicable to June and September, 1984 and January 1985 administrations of NABPLEX®. Uniform dates provide the examining board of pharmacy and the candidate with a secure examination and insures that candidates who pass are competent to enter the profession. Testing dates for the coming year include June 26-27, 1984; September 25-26, 1984; and January 22-23, 1985. Only three uniform dates will be offered for the coming testing year. Dates are designated to provide for timely administrations with relation to the majority of graduation dates among schools of pharmacy. Candidates should contact the state in which they seek licensure to determine whether that state will administer on any one of the uniform dates.

Individual copies of the *1984 Guide* are available through the NABP Publication's Desk for \$7.50 per copy, prepaid. Future pharmacists or current practitioners wishing to brush up on their knowledge are encouraged to contact NABP, One East Wacker Drive, Suite 2210, Chicago, IL 60601.

FEE INCREASES IMPLEMENTED BY DEA

The Drug Enforcement Administration (DEA) has now issued its final notice establishing a new fee structure for all DEA registrants.

The previous DEA fee structure was not covering federal costs that were incurred by the agency in its registration and regulation of manufacturers, distributors, and dispensers of controlled substances. The new fee schedule was established in order to cover those administrative costs.

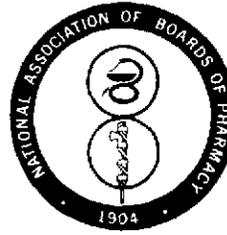
DEA's new fee structure applies to all new applications post-marked on June 1, 1984 or later and for all renewals of registrations with an expiration date of June 30, 1984 or later. The new fee schedule is as follows:

Manufacturer	\$250
Distributor	\$125
Importer	\$125
Exporter	\$125
Narcotic Treatment Program	\$20
Hospital/Clinic	\$20
Practitioner	\$20
Teaching Institution	\$20

BUTAZOLIDIN REMOVAL ASKED

The Food and Drug Administration recently released the following information regarding a request it received calling for the re-

Compliance News



removal of Butazolidin and Tandearil from the market.

The Health Research Group, the Nader Organization headed by Dr. Sidney M. Wolfe, has written HHS Secretary Margaret M. Heckler asking that Phenylbutazone (Butazolidin) and the related Oxyprenbutazone (Tandearil) be removed from the market as an "imminent hazard". Dr. Wolfe also pointed out that FDA's adverse reactions reporting system included more than 300 deaths.

Dr. Wolfe said Norway is banning the drugs effective in April, 1984.

Secretary Heckler has asked FDA for a comprehensive review of the drugs. The drugs' known side-effects, clearly emphasized in the current labeling, have, properly, led to declining use. These risks must be weighed against the possibility that the drug has particular benefits in some patients who may not be helped by other treatments—a risk-benefit ratio that will be re-examined in light of Dr. Wolfe's request.

Clearly, the medical profession should be aware of the cautions and contraindications for the drugs, which are labeled for active rheumatoid arthritis, short-term treatments for acute attacks of degenerative joint disease of the hips and knees "not responsive to other treatment" and painful shoulder. Butazolidin was approved in 1952 for U.S. sale and has been prescribed for perhaps 100 million people nationwide. It and Tandearil are labeled with an advisory against use in patients who can respond to less toxic drugs and anyone who cannot be followed closely and regularly to check for gastrointestinal symptoms, liver dysfunction and anemia—in order to prevent such life-threatening problems as perforated ulcers and suppression of bone marrow.

The labeling says patients should be advised to stop taking the drugs and report to their physicians immediately if they have gastrointestinal pain, fever, sore throat, skin rashes or edema because these can be early signs of the severe problems associated with the drug.

SOUTH CAROLINA ADDRESSES MULTIPLE PRESCRIPTION BLANKS

The South Carolina Board of Pharmacy and the South Carolina Medical Association jointly have attempted to address the difficulties faced by pharmacists when they are presented with prescription blanks that contain multiple prescriptions. The thrust of the South Carolina effort was aimed at educating physicians to the problems they create by writing multiple prescriptions on a single prescription blank.

The educational effort developed by SCMA and the SC Board of Pharmacy address the problems pharmacists face in filling of prescription blanks containing multiple prescriptions, the increased likelihood that errors will be made when multiple prescriptions are written on the same blank, and the problems associated with recording refills and keeping track of which of the prescriptions have been refilled and which have not.

The South Carolina Board of Pharmacy and the South Carolina Medical Association hope that through this educational program they can reduce or even eliminate the tendency of physicians to write more than one prescription on a single prescription blank.

WHERE ARE THE IMPAIRED PHARMACISTS?

The problem of alcohol and chemical abuse has and continues to be a major social problem in our society. Setting the street drug problem aside, there still exists the problem of alcoholism and prescription drug abuse which has reached major proportions. Health professionals, including pharmacists, are as vulnerable to the disease of addiction as any other health professional, since exposure is constant and tempting. Pharmacists are human just like the rest of society, and they have their reactions to stress and the everyday problems of facing reality. Many health professionals are reluctant to discuss substance abuse as an addiction that affects them or their colleagues personally. Yet, it is a condition which must be recognized and addressed.

Medicine, nursing—most of the health professions have taken steps to educate practitioners, assist in the identification of the problem and provide mechanisms of recovery for those who are chemically impaired. Medicine has probably done more as a profession to combat the problem as any. Some state laws require the physician to report impairment of their colleagues to the state regulatory agency. All professional regulatory agencies' charge regarding the impaired professional is clear. There must be suspension, revocation or discipline correlated to the degree of impairment and how it affects the practice and influences one's ability to protect the public. By the time the board receives a complaint and investigates the situation involving an impaired practitioner, it may be too late. The problem lies in assisting the impaired pharmacist before a time of crisis arises. The key to helping the impaired professional pharmacist is to identify the problem, confront him/her and offer assistance.

There are a vast array of treatment programs for those pharmacists who ask for help. The AA community is always available and recognizes that it is their responsibility to assist if asked. The AA community is composed of recovering persons. It may be important to seek out a recovering AA pharmacist. But don't let that deter you. Ask any AA member and they will go to great lengths to explain the program and assist anyone who needs help. If you know a pharmacist that needs help, seek the advice of a professional in the area of alcoholism and drug abuse—they are readily available.

There are many state pharmaceutical association programs that offer excellent support and counsel if called upon. They will assist in confronting the pharmacist and will make recommendations for a treatment program. The assistance you might give your colleagues who wish to recognize their problem, will be returned to you two-fold, should the pharmacist become rehabilitated and return to a productive professional life. It's for the good of pharmacy.

MOVED OR MOVING?

In many states, the responsibility to alert the pharmacy board of a move or intended move by a pharmacist is dictated by law or regulation. In addition, if you hold more than one license to practice in more than one jurisdiction, renewal information may be delayed or returned jeopardizing your continued status as a pharmacist. Do yourself, and the board, a service. If you move, let the board know.

ding an inspection by the Board Inspector with further action, if any, after receipt of that report.

ITEM 454—PRESCRIBING BY OPTOMETRISTS

Optometrists were granted the right to prescribe drugs within the practice of optometry several years ago by the General Assembly. This has caused some concern among pharmacists in filling their prescriptions and questions regularly arrive in the Board office on this subject. The following commentary by the editor is offered in the hope that it will answer some of these questions and alleviate some other anxieties expressed by pharmacists.

North Carolina General Statute 90-114 clearly provides that optometrists can prescribe drugs in the treatment of "conditions of the human eye or its adnexa". While some individuals may believe this is limited to topical products, a close reading of the statute indicates that optometrists can also prescribe systemic drugs but may need to "communicate and collaborate" with a physician. Provisions exist for optometrists to prescribe controlled substances, see G.S. 90-87(22), but they must, of course, have a DEA registration to do so. Naturally any prescribing that dentists, veterinarians and others can prescribe only within their practice.

Several years ago the Board asked for an Attorney General's opinion on what, if any, duties the pharmacist had in filling prescriptions from optometrists. The reply at that time indicated that pharmacists had no additional responsibility (liability) in filling such prescriptions, that the pharmacist did not need to ascertain that the optometrist had been approved to prescribe drugs nor was it the pharmacist's responsibility to determine whether or not communication and collaboration had occurred between an optometrist and a physician.

ITEM 455—QUARTERLY QUERY

Which of the following acts may be appropriately performed only by a pharmacist and not by other pharmacy personnel working under his supervision?

1. Supplying telephone information about drugs to physicians and other prescribers.
 2. Prepackaging prescription medications for subsequent dispensing.
 3. Inventorying controlled substances.
 4. Dispensing Schedule V otc preparations.
 5. Instructing patients with regard to medication dosage schedules.
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ITEM 456—PROFILES AND PRESCRIPTION REFILLS

Inspectors report that questions regularly arise regarding the appropriateness of indicating prescription refills only on profile cards and not on the prescription document. In reviewing this matter at the February meeting it was the consensus of the Board members that prescription refills must be indicated on the prescription document. The Board recognized that prescription profiles are good and often valid records and encouraged their use by pharmacists who are so inclined. The Board did not feel, however, that such recordkeeping replaced what needs to be indicated on a prescription document. The answer to quarterly query is (4). - Dispensing Schedule V otc preparation.

ITEM 457—PRESCRIPTION MODIFICATION

Questions occur from time to time pertaining to situations where a pharmacist might not have in stock a certain strength of a drug and what procedure needs to be followed. For example, if a physician had prescribed 12 tablets of Demerol® 100mg., 1 qid for pain, could the pharmacist modify this prescription if 100 mg. tablets are not in stock to provide 50 mg. tablets, doubling the dosage and the quantity? It is the editor's opinion that such a modification, in this case from 100 mg. to 50 mg. and doubling the tablet dose and amount dispensed is within the normal and accepted practice of pharmacy, providing that the 100 mg. strength was not available. While such a change would not require consultation with the physician, it would be prudent judgment to inform the prescriber or arrange for a notation in the patient's medical records that a change was necessary although no change in net therapy was produced.

ITEM 458—REPETITION HELPS

Item 427 in our July, 1983 issue of the *Newsletter* dealt with labeling generics and certain typographical errors occurred during the printing process. It is possible that parts of the Item were difficult to understand and it is therefore repeated below.

One common question from pharmacists is the proper labeling of prescriptions when a generic drug is dispensed. Pharmacists often desire to use a brand name on the label for ease of identification and this can present some serious litigation problems, unless properly labeled. See Item 432.

Problems arise in at least two different areas - misbranding where the label is false or misleading in any particular or a misrepresentation that a product is the brand name when a generic is dispensed. Using, for purposes of illustration only, the drug name Sumycin®, the following labeling would be violative of misbranding law - trademark rights or both if generic Tetracycline is dispensed; Sumycin®, generic Sumycin, Sumycin G, Sumycin/Tetracycline, Sumycin (manufacturer) or any other combination which would be misleading to the public or unfairly used the brand name which is property right belonging to the company. One example which could be acceptable is the phrase "Tetracycline used for Sumycin®". Inspectors will be making spot checks of labels to be certain that pharmacists are properly indicating the drug in each container.

ITEM 459—MEETING DATE

The board will meet on Tuesday, May 22, 1984, in their office in Carrboro.

MOVED? LET THE BOARD KNOW WHERE!

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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