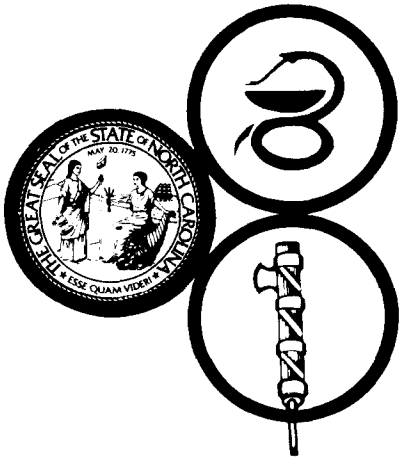
October, 1989



North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510 Published to promote voluntary compliance of pharmacy and drug law.

Item 619 - Election Results

The Run-off Election in Districts III and IV was tallied prior to the August Board meeting. The ballot count is listed below.

District III - June McDermott, 653 and Whit Moose, 1,222

District IV - Al Lockamy, 1,083 and Julian Upchurch, 770

The Board of Pharmacy elections certified these results as final at the August 22nd meeting and the names of Mr. Lockamy and Mr. Moose will be forwarded to the Governor for appointment to serve five year terms beginning in the Spring of 1990. Whit Moose has served on the Board since 1977, owns two pharmacies, and is active at the national level as a Vice President 'ARD. Al Lockamy, the first Revco National Pharmacist of , Year, is the first chain store pharmacist elected to the Board. He also serves on the American Pharmaceutical Association's Executive Committee of the Academy of Pharmacy Practice and Management.

Item 620 - Disciplinary Actions Of The Board

May: *Erma J. Cunningham*, Winston Salem. Dispensing controlled substances without valid prescriptions. License suspended three months, stayed three years.

James C. McCowen, III, Greensboro. Appropriating controlled substances for his own use without obtaining authorization from a physician and consuming those controlled substances; indulgence in the use of drugs to an extent that renders him unfit to practice pharmacy. License revoked, stayed for five years with 30 day active suspension and other conditions.

James Gary Shively, Kentucky. Emergency action by the Board to summarily suspend license to protect the public health, safety and welfare.

June: *Asa Gatlin, Bayboro* and *Pamlico Drug Store*, Bayboro. Dispensing prescription drugs without valid prescription; refilling prescriptions without authorization; dispensing generic drugs without authorization. License suspended 90 days, stayed five years with conditions. Permit suspended 30 days, stayed five years.

'ohn Kenneth Carter, Salisbury. Dispensing prescription gs without valid prescriptions; failing to keep and maintain adequate records of dispensation of prescription drugs. License suspended six months, stayed five years with specific conditions.

July: *Wayne Allen Rinehart*, Matthews and *Charlotte Memorial Hospital and Medical Center Pharmacy*, Charlotte. The Pharmacist-Manager and the Hospital failed to comply with the rules and regulations of the Board and were negligent in the practice of pharmacy which produced three patient deaths in two separate incidents. (See also Item 589) License suspended two years, stayed two years with active suspension of ninety (90) days and other conditions. Permit for hospital suspended one year, stayed three years with specific conditions.

Item 621 - Review Of Product Selection

From time to time pharmacists call the Board office requesting clarification of the Product Selection Law in North Carolina. This state has a fairly clear statute which provides for a two-line form to be used by a prescriber in order to instruct the pharmacist regarding the dispensing of drugs. This form consists of a line at the lower left and the lower right of the prescription blank with the notation under the line in the lower left, "Product Selection Permitted," and under the line in the lower right, "Dispense As Written".

The Board of Pharmacy has ruled that a prescription format other than the one described by statute (see prior paragraph) is amendable to substitution or product selection by the pharmacist. This includes prescription forms where there is a one line blank, a checkbox indicating "dispense as written" or "substitution permitted," a reversal of the lines with "DAW" on the lower left and "Product Selection Permitted" on the lower right, as well as prescription blanks with lines one on top of the other. In each of these cases it is the ruling of the Board that product selection is permitted regardless of where the signature occurs. In a case where a prescriber has written a prescription for a brand name drug and signed on the DAW line, it is the Board's opinion that the pharmacist must use a brand name drug. If a generic drug is used under these circumstances some liability would be incurred, but at this point the extent of that liability has not been established.

When generic drugs are dispensed, the label needs to be accurate. Under these circumstances, it is most important to remember the short definition of misbranding which occurs

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HIGHLIGHTS OF FDA'S DRUG RECALL POLICY

FDA considers its recall policy to be an effective method of removing or correcting consumer products, such as drugs, that are in violation of the laws it administers. Recall is a voluntary action that takes place when manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception, or are otherwise defective. An alternative to a court action, an FDA request for recall is reserved for urgent situations and is directed towards the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled. FDA feels that the recall procedure is generally more appropriate and affords better protection for consumers than seizure when many lots of a product have been widely distributed.

If a firm refuses to undertake a recall requested by FDA or if the agency has reason to believe that a recall would not be effective, seizures, multiple seizures, or other court actions may be indicated.

A "recall classification" is a numerical designation assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product in question.

A Class I recall is reserved for situations in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II denotes a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

Class III recalls apply to situations in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

More information on FDA's recall policy can be obtained from the Department of Health and Human Services, Public Health Service, FDA in Rockville, MD.

DOES IT MEAN WHAT IT SAYS?

The body of knowledge that defines pharmacy is ever-expanding and complex. You are reminded of this fact throughout your professional education. The professional literature is the source for new theories, and new courses of therapy. It is an active moiety that is effective, vibrant, and often confusing.

Once you have have matriculated through your professional programs, the responsbility for maintaining your competence to practice pharmacy rests entirely with you. New therapeutic discoveries, drug product selection laws, and therapeutic equivalence considerations are daily concerns. In most instances, information about these important decisions is taken from the professional literature with little or no opportunity to discuss the information.

A recent editorial in the Journal of the Amercian Medical Association (JAMA, May 5, 1989) illustrates how careful we must be when utilizing information from the professional periodicals as the sole source for our decision-making processes. The editorial detailed the incidents surrounding a manuscript published by JAMA in 1987 concerning the therapeutic equivalence of a generic drug. The generic drug is listed in the Food and Drug Administration's (FDA) list of approved drug products as being therapeutically equivalent to the brand name product.

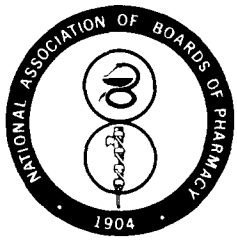
The manuscript documented effects on a patient's incidence of seizures when the drug therapy was changed between brand and generic. Prior to publication, the manuscript was reviewed by three experts in pharmacology, all of whom recommended publication of the article. After publication, the FDA investigated the data supplied from the clinic and found that patient had responded poorly to both the generic and brand name drug products. Upon notification of this finding and other relevant data, the authors replied that they had reported the case completely and that "no relevant or important information was excluded from our published report."

Further FDA investigation revealed that the authors had based their conclusions on a period of observation totaling less than three weeks, and had failed to follow and report the patient's history with continued use of the generic and brand name drug products.

The information provided by the FDA caused one reviewer of the original manuscript to suggest that the matter be investigated and a retraction published. The reviewer believed that he had not been furnished with important relevant data that could have completely altered his opinion of the manuscript.

While no one has been accused of a deliberate deception, serious concerns have been raised. The editorial maintains that, "science cannot proceed if error is not permitted, but that fraud can never be allowed." It asks what editors can do to ensure that the reader gets the truth, the whole truth, and nothing but the truth.

An obvious answer seems to be the thorough investigation of every manuscript including the source documents and institution. However noble this solution may be, it does not seem practical. The scientific community is also worried about regulatory system that they would view as intimidating, exp sive, and unworkable. The fact remains that to "to hold back



relevant information is unscientific, even antiscientific, but how are editors, reviewers, or readers to know that this has happened?"

We recommend that, before you make decisions regarding therapeutic equivalence, etc., you consult with the FDA or your state board of pharmacy about any concerns you may have. These agencies can provide information that will be helpful in evaluating other sources of information, and will also alert you to the applicable federal and state laws.

TRANSDERMAL ADMINISTRATION OF OTC DRUGS

The following is an excerpt from a recent memo issued by FDA's Department of Health and Human Services.

A drug is defined under the Food, Drug and Cosmetic Act as any "article" that is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" as well as any article, other than food, that is "intended ·· ·ffect the structure or any function of the body of man or other als." A "new drug" is defined under the Act as, any drug ⌣ composition of which is such that such drug is not generally recognized, and among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested" in its labeling. New drugs may not be marketed without prior FDA approval.

All over-the-counter (OTC) drug products that deliver medication via the transdermal route of administration are new drugs irrespective of the status of the ingredients or the labeling claims because of, among other reasons, the newness of the method of administration, the duration of the administration, or the application of the drug products. The FDA is unaware of any adequate and well-controlled clinical studies which demonstrate that OTC transdermal patch products are safe and effective for their intended uses. Without such studies, the products cannot be "generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective."

All OTC drug products delivering medication via the transdermal route of administration are also regarded as misbranded under the Act. The Act states that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. The labeling for such an OTC transdermal product would be false and misleading by representations and estions that there is substantial scientific evidence to establ- hat the product would be safe and effective for its intended uses. The Act requires the labeling of a drug product to bear adequate directions for use; and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such a manner and form as are necessary for the protection of the user. OTC transdermal products would be deemed to be misbranded since the labeling would fail to bear adequate directions for use or such adequate warnings against use that are necessary, if any, for the protection of the user.

NONPRESCRIPTION APHRODISIAC DRUGS

FDA recently published a final rule that will result in a ban on the sale of all nonprescription aphrodisiac drug products. The FDA drafted the rules after evaluating an expert advisory panel's report and considering public comments. The panel did not find evidence that any of these products are safe or effective. FDA agrees.

Relatively few aphrodisiac drug products are being marketed at this time, and no manufacturers of these products have commented on the proposal to ban them. Once the ban takes effect, manufacturers of these drugs would have to provide safety and effectiveness data on each individual ingredient before reintroducing the product for sale.

Among the ingredients present in many of the products are cantharides ("Spanish Fly"), estrogens, strychnine, yohimbine, fennel, mandrake anise, licorice, and zinc. While a number of foods contain many of these ingredients, foods are not covered in the final rule, unless labeled as an aphrodisiac.

FDA agrees with the expert panel that:

- Persons with sexual problems should not try to medicate themselves but should instead seek treatment by a medical professional.
- Serious health risks are associated with alleged aphrodisiacs, including cantharides.
- There is no conclusive scientific evidence demonstrating the effectiveness or safety of any of the plant materials that have been historically used for aphrodisiac purposes.
- Male sex hormones have a recognized influence on libido and sexual performance, but are powerful hormones with potentially serious effects and should be used only under a physician's supervision.

On a lighter note, this editor wonders what scientific testing methods were employed to evaluate the effectiveness of these products, and who are considered to be the "experts" in this area.

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when a label is "false or misleading in any particular." It is the Board staff's opinion that a prescription written for Darvon and filled with Propoxyphene that has a label "Generic Darvon," or "Darvon G," or "Darvon Rugby" would be misleading. One way to get the brand name drug on the label without being misleading would be to use the phrase "Propoxyphene used for Darvon".

Item 622 - Continuing Education Audit And Continuing Education Credit

Item 617 in the July Newsletter announced the continuing education audit of 250 pharmacists for their 1988 hours that is being conducted by the Board. As of the copy deadline for this Newsletter, all but four audited pharmacists met the Board's standard of ten hours with not more than half in correspondence courses. Those pharmacists who have not satisfied the continuing education standard have received a notice of hearing for disciplinary action on their license to practice. These hearings will occur at 2:00 p.m. on Tuesday, October 17, 1989, in the Board offices in Carrboro.

Please note that the Board's acceptance of continuing education has changed slightly this year. In prior years, courses for computer programs for operating systems in pharmacies were acceptable for half-time credit. For the 1990 renewal, such courses will not be acceptable for credit. Don't wait too long to get your CE credit for license renewal.

Item 623 - FAXWEB

On September 1, 1989, the Board began a Fax Network to disseminate important information such as FDA Class I Recalls or other material important to pharmacists. Class I Recalls are those in which there is a reasonable possibility that the use of or exposure to a violative product will cause either serious adverse health effect or death. There are two lesser categories of Recalls that are less serious and probably would not be forwarded on the Network, except in unusual circumstances.

The primary participants in this Network are hospital pharmacies with some other locations such as the Schools of Pharmacy and the North Carolina Pharmaceutical Association. As of this publication, there are 68 participants in the FAXWEB. While it would be natural to extend the Network to retail pharmacies, there is a paucity of FAX machines at those locations. Additional telephone networks from individual hospitals would also be a natural extension of this effort but, since the Board has no authority in this area, it would need to be voluntary.

The name FAXWEB was selected as descriptive of any effort information to transmit information by Fax machine throughout the state similar to a web woven by a spider. We want this web to catch the attention of pharmacists so that they can better serve the public.

Item 624 - Disciplinary Hearings And Pre-Hearing Conferences; Board Member Disqualification

When violation of statute or regulation by pharmacists is discovered, it is incumbent on the Board staff and/or the Board to consider the situation, review all the relevant facts, and pose of the matter. In some cases there may be offenses that be resolved by a letter of reprimand or admonishment from the Executive Director. Other cases can require a hearing before the Board or may be handled with a Pre-hearing Conference.

A Pre-hearing Conference is a procedure whereby a Member of the Board hears the case and makes a recommendation to the remainder of the Board as to its proper disposition. If the pharmacist agrees to the recommendation, it is then presented to the Board as a proposal for approval. To date, the Board has accepted the Member's recommendation in each case.

A Pre-hearing Conference can have two positive outcomes: first it can arrive at a decision that the pharmacist finds acceptable, and second it avoids a hearing before the full Board. If, for any reason, the matter must go to a hearing before the Board, it would be necessary for the Member who first heard the case to be disqualified from the hearing.

It is appropriate here to remind pharmacists that Board Members should not be contacted about matters that will be the subject of a disciplinary hearing. If Board members have been subjected to pressure about a particular case, they are required to disqualify themselves from any hearing on the matter.

Item 625 - Exam Schedule

At the Board's regular meeting in July, the members considered holding an additional exam in September each year. After discussing the matter, it was decided to plan for a September exam in 1990, in addition to the regular January and June dates. This decision will be finalized at a later date.

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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