January, 1990

North Carolina Board of Pharmacy

P.O. Box 459, 602H Jones Ferry Road, Carrboro, NC 27510 Published to promote voluntary compliance of pharmacy and drug law.

Item 626 - Disciplinary Actions

August: *Sandra Brown White*, Rural Hall. Indulged in the use of drugs to an extent that renders her unfit to practice pharmacy; failed to comply with the laws governing the practice of pharmacy and the distribution of drugs; failed to comply with the rules and regulations of the Board. License suspended indefinitely with specific conditions.

Hugh Alan Myers & Arthur's Pharmacy, High Point. Dispensing prescription drugs without valid prescriptions and refilling prescriptions without authorization. Pharmacy in violation by ... to prevent the events when the permit holder knew or ... have known the violations were occurring. License suspended one year, stayed five years with 14 day active suspension and other conditions. Permit suspended 30 days, stayed five years.

James Gary Shively, Kentucky. Indulged in the use of drugs to an extent that renders him unfit to practice pharmacy; a physical or mental disability that renders him unfit to practice pharmacy with reasonable skill, competence, and safety to the public; failure to comply with the laws governing the practice of pharmacy and the distribution of drugs; failure to comply with the rules and regulations of the Board. License revoked.

No September Board disciplinary actions. Meeting cancelled because of Hurricane Hugo.

October: *Barry Gene Wall*. Emergency action by the Board to summarily suspend license to protect the public health, safety, and welfare.

Eckerd Drugs, Winston-Salem. Permit holder negligent in the practice of pharmacy. Pharmacy reprimanded, which reprimand will be rescinded after a period of one year with conditions.

Steven Ray Noll and *Hometown Pharmacy*, Wilmington. Dispensing drugs without valid prescriptions. Permit holder's failure to prevent events when the permit holder knew or should have known the violations were occurring. License revoked, stayed for ten years on condition of 30 days active suspension and other conditions; permit revoked, stayed under similar conditions.

... 627 - Proposed Regulations

... notice accompanies this *Newsletter* concerning several ... regulations that the Board proposes to adopt. These cover important subjects, including home health care or sterile pharmaceuticals, nuclear pharmacy, prescription devices, pharmacist-manager responsibilities, and permits required for preceptor sites and examinations. Please note the time and date of the public hearing. If you wish copies of the proposals, please contact the Board office.

Item 628 - Law Book Available

A new and updated pharmacy law publication is now available from the Board at a charge of $5 to recover costs. Please send a check or money order for each copy desired and it will be mailed to you.

Item 629 - Disciplinary Actions Of Other Licensing Boards

From time to time the Pharmacy Board receives inquires about possible disciplinary actions involving physicians, dentists, nurses, etc. For your information, the telephone numbers of the respective licensing boards are listed below:

Board of Medical Examiners 919/876-3885
Board of Nursing 919/828-0740
Board of Dental Examiners 919/781-4901
Board of Optometry 919/284-3160
Board of Opticians 919/733-9321
Veterinary Medical Board 919/733-7689

The Drug Enforcement Administration's local office in Greensboro is also a number which might be useful from time to time. It is 919/333-5052 and its address is 2300 West Meadowview Road, Suite 224, Greensboro, North Carolina, 27407.

Item 630 - FDA Recalls

Periodically the Food and Drug Administration issues a recall of a product which is violative of federal statute or regulations. Using its Faxweb system, the Board of Pharmacy will relay all Class I recalls to hospitals and other places that are part of that system.

FDA recalls fall into three categories: Class I - A situation 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 - 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 or serious adverse health consequences is remote; Class III - A situation in which the use of, or exposure to a violative product is not likely to cause adverse health consequences.

continued on page 4

(Applicability of the contents of articles in the National Pharmacy Co
and can only be ascertained by examin

PRESCRIPTION DRUGS - NO EXPIRATION DATES

The Food and Drug Administration (FDA) periodically receives inquiries about the status of prescription drugs in containers (as supplied by the manufacturer or distributor) *with no expiration dates.* A recent pharmacy inspection revealed prescription drug containers without expiration dates, but with purchase dates from 1968 to 1978.

The following statement was provided by FDA's Clifford D. Broher, Chief of the Policy and Guidance Branch, Division of Manufacturing and Product Quality Center for Drug Evaluation & Research:

> There is no specific prohibition against using stocks of drug products without expiration dates if they were shipped from the manufacturer prior to March 28, 1979, the effective date of the Current Good Manufacturing Practice Regulations (Parts 210 and 211). This presumes the drug products were in compliance with the regulations in effect prior to March 28, 1979, which required that only drug products subject to degradation bear expiration dates.
>
> Notwithstanding the absence of a specific prohibition, *drug products ten years or older are most certainly suspect in regard to declared potency and would be in violation of Federal Law if used in that condition.* (Emphasis added.)

APPROVED DRUGS FOR UNLABELED USES

The practice of pharmacy is a comprehensive delivery of patient care and drug information. The pharmacist, as the drug knowledge expert, is continually called upon to evaluate information and make appropriate therapy decisions.

An issue that always arises is whether or not approved drugs can be used for unlabeled uses. In response to an inquiry made to the FDA, Stuart Nightingale, M.D., Associate Commissioner for Health Affairs, clarified the FDA's position on the issue. For the first time, the letter defined the distinction between promotion of approved drugs for unlabeled uses (for monetary gain) and the professional responsibility of the pharmacist.

> Your concern focuses on language in the October 1971 *Drug Bulletin* that states it is a direct violation of the Act for anyone in the chain of distribution to do anything that directly or indirectly suggests that an approved drug may be properly used for an unapproved use (i.e., uses for which it is neither labeled nor advertised).
>
> Your letters raise complex legal and policy issues. In essence, you ask whether the absence of the precise language you noted in the 1971 *Drug Bulletin* article on this subject indicates that the Agency's position on this issue has changed.

The statement you cite from the 1971 *Drug Bulletin* was taken *verbatim* from a 1971 *Federal Register* proposal that addresses drug labeling, Investigational New Drug Applications (INDS), legal responsibilities, and the practice of medicine. The specific passage that you cite elaborated the term "intended use" within this context. None of the referenced documents (the 1972 *Drug Bulletin*, the 1982 Drug Bulletin, or the 1972 *Federal Register* notice) were published to directly clarify the agency's position on promoting or disseminating information on the unlabeled use of an approved drug. However, the 1972 statements (the 1972 *Drug Bulletin* and the 1972 *Federal Register*) have been cited historically by FDA as agency policy on promotion. Accordingly, in response to the question posed in your December 19 letter, the language in the 1972 *Drug Bulletin* remains in effect as it applies to promoting the unlabeled use of an approved drug for commercial purposes.

Although the 1972 passage is still a correct statement of FDA policy in a general sense, it does not address an important element of the policy that is applicable to pharmacists. While a pharmacist's promotion of a drug for an unapproved use may result in the product becoming misbranded while held for sale by that pharmacist, the agency recognizes a distinction between promotion and the professional responsibility on the part of a pharmacist to share his knowledge with the community of physicians and consumers he or she serves.

The line between illegal promotion and providing information to consumers has, of course, always been a difficult one to draw. There are no regulations directly on point, and the agency has traditionally dealt with the issue by abstaining from taking any enforcement action where a pharmacist responds to an unsolicited request for advice within the expertise of the pharmacist. Were a pharmacist to actively promote an approved drug for an unapproved use, however, he or she would face the possibility of regulatory action on the part of FDA for misbranding a product they sell. FDA's policy has always been to prevent the promotion and commercial exploitation of approved drugs for unlabeled uses. Our intent has not been to inhibit or prevent scientific information exchange. A similar, but not identical, policy

is in place for drugs that are the subject of Investigational New Drug Applications (INDs). The IND regulations reflect the Agency's intent in prohibiting the commercial promotion of unapproved drugs while not restricting the full exchange of scientific information from scientific or lay media. Indeed, the agency has long recognized the valuable educational role played by pharmacists and other health professionals in disseminating this type of information.

FDA's recognition of this educational role on the part of pharmacists is similar to the educational role recognized by the Agency for pharmaceutical manufacturers who often distribute scientific studies or other data on their products containing information on unapproved uses in response to unsolicited requests for such scientific information.

Since FDA recognizes the states' responsibilities in regulating the practice of pharmacy, we remain available to assist when necessary to resolve specific cases that may arise in this complex area. To this end, FDA's Division of Drug Advertising and Labeling is presently developing guidelines that may be of value as a reference when determining promotion versus information dissemination activities.

GENERIC DRUGS

The recent discovery that some generic manufacturers have engaged in fradulent practices in an attempt to hasten the FDA's approval system, has had dramatic effects on the FDA and pharmacy. It has resulted in the indictment of three FDA employees on the charge of accepting illegal gratuities and has triggered a massive investigation of the generic drug manufacturers.

Although the findings to date are serious and raise public health concerns, an indemnification of the entire industry must be avoided. Dr. Carl Peck, Director of the Food and Drug Administration's Center for Evaluation and Research, states repeatedly, "I believe that the drugs that are marketed, both in the generic and brand name area, are both safe and effective, and that there are no unsafe or ineffective drugs on the market at the present time. I would give that advice to my mother and my father and my children, and to myself."

Updates will be provided on the FDA investigations and ıdings through your state board of pharmacy and these ıNational News Sections.

RECORDING VACCINATION INFORMATION

It has come to our attention from David R. Work, Executive Director of the North Carolina Board of Pharmacy, that federal statute sets forth certain requirements for practitioners when vaccines are administered. Federal law now requires each health care provider who administers a vaccine to record the following information in the person's permanent medical record:

1. The date of administration of the vaccine;
2. The vaccine manufacturer and lot number of the vaccine;
3. The name and address of the person administering the vaccine; and
4. Other pertinent information.

SURVEY OF PHARMACY LAW *AVAILABLE*

The *1989-90 Survey of Pharmacy Law* is now available from the National Association of Boards of Pharmacy. This survey of the 50 state boards plus Washington D.C. and Puerto Rico includes information on organizational, licensing, internship, and drug law. The NABP "Census of Pharmacy" has been included in this year's *Survey,* detailing:

- total number of licensed pharmacists by state;
- number of pharmacists practicing in community or hospital pharmacies;
- the number of pharmacists in the manufacturing or wholesaling sectors, teaching, and government;
- number of female pharmacists in each state;
- total number of licenses suspended, revoked, or reinstated;
- total number of licensed hospital, community, and chain pharmacies; and
- number of dealers licensed to sell OTC drugs.

Pharmacists who are contemplating reciprocating to other states and who are interested in learning about the licensure requirements in various states will find the publication useful. As in the past, A.H. Robins is providing copies to all last year pharmacy students free of charge.

The *1989-90 Survey of Pharmacy Law* can be ordered from the NABP Publications Desk, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068, at a cost of $20 per copy. Please send a check with your order.

continued from page 1

On one occasion last year it was reported to the Board of Pharmacy that a pharmacist had declined to participate in a Class I recall of a vitamin product with fluoride that could have produced death in some children. While it is shocking that a pharmacist would lack the perception to respond to a Class I recall, the Board staff feels obligated to include this information in this item. Pharmacists should understand that failure to respond to a request for a Class I Recall will initiate disciplinary proceedings before the Board. In addition, there is substantial liability exposure for any pharmacist or pharmacy that fails or refuses to positively respond to such a recall.

Item 631 - Limitation On PRN Refills

Regular questions arrive at the Board office regarding the length of time which prescriptions can be refilled. State statute at GS 90-85.32 explains the statutory presumption on prescriptions marked on PRN refill. It plainly states that such prescriptions shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified.

This means that prescriptions marked PRN, ad. lib. or other similar abbreviations can be refilled only one year after the date they are issued. Any refills after that date must be preceded by a new authorization. The Board has not specified whether such prescriptions should be brought forward in the prescription files and Board staff finds it acceptable to either indicate an update on the old prescription or bring it forward in the file.

It is the Board's opinion that prescriptions with specific numbers of refills can be refilled even if it is beyond the one year limitation on PRN prescriptions. For example, a prescription for a cortisone cream which is marked for six refills can be refilled six times even if such refilling goes beyond one year. It is also possible for prescribers to specifically mark prescriptions on PRN for three years. In that case, prescriptions so marked can be refilled for three years.

Item 632 - License Renewal

During the license renewal season, the Board is asked questions about continuing education. It is *not* necessary for licensees to submit CE certificates with their license renewal. All that is necessary is that the pharmacist list the courses completed and the total number of hours in the appropriate place on the license renewal form.

For your information, the Board does not accept pharmacy computer courses for continuing education credit this year.

Item 633 - Nationwide Pharmacy Manpower Survey Begins

In an effort to assure that there will be an adequate supply of pharmacists to serve the nation's future health care needs, the National Association of Boards of Pharmacy (NABP) and the American Association of Colleges of Pharmacy (AACP) have joined forces to co-manage the development of a national plan for ongoing pharmacy manpower data collection. NABP and AACP are working under the auspices of a national steering committee composed of representatives from 13 major pharmacy organizations. NABP Managing Director Beth W. Aylward, has been named Project Director.

The Steering Committee will utilize the services of the state boards of pharmacy to gather accurate and timely information on a continuing basis through their pharmacy licensure renewal procedures. The committee recognizes that the state boards are in the best position to collect the necessary data.

Initially, the data base information will include the pharmacist's name, address, social security number, date of birth, sex, and race. Pharmacists will also be asked to list their degrees in pharmacy and to state the number of hours spent per week in practice environments such as independent community pharmacy, chain pharmacy, hospital pharmacy, long-term care pharmacy, managed care pharmacy, industry, or other pharmacy activities, in each state in which they are licensed. The data base will also note if the pharmacist is not currently active in the profession.

All information collected for the data system will be held in strict confidence. "The collected data and the list of participating pharmacists will not be available for sale or commercial use," stressed Project Director Beth Aylward.

This is not the first time the profession has collected comprehensive pharmacy manpower data. NABP and AACP conducted Pharmacy Manpower Information Projects (PMIP) in 1973 and 1976. Eleven years later, that information is still being used by the Bureau of Health Professions to make its reports to Congress about the future of the profession. Pharmacy leaders are concerned that the old data is unreliable and does not reflect recent trends in the nation's health care delivery system. The increased popularity of ambulatory and home-based health care, the new high-tech drug development and delivery systems, more advanced computer technology and other automated systems, as well as the greater emphasis on patient information counseling have changed the face of pharmacy.

Funding for the Manpower Project comes from financial and in-kind donations from the member organizations of the Steering Committee, industry, and, in a large part, from the in-kind contributions of the individual state boards of pharmacy.

The initial data collection phase of the current project is expected to take two years to complete. Unlike the previous Manpower projects, however, this program will be updated on a regular basis in order to provide accurate information about the pharmacy profession. Each state board will establish a calendar for ongoing data collection, either every third or fourth year.

North Carolina will include Manpower survey information on its 1989 License Renewal Applications, which will be mailed in November. The North Carolina Board of Pharmacy encourages your participation in this very important nationwide project. Comprehensive pharmacy manpower information will help federal and state governments, educational institutions, and business and industry alike to more thoroughly evaluate trends in health care. This is the key to meeting the changing demands of our profession.

Once all of the initial information has been collected, we will update the records by sending questionnaires every four years. Additional information about the Manpower Data Collection Program is available from the North Carolina Board of Pharmacy, or from Beth Aylward, Project Director, at the National Association of Boards of Pharmacy at (708) 698-6227.

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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