



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 553 — Disciplinary Actions Of The Board

From March, 1987: *Marcus Cameron*, Sanford. Negotiated Plea resulting from Medicaid Fraud. License suspended sixty days, stayed three years with conditions.

Pre-Hearing Conference, July, 1987. *Edward Vaughn*, Carrboro. Unexplained inventory discrepancies of controlled substances; unable to produce biennial inventory of controlled substances; did not maintain a daily signed records of computer transactions as required by federal regulations; prescriptions for Schedule II controlled substances filled in excess of originally prescribed quantities. License suspended fifteen days, stayed two years.

July: *George Thomas Winters* and *Rexco Discount Drugs, Inc*, Denver. Dispensing controlled substances to third parties without a valid prescription when there should have been a question as to their validity. License suspended one year, stayed five years with conditions.

August: *Donald Larry Glock* and *Charlotte Memorial Hospital and Medical Center*, Charlotte. Practicing pharmacy without a valid license. License suspended ninety days, stayed five years with conditions. Charlotte Memorial Hospital and Medical Center, reprimand with conditions.

No disciplinary actions in September or October.

Item 554 — Pharmacist Recovery Network

The Pharmacist Recovery Network (PRN) is a group of pharmacists throughout North Carolina who help other pharmacists overcome personal problems which may impair their health, professional status or employment. If you, a pharmacist, or a pharmacy student you know has a problem related to alcohol, drug abuse or other problems which impede their ability to function, call 1-800-852-7343. You may leave your name and number and your call will be returned promptly. Alternatively, you may ask for the name and phone number of the nearest PRN volunteer, and call him or her directly. If you like more information about the PRN Program you may write to Dennis F. Moore, Pharmacist Recovery Network, P.O. Box 151, Chapel Hill, North Carolina, .7514. Strict confidentiality will be maintained.

Item 555 — Messages From Inspectors

During their normal inspection visits Board inspectors have noticed that some pharmacists are neglecting to mark the original

prescription as "void" or its equivalent. This is a reminder that compliance with Board regulation .1806 requires that transferred prescriptions be so marked on their original or indicated in a computer system to prevent refilling. Prescriptions for controlled substances can be transferred only one time while prescriptions for other drugs may be transferred multiple times within authorized refill limits. Transfers must be from pharmacist to pharmacist and not by accessing a common data base.

Board regulation now requires when using a manual record system, that initials of the pharmacist must be on the prescription document. Please note that this applies to new as well as refilled prescriptions. Computer systems need to indicate the pharmacist who filled or refilled the prescription in each case. This is an appropriate place to note that the use of a computer does not eliminate the necessity for proper and orderly prescription files. While it is not necessary to refer to the original document for refills with a computer system, the federal prescription filing requirements using a two or three file system still apply. The name of the pharmacist who fills the prescription must be on the label. Initials are not enough.

Item 556 — Notice To Pharmacist-Managers

Pharmacist-managers have a responsibility to report to the Board certain events concerning their pharmacy. Whenever a pharmacy changes its location, changes its name or discontinues business the pharmacist-manager should report these changes to the Board office in writing, including the DEA registration number of the pharmacy.

Item 557 — Law Affects Animal Rabies Vaccine

A statute enacted by the 1987 General Assembly restricts the sale of animal rabies vaccine. It does not affect the sale of human diploid cell vaccine.

As of October 1, 1987 only licensed veterinarians, certified rabies vaccinators and persons engaged in the distribution of animal rabies may possess animal rabies vaccines. Distributors of animal rabies vaccines may distribute, sell and offer to sell animal rabies vaccine only to licensed veterinarians and certified rabies vaccinators. A certified rabies vaccinator is a person appointed by a local health director to administer animal rabies vaccine.

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy, C and can only be ascertained by exami

GENERIC DRUGS AND THE ABBREVIATED APPROVAL PROCESS

Managed health care, consumer awareness of generic drugs and other socio-economic factors are increasing the use of generic drugs. What was once only a novel idea has now become an important consideration before almost any prescription is dispensed. The pharmacist, when evaluating if a generic substitution should be made must follow state substitution laws, use appropriate drug formularies and understand what equivalence means.

Drug Price Competition And Patent Term Restoration Act Of 1984

The Drug Price Competition and Patent Term Restoration Act of 1984 mandated for all generic drugs an abbreviated application procedure, one not requiring the sponsor to repeat safety and effectiveness studies already conducted by the pioneer drug company. Instead, the sponsor of a generic drug is required to demonstrate that the product is bioequivalent to the pioneer product and the drug will be manufactured in accordance with the same standards.

During the 12 months from October '86 to October '87 the FDA has approved 660 abbreviated new drug applications (ANDAs). Most of the approved drugs have been for generic versions of post-1962 drugs. Before the enactment of the 1984 law, the average approval rate was approximately 350 ANDAs annually.

The Process

The 1984 law had a dramatic impact on pharmacy and sparked an unprecedented interest in the quality and equivalence of generic drugs. Over the past three years the FDA has devoted considerable effort to making sure that the quality safeguards provided through the ANDA review procedures and policies are fully understood. Criticism of the process has centered on the review criteria for bioequivalence used by the FDA and claims of actual harm alleged to have occurred to patients as a result of their having taken generic drugs.

The FDA contends that these criticisms are not valid. The FDA's review of generic drugs is based on its longstanding requirement that a generic solid oral dosage drug product must be shown to have a rate and extent of absorption that from a statistical standpoint, will not differ from an innovator's product by more than 20 percent. In regard to claims of harm, the FDA maintains that they have not seen a documented instance that showed a generic product that it rated as therapeutically equivalent to be, in fact, not bioequivalent.

The Final Decision

As the pharmacist, you are responsible for safe and rational drug therapy and realize that not all generic drug products are therapeutically equivalent to their brand name counterparts. An understanding of your state drug substitution laws and the FDA's

"Orange Book" (Approved Drug Products With Therapeutic Equivalence Evaluations) will assure this. The "Orange Book" currently contains over 8000 approved prescription drug products of these, approximately 6000 are multi source drugs with about 5000 of the 6000 evaluated as therapeutically equivalent by the FDA. Care must be exercised in using the List. Evaluations of therapeutic equivalence for prescription drug products are based on scientific evaluations by the FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of the FDA, to have an equivalent therapeutic effect and no greater potential for adverse effects when used under the conditions of their labeling. However, these products may differ in other characteristics such as color, flavor, shape, packaging, preservatives, expiration date, and, in some instances, labeling. Further, a few differ in dosing schedules. In this case, bioequivalence means that the different brands produce equivalent blood levels when each is taken in accordance with its labeling ("package insert"). If products are substituted for each other, certain patients may be confused by differences in color or shape of tablets. This may require explanation to the patient. Different flavors may make a product more or less acceptable to an individual patient. Possible allergic reactions to a coloring or a preservative ingredient are additional considerations in prescribing and product selection. In addition, pharmacists must be familiar with the expiration dates and labeling conditions for storage of reconstituted products to assure that patients are properly advised when one such product is substituted for another. When such characteristics of a specific product are important in the treatment of a particular patient, a physician can always specify that a particular manufacturer's product be dispensed. It is important to remember that the pharmacist, in concert with the physician and patient, must decide whether a brand-name or generic product is dispensed based on knowledge of the special needs of the patient.

SURVEY OF PHARMACY LAW AVAILABLE

The 1987-88 *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 practicing in community or hospital pharmacies
- manufacturer or wholesaler, teaching and government
- number of female pharmacists in each state
- total number of licenses suspended, revoked, reinstated
- total number of licensed hospital, community and chain pharmacies, and
- number of dealers licensed to sell OTC drugs

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed. Consulting the law of such state or jurisdiction.)



Pharmacists contemplating reciprocating to other states and who are interested in learning the licensure requirements in various states will find the publication useful. Copies are being provided to all last year pharmacy students free of charge by A.H. Robins.

The 1987-88 *Survey of Pharmacy Law* can be ordered through 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.

1988 USAN AND THE USP DICTIONARY OF DRUG NAMES PROVIDES FDA ESTABLISHED NAMES

The 1988 edition of the United States Adopted Names (USAN) and the United States Pharmacopeial Convention, Inc., (USP) Dictionary of Drug Names have been published by the USP.

The dictionary is the authoritative list of established names for drugs in the USA. The 1988 edition is completely updated and is in one volume instead of two. After two editions in which the dictionary provided three separate lists of names, the 1988 edition returns to the original format of a single main list that includes all names in alphabetic sequence.

USAN are adopted by the USAN Council. This council is co-sponsored by the American Medical Association (AMA), the American Pharmaceutical Association (APhA), and the Pharmacopeial Convention, with participation by the U.S. Food and Drug Administration (FDA).

The FDA has established that interested parties may rely on the dictionary for the established names for any drug in the United States.

COUNTERFEIT DRUG CASES

The following information on counterfeit drug cases was first printed in the Canada October 1, 1987 FDA Talk Paper. It was later distributed to all state health officers, state drug officials, and boards of pharmacy by Heinz G. Wilms, director, division of Federal-State Relations.

Counterfeit drugs are unauthorized copies of legitimate drugs that bear, without authorization, the tradename or other marks of the authentic product. Some may have the same active ingredients; others may not. Their manufacture and distribution is prohibited under Section 301(i) of the Food, Drug and Cosmetic Act.

The following may be used to answer questions about recent drug counterfeiting cases:

FDA believes legitimate drugs in U.S. commerce are of high quality. The sale of counterfeit drugs is an unusual occurrence. The agency has investigated all reported instances of drug counterfeiting and has taken steps to halt, eliminate and prevent, as well as punish, this activity.

Because the cases of counterfeiting to date have usually appeared to be with drugs brought into the U.S. under the guise of being returned U.S. exports, the agency has established controls to monitor all entries into this country of 'American Goods Returned' — goods identified as having been made by an American Drug Company, shipped abroad and, for whatever reason, returned. In cooperation with the U.S. Customs Service, FDA is checking to be sure there is proof that the 'returned' goods can be shown to truly have originated in the U.S. and to be pure and potent.

UPDATE ON EXPERIMENTAL AIDS THERAPIES AND VACCINES

The fight against AIDS has been designated by President Reagan to be the nation's number one health priority. FDA is one agency among several in the Public Health Service and the rest of the Department of Health and Human Services that are leading the fight against this disease. The following information is being provided to help answer questions about potential AIDS therapies and vaccines now being studied.

New Drug Applications (NDA)

FDA has given all potential AIDS drugs a 1-AA classification in the Center for Drugs and Biologics's drug priority classification system. This assures them the very top priority in the agency's review process. The agency's expedited review of zidovudine (marketed as Retrovir and more commonly known as AZT), which became the first approved treatment for AIDS, served as the prototype for the new 1-AA classification.

The agency reviewed and approved zidovudine's new drug application (NDA) in less than four months after its submission.

There are currently no new drug applications for AIDS drugs pending before the agency.

Investigational New Drug (IND)

FDA has approved more than 100 on-going human studies to test potential AIDS drugs. In many cases, the FDA has granted permission to begin these trials within five days of receiving an application.

At present these studies involve nearly 40 different anti-viral or immuno-modulating drugs (anti-virals act directly against the virus while immuno-modulators are intended to boost the body's own defense system and combat the disease). In several cases, separate human trials are being conducted with the same proposed AIDS therapy to test its effect on different AIDS conditions. In a few cases, two or more experimental therapies are being used in combination.

Under the Freedom of Information Act, FDA employees are prohibited from publicly discussing or acknowledging the status of drugs currently under agency review.

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Item 558 — Permits Issued To Dispensing Physicians

The 1987 session of the General Assembly amended the Pharmacy Practice Act to require physicians who dispense drugs for a fee or other charge to obtain a permit from the Board of Pharmacy. Dispensing physicians must follow all packaging and labelling requirements which apply to pharmacists as well as the laws governing the distribution of drugs.

In other words, physicians who dispense drugs for a charge will need to follow the same rules that apply to pharmacists. The Board requires a pharmacist to personally appear at a staff meeting to receive a pharmacy permit and the same will be required of physicians who apply for a permit. In order to facilitate the beginning of this process the Board staff held a series of meetings to issue physician dispensing permits in eight cities throughout the state in December. The issuing of permits in the future will occur twice monthly in the Board office in Carrboro when pharmacy permits are issued.

Item 559 — Drug Information

North Carolina is fortunate to have three universities with a drug information service available to health professionals such as physicians and pharmacists. If you have questions about drugs that are not answerable at your place of practice, you can contact these services who may be helpful. These services are, in alphabetical order, Campbell University, 800-327-5467; Duke University, 919-684-5125; UNC, 919-966-2373.

Item 560 — Note To Local Associations On Continuing Education

Several members of the Board have consistently supported the concept of pharmacists being able to obtain their continuing education at local association meetings. A procedure for approval of programs offered by these associations has been established and involves submission of information to a committee at least one month prior to the program date. It is important to note that the committee will not consider retroactive approval and inquiries should be made to P.O. Box 151, Chapel Hill, North Carolina, 27514.

Item 561 — Board Meeting On March 22nd

The Board will hold its regular meeting on Tuesday, March 22, 1988 at its office in Carrboro. Monthly meetings of

the Board are open to the public and pharmacists are encouraged to attend. Disciplinary actions involving pharmacists occur at some of these monthly open meetings. The only part of these meetings which is not open to the public is the executive session at the end of a hearing when members decide on the disposition of a case.

Item 562 — Board Member Election

At least one member of the Board is elected annually from ballots distributed with the April Newsletter. Two seats are involved in this year's election, one from the north central now held by Evelyn Lloyd and the other from the west now occupied by Harold Day. The election is for a three year term to begin in the Spring of 1989. President Randall will appoint a committee from each region in January which will submit the names of at least two pharmacists from the region by March when the ballot will be finalized.

Item 563 — Public Hearing On Proposed Regulations

The Board will hold two public hearings on proposals which would amend Board regulations on Prescriptions: Receiving and Dispensing, section .1804 and part of the regulation on permits, section .1601(g) which addresses prescriptions by mail. There is also a proposed new regulation on procedures to follow in an emergency for suspension of a license and another proposal on revision of certain procedural regulations. The hearing will occur at 2 p.m. on Tuesday, February 16, 1988 at the Institute of Pharmacy, Rosemary and Church Streets in Chapel Hill and at 9:30 a.m. on Friday, February 5, 1988 in the Convention Center, Mid Pines in Southern Pines, North Carolina. The Chapel Hill hearing is intended for comments from people or groups within the state while the Southern Pine meeting is expected to draw comments from national organizations. A copy of the proposals may be obtained by writing or calling the Board office.

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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