



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 403—NEW PHARMACY PRACTICE ACT

The most significant event in North Carolina Pharmacy during the last 100 years is the enactment of the Pharmacy Practice Act, effective July 1, 1982. Many people helped mold this law including the Committee which developed the first proposal, beginning their deliberations in 1978. Members of this Committee were William H. Randall—Chairman; Fred Eckel—Vice/Chairman; Keith Fearing; William R. Adams; Ernest Rabil; and alternate member William Whitaker Moose. There is no doubt that these pharmacists deserve credit for the many days of effort over several years necessary to develop the original proposal. Staff from the Board, Association of Institute of Government served as resources for the Committee. The final persuasion for passage occurred in the June, 1982 session of the General Assembly with a joint effort by officers and executives of the North Carolina Pharmaceutical Association and the North Carolina Merchants Association.

Significant changes in pharmacy law have occurred and one area which has prompted many inquiries is that of PRN refills. Several questions have arisen regarding the change in status of PRN refills on prescriptions as the result of the new Pharmacy Practice Act, effective July 1, 1982. The pertinent phrase in the statute is "Prescriptions marked PRN shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified." More than 20 other states have enacted a similar requirement.

Until advised otherwise, pharmacists should consider all prescriptions marked PRN which are more than one year old as in need of confirmation with or re-issuance by the prescriber. As of this time the Board has not ruled on whether it is necessary to bring a prescription for non-controlled drugs forward in the file. Under these circumstances pharmacists could note prescriber approval for continuance of the drug on the document or update the prescription, whichever best fits their circumstances.

The phrasing of the statute also seems to allow prescription refills up to a specific number of specific date. For example, a prescription marked for 5 refills could be refilled to that limit even if past one year. Also, a prescription marked "PRN for 18 months" would be valid for that 18-month period specified. Obviously the statements on this page are limited by federal and state regulations which absolutely precludes refilling prescriptions for controlled substances beyond 6 months or 5 refills if authorized. Pharmacists still need to exercise some professional judgment in filling and refilling prescriptions which might be inappropriate for whatever reason.

For the first time in North Carolina, the Practice of Pharmacy is

now defined. The pertinent part of the current Act states that it "means the responsibility for interpreting and evaluating drug orders including prescription orders; compounding, dispensing and labeling prescription drugs and devices; properly and safely storing drugs and devices; maintaining proper records; and controlling pharmacy goods and services. A pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses and significant problems of drugs and devices; assess, record and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record and report drug therapy and device usage; perform drug utilization reviews; and participate in drug and drug source selection and device and device source selection. . . ."

A prescription order is now defined as "a written or verbal order for a prescription drug, prescription device, or pharmaceutical service from a person authorized by law to prescribe such drug, device or service. A prescription order includes an order entered in a chart or other medical record of a patient." This should ease the paper-work burden of nursing home pharmacists but does not relieve them from keeping prescription records.

Board members, 5 pharmacists elected by all licensed pharmacists in the state and 1 public member appointed by the Governor, serve three year terms. No member may serve more than 2 complete consecutive three year terms. Pharmacist members are currently elected from geographic areas in a statewide election and candidates may be nominated by a petition of ten pharmacists licensed in the state.

Pharmacists are now required to notify the Board of a change of mailing address or change of employment within 30 days and pharmacist-managers need to notify the Board of any personnel change in the pharmacy within 30 days.

The Board can now issue regulations on the filling and refilling of prescriptions as well as the transfer of prescriptions from one pharmacy to another. Pharmacists are reminded that there is **no provision for prescription copies or transfers** at this time in North Carolina. No proposals are under current consideration but if you have any suggestions please forward them to the Board office.

By law, pharmacists in hospitals now have access to patient records in the course of their practice and need to make appropriate entries in these records. The new statute places an affirmative duty on hospital pharmacists or those in any health care facility to make "appropriate entries" in patient records. This is a substantial and serious duty which should be of concern to all affected pharma-

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National Pharmacy

STARCH BLOCKER UPDATE

Since FDA's July 1 announcement that the group of products popularly known as "starch blockers" are drugs requiring premarket approval under the Food, Drug and Cosmetic Act, some manufacturers and distributors have stated publicly that they intend to continue marketing. News media reporters and consumers are being confused by intentional dissemination of the following five *incorrect statements* about the status of starch blocker products: 1) FDA has changed its mind and reversed its July 1 decision that starch blockers are drugs. 2) FDA's July 1 announcement was only a request for voluntary action that would result in no legal or regulatory consequences if ignored. 3) Promoters of starch blockers who are plaintiffs in pending legal actions are exempt from compliance with FDA's July 1 decision. 4) Individual promoters have reached agreements with FDA which allow them to continue to market their particular starch blocker products. 5) Particular starch blocker products are exempt from FDA's July 1 ruling because they are made from a different kind of bean or alternative raw ingredient material.

The above statements are all **false**. 1) FDA still considers all starch blockers to be unapproved new drugs which may not be legally marketed. 2) FDA will take regulatory action against products and/or companies, if necessary, to ensure compliance and to protect the public health. 3) Although 19 plaintiffs have filed 3 lawsuits (2 in Chicago, 1 in New York City) asking federal courts to declare their starch blocker products to be foods, the filing of the lawsuits is not a license to violate the law. 4) and 5) No exemptions exist that allow marketing for any starch blocker product.

Shipment in interstate commerce and the sale after receipt in interstate commerce of starch blockers are illegal. Retail stores that continue to sell or advertise starch blockers could subject themselves to civil suits. Since July 1, FDA has received an increasing number of adverse reaction reports associated with starch blockers, including some requiring emergency room hospitalization. The most serious of these are being investigated by FDA field personnel.

At least 263 starch blockers manufacturers and distributors have been sent a letter by FDA requesting market discontinuation. Most of the companies have responded and most responses indicate the intention to discontinue marketing, although some companies have linked their discontinuance to the outcome of the pending legal actions. FDA is preparing its response to these legal challenges.

DEVICES ARE REPORTABLE TOO

Medical devices, laboratory products, dietary supplements and biologicals may also develop quality problems. Pharmacists encounter many of these products in their practices and they are in an excellent position to observe product quality and problems. The products fall under the jurisdiction of a myriad of government agencies and it can be difficult to determine who is responsible for such varied products. The Practitioner Reporting System of the U.S. Pharmacopeial Convention can simplify reporting such problems. Call 800-638-6725 (in Maryland call collect 301-881-0256) to report a problem or for additional information. There's no charge for the service and reporter anonymity can be maintained.

ARE YOU GETTING THROUGH TO PATIENTS?

This article appeared in "Wellcome Trends in Pharmacy", Vol. 4 No. 7, August 1982. "If you've been wondering whether your advice on health matters gets through to patients, the answer is an unqualified "yes," according to a recent study. Community pharmacists can be effective educators, and can modify patients' health styles and their attitudes toward health.

These important findings come from the American College of Apothecaries here, whose Research and Education Foundation undertook the project entitled "Effectiveness of Education Provided By the Community Pharmacist in Modifying Patron Attitudes and Behavior Toward Health."

In the study, a community pharmacist/researcher provided health style education and recommendations to improve health style to randomly selected community pharmacy patrons. His advice included areas of health such as tobacco and smoking, alcohol and drugs, exercise and fitness, stress, eating habits and safety.

Pharmacists' recommendations "significantly modified" patient's behavior in each category, and resulted in the adoption of "positive health behavior." The study concludes that health education provided by a community pharmacist is a positive force in modifying consumer behavior and attitudes, and that these improvements were observed following pharmacist consultations."

NEW REFERENCES NOW AVAILABLE

The United States Pharmacopeial Convention, Inc. has recently released the 1983 editions of the USP/DI Volumes I and II and the USAN and the USP Dictionary of Drug Names.

The USP/DI (United States Pharmacopeia Dispensing Information), has, in the 1983 edition, been divided into volumes one and two. Volume I provides drug information for the health care provider while Volume II provides advice for the patient. These references have proven to be invaluable to the pharmacist and are now being required as part of the reference library in a number of states.

The 1983 edition of USAN and the USP Dictionary of Drug Names provide brand names, generic and chemical names, graphic and molecular formulas, molecular weights, and other information on more than 18,000 drug name entries. Copies of the USP/DI and of the USAN and USP Dictionary of Drug Names can be obtained by contacting the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

CAMPAIGN SET TO SUPPORT USE OF SAFETY CAP

Since the introduction of child resistant closures by the Consumer Product Safety Commission, accidental poisonings have been reduced by 50%. CPSC and Washington, DC-based Closure Manufacturer's Association now are seeking to alert adults to the life-saving potential of child resistant closures. A series of public service announcements will be carried by many radio stations across the country in order to encourage the continuing support of the adult public of child resistant closures and also encourage them to request products sealed with child resistant closures when purchasing products covered by the CPSC requirement.

Compliance News



FDA PUBLISHES 3rd EDITION

FDA has recently announced the forthcoming availability of the third edition of FDA's Approved Prescription Drug Products With Therapeutic Equivalence Evaluation. This new edition will continue to list currently marketed prescription drug products which have been approved for both safety and effectiveness by the Food and Drug Administration. This list will be of great value not only to large purchasers of drugs, such as hospital buying groups, but also to community pharmacists who, of course, will want to dispense only those drug products approved by FDA.

In addition, the publication contains therapeutic equivalence evaluations for multiple source drug products. These evaluations have been prepared to foster containment of health care costs and to serve state health agencies in the administration of their drug product selection laws. This publication will be available beginning in October from: Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

FDA PROPOSES TO WITHDRAW APPROVAL

On August 9, 1982 the Food and Drug Administration proposed to remove Phenacetin from various prescription and OTC pain medications because its prolonged or abusive use can cause serious injury or death associated with urinary tract and kidney disorders.

Under the FDA notice manufacturers of any drug product containing Phenacetin would be required to reformulate their products to delete Phenacetin or replace it with another analgesic on or before August 10, 1983. After that date, the marketing of any drug product containing Phenacetin that is not the subject of a pending hearing request will be regarded as unlawful.

Manufacturers requesting a hearing on the FDA proposal must do so on or before September 9, 1982. FDA's action was taken in response to recommendations from its Advisory Review Panel On Over-the-Counter Internal Analgesic And Antirheumatic Products. In the opinion of the panel the evidence relating Phenacetin to severe renal disease now derived from a world body of published reports so numerous and varied in design that the possibility of coincidental association is negligible and requires that Phenacetin be removed from the OTC drug market.

Most of the products that contain Phenacetin lend themselves to ready reformulation. Many have already been reformulated in response to the panel's report. Phenacetin is generally easily replaced by either aspirins or acetaminophens, which have similar analgesic and antipyretic qualities.

FDA ANNOUNCES NEW DRUG STATUS OF OTC COMBINATION PRODUCTS CONTAINING CAFFEINE, PHENYLPROPANOLAMINE AND EPHEDRINE

In a *Federal Register* announcement of Friday, August, 13, 1982 the Food and Drug Administration announced that it has determined that combination drug products consisting of Caffeine, Phenylpropanolamine and Ephedrine are new drugs and as such are required to be the subject of an approved new drug application (NDA). FDA has concluded that this combination, available over-the-counter and typically labeled for use as a nasal decongestant,

bronchodilator, and stimulant, is not included in the OTC Drug Review. FDA further states its conclusion that these products present a potential hazard to health. In providing the notice FDA revoked any prior advisory opinion that would preclude enforcement.

The *Federal Register* announcement indicated that "As a general rule, FDA has deferred new drug enforcement actions with respect to products included in the ongoing OTC Drug Review. In the agency's view, however, this triple-combination product is not the kind of product that is, or was ever intended to be, included in the OTC Drug Review. No evidence on the safety or effectiveness of the triple combination was submitted to the Review. In addition to having no known medical rationale, the triple combination has a highly suspect marketing history suggesting that it is frequently used to mimic and capitalize on the market for controlled substances.

Although individual active ingredients of this triple combination, at certain levels and for certain indications, alone and in some combinations are being reviewed in the OTC Drug Review, the agency has concluded that the triple combination is not included in the Review. Any prior statements by FDA employees suggesting that the triple combination is included in the OTC Drug Review are incorrect and are hereby revoked.

The agency also believes that this triple combination presents a potential health hazard. The combination of caffeine, phenylpropanolamine, and ephedrine has been marketed and promoted as a product capable of producing effects similar to those produced by controlled substances, and has been widely misused and abused. Even when taking as indicated in its labeling, however, this combination drug product is known to cause excess central nervous system stimulation that could have adverse physiological consequences. Further, the combination of these three ingredients is irrational and without medical justification; the concomitant symptoms of nasal congestion, asthma, and the need for stimulation at the same time does not occur in any significant patient population. Nor has ephedrine been shown effective as a diet aid. Thus, because of this potential health hazard, even if the combination were under review as part of the OTC Drug Review, enforcement action against the triple combination as a new drug would be appropriate.

Therefore, because products containing the triple combination of ingredients, i.e., caffeine, phenylpropanolamine, and ephedrine and/or their salts, are new drugs and no approval of an application filed pursuant to section 505(b) of the act is effective for such drugs, nor is a notice of claimed investigational exemption pursuant to section 505(i) of the act and 21 CFR 312.01 on file, shipment of these products in interstate commerce violates section 301(d) of the act (21 U.S.C. 331(d)). Further, under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), these drugs are misbranded in that their labeling fails to bear adequate directions for use and they are not exempt from such requirements under 21 CFR 201.115 because they are unapproved new drugs. Shipment of these drugs in interstate commerce and their manufacturer from components received in interstate commerce violate section 301(a) and (k) of the act, respectively. Persons engaging or participating in or causing the manufacture or shipment of these drugs are subject to regulatory action, and the drugs themselves are subject to seizure under section 304 of the act (21 U.S.C. 334)."

cists. If you receive requests to release records or provide information on prescription records in a pharmacy you need to refer to the revised Act. This is covered in G.S. 90-64 which contains 3 subsections and 14 parts stating the specific circumstances when records can be released. Reproducing the section in this publication would consume too much space.

Prescriptions need to be kept for 3 years and admission to the licensure examination now requires that a candidate be a graduate of an accredited school of pharmacy.

Devices are defined in the new statute and, unless a pharmacy permit exists for a location, a place which dispenses devices to patients must have a device dispensing permit from the Board.

The Board now has the authority to require a pharmacist to obtain up to 10 hours of continuing education to renew their license. No proposals are now being considered by the Board and we would appreciate comments from pharmacists.

The statute provides for the Board to adopt regulations on unit dose medication systems and allows the regulation of unique pharmacy practice. The Board has not adopted a definition for unique pharmacy practice.

The section on Disciplinary Actions for pharmacists or pharmacies was rewritten in contemporary language and no significant changes were made. Pharmacists are reminded that negligence was added as a ground for discipline by the Sunset Commission in June of 1981 and it is retained in the new Act. Violation of the Pharmacy Practice Act is a misdemeanor.

ITEM 404—DISCIPLINARY ACTIONS

June: A pharmacist-manager from Burlington appeared before the Board to respond to charges of dispensing controlled substances without a prescription -- Dilaudid[®], Quaalude[®] and Percodan[®]. Testimony, including tape recordings of purchases with a forged prescription by an informer, was presented to the Board. The pharmacist claimed poor hearing, now wears a hearing aid, and that he only dispensed the drug to prevent the woman from buying the drug on the street. An audit revealed no significant shortages and the Board issued a 45-day active suspension with a 5 year probation.

Two pharmacists from Williamston appeared to respond to charges of failure to keep records of controlled substances in the case of the pharmacist-manager and habitual use of drugs in the case of the other pharmacist. The problem was revealed when a customer complained that "lonamin"[®] dispensed at the pharmacy was not effective. Analysis revealed that the drug dispensed, which closely resembled lonamin[®] in appearance, contained caffeine and phenyl propanolamine. Further investigation produced a voluntary statement from the second pharmacist that she had replaced the lonamin[®] in the pharmacy with a non-prescription substitute and consumed the original product. She admitted personal use of a number of other drugs but there was no evidence of replacing other drugs in the pharmacy or diversion to others for consumption. She said she was under great pressure from marital problems, family responsibilities for a parent with a terminal illness and her support of other brothers and sisters. The Board issued a 2-year probation under conditions including unannounced urine tests and the Board dismissed charges against the pharmacist-manager.

July: A pharmacist-manager from Denver appeared to respond to charges of filling forged prescriptions. Testimony of the person who presented the prescriptions indicated that 22 were forged. He is a local resident and had been a customer at the pharmacy prior to submitting the forgeries. He has paramedical training, works for a local rescue squad and became addicted after an injury which was

treated with controlled substances for pain. Other evidence was available indicating that many, if not all, of the alleged forged prescriptions had actually been written by physicians. It was the decision of the Board to dismiss the charges. The Board also proceeded to dismiss charges in similar cases against pharmacists and pharmacies in Maiden, Charlotte and Lincolnton which relied on similar evidence.

ITEM 405—BOARD ELECTION RESULTS

Ms. Evelyn P. Lloyd of Hillsborough prevailed in the recent election for a seat on the Board from the North Central part of the State. Evelyn will become a member of the Board after she is commissioned by the Governor and takes the oath of office. She will succeed Mr. James A. Way, Jr., of Winston-Salem who will serve until April 28, 1983 or until Ms. Lloyd is commissioned and sworn in as the first female member of the Board. Other Board members are William R. Adams, Jr., Wilson; Harold Vann Day, Spruce Pine; William Whitaker Moose, Mt. Pleasant; William H. Randall, Jr., Lillington and Joseph B. Roberts, III, Gastonia.

ITEM 406—PHARMACY CALENDAR

Enclosed with this issue of the Newsletter is a Pharmacy Calendar. It notes Board meetings and exams, State Association meetings, School of Pharmacy activities, national pharmacy organization meetings and some sporting events. Your comments would be appreciated.

ITEM 407—NOTICE OF REVISIONS OF BOARD RULES AND REGULATIONS

This is a notice of a public hearing scheduled for 10:00 a.m. on Wednesday, November 17, 1982 in Board offices at 209 Carr Hill Mall in Carrboro for the purpose of revising the Board's Rules and Regulations. The primary purpose of the hearing will be to revise current regulations so that they will correspond to the Pharmacy Practice Act effective July 1, 1982. Other changes or new regulations may also be considered and a specific proposal will be available from the Board office on or before October 27, 1982.

ITEM 408—CHANGE IN BOARD MEETING DATES AND LOCATION

The Board has changed its meeting in May of 1983 to Tuesday, May 10th to avoid conflict with the Annual Meeting of the National Association of Boards of Pharmacy. The June, 1983 meeting will be held with the State Pharmaceutical Association convention in Boone on June 21, 1983.

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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