



North Carolina Board of Pharmacy

P.O. Box 459, 620H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 652 – Election Results

The ballots for the Runoff Election were counted on August 20th at the Board's office in Carrboro. The results are Bruce Canaday 737 votes and William H. Randall 1,381 votes.

On August 21st, the Board of Pharmacy Elections certified the results as final, and Mr. Randall will begin serving a five-year term in the Spring of 1991.

Item 653 – Disciplinary Actions

May: *Justin Benfield, Concord.* Substituting Amitriptyline for Elavil. Official Board Reprimand.

June: *William T. Rhodes & Red Springs Drug Company, Red Springs.* Failure to renew pharmacist license and pharmacy permit while continuing to operate the pharmacy and practice pharmacy and failure to display current license and permit renewals; indulgence in the use of drugs. License suspended 90 days, stayed five years with specific conditions. No action on pharmacy permit.

Connie Mac McGee, East Bend. Misfilling prescription orders. License suspended indefinitely, stayed indefinitely with conditions.

Item 654 – License and Permit Renewal

This *Newsletter* has been mailed with the application for renewal of your license to practice pharmacy. Your license expires on December 31st of this year and needs to be renewed in a timely manner. Every year there are some pharmacists who are close to the deadline, even with a grace period, and 1990 had some who were exceptionally tardy.

After discussing the matter with the members, the staff brought two cases to hearings in front of the full Board. The results of one are printed in the disciplinary section of this *Newsletter*. Another case will be reported in the January *Newsletter*.

During these hearings, it was pointed out to pharmacists that their malpractice insurance probably would not cover them for actions which occurred after their license had expired. This should be a sufficient reminder to renew your license or permit on time.

Item 655 – To Tax or Not To Tax, That is the Question

Several devices and prescription drugs are exempt from the North Carolina Sales and Use Tax. G.S. 105-164.13 exempts the following items from the North Carolina Sales and Use Tax:

Therapeutic, prosthetic, or artificial devices, such as pulmonary respirators or medical beds . . . that are sold on the written prescription of a physician, dentist, or other professional person licensed to prescribe, and crutches, artificial limbs, artificial eyes, hearing aids, false teeth, eyeglasses, ground on prescription of a physician or an optometrist, and orthopedic appliances designed to be worn by the purchaser or user [and]... [m]edicines sold on prescription of physicians, dentists, or veterinarians; insulin whether or not sold on prescription.

Thus, any medicines that are prescribed by a physician as well as the other devices and articles listed above are exempt. Also note, there is no sales tax on insulin.

Over-the-counter medicines and devices not listed above will be subject to the sales and use tax. Exemptions in the sales tax statute are strictly construed in favor of imposing tax and against allowing an exemption.

Item 656 – Prilosec Nee Losec

Pharmacists probably know by now that Merck Sharp & Dohme has changed the name of its product to Prilosec, to avoid confusion that has occurred between the product's prior name of Losec and Lasix. While there has been ample notice in the trade press about this change, this notice to every licensed pharmacist in the state should be just a reminder.

Item 657 – New Rules

Earlier this year, the Board proposed new rules and revisions in some other rules, with four public hearings scheduled in March. In response to comments at the hearings, significant changes were made in the proposals. Revisions were adopted in July and became effective on September 1, 1990. You should take particular note since some portion of these rules will almost certainly affect every active pharmacist in this state.

Continued on page 4



National Pharmacy

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

The Clozaril Patient Management System and the Public Health, Safety and Welfare

In September 1989, the FDA approved the drug clozapine (Clozaril®), a major breakthrough treatment for schizophrenia in patients who do not respond to standard antipsychotic drug therapy. When Sandoz Pharmaceuticals brought the drug to market in February 1990, it was made available only through a restrictive distribution system called the Clozaril Patient Management System (CPMS). CPMS allows patients to receive Clozaril through an exclusive distribution system that limits the quantity of drug received to a one week supply and requires patients to have weekly blood tests performed in order to obtain the following week's supply of medication.

As the system is outlined by Sandoz, only one company, the Caremark Home Health Care Division of Baxter Healthcare, may dispense the medication and provide the phlebotomy services. A second company, Roche Biomedical Laboratories, has been designated as the only company allowed to perform the blood lab work.

Since clozapine was introduced and approved, concerns regarding CPMS have been raised by a number of professional organizations and state government agencies. As stated in the Clozaril package insert, "Clozaril is available only through the Clozaril Patient Management System, a program that combines white blood cell testing, patient monitoring, pharmacy and drug distribution services, all linked to compliance with required safety monitoring." Thus, as outlined by the manufacturer, CPMS is, ostensibly, the only FDA-sanctioned method of providing the level of monitoring required to protect patients receiving the drug from agranulocytosis — a possibly fatal blood disorder which appeared in one to two percent of those patients who received clozapine during clinical trials.

Under the conditions of the Clozaril Patient Management System, all charges to the patient are bundled, rather than itemized, into a fee totaling approximately \$9,000 per patient per year, regardless of the dosage received. In addition, all the usual channels of distribution are excluded. Hospitals are also charged the full bundled fee as their acquisition cost — an arrangement which holds even if a hospital's established policies require that all blood work be done by in-house phlebotomy and laboratory staff.

Such considerations coupled with the fact that their own proposed clozapine monitoring system was rejected by Sandoz, led the Veterans Administration (VA) to exclude clozapine from its hospital and outpatient formulary systems. Presently, only about 36 VA patients receive clozapine therapy. Current VA policy indicates that clozapine therapy will not be initiated under the terms of CPMS for the approximately 3,000 to 4,000 patients in the VA system who are considered candidates likely to benefit from this treatment. Likewise, many already strained state Medicaid budgets would be hard pressed to provide fund-

ing for the significant number of patients who may benefit from clozapine therapy.

Organizations such as the American Pharmaceutical Association (APhA) and the American Medical Association (AMA) have expressed concern that CPMS fails to take into account the checks and balances of the traditional distribution channels. Their representatives point out that existing safeguards in the physician-pharmacist-patient relationship have protected the public health and welfare for many years.

Concern about the disruption of this traditionally successful relationship led APhA with support from the Joint Commission of Pharmacy Practitioners (JCPP) to convene a "National Discussion Group on Clozaril" at its Washington headquarters on May 15, 1990. Organizations participating in this discussion included the American Pharmaceutical Association, the American Medical Association, the American Mental Health Association, the American Psychiatric Association, the American Public Welfare Association, the American Society of Hospital Pharmacists, the Blue Cross & Blue Shield Association, the Group Health Association of America, the Kaiser Foundation of America, the National Association of Attorneys General, and the National Association of State Mental Health Program Directors. Organizations attending the meeting as observers were the Department of Veterans Affairs, the General Accounting Office, the Senate Veterans Affairs Committee, and the Office of Technology Assessment. As outlined in a May 18, 1990 memorandum to APhA Executive Vice-President, John Gans:

The focus of the meeting was to provide all organizations with an opportunity to share information and concerns regarding clozapine/CPMS, and to begin to identify additional efforts, either as individual organizations or as a coalition, that might be undertaken.

The common theme from all participants was significant dissatisfaction with the restricted distribution system for clozapine. As would be expected, this dissatisfaction arises for several reasons:

1. Interference in pharmacist-patient and physician-patient relationships, and professional practice prerogatives;
2. Expensive duplication of health care resources and fragmentation of patient care;
3. Disruption of existing, proven patient care systems and services, and the precedent such a system sets for the future;
4. Excessive costs and extraordinary financial impact on federal, state, and private health care programs;
5. Concerns regarding regulation of medical and pharmacy practice by FDA labeling and approval activities;
6. Reports of patient selection and treatment decisions made on the basis of financial qualifications rather than clinical need;
7. Allegations that CPMS may violate national and/or state anti-trust laws.

Compliance News



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

...this meeting is further evidence of the growing importance this issue has assumed at the national and state health policy level. It is now clear that this is anything but "just a pharmacist's issue" and that the momentum for achieving change may be building. It appears that the discussion group effort lays the foundation for an effective, coordinated strategy to continue to address this issue.

In a July 13, 1990 letter, the FDA instructed Sandoz Pharmaceuticals to "immediately" delete references to CPMS in Clozaril's labeling and replace them with "more general descriptions of the essential elements of an acceptable system."

Pharmacy Manpower Survey Continues

During the past year and a half, many of you received a "Pharmacy Manpower Survey" which you were asked to complete and return to your Board of Pharmacy. To date, 40 states have either completed this data collection process for all of their pharmacist licensees, or are currently conducting the survey.

On behalf of the profession and the state boards, we would like to thank those of you who have completed the manpower survey form for taking the time to participate in this landmark project. If you did not respond, or if your state sends you a survey within the next several months, we urge you to complete and return the form to the state board of pharmacy as soon as possible.

The data collected through this project is crucial to the profession, licensed pharmacists, and the continued protection of the public health and welfare. Leaders within the profession of pharmacy, state and federal government, education, and industry are making decisions that will ultimately affect the way pharmacy is practiced in the United States. The information you provide about your area of practice, educational background, and professional activities will be utilized by these groups as they plan the future of your profession.

The manpower information is being fed into a national database which will give us a complete picture of the number of pharmacists who currently practice the profession, and the way in which this number relates to the health needs of the public.

Manpower Project officials stress that **NO IDENTIFYING INFORMATION WILL BE RELEASED TO ANYONE OTHER THAN THE STATE BOARD OF PHARMACY THAT COLLECTS IT.** Only aggregate data will be provided to the profession so that it can assess the practice of pharmacy today and plan for its future. Such identifying information requested on the form as your name and social security number is used **ONLY** to eliminate duplication in the database. Your address provides demographic information that is useful in predicting trends within the pharmacy workforce.

We appreciate your support of this nationwide effort. If you are licensed in more than one state you may receive more than one survey; please complete **ALL** survey forms sent to you and return them accordingly. If you have questions about the project, feel free to contact your state board of pharmacy, or the National Association of Boards of Pharmacy at (708) 698-6227.

Exercise Caution when Changing Insulin Products

The number of insulins available for use by patients with diabetes continues to expand. New fixed mixture formulations, new administration devices, such as insulin pens, and new manufacturers of insulin offer a potentially confusing choice for the patient.

When purified insulins were introduced in the United States, the Food and Drug Administration, based on clinical data, required that all insulins carry a boldfaced warning statement in the package literature. This warning reads in part, "Any change of insulin should be made cautiously and only under medical supervision. Changes in refinement, purity, strength (U-40, U-100), brand (manufacturer), type (Lente, NPH, Regular, etc.), species source (beef, pork, beef-pork, or human), and/or method of manufacture (rDNA versus animal-source), may result in the need for a change in dosage."

The USP, in its *Drug Information for the Health Care Professional*, Vol. 1B 1990, states: "Patients changing to different formulation types of insulin products should be informed of the possible need for dosage adjustment. Patients should be advised to consult their physician." The *USP DI for Patients*, Vol. 2 1990, states, "It is very important to use insulin only as directed. Do not change the strength, brand, or type of insulin unless told to do so by your doctor."

Although insulin is, strictly speaking, an over-the-counter product, it is a very potent pharmaceutical and its misuse can have serious or fatal consequences. Pharmacists have a very important role to play, and often fail to realize the great significance of minor changes in the insulin being used can have on the patient. Pharmacists should take the time to consult with their diabetic patients and urge them not to make any changes in their insulin without first consulting their physician.

1991 Survey Available Now

NABP's *Survey of Pharmacy Law*, one of the Association's most requested and quoted publications, has been revised in time for a September distribution to final year pharmacy students throughout the United States.

New charts addressing prescription faxing regulations and the status of pharmacy technicians have been added to this year's *Survey*. Readers will also notice that the existing charts have been streamlined and edited to provide information clearly and concisely.

Publication of this year's *Survey* was sponsored by Wyeth-Ayerst Laboratories, a division of American Home Products Corporation. Wyeth-Ayerst representatives will distribute copies of the 1990 edition to the pharmacy students.

Additional copies of the updated *Survey* are available from the NABP Publications Desk at a cost of \$20.00. For information, write to Janice Teplitz, Editor, NABP, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068.



"I'm sorry. The doctor no longer makes phone calls."

The New Yorker, August 20, 1990, page 69

Do you have a physician in your area like the one in the illustration above? Or have you called for refill approval and had the receptionist or office nurse respond, "Oh, that's OK for refill" without even a pause to note the entry in the patient's record? If the answer is yes, there is something for you in the new rule on fax transmission of prescription orders. The frustration in the first case and discomfort in the second example are easily cured by requesting approval by fax as provided by the new Board rule.

The Board has had several disciplinary hearings in which the key factor was whether refills had been approved by telephone. One such action will be reported in the January *Newsletter*. In the most common situation, the pharmacist has refill records and the physician's office has virtually none. When it comes to a showdown, the pharmacist claims he has called for approval and has all the records while there are no records in the physician's office. The nurse can't remember any of it, and the doctor denies any involvement. Fax records of approval would exonerate the pharmacist in such cases.

You should note that DEA does not approve of fax transmission of prescriptions for controlled substances. At the same time, it should be stated that no federal rule exists prohibiting the use of fax transmissions for controlled substance prescriptions. Pharmacists would be well advised not to accept Schedule II prescriptions by fax, as they require the original signature of the prescriber.

New rules also apply to prescription devices as defined by the Food and Drug Administration. They bear the label "Caution: Federal law restricts this device to sale by or on the order of a physician." These rules place prescription devices in an accountability system similar to prescription drugs. All dispensers of such devices must have a device dispensing permit or pharmacy permit from the Board.

Other rules affecting practice which were adopted concern the responsibilities of a pharmacist-manager; sterile parenteral products; nuclear pharmacy; and eligibility of foreign graduates for licensure.

Copies of these rules have been sent to each pharmacy in the state as a "supplement" to the orange *Pharmacy Law Book*. If you do not have the current (orange) law book, one can be obtained by sending a request with \$5.25 to the Board office.

Item 658 – Insulin Use

It has come to the Board's attention that patients discharged from hospitals today are normally stabilized on human insulin. Many physicians assume that human insulin will be dispensed on their prescriptions regardless of how they are written.

Unless brand or product specific, the Board believes that prescriptions for insulin should be verified as to the physician's choice of human or animal source insulin and not assumed to be the latter. Pharmacists should exercise care in this area and not switch a patient stabilized on animal source insulin to human insulin without a complete consultation with the prescriber.

Item 659 – Index Available

Have you ever remembered seeing an article in the *Newsletter*, but can't find it no matter how long you search? An index may be helpful, and one is available at a charge of \$2 plus \$.10 tax, for a total of \$2.10 per copy.

If you desire a copy, please send the appropriate amount to our office. We are unable to invoice such charges, but we will provide a receipt on request.

Item 660 – Election Procedure

The Board of Pharmacy Elections intends to adopt a rule that makes the procedures for electing Board members consistent with state election laws. Further details are available through 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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