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North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 903– Disciplinary Actions

Correction: It was reported in the October 1996 Board *Newsletter* that the license of **Gregory Elkins,** Charlotte, (DOB February 13, 1966), had been suspended for three (3) years by the Board. This was in error. It should have been reported that the license was suspended 15 days, stayed three (3) years with conditions. We apologize for the error in this reporting.

September:

James Grant Dorough, Monroe, (DOB March 28, 1959). Numerous dispensing errors reported to the Board pursuant to Board Order of March 1, 1996, and accepted by Mr. Dorough on March 6, 1996. Order Summarily Suspending License entered on August 6, 1996, pending issuance by the Board of a Final Agency Decision. License suspended indefinitely.

Pre-Hearing Conference Recommendations

David Lee Barker (DOB March 5, 1939), **Clifford Ervin Hemingway** (DOB September 13, 1927), and **Stanley Drugs,** Charlotte. Medications were dispensed to patients without authorization from a physician; patient counseling was not provided as required by law; proper documentation on compounding of prescriptions was not provided.

Recommendation: **Barker:** License suspended 15 days, stayed for a period of three (3) years with condition of seven- (7) day active suspension and other conditions; **Hemingway:** License suspended 15 days with conditions and permit issued to operate Stanley Drugs be suspended 15 days, stayed three (3) years with conditions. Accepted by Mr. Barker, Mr. Hemingway, and the Board.

Edward F. Swann, Jr., Hickory, (DOB June 9, 1939), and **Phil's Pharmacy,** Hickory. Dispensed sample medications that were obtained from a local physician to patients and also had in stock numerous bottles of out-of-date medications as well as bottles whose expiration date had been removed.

Recommendation: License suspended 90 days, stayed five (5) years with an active 15-day suspension prior to January 1, 1997, and other conditions. Permit issued to Phil' s Pharmacy suspended 30 days, stayed five (5) years with active three- (3) day suspension of the permit to be completed by January 1, 1997. Accepted by Mr. Swann and the Board.

Deborah Eversole Stellings, Rock Hill, SC, (DOB December 24, 1951). Dispensed an incorrect medication to a patient in the hospital where employed.

Recommendation: License suspended 30 days, stayed three (3) years with conditions. Accepted by Ms. Stellings and the Board.

Waymon Ronald Gainey, Fayetteville (DOB March 4, 1953). Engaged in the use and abuse of drugs contrary to the Pharmacy Practice Act and its rules.

Recommendation: License suspended 12 months, stayed five (5) years with conditions that included an active period of not being in the practice of pharmacy and other conditions. Accepted by Mr. Gainey and the Board.

October:

Barbara E. Levy, Asheville, (DOB September 15, 1961). Violated pharmacy law by consuming Fioricet without authorization. License suspended five (5) years, stayed, with five- (5) month active suspension beginning April 23, 1996, and other specific conditions. Accepted by Ms. Levy and the Board.

A Consent Order was entered for **James J. McVerry,** Lenoir, (DOB May 26, 1934), and **Caldwell Memorial Hospital,** Lenoir. Failure to disclose criminal and administrative charges against Mr. McVerry constituted making false representations or withholding material information in connection with securing a license or permit; failure to provide patient counseling; selling prescription drugs to the local hospice organization and physicians' practices; failure to submit a report to the Board follow-

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National Pharmacy

(Applicability of the contents of articles in the National Pr
and can only be ascertained

Tobacco Regulations Target Youths

On August 23, 1996, President Clinton announced the nation's first comprehensive program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco. The plan comes a little more than a year after the Food and Drug Administration (FDA) proposed measures to reduce the access and appeal of tobacco products to children and adolescents. The goal is to cut tobacco use by children and adolescents in half by the year 2003.

Each year, more than 400,000 Americans die from smoking-related diseases; more Americans than are killed each year by AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined. But while the death and disease caused by tobacco use occurs primarily in adulthood, addiction to nicotine begins in adolescence. In fact, more than 80 percent of people who smoke had their first cigarette by their 18th birthday. Tragically, of the 3,000 young people in the United States who become regular smokers every day, about 1,000 will die prematurely as a result of their tobacco use.

During the past four years, the United States has witnessed a dramatic increase in tobacco use by youngsters. Between 1991 and 1995, the percentage of eighth and tenth graders who smoke increased 34 percent. In 1995, more than a third of twelth graders casually smoked and daily smoking in that group was up to 21.6 percent. Among tenth graders, daily use was up to 16.3 percent.

The Administration's initiative follows the recommendations of major medical and scientific organizations, including the American Medical Association and the National Academy of Science Institute of Medicine. It is a prevention strategy based on reducing children's access to tobacco products and limiting the appeal of these products to children.

The FDA rule reduces children's easy access to tobacco products by:

- Prohibiting the sale of tobacco to anyone under 18, and requiring retailers to check photo identification for anyone 26 and under purchasing tobacco products;
- Banning vending machines and self-service displays, except in facilities where children and adolescents are not present at any time; and
- Banning free samples, the sale of single cigarettes, and "kiddie packs" containing fewer than 20 cigarettes.

The rule limits the appeal of tobacco to children by:

- Prohibiting billboards and other outdoor advertising within 1,000 feet of schools and playgrounds;
- Restricting most advertising to black-and-white text only. This includes all outdoor advertising beyond 1,000 feet of schools and playgrounds, signs inside and outside of buses, and advertising in stores. It also includes advertisements in publications with a significant youth readership, which is defined as more than 15 percent or more than 2 million readers under age 18. There are no restrictions on print advertising below these thresholds;
- Prohibiting sales or giveaways of products, like caps or gym bags, that carry cigarette or smokeless tobacco product brand names or logos; and
- Prohibiting brand-name sponsorship of sporting or entertainment events (including teams and entries), but permitting it in the corporate name.

Most of these provisions become effective one year from the date of publication of the final rule in the *Federal Register*. However, the age and photo identification requirements become effective on February 28, 1997.

Finally, the preamble to the final rule states that the FDA will propose to require tobacco companies to fund and place educational messages for children and adolescents on the dangers of smoking and using smokeless tobacco. This national multimedia campaign would include television spots and would be monitored to ensure effectiveness.

NABP to Develop Pharmacist Competency Assessment Mechanism

The Executive Committee of the National Association of Boards of Pharmacy (NABP) recently approved the development of a computer-administered, multiple-choice examination that will be offered to state boards of pharmacy for use in assessing whether a licensed pharmacist has the required knowledge and skills to meet the established standards for professional practice. The exam will not only determine the pharmacist's competence, but will also diagnostically inform the pharmacist of his or her strengths and weaknesses.

Such diagnostic information will serve to complement existing continuing pharmaceutical education (CPE) requirements by facilitating pharmacists' selections of CPE offerings tailored to their specific practice or to areas in need of improvement. The competency assessment examination will also support the development of appropriate and effective CPE programs by American Council of Pharmaceutical Education (ACPE) approved providers in accordance with articulated practice guidelines.

The development of this examination will be a cooperative effort that will consider input from all areas of the profession. NABP expects to make the examination available to state boards of pharmacy beginning in 1999.

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FDA Develops New Bioequivalency Subcategories for "AB" Rating

The Food and Drug Administration (FDA) recently established a new therapeutic equivalence evaluations code in its *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." This new code has caused some confusion among those pharmacists and health care professionals who rely upon the Orange Book for guidance regarding questions of interchangability and generic substitution.

The common codes found in the Orange Book that compare a reference product (i.e., typically the innovator drug or brand name product), which must satisfy a New Drug Application (NDA), to the generic version of that product, which must satisfy an Abbreviated New Drug Application (ANDA), fall into two general categories: "A" rated products and "B" rated products. A generic product designated as "A" rated is bioequivalent and, therefore, "therapeutically equivalent" to the brand name or reference product. Conversely, "B" rated generic products are not considered to be bioequivalent and, thus, "not therapeutically equivalent" to the brand name or reference drug product.

The most common code in the "A" rated category is the "AB" rating, which signifies that the product meets "necessary bioequivalence requirements" such that the generic product is considered to be bioequivalent to the brand name or reference product. Interestingly, the AB rating code has recently taken on a new form wherein subcategories have been created by the FDA that further define which products are bioequivalent to others within the AB category. In the case where more than one reference product of the same strength exists, a number has been added to the AB code to make a three-character code. Designated as AB1, AB2, AB3, etc., this code designates which generic product(s) is bioequivalent to the reference products.

For example, in evaluating transdermal nitroglycerin patches for purposes of inclusion into the Orange Book, the FDA is now utilizing the revised AB rating code. Classified as AB1 products, Key Pharmaceuticals, Inc.'s product Nitro-Dur® (nitroglycerin) Transdermal Infusion System has been designated as the reference product with 3M Pharmaceuticals' Minitran™ (nitroglycerin) Transdermal Delivery System as the AB1 rated generic. Classified as AB2, Summit Pharmaceuticals' Transderm-Nitro® (nitroglycerin) Transdermal Therapeutic System has been designated as the reference product with Mylan Pharmaceuticals, Inc.'s Nitroglycerin Transdermal System patch designated as the AB2 rated generic.

The two reference listed drugs (Nitro-Dur and Transderm-Nitro) are not therapeutically equivalent or bioequivalent to each other. Therefore, the FDA has determined that Minitran is only therapeutically equivalent to Nitro-Dur, while Mylan's nitroglycerin patch is only therapeutically equivalent to Transderm-Nitro. In essence while Minitran and the Mylan patch both have an AB rating, the distinction in the AB1 rating for Minitran and the AB2 rating for the Mylan nitroglycerin patch means the two products are not considered to be therapeutically equivalent and, therefore, not bioequivalent to each other (or their respective reference products).

The FDA has indicated that these subcategories in the AB rating system will increase in number when bioequivalent generic versions of such products as extended release nifedipine, found in Procardia XL® Extended Release Tablets and Adalat® CC (nifedipine) Extended Release Tablets, become available.

The confusion surrounding the subcategories of AB1, AB2, etc., should subside as they become more prevalent within the Orange Book. However, all health care professionals, especially pharmacists, should be aware of the distinction that exists between the subcategories when it comes to issues of drug product selection or generic substitution. Pharmacists should consult the state pharmacy laws and regulations for their specific state if they have any questions or concerns.

FDA's MEDWATCH Program Offers Free Continuing Education Article

MED*WATCH,* the Food and Drug Administration's (FDA) Medical Products Reporting Program, announces the availability of a continuing education article that provides two free hours of American Council on Pharmaceutical Education-(ACPE) approved credit.

Entitled "The Clinical Impact of Adverse Event Reporting," this article is intended to increase the health professional's insight into the limitations and strengths of data derived from postmarketing surveillance and how a national postmarketing surveillance program impacts clinical practice. The article also hopes to emphasize the responsibility of health care providers to identify and report adverse events related to the use of medical products. Through the MED*WATCH* program, health professionals can report serious adverse events and product problems that occur with such medical products as drugs, biologics, medical and radiation-emitting devices, and special nutritional products.

This article is available through the Internet on the FDA's home page (http://www.fda.gov), or by mail at the following address: MED*WATCH*, FDA, HF-2, 5600 Fishers Lane, Room 9-57, Rockville, MD 20857. Interested individuals may also contact the MED*WATCH* office by phone at 301/443-0117 or by fax at 301/443-5776.

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ing a patient death; maintaining excessive stocks of prescription drugs in areas outside the pharmacy; failure to maintain adequate record keeping and inventory control system for pharmacy. License of McVerry suspended 30 days, stayed three (3) years with conditions. Permit for Caldwell Memorial Hospital suspended seven (7) days, stayed three (3) years with conditions.

Richard Phillip Jump, Greensboro, (DOB November 23, 1947). License reinstated subject to Mr. Jump meeting specific conditions set by the Board.

Item 904 – A Month's Supply

Officials with the Division of Medical Assistance in Raleigh have advised us that when some pharmacists fill prescriptions for controlled substances and Schedule II drugs, they assume that the phrase "one month's supply" means 30 days. This may or may not be the case.

Pharmacists need to indicate on each controlled substance prescription the exact amount they are dispensing at any given time. Specifically, this should be noted on the prescription document and in any computer records used in the pharmacy. To review what is necessary on a prescription document, see the Board rules at section .2300 and federal rules 21 CFR .1306.

Item 905 – Medical Spanish

A pharmacist has asked about the acceptability for continuing education (CE) purposes of a medical Spanish course taught at a local community college. After investigating the situation, the opinion of the Board staff is that such courses are acceptable on a credit-hour basis for CE to renew a pharmacist's license.

These institutions offer courses on the basis of local demand. You may inquire with your local association for any interest in a group taking such courses. Nurses and physicians would also be natural customers for such an offering. A list of the 58 community colleges in the state is available from the Board office on request.

Item 906 – Local Associations

In late 1996 the Board began sending communications to one officer of each local association to inform them of current activities of interest. This includes material that is important but ordinarily would not appear in the Board *Newsletter* because of space limitations. Items such as the list of disciplined physicians would be a prime example of such information.

This list of local associations currently includes: Alamance Pharmaceutical Society; Blue Ridge Pharmaceutical Association; Cape Fear Pharmaceutical Society; Catawba Valley Society of Pharmacists; Cleveland County Pharmaceutical Association; Columbus-Bladen County Pharmaceutical Association; Crystal Coast Pharmaceutical Association; Davidson County Pharmaceutical Association; Down East Pharmacy Society; Durham Orange Pharmaceutical Association; Four County Pharmaceutical Association; Guilford County Society of Pharmacists; High Country Pharmacy Society; Lincoln County Pharmaceutical Association; Mecklenburg Pharmaceutical Association; Moore County Pharmaceutical Society; New Hanover County Pharmaceutical Society; North Eastern Carolina Pharmaceutical Society; North West Pharmaceutical Association; Person County Society of Pharmacists; Piedmont Pharmaceutical Society; Randolph County Pharmaceutical Society; Richmond County Pharmaceutical Association; Rockingham County Society of Pharmacists; Rutherford County Pharmaceutical Association; Southeastern Pharmaceutical Association; Surry County Pharmaceutical Association; Union County Pharmaceutical Association; Wake County Pharmaceutical Society; Wayne County Pharmaceutical Association; Western Carolina Pharmaceutical Association; and Wilson County Pharmaceutical Association.

If you are aware of any other local associations in North Carolina that need to be on this list, please contact the Board office at 919/942-4454 or by fax at 919/967-5757.

Item 907 – Compounding Practices from USP

The United States Pharmacopeia (USP) has recently published a chapter on pharmacy compounding practices in the fifth supplement to the USP. It is official as of November 15, 1996, and addresses such topics as: the stability of compounded preparations, including guidelines for beyond-use dating; ingredient selection; and guidelines and standards for specific compounded dosage forms, including capsules, tablets, solutions, suppositories, etc.

Copies can be obtained from the North Carolina Board of Pharmacy or by contacting Kim Keller Reid, USP staff attorney, at 301/816-8227.

Item 908 – Insulin

Pharmacists should be aware of a new insulin product, Humalog Recombinant DNA Insulin. One of its medical benefits is its claim to eliminate "clumping," which can be a problem with regular insulin. Intended to replace regular insulin in the marketplace, this item is available by prescription only. This is a significant change for insulin products, which are generally available without a prescription.

Item 909 – Competency Test

On page 2 of this *Newsletter,* an article entitled "NABP to Develop Pharmacist Competency Assessment Mechanism" describes a pharmacist competency assessment mechanism to be available in 1999 from the National Association of Boards of Pharmacy. The North Carolina Board

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of Pharmacy plans to use this tool to assess the status of pharmacists who have been absent from practice for a long period of time.

It is not unusual for the Board to receive a request from a pharmacist who has been, for example, selling real estate for the last seven years and has not practiced in a pharmacy during that time. Cases also arise in which pharmacists commit frequent errors, and this test could be used to verify their continued suitability for practice. These are the only projected uses for this instrument.

Item 910 – OTC Pet Vaccines

Gigi Davidson, director of pharmacy at North Carolina State University College of Veterinary Medicine, and pharmacy externs Melanie Holshouser and Michael Griffin submitted the following article in response to a request from the Newsletter *editor.*

Over-the-counter (OTC) sales of pet vaccines have been suggested as a way to broaden the veterinary product line in pharmacies. This activity is currently legal, provided no rabies vaccine is sold (NC G.S. 130A-191) and vaccines are not repackaged but are sold in the manufacturer's original container with package insert (9 CFR 112.6). As a result, many retail pharmacists have chosen to provide canine and feline vaccines OTC, thereby increasing profits as well as access to inexpensive pet vaccines. While providing these vaccines potentially increases vaccination rates and decreases the spread of disease, selling pet vaccines outside of the veterinarian-client-patient relationship comes with risk to both animal and human health.

Most pharmacists have limited knowledge of veterinary disease states, vaccinology, and species correlations between pathogens. Any vaccination represents a significant challenge to the immune system, and adverse effects from such challenges can be life-threatening. Sick, pregnant, or debilitated animals are at extreme risk for adverse reactions, and few pet owners or pharmacists can provide a proper physical exam to assess a pet's soundness for vaccination. Anaphylaxis and death can occur in minutes and most pharmacists are not prepared to recommend action in such emergencies. More subtle changes such as immune-mediated hemolytic anemias, vaccine-induced disease or injury, and vaccine-induced fibrosarcomas may not be recognized at all outside the veterinarian-client-patient relationship, resulting in great suffering to the animal and expense to the owner. Zoonotic disease from accidental injections is also more likely to occur outside of the veterinarian-client-patient relationship.

While the pharmacist is capable of offering superior service (professional counseling and quality handling) as compared to feed stores and mail-order catalogs, the veterinarian is indisputably the best provider of animal health care. The market is already saturated with inferior outlets for pet vaccines, and pharmacists are well-advised not to engage in this less than ideal practice. Despite the risks, many corporate executives will still choose to have their stores sell pet vaccines. Pharmacists finding themselves in this position should take several steps to decrease the risk of animal harm and pharmacist liability.

First, pharmacists should educate themselves in veterinary vaccinology and disease states, as well as injection techniques and vaccine reactions. This can be accomplished through literature review as well as through collaboration with local veterinarians and colleges of veterinary medicine. Pharmacists should also increase their awareness of all regulations regarding animal vaccines. Because some animal patients end up in the human food chain, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have strict regulations regarding the use and distribution of animal drugs and vaccines. Pharmacists can stay abreast of changes by calling these regulatory agencies and by visiting their web sites.[1]

Pharmacists and veterinarians are on the threshold of a new relationship with the recent passage of the Animal Medicinal Drug Use Clarification Act (21 CFR 530), an act which legalizes the veterinarian's use of human legend drugs in animals. This law is expected to greatly increase the number of veterinary prescriptions in retail pharmacies, and therefore broaden the professional collaboration between veterinarians and pharmacists. Providing OTC pet vaccines in a retail pharmacy can only damage this mutually beneficial relationship, and these authors strongly recommend that retail pharmacies not sell pet vaccines.

[1]USDA 515/232-5789, or http://www.usda.gov; and FDA 301/594-1751, or http://www.cvm.fda.gov

Item 911 – DME Subcommittee Meets

The first meeting of the Devices and Medical Equipment (DME) Subcommittee occurred on October 1, 1996, in Board offices in Carrboro. Present were Mr. Wayne Link, Ms. Kathrine Noel, and Mr. Larry Lankford along with Board of Pharmacy members Whit Moose and Tim Rogers. Also participating in the meeting were Executive Director David Work; Steve Hudson, director of Inspections and Investigations; and investigators J. Kenneth Wilkins, Terri Readling, and Timothy Jones. The group reviewed a summary of facility inspections during the first year, and Subcommittee members gave guidance to staff on future plans. The group supported efforts to amend the Pharmacy Practice Act to bring out-of-state suppliers under the same rules as North Carolina DME providers.

The group discussed oxygen matters at length. It was eventually decided that the United States Pharmacopeia (USP) designation on oxygen containers would be accepted for quality control purposes. The Subcommittee meeting occurred shortly after Hurricane Fran, thus much discussion occurred about the amount of back-up oxygen that

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should be available for home patients. Amounts discussed ranged from one day to 72 hours with an acceptable average being two to two-and-a-half days. No final decision was made on this issue, but it was suggested that permit holders develop a close relationship with local rescue squads.

The Subcommittee also determined the length of each term for DME Subcommittee members. Mr. Lankford volunteered for a one-year term, Ms. Noel received a two-year term, and Mr. Link was designated to have a three-year term and was elected chairman of the Subcommittee. The next meeting is scheduled for February 4, 1997.

Item 912 – Drug Interaction Update

When was the last time your computer was updated on drug interactions? This could be a key issue in futu gence cases involving prospective drug use review. macy that has not had its drug interaction comp updated in 10 years would have a difficult time ex that fact.

Item 913 – Sample Policy

Questions frequently come to the Board office regarding the proper dispensing of sample medications. First of all, it needs to be stated that there is no exemption from the packaging, labeling, and record keeping requirements of the law for sample prescription drugs. State law clearly provides for labeling of prescription drugs dispensed to the public at G.S. 106-134.1(b). This includes a label affixed to the container with the name of the patient, directions for use, etc. Federal law also provides, as a general rule, that prescription drugs shall be dispensed in child-resistant (safety closure) containers. The Board's rule on patient counseling and prospective drug use review also applies to sample prescription drugs.

It is acknowledged that the dispensing of most sample medications does not comply with state and federal law as previously noted. It is also true that the Board of Pharmacy staff has much to do with 8,000 licensees and over 2,000 permits. We must, therefore, prioritize matters, and at this time samples are very low on our priority list.

While pharmacists, nurses, physicians, and others who encounter samples in their practice need to be cognizant of dispensing requirements, problems are most likely to arise in private litigation. If a child were to become injured after consuming sample medication that was not in a safety-closure container, it is questionable whether malpractice insurance would be effective when the current practice is not in conformance with the law.

Item 914 – Board Inspections

nuary 1997, Board staff will begin making regular ion visits again. Because of work overload all phar- may not get inspected for two or more years, but ocess will begin now. So, if an inspector shows up at harmacy do not think anything is necessarily out of order.

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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