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Board Elections

At the June 2004 meeting, the South Carolina Board of Pharmacy members elected J. Robert “Bobby” Bradham, RPh, as its new chairman. Mr Bradham is a pharmacist representing the First Congressional District. Mr Terry T. Lewis was elected to serve as the vice chairman. Mr Lewis is a pharmacist representing the Sixth Congressional District. Each will serve a one-year term from July 1, 2004 through June 30, 2005. Congratulations!

Board Welcomes New Member

Governor Mark Sanford appointed a new member to the Board. Representing the Third Congressional District will be Allen Toole, RPh, who replaces Mr Rufus E. Sadler, RPh. Mr Toole operates Liberty Family Pharmacy, an independent pharmacy in Liberty, SC. Mr Toole’s six-year term is July 1, 2004 through June 30, 2010. The Board would like to welcome Mr Toole and we offer our sincere appreciation to Mr Sadler for his dedicated service to the citizens of South Carolina and the profession of pharmacy.

Pharmacy Technician Ratio Bill Passed

The following bill relating to pharmacy technicians was signed by Governor Mark Sanford and became effective June 17, 2004. Section 40-43-86(B)(4)(b) was amended to read:

The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; through June 30, 2006, at least one of these three technicians must be state-certified, and after June 30, 2006, at least two of these three technicians must be state-certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state-certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30(14).

The full text of this and all sections of the Pharmacy Practice Act can be viewed on the Board’s Web site at www.llr.state.sc.us/POL/pharmacy. This should be reviewed by all pharmacists and pharmacy technicians.

Vaccinate and Vote Program

The South Carolina Coalition on Older Adult Immunizations (SCCOAI), in conjunction with the Carolina Medical Review and the Board of Pharmacy, is organizing a *Vaccinate and Vote* campaign on November 2, 2004. Because this is a presidential election year, high voter turnout is expected. While voting, people can also receive flu and pneumonia vaccines. The project relies on existing resources and local volunteers from faith-based organizations, senior groups, pharmacists, pharmaceutical companies, state and local health departments, and others interested in improving health care, particularly in rural areas. These volunteers will help with publicity, volunteer recruitment, Election Day staffing, organization of vaccine clinics on that day, vaccine availability, staff to administer the vaccines, help with billing (roster billing is advised), and volunteer recognition. SCCOAI will be targeting two to three areas this year. Anyone interested in obtaining more information about this event or becoming a sponsor of the event should contact Natalie Cobb at the Board office via e-mail at cobbn@llr.sc.gov.

SCPhA Launches Community Pharmacy Apprenticeship Program

Jennifer Baker, PharmD

This October, the South Carolina Pharmacy Association (SCPhA)/Carolina Pharmacy Network (CPN) will launch the Independent Community Pharmacy Apprenticeship Program. SCPhA/CPN is considering applications from pharmacists currently licensed in South Carolina who have a strong interest in becoming a community pharmacy independent owner or partner.

The Independent Community Pharmacy Apprenticeship Program will be an intense, full-time, 27-week scholarship-funded program providing the selected pharmacist apprentices with a foundation of hands-on knowledge of how to manage a successful community independent pharmacy. This will be achieved through three key components: practical experience in a preceptor independent pharmacy, a college level pharmacy management course, and vital business/professional networking.

The Apprenticeship Program funded by the CPN Wholesaler Partners is a wonderful opportunity to grow independent community pharmacy practice in South Carolina. Before completion of the program, the apprentice will be offered opportunities to buy into, take over, or start his or her own community pharmacy. Please contact Jennifer Baker, PharmD, at SCPhA by phone (1-800/532-4033) or e-mail (jl baker@scrx.org) for more information.

Bioterrorism Awareness Training Workshop

Since 9/11, America has faced the reality of overt attacks by terrorists as well as increased concerns about covert bioterrorism

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National Pharmacy C

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FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.



According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of



Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- ◆ If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- ◆ Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- ◆ Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- ◆ Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- ◆ Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- ◆ Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- ◆ Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

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attacks and naturally occurring biologic threats such as SARS and West Nile virus. Traces of ricin have already been found in an upstate post office. In addition, South Carolina may find itself unusually vulnerable given that we have five nuclear power plants, are the home of the fourth busiest container port on the East Coast, and house C-17 airplanes at our United States Air Force bases, which are major transporters for soldiers and supplies.

If health care professionals lack knowledge of the syndromes caused by biological agents or are unprepared to recognize and respond appropriately, the attack could go unrecognized until it is too late, with disastrous results. This vulnerability creates an urgent need for health professionals to become more attuned to public health emergencies and their response to such events. Toward meeting that need, a day-long conference titled "Bioterrorism Update for Pharmacists" co-sponsored by the University of South Carolina College of Pharmacy and South Carolina Area Health Education Consortium (AHEC) and funded by a grant from the US Department of Health and Human Services Health Resources and Services Administration will be held on Saturday, August 28, 2004, at Seawells Conference Center, 1125 Rosewood Dr, Columbia.

The program will provide six contact hours (0.6 CEUs) of Accreditation Council for Pharmacy Education continuing education credit and will be associated with a minimal fee to cover the cost of food since this cannot be provided under federal grants. Pharmacists should receive a brochure in the mail this summer, but can contact Michael P. Dunphy, RPh, MS, for more information at dunphy@pharm.sc.edu. In addition to this pharmacy-specific workshop, South Carolina AHEC is providing one- to four-hour bioterrorism awareness seminars throughout the state, which are beneficial to all health care providers. A calendar of these events can be found at the South Carolina AHEC Bioterrorism Network Web site, www.musc.edu/bioterrorism.

Pharmacy Technician State Certification Training

Don Ballington, Director, Pharmacy Technician Training Program, Midlands Technical College

One of the requirements for South Carolina pharmacy technician state certification is proof of completion of an American Society of Health-System Pharmacists®-accredited formal academic training program. Currently, three colleges in South Carolina offer this approved training. These colleges are Greenville Technical College, Midlands Technical College, and Trident Technical College. For technicians desiring to gain certification, Midlands Technical College has an approved two-semester curriculum called *Community Pharmacy Technician Certificate*. In consideration for technicians

needing to work and schedule classes around work, the curriculum will be offered one day a week for two semesters. Classes will start with fall semester 2004 and complete at the end of spring semester 2005. Another class will start spring semester 2005 and complete at the end of summer semester 2005.

This curriculum includes 300 hours of lecture, 45 hours of seminar, and 270 hours of experiential (hands-on training) for a total of 615 hours and 28 college credits. The general education courses, anatomy and physiology and medical terminology, will be taught at the student's local college and will be scheduled around pharmacy classes. These two classes can be taken at any time and previously taken credit can be accepted if completed within the last three years. Pharmacy classes will be broadcast from Midlands Technical College and received at the following colleges: Aiken Technical College, Denmark Technical College, Central Carolina Technical College, Florence Technical College, Horry-Georgetown Technical College, Technical College of the Lowcountry, and Tri-County Technical College.

The Community Pharmacy Technician Certificate curriculum is a college-level nationally accredited program. Applicants desiring to enter this program will meet entry standards under which this program is accredited. For application information, the applicant should contact his or her local technical college to start the admissions process. Midlands Technical College Application Forms are available at the applicant's local college or by applying online at Midlands' Web site at www.midlandstech.edu. Once enrolled in the pharmacy technician program, the student may qualify for financial assistance, scholarships, loans, or lottery-funded tuition assistance. For further information and to start the application process, contact your local technical college or the Midlands Technical College Admissions Office at 803/738-8324 or the Pharmacy Technician Program at 803/822-3591 or 3589, or e-mail ballingtond@midlandstech.edu. If your local technical college is not listed above, you will want to contact Midlands Technical College directly.

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