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Virginia Board of Pharmacy News

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Board Officer Election Results and Member Appointments

Elections for the offices of the Virginia Board of Pharmacy chairman and vice chairman for the period of July 1, 2011 through June 30, 2012, were held during the full Board meeting on June 8, 2011. The Board voted unanimously to elect Gill B. Abernathy to the position of Board chairman and David C. Kozera to the position of vice chairman. Also, two new Board members, R. Crady Adams and Empsy Munden, were recently appointed by Governor Bob McDonnell to the Virginia Board of Pharmacy. They replace John O. Beckner and Leo H. Ross, who were not eligible for reappointment, having served two full terms after eight and nine years respectively. For a complete list of current Board members, please visit *www.dhp.virginia.gov/Pharmacy/pharmacy_board.htm.*

2012 Board Meeting Schedule

The full Board will meet on the following dates in 2012: March 13, June 12, September 19, and December 12. Board meetings are held at the Department of Health Professions, Perimeter Center Conference Center, 9960 Mayland Drive, Henrico, VA 23233. Meeting dates are subject to change due to unforeseen circumstances. A complete and current listing of all Board meeting dates may be accessed at *www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm.*

Pharmacist and Pharmacy Technician Renewal

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2011. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Board. Renewal notification letters were mailed in early November. The letter stated that pharmacists and pharmacy technicians may renew their license or registration via the online renewal process on the Board of Pharmacy's Web page using a personal identification number (PIN). Either an established login and password for a previous renewal cycle may be used to gain access or licensees may use the license number and PIN provided in the renewal letter. Licensees are encouraged to renew online. If you are unable to renew online, the notification letter includes instructions for obtaining a paper renewal form that may be mailed to the Board. Fees for renewals received by the Board by December 31, 2011, are as follows: pharmacist active license – $90; pharmacist inactive license – $45; and pharmacy technician registration – $25. You are encouraged to renew early as an additional late fee of $30 for active pharmacist licenses, $15 for inactive pharmacist licenses, and $10 for pharmacy technicians must be submitted for renewals received by the Board after December 31, 2011.

In addition to submitting the renewal fee, each current active pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2011 calendar year. Each year pharmacists are required to obtain 15 hours of CE per calendar year and pharmacy technicians must obtain five hours per calendar year. Individuals that have not obtained the appropriate amount of CE during 2011 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause only. Such requests must be made in writing and prior to renewing the license. Any individual who requests an extension will have his or her CE audited the following year and be required to submit the original CE documents as proof of compliance. Refer to Guidance Documents 110-4 and 110-42 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm* for more information related to CE.

Reporting Requirements for an Unusual or Significant Loss of Drugs

The Virginia Drug Control Act in §54.1-3404 requires a registrant or licensee who discovers a theft or any other unusual loss of a drug in Schedules II, III, IV, or V, to immediately report the theft or loss to the Board of Pharmacy. Additionally, in federal regulation 21 CFR 1301.74, enforced by the Drug Enforcement Administration (DEA), there is a similar reporting requirement: "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." The licensee or registrant must also then submit a DEA Form 106, which documents the actual circumstances of the theft or significant loss and the quantities of controlled substances involved, and within 30 days after the discovery of a loss of drugs, he or she must furnish the Board with a listing of the kind, quantity, and strength of such drugs lost. Submission of a copy of DEA Form 106 is acceptable for complying with the Board's reporting requirement.

While it is clear that a "theft" of any quantity of drug in Schedules II-V must be reported to the Board and DEA, there is occasionally confusion regarding the reporting requirements for

continued on page 4

2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm,* and information about the ACIP recommendations are available on the CDC Web site at *www.cdc.gov/media/pressrel/2010/r100224.htm.*

Another TEAspoon – mL Mix-Up

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 **TEA**spoonfuls of a liquid antibiotic for 10 days instead of 3.5 **mL.** The medication was dispensed in a 60 mL bottle. The child was given 3.5 **TEA**spoonfuls each day for three days. By the fourth day only one **TEA**spoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" *(www.ismp.org/Newsletters/acutecare/articles/20000628_2.asp).* ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of **TEA**spoonful and other non-metric measurements to prevent errors *(www.ismp.org/pressroom/PR20090603.pdf).* In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses *(www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm).* Unfortunately, the guidance still mentions both **TEA**spoon and **TABLE**spoon. The Consumer Healthcare Products Association has also published guidelines *(www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)* to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL **and** the **"TEA**spoonful" equivalent (eg, 5 mL (1 **TEA**spoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched *www.KnowYourDose.org,* a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-

nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever." FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table,* and advises that "Methylene blue should generally not be given to patients taking serotonergic drugs." Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm.*

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table,* and advises that "Linezolid should generally not be given to patients taking serotonergic drugs." Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm.*

NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- Licensure, registration, certification, and operational requirements
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social, behavioral, and administrative pharmacy sciences
- Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at exec-office@nabp.net; or via fax at 847/391-4502.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net.

Clarification Regarding Pradaxa Storage and Handling Requirements

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News.* As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm* provides more details, and the manufacturer's Pradaxa safety information is available at *www.pradaxa.com* by clicking on the link for "Important Storage & Handling Information" at the top of the page.

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continued from page 1

a loss when it is unclear whether the loss constitutes an "unusual" or "significant" loss. While the terms "unusual loss" as used in the Drug Control Act and "significant loss" as used in federal regulation are not defined in state or federal rules, DEA does offer guidance in 21 CFR 1301.74 and the *Pharmacist's Manual* for determining if a loss constitutes a "significant loss." It is suggested that pharmacists and pharmacy technicians follow DEA's guidance for satisfying the state and federal reporting requirements for both unusual and significant drug losses. To determine whether a loss is "significant," federal regulation 21 CFR 1301.74 states . . .

> a registrant should consider, among others, the following factors:
>
> 1. The actual quantity of controlled substances lost in relation to the type of business;
> 2. The specific controlled substances lost;
> 3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
> 4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
> 5. Whether the specific controlled substances are likely candidates for diversion;
> 6. Local trends and other indicators of the diversion potential of the missing controlled substances.

Furthermore, DEA's 2010 edition of the *Pharmacist's Manual* states:

> Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.
>
> Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

In accordance with §54.1-3404 of the Virginia Drug Control Act, if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he or she shall immediately make a complete inventory of all Schedule II through V drugs. Also, if after the initial notification of a theft or loss to the Board or DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, then a complete listing and DEA Form 106 are not required to be filed. However, the licensee or registrant should notify the Board and DEA in writing of this fact in order to resolve the initial report.

If it is determined that a loss occurred, but it is not significant, DEA indicates in the *Pharmacist's Manual* that " . . . the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion." Lastly, as indicated in the *Pharmacist's Manual* and supported by the Board, if there is a question as to whether a theft has occurred or a loss is significant, a licensee or registrant should err on the side of caution and report it to DEA and the Board of Pharmacy. For a complete reading of this subject in the *Pharmacist's Manual,* visit *www.deadiversion .usdoj.gov/pubs/manuals/pharm2/pharm_manual.htm#5*.

Prescriptions Written for 'Office Use Only'

A pharmacy may provide prescription drugs to a physician for office use in accordance with §54.1-3435.02 of the Drug Control Act, which states that a pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as a wholesale distributor when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances do not exceed 5% of the gross annual sales of prescription drugs by the relevant permitted pharmacy or such wholesale distributions of Schedules II through V controlled substances do not exceed 5% of the total dosage units of the Schedule II through V controlled substances dispensed annually by the relevant permitted pharmacy. Occasionally, a physician will request prescription drugs by providing the pharmacy with a prescription indicating "For Office Use Only" in the name field. This does not constitute a valid prescription because it is not issued in the name of a specific patient for a specific drug that resulted from a bona fide practitioner-patient relationship. Pharmacists must not dispense prescriptions written For Office Use Only. To properly transfer the requested drugs, the pharmacy must create an invoice containing the following information: the date of transfer, the name and address of the physician to which the drugs are to be transferred, the name and address of the pharmacy from where the drugs were transferred, and the kind and quantity of drugs transferred. The transferring pharmacy maintains the original invoice for two years from the date of transfer and provides a copy to the receiving physician or pharmacy. Once received, the physician must indicate the date of receipt on the invoice and maintain the invoice for two years from the date of receipt. If the requested drug is classified in Schedule II, the physician wishing to obtain the drug must execute a DEA Form 222 as the "purchaser" and provide this form to the transferring pharmacy. The transferring pharmacy would then complete DEA Form 222 acting as the "supplier" in this instance. Copies of DEA Form 222 must then be properly forwarded as required by federal law.

Page 4 – December 2011

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