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First Pharmacy Outreach Meeting

Back Row from Left: Peggy Whitworth, public member; DeeAnn Wedemeyer-Oleson, pharmacist member; and Sue Frey, chair. Front Row from Left: Mark Anliker, pharmacist member; Ed Maier, vice chair; Lloyd Jessen, executive director; and Jim Miller, pharmacist member. Not pictured: LaDonna Gratias, public member.

The Iowa Board of Pharmacy held its first Pharmacy Outreach Meeting on Tuesday evening, September 13, 2011, at the Blank Park Zoo in Des Moines, IA. Approximately 100 pharmacists and 50 pharmacy technicians attended and made the meeting a success. The program included a review of new laws and administrative rules, as well as a discussion of current pharmacy projects and study groups. A "town hall" meeting was also held to allow participants to provide input to the Board on topics of concern. The next Pharmacy Outreach Meeting will be held at the Amana Clarion Inn in Williamsburg, IA, on Thursday evening, November 10. A Pharmacy Outreach breakfast meeting is planned for Sunday morning, January 22, 2012, at the Marriott Hotel in downtown Des Moines. It will be held during the Iowa Pharmacy Association (IPA) Expo.

Participants gather for the first Board of Pharmacy Outreach Meeting.

New Laws

Pharmacy Pilot Projects

New legislation permits the Board to allow pharmacy "pilot projects." The Board may only consider projects that expand pharmaceutical care services that contribute to positive patient outcomes. The Board may not consider any project intended only to provide a competitive advantage. In addition, pilot projects may not expand the definition of the practice of pharmacy. Projects will be approved for a specified period of time and may not exceed 18 months. New administrative rules will identify the procedures for applying for approval of pilot or demonstration research projects. The Board will review all applications and either approve or deny them. The pharmacist who is responsible for any approved project must file a written summary of the project results with the Board within three months after the completion of the project. The Board must submit reports to the legislature.

Iowa Prescription Monitoring Program

The two-year sunset provision has been removed and the prescription monitoring program (PMP) is now permanent. There was a change made in the PMP law to allow an "agent" of a practitioner to register and request information from the PMP. New administrative rules will identify the qualifications for a pharmacist's or prescribing practitioner's agent and will limit the number of agents to whom PMP access may be delegated.

Epilepsy Drugs

New legislation has created a task force of patients, physicians, and pharmacists to provide education and information on epilepsy drugs. The task force will also assess the impact on patients of the use of generic antiepileptic drugs to treat epileptic seizures. The task force will be composed of three patients appointed by the Epilepsy Foundation of Iowa; three physicians appointed by the Iowa Medical Society and the Iowa Osteopathic Medical Association; and three pharmacists appointed by the IPA. The task force shall submit a report of its activities, findings, and recommendations to the legislature by January 1, 2013.

Drug Disposal Take-Away Program

New legislation allows the Board to provide annual funding for the administration of the pharmaceutical collection and disposal program – the TakeAway™ Environmental Return System – that was established in 2009. The Board may allocate up to $125,000 of its license fees per year for this purpose. The program provides

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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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for the management and disposal of unused, excess, and expired pharmaceuticals.

New, Revised, and Proposed Administrative Rules

For detailed information about rule changes, please visit the Board's Web site at *www.legis.state.ia.us/aspx/ACODocs/chapterList.aspx?agency=657.*

- **Continuing Pharmacy Education**
  657 IAC Subrule 2.12: Two hours of continuing education (CE) are now required in both pharmacy law and medication safety every two years.
- **Patient Counseling**
  657 IAC Rule 6.14: Pharmacist counseling is required whenever changes to a patient's drug therapy occur.
- **Hospital Pharmacy**
  657 IAC Rule 7.1: The definition of "hospital pharmacy" has been expanded to include animal patients; verbal orders for drug administration have been clarified.
- **Pharmacy Closings**
  657 IAC Subrule 8.35(7): Thirty-day notification is now required for the Board, Drug Enforcement Administration, and patients; 40-day notification is required for the pharmacist-in-charge.
- **Controlled Substances**
  657 IAC Chapter 10: Electronic prescribing requirements and prescription transmission requirements have been updated.
- **Drugs in Emergency Medical Service Programs**
  657 IAC Chapter 11: This newly rewritten chapter establishes emergency medical service drug standards and requirements.
- **Electronic Data in Pharmacy Practice**
  657 IAC Chapter 21: Rules for electronic prescribing, electronic record requirements, and electronic transmission of prescriptions have been updated.
- **Pharmacy Internet Sites *(Proposed)***
  657 IAC Chapter 24: This is a new chapter that establishes standards and minimum requirements for Internet pharmacies, including the National Association of Boards of Pharmacy® Verified Internet Pharmacy Practice Sites℠ (VIPPS®) accreditation.
- **Iowa Prescription Monitoring Program *(Proposed)***
  657 IAC Chapter 37: This proposed change will allow up to three agents of a prescriber or a pharmacist to register and request information from the PMP, including certified pharmacy technicians.
- **Tech-Check-Tech Programs *(Proposed)***
  657 IAC Chapter 40: This is a new chapter that establishes tech-check-tech (TCT) program requirements. TCT is only allowed for drug delivery to institutionalized patients. Board approval is required 90 days prior to TCT implementation. Only qualified, certified pharmacy technicians may participate.

Board Calendar for 2012

The Board will hold regular Board meetings on the following dates (all meetings will be held at the Board office in Des Moines):

January 17-18	June 26-27
March 20-21	August 28-29
May 2-3	November 7-8

Dates are subject to change. Please contact the Board office at 515/281-5944 to confirm meeting dates.

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