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Preventing Compounding Errors

By Amy Puckett, PharmD Candidate

There are an estimated 30 to 40 million prescriptions compounded nationally each year. A small portion of those are for Wyoming residents and the compounding pharmacy must follow Wyoming Pharmacy Act Rules and Regulations. Being familiar with the Wyoming Pharmacy Act Rules and Regulations can help reduce compounding errors. Rules are designed to help protect both the pharmacist and the public. A compounded product can be prepared for three reasons: as the result of a practitioner's order; for research, teaching, or chemical analysis; or in anticipation of orders if the drug product is regularly prescribed. It is not considered compounding when mixing or reconstituting as a result of following the manufacturer's directions on the labeling. Pharmacies cannot compound medications or dosage forms that are commercially available and they cannot sell compounded products to other pharmacies for resale. A pharmacy may, however, sell a compounded product to a practitioner or an institutional pharmacy if it is to be administered to patients in the practitioner's office or institution. The provision to this is that neither the transfer pharmacy nor the transferee pharmacy can exceed 5% of their total prescription drug sales revenue when selling the compounded products.

The Wyoming Pharmacy Act Rules and Regulations also indicate which compounding functions each pharmacy employee can perform. Technicians-in-training cannot compound in an institutional or retail pharmacy. Technicians may compound if the prescription is first reviewed by a pharmacist. The pharmacist-in-charge must certify competency of the technician, in 11 different areas including calculations, before allowing them to compound, and certify the technician annually thereafter. Pharmacists must maintain their competency and proficiency in compounding and must be familiar with good compounding practices. They too must be evaluated by the pharmacist-in-charge, and like technicians, documentation of the evaluation must be kept on file. Pharmacists-in-charge are also responsible for establishing compounding policies and procedures.

The National Association of Boards of Pharmacy® (NABP®) suggests using both a formulation record and a compounding record. A formulation record is similar to a recipe that indicates the components and directions for preparing the product, while a compounding record indicates the actual components used to make the product and the name of the person doing the compounding. Another way to prevent calculation errors is through continuing education (CE).

CPE Monitor

Pharmacists and pharmacy technicians are encouraged to visit the NABP Web site at *www.nabp.net* and click on CPE Monitor™ in the Programs section to create an e-Profile ID for CE. In the future, your CE will be tracked at the continuing pharmacy education (CPE) site and audits will be done online. Keep track of your CPE Monitor e-Profile ID. In the future, both pharmacists and pharmacy technicians will be required to begin providing the e-Profile ID when registering and completing any CE accredited through the Accreditation Council for Pharmacy Education.

The Compounding and Use of Domperidone

By Joshua W. Jons, PharmD Candidate

Questions regarding the legality of compounding domperidone-containing preparations have begun to resurface. Domperidone, a medication being compounded for the use of increasing lactation as well as treating gastrointestinal disorders, has not gained approval from Food and Drug Administration (FDA). Domperidone is a peripherally acting dopamine$_2$-receptor antagonist. Unlike metoclopramide, it does not cross the blood-brain barrier, which decreases its likelihood of causing central nervous system-related adverse effects. Domperidone is being used for increasing lactation because of its proposed ability to increase prolactin levels. Although the medication's use has been approved in several other countries for gastric disorders, the countries have warned against its use in those who are lactating because the medication is excreted in breast milk. It is unknown at this time what risks this may pose to infants. Despite this warning, and along with serious adverse effects like cardiac arrhythmias, cardiac arrest, and sudden cardiac death from receiving the medication intravenously, pharmacies are still attempting to compound domperidone. Due to the danger of the intravenous preparation, this dosage form has been removed from the market in many countries. Currently, a 10 mg tablet is being investigated here in the United States, but only for treating gastrointestinal disorders.

FDA has issued several statements in the past informing health care providers that compounding domperidone is illegal and that FDA will take action against those who are involved in compounding this drug. FDA has also voiced its concerns about the lack of safety data for domperidone's use to increase lactation. The use of domperidone, because it is not FDA approved, violates the Federal Food, Drug, and Cosmetic Act (FDCA). Per this act (SEC. 505; 21 U.S.C. §335(a)), no person shall introduce into interstate commerce

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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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any new drug unless that drug has an approved application by FDA. Since domperidone is an unapproved medication, it is considered to be a new drug. As a result, those compounding it would be unable to provide "adequate directions for use" on the label. According to the FDCA (SEC 502; 21 U.S.C. §352(f)(1)) this deems the medication misbranded. The act also makes compounding domperidone illegal under Prohibited Acts: "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded (SEC. 301; 21 US § 331(a))."

It is also important to remember that according to the Wyoming Pharmacy Act Rules and Regulations Chapter 13, Section 3(b), one must obtain a Certificate of Analysis (COA) for the ingredients being used to compound if they are not designated United States Pharmacopeia (USP)-National Formulary (NF). Since domperidone is not listed in either USP or NF, a COA would need to be obtained. Under Title 33, Chapter 24 of the Wyoming Pharmacy Act (33-24-113 (d)(viii) and 33-24-152 (e)(viii)) purchasing or receiving a drug that is not FDA approved, gives the Wyoming State Board of Pharmacy the right to "deny, suspend, revoke, or refuse to renew" a license for both resident and nonresident pharmacies.

Those physicians wishing to prescribe the medication for patients with severe gastrointestinal disorders refractory to other treatments should file an Investigational New Drug Application. This would permit the importation, interstate shipment, and administration of domperidone, if the application is approved by FDA.

Disciplinary Actions

Note: all fines are payable to the county treasurer where the action occurred for the credit of the public school fund in that county pursuant to Wyoming Statute §33-24-113(f).

A.H. Pharmacy Technician License #1754T. Error in calculating and preparing a compounded product. Letter of Admonition. Order: additional three hours of CE on medication error prevention.

L.L. Pharmacist License #3320. Error in calculating and preparing a compounded product. Letter of Admonition. Order: additional five hours of CE on medication error prevention.

K.G. Pharmacist License #2811. Completed four hours of CE in 2010; 12 hours required. Administrative penalty of $300. Order: complete an additional eight hours of CE in 2011.

J.M. Pharmacist License #2771. Pharmacist-in-charge, lack of record keeping of competency of pharmacy technicians and pharmacists in compounding, lack of policy/procedures in compounding. Letter of Admonition. Order: submit a plan to Board office.

G.A. Pharmacist License #3051. Completed eight hours of CE in 2010 from approved providers;12 hours required. Administrative penalty of $200. Order: complete four hours of CE in addition to the annual 12 hours required in 2011.

Retail Pharmacy License #52-00251. Failure to certify competency of a pharmacy technician to perform compounding, failure to document competency of a pharmacist in compounding, failure to have recorded procedures for a compounded product, failure to have written control procedures to validate the performance of compounding processes. Administrative penalty of $10,000. Order: submit a plan.

Transferring Prescriptions

By Bree Bertz, PharmD Candidate

Wyoming Pharmacy Act, Rules Chapter 2, Section 10 was revised in 2011 to state that a pharmacist **or pharmacy intern** will transfer prescription order information upon request of a patient. The information is communicated directly by one pharmacist **or pharmacy intern** to another pharmacist, or the information may be electronically transferred between pharmacies. For controlled substances several revisions on transfers for Schedules III, IV, and V were made. Pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the practitioner's authorization. The transfer must be communicated directly **between two licensed pharmacists** (Code of Federal Regulations 21 CFR 1306.25). If a paper or oral prescription is received by a pharmacist that indicates it was originally transmitted electronically to another pharmacy, the pharmacist must contact the pharmacy to determine if it was received and dispensed. The Board recommends that transfers be communicated via **fax** whenever possible, to reduce transcription errors.

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