



Minnesota Board of Pharmacy

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of June 16, 2011 and September 9, 2011:

Elo, Thomas W., License #111768. Mr Elo admitted to the diversion of controlled substances from his employer for his personal use. He further admitted to the daily use of alcohol for a period of five or six years. Consequently, at its August 10, 2011 meeting, the Board issued a stipulation and consent order that suspends Mr Elo's license but stays the suspension on condition that he successfully completes participation in the Health Professionals Services Program and abstains from the use of mood-altering chemicals not expressly prescribed for him. The Board also imposed a civil penalty in the amount of \$500.

Katz, Roy D., License #119612. Mr Katz acknowledged that, after being licensed by the Board via reciprocity, he pleaded guilty in Connecticut Superior Court to two counts of misdemeanor, fourth-degree vendor fraud after being charged with improperly dividing 30-, 60-, and 90-day prescriptions into seven-day units, thus generating multiple dispensing fees when only one dispensing fee was legally payable, resulting in fraudulent charges extrapolated to \$3,283,403.88. Consequently, the Board adopted a stipulation and consent order at its August 10, 2011 meeting, reprimanding Mr Katz and assessing a civil penalty in the amount of \$2,500. In addition, the Board placed the following limitation on his license: no participation in Medicare, Medicaid, or any other federal health care program until he is reinstated into such programs. The Board further imposed the following conditions: completion of the course "Preventing Fraud, Waste and Abuse in Pharmacy Practice – 2011" and submission of a typewritten paper at least four pages in length that addresses what Mr Katz has learned and achieved from completing the above-mentioned course.

Passe, Lori J., License #118772. Dr Passe petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions and limitations on her license after she admitted that she had participated in the dispensing and distribution of orders for legend drugs that were not legitimate prescriptions in that they were based on online

questionnaires. The Board granted her petition and issued an order of unconditional license at its August 10, 2011 meeting.

Board Adopts Rule Changes

The Board started working on a large package of proposed rule changes in 2008. That process concluded with publication of A Notice of Adopted Permanent Rules for Pharmacy Practice in the September 6, 2011 issue of the *Minnesota State Register*. The rule changes became effective on September 13, 2011, and address a wide range of topics, with the most significant being pharmacy license categories, pharmacy counseling areas, automated counting and distribution devices, registration of pharmacy technicians, training and educational requirements for pharmacy technicians, unprofessional conduct, compounding, interns and preceptors, and consulting services to licensed nursing homes. Since many other topics were also addressed, licensees and registrants are advised to review the various documents related to the rule changes that are on the Board's Web site at www.pharmacy.state.mn.us/rulemake2010.htm. A brief discussion of select rule changes is provided on the Web site. Further information will be provided in the next issue of the Board's *Newsletter*.

Pharmacy License Categories

The Board has added several pharmacy license categories and revised the names of others. The current categories are community/outpatient, hospital, home health care, long-term care, nuclear, central service, nonsterile preparation compounding, sterile preparation compounding, veterinary, and limited service. No pharmacy may engage in providing products or services in categories for which it is not licensed. A pharmacy must designate its category or categories upon license renewal or application for an initial license. Effective July 1, 2012, an initial or renewal license issued by the Board will list each license category for which the pharmacy has received Board approval; a pharmacy must receive Board approval before providing services in a license category not listed on its license; a pharmacy must notify the Board if it no longer provides services in a license category; and the Board will issue a revised license, without imposing an additional fee, if it approves a pharmacy's request to provide services in additional license categories or if a pharmacy no longer provides services in one or more license categories.

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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 TEAspoonfuls 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 TEAspoonfuls each day for three days. By the fourth day only one TEAspoonful (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/acute/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 TEAspoonful 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 TEAspoon and TABLEspoon. 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 "TEAspoonful" equivalent (eg, 5 mL (1 TEAspoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of TEAspoonful 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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Pharmacy Counseling Areas

The Board has modified the rules concerning patient counseling areas to include the recommendations that it has been making concerning the dimensions and characteristics of partitioned counseling areas. If a pharmacy uses partitions to create a consultation area in which the patient will typically remain standing, the partitions must be sound-dulling and at least seven feet high and 24 inches deep. A patient must be able to enter the partitioned area so that the partitions are on each side of the patient. Consultation areas without partitions may be approved if the Board deems the consultation area will provide a reasonable assurance of privacy. Pharmacists must have access to patient profiles in order to comply with counseling requirements. All new and remodeled pharmacies must meet the new standards. A pharmacy licensed before January 1, 2011, must meet the new standards within two years of that date unless the pharmacy has an existing counseling area that has been deemed by the Board to provide a reasonable assurance of privacy.

Automated Counting and Distribution Devices and Systems

The Board has extensively revised the rules concerning the approval and use of automated counting and distribution devices and systems. Pharmacies will no longer need to receive affirmative approval from the Board before using these devices and systems. However, pharmacies **will still need to submit** detailed policies and procedures at least 60 days in advance of using such a device or system. The pharmacy that controls the device or system may proceed with its use unless the Board has provided written notification that it may not be used. Pharmacies currently using such devices and systems, as well as pharmacies contemplating such use, should thoroughly review Minnesota Rules 6800.2600 when developing or reviewing required policies and procedures.

Pharmacy Technicians

The Board adopted many significant rule changes concerning pharmacy technicians that address their registration, training and educational requirements, and the duties that they may perform. Language has been added that clarifies that an “individual may not, under any circumstances, perform tasks as a pharmacy technician prior to being registered as a pharmacy technician.” This has actually been the case since the Board first started registering technicians. After years of issuing warnings to pharmacies for allowing individuals to work as pharmacy technicians without being registered, the Board has recently started initiating disciplinary proceedings against pharmacies with unregistered “technicians.”

Effective January 1, 2012, the minimum age for registration as a pharmacy technician will increase from 16 to 18. Individuals who are less than 18 years of age and who are registered by the Board as a pharmacy technician prior to January 1, 2012, will be allowed to renew their registration provided that all other requirements for renewal are met.

Effective January 1, 2013, the Board will not issue an initial pharmacy technician registration to any individual who has not either graduated from high school or received a general educational development (GED) certificate. Individuals who have neither graduated from high school nor obtained a GED certificate but who are registered as a pharmacy technician prior to January 1, 2013, will be allowed to renew their regis-

trations provided that all other requirements for renewal are met and provided that they have maintained their registrations on an uninterrupted basis. Any individual whose registration lapses for a period of more than one year must meet the registration requirements in effect at the time the individual applies for reinstatement of registration.

Effective January 1, 2013, the Board will not renew the registration of a pharmacy technician who was initially registered after January 1, 2012, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual has completed a pharmacy technician training program. There are several types of training that will be acceptable, including a program offered by a Board-approved, accredited vocational/training institution or college; a program accredited by a Board-approved, national organization that accredits pharmacy technician training programs; a program offered by a branch of the United States armed forces or the Public Health Service; or an employer-based program that includes a minimum of 240 hours in a one-year period of both theoretical and practical instruction. An employer that uses an internal training program must develop and regularly update a technician training manual that must be available for Board inspection. (Since it has taken longer than anticipated to promulgate this rules package, the Board may delay this requirement until January 1, 2014, in order to give pharmacies additional time to develop employer-based training programs – and to give the Board time to evaluate training programs.)

A pharmacy technician’s registration renewal for calendar year 2014 will not be issued unless the technician has completed 20 hours of approved continuing pharmacy technician education (CPTe) during the two-year period between August 1, 2011, and July 31, 2013. Thereafter no annual pharmacy technician registration renewal will be issued unless the technician presents the Board with satisfactory evidence of completion of 20 hours of approved CPTe per two-year reporting period, with each period ending on July 31, of odd-numbered years. This means that all currently registered pharmacy technicians who plan on continuing to be registered should now begin completing approved CPTe programs.

The Board adopted a change that clarifies that pharmacy technicians may not take new prescription orders off of an answering machine or other interactive voice response system. A technician may take **refills** off of such systems as long as no changes are made to the prescription order. Pharmacy technicians are now allowed to participate in extemporaneous compounding but only a pharmacist is allowed to establish and validate the initial formulation record of compounded preparations. In other words, if a pharmacy receives a prescription for a compounded product that has never been compounded at the pharmacy, a pharmacist must prepare and validate the initial formulation record before a technician can assist in the compounding process.