



**State of Minnesota**  
**The Office of Ombudsman for**  
**Mental Health and Developmental Disabilities**  
121 7<sup>th</sup> Place E. Suite 420 Metro Square Building, St. Paul, Minnesota 55101-2117

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May 2014

Dear Colleague:

The Medical Review Subcommittee reviews reports of individual deaths and also reviews accumulated data on all deaths and serious injuries reported to our office. Periodically, the MRS develops Medical Alerts based upon its reviews. This cover letter is to announce the [Summer Alerts for 2014](#):

**Summer Alert      Heat Stroke Alert      Insect Sting Alert      Water Safety Alert      *New - Metabolic Syndrome Update***

We are working to be able to provide on-line Death and Serious injury reporting through the Ombudsman's website. Please be sure to watch your e-mail for notification (via our List Service) of the availability of on-line reporting. Encourage your co-workers and colleagues to become List Service members, so they will receive notice when on-line reporting is available. You can sign up for the List Service at

**Medical Alerts E-Mail List Service** - [Click here to Subscribe or Unsubscribe to the Medical Alerts E-Mail List Service.](#)

When you subscribe to this service, we will notify you by e-mail when we post new Medical Alerts to our website.

**Reports of deaths and serious injuries** can be faxed or telephoned to the Office of Ombudsman for Mental Health and Developmental Disabilities at the following numbers:

**Fax: 651-797-1950**

**Voice: 651-757-1800**

**Toll Free: 1-800-657-3506**

**Please note our fax number.** If your fax report transmission does not appear to be successful when using the preferred fax number, please use our back-up fax number: **651-296-1021**.

**MedWatch Safety Alerts** - Since the 2013-2014 Winter Alert, the FDA has released MedWatch Safety Alerts for many medications and devices, many of which are prescribed for clients of this Office. These medications and devices include:

**Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement - Recommendation to Discontinue Prescribing and Dispensing** - [Posted 01/14/2014] Cases of severe liver injury with acetaminophen have occurred in patients who: took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period; took more than one acetaminophen-containing product at the same time; or drank alcohol while taking acetaminophen products. For more information see <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm381650.htm>

**Eszopiclone Containing Sleep Aids: Drug Safety Communication - Can Cause Next-Day Impairment - Including Lunesta and generics** - [Posted 05/15/2014] **ISSUE:** FDA has notified health professionals and their medical care organizations of a new warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. FDA recommends a decreased starting dose of Lunesta to 1 mg at bedtime. Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. FDA approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes. For additional information see: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm397536.htm>

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**May, 2014**

**Methylphenidate ADHD Medications: Drug Safety Communication - Risk of Long-lasting Erections -** Including Concerta, Daytrana, Focalin/Focalin XR, Metadate CD/Metadate ER, Methylin/Methylin ER, Quillivant XR, Ritalin/Ritalin LA/Ritalin SR [Posted 12/17/2013] ISSUE: FDA is warning that methylphenidate products, one type of stimulant drug used to treat attention deficit hyperactivity disorder (ADHD), may in rare instances cause prolonged and sometimes painful erections known as priapism. Based on a recent review of methylphenidate products, FDA updated drug labels and patient Medication Guides to include information about the rare but serious risk of priapism. If not treated right away, priapism can lead to permanent damage to the penis. Priapism can occur in males of any age and happens when blood in the penis becomes trapped, leading to an abnormally long-lasting and sometimes painful erection. Another ADHD drug, Strattera (atomoxetine), has also been associated with priapism in children, teens, and adults. Priapism appears to be more common in patients taking atomoxetine than in those taking methylphenidate products; however, because of limitations in available information, FDA does not know how often priapism occurs in patients taking either type of product. See the FDA Drug Safety Communication for additional information, including a Data Summary. For additional information see: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm378876.htm>

**Over-the-Counter Topical Antiseptic Products: Drug Safety Communication - FDA Requests Label Changes and Single-Use Packaging to Decrease Risk of Infection** [Posted 11/13/2013] ISSUE: The U.S. Food and Drug Administration (FDA) is requesting label and packaging changes to enhance the safe use of certain over-the-counter (OTC) topical antiseptic products. This request is the result of our ongoing evaluation of infrequent but continuing reports of infections resulting from antiseptic products labeled for preoperative or preinjection skin preparation. When used properly, topical antiseptics are safe and effective products to reduce the number of bacteria on patients' skin prior to surgery or injections. However, most often, contamination of topical antiseptics occurs when organisms are introduced into the product by users. Therefore, health care professionals and patients should follow all label directions to decrease the chances of infection.

Outbreaks associated with the use of contaminated topical antiseptics have been reported in the medical literature and to the Centers for Disease Control and Prevention (CDC). Clinical infections have also been reported to FDA, leading to some product recalls. The reported outcomes ranged from localized infections at injection sites to systemic infections that resulted in death. FDA has reviewed reports of four deaths, five cases of wound infection, seven cases of peritonitis, 10 cases of septic arthritis, 14 cases of indwelling catheters requiring replacement, 16 cases of injection site infection, and 32 cases of bacteremia. These infections have been confirmed to be caused by contaminated antiseptic products. Affected products included all commonly used antiseptic ingredients, including alcohol, iodophors, chlorhexidine gluconate, and quaternary ammonium products. Organisms implicated in the outbreaks included *Bacillus cereus*, *Burkholderia cepacia*, *Pseudomonas aeruginosa*, *Achromobacter xylosoxidans*, *Ralstonia pickettii*, *Serratia marcescens*, and *Mycobacterium abscessus*.

For more information see <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm374892.htm>

**Pradaxa (dabigatran): Drug Safety Communication - Lower Risk for Stroke and Death, but Higher Risk for GI Bleeding Compared to Warfarin -** [Posted 05/13/2014] ISSUE: The FDA recently completed a new study in Medicare patients comparing Pradaxa to warfarin, for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. The new study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs, Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death, than warfarin. The study also found an increased risk of major gastrointestinal bleeding with use of Pradaxa as compared to warfarin. The MI risk was similar for the two drugs. For more information see <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm397179.htm>

**Sodium Phosphate Over-the-Counter Products: Drug Safety Communication - Possible Harm From Exceeding Recommended Dose** - Marketed under the brand-name Fleet, and as store brands and generic products. [Posted 01/08/2014] ISSUE: FDA is warning that using more than one dose in 24 hours of over-the-counter (OTC) sodium phosphate drugs to treat constipation can cause rare but serious harm to the kidneys and heart, and even death. FDA has become aware of reports of severe dehydration and changes in the levels of serum electrolytes from taking more than the recommended dose of OTC sodium phosphate products, resulting in serious adverse effects on organs, such as the kidneys and heart, and in some cases resulting in death. These serum electrolytes include calcium, sodium, and phosphate. According to the reports, most cases of serious harm occurred with a single dose of sodium phosphate that was larger than recommended or with more than one dose in a day. For additional clinical information, see the FDA Drug Safety Communication Data Summary. For additional information see <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380833.htm>

**Testosterone Products: Drug Safety Communication** - FDA Investigating Risk of Cardiovascular Events [Posted 01/31/2014] ISSUE: FDA is investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. We have been monitoring this risk and decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy. FDA is providing this alert while it continues to evaluate the information from these studies and other available data. FDA will communicate final conclusions and recommendations when the evaluation is complete. For more information see <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm384225.htm>

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380008.htm>

When administering prescription and over-the-counter medications to your clients, please be aware of the potential side effects of the medications. Document any changes in the client's condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the health care provider can be informed.

Thank you for your interest in our Medical Alerts. Please call me at 651-431-5202 or 1-800-657-3506 with any questions or concerns. We look forward to receiving your on-line death and serious injury reports via our website when the service is available.

Sincerely,



Jo Zillhardt, RN-BC, PHN  
Medical Review Coordinator