



State of Minnesota

The Office of Ombudsman for Mental Health and Developmental Disabilities

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“Giving Voice to Those Seldom Heard”

May 2017

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 2017:

Summer Alert

Heat Stroke Alert

Insect Sting Alert

Water Safety Alert

For continued updates from the Office of Ombudsman for Mental Health and Developmental Disabilities, you can sign up for the List Service at [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.

Or go to: <https://mn.gov/omhdd/documents/medical-alerts.jsp>

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

Thank you for continuing to fax your Serious Injury and Death reports to our Office and for your cooperation with our review process.

MedWatch Safety Alerts - Since the 2016-2017 Winter Alert, the FDA has released MedWatch Safety Alerts for many medications and devices, some of which are prescribed for clients of this Office. These medications and devices include:

Pioglitazone-containing Medicines: Drug Safety Communication - Updated FDA Review, Increased Risk of Bladder Cancer – Posted 12/12/2016 - **ISSUE:** As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and FDA has approved label updates to describe the additional studies reviewed. See the FDA Drug Safety Communication for more details, including a data summary. Additional information can be found at <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm532772.htm>



Serving Minnesotans receiving services for

Mental Illness

Developmental Disabilities

Chemical Dependency

Emotional Disturbance

Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Increased Risk of Leg and Foot Amputations – 5-15-2017 - ISSUE: Based on new data from two large clinical trials, the FDA has concluded that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations. FDA is requiring new warnings, including the most prominent Boxed Warning, to be added to the canagliflozin drug labels to describe this risk.

Final results from two clinical trials – the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus) – showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo, which is an inactive treatment. Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs. See the FDA Drug Safety Communication for additional information, including a data summary.

https://www.fda.gov/Drugs/DrugSafety/ucm557507.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Codeine and Tramadol Medicines: Drug Safety Communication - Restricting Use in Children, Recommending Against Use in Breastfeeding Women - Posted 04/20/2017 - ISSUE: FDA is restricting the use of codeine and tramadol medicines in children. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

As a result, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond the 2013 FDA restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. Additional information can be found at -

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm554029.htm>

Viberzi (eluxadoline): Drug Safety Communication - Increased Risk of Serious Pancreatitis In Patients Without A Gallbladder - Posted 03/15/2017 - ISSUE: FDA is warning that Viberzi (eluxadoline), a medicine used to treat irritable bowel syndrome with diarrhea (IBS-D), should not be used in patients who do not have a gallbladder. An FDA review found these patients have an increased risk of developing serious pancreatitis that could result in hospitalization or death. Pancreatitis may be caused by spasm of a certain digestive system muscle in the small intestine. As a result, FDA is working with the Viberzi manufacturer, Allergan, to address these safety concerns. For additional information -

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm546771.htm>

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm535957.htm>

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.

Sincerely,
Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator