



State of Minnesota
**The Office of Ombudsman for
Mental Health and Developmental Disabilities**
121 7th Place E. Suite 420 Metro Square Building, St. Paul, Minnesota 55101-2117
Voice: 651-757-1800 or Toll Free: 1-800-657-3506
TTY/Voice Minnesota Relay Service 711 Fax: 651-797-1950

“Giving Voice to Those Seldom Heard”

July 2016

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 2016:

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://webmail.mnet.state.mn.us/mailman/listinfo/Medical-alert>

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, 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 2015-2016 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:

Aripiprazole (Abilify, Abilify Maintena, Aristada): Drug Safety Communication - FDA Warns About New Impulse-control Problems - AUDIENCE: Psychiatry, Internal Medicine, Patient. **ISSUE:** FDA is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized. See the [FDA Drug Safety Communication](#) for additional information.



Fluoroquinolone Antibacterial Drugs: Drug Safety Communication - FDA Advises Restricting Use for Certain Uncomplicated Infections - AUDIENCE: Internal Medicine, Family Practice, Pharmacy, Patient. **ISSUE:** FDA is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options. See the [FDA Drug Safety Communication](#). **RECOMMENDATION:** Patients should contact your health care professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include tendon, joint and muscle pain, a “pins and needles” tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your health care professional if you have any questions or concerns

Olanzapine: Drug Safety Communication - FDA Warns About Rare But Serious Skin Reactions - AUDIENCE: Psychiatry, Dermatology, Patient. **ISSUE:** FDA is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. See the Data Summary section of the [FDA Drug Safety Communication](#) for more information. DRESS may start as a rash that can spread to all parts of the body. It can include fever and swollen lymph nodes and a swollen face. **BACKGROUND:** Olanzapine is an antipsychotic medicine used to treat mental health disorders schizophrenia and bipolar disorder. It can decrease hallucinations and other psychotic symptoms such as disorganized thinking. Olanzapine is available under the brand names Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax, and also as generics. **RECOMMENDATIONS: Patients** taking olanzapine-containing products who develop a fever with a rash and swollen lymph glands, or swelling in the face, should seek medical care right away.

Opioid Pain Medicines: Drug Safety Communication - New Safety Warnings Added to Prescription Opioid Medications AUDIENCE: Family Practice, Psychiatry, Pain Management, Nursing, Endocrinology. **ISSUE:** FDA is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. **Opioids can interact with antidepressants and migraine medicines** to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of the chemical serotonin build up in the brain and cause toxicity. **Taking opioids may lead to a rare, but serious condition in which the adrenal glands do not produce adequate amounts of the hormone cortisol. Long-term use of opioids may be associated with decreased sex hormone levels** and symptoms such as reduced interest in sex, impotence, or infertility. **BACKGROUND:** Opioids are powerful prescription medicines that can help manage pain when other treatments and medicines are not able to provide enough pain relief (see List of Opioid Medicines in the [FDA Drug Safety Communication](#)).

Additional information about MedWatch Safety Alerts can be obtained at the FDA’s website:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.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, concerns or additional information about MedWatch Safety Alerts.

Sincerely,



Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator

