MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

"Giving Voice to Those Seldom Heard"

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Dear Colleague:

Extending best wishes to you and the clients with whom you work. This office recommends the following sources of up to date information about COVID-19:

Minnesota Department of Health Coronavirus Disease 2019 (COVID-19) Homepage (https://www.health.state.mn.us/diseases/coronavirus/index.html)

DHS provides information about the COVID waiver wind down (https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=DHS-329611)

The Medical Review Subcommittee (MRS) continues to review reports of individual deaths and reviews accumulated data on all deaths and serious injuries reported to the Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD). Periodically, the MRS develops Medical Alerts based upon those reviews.

Announcing the Summer Alerts for 2021 (https://mn.gov/omhdd/documents/medical-alerts.jsp):

Summer Alert **Heat Stroke Alert** **Insect Sting Alert** **Water Safety Alert**

For continued updates from the (OMHDD), you can Subscribe to the OMHDD Medical Alerts E-Mail List Service. When you subscribe to this service, you will be notified by e-mail when new Medical Alerts are posted to the OMHDD website.

New Method for Reporting Deaths and Serious Injuries

Earlier in 2020 the OMHDD made webform reporting available for the routine reporting of deaths and serious injuries. Webform reporting is the preferred method of reporting deaths and serious injuries, but the paper forms remain available on the OMHDD website for use when preferred by reporters.

Death Review webform (https://omhddcms.i-sight.com/portal/death-review)

Serious Injury webform (https://omhddcms.i-sight.com/portal/serious-injury)

Reporting Death or Serious Injury – Downloadable Forms (https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp)

The OMHDD appreciates the use of the death report webform and the serious injury webform.

While the office recognizes that you may not have all the information requested on the forms, please provide the information to which you do have access, for example: the client's first and last names, the client's date of birth, the date of death, if known, and the contact information for the reporter including the reporter title (case manager, social worker, program director, mental health practitioner, etc.) and the Reporter Facility/Agency Name (when applicable).

Reports of deaths and serious injuries can still be faxed to the OMHDD at the following number:

Fax: 651-797-1950 Please note the fax number. (The old back-up fax number is no longer available.)

Thank you for continuing to report Serious Injuries and Deaths to the OMHDD and for your continuing cooperation with the review process. Please call Voice: 651-757-1800 or Toll Free: 1-800-657-3506 with any questions.

MedWatch Safety Alerts are now called Drug Safety Communications by the FDA

Since the 2020-2021 Winter Alert, the FDA has released **Drug Safety Communications** for many medications, some of which are prescribed for clients of the OMHDD. These medications include the following:

> **Initial safety trial results find increased risk of serious heart-related problems and cancer with arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib)** - *FDA will evaluate the trial results* (https://www.fda.gov/drugs/drug-safety-and-availability/initial-safety-trial-results-find-increased-risk-serious-heart-related-problems-and-cancer-arthritis)
>
> **2-4-2021 FDA Drug Safety Communication**
>
> The U.S. Food and Drug Administration (FDA) is alerting the public that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with the arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. FDA required the safety trial, which also investigated other potential risks including blood clots in the lungs and death. Those final results are not yet available.
>
> We will evaluate the clinical trial results we have received to date and will work with the drug manufacturer to obtain further information as soon as possible. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share.
>
> **Patients** should not stop taking tofacitinib without first consulting with your health care professionals, as doing so may worsen your condition. Talk to your health care professionals if you have any questions or concerns.

Health care professionals should consider the benefits and risks of tofacitinib when deciding whether to prescribe or continue patients on the medicine. Continue to follow the recommendations in the tofacitinib prescribing information.

Tofacitinib was first approved in 2012 to treat adults with rheumatoid arthritis (RA) who did not respond well to the medicine methotrexate. In RA, the body attacks its own joints, causing pain, swelling, and loss of function. In 2017, we approved tofacitinib to treat patients with a second condition that causes joint pain and swelling, psoriatic arthritis (PsA), who did not respond well to methotrexate or other similar medicines. In 2018, we approved the medicine to treat ulcerative colitis, which is a chronic, inflammatory disease affecting the colon. Tofacitinib works by decreasing the activity of the immune system; an overactive immune system contributes to RA, PsA, and ulcerative colitis…

FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm *This includes heart and mental health problems or death*
(https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-abuse-and-misuse-nasal-decongestant-propylhexedrine-causes-serious-harm)

3-25-2021 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is warning that the abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine can lead to serious harm such as heart and mental health problems. Some of these complications, which include fast or abnormal heart rhythm, high blood pressure, and paranoia, can lead to hospitalization, disability, or death. Reports of individuals abusing and misusing propylhexedrine have increased in recent years. Propylhexedrine is safe and effective when used as directed.

We are requesting that all manufacturers of OTC propylhexedrine nasal decongestant inhalers consider product design changes that support its safe use. For example, modifying the product to create a physical barrier that would make tampering with the device and abusing the propylhexedrine inside more difficult. In addition, decreasing the amount of medicine the device contains could also reduce the risk of serious side effects if abused or misused. We continue to evaluate this safety issue and will determine if additional FDA actions are needed.

Consumers should only use propylhexedrine according to the directions on the Drug Facts label. Do not use it in ways other than by inhalation because doing so can cause serious harm, such as heart and mental health problems. Some of these problems can lead to death. Seek medical attention immediately by calling 911 or poison control at 1-800-222-1222 for anyone using propylhexedrine who experiences the following:

- Severe anxiety or agitation, confusion, hallucinations, or paranoia
- Rapid heartbeat or abnormal heart rhythm
- Chest pain or tightness

Ask a pharmacist or your health care professional if you have any questions about propylhexedrine, how to use it, or whether a medicine you are taking may interact with it. Always tell your health care professionals about all medicines you are taking, including OTC medicines…

Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease *FDA now requiring studies to evaluate heart risk across the drug class* (https://www.fda.gov/drugs/drug-safety-and-availability/studies-show-increased-risk-heart-rhythm-problems-seizure-and-mental-health-medicine-lamotrigine)

03-31-2021 FDA Drug Safety Communication

A U.S. Food and Drug Administration (FDA) review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine lamotrigine (Lamictal). We want to evaluate whether other medicines in the same drug class have similar effects on the heart and are requiring safety studies on those also. We will update the public when additional information from these studies becomes available.

FDA required these studies, called in vitro studies, to further investigate Lamictal's effects on the heart after we received reports of abnormal electrocardiographic (ECG) findings and some other serious problems. In some cases, problems including chest pain, loss of consciousness, and cardiac arrest occurred. In vitro studies are studies done in test tubes or petri dishes and not in people or animals. We first added information about this risk to the lamotrigine prescribing information and Medication Guides in October 2020, which we have updated.

Lamotrigine is used alone or with other medicines to treat seizures in patients 2 years and older. It may also be used as maintenance treatment in patients with the mental health condition bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Lamotrigine has been approved and on the market for more than 25 years and is available under the brand name Lamictal and as generics.

Patients should not stop taking your medicine without first talking to your prescriber because stopping lamotrigine can lead to uncontrolled seizures, or new or worsening mental health problems. Contact your health care professional right away or go to an emergency room if you experience an abnormal heart rate or irregular rhythm, or symptoms such as a racing heartbeat, skipped or slow heartbeat, shortness of breath, dizziness, or fainting…

Magnets in Cell Phones and Smart Watches May Affect Pacemakers and Other Implanted Medical Devices (https://www.fda.gov/radiation-emitting-products/cell-phones/magnets-cell-phones-and-smart-watches-may-affect-pacemakers-and-other-implanted-medical-devices)

5-13-2021 FDA Safety Information and Adverse Event Reporting Program

Some consumer electronic devices, such as certain cell phones and smart watches, include high field strength magnets. Recent studies have shown that consumer electronic devices with high field strength magnets may cause certain implanted medical devices to switch to "magnet mode" and suspend normal operations until the magnet is moved away from the medical device.

Many implanted medical devices are designed with a "magnet mode" to allow for safe operation during certain medical procedures such as undergoing an MRI scan. These safety features are typically engaged by physicians with the use of a high field strength magnet that is placed near the implanted device placing it into a "magnet mode." Removal of the magnetic field causes the device to return to normal operation.

Precautions for Patients with Pacemakers and Other Implanted Medical Devices

The FDA recommends patients keep any consumer electronic devices that may create magnetic interference, including cell phones and smart watches, at least six inches away from implanted medical devices, in particular cardiac defibrillators. Many implanted medical devices have FDA-approved information written for patients (patient labeling), which cautions patients to keep all cell phones and smart watches at least six inches from the implanted medical device….

Additional information can be obtained at FDA Drug Safety Communications (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications).

Medication Administration

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/prescriber can be informed.

Please be aware of the Medical Review Subcommittee's Medical Alerts that may apply to your clients. The OMHDD still continues to receive reports of the deaths of clients who had been given pain reducing medications for fevers of unknown origin and clients whose pulse oximeter reading were under 90%. In these cases, neither the client's physician, nor other health care provider was notified, nor was 911 called until after the client stopped breathing.

Use of over-the-counter medications and possible delay of treatment [PDF] (https://mn.gov/omhdd/assets/OTC-and-Delay-of-Tx-2013_tcm23-27625.pdf)

Breathing Alert – think pink, not blue! [PDF] (https://mn.gov/omhdd/assets/breathing-alert-2013_tcm23-27664.pdf)

Medical Alert - Pulse Oximetry [PDF] (https://mn.gov/omhdd/assets/PulseOximetry2016_tcm23-264999.pdf)

Thank you for your interest in the 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