SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals:
Zofran (ondansetron):
Drug Safety Communication - Risk of Abnormal Heart Rhythms

SOURCE: FDA MedWatch

ISSUE: FDA notified healthcare professionals and patients of an ongoing safety review and labeling changes for the anti-nausea drug Zofran (ondansetron, ondansetron hydrochloride and generics). Ondansetron may increase the risk of developing prolongation of the QT interval of the electrocardiogram, which can lead to an abnormal and potentially fatal heart rhythm, including Torsade de Pointes. Patients at particular risk for developing Torsade de Pointes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation.

BACKGROUND: Zofran (ondansetron) is in a class of medications called 5-HT3 receptor antagonists. It is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery. FDA is requiring GlaxoSmithKline to conduct a thorough QT study to determine the degree to which Zofran (ondansetron) may cause QT interval prolongation.

RECOMMENDATION: The labels are being revised to include a warning to avoid use in patients with congenital long QT syndrome because these patients are at particular risk for Torsade. Recommendations for ECG monitoring in patients with electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmias, or in patients taking other medications that can lead to QT prolongation, are being included in the labels.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the Drug Safety Communication, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm272041.htm

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx. This information is provided as a service for information and education only.