

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Propoxyphene-Containing Products:  
FDA Taking Actions to Reduce Risk of Overdose Because of Data Linking  
Propoxyphene and Fatal Overdoses**

According to FDA Medwatch, FDA notified healthcare professionals that it is taking several actions to reduce the risk of overdose in patients using pain medications that contain propoxyphene because of data linking propoxyphene and fatal overdoses. The agency will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products and to provide a medication guide to patients stressing the importance of using the drugs as directed.

FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. To further evaluate the safety of propoxyphene, FDA plans to work with several groups including the Centers for Medicare & Medicaid Services and the Veterans Health Administration to study how often the elderly are prescribed propoxyphene instead of other pain relievers and the difference in the safety profiles of propoxyphene compared to other drugs.

Read the complete MedWatch Safety summary, including links to the FDA news release and Q&A's, at:

[www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170763.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170763.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.