

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Botox And Botox Cosmetic (Botulinum toxin Type A) And Myobloc (Botulinum toxin Type B)- Reports of Respiratory Compromise And Death

According to MedWatch, FDA issued an early communication about an ongoing safety review regarding Botox and Botox Cosmetic. FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of botulinum toxins types A and B for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity. Use of botulinum toxins for treatment of limb spasticity (severe arm and leg muscle spasms) in children or adults is not an approved use in the U.S. See the FDA's "Early Communication about an Ongoing Safety Review" for Agency recommendations and additional information for healthcare professionals.

Read the complete 2008 MedWatch Safety Summary including a link to the FDA's Early Communication about an Ongoing Safety Review regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#botox>

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.