

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Epogen and Procrit (epoetin alfa):  
Recall - Particulate Matter in Vials**

**AUDIENCE:** Risk Manager, Oncology, Nephrology

**ISSUE:** Amgen and FDA notified healthcare professionals that certain lots of Epogen and Procrit (Epoetin alfa) vials are being recalled as a precaution, because the vials may contain extremely thin glass flakes (lamellae) that are barely visible. The potential serious adverse events resulting from the use of a sterile injectable product with particulates by the intravenous route include embolic, thrombotic and other vascular events (e.g., phlebitis), and by the subcutaneous route include foreign body granuloma, local injection site reactions, and increased immunogenicity.

**BACKGROUND:** The products are indicated for the treatment of anemia related to HIV therapy, chronic renal failure, and chemotherapy. The lamellae result from the interaction of the formulation with glass vials over the shelf life of the product. The affected product lot numbers and expiration dates are included in the table in the firm press release, linked below.

**RECOMMENDATIONS:** Amgen has initiated recall letters which include instructions to return the referenced product to the returned goods service provider.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to 1-800-77-AMGEN or to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://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 firm Press Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm227225.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.