**American Academy of Orthopaedic Surgeons**

Patient Safety Member Alert Meningitis and Stroke Associated with

Potentially Contaminated Product

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are coordinating a multistate investigation of fungal meningitis among patients who received an **epidural steroid injection.** Several of these patients also sustained strokes that are believed to have resulted from the infection. The investigation is ongoing and interim data show that all infected patients received injections with preservative-free **methylprednisone acetate (80 mg/mL)** prepared by New England Compounding Center, located in Framingham, Mass.

**Infected patients have presented approximately 1 to 4 weeks following their injection with a variety of symptoms, including fever, new or worsening headache, nausea, and new neurological deficit (consistent with deep brain stroke). Some of these patients’ symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically shown elevated white cell count (with a predominance of neutrophils), low glucose, and elevated protein.**

On Sept. 25, 2012, the New England Compounding Center located in Framingham, Mass., voluntarily recalled the following lots of methylprednisolone acetate (PF) 80mg/mL: ·

Methylprednisolone Acetate (PF) 80 mg/mL Injection, Lot #05212012@68, BUD 11/17/2012 · Methylprednisolone Acetate (PF) 80 mg/mL Injection, Lot #06292012@26, BUD 12/26/2012 · Methylprednisolone Acetate (PF) 80 mg/mL Injection, Lot #08102012@51, BUD 2/6/2013

On Oct. 3, 2012, the compounding center ceased all production and initiated recall of all methylprednisolone acetate and other drug products prepared for intrathecal administration.

Physicians should contact patients who have had an injection (e.g., spinal, joint) using any of the three lots of methylprednisolone acetate listed above to determine if they are having any symptoms.

For guidance on diagnostic testing that should be performed on patient specimens, physicians can go to

<http://www.cdc.gov/hai/outbreaks/meningitis.html>

State health departments should be informed of patients undergoing evaluation.

Clinicians should report any suspected adverse events following use of these products to FDA’s MedWatch program at 1-800-332-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)