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# **HEALTH ALERT**

OCTOBER 9, 2012

## **New England Compounding Center (NECC) Recall and Meningitis**

CDC and FDA are investigating a multistate outbreak of fungal meningitis, often with sequelae of stroke, associated with epidural injection of **preservative-free methylprednisolone acetate** (80mg/ml) manufactured by the New England Compounding Center (NECC). To date, 119 cases have been identified and 11 deaths have been reported in 10 states; none of these have occurred in California.

As of October 5, three lots of NECC-compounded methylprednisolone were recalled. **None of the recalled drug lots were shipped to San Francisco.** However, San Francisco facilities and clinicians could have received other products from NECC. To date, no other NECC products have been associated with contamination or infection. Nonetheless, **NECC has ceased all operations, and has recalled <u>all</u> its products. A list of NECC products is available here: <a href="http://www.neccrx.com/">http://www.neccrx.com/</a>. NECC has notified its customers to stop using its products immediately, to retain and secure them, and to follow instructions from the company.** 

### **Actions requested of all clinicians:**

- 1. Immediately discontinue use of all NECC products.
- 2. Review CDC outbreak-associated case definitions below. Report cases and potential cases to the **Communicable Disease Control Unit** (CDCU) at (415) 554-2830. <u>Reminder</u> all meningitis cases are legally reportable in California.
- 3. Remain vigilant, and report to CDCU <u>any</u> infection identified in a patient known to have received an NECC product of any type.
- 4. Report complaints or problems associated with NECC products to FDA (By phone to 1-800-FDA-1088 or on line at <a href="https://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a>)

#### CDC Case Definitions (Any One of the Following Meets Case Criteria)

- 1. <u>Meningitis</u> with sub-acute onset (1-4 weeks) following epidural injection after May 21, 2012. (Including clinically diagnosed meningitis, consisting of one or more of: headache, fever, stiff neck, photophobia, and CSF profile consistent with meningitis e.g. pleocytosis +/- low glucose, elevated protein).
- 2. <u>Basilar stroke</u> 1-4 weeks following epidural injection after May 21, 2012, in a patient who has not received a lumbar puncture. These patients should have a lumbar puncture, if not contraindicated.
- 3. Evidence of <u>spinal osteomyelitis or epidural abscess</u> at the site of an epidural injection diagnosed 1-4 weeks after epidural injection after May 21, 2012.
- 4. <u>Septic arthritis</u> diagnosed 1-4 weeks following steroid joint injection after May 21, 2012. (Including clinically diagnosed septic arthritis, meaning new or worsening pain with presence of effusion, or new or worsening effusion.)

#### **Additional Resources:**

CDC Clinician guidance: http://www.cdc.gov/hai/outbreaks/clinicians/index.html.

CDC General Public FAQ's http://www.cdc.gov/hai/outbreaks/patients/faq-meningitis-outbreak-patients.html.

FDA NECC recall information: <a href="http://www.fda.gov/Safety/Recalls">http://www.fda.gov/Safety/Recalls</a>.