October 15, 2012

To: NC Clinicians and Pharmacists
From: Megan Davies, MD, State Epidemiologist
Re: Meningitis Cluster Investigation Associated with Spinal Injection Procedures – UPDATE #2

The North Carolina Division of Public Health is continuing to work with other state and federal agencies to investigate an outbreak of fungal meningitis among patients who received potentially contaminated steroid injections.

As of October 15th, 214 cases from fifteen states had been identified, including two cases from North Carolina. At least fifteen deaths have been reported (none in North Carolina). *Exserohilum rostratum*, a common environmental mold, is the organism most frequently identified among cases in this outbreak. This form of fungal meningitis is not contagious.

The vast majority of infected patients identified thus far have received preservative-free (PF) methylprednisolone acetate (80 mg/ml) from among the three lots voluntarily recalled by the New England Compounding Center (NECC) in Framingham, Massachusetts, on September 26, 2012. These three lots are:

- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, Beyond-use date 11/17/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, Beyond-use date 12/26/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, Beyond-use date 2/6/2013

All North Carolina providers listed as having received the recalled steroid product have been notified. All North Carolina patients who received these products for epidural injection or any other use have been individually contacted and referred for care if needed.

On October 6, NECC expanded its voluntary recall to include all NECC products. If you have an NECC product in your facility, this product should be retained, secured, and withheld from use. Currently, three confirmed or potential fungal infections have been identified among recipients of other NECC products, but it is not yet known whether these were the result of product contamination.

Today, FDA released a statement expressing concern about the sterility of any injectable drugs produced by NECC (http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm). Based on this concern, FDA is encouraging all providers that have used injectable products purchased from or produced by NECC since May 21, 2012 to inform patients who received these products of the risk of infection and advise them to contact a healthcare provider immediately for any symptoms of possible infection. Clinicians are also requested to 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.

Additional information about this outbreak, including testing and treatment guidelines and case definitions, can be found on the CDC Multistate Fungal Meningitis Outbreak Investigation website: www.cdc.gov/hai/outbreaks/meningitis.html.