Deadly meningitis outbreak linked to contaminated steroids

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The number of people who have contracted a fungal form of meningitis linked to contaminated steroid injections rose to 105 on Monday, jumping by 14 people in one day, the Centers for Disease Control and Prevention (CDC) reported. The death toll stands at eight, while possibly thousands of people are at risk for infection.

According to the CDC, all of those who contracted the disease are believed to have received spinal injections of methylprednisolone acetate, a steroid drug commonly used for back pain, which investigators suspect was contaminated with a fungus usually found in leaf mold. The drug was manufactured by a specialty compounding pharmacy, the New England Compounding Center (NECC) in suburban Boston.

The 105 cases of fungal meningitis have been found in the Florida, Indiana, Maryland, Michigan, Minnesota, North Carolina, Ohio, Tennessee and Virginia. Last Friday the CDC released a list of approximately 75 health care facilities in 23 states that reportedly received the contaminated product beginning on May 21, 2012.

Meningitis is an inflammation of the protective membranes covering the brain and spinal cord. While usually caused by an infection from bacteria or a virus, it can also be caused by less common pathogens such as fungi. Fungal meningitis is rare and, unlike other forms of the disease, is not contagious.

Typical symptoms of meningitis include severe headache, fever, nausea, and stiffness of the neck. In addition to these symptoms, those contracting fungal meningitis may also experience stroke-like episodes, as well as confusion, dizziness and sensitivity to bright lights. As the incubation period for the fungal variety of the disease can be up to a month or longer, patients presently showing no symptoms may become infected for months to come.

The Food and Drug Administration (FDA) has asked all health care providers and consumers to stop using any products produced by NECC. The Framingham, Massachusetts company voluntarily recalled three lots of the steroid last week, and last Wednesday voluntarily surrendered its license to operate until an FDA investigation into the contamination is complete. On Saturday the compounding pharmacy announced a voluntary nationwide recall of all its products.

Federal health inspectors began an inspection of the NECC facility last Monday, October 1. Inspectors found foreign particles in unopened vials; after testing this substance was determined to be a fungus. The investigation is ongoing.

The outbreak of the deadly disease points to a lack of government regulation of drug manufacturing as well as the growing problem of drug shortages. Both of these issues are exacerbated by the for-profit production of medicines that are depended upon by millions of people to treat diseases and other conditions. In this case, patients seeking treatment for neck and back pain have been injected with a drug that could kill them.

About 10 percent of drugs in the United States are prepared in so-called compound pharmacies. Unlike drugs produced by pharmaceutical companies, drugs produced in these facilities are not required to go through FDA-mandated premarket approval, but are instead overseen and licensed by state health pharmacy boards.

According to the International Academy of Compounding Pharmacists, compounding pharmacies create customized medication for patients in cases where manufactured pharmaceuticals won’t work. In reality, the scope of operations of these companies is

far wider. In relation to the current meningitis outbreak, New England Compounding began to produce methylprednisolone acetate when the two manufacturers of a generic version of the injectable steroid stopped producing it.

One of these manufacturers, Teva, stopped production in 2010 following the temporary closure of its factory in Irvine, California, after receiving a warning letter from the FDA about manufacturing quality problems. The other company, Sandoz, which has been reprimanded by the FDA in the past for manufacturing problems, stopped selling the product in the US this year, but has not provided an explanation why.

The FDA maintains that the brand-name drug is not in short supply. However, some medical practices may have turned to use of the product from the compounding company because it is less expensive. According to NBC News, PainCare, a medical practice with 12 New Hampshire locations, paid NECC $25 for each five-dose vial of the drug. A vial of Depo-Medrol produced by Pfizer, a similar drug but with an alcohol preservative, costs $40 to $46, according to distributor Clint Pharmaceuticals.

A series of complaints have been lodged over the past decade against NECC, which has annual revenues of about $2.2 million, according to corporate filings. The Massachusetts Department of Public Health inspected the company's two-story brick facility in 2006.

That same year, NECC received a warning letter from the FDA, accusing the company of illegally producing a standardized anesthetic topical cream and inappropriately repackaging a drug. They were also accused of telling doctors that a staff member's name sufficed for putting through an order, while rules require a prescription be provided for each individual patient.

The patients who may have received the tainted injections of the drug produced at the NECC facility must now play a frightening waiting game. Anyone who feels any of the symptoms associated with meningitis has been told to contact their health care provider immediately, as the earlier a patient gets treatment, the better.

The CDC's web site details the grueling treatment infected patients must undergo: "Fungal meningitis is treated with long courses of high-dose antifungal medications, usually given through an IV line in the hospital. The length of treatment depends on the status of the immune system and the type of fungus that caused the infection. For people with immune systems that do not function well because of other conditions, like AIDS, diabetes, or cancer, treatment is often longer."