

## US clinics rush to warn of tainted steroid; 5 dead

October 5 2012, by Mike Stobbe



Dr. Robert Latham, chief of medicine at Saint Thomas Hospital in Nashville, Tenn., is interviewed on Thursday, Oct. 4, 2012, in Nashville. Latham said a fifth person has died in a growing outbreak of a rare form of meningitis that has sickened more than two dozen people in five U.S. states. (AP Photo/Mark Humphrey)

(AP)—Health providers scrambled to notify patients in nearly two dozen U.S. states that the steroid injections they received for back pain may have been contaminated with a deadly fungal meningitis. Five people have died.

It became apparent Thursday that hundreds, perhaps thousands, of people who got the routine shots between July and September could be at risk after officials revealed that a tainted steroid suspected to have caused a meningitis outbreak in the South had made its way to 75 clinics



in 23 states.

The <u>Food and Drug Administration</u> urged physicians not to use any products from the Massachusetts pharmacy that supplied the steroid.

So far, 35 people in six states—Tennessee, Virginia, Maryland, Florida, North Carolina and Indiana—have contracted <u>fungal meningitis</u>, and five of them have died, according to the <u>Centers for Disease Control and</u> <u>Prevention</u>.

It is not clear how many patients received tainted injections, or whether everyone who got one will get sick. The time from infection to onset of symptoms is anywhere from a few days to a month, so the number of people stricken could rise.

The pharmacy involved, the New England Compounding Center of Massachusetts, has recalled three lots consisting of a total of 17,676 single-dose vials of the steroid, preservative-free <u>methylprednisolone</u> <u>acetate</u>, Massachusetts <u>health officials</u> said.

Investigators this week found contamination in a sealed vial of the steroid at the company, FDA officials said. Tests are under way to determine if it is the same <u>fungus</u> blamed in the outbreak.





Dr. Lucy Wilson, left, chief of surveillance, infection protection and outbreak response with the Maryland Department of Health and Mental Hygiene, speaks during a news conference in Baltimore, Thursday, Oct. 4, 2012, about response efforts to an outbreak of meningitis that may be linked to steroid injections. Two cases of the illness, one fatal, have been reported in Maryland. (AP Photo/Patrick Semansky)

Several hundred of the vials, maybe more, have been returned unused, but many others were used.

The company has shut down operations and said it is working with regulators to identify the source of the infection.

The first known case in the meningitis outbreak was diagnosed about two weeks ago in Tennessee, which still has by far the most cases with 25, including three deaths. Deaths have also been reported in Virginia and Maryland.

Meningitis is an inflammation of the lining of the brain and spinal cord. Symptoms include severe headache, nausea, dizziness and fever.

The type of fungal meningitis involved is not contagious like the more common forms. It is caused by a fungus often found in leaf mold and is treated with high-dose antifungal medications, usually given intravenously in a hospital.

The company that supplied the steroid is what is known as a compounding pharmacy. These pharmacies custom-mix solutions, creams and other medications in doses or in forms that generally aren't commercially available.



Other compounding pharmacies have been blamed in recent years for serious and sometimes deadly outbreaks caused by contaminated medicines.

Two people were blinded in Washington, D.C., in 2005. Three died in Virginia in 2006 and three more in Oregon the following year. Earlier this year, 33 people in seven states developed fungal eye infections.

Compounding pharmacies are not regulated as closely as drug manufacturers, and their products are not subject to FDA approval.

A national shortage of many drugs has forced doctors to seek custommade alternatives from compounding pharmacies.

A 2011 state inspection of the Framingham facility gave the business a clean bill of health.

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