Long wait for answers in US tainted drug outbreak

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Thousands of Americans who may have been injected with a tainted steroid will have to wait weeks to see if they have been infected with meningitis as investigators seek answers to a widening outbreak.

That is because testing for the deadly fungus carries its own risks and only a small fraction of the nearly 14,000 people exposed have gotten sick, health officials said.

"It will take months for this whole story to be told," said John Dreyzehner, head of the department of health in Tennessee, the hardest-hit US state.

The number of cases nationwide has risen sharply since health officials began contacting patients in 23 states to warn them of the danger, climbing from 64 on October 6 to 185 on Friday. The death toll currently stands at 14, with six of the fatalities in Tennessee.

Patients have been cautioned to contact their doctors if they develop any of the flu-like symptoms of the slow-moving infection, which causes an inflammation of the protective membranes that cover the brain and spinal column.

A long incubation period has complicated efforts—one patient did not develop symptoms until 42 days after receiving a tainted injection.

"We're not testing people generally unless there's a reason to test them

because the test itself is not entirely benign," Dreyzehner told reporters Friday.

"It's fairly routine—it's a lumbar puncture—but it's more significant than a simple blood test and it's not entirely without risk."

While the test can catch signs of infection by a quick analysis of the spinal fluid, it cannot rule out a dormant infection and patients could need to be retested, he added.

Quick detection is key to keeping the infection under control, but patients will require at least 10 days and possibly as much as four to six weeks of hospitalization to receive intravenous anti-fungal therapy.

The outbreak has led to calls for tighter regulation of the loosely controlled pharmaceutical compounding industry.

Critics said drug manufacturers have found a way to sidestep costly and strict oversight by classifying themselves as pharmacies, which are given freer rein to mix drug compounds for patients.

A senior official with the Food and Drug Administration said Thursday it is "really unfortunate" that it has taken a crisis to highlight the long-standing regulatory gap and called for more authority to oversee the industry.

"The world has changed a lot since the days of mortar and pestle, and this is the time for pharmacists, for lawmakers, for regulators and for doctors to sit down to grapple with this new model of pharmacy compounding and come up with a regulatory scheme that appropriately controls the risk," said Deborah Autor, deputy commissioner for global regulatory operations and policy.

Investigators have not yet determined how the steroids—which are typically injected into the spine to treat back pain—were contaminated but said 50 vials have already been found to contain fungus.

The New England Compounding Pharmacy has voluntarily shut down operations and recalled all of its products after it was discovered that three lots amounting to some 17,000 doses were contaminated.

The sheer volume indicates that the firm had broken the rules, officials said.

"NECC, under Massachusetts board of pharmacy licensing regulations, was licensed to deliver compounded products in response to individual patient specific prescriptions," said Madeleine Biondolillo of the Massachusetts Department of Public Health.

"And it looks through the investigation as though they have violated that aspect of the state licensing regulation despite their assertion that they were operating under the regulations."

Several lawmakers have already vowed to introduce new legislation to tighten oversight and Senator Richard Blumenthal has called for a criminal investigation.

The company had been warned by the FDA in 2006 that its practices were violating the rules and has also been under investigation by state authorities, who have the primary regulatory responsibility for pharmacies.

Meanwhile, the first class action suit against the firm was filed Thursday on behalf of a Minnesota woman who injected with the drug and had to undergo testing after she developed a headache and nausea. The court filings did not indicate whether Barbe Puro was actually infected with

meningitis.