

## US firm loses license as tainted drug toll rises to 24

## October 25 2012

US officials revoked the license Wednesday of a Massachusetts pharmacy cited for significant sanitary violations as the toll from a meningitis outbreak tied to its tainted drugs rose to 24.

The New England Compounding Center voluntarily shut down operations and recalled all of its products in the wake of the unprecedented outbreak.

The fungus which contaminated the steroids and caused the potentially deadly infections was so prevalent it could be seen with the naked eye in some vials.

Massachusetts officials formally revoked the license of NECC and its three main pharmacists after releasing an inspection report detailing how the firm broke the law by mass producing drugs in an un-sterile environment.

On at least 13 occasions NECC shipped the tainted drugs to customers before internal tests came back to determine if the vials of steroids—which are typically injected into the spine to treat back pain—were sterile.

"Medication was shipped as long as 11 days before results were received," said Madeleine Biondolillo, who leads the northeastern US state's public health department.



Investigators also found a leaking boiler next to the "clean room," dirty mats outside sterile rooms and powder left on hoods meant to protect workers from inhaling compounds in sterile areas.

They also noted multiple failures to follow standard sterilization practices such as testing equipment to make sure it still worked.

The outbreak has led to calls for tighter regulation of the loosely controlled pharmaceutical compounding industry and <u>federal</u> <u>investigators</u> have launched a <u>criminal probe</u>.

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

Massachusetts Governor Deval Patrick put pharmacies in his state on notice that officials will be stepping up inspections and urged Congress to strengthen the powers of federal regulators.

"No one should live in fear that medicine is unsafe," he told reporters Tuesday.

"In these times of constantly questioning the role of government, surely we can all agree that protecting the public's health and safety is paramount."

Congresswoman Rosa DeLauro of Connecticut is among a number of lawmakers who have vowed to introduce legislation to strengthen federal oversight.

"The current patchwork of regulations has clearly failed us," she said in a statement Wednesday.



Some 14,000 people in 23 states are at risk after receiving potentially tainted doses of the NECC steroids.

The number of cases rose to 317 in 17 states Wednesday, according to the latest tally from the Centers for Disease Control and Prevention.

Officials have said it could be weeks or even months before authorities have a final tally of the infections, due to the disease's long incubation period.

The southern state of Tennessee remains the hardest hit with 70 cases and nine deaths, followed by Michigan with 73 cases and five fatalities.

Other states that were hit badly include Florida, Indiana, Maryland, New Jersey and Virginia.

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