

US firm found mold long before shipping tainted drugs

27 October 2012, by Mira Oberman

A pharmacy tied to a meningitis outbreak repeatedly found bacteria and mold in its facility long before shipping tainted drugs to patients, US officials said Friday as the death toll rose to 25.

The New England Compounding Center (NECC) voluntarily shut down operations and recalled all of its products in the wake of the unprecedented outbreak, which [health authorities](#) say has sickened 338 people in 18 states.

The fungus that contaminated the steroids and caused the potentially [deadly infections](#) was so prevalent it could be seen with the naked eye.

Investigators searching a bin of 321 vials found "greenish black foreign matter" in 83 vials and "white filamentous material" in 17 others, according to a preliminary report by the [Food and Drug Administration](#).

The firm's own inspection reports also painted a dirty picture.

While internal tests found mold and bacteria on 29 occasions since January 3, there was "no investigation conducted by the firm when levels exceeded their action limits, and no identification of the isolates," the FDA report said.

The company also did not have any documentation of efforts to remove the contaminants.

"Manufacturers and compounding firms know what to do," Paul Teitell, of the FDA's office of regulatory affairs, said in a conference call.

"They have the responsibility to manufacture quality drugs and to have processes in place to make sure there's no breakdown in the supply or processes that would cause contamination."

Federal investigators found visibly dirty equipment and a failure to follow standard practices when

they inspected the facility after tracing the outbreak to NECC's products earlier this month.

The pharmacy's staff told them that the air conditioning in the 'clean rooms' was turned off overnight, even though a consistent temperature is needed to prevent growth of bacteria and mold.

Inspectors also found pools of dirty water surrounding a leaking boiler just steps from the clean rooms and noted that the facility's air intake unit was within range of dust kicked up by a neighboring recycling company.

State officials formally revoked NECC's license on Wednesday after citing the firm for significant sanitary violations.

Massachusetts officials also noted that 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.

The FDA said it is too early to discuss consequences, however criminal prosecutors are participating in the investigation.

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

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 drug compounds for patients.

Some 14,000 people in 23 states are at risk after receiving potentially tainted doses of the NECC steroids and the FDA has warned that patients receiving a host of other NECC products are also at risk.

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

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