Massachusetts: Fungus at meningitis-linked firm

October 23 2012, by Jay Lindsay

(AP)—Massachusetts state officials investigating a pharmacy linked to a deadly outbreak of meningitis said Tuesday they found shoddy sterilization practices and unclean conditions there, including debris-covered floor mats and standing water from a leaking boiler.

State officials also said the New England Compounding Center shipped steroids from the possibly contaminated batches suspected in the outbreak before it received its own test results confirming the drugs were sterile.

Gov. Deval Patrick said he's ordered state pharmacy regulators to conduct surprise inspections—the first of which happened Tuesday—at companies similar to the NECC and take other steps to tighten oversight. The state also has moved to revoke the company's operating license and the licenses of its top three pharmacists.

"Those whose laboratory practices caused this outbreak should never practice pharmacy or manufacture in Massachusetts again," Patrick said.

The outbreak of fungal meningitis, an inflammation of the lining of the brain and spinal cord, has sickened 308 people, including 23 who have died, in 17 states. The outbreak has been linked to a steroid made by the NECC and taken mainly for back pain. Compounding pharmacies like NECC custom mix solutions in doses or forms generally not commercially available.

The U.S. government is conducting a criminal investigation.

The state said Tuesday that its preliminary investigation, which began last month after the company was first suspected in the growing outbreak, found large batches of drugs ready for general distribution but not labeled for specific patients.

Its state license permits the company to fill out only specific prescriptions for specific patients, and distributing drugs in bulk like a manufacturer would violate that, said Dr. Madeleine Biondolillo, director of the state Department of Public Health's Bureau of Healthcare Safety.

But company attorney Paul Cirel said it's "hard to imagine" state regulators weren't previously aware of the scale of its operations because they've worked so closely together. The state Board of Pharmacy has always had complete access to the facility, and board members were there as recently as last summer, he said.

"NECC's transparency in dealing with the board since inception in 1998 demonstrates its good-faith intention to operate in compliance with the requirements of its license," Cirel said.

Besides possible state license violations, Biondolillo said the inspections also revealed "several health and safety deficiencies" at the NECC facility in Framingham, just west of Boston.

Biondolillo also detailed signs of flawed sterilization procedures, including black specks of fungus in sealed vials of the steroids, which were returned to the company during a recall.

Investigators found the company didn't sterilize its products long enough and didn't adequately test whether its sterilization equipment was

working, she said.

In addition, mats on which people wiped their shoes to remove contamination before entering a sterile environment were "visibly dirty and soiled with assorted debris," she said. And a leaking boiler adjacent to a pharmacy clean room left an unsanitary pool of water around it and the adjacent walls, she said.

None of what's been found is enough to definitively determine what caused the contamination, and the investigation is ongoing, Biondolillo said.

Meanwhile, Patrick's moves to increase oversight at the state's 25 compounding pharmacies have already started.

The first of the unannounced inspections, to take place at least annually, was done on Tuesday, health department spokesman Alec Loftus said. He wouldn't give the inspected facility's name and said the results are being reviewed.

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