Massachusetts official fired for ignoring complaints against meningitis-linked pharmacy

Kate Randall
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A top state of Massachusetts official, James D. Coffey, has been fired after investigators charged that he ignored complaints from the state of Colorado about the compounding pharmacy linked to the current deadly meningitis outbreak.

According to the latest figures from the Centers for Disease Control and Prevention (CDC), tainted steroids from the Framingham, Massachusetts-based New England Compounding Center (NECC) are blamed for 448 cases of fungal meningitis and joint infections in 19 states, and have killed 32 people.

As a Food and Drug Administration (FDA) investigation into NECC continues, the latter's sister company, Ameridose, notified hundreds of workers on Friday that they were being laid off. Ameridose, a supplier of injectable drugs, will lay off 650 workers, and its affiliated marketing company, Medical Sales Management, will lay off 140. The compounding pharmacy remains under a temporary closure order after regulators raised concerns about the company's sterility practices. NECC has been permanently shut down and its license revoked.

FDA inspectors at NECC's facility found "greenish-black" material in vials of the injectable steroid methylprednisolone acetate, as well as sanitary and sterility violations in the "clean rooms" where medications were prepared. (See "US health officials find mold at facility at center of meningitis outbreak") An estimated 14,000 people received injections of the contaminated steroid for treatment of back and joint pain.

Coffey, the longtime director of the Massachusetts Pharmacy Board, was fired on Tuesday after it was revealed that he had ignored a complaint about NECC from the Colorado pharmacy board in July, before the third and final batch of steroids linked to the meningitis outbreak was shipped in August.

According to Massachusetts health officials, Coffey reportedly told Colorado officials that the state Board of Registration in Pharmacy would "respond as soon as possible following a thorough review and analysis." Nothing was done. He forwarded the complaint to Susan Manning, the board's attorney, who also failed to act. She has been placed on administrative leave.

As a compounding pharmacy, NECC was authorized by its state license to fill only specific prescriptions for individual patients. On July 26, Colorado officials informed Coffey that their inspectors had found that NECC distributed batches of drugs to Colorado hospitals from 2010 to 2012 without first obtaining patient-specific prescriptions. Previously, in April 2011, Colorado officials issued a cease-and-desist order, ordering NECC to stop "the unlawful distribution of prescription drugs in the state of Colorado."

The Colorado complaints were uncovered by Massachusetts officials sifting through Coffey's emails, according to a spokesperson for the state Office of Health and Human Services. Even after the meningitis outbreak became public, neither Coffey nor Manning informed state health officials of the Colorado complaints.

The tragic scope of the meningitis outbreak has prompted calls for investigation at both the state and local level, with politicians and state officials expressing indignation over NECC's ability to produce and distribute the contaminated drugs virtually without oversight.

Barry Cadden, director and co-founder of New England Compounding, has been subpoenaed to appear at hearings before the Massachusetts House and Senate next week into links between his company's practices and the meningitis infections and deaths. Officials from the FDA and CDC are also expected to testify.

Hearings are also scheduled next week in Washington, D.C. FDA Commissioner Dr. Margaret Hamburg will appear before the US House Energy and Commerce Committee on November 14 at a hearing on the meningitis outbreak. Committee staffers have also invited Cadden and Coffey to testify, but are still awaiting their responses.

The US Senate Committee on Health, Education, Labor, and Pensions will hold hearings on November 15. Committee member Senator Lamar Alexander (Republican, Tennessee) has solicited testimony from a number of organizations in his home state, where 81 have been sickened and eight have died in the outbreak.

Rep. Ed Markey (Democrat, Massachusetts) has introduced legislation to increase federal oversight over compounding pharmacies. Under the legislation, such companies would be regulated by the FDA if they operate like a drug manufacturer and produce large quantities of drugs for general distribution.

In fact, similar legislation was overturned by the US Supreme Court in 2002. The 1997 law, an amendment to the Food, Drug and Cosmetic Act, would have given the FDA more authority to regulate compounding pharmacies. At issue in *Thompson vs. Western States Medical* was whether Congress could forbid compounding pharmacies from advertising the drugs they sold.

As compounding pharmacies are only supposed to be filling prescriptions for medications for specific patients and which aren't readily available, such advertisement would appear to be unnecessary. But seven compounding pharmacies challenged the ban on advertising as an unconstitutional restriction of free speech.

Despite this ruling, the FDA issued a policy guide requiring compounding pharmacies to follow certain rules. These included a directive that such pharmacies could not make significant quantities of drugs before having prescriptions in hand, and that they had to follow the laws and regulations of the states where they operated.

These FDA recommendations did little to stop NECC from pursuing a policy that has led to hundreds of illnesses and scores of deaths. In reality, the underfunded FDA presently faces the threat of tens of billions of dollars in cuts in any budget deal worked out in the post-election drive to reduce the deficit and avoid the "fiscal cliff."

These budget cuts—combined with the relentless lobbying efforts not only of the compounding pharmacies, but the entire pharmaceutical industry, as well as the relentless drive toward deregulation—mean that tragedies such as the present meningitis outbreak are all but inevitable.

Truth-out.org quotes Sarah Sellers, a former FDA officer who left the agency in 2008 after unsuccessfully pushing for increased regulation of compounding pharmacies. She described the consequences of the lack of oversight of NECC, where the deadly black fungus Exserohilum found its way to vials of medicine, eventually leading to a deadly threat to unsuspecting patients: "The entire pharmacy was an incubator of bacteria and fungus. The pharmacy knew this through monitoring results, and chose to do nothing."