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Center of Meningitis Outbreak: US Health Officials Find Suspected Cause

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During a tour of the New England Compounding Center (NECC), investigators from the US Food and Drug Administration (FDA) found foreign "greenish-black" material in some vials of the injectable steroid suspected as the cause of the ongoing meningitis outbreak.

The contaminated vials of medicine were only one of a host of potential violations discovered during a recent inspection of NECC's facility in Framingham, Massachusetts, FDA officials reported last Friday.

According to the latest figures released by the US Centers for Disease Control and Prevention (CDC) Saturday, 344 cases of fungal meningitis linked to the suspect steroid have been reported in 18 states. Twenty-five people have died. Meningitis is an inflammation of the lining surrounding the brain and spinal cord that is potentially fatal.

Most of those stricken received injections of methylprednisolone acetate to treat back pain, while seven received injections in the knee or other peripheral joints. The estimated 14,000 people who received injections of the steroid produced by NECC and have not yet fallen ill must now play a harrowing waiting game to see if they come down with the deadly disease.

The FDA's initial investigation, as well as other emerging details about NECC's practices, indicate that the compounding pharmacy ran an operation that—even by the company's own evaluation—clearly disregarded basic pharmaceutical safety and sterility standards.

FDA officials detailed their observations at a news conference on Friday. Steven Lynn, director of the FDA's office of Manufacturing and Product Quality, said, "The investigators observed approximately 100 vials of the steroid drug, which purports to be a sterile injectable drug, that had a greenish-black foreign material and a white filamentous material [containing filaments] inside."

The FDA report also revealed that the compounding pharmacy was unable to demonstrate that the equipment used to sterilize their products was actually able to sterilize them. In particular, the company did not keep its "clean room" clean. "A clean room is a space designed to maintain a controlled environment with lower levels of airborne particles and surface contamination," Lynn explained.

The FDA report shows that NECC's own environmental monitoring program between January and September of 2012 yielded "microbial isolates (bacteria and mold) within Clean Room 1 and Clean Room 2." In some cases, entire testing dishes were overrun with an "OG," or overgrowth, of bacteria and fungi. Tables reprinted in the FDA report from NECC's own records include 11 instances where findings related to mold and bacteria have been

redacted in NECC's original documents.

NECC personnel failed to keep the air conditioning running in the clean room at night, according to the FDA, which is standard practice for maintaining proper humidity and temperature control. They also found leaking pipes and standing water at the entrance to a room where equipment is prepared for use in the clean room.

FDA inspection also found an autoclave tarnished with "greenish-yellow discoloration." This equipment is used for steam sterilization of beakers, spatulas "used in the formulation of sterile drug products," the report notes.

The FDA investigators also observed that a recycling plant adjacent to the NECC facility takes in mattresses and plastics and contains recycling equipment that produces airborne particles. The facility is owned by Gregory Conigliaro, who also owns a stake in NECC. The air conditioning units on the NECC's rooftop are only about 100 feet from the recycling facility.

The FDA report, known as a "483," is issued "at the end of an inspection when the investigators believe that they observed conditions or practices that, in their judgment, may indicate violations of the Federal Food, Drug, and Cosmetic Act, or related regulations," the agency said in a statement. Further inspections will be undertaken.

Health officials from Massachusetts, which had authority over NECC's operations as a compounding pharmacy, released preliminary results of an investigation October 23 that found similar violations by the company. They also determined that compounded drugs were not labeled with identification that was patient-specific.

Compounding pharmacies such as NECC are meant to prepare specialty prescriptions when a drug is not available to treat specific patients who may have an allergy to one of the ingredients usually found in a drug, or need it to be prepared in a particular way, for example, without preservatives or as a liquid.

In practice, however, many of these "compounders" function more like large-scale drug manufacturers and operate under the radar of FDA regulators. Lobbyists for the compounding pharmacy industry have spent more than $1 million over the past decade to thwart FDA regulation of facilities such as the one that has now shipped thousands of vials of tainted steroids to clinics across the country.

Massachusetts authorities have suspended NECC's license to operate, as have at least eight other states. Dr. Madeleine Biondolillo, director of the state Bureau of Healthcare Safety, declared at a recent news conference that NECC "was operating beyond the scope of [its] compounding license." Massachusetts Governor Deval Patrick spoke of the "decisive steps" state health officials were taking to protect the public from compounders such as NECC.

However, state records that have now become public show that as early as 14 years ago NECC and a nearby firm with the same owners, Ameridose, asked and eventually received a waiver to bypass state laws governing compounding pharmacies. In a license application in 1998, NECC requested that they be exempt from maintaining a supply of drugs "in accordance with the usual needs of the community," a practice required of pharmacies.

In 2003, in response to a complaint, NECC attorney Paul Cirel explained in a letter to the

state pharmacy board that “NECC compounds some prescription medication in advance of the receipt of valid prescription orders from authorized prescribers” and that the pharmacy prepared batches of some drugs ahead of time “based on the historical demand for that particular compound.”

NECC faced an investigation from the state pharmacy board in 2004 triggered by an adverse event involving methylprednisolone acetate—the same drug at the center of the meningitis outbreak. Pharmacy board staff recommended the compounder receive a three-year probation and an official reprimand.

In early 2006, however, the state pharmacy board overruled its own staff, approving a consent agreement whereby NECC was placed on probation for a year, with this probation immediately stayed. The deal followed a plea from NECC attorney Cirel, who argued that probation would place an undue financial burden on NECC and could trigger punitive action against the firm in other states where it was licensed.

The NECC attorney wrote at the time, “The collateral consequences to many if not all of NECC’s other licenses in 42 states would be potentially fatal to the business.” State officials agreed not to report the reduced probation agreement to regulators in other states.
