More contaminated drugs linked to US meningitis outbreak

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The Centers for Disease Control and Prevention (CDC) said Tuesday that another 19 people have been diagnosed with fungal meningitis linked to contaminated vials of a steroid medication from a Massachusetts compounding pharmacy. The total number of cases stands at 231 in 15 states. Fifteen people have died from the illness.

The growing outbreak of the rare, non-contagious fungal form of meningitis has been tied to vials of the steroid methylprednisolone acetate produced by the New England Compounding Center (NECC). The compounding pharmacy, located in suburban Boston, shipped the medication to about 75 clinics in 23 states to be used in spinal injections for back and neck pain.

Meningitis is an inflammation of the protective membranes covering the brain and spinal cord that is often fatal. An estimated 14,000 people are potentially at risk of developing fungal meningitis from the medication used in the injections produced by NECC, which have been discovered to be contaminated with a fungus called Exserohilum, a leaf mold usually found in soil and dirt.

On Monday, the Food and Drug Administration (FDA) reported a new danger that threatens to widen the risk to patients treated with drugs produced by NECC. The FDA initially stated it had received reports of three new cases of infections tied to additional medicines, but later corrected its statement to say it had reports of two cases. FDA officials say it is still unclear whether these products came from NECC.

In the first case, a heart transplant patient exposed to a cardioplegic solution used in open heart surgery developed a chest infection with the fungus Aspergillus. The solution is chilled and poured into the opened chest to stop the heart during surgery. According to the FDA, such solutions have caused problems in the past, and the agency issued a warning letter in 2006 to a firm that had produced a similar solution that has caused fatal infections in three patients.

The other new case involved a patient who developed meningitis after receiving a spinal injection of triamcinolone acetonide, another steroid produced by NECC. In its statement, the FDA also warned health care providers of possible contamination in drugs made by the compounding pharmacy that are either injected into the eye or used during eye surgery.

The FDA is recommending that health care providers notify patients that have been exposed to any products produced by NECC to be on the alert for signs of infection. Symptoms of meningitis may include headache, fever, nausea, stiffness of the neck, confusion, dizziness and sensitivity to light. Treatment involves months-long courses of high-dose antifungal medications, usually administered intravenously in a hospital setting.

The New England Compounding Center has shut down operations and recalled all of its products. It is reportedly cooperating with federal health authorities in an ongoing investigation. The company’s license to operate has been suspended in Massachusetts, Michigan, New Hampshire, Ohio, Maryland and Virginia. Tennessee, the hardest-hit state with 53 reported fungal meningitis cases and six deaths, is considering suspending NECC’s license.

So-called compounding pharmacies initially sprung up to create customized drugs to meet the specific needs of individual patients, such as the removal of an ingredient that might cause an allergic reaction. Over the past several decades, however, they have developed into large-scale businesses, many of them mass-producing drugs and promoting and distributing them

nationwide.

More than half of the nation's estimated 56,000 pharmacies do some compounding, and the industry has grown into a $3 billion business with more than 7,500 large-scale pharmacies. NECC reportedly had annual revenues of about $8 million. Shortages of some popular drugs have encouraged the growth of compounders. Compounding pharmacy products are also cheaper than those produced by traditional drug companies, making them more attractive to clinics and other health care providers.

Because compounders are technically "pharmacies," state pharmacy boards are tasked with regulating their operations instead of the FDA, which was established in 1938 to oversee drug manufacturers. The 1938 Food, Drug, and Cosmetic Act (FDCA) was introduced after more than 100 patients died from a sulfanilamide medication in which diethylene glycol was used to dissolve the drug and make it into a liquid form.

FDCA specifically forbids the sale and distribution of new, unapproved drugs across state lines. While it would appear that this law would apply to compounders such as NECC, the FDA took no action against the company, except to issue a warning in 2006 that read in part: "Your firm has reportedly also told physicians' offices that using a staff member's name on the prescription would suffice." Compounding pharmacies operating in Massachusetts and other states are only licensed to produce medications to fill single patient prescriptions.

To date, the Obama administration has released no official statement on the deadly meningitis outbreak. Speaking on condition of anonymity, an official from the Department of Health and Human Services, which oversees the FDA, told Reuters last week, "We urge Congress to give FDA the authority it needs to assure these kinds of outbreaks do not happen again."

The International Academy of Compounding Pharmacists, the main trade association representing compounders, has spent more than $1.1 million on lobbying since 2000 to thwart efforts to bring the industry under the direct supervision of the FDA.